Message

From: Alise, Mark A [malise@tulane.edu]
Sent: 2/3/2015 11:07:01 PM
To: Martin, John [martin.john@epa.gov]
Subject: Message Sent to our Community Neighbors

John

Below is a copy of the message that we sent to our Community Advisory Board (a board of our neighbors in the business, education, local government, and residential community). We duplicated this message and also sent it to the homeowners associations of the two adjoining residential developments (Estates of Northpark and Versailles) as well as the headmaster at the adjoining school (Northlake Christian School):

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I write to update you on a recent situation at the TNPRC.

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Andrew
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Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433

We have not provided further updates beyond this message which was sent to the various recipients between Jan 17-20, 2015.

Let me know if you have any questions,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

90043354

TULANE NATIONAL PRIMATE
RESEARCH CENTER

Message

From: Alise, Mark A [malise@tulane.edu]
Sent: 2/4/2015 3:53:09 PM
To: Martin, John [martin.john@epa.gov]
Subject: Re: Message Sent to our Community Neighbors
Attachments: 39980F81-6868-4F65-89A1-CEE04773E6E1[18].png

John,

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On Jan 17, 2015 message

Dear members of the TNPRC Community Advisory Board

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In November two animals presented to the clinic with nonspecific clinical signs. After extensive clinical workups, including exploratory surgeries and bacterial cultures and assistance from the Centers of Disease Control (CDC), we determined that the animals were infected with the bacteria *Burkholderia pseudomallei* (the cause of melioidosis). One animal was euthanized on November 26 and the remaining animal has recovered. No additional cases have been recognized.

Risk of the bacteria becoming a threat to people or animals is negligible. Transmission of the bacteria generally occurs through contact with contaminated soil. Animal to human transmission of this bacteria is not known to occur and person-to-person transmission is extremely rare. No people have been infected and any TNPRC employee who was possibly exposed is being monitored.

TNPRC personnel contacted the CDC in accordance with federal research protocols. CDC officials are expected at the TNPRC next week and will join scientists at the TNPRC to continue ongoing collaborative efforts to identify the source of the infection in the macaques.

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January 26 message:

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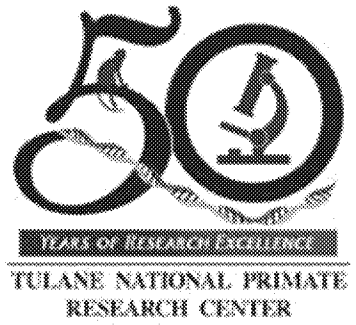

From: <Martin>, John <martin.john@epa.gov>
Date: Tuesday, February 3, 2015 at 8:00 PM
To: Mark Alise <malise@tulane.edu>
Subject: RE: Message Sent to our Community Neighbors

Received. Thank you.

Sent from my Windows Phone

From: Alise, Mark A
Sent: 2/3/2015 5:07 PM
To: Martin, John
Subject: Message Sent to our Community Neighbors

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Message

From: Hubbard, Joseph [Hubbard.Joseph@epa.gov]
Sent: 2/4/2015 4:50:17 PM
To: Martin, John [martin.john@epa.gov]; Canzler, Erica [Canzler.Erica@epa.gov]; Nalipinski, Mike [Nalipinski.Mike@epa.gov]; Petersen, Chris [petersen.chris@epa.gov]; Crossland, Ronnie [Crossland.Ronnie@epa.gov]
Subject: RE: Message Sent to our Community Neighbors

Hi John,

What is our role? Do you have contact info for PIO at St. Tammy Parish?

From: Martin, John
Sent: Wednesday, February 04, 2015 10:32 AM
To: Canzler, Erica; Nalipinski, Mike; Petersen, Chris; Crossland, Ronnie; Hubbard, Joseph
Subject: FW: Message Sent to our Community Neighbors

Fyi. This event seems. To be expanding. Uc needs to develop their message yesterday.
St Tammany is the pio at this but he was to form a JIC.
Sent from my Windows Phone

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TULANE NATIONAL PRIMATE
RESEARCH CENTER

Message

From: Ojeda, Jose [Jose.Ojeda@WestonSolutions.com]
Sent: 2/19/2015 5:22:17 PM
To: Martin, John [martin.john@epa.gov]
CC: Rhotenberry, William [Rhotenberry.William@epa.gov]; McAteer, Mike [mcateer.mike@epa.gov]
Subject: Tulane - QASP
Attachments: Tulane University ER QASP - v2.pdf

See attached

José L. Ojeda
Senior Project Leader – START Team
Weston Solutions, Inc.
3900 Dallas Pkwy, Suite 175
Plano, TX 75093-7805

Direct: (469) 666-5506 • Cell: (619) 417-3298 • Office: (469) 666-5500 • Fax: (469) 666-5540
Jose.Ojeda@westonsolutions.com

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EMERGENCY RESPONSE
QUALITY ASSURANCE SAMPLING PLAN

FOR

TULANE UNIVERSITY - NATIONAL PRIMATE RESEARCH CENTER
18703 THREE RIVERS ROAD
COVINGTON, ST TAMMANY PARISH, LOUISIANA

Prepared for

U.S. Environmental Protection Agency Region 6
Will LaBombard, Project Officer
1445 Ross Avenue
Dallas, Texas 75202

Contract No. EP-W-06-042
Technical Direction Document No. 1/WESTON-042-15-008
WESTON Work Order No. 20406.012.001.0933.01
NRC No: N/A
CERCLIS ID: N/A
FPN: N/A
EPA TM: John Martin
START-3 PTL: Sam Cheek

Prepared by

Weston Solutions, Inc.
Cecilia H. Shappee P.E., Program Manager
5599 San Felipe, Suite 700
Houston, Texas 77056
(713) 985-6600

February 2015

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1. INTRODUCTION

Weston Solutions, Inc. (WESTON®), the Superfund Technical Assessment and Response Team (START-3) contractor, has been tasked by U.S. Environmental Protection Agency (EPA) Region 6 Prevention and Response Branch (PRB) under Contract Number EP-W-06-042 and Technical Direction Document (TDD) No. 1/WESTON-042-15-008 to conduct an Emergency Response (ER) at the National Primate Research Center, located in Covington, St Tammany Parish, Louisiana.

The EPA Team has prepared this ER Quality Assurance Sampling Plan (QASP) to describe the field investigation activities, sampling, and analytical scope of work to be conducted as part of the response.

1.1 PROJECT OBJECTIVES

The EPA Team is providing technical assistance to EPA Region 6 for the performance of the biological assessment as part of the ER. EPA will be responsible for coordinating the collection and analysis of environmental samples. However, personnel from the Tulane National Primate Research Center (TNPRC) will collect the on-site soil, sediment, and water samples with EPA oversight. The EPA Team will collect the air samples.

1.2 PROJECT TEAM

The EPA Team will consist of EPA Task Monitor (TM), John Martin; Sam Cheek, the EPA Team Project Team Leader (PTL); Jose Ojeda, the Field Team Leader (FTL); Jeff Wright, Project Chemist; Janine Latham, IT and Data Manager (DM); and additional EPA Team members as necessary to assist with sample preparation, packing, and shipment.

The EPA Team PTL will be responsible for the technical quality of work performed in the field and will serve as the EPA team liaison to the EPA TM during the field activities. The PTL will log the activities at each sample location in the field logbook and verify the sample

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documentation. The DM will be responsible for entering all samples collected into the Scribe Environmental Sampling Data Management System (SCRIBE), for producing accurate chain-of-custody documentation for the samples during the ER, and for entering daily operations and sample collection data into EPA Response Manager. The PTL will oversee the packaging and shipping of samples to the designated laboratory. The PTL will also be responsible for providing overall site health and safety support during field activities.

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2. SITE BACKGROUND

Two macaques at TNPRC were potentially infected with the bacteria Burkholderia pseudomallei (abbreviated Bp, the cause of Melioidosis). One animal was euthanized on 26 November 2014, and the second macaque has reportedly recovered. According to the Center for Disease Control (CDC) Burkholderia pseudomallei is a bacterium endemic to Southeast Asia and Northern Australia, and is typically found in contaminated water and soil. The bacterium spreads through direct contact with the contaminated source. The manner in which the macaques were exposed to the Bp is not known at this time.

An Inspector for the U.S. Department of Agriculture was reported to have become sick after performing an inspection at the facility. However, it has not been determined if the Inspector's illness is related to or is the result of exposure to Bp.

2.1 SITE LOCATION AND DESCRIPTION

The TNPRC is divided into a "North Campus" and a "South Campus." The North Campus is located north of Three Rivers Road and contains the offices and laboratories. The South Campus is located south of Three Rivers Road and contains the macaque breeding colonies, the storm-water treatment system, and the sewage treatment system. The macaques were located in cages in the South Campus when they were discovered to be sick.

2.2 OPERATIONAL HISTORY AND OWNERSHIP

The TNPRC has a national mission to improve human and animal health through basic and applied biomedical research. The TNPRC website states their purpose is the following:

- Conduct basic and applied biomedical research on human health problems using nonhuman primate models.
- Investigate nonhuman primate biology and diseases with particular regard to the study of human health problems.
- Serve as a regional and national resource and center of excellence for biomedical research using nonhuman primates.

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- Provide training for graduate students, postdoctoral fellows, veterinarians, undergraduates, veterinary students, and visiting scientists.
- Educate the general public about the critical link between basic research with animal models and improvements in human health.

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3. RESPONSE ACTIVITIES

The activities that will be conducted during the response are discussed in this section. Sampling of surface water, sediment and waste sampling procedures, locations, analytical approach, and quality assurance (QA) that will be conducted during the response are also discussed.

3.1 SAMPLING STRATEGY

A sampling strategy was developed by TNPRC and EPA representatives to collect the data necessary to evaluate and meet the objectives of the response. The sampling strategy focuses on the collection of soil, water, and air samples by employees of the TNPRC. Sampling Standard Operating Procedures (SOPs) for naturally occurring Bp in the soils of Southeast Asia call for a sample depth of 30 centimeters. However, for this response the source of the Bp is believed to be runoff of waste products from the macaque cages which could have been deposited onto the top of the soil or sediment. Therefore, soil and sediment samples will be collected in the top 2 inches of soil. Samples may be collected at a greater depth as the project progresses.

Table 3-1 has been prepared to include a summary of Sample Locations and Sampling Rationale as part of the ER field effort.

3.2 DATA QUALITY OBJECTIVE

The objective of sampling activities is to determine if Bp is present in the soil, sediment, water, and air at the facility. Soil, sediment, and water sampling will be conducted by TNPRC personnel. The EPA Team will conduct air sampling. The sampling will be conducted under direction of the EPA TM and TNPRC representatives. Media specific data quality objectives (DQOs) are not applicable. If DQOs are determined to be applicable, they will be developed using the seven-step process set out in the *EPA Guidance for Quality Assurance Project Plans: EPA QA/G-5*.

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3.3 PRELIMINARY FIELD ACTIVITIES

Mobilization and preliminary field activities for the ER are discussed in the following subsections.

3.3.1 Field Activities Review Meeting

The EPA Team FTL will conduct a meeting with the entire field team to familiarize them with the ER Scope of Work; to discuss EPA TM expectations, including planned field investigation activities; and to review the project Health and Safety Plan (HASP) and other relevant EPA team operating procedures. This meeting will be conducted in the WESTON Houston, Texas, office or via video conferencing for team members in other offices prior to mobilizing to the field.

3.3.2 Mobilization and Command Post Establishment

The EPA Team will mobilize the equipment required for the response from the EPA warehouse in Addison, Texas, and the WESTON equipment stores in Dallas and Houston, Texas. The field team will utilize the EPA mobile Logistics Response Vehicle (LRV) as a command post. Equipment used during the ER will be stored in the command post. Dedicated (nondisposable and disposable) sampling equipment will be used to collect samples in a manner minimizing the number of times that decontamination is performed on a daily basis.

Prior to demobilization, field supplies and equipment will be transported back to the EPA warehouse and WESTON equipment stores.

3.3.3 Health and Safety Plan Implementation

The ER field activities will be conducted in accordance with the site-specific HASP prepared for this investigation. In general, the HASP specifies that work on the North Campus will proceed in Level D personal protective equipment (PPE). During sampling events on the South Campus the EPA will be teamed with TNPRC personnel and follow TNPRC protocols wearing a modified Level C consisting of Tyvek coveralls, nitrile gloves, boot covers, surgical caps, face shields, and N95 masks. The EPA Team FTL will serve as the Field Safety Officer (FSO) and

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will be responsible for implementation of the HASP during field investigation activities. Daily tailgate safety meetings will be held prior to initiation of each work day.

In accordance with the EPA Team's general health and safety operating procedures, the field team will also drive the route to the hospital specified in the HASP prior to initiating sampling activities.

3.3.3 Documentation of Field Sampling Activities

The EPA Team will document the ER field activities in bound field logbooks. At a minimum, the information documented in the field logbook for each sample location will include the following:

- The sample location number and the depths of sample collection.
- A description of the sample location at the site.
- The sample matrix and sample description.
- The analyses for which the samples were collected.
- The date and time of sample collection.

Locations where samples are collected will be documented using a global positioning system (GPS) to obtain horizontal control.

3.3.4 Decontamination and Investigation-Derived Wastes (IDW)

The nondisposable sampling equipment (portable sampling unit) used during the sample collection process will be thoroughly decontaminated before initial use, between locations, and at the end of the response before leaving the Site. Decontamination activities will be conducted at a designated decontamination area. Equipment decontamination will be completed in the following steps:

- High-pressure water spray or brush, if needed, to remove soil from the equipment.
- Nonphosphate detergent and potable water wash to clean the equipment.
- Final potable water rinse.
- Equipment air dried.

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The fluids and excess soil/sediment generated as a result of equipment decontamination will be containerized and disposed of by TNPRC personnel according to facility protocols.

3.4 SAMPLING/MONITORING APPROACH

Air sampling will be conducted by the EPA Team. Soil/sediment sampling and water sampling will be conducted by the TNPRC with supervision by the EPA Team. The specific sampling, decontamination, sample handling procedures, and disposition of IDW are described in the following subsections.

3.4.1 Soil Sampling

Soil/sediment samples will be collected by employees of the TNPRC with supervision and documentation by the EPA Team. Sampling SOPs for naturally occurring Bp in the soils of Southeast Asia call for a sample depth of 30 centimeters. However, for this response the source of the Bp is believed to be runoff of waste products from the macaque cages which could have been deposited onto the top of the soil or sediment. Therefore, soil and sediment samples will be collected in the top 2 inches of soil. Soil sampling procedures include:

- Wear modified Level C PPE protective gear including Tyvek coveralls, nitrile gloves, boot covers, surgical caps, face shields, and N95 respirators, according to TNPRC safety protocols.
- Dig a hole using a clean, disposable shovel to collect a soil sample in the top 2 inches of soil.
- Transfer approximately 30 to 40 grams of soil to sterile containers.
- Upon collection of the sample, the outside of the jar will be cleaned with disinfecting wipes, placed in a resealable plastic bag, and placed into a cooler or other container out of direct sunlight.
- Deliver samples to the laboratory at ambient temperature without exposure to direct sunlight and process as quickly as possible.

Soil sample locations and the sampling order will be determined by the EPA Team while on-site. Sample locations will initially include areas associated with the storm-water treatment system and the sewage treatment system. As the project progresses, samples will be collected from

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other locations on the South Campus working from outer areas and moving inward to the cages that contained the affected macaques. Samplers will coordinate with the laboratory to determine how many samples can be shipped each day. Generally, samples will be collected from areas as follows:

- All four sides of macaque cage G12.
- South and east side of macaque cage R24.
- Next to any potential waste streams from impacted field cages.
- Background (near front entrance gate).
- Wetlands sludge.
- Near the outfall 003 and 004.
- Outfall sludge.

Table 3-1 presents a summary of the samples and the sample rational associated with each. Information regarding sample analysis is presented in Section 4.

3.4.2 Water Sampling

Water samples will be collected on-site from within drainage ditches, the sewage treatment system, and the storm-water treatment system. Water samples will be collected by employees of the TNPRC with supervision and documentation by the EPA Team. Sampling procedures include the following:

- Wear modified Level C PPE protective gear including Tyvek coveralls, nitrile gloves, boot covers, surgical caps, face shields, and N95 respirators, according to TNPRC safety protocols.

- Transfer approximately 1 liter of water into sterile containers (two 1-liter containers per sample). Surface water can be "dipped" directly from the water and transferred into the sample jars using a funnel.

- Upon collection of the sample, the outside of the jar will be cleaned with disinfecting wipes, placed into a resealable plastic bag, and placed into a container or cooler out of direct sunlight.

- Deliver samples to the laboratory at ambient temperature without exposure to direct sunlight and process as quickly as possible.

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Table 3-1 presents a summary of the samples and the sample rational associated with each. Information regarding sample analysis is presented in Section 4.

3.4.3 Air Sampling

Air samples will be collected by the EPA Team using Portable Sampling Units (PSUs). Three PSUs will be deployed throughout the site. PSUs will initially be deployed on the South Campus at the fence line closest to Northlake Christian School, near the aerator on the sewage treatment system, and at the gravel filter near water outlet 3. The locations of the samplers may change due to changes in weather or changes in work activities. Samples will be collected for 24-hour periods.

1. PSU-247: Fenceline near Northlake Christian School (east side of South Campus).
2. PSU-465: Near sewage aeration pond (west side of South Campus).
3. PSU-340: Near gravel filter (center of South Campus).

The flow rate will be set to 100 liters per minute (L/min) at the beginning of the run. The flow rate will be noted at the completion of the run. The flow rate for the run will be the average of the flow rates at the beginning and end of the run. The reading on the time counter will be noted at the beginning of the sample run and at the end of the run. The difference on the time counter from the end of the run and the beginning of the run will be the sample run time. The sample counter is more accurate than elapsed time in that it will correct for any down time due to power outages.

The sampling head from the PSUs will be collected, bagged, and sent to the laboratory for analysis.

At the completion of the project, the PSU will be decontaminated with antiseptic wipes. After decontamination, the EPA Team will collect swab samples at the PSU inlet hood and on the lid of the PSU. The swab samples will be sent to the laboratory for QA/QC analysis.

Table 3-1 presents a summary of the samples and the sample rational associated with each. Information regarding sample analysis is presented in Section 4.

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3.4.4 Wipe Sampling

The EPA Team will collect wipe samples from flat surfaces using sterile swabs made of synthetic fibers. Wipe samples will be collected from the vans that were used to transport macaques from the South Campus to the North Campus and from the PSUs at the completion of the project.

3.4.5 Investigation-Derived Wastes

Any used PPE, excess fluids generated as a result of equipment decontamination, and non-dedicated sampling equipment will be stored on-site and be disposed by the TNPRC.

3.4.6 Quality Assurance/Quality Control Samples

The EPA Team will observe collection of field duplicates of soil samples, water and air samples and document preparation of QA/QC samples as needed during the response sampling activities. QA/QC samples may include but not be limited to the following:

- Blind field duplicate soil samples and sediment samples may be collected to assist in the QA of the sampling procedures and laboratory analytical data by allowing an evaluation of reproducibility of results. Efforts will be made to collect duplicate samples in locations where there is visual evidence of contamination or where contamination is suspected. Blind field duplicate samples will be collected at the rate of one duplicate for every 10 samples collected.

- Equipment rinsate blanks may be prepared by pouring laboratory-grade de-ionized water over non-disposable sampling equipment after it has been decontaminated and by collecting the rinse water in sample containers for analyses.

- Field blanks may be prepared by pouring laboratory-grade de-ionized water into pre-cleaned laboratory-grade sample containers for analysis. These samples will be prepared to demonstrate the impact the surrounding environment is having on the samples being collected. Field blank samples will be collected for this particular scope of work at a rate of one per day.

- Wipe (swab) samples will be collected during decontamination activities of the PSU units. These samples will be prepared to demonstrate that the equipment decontamination

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procedures for the sampling equipment were performed effectively. The wipe samples will be collected at the end of each air sample collection period.

Specific laboratory information is included in Section 4 of this QASP.

3.5 DEVIATIONS FROM THE SAMPLING PLAN

Deviations from the sample locations may occur at the EPA TM direction due to new observations made prior to sampling, information obtained in the field that warrants an altered sampling point, difficulty in sample collection, or limited access. The EPA TM will be notified, and concurrence will be obtained should significant deviations from the planned sampling points be proposed. Details regarding deviations of the QASP will be documented in the site logbook and reported in the final ER report to EPA.

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Table 3-1
Sample Locations and Sampling Rationale
Tulane University – National Primate Research Center
Covington, Louisiana

Sample Name	Sample Matrix	Sample Location (refer to Figure 3-1)	Rationale
SW01-G-150209-N-01	Surface Water	Pond 9	Part of the storm water treatment system.
SW02-G-150209-N-01	Surface Water	Pond 8	Storm water collects here.
SW03-G-150209-N-01	Surface Water	Outfall 004	Confluence of site storm water.
SW03-G-150209-D-01	Surface Water	Outfall 004 - Duplicate	Duplicate -- collected for QA/QC
SW04-G-150209-N-01	Surface Water	Outfall 003	Outlet of water treatment system. All sewage and storm water exits here.
SW05-G-150209-N-01	Surface Water	Field Blank	Tap Water -- collected for QA/QC
SW06-G-150209-N-01	Surface Water	Contact Basin	Part of water treatment system. Sewage and storm water flow through here.
SW07-G-150209-N-01	Surface Water	Rock Filter	Part of water treatment system. Sewage and storm water flow through here.
SW08-G-150209-N-01	Surface Water	Wetlands – South	Part of water treatment system. Sewage and storm water flow through here.
SW09-G-150209-N-01	Surface Water	Wetlands – West	Part of water treatment system. Sewage and storm water flow through here.
SW10-G-150209-N-01	Surface Water	Wetlands – North	Part of water treatment system. Sewage and storm water flow through here.
SW11-G-150209-N-01	Surface Water	Ditch near Macaque Cage - G12	G12 was a cage that held an affected macaque. Determine if waste products spread Bp into the ditch near the cage.
SW12-G-150209-N-01	Surface Water	Ditch near Macaque Cage - R24	R24 was a cage that held an affected macaque. Determine if waste products spread Bp into the ditch near the cage.
SW13-G-150209-N-01	Surface Water	Aeration Pond	Part of water treatment system. Sewage passes through here.
WW14-G-150212-N-01	Waste Water	Lift Station	Part of water treatment system. Sewage from North Campus passes here.
PSU01-C-YYMMDD-N-01	Air	Fenceline near Northlake Christian School (East side of South Campus)	Collected to document air monitoring – one sample per day

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Sample Name	Sample Matrix	Sample Location (refer to Figure 3-1)	Rationale
PSU02-C-YYMMDD-N-01	Air	Near sewage aeration pond (West side of South Campus)	Collected to document air monitoring – one sample per day
PSU03-C-YYMMDD-N-01	Air	Near gravel filter (Middle of South Campus)	Collected to document air monitoring – one sample per day
PSU04-C-150212-N-01	Air	Near maintenance building (North Campus)	Collected to document air monitoring – one sample only
SWAB01-G-150212-N-01	Swab	Steering wheel of van 1 TPC09 Lic# V340918	Vehicle used to transfer macaques
SWAB02-G-150212-N-01	Swab	Front of bed of van 1 TPC09 Lic# V340918	Vehicle used to transfer macaques
SWAB03-G-150212-N-01	Swab	Middle of bed of van 1 TPC09 Lic# V340918	Vehicle used to transfer macaques
SWAB04-G-150212-N-01	Swab	Back of bed of van 1 TPC09 Lic# V340918	Vehicle used to transfer macaques
SWAB05-G-150212-N-01	Swab	Steering wheel of van 2 TPC22 Lic# KIB568	Vehicle used to transfer macaques
SWAB06-G-150212-N-01	Swab	Bed of van 2 TPC22 Lic# KIB568	Vehicle used to transfer macaques
SWAB07-G-150212-N-01	Swab	Head of PSU247	PSU was used inside of South Campus
SWAB08-G-150212-N-01	Swab	Lid of PSU247	PSU was used inside of South Campus
SWAB09-G-150212-N-01	Swab	Head of PSU340	PSU was used inside of South Campus
SWAB10-G-150212-N-01	Swab	Lid of PSU340	PSU was used inside of South Campus
SWAB11-G-150212-N-01	Swab	Head of PSU465	PSU was used inside of South Campus
SWAB12-G-150212-N-01	Swab	Lid of PSU465	PSU was used inside of South Campus

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Table 3-1
Sample Locations and Sampling Rationale
Tulane University – National Primate Research Center
Covington, Louisiana
(Continued)

Sample Name	Sample Matrix	Sample Location (refer to Figure 3-1)	Rationale
SS01-G- 150210-N-01 through SS10-G- 150210-N-01	Soil/Sediment	Near cage G12	G12 was a cage that held an affected macaque. Samples will determine if waste products spread Bp into the soil near the cage.
SS11-G- 150210-N-01 through SS16-G- 150210-N-01	Soil/Sediment	Near cage R24	R24 was a cage that held an affected macaque. Samples will determine if waste products spread Bp into the soil near the cage.
SS17-G- 150210-N-01	Soil/Sediment	Outfall 003	Outlet of water treatment system. All sewage and storm water exits here.
SS18-G- 150210-N-01	Soil/Sediment	Outfall 004	Collection of all storm water on the site.
SS19-G- 150210-N-01 through SS22-G- 150210-N-01	Soil/Sediment	Ditches near G12	Col G12 was a cage that held an affected macaque. Samples will determine if waste products spread Bp into the soil near the cage.
SS23-G- 150210-N-01 through SS28-G- 150210-N-01	Soil/Sediment	Ditches near R24	R24 was a cage that held an affected macaque. Samples will determine if waste products spread Bp into the soil near the cage.
SS29-G- 150210-N-01	Soil/Sediment	Outfall 004 Ditch	Collection of all storm water on the site.
SS30-G- 150210-N-01 through SS32-G- 150210-N-01	Soil/Sediment	Wetland area, North, Middle, and South	Part of the water treatment system. All sewage and storm water passes through here.
SS33-G- 150210-N-01 through SS35-G-150210-N-01	Soil/Sediment	Duplicates, TBD	Duplicate -- collected for QA/QC
SS36-C- 150211-N-01	Soil/Sediment	Surface composite from inside of cage G12 – 4 points under perches	Cage held an affected macaque
SS37-C- 150211-N-01	Soil/Sediment	Grab depth sample inside of cage G12 – under a perch	Cage held an affected macaque
SS38-G- 150211-N-01	Soil/Sediment	Surface composite from inside of cage G12 – 4 points not under perches	Cage held an affected macaque
SS39-C- 150211-N-01	Soil/Sediment	Grab depth sample inside of cage G12 – not under a perch	Cage held an affected macaque

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SS40-G- 150211-N-01	Soil/Sediment	Surface composite from inside of cage R24	Cage held an affected macaque
SS41-G- 150212-N-01	Soil/Sediment	Surface grab from van parking area	Vans used to transport macaques
SS42-G- 150212-N-01	Soil/Sediment	Surface grab from van parking area	Vans used to transport macaques

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4. ANALYTICAL APPROACH

Samples collected as part of the response will be prepared for shipment and shipped by TNPRC personnel who have training and certification in the proper shipment of biological samples. The EPA team will prepare chain-of-custody (COC) documentation and will assist TNPRC personnel with the sample packaging. Samples will be sent to the CDC laboratory in Atlanta, Georgia.

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Table 4-1
Requirements for Containers, Preservation Techniques, Sample Volumes, and Holding Times
Tulane University – National Primate Research Center
Covington, Louisiana

Name	Analytical Methods	Container	Preservation	Sample Containers	Maximum Holding Time
Bp bacteria in soil	CDC methods	Glass	None. Keep at ambient temperature and out of UV light	One 8 oz jar	N/A
Bp bacteria in water	CDC methods	Glass	None. Keep at ambient temperature and out of UV light	Two 1-liter jars	N/A
Bp bacteria in air	CDC methods	PTFE Filter	None. Keep at ambient temperature and out of UV light	One sample filter assembly	N/A
Bp bacteria on a surface	CDC methods		None. Keep at ambient temperature and out of UV light		N/A

oz = ounce
PTFE = Polytetrafluoroethylene
Note: Information on containers, preservation, and holding times provided by CDC.

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5. QUALITY ASSURANCE

Quality assurance will be conducted in accordance with the WESTON Corporate Quality Management Manual, dated March 2014, and the WESTON Programmatic Quality Assurance Project Plan (QAPP). Following receipt of the TDD from EPA, a Quality Control (QC) officer is assigned and monitors work conducted throughout the entire project including reviewing interim report deliverables and field audits. The EPA Team FTL will be responsible for QA/QC of the field investigation activities. The designated laboratory utilized during the investigation will be responsible for QA/QC related to the analytical work. The EPA Team will also collect samples to verify that laboratory QA/QC is consistent with the required standards and to validate the laboratory data received as described above.

All sampling will be conducted following SOPs, which are found in Appendix A.

5.1 SAMPLE CUSTODY PROCEDURES

After sample collection and identification, samples will be maintained under COC procedures. If the sample collected is to be split (laboratory QC), the sample will be allocated into similar sample containers. Sample labels completed with the same information as that on the original sample container will be attached to each of the split samples. Personnel required to package and ship coolers containing potentially hazardous material will be trained accordingly.

The EPA Team will prepare and complete COC forms using SCRIBE for samples sent to an off-site laboratory. The COC procedures are documented and will be made available to personnel involved with the sampling. A typical COC record will be completed each time a sample or group of samples is prepared for shipment to the laboratory. The record will repeat the information on each sample label and will serve as documentation of handling during shipment. A copy of this record will remain with the shipped samples at all times, and another copy will be retained by the member of the sampling team who originally relinquished the samples. At the completion of the project, the DM will export the SCRIBE COC documentation to the Analytical Service Tracking System (ANSETS) database.

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Samples relinquished to the participating laboratories will be subject to the following procedures for transfer of custody and shipment:

- Samples will be accompanied by the COC record. When transferring possession of samples, the individuals relinquishing and receiving the samples will sign, date, and note the time of the sample transfer on the record. This custody records document transfer of sample custody from the sampler to another person or to the laboratory.
- Samples will be properly packed for shipment and dispatched to the appropriate laboratory for analysis with separate, signed custody records enclosed in each sample box or cooler. Sample shipping containers will be custody-sealed for shipment to the laboratory. The preferred procedure includes use of a custody seal wrapped across filament tape that is wrapped around the package at least twice. The custody seal will then be folded over and adhered to seal and ensure that the only access to the package is by cutting the filament tape or breaking the seal to unwrap the tape.
- If sent by common carrier, a bill of lading or airbill will be used. Bill of lading and airbill receipts will be retained in the project file as part of the permanent documentation of sample shipping and transfer.

5.2 PROJECT DOCUMENTATION

Documents will be completed legibly in ink and by entry into field logbooks and SCRIBE as described above. Response Manager will be used based on direction of the EPA TM.

5.2.1 Custody Seal

Custody seals demonstrate that a sample container has not been tampered with or opened. The individual who has custody of the samples will sign and date the seal and affix it to the container in such a manner that it cannot be opened without breaking the seal.

5.2.2 Photographic Documentation

The EPA Team will take photographs to document site conditions and activities as site work progresses. Initial conditions should be well documented by photographing features that define the working conditions. Representative photographs should be taken of each type of site activity. The photographs should show typical operations and operating conditions as well as special

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situations and conditions that may arise during site activities. Site final conditions should also be documented as a record of how the site appeared at completion of the work.

Photographs will be taken using digital cameras capable of recording the date, time, and location. Each photograph will be recorded in the logbook with the location of the photographer, direction the photograph was taken, the subject of the photograph, and its significance (i.e., why the picture was taken).

5.2.3 Report Preparation

At the completion of the project, the EPA Team will review and validate laboratory data and prepare a draft report of field activities and analytical results for EPA TM review. Draft deliverable documents will be uploaded to the EPA TeamLink Web-site for EPA TM review and comment.

ED_005457_00000007-00024

Message

From: Deitchman, Scott (CDC/ONDIEH/NCEH) [sed2@cdc.gov]
Sent: 2/20/2015 8:56:27 PM
To: Kevin Davis (Kevin.Davis@LA.GOV) [Kevin.Davis@LA.GOV]; daccardo@stpgov.org; dsibley@tulane.edu; bohm@tulane.edu; Jimmy Guidry (DHH) [Jimmy.Guidry2@LA.GOV]; jmlacour@wlf.la.gov; Jeff Dauzat (Jeff.Dauzat@LA.GOV) [Jeff.Dauzat@LA.GOV]; Brent Robbins (brobbins@ldaf.state.la.us) (brobbins@ldaf.state.la.us) [brobbins@ldaf.state.la.us]; Collins Simoneaux (Collins.Simoneaux@LA.GOV) [Collins.Simoneaux@LA.GOV]; Raoult Ratard <Raoult.Ratard@LA.GOV> (Raoult.Ratard@LA.GOV) [Raoult.Ratard@LA.GOV]; dstacy@ldaf.la.gov; Isaac, Freeda (CDC aphis.usda.gov) [freeda.e.isaac@aphis.usda.gov]; Katie.Portacci@aphis.usda.gov; Martin, John [martin.john@epa.gov]; Canzler, Erica [Canzler.Erica@epa.gov]; Nalipinski, Mike [Nalipinski.Mike@epa.gov]
Subject: Soil and water samples negative
Attachments: FIGURE 1 - SAMPLE LOCATION MAP.PDF; Sample Locations.xls.pdf; Tulane University ER QASP - v2.pdf

This afternoon the CDC laboratory informed us that they were able to complete the analysis of all soil and water samples. **All samples were negative for *Burkholderia pseudomallei*.**

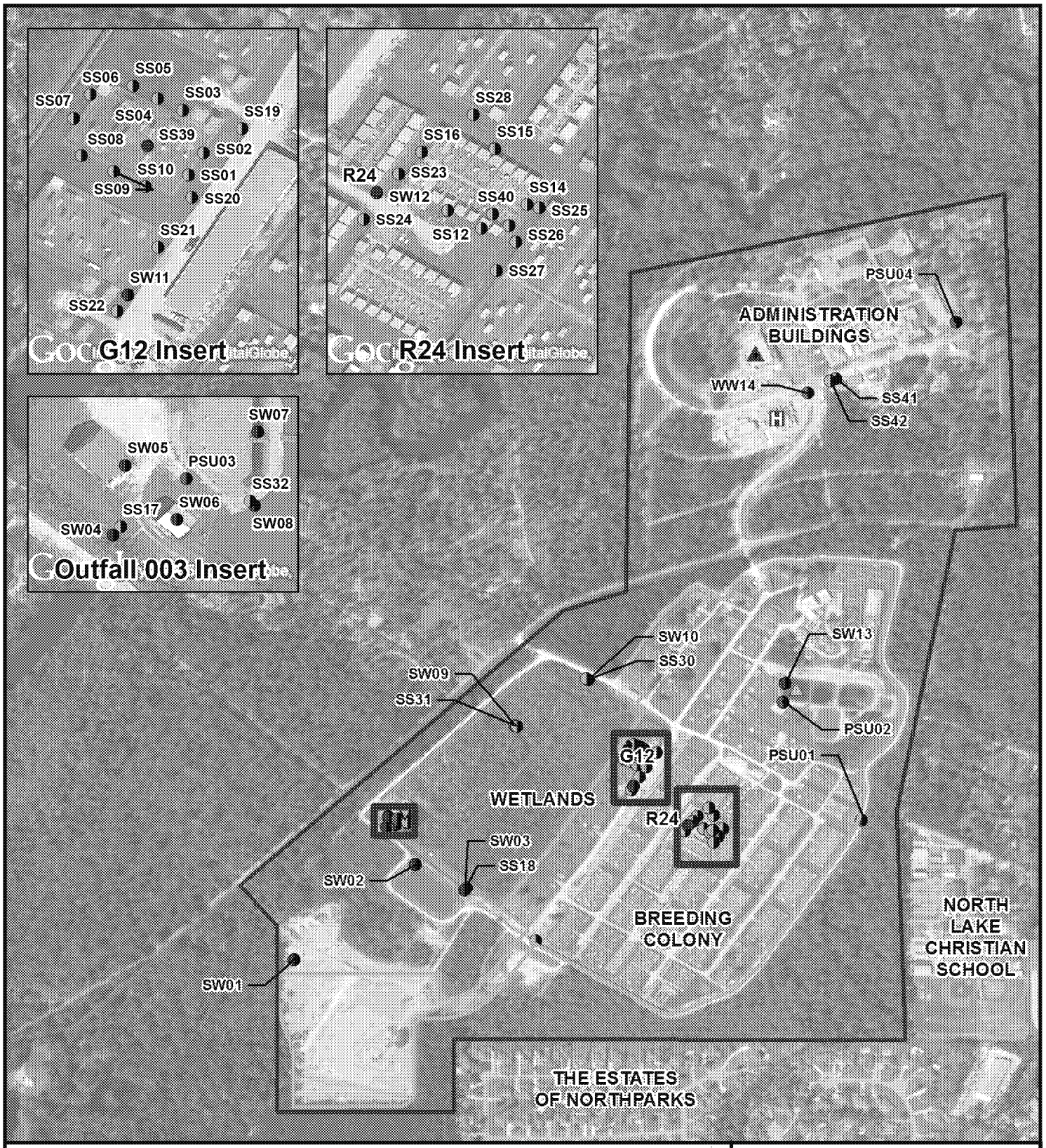
The laboratory performed two tests: polymerized chain reaction (PCR) which looks for the organism, whether dead or alive, by detecting its genetic material (DNA); and culturing, which should grow any live organisms. All samples were negative by both tests.

The samples included: 42 soil samples; 15 water samples; and 12 swab samples. Attached are the sample location information and sampling plan that was provided by EPA.

Please share as appropriate within your organizations.

Regards,
Scott

RADM Scott Deitchman, MD MPH, USPHS
Assistant Surgeon General
Associate Director for Environmental Health Emergencies
National Center for Environmental Health and
Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention
Atlanta GA USA



LEGEND

- SITE BOUNDARY
- BREEDING COLONY
- PRIMATE LOCATIONS
- ANIMAL HOSPITAL
- ONSITE LABRATORY
- AERATION POND
- CHLORINATED CONTACT BASIN

SAMPLE LOCATIONS

- AIR SAMPLE
- SOIL SAMPLE
- WATER SAMPLE
- WASTE WATER SAMPLE

LOUISIANA

N

0 750 1,500

SCALE IN FEET

SOURCE: BING MAPS AERIAL IMAGERY; GOOGLE EARTH IMAGERY

Tulane National Primate Research Center

FIGURE 1

SAMPLE LOCATION MAP

TULANE NATIONAL PRIMATE RESEARCH CENTER

18703 3 RIVERS ROAD

COVINGTON, ST. TAMMANY PARISH, LOUISIANA

DATE	PROJECT NO	SCALE
FEBRUARY, 2015		AS SHOWN

Sampling Location	Location Description	Property ID	Latitude	Longitude
PSU01		AIR	30.4486974	-90.09234846
PSU02		AIR	30.4505	-90.09354
PSU03		AIR	30.44872	-90.09942
PSU04		Air	30.4563	-90.0909
PSU247		PSU Unit	0	0
PSU340		PSU Unit	0	0
PSU465		PSU Unit	0	0
SS01		SOIL	30.4495797	-90.09563576
SS02		SOIL	30.449648	-90.09558963
SS03		SOIL	30.449779	-90.09565307
SS04		SOIL	30.4498149	-90.09573032
SS05		SOIL	30.4498531	-90.09580619
SS06		SOIL	30.4498262	-90.09593607
SS07		SOIL	30.4497542	-90.09598782
SS08		SOIL	30.4496391	-90.09596338
SS09		SOIL	30.4495911	-90.09586456
SS10		SOIL	30.4495445	-90.09576748
SS11		SOIL	30.4485606	-90.0947539
SS12		SOIL	30.4485011	-90.09464322
SS13		SOIL	30.44851	-90.09455
SS14		SOIL	30.44858	-90.09449
SS15		SOIL	30.4487664	-90.09459805
SS16		SOIL	30.4487559	-90.09484161
SS17	Outfall 003	SOIL	30.44861	-90.09957
SS18	Outfall 004	SOIL	30.44766	-90.09837
SS19	Ditch	SOIL	30.4497224	-90.09547163
SS20	Ditch	SOIL	30.4495114	-90.0956255
SS21		SOIL	30.4493583	-90.09572925
SS22		SOIL	30.4491641	-90.09585375
SS23		SOIL	30.4486816	-90.09491776
SS24		SOIL	30.4485319	-90.09503415

Sampling Location	Location Description	PropertyID	Latitude	Longitude
SS25		SOIL	30.44857	-90.09445
SS26		SOIL	30.4484561	-90.0945282
SS27		SOIL	30.4483614	-90.09459161
SS28		SOIL	30.44888	-90.09467
SS29	South Ditch	SOIL	30.4468634	-90.09730328
SS30	Wetlands North	SOIL	30.4508609	-90.09654271
SS31	Wetlands Middle	SOIL	30.45013	-90.0976
SS32	Wetlands South	SOIL	30.4486683	-90.09927447
SS36	G12	SOIL	30.44967	-90.095762
SS37	G12	SOIL	30.44967	-90.095762
SS38	G12	SOIL	30.44967	-90.095762
SS39	G12	SOIL	30.44967	-90.095762
SS40	R24	SOIL	30.4485495	-90.09460484
SS41		SOIL	30.45543	-90.09274
SS42		SOIL	30.4554013	-90.09282125
SW01	Pond 9	WATER	30.44657	-90.101
SW02	Pond 8	WATER	30.44802	-90.09915
SW03	Outfall 004	WATER	30.44763	-90.0984
SW04	Outfall 003	WATER	30.4485911	-90.09958663
SW05	FB from Faucet	WATER	30.44875	-90.09956
SW06	Contact Basin	WATER	30.448627	-90.0994422
SW07	Rock Filter	WATER	30.4488266	-90.09925759
SW08	Wetlands South	WATER	30.4486583	-90.09926502
SW09	Wetlands Middle	WATER	30.45014	-90.09763
SW10	Wetlands North	WATER	30.4508381	-90.09650415
SW11	Ditch Near G12	WATER	30.4492127	-90.09582126
SW12	Ditch Near R24	WATER	30.44862	-90.09499
SW13	Aeration Pond	WATER	30.45079	-90.09351
Van 1		Vehicle	0	0
Van 2		Vehicle	0	0
WW14		Waste Water	30.4552163	-90.09316

Message

From: Lackner, Andrew A [alackner@tulane.edu]
Sent: 2/28/2015 5:33:35 PM
To: Kevin Davis (Kevin.Davis@LA.GOV) [Kevin.Davis@LA.GOV]; daccardo@stpgov.org; Sibley, Don A [dsibley@tulane.edu]; Bohm, Rudolf P [bohm@tulane.edu]; Jimmy Guidry (DHH) [Jimmy.Guidry2@LA.GOV]; jmlacour@wlf.la.gov; Brent Robbins (brobbins@ldaf.state.la.us) (brobbins@ldaf.state.la.us) [brobbins@ldaf.state.la.us]; Raoult Ratard <Raoult.Ratard@LA.GOV> (Raoult.Ratard@LA.GOV) [Raoult.Ratard@LA.GOV]; Isaac, Freeda (CDC aphis.usda.gov) [freeda.e.isaac@aphis.usda.gov]; Katie.Portacci@aphis.usda.gov; Martin, John [martin.john@epa.gov]; Deitchman, Scott (CDC/ONDIEH/NCEH) [sed2@cdc.gov]; Hoffmaster, Alex (CDC/OID/NCEZID) [amh9@cdc.gov]; David Blaney [znr5@cdc.gov]; xdf8@cdc.gov; Grant, Deborah L [dgrant@tulane.edu]; Alise, Mark A [malise@tulane.edu]; Bohm, Rudolf P [bohm@tulane.edu]; Victoria.Y.Guilfoil@aphis.usda.gov; Kenneth.L.Angel@aphis.usda.gov
Subject: additional samples sent to CDC for confirmatory testing
Attachments: removed.txt

Dear all,

We have sent a bacterial isolate from a nonhuman primate (IL88) that we are concerned could be Burkholderia to Alex Hoffmaster at CDC for confirmatory testing.

Here are relevant aspects of the case:

- Admitted to the animal hospital on 12/30/14 for trauma from R/12D. This was during the window of time when one of the infected cases (IB22) was in the hospital
- No clinical signs associated with a bacterial infection at admission
- The animal was treated in the same procedure room as the other 2 infected and 2 seropositive animals
- IL88 was treated twice in this procedure room prior to its initial decontamination
- Clinical signs of trauma resolved
- On a recheck on February 23 the animal had two small ulcerations on the abdomen. Bacterial cultures were taken, the animal was euthanized and a complete necropsy performed.

****
Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu

****

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Message

From: Martin, John [martin.john@epa.gov]
Sent: 2/25/2015 11:01:17 PM
To: Petersen, Chris [petersen.chris@epa.gov]
Subject: FW: USDA risk assessment team
Attachments: FIGURE 1 - SAMPLE LOCATION MAP.pdf; Sample Locations.xls.pdf; Tulane University ER QASP - v2.pdf

Sent from my Windows Phone

From: Martin, John
Sent: 2/20/2015 2:56 PM
To: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: FW: USDA risk assessment team

Fyi

Sent from my Windows Phone

From: Martin, John
Sent: 2/19/2015 11:54 AM
To: Katie.Portacci@aphis.usda.gov; mgc8@cdc.gov
Cc: Rhotenberry, William; McAteer, Mike; Nalipinski, Mike; Canzler, Erica; Jeff.dauzat@la.gov
Subject: RE: USDA risk assessment team

Here's the information you requested. Apologies it took so long. Not sure if you participated in this morning's UC Tulane Primate Center conf call but Dr Isaac (sp?) with USDA was asking about the status of these attachments and when be a good time to meet on site; the week of Feb 23 or Mar 2? Not sure if she got her answer but EPA won't be there next week. However, we should be in Covington the week of Mar 2.

The analytical results from our/Tulane's sampling activities should come from the CDC lab on Wed for the cultures. If any samples are positive, then the lab should conduct further analysis to determine the bacterium species. Not sure of the timing on that analysis.

Not sure if an environmental working group has been formally established but that is a good idea. If you like, please give me a call and we can discuss the next steps.

thanks

John J. Martin
Federal On-Scene Coordinator (OSC)
1445 Ross Ave (6SF-PE)
Dallas, Texas 75202

214.665.6748 * *fax 214.665.2278*

From: Rhotenberry, William
Sent: Tuesday, February 17, 2015 4:48 PM
To: Martin, John; McAteer, Mike
Subject: Fwd: USDA risk assessment team

Fyi
Sent from my iPhone

Begin forwarded message:

> **From:** "Portacci, Katie - APHIS" <Katie.Portacci@aphis.usda.gov>
> **To:** "Canzler, Erica" <Canzler.Erica@epa.gov>, "Cruz, Miguel (CDC/ONDIEH/NCEH) <mgc8@cdc.gov> (mgc8@cdc.gov)" <mgc8@cdc.gov>, "Rhotenberry, William" <Rhotenberry.William@epa.gov>, "Nalipinski, Mike" <Nalipinski.Mike@epa.gov>, "jmlacour@wlf.la.gov" <jmlacour@wlf.la.gov>, "" <Jeff.dauzat@la.gov>
> **Cc:** "ROONEY, Alejandro - ARS" <Alejandro.Rooney@ARS.USDA.GOV>, "Clouse, Timothy L - APHIS" <Timothy.L.Clouse@aphis.usda.gov>
> **Subject: USDA risk assessment team**
>
> Hi everyone,
> I do not think I am reaching the entire environmental working group, but I wanted to reach out to you and suggest meeting in Covington beginning 2/24 as a working group. Miguel, feel free to share and hopefully we can coordinate with everyone in the group. Sorry if I am jumping the gun, but we wanted to make plans in advance so we can get all our medical stuff out of the way. (If results from EPA will be longer than next Monday please let us know).
>
> The USDA risk assessment team would like to come take a look at the environment outside of the facility. Coordinating our visit with the other agencies would give us all the opportunity to tour together and discuss the results as they come in. If all samples are negative, we need to discuss options for next steps and make sure we are all on the same page. It would be great if all agencies were able to give a collective recommendation to the state. Meeting with others concerned about these issues would help us discuss long-term monitoring options as well as potential mitigations.
>
> Our proposed visit would include:
>
> 1. Walking the outer perimeter of the facility, particularly along water ways
>
> 2. Visiting sites downstream and upstream for current and future risks
>
> 3. Visiting livestock facilities (USDA would do alone unless others were interested)
>
> 4. Meeting with the group to discuss results interpretation and long term strategies/recommendations or next steps for analyses
>
> 5. Discussion additional sampling of soil or wildlife
>
> We are concerned about the long-term establishment of B. pseudomallei outside of the facility. The environmental conditions in the area lend itself to this possibility (SEE MAP ATTACHED) On the left hand side of your screen, under the paper clip, you will see a layer

symbol. You can use this to turn on/off layers.) If this occurs, the continued risk to humans and other animals would be present. We are going to look at the possible national extent that this organism could establish. The layers we are looking at are soil PH, Soil moisture, soil clay, and soil temperature. Please let us know if there are other layers you are looking at or would like us to look at. Water would be nice but we don't have great water layers and even if water gets too cold, it could hide in soil in the area.

Also data we are still missing and would love to fill in the gaps:

- Soil sampling plan/protocol
- Information on compost pile (what is in here, is it covered?)

Please let us know if others are on board! Miguel it'd be really great to have someone from your staff come with us.
(Also I'm not clear on how this group will interact with the science and technical working group so if someone from that group need to join us please do so!)

Thanks!

Katie Portacci, DVM, MPH, DACVPM | USDA APHIS Veterinary Services
Center for Epidemiology and Animal Health
Project Manager: Risk Analysis
2150 Centre Avenue, Bldg B | Ft Collins, CO 80526
970-494-7189 (office)/ 970-494-1741 (cell)
Katie.Portacci@aphis.usda.gov

The best doctor in the world is a veterinarian. He can't ask his patients what is the matter -- he's got to just know. – Will Rogers

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Message

From: Lackner, Andrew A [alackner@tulane.edu]
Sent: 7/9/2015 7:05:11 PM
To: Collins Simoneaux [Collins.Simoneaux@LA.GOV]
CC: Scott Deitchman [sed2@cdc.gov]; Rosanne Prats [Rosanne.Prats@la.gov]; freeda.e.isaac@aphis.usda.gov; katie.portacci@aphis.usda.gov; kenneth.l.angel@aphis.usda.gov; brobbins@ldaf.la.gov; Martin, John [martin.john@epa.gov]; Mike Algero [Mike.Algero@LA.GOV]; Jim LaCour [JLaCour@wlf.la.gov]; Logan, Michael J - APHIS (Michael.J.Logan@aphis.usda.gov) [Michael.J.Logan@aphis.usda.gov]; DSosin@cdc.gov; tpracheil@tulane.edu; pjreeb@stpgov.org; Clarence Powe [cpowe@stpgov.org]; Kevin Davis [Kevin.Davis@LA.GOV]; Dexter Accardo [daccardo@stpgov.org]; Jimmy Guidry (DHH) [Jimmy.Guidry2@LA.GOV]; Christopher Guilbeaux [Christopher.Guilbeaux@LA.GOV]; Mike Steele [Mike.Steele@LA.GOV]; Jason Lachney [Jason.Lachney@LA.GOV]; Melton Gaspard [Melton.Gaspard@LA.GOV]
Subject: Re: TNPRC Updates

Here is the update from the TNPRC

Ongoing testing of the seropositive healthy macaques has not revealed any evidence of shedding of *Burkholderia pseudomallei*: more than 130 cultures to date: 63 urine samples, 68 rectal swabs.

Wildlife testing on primate center grounds is ongoing and to date each animal tested (n = 143) has been negative by culture. This includes feral cats, rats, mice, opossums, armadillo, nutria and raccoons.

As noted previously, additional soil testing in and immediately around the field cages that housed the original two animals occurred the week of April 27 utilizing rigorous consensus methods developed by the international *Burkholderia pseudomallei* research community. The soil collection was extensive and included approximately 600 samples. Each sample was tested three ways: 1) PCR on total DNA extracted from soil, 2) PCR on soil after enrichment involving inoculation in water and Ashdown broth, and 3) culture on Ashdown agar followed by PCR; three replicates from each of these samples were tested with PCR. All samples were negative for *Burkholderia pseudomallei* by all three techniques.

****
Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu
****

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On Jul 9, 2015, at 9:12 AM, Collins Simoneaux <Collins.Simoneaux@LA.GOV> wrote:

All,

The Unified Command has decided to transition from weekly Incident Action Plans (IAPs) to Situation Reports issued every two weeks. Tomorrow will be the first biweekly Sitrep. Please send me any TNPRC updates for tomorrow's situation report not later that 4:30pm CDT today, Thursday, July 9, 2015.

V/r,

Collins

Collins R. Simoneaux
Region 9 Coordinator
Governor's Office of Homeland Security
and Emergency Preparedness
225-925-7500 GOHSEP Office
225-329-4261 Cell Phone
collins.simoneaux@la.gov
www.getagameplan.org
www.gohsep.la.gov

Message

From: Alise, Mark A [malise@tulane.edu]
Sent: 4/14/2015 1:15:10 PM
To: Nalipinski, Mike [Nalipinski.Mike@epa.gov]; Martin, John [martin.john@epa.gov]
CC: Lackner, Andrew A [alackner@tulane.edu]
Subject: Response to the Committee on Homeland Security and Governmental Affairs

Flag: Follow up

Mike and John,

On March 25 Senators Johnson and Carper of the US Senate Committee on Homeland Security and Governmental Affairs sent a letter to The Honorable Gina McCarthy, Administrator of the EPA regarding the incident at Tulane and requested a response. We would appreciate receiving a copy of the EPA response.

Please let me know if that is possible.

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

Message

From: Alise, Mark A [malise@tulane.edu]
Sent: 4/14/2015 1:20:14 PM
To: Martin, John [martin.john@epa.gov]; Nalipinski, Mike [Nalipinski.Mike@epa.gov]
CC: Lackner, Andrew A [alackner@tulane.edu]
Subject: Re: Response to the Committee on Homeland Security and Governmental Affairs
Attachments: removed.txt

Flag: Follow up

Thanks very much.

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

From: <Martin>, John <martin.john@epa.gov>
Date: Tuesday, April 14, 2015 at 8:18 AM
To: Mark Alise <malise@tulane.edu>, "Nalipinski, Mike" <Nalipinski.Mike@epa.gov>
Cc: Andrew Lackner <alackner@tulane.edu>
Subject: RE: Response to the Committee on Homeland Security and Governmental Affairs

Yes that's possible. When I get a copy of the signed final version, I'll be happy to forward it.

John J. Martin
Federal On-Scene Coordinator (OSC)
1445 Ross Ave (6SF-PE)
Dallas, Texas 75202

214.665.6748 * *fax 214.665.2278*

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Tuesday, April 14, 2015 8:15 AM
To: Nalipinski, Mike; Martin, John
Cc: Lackner, Andrew A
Subject: Response to the Committee on Homeland Security and Governmental Affairs

Mike and John,

On March 25 Senators Johnson and Carper of the US Senate Committee on Homeland Security and Governmental Affairs sent a letter to The Honorable Gina McCarthy, Administrator of the EPA regarding the incident at Tulane and requested a response. We would appreciate receiving a copy of the EPA response.

Please let me know if that is possible.

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

Appointment

From: Smith, Monica [smith.monica@epa.gov]
Sent: 4/13/2015 2:20:02 PM
To: Martin, John [martin.john@epa.gov]; Rhotenberry, William [Rhotenberry.William@epa.gov]

Subject: FW: CALL - Tulane Panel - call in number 866-299-3188 code 202-566-0184
Location: CALL IN NUMBER - 866-299-3188 CODE 202-566-0184

Start: 4/13/2015 3:00:00 PM
End: 4/13/2015 3:30:00 PM
Show Time As: Tentative

John – per Ronnie you should plan on listening in to the call. We will let Carl know you are on the call.

Bill - per Ronnie, please come up to Carl's conference room to sit in on the call with us. Monica

-----Original Appointment-----
From: Natarajan, Nitin
Sent: Thursday, April 09, 2015 2:05 PM
To: Natarajan, Nitin; Crossland, Ronnie; Petersen, Chris; Smith, Monica; Cheatham, Reggie; Tulis, Dana; 'dms8@cdc.gov'
Cc: Edlund, Carl
Subject: CALL - Tulane Panel - call in number 866-299-3188 code 202-566-0184
When: Monday, April 13, 2015 11:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: CALL IN NUMBER - 866-299-3188 CODE 202-566-0184

POC: Caroline Kenely – 202-566-2235 (scheduler)

From: Natarajan, Nitin
Sent: Wednesday, April 08, 2015 3:04 PM
To: Sosin, Dan (CDC/OPHPR/OD)
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH); Kenely, Caroline; Brooks, Becky
Subject: RE: information

I'm traveling tomorrow so was hoping for Friday. Maybe we can do Mon or Tuesday.

I've cc'd Caroline who can help with scheduling on our side.

Caroline - it'll be me, Reggie or Dana and Erica from HQ and Carl eglund and Ronnie crossland from R6.

Thanks all.

N

Nitin Natarajan
Deputy Assistant Administrator
Office of Solid Waste and Emergency Response

Environmental Protection Agency
202-566-0200 Office

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: 4/8/2015 14:55
To: Natarajan, Nitin
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: RE: information

I don't have anything on my calendar Nitin. Do you still have a desire for a call this week? I am out on Friday, so need to schedule tomorrow. Scott and I would try to both be on the call.

Thank you.

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Natarajan, Nitin [mailto:Natarajan.Nitin@epa.gov]
Sent: Tuesday, April 07, 2015 12:55 PM
To: Sosin, Dan (CDC/OPHPR/OD)
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: RE: information

I've chatted with our folks and we think we can get there from here. Can we setup a call this week with our folks to discuss?

N

Nitin Natarajan
Deputy Assistant Administrator
Office of Solid Waste and Emergency Response
Environmental Protection Agency
202-566-0200 Office

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: 4/7/2015 12:50
To: Natarajan, Nitin
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: FW: information

Nitin: in case you are not aware, it appears that Tulane is acting on its own to convene a panel of independent experts to weigh in on the environmental sampling needs. The deliberations of this group should be helpful for considering additional USG-sponsored deliberations on sampling for biological threats in the environment.

It will be good to have a suitable lab or two in mind to conduct the testing should Tulane and the local authorities decide to do more testing.

Best regards,

Dan

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: Tuesday, April 07, 2015 12:47 PM
To: Helfand, Rita (CDC/OID/NCEZID); Deitchman, Scott (CDC/ONDIEH/NCEH); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: RE: information

Thank you Rita ... based on where we are in this response and our position on environmental testing, it seems best to be responsive to this panel's information requests regarding how we tested samples (as you are), and be particularly careful not to offer a contrary position to the EPA sampling methods as provided initially on request of the state.

It may be helpful to the community members to have an independent panel offer advice on further sampling at this point as long as Tulane is prepared to act on the input. The results of this panel should be informative of the need to further USG planning work for future events as well.

Dan

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Helfand, Rita (CDC/OID/NCEZID)
Sent: Tuesday, April 07, 2015 12:38 PM
To: Deitchman, Scott (CDC/ONDIEH/NCEH); Sosin, Dan (CDC/OPHPR/OD); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: FW: information

Fyi too

From: Hoffmaster, Alex (CDC/OID/NCEZID)
Sent: Tuesday, April 07, 2015 6:51 AM
To: Gee, Jay (CDC/OID/NCEZID); Glass Elrod, Mindy (CDC/OID/NCEZID); Blaney, David (CDC/OID/NCEZID); Nolen, Leisha (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID)
Cc: Belay, Ermias (CDC/OID/NCEZID); Helfand, Rita (CDC/OID/NCEZID); Damon, Inger K. (CDC/OID/NCEZID)
Subject: FW: information

See below regarding Tulane panel. Henry, Dave and I were just talking about this yesterday.

Mindy – well just send the consensus document along with any modifications done short description of how water was processed.
Alex

From: Lackner, Andrew A [mailto:alackner@tulane.edu]
Sent: Tuesday, April 07, 2015 6:17 AM
To: Hoffmaster, Alex (CDC/OID/NCEZID); Gee, Jay (CDC/OID/NCEZID)
Cc: Bohm, Rudolf P; Sibley, Don A
Subject: information

Alex,

As part of our response to the Burkholderia pseudomallei incident at Tulane an expert panel has been put together to help us work through the various issues that this has brought up. Among the members are David Wagner, Paul Keim and David Dance. Among the issues to consider is additional environmental testing. A question that came up in the discussion involved the methods used for environmental analyses to be sure that any future testing, if done, would be comparable with prior work. Thus, I would appreciate it if you could share details of how the analyses were performed.

best regards

Andrew
****
Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
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Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu
****

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Message

From: Petersen, Chris [petersen.chris@epa.gov]
Sent: 2/26/2015 4:58:00 PM
To: Martin, John [martin.john@epa.gov]
Subject: FW: Soil and water samples negative
Attachments: FIGURE 1 - SAMPLE LOCATION MAP.PDF; Sample Locations.xls.pdf; Tulane University ER QASP - v2.pdf

Importance: High

J. Chris Petersen
Deputy Associate Director
Response and Prevention Branch
US EPA Region 6
1445 Ross Ave, Ste. 1200
Dallas, TX 75202
214-665-3167 office
214-665-7447 fax
214-789-2535 cell

From: Deitchman, Scott (CDC/ONDIEH/NCEH) [mailto:sed2@cdc.gov]
Sent: Thursday, February 26, 2015 10:50 AM
To: Petersen, Chris
Subject: FW: Soil and water samples negative
Importance: High

As discussed.

Thanks,
Scott

RADM Scott Deitchman, MD MPH, USPHS
Assistant Surgeon General
Associate Director for Environmental Health Emergencies
National Center for Environmental Health and
Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention
Atlanta GA USA

From: Deitchman, Scott (CDC/ONDIEH/NCEH)
Sent: Friday, February 20, 2015 3:56 PM
To: Kevin Davis (Kevin.Davis@LA.GOV); daccardo@stpgov.org; dsibley@tulane.edu; bohm@tulane.edu; Jimmy Guidry (DHH); jmlacour@wlf.la.gov; Jeff Dauzat (Jeff.Dauzat@LA.GOV); Brent Robbins (brobbins@ldaf.state.la.us) (brobbins@ldaf.state.la.us); Collins Simoneaux (Collins.Simoneaux@LA.GOV); Raoult Ratard <Raoult.Ratard@LA.GOV> (Raoult.Ratard@LA.GOV); dstacy@ldaf.la.gov; Isaac, Freeda (CDC aphis.usda.gov) (freeda.e.isaac@aphis.usda.gov); Katie.Portacci@aphis.usda.gov; Martin.john@epa.gov; Erica Canzler (canzler.erica@epa.gov); nalipinski.mike@epa.gov
Subject: Soil and water samples negative

This afternoon the CDC laboratory informed us that they were able to complete the analysis of all soil and water samples. **All samples were negative for *Burkholderia pseudomallei*.**

The laboratory performed two tests: polymerized chain reaction (PCR) which looks for the organism, whether dead or alive, by detecting its genetic material (DNA); and culturing, which should grow any live organisms. All samples were negative by both tests.

The samples included: 42 soil samples; 15 water samples; and 12 swab samples. Attached are the sample location information and sampling plan that was provided by EPA.

Please share as appropriate within your organizations.

Regards,
Scott

RADM Scott Deitchman, MD MPH, USPHS
Assistant Surgeon General
Associate Director for Environmental Health Emergencies
National Center for Environmental Health and
Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention
Atlanta GA USA

BOBBY JINDAL
GOVERNOR

State of Louisiana

Governor's Office of Homeland Security and Emergency Preparedness

KEVIN DAVIS
DIRECTOR

March 13, 2015

Mr. Ron Curry
Regional Administrator (6-RA)
EPA Region VI
1445 Ross Avenue, Suite 1200
Dallas, TX 75202-2733

Re: Tulane National Primate Research Center (TNPRC) Incident
(Reference previous letter dated February 20, 2015 – copy attached)

Dear Mr. Curry:

Please consider this email my official request on behalf of the State of Louisiana to have appropriate representatives from your agency continue to participate and assist in activities related to the Tulane National Primate Research Center (TNPRC) investigation as previously detailed in my email to you dated February 20, 2015, including but not limited to:

- Working with TNPRC, Louisiana Department of Environmental Quality (LDEQ), U.S. Department of Agriculture (USDA), Center for Disease Control (CD), and other local, state and federal agencies involved in the response to this incident, in developing and coordinating **short term and long term environmental monitoring plans** for possible contamination of the environment with *Burkholderia pseudomallei (Bp),* both on and off the TNPRC site, by sampling of air, water, soil, or by whatever other means your agency, in coordination with other agencies, deems appropriate.
- In furtherance of the efforts listed above, to coordinate and lead conference calls among TNPRC, and other federal, state and local agencies that have created a "Science Working Group" to develop short term and long term environmental monitoring plans, decontamination plans, remediation plans, and other action plans in the event test results come back positive for Bp.
- Attendance by an appropriate representative from your agency at a town hall meeting in St. Tammany Parish on March 31, 2015 at 6:00pm, in conjunction with TNPRC and other federal, state and local agencies, to address and answer questions from the public concerning your agency's participation in the response to this incident.

7667 Independence Boulevard • Baton Rouge, Louisiana 70806 • (225) 925-7500 • Fax (225) 925-7501

- Continued representation and participation by your agency in the regular activities of the Unified Command as this incident evolves, and until such time as the Unified Command determines such assistance from your agency is no longer needed on a regular (daily) basis.

Effective planning and response are essential to our joint responsibility to protect the health and safety of our citizens. We appreciate your agency's ongoing assistance in achieving these objective through our unified response to this incident.

If you have any questions, please contact me at (225) 925-7345 or by email at Kevin.Davis@la.gov

Sincerely,

Kevin Davis,

cc: RADM Scott Deitchman, CDC (Unified Commander)
Dr. Jimmy Guidry, DHH (Unified Commander)
Mr. Dexter Accardo, St. Tammany Parish OHSEP, (Unified Commander)
Mr. John Martin, EPA
Mr. Chris Petersen, EPC

EMERGENCY RESPONSE
QUALITY ASSURANCE SAMPLING PLAN

FOR

TULANE UNIVERSITY - NATIONAL PRIMATE RESEARCH CENTER
18703 THREE RIVERS ROAD
COVINGTON, ST TAMMANY PARISH, LOUISIANA

Prepared for

U.S. Environmental Protection Agency Region 6
Will LaBombard, Project Officer
1445 Ross Avenue
Dallas, Texas 75202

Contract No. EP-W-06-042
Technical Direction Document No. 1/WESTON-042-15-008
WESTON Work Order No. 20406.012.001.0933.01
NRC No: N/A
CERCLIS ID: N/A
FPN: N/A
EPA TM: John Martin
START-3 PTL: Sam Cheek

Prepared by

Weston Solutions, Inc.
Cecilia H. Shappee P.E., Program Manager
5599 San Felipe, Suite 700
Houston, Texas 77056
(713) 985-6600

February 2015

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LIST OF APPENDICIES

Appendix A Standard Operating Procedures (SOPs)

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1. INTRODUCTION

Weston Solutions, Inc. (WESTON®), the Superfund Technical Assessment and Response Team (START-3) contractor, has been tasked by U.S. Environmental Protection Agency (EPA) Region 6 Prevention and Response Branch (PRB) under Contract Number EP-W-06-042 and Technical Direction Document (TDD) No. 1/WESTON-042-15-008 to conduct an Emergency Response (ER) at the National Primate Research Center, located in Covington, St Tammany Parish, Louisiana.

The EPA Team has prepared this ER Quality Assurance Sampling Plan (QASP) to describe the field investigation activities, sampling, and analytical scope of work to be conducted as part of the response.

1.1 PROJECT OBJECTIVES

The EPA Team is providing technical assistance to EPA Region 6 for the performance of the biological assessment as part of the ER. EPA will be responsible for coordinating the collection and analysis of environmental samples. However, personnel from the Tulane National Primate Research Center (TNPRC) will collect the on-site soil, sediment, and water samples with EPA oversight. The EPA Team will collect the air samples.

1.2 PROJECT TEAM

The EPA Team will consist of EPA Task Monitor (TM), John Martin; Sam Cheek, the EPA Team Project Team Leader (PTL); Jose Ojeda, the Field Team Leader (FTL); Jeff Wright, Project Chemist; Janine Latham, IT and Data Manager (DM); and additional EPA Team members as necessary to assist with sample preparation, packing, and shipment.

The EPA Team PTL will be responsible for the technical quality of work performed in the field and will serve as the EPA team liaison to the EPA TM during the field activities. The PTL will log the activities at each sample location in the field logbook and verify the sample

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documentation. The DM will be responsible for entering all samples collected into the Scribe Environmental Sampling Data Management System (SCRIBE), for producing accurate chain-of-custody documentation for the samples during the ER, and for entering daily operations and sample collection data into EPA Response Manager. The PTL will oversee the packaging and shipping of samples to the designated laboratory. The PTL will also be responsible for providing overall site health and safety support during field activities.

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2. SITE BACKGROUND

Two macaques at TNPRC were potentially infected with the bacteria Burkholderia pseudomallei (abbreviated Bp, the cause of Melioidosis). One animal was euthanized on 26 November 2014, and the second macaque has reportedly recovered. According to the Center for Disease Control (CDC) Burkholderia pseudomallei is a bacterium endemic to Southeast Asia and Northern Australia, and is typically found in contaminated water and soil. The bacterium spreads through direct contact with the contaminated source. The manner in which the macaques were exposed to the Bp is not known at this time.

An Inspector for the U.S. Department of Agriculture was reported to have become sick after performing an inspection at the facility. However, it has not been determined if the Inspector's illness is related to or is the result of exposure to Bp.

2.1 SITE LOCATION AND DESCRIPTION

The TNPRC is divided into a "North Campus" and a "South Campus." The North Campus is located north of Three Rivers Road and contains the offices and laboratories. The South Campus is located south of Three Rivers Road and contains the macaque breeding colonies, the storm-water treatment system, and the sewage treatment system. The macaques were located in cages in the South Campus when they were discovered to be sick.

2.2 OPERATIONAL HISTORY AND OWNERSHIP

The TNPRC has a national mission to improve human and animal health through basic and applied biomedical research. The TNPRC website states their purpose is the following:

- Conduct basic and applied biomedical research on human health problems using nonhuman primate models.
- Investigate nonhuman primate biology and diseases with particular regard to the study of human health problems.
- Serve as a regional and national resource and center of excellence for biomedical research using nonhuman primates.

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- Provide training for graduate students, postdoctoral fellows, veterinarians, undergraduates, veterinary students, and visiting scientists.
- Educate the general public about the critical link between basic research with animal models and improvements in human health.

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3. RESPONSE ACTIVITIES

The activities that will be conducted during the response are discussed in this section. Sampling of surface water, sediment and waste sampling procedures, locations, analytical approach, and quality assurance (QA) that will be conducted during the response are also discussed.

3.1 SAMPLING STRATEGY

A sampling strategy was developed by TNPRC and EPA representatives to collect the data necessary to evaluate and meet the objectives of the response. The sampling strategy focuses on the collection of soil, water, and air samples by employees of the TNPRC. Sampling Standard Operating Procedures (SOPs) for naturally occurring Bp in the soils of Southeast Asia call for a sample depth of 30 centimeters. However, for this response the source of the Bp is believed to be runoff of waste products from the macaque cages which could have been deposited onto the top of the soil or sediment. Therefore, soil and sediment samples will be collected in the top 2 inches of soil. Samples may be collected at a greater depth as the project progresses.

Table 3-1 has been prepared to include a summary of Sample Locations and Sampling Rationale as part of the ER field effort.

3.2 DATA QUALITY OBJECTIVE

The objective of sampling activities is to determine if Bp is present in the soil, sediment, water, and air at the facility. Soil, sediment, and water sampling will be conducted by TNPRC personnel. The EPA Team will conduct air sampling. The sampling will be conducted under direction of the EPA TM and TNPRC representatives. Media specific data quality objectives (DQOs) are not applicable. If DQOs are determined to be applicable, they will be developed using the seven-step process set out in the *EPA Guidance for Quality Assurance Project Plans: EPA QA/G-5*.

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3.3 PRELIMINARY FIELD ACTIVITIES

Mobilization and preliminary field activities for the ER are discussed in the following subsections.

3.3.1 Field Activities Review Meeting

The EPA Team FTL will conduct a meeting with the entire field team to familiarize them with the ER Scope of Work; to discuss EPA TM expectations, including planned field investigation activities; and to review the project Health and Safety Plan (HASP) and other relevant EPA team operating procedures. This meeting will be conducted in the WESTON Houston, Texas, office or via video conferencing for team members in other offices prior to mobilizing to the field.

3.3.2 Mobilization and Command Post Establishment

The EPA Team will mobilize the equipment required for the response from the EPA warehouse in Addison, Texas, and the WESTON equipment stores in Dallas and Houston, Texas. The field team will utilize the EPA mobile Logistics Response Vehicle (LRV) as a command post. Equipment used during the ER will be stored in the command post. Dedicated (nondisposable and disposable) sampling equipment will be used to collect samples in a manner minimizing the number of times that decontamination is performed on a daily basis.

Prior to demobilization, field supplies and equipment will be transported back to the EPA warehouse and WESTON equipment stores.

3.3.3 Health and Safety Plan Implementation

The ER field activities will be conducted in accordance with the site-specific HASP prepared for this investigation. In general, the HASP specifies that work on the North Campus will proceed in Level D personal protective equipment (PPE). During sampling events on the South Campus the EPA will be teamed with TNPRC personnel and follow TNPRC protocols wearing a modified Level C consisting of Tyvek coveralls, nitrile gloves, boot covers, surgical caps, face shields, and N95 masks. The EPA Team FTL will serve as the Field Safety Officer (FSO) and

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will be responsible for implementation of the HASP during field investigation activities. Daily tailgate safety meetings will be held prior to initiation of each work day.

In accordance with the EPA Team's general health and safety operating procedures, the field team will also drive the route to the hospital specified in the HASP prior to initiating sampling activities.

3.3.3 Documentation of Field Sampling Activities

The EPA Team will document the ER field activities in bound field logbooks. At a minimum, the information documented in the field logbook for each sample location will include the following:

- The sample location number and the depths of sample collection.
- A description of the sample location at the site.
- The sample matrix and sample description.
- The analyses for which the samples were collected.
- The date and time of sample collection.

Locations where samples are collected will be documented using a global positioning system (GPS) to obtain horizontal control.

3.3.4 Decontamination and Investigation-Derived Wastes (IDW)

The nondisposable sampling equipment (portable sampling unit) used during the sample collection process will be thoroughly decontaminated before initial use, between locations, and at the end of the response before leaving the Site. Decontamination activities will be conducted at a designated decontamination area. Equipment decontamination will be completed in the following steps:

- High-pressure water spray or brush, if needed, to remove soil from the equipment.
- Nonphosphate detergent and potable water wash to clean the equipment.
- Final potable water rinse.
- Equipment air dried.

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The fluids and excess soil/sediment generated as a result of equipment decontamination will be containerized and disposed of by TNPRC personnel according to facility protocols.

3.4 SAMPLING/MONITORING APPROACH

Air sampling will be conducted by the EPA Team. Soil/sediment sampling and water sampling will be conducted by the TNPRC with supervision by the EPA Team. The specific sampling, decontamination, sample handling procedures, and disposition of IDW are described in the following subsections.

3.4.1 Soil Sampling

Soil/sediment samples will be collected by employees of the TNPRC with supervision and documentation by the EPA Team. Sampling SOPs for naturally occurring Bp in the soils of Southeast Asia call for a sample depth of 30 centimeters. However, for this response the source of the Bp is believed to be runoff of waste products from the macaque cages which could have been deposited onto the top of the soil or sediment. Therefore, soil and sediment samples will be collected in the top 2 inches of soil. Soil sampling procedures include:

- Wear modified Level C PPE protective gear including Tyvek coveralls, nitrile gloves, boot covers, surgical caps, face shields, and N95 respirators, according to TNPRC safety protocols.
- Dig a hole using a clean, disposable shovel to collect a soil sample in the top 2 inches of soil.
- Transfer approximately 30 to 40 grams of soil to sterile containers.
- Upon collection of the sample, the outside of the jar will be cleaned with disinfecting wipes, placed in a resealable plastic bag, and placed into a cooler or other container out of direct sunlight.
- Deliver samples to the laboratory at ambient temperature without exposure to direct sunlight and process as quickly as possible.

Soil sample locations and the sampling order will be determined by the EPA Team while on-site. Sample locations will initially include areas associated with the storm-water treatment system and the sewage treatment system. As the project progresses, samples will be collected from

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other locations on the South Campus working from outer areas and moving inward to the cages that contained the affected macaques. Samplers will coordinate with the laboratory to determine how many samples can be shipped each day. Generally, samples will be collected from areas as follows:

- All four sides of macaque cage G12.
- South and east side of macaque cage R24.
- Next to any potential waste streams from impacted field cages.
- Background (near front entrance gate).
- Wetlands sludge.
- Near the outfall 003 and 004.
- Outfall sludge.

Table 3-1 presents a summary of the samples and the sample rational associated with each. Information regarding sample analysis is presented in Section 4.

3.4.2 Water Sampling

Water samples will be collected on-site from within drainage ditches, the sewage treatment system, and the storm-water treatment system. Water samples will be collected by employees of the TNPRC with supervision and documentation by the EPA Team. Sampling procedures include the following:

- Wear modified Level C PPE protective gear including Tyvek coveralls, nitrile gloves, boot covers, surgical caps, face shields, and N95 respirators, according to TNPRC safety protocols.

- Transfer approximately 1 liter of water into sterile containers (two 1-liter containers per sample). Surface water can be "dipped" directly from the water and transferred into the sample jars using a funnel.

- Upon collection of the sample, the outside of the jar will be cleaned with disinfecting wipes, placed into a resealable plastic bag, and placed into a container or cooler out of direct sunlight.

- Deliver samples to the laboratory at ambient temperature without exposure to direct sunlight and process as quickly as possible.

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Table 3-1 presents a summary of the samples and the sample rational associated with each. Information regarding sample analysis is presented in Section 4.

3.4.3 Air Sampling

Air samples will be collected by the EPA Team using Portable Sampling Units (PSUs). Three PSUs will be deployed throughout the site. PSUs will initially be deployed on the South Campus at the fence line closest to Northlake Christian School, near the aerator on the sewage treatment system, and at the gravel filter near water outlet 3. The locations of the samplers may change due to changes in weather or changes in work activities. Samples will be collected for 24-hour periods.

1. PSU-247: Fenceline near Northlake Christian School (east side of South Campus).
2. PSU-465: Near sewage aeration pond (west side of South Campus).
3. PSU-340: Near gravel filter (center of South Campus).

The flow rate will be set to 100 liters per minute (L/min) at the beginning of the run. The flow rate will be noted at the completion of the run. The flow rate for the run will be the average of the flow rates at the beginning and end of the run. The reading on the time counter will be noted at the beginning of the sample run and at the end of the run. The difference on the time counter from the end of the run and the beginning of the run will be the sample run time. The sample counter is more accurate than elapsed time in that it will correct for any down time due to power outages.

The sampling head from the PSUs will be collected, bagged, and sent to the laboratory for analysis.

At the completion of the project, the PSU will be decontaminated with antiseptic wipes. After decontamination, the EPA Team will collect swab samples at the PSU inlet hood and on the lid of the PSU. The swab samples will be sent to the laboratory for QA/QC analysis.

Table 3-1 presents a summary of the samples and the sample rational associated with each. Information regarding sample analysis is presented in Section 4.

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3.4.4 Wipe Sampling

The EPA Team will collect wipe samples from flat surfaces using sterile swabs made of synthetic fibers. Wipe samples will be collected from the vans that were used to transport macaques from the South Campus to the North Campus and from the PSUs at the completion of the project.

3.4.5 Investigation-Derived Wastes

Any used PPE, excess fluids generated as a result of equipment decontamination, and non-dedicated sampling equipment will be stored on-site and be disposed by the TNPRC.

3.4.6 Quality Assurance/Quality Control Samples

The EPA Team will observe collection of field duplicates of soil samples, water and air samples and document preparation of QA/QC samples as needed during the response sampling activities. QA/QC samples may include but not be limited to the following:

- Blind field duplicate soil samples and sediment samples may be collected to assist in the QA of the sampling procedures and laboratory analytical data by allowing an evaluation of reproducibility of results. Efforts will be made to collect duplicate samples in locations where there is visual evidence of contamination or where contamination is suspected. Blind field duplicate samples will be collected at the rate of one duplicate for every 10 samples collected.

- Equipment rinsate blanks may be prepared by pouring laboratory-grade de-ionized water over non-disposable sampling equipment after it has been decontaminated and by collecting the rinse water in sample containers for analyses.

- Field blanks may be prepared by pouring laboratory-grade de-ionized water into pre-cleaned laboratory-grade sample containers for analysis. These samples will be prepared to demonstrate the impact the surrounding environment is having on the samples being collected. Field blank samples will be collected for this particular scope of work at a rate of one per day.

- Wipe (swab) samples will be collected during decontamination activities of the PSU units. These samples will be prepared to demonstrate that the equipment decontamination

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procedures for the sampling equipment were performed effectively. The wipe samples will be collected at the end of each air sample collection period.

Specific laboratory information is included in Section 4 of this QASP.

3.5 DEVIATIONS FROM THE SAMPLING PLAN

Deviations from the sample locations may occur at the EPA TM direction due to new observations made prior to sampling, information obtained in the field that warrants an altered sampling point, difficulty in sample collection, or limited access. The EPA TM will be notified, and concurrence will be obtained should significant deviations from the planned sampling points be proposed. Details regarding deviations of the QASP will be documented in the site logbook and reported in the final ER report to EPA.

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Table 3-1
Sample Locations and Sampling Rationale
Tulane University – National Primate Research Center
Covington, Louisiana

Sample Name	Sample Matrix	Sample Location (refer to Figure 3-1)	Rationale
SW01-G-150209-N-01	Surface Water	Pond 9	Part of the storm water treatment system.
SW02-G-150209-N-01	Surface Water	Pond 8	Storm water collects here.
SW03-G-150209-N-01	Surface Water	Outfall 004	Confluence of site storm water.
SW03-G-150209-D-01	Surface Water	Outfall 004 - Duplicate	Duplicate -- collected for QA/QC
SW04-G-150209-N-01	Surface Water	Outfall 003	Outlet of water treatment system. All sewage and storm water exits here.
SW05-G-150209-N-01	Surface Water	Field Blank	Tap Water -- collected for QA/QC
SW06-G-150209-N-01	Surface Water	Contact Basin	Part of water treatment system. Sewage and storm water flow through here.
SW07-G-150209-N-01	Surface Water	Rock Filter	Part of water treatment system. Sewage and storm water flow through here.
SW08-G-150209-N-01	Surface Water	Wetlands – South	Part of water treatment system. Sewage and storm water flow through here.
SW09-G-150209-N-01	Surface Water	Wetlands – West	Part of water treatment system. Sewage and storm water flow through here.
SW10-G-150209-N-01	Surface Water	Wetlands – North	Part of water treatment system. Sewage and storm water flow through here.
SW11-G-150209-N-01	Surface Water	Ditch near Macaque Cage - G12	G12 was a cage that held an affected macaque. Determine if waste products spread Bp into the ditch near the cage.
SW12-G-150209-N-01	Surface Water	Ditch near Macaque Cage - R24	R24 was a cage that held an affected macaque. Determine if waste products spread Bp into the ditch near the cage.
SW13-G-150209-N-01	Surface Water	Aeration Pond	Part of water treatment system. Sewage passes through here.
WW14-G-150212-N-01	Waste Water	Lift Station	Part of water treatment system. Sewage from North Campus passes here.
PSU01-C-YYMMDD-N-01	Air	Fenceline near Northlake Christian School (East side of South Campus)	Collected to document air monitoring – one sample per day

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Sample Name	Sample Matrix	Sample Location (refer to Figure 3-1)	Rationale
PSU02-C-YYMMDD-N-01	Air	Near sewage aeration pond (West side of South Campus)	Collected to document air monitoring – one sample per day
PSU03-C-YYMMDD-N-01	Air	Near gravel filter (Middle of South Campus)	Collected to document air monitoring – one sample per day
PSU04-C-150212-N-01	Air	Near maintenance building (North Campus)	Collected to document air monitoring – one sample only
SWAB01-G-150212-N-01	Swab	Steering wheel of van 1 TPC09 Lic# V340918	Vehicle used to transfer macaques
SWAB02-G-150212-N-01	Swab	Front of bed of van 1 TPC09 Lic# V340918	Vehicle used to transfer macaques
SWAB03-G-150212-N-01	Swab	Middle of bed of van 1 TPC09 Lic# V340918	Vehicle used to transfer macaques
SWAB04-G-150212-N-01	Swab	Back of bed of van 1 TPC09 Lic# V340918	Vehicle used to transfer macaques
SWAB05-G-150212-N-01	Swab	Steering wheel of van 2 TPC22 Lic# KIB568	Vehicle used to transfer macaques
SWAB06-G-150212-N-01	Swab	Bed of van 2 TPC22 Lic# KIB568	Vehicle used to transfer macaques
SWAB07-G-150212-N-01	Swab	Head of PSU247	PSU was used inside of South Campus
SWAB08-G-150212-N-01	Swab	Lid of PSU247	PSU was used inside of South Campus
SWAB09-G-150212-N-01	Swab	Head of PSU340	PSU was used inside of South Campus
SWAB10-G-150212-N-01	Swab	Lid of PSU340	PSU was used inside of South Campus
SWAB11-G-150212-N-01	Swab	Head of PSU465	PSU was used inside of South Campus
SWAB12-G-150212-N-01	Swab	Lid of PSU465	PSU was used inside of South Campus

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Table 3-1
Sample Locations and Sampling Rationale
Tulane University – National Primate Research Center
Covington, Louisiana
(Continued)

Sample Name	Sample Matrix	Sample Location (refer to Figure 3-1)	Rationale
SS01-G- 150210-N-01 through SS10-G- 150210-N-01	Soil/Sediment	Near cage G12	G12 was a cage that held an affected macaque. Samples will determine if waste products spread Bp into the soil near the cage.
SS11-G- 150210-N-01 through SS16-G- 150210-N-01	Soil/Sediment	Near cage R24	R24 was a cage that held an affected macaque. Samples will determine if waste products spread Bp into the soil near the cage.
SS17-G- 150210-N-01	Soil/Sediment	Outfall 003	Outlet of water treatment system. All sewage and storm water exits here.
SS18-G- 150210-N-01	Soil/Sediment	Outfall 004	Collection of all storm water on the site.
SS19-G- 150210-N-01 through SS22-G- 150210-N-01	Soil/Sediment	Ditches near G12	Col G12 was a cage that held an affected macaque. Samples will determine if waste products spread Bp into the soil near the cage.
SS23-G- 150210-N-01 through SS28-G- 150210-N-01	Soil/Sediment	Ditches near R24	R24 was a cage that held an affected macaque. Samples will determine if waste products spread Bp into the soil near the cage.
SS29-G- 150210-N-01	Soil/Sediment	Outfall 004 Ditch	Collection of all storm water on the site.
SS30-G- 150210-N-01 through SS32-G- 150210-N-01	Soil/Sediment	Wetland area, North, Middle, and South	Part of the water treatment system. All sewage and storm water passes through here.
SS33-G- 150210-N-01 through SS35-G-150210-N-01	Soil/Sediment	Duplicates, TBD	Duplicate -- collected for QA/QC
SS36-C- 150211-N-01	Soil/Sediment	Surface composite from inside of cage G12 – 4 points under perches	Cage held an affected macaque
SS37-C- 150211-N-01	Soil/Sediment	Grab depth sample inside of cage G12 – under a perch	Cage held an affected macaque
SS38-G- 150211-N-01	Soil/Sediment	Surface composite from inside of cage G12 – 4 points not under perches	Cage held an affected macaque
SS39-C- 150211-N-01	Soil/Sediment	Grab depth sample inside of cage G12 – not under a perch	Cage held an affected macaque

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SS40-G- 150211-N-01	Soil/Sediment	Surface composite from inside of cage R24	Cage held an affected macaque
SS41-G- 150212-N-01	Soil/Sediment	Surface grab from van parking area	Vans used to transport macaques
SS42-G- 150212-N-01	Soil/Sediment	Surface grab from van parking area	Vans used to transport macaques

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4. ANALYTICAL APPROACH

Samples collected as part of the response will be prepared for shipment and shipped by TNPRC personnel who have training and certification in the proper shipment of biological samples. The EPA team will prepare chain-of-custody (COC) documentation and will assist TNPRC personnel with the sample packaging. Samples will be sent to the CDC laboratory in Atlanta, Georgia.

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Table 4-1
Requirements for Containers, Preservation Techniques, Sample Volumes, and Holding Times
Tulane University – National Primate Research Center
Covington, Louisiana

Name	Analytical Methods	Container	Preservation	Sample Containers	Maximum Holding Time
Bp bacteria in soil	CDC methods	Glass	None. Keep at ambient temperature and out of UV light	One 8 oz jar	N/A
Bp bacteria in water	CDC methods	Glass	None. Keep at ambient temperature and out of UV light	Two 1-liter jars	N/A
Bp bacteria in air	CDC methods	PTFE Filter	None. Keep at ambient temperature and out of UV light	One sample filter assembly	N/A
Bp bacteria on a surface	CDC methods		None. Keep at ambient temperature and out of UV light		N/A

oz = ounce
PTFE = Polytetrafluoroethylene
Note: Information on containers, preservation, and holding times provided by CDC.

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5. QUALITY ASSURANCE

Quality assurance will be conducted in accordance with the WESTON Corporate Quality Management Manual, dated March 2014, and the WESTON Programmatic Quality Assurance Project Plan (QAPP). Following receipt of the TDD from EPA, a Quality Control (QC) officer is assigned and monitors work conducted throughout the entire project including reviewing interim report deliverables and field audits. The EPA Team FTL will be responsible for QA/QC of the field investigation activities. The designated laboratory utilized during the investigation will be responsible for QA/QC related to the analytical work. The EPA Team will also collect samples to verify that laboratory QA/QC is consistent with the required standards and to validate the laboratory data received as described above.

All sampling will be conducted following SOPs, which are found in Appendix A.

5.1 SAMPLE CUSTODY PROCEDURES

After sample collection and identification, samples will be maintained under COC procedures. If the sample collected is to be split (laboratory QC), the sample will be allocated into similar sample containers. Sample labels completed with the same information as that on the original sample container will be attached to each of the split samples. Personnel required to package and ship coolers containing potentially hazardous material will be trained accordingly.

The EPA Team will prepare and complete COC forms using SCRIBE for samples sent to an off-site laboratory. The COC procedures are documented and will be made available to personnel involved with the sampling. A typical COC record will be completed each time a sample or group of samples is prepared for shipment to the laboratory. The record will repeat the information on each sample label and will serve as documentation of handling during shipment. A copy of this record will remain with the shipped samples at all times, and another copy will be retained by the member of the sampling team who originally relinquished the samples. At the completion of the project, the DM will export the SCRIBE COC documentation to the Analytical Service Tracking System (ANSETS) database.

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Samples relinquished to the participating laboratories will be subject to the following procedures for transfer of custody and shipment:

- Samples will be accompanied by the COC record. When transferring possession of samples, the individuals relinquishing and receiving the samples will sign, date, and note the time of the sample transfer on the record. This custody records document transfer of sample custody from the sampler to another person or to the laboratory.
- Samples will be properly packed for shipment and dispatched to the appropriate laboratory for analysis with separate, signed custody records enclosed in each sample box or cooler. Sample shipping containers will be custody-sealed for shipment to the laboratory. The preferred procedure includes use of a custody seal wrapped across filament tape that is wrapped around the package at least twice. The custody seal will then be folded over and adhered to seal and ensure that the only access to the package is by cutting the filament tape or breaking the seal to unwrap the tape.
- If sent by common carrier, a bill of lading or airbill will be used. Bill of lading and airbill receipts will be retained in the project file as part of the permanent documentation of sample shipping and transfer.

5.2 PROJECT DOCUMENTATION

Documents will be completed legibly in ink and by entry into field logbooks and SCRIBE as described above. Response Manager will be used based on direction of the EPA TM.

5.2.1 Custody Seal

Custody seals demonstrate that a sample container has not been tampered with or opened. The individual who has custody of the samples will sign and date the seal and affix it to the container in such a manner that it cannot be opened without breaking the seal.

5.2.2 Photographic Documentation

The EPA Team will take photographs to document site conditions and activities as site work progresses. Initial conditions should be well documented by photographing features that define the working conditions. Representative photographs should be taken of each type of site activity. The photographs should show typical operations and operating conditions as well as special

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situations and conditions that may arise during site activities. Site final conditions should also be documented as a record of how the site appeared at completion of the work.

Photographs will be taken using digital cameras capable of recording the date, time, and location. Each photograph will be recorded in the logbook with the location of the photographer, direction the photograph was taken, the subject of the photograph, and its significance (i.e., why the picture was taken).

5.2.3 Report Preparation

At the completion of the project, the EPA Team will review and validate laboratory data and prepare a draft report of field activities and analytical results for EPA TM review. Draft deliverable documents will be uploaded to the EPA TeamLink Web-site for EPA TM review and comment.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 6
1445 ROSS AVENUE, SUITE 1200
DALLAS, TEXAS 75202 – 2733

April 8, 2015

Office of the Regional Administrator

The Honorable Ron Johnson
Chairman
U.S. Senate Committee on Homeland Security and Governmental Affairs
Washington, D.C. 20510-6250

Dear Senator Johnson:

Thank you for your interest in the U.S. Environmental Protection Agency's role in the Centers for Disease Control and U.S. Department of Agriculture lead investigation into how the exposure to the *Burkholderia pseudomallei* (Bp) occurred at the Tulane National Primate Research Center. Below is a summary of the EPA's activities and enclosed are responses to your specific requests.

On January 27, 2015, the CDC requested the EPA, as an assisting agency, provide technical assistance on the development of a rapid response environmental sampling plan and on possible methods to decontaminate soil in the non-human primate enclosures that could be implemented on an emergency basis. The EPA drafted and presented a sampling plan to the Unified Command which included the Saint Tammany Parish, Louisiana Governor's Office of Homeland Security and Emergency Preparedness, Louisiana Department of Health and Hospitals and the CDC on February 6, 2015. The EPA also provided assistance to the primate center in the development of options for its consideration regarding the decontamination of cages.

The Unified Command adopted the sampling plan and the EPA initiated air sampling on February 8, 2015, and the primate center initiated soil and water sampling on February 9, 2015. The samples (air, soil and water) were shipped to the CDC for analysis and interpretation.

On February 20, 2015, the CDC informed the Unified Command that none of the environmental samples contained live or dead traces of Bp. On March 13, 2015, the CDC announced there was no evidence at that time to suggest that Bp was released into the surrounding environment and that it was unlikely there was any threat to the general population. The CDC also found the cause of the bacteria transmission was due to lapses of internal controls.

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I hope that this letter and enclosures are helpful in your inquiry regarding the public and private sector response to this incident. If you have any questions, please contact me at (214) 665-2100, or your staff may contact Ms. LaWanda Thomas, Congressional Liaison, at (214) 665-7466.

Sincerely,

Ron Curry
Regional Administrator

Enclosures

Identical letter sent to: The Honorable Thomas R. Caper
United States Senate

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 6
1445 ROSS AVENUE, SUITE 1200
DALLAS, TEXAS 75202 – 2733

April 8, 2015

Office of the Regional Administrator

The Honorable Thomas R. Carper
Ranking Member
U.S. Senate Committee on Homeland Security and Governmental Affairs
Washington, D.C. 20510-6250

Dear Senator Carper:

Thank you for your interest in the U.S. Environmental Protection Agency's role in the Centers for Disease Control and U.S. Department of Agriculture lead investigation into how the exposure to the *Burkholderia pseudomallei* (Bp) occurred at the Tulane National Primate Research Center. Below is a summary of the EPA's activities and enclosed are responses to your specific requests.

On January 27, 2015, the CDC requested the EPA, as an assisting agency, provide technical assistance on the development of a rapid response environmental sampling plan and on possible methods to decontaminate soil in the non-human primate enclosures that could be implemented on an emergency basis. The EPA drafted and presented a sampling plan to the Unified Command which included the Saint Tammany Parish, Louisiana Governor's Office of Homeland Security and Emergency Preparedness, Louisiana Department of Health and Hospitals and the CDC on February 6, 2015. The EPA also provided assistance to the primate center in the development of options for its consideration regarding the decontamination of cages.

The Unified Command adopted the sampling plan and the EPA initiated air sampling on February 8, 2015, and the primate center initiated soil and water sampling on February 9, 2015. The samples (air, soil and water) were shipped to the CDC for analysis and interpretation.

On February 20, 2015, the CDC informed the Unified Command that none of the environmental samples contained live or dead traces of Bp. On March 13, 2015, the CDC announced there was no evidence at that time to suggest that Bp was released into the surrounding environment and that it was unlikely there was any threat to the general population. The CDC also found the cause of the bacteria transmission was due to lapses of internal controls.

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Sincerely,

Ron Curry
Regional Administrator

Enclosures

Identical letter sent to: The Honorable Ron Johnson
United States Senate

Final Planning Guidance for Recovery Following Biological Incidents

Subcommittee on Chemical, Biological, Radiological, Nuclear, and Explosives Standards
Formerly, Biological Decontamination Standards Working Group
Subcommittee on Decontamination Standards & Technology

Committee on Homeland and National Security

National Science and Technology Council

February 2014

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Executive Summary

This guidance describes a general risk management framework for government and nongovernmental decision-makers, at all levels, in planning and executing activities required for response and recovery from a biological incident in a domestic, civilian setting. The objective of this guidance is to provide Federal, State, local, and tribal decision makers with uniform Federal guidance to protect the public, emergency responders, and surrounding environments and to ensure that local and Federal first responders can prepare for an incident involving biological contamination. This guidance was developed by an interagency working group of the White House National Science and Technology Council (NSTC), Committee on Homeland and National Security, Subcommittee on Decontamination Standards and Technology (SDST).

Although an overall risk management framework covers all phases of a response to a biological incident, this document emphasizes the remediation/cleanup and restoration phases of a response. This guidance is intended to achieve effective cleanup following a biological incident while minimizing the expected total social cost, which includes human health costs, ecological and environmental damage, loss of site utility, and the economic costs of the actions taken. The guidance does not address critical public health (such as antibiotic distribution) or public safety (security) aspects of the First Response portion of Crisis Management. This Guidance is not intended to impact site cleanups occurring under other statutory authorities such as the Environmental Protection Agency's (EPA) Superfund program, or other Federal and State cleanup programs. Companion documents have also been developed and are under modification for both radiological and chemical response.

This guidance applies to characterization, decontamination, clearance, and restoration/reoccupancy of a variety of public facility types, drinking water infrastructure, and open areas. Principal topics include the unique characteristics and hazards of biological agents, a risk management framework for responding to a biological incident, and all remediation and restoration activities. A process is identified for making timely and effective decisions despite incomplete data and uncertainties associated with potential risks posed by biological agents.

Chapter 1 summarizes the purpose, audience, and scope of this document.

Chapter 2 focuses on pathogenic microorganisms and biotoxins considered likely threats and the unique aspects of each relevant to cleanup. There is no consensus-based methodology for evaluating human health risks posed by environmental exposure to biological agents or standard cleanup goals to be employed after biological attacks. Risk assessments for most biological agents are qualitative and inherently contain significant uncertainty and variability. This document emphasizes that in the face of potentially serious consequences from contamination, judgments concerning the assessment of risks should be based on a weight-of-evidence approach that reflects a qualitative assessment of all risks arising from a particular contamination incident. This process is known as "optimization" and is recommended to guide the choice of targets during the remediation and restoration phases of the response. Through the use of this process, many different considerations are taken into account, including societal objectives for expected land or structure uses with the goal being to balance achievable and practical results.

Hazard information on the virulence and drug resistance of organisms may be collected from clinical isolates and epidemiological evidence. Exposure information may be collected from clinical samples taken from people who are thought to have been near exposed individuals or

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those present before or after a presumed exposure incident. Law enforcement and intelligence information may also provide information about the potential for environmental contamination.

Chapter 3 is the framework for decision-making, which consists of four principal components:

(1) A risk management process: Risk management is the process of identifying, evaluating, and implementing actions to reduce risk to human health and ecosystems.

(2) A clear delineation of roles and responsibilities of relevant agencies and responders: The *National Response Framework* establishes a comprehensive, all-hazards approach to manage domestic incidents and delineates the roles and responsibilities of the numerous agencies that work together during incidents.

(3) The phases of response: The basic phases of response to a biological incident are notification, first response, characterization, decontamination, clearance, and restoration, which incorporates site-specific optimization into the response effort. (Figure 3).

(4) A decision tree that defines key decision points and actions for decision-makers.

Chapter 4 explains the decision process, namely, all actions required during response to a biological incident. Beginning with notification and screening environmental sampling, each step in the decision-making process is described, and the various actions are explicitly linked to numbered boxes in a five-page decision-tree flowchart (Figure 4).

An important step in the decision process is setting a clearance (or cleanup) goal for determining whether a remediation is successful and the treated area may be returned to normal use. No formula is available for setting a clearance goal for biological agents. The collective, professional judgment of experts, considered within the context of the concerns of a broad range of local, regional, and Federal stakeholders, should be used to set a clearance goal appropriate to the site-specific circumstances. A practical clearance goal is to reduce residual risk to levels acceptable by employing an optimization process. The aim of such a process is to reduce exposure levels, as low as is reasonable, while considering potential future land uses, technical feasibility, costs and cost effectiveness, and public acceptability. After the remediation is carried out, a clearance decision is made based on a judgment whether decontamination verification criteria and the clearance goals have been met. This judgment is based on a thorough analysis of all sampling, processes, and other pertinent data.

This document focuses on the decision making framework in response to a biological event; it is designed to be consistent with the *National Response Framework* (NRF) and our scientific understanding of the characteristics of biological agents. Neither of these areas are static. We expect both our response planning and our scientific understanding of the characteristics of biological agents to evolve over time.

In addition to the guidance presented here, there are two scenarios that have been developed to illustrate the principles and application of site specific optimization. Because of the response details contained in these scenarios, they are sensitive and contained in a separate, Official Use Only document.

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Planning Guidance for Recovery Following Biological Incidents

1. Introduction

The Homeland Security Act of 2002 (PL 107-296 Section 301) directs DHS, in partnership with other Federal agencies, to develop and implement countermeasures to prepare for and respond to chemical, biological, radiological, and nuclear threats. Homeland Security Presidential Directive - 10: Biodefense for the 21st Century, describes the interagency activity required to meet this charge. This document is part of a series of guidance being prepared by the Federal Government. Response and recovery following an incident involving a biological agent is likely to be a complex, resource-intensive, and challenging undertaking. Biological contamination presents a unique cleanup challenge because of the ability of certain pathogenic microorganisms to persist in the environment. Clear, consistent Federal decontamination guidance is needed to address all phases and activities involved in response and recovery following a biological incident (Government Accountability Office [GAO], 2003). The National Science and Technology Council (NSTC) is the principal means by which the President coordinates science, space, and technology policies across the Federal government.

To develop coordinated Federal guidance, the NSTC Committee on Homeland and National Security convened a Subcommittee on Decontamination Standards and Technologies (SDST). The Subcommittee chartered an interagency Biological Decontamination Standards Working Group (BDSWG) to develop risk management guidance for safe recovery from an incident involving biological contamination in a domestic, civilian setting. The interagency working group included participants from the Departments of Homeland Security, Agriculture, Commerce, Defense, Energy, Labor, Health and Human Services, Transportation, and the Environmental Protection Agency.

This guidance describes a general risk management framework and activities for decision-makers, at all levels, in planning and executing activities required for response and recovery from a biological incident in a domestic, civilian setting. The objective is to provide uniform Federal guidance that enhances the ability of Federal, State, local and tribal emergency responders and decision makers to prepare for and respond to an incident involving biological contamination. This Guidance is not intended to impact site cleanups occurring under other statutory authorities such as the Environmental Protection Agency's (EPA) Superfund program, or other Federal and State cleanup programs.

In developing the guidance, the Federal Government recognized that experience and scientific knowledge from existing programs such as EPA's Superfund and research programs, from multi-agency cleanups of sites contaminated with *Bacillus anthracis* spores (EPA, 2002), and from other national recommendations will be useful in planning response and recovery efforts following a biological incident. This guidance allows the consideration and incorporation, as appropriate, of any or all of this existing experience and knowledge, and does not alter existing

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programs. It is sufficiently flexible to address the extremely broad range of situations that can occur under various biological contamination scenarios, more than most existing programs or recommendations address. Finally, this guidance will enable State and local officials, working with Federal counterparts, to make informed decisions with the best available information to decide what is best for their community.

1.1 Purpose

This document provides guidance that focuses primarily on remediation and restoration activities associated with a domestic, civilian site that has been contaminated, intentionally or otherwise, with a biological agent. This guidance document covers intentional or accidental releases of biological agents; henceforth the term "biological agents" will be used rather than "biological warfare agent" (BWA), except where noted. Throughout the overall response and recovery process, remediation activities conducted to clean up facilities take place in parallel with other activities such as risk communications and addressing public health issues. The document explains the unique characteristics and hazards of biological agents (i.e., pathogenic microorganisms and biotoxins); provides a risk management framework for responding to a biological incident in a domestic, civilian setting; and addresses the environmental remediation and restoration activities necessary for successful cleanup and reoccupation.

Most importantly, this document describes the process for making timely and effective decisions despite incomplete data and uncertainties associated with characterizing the potential risks posed by biological agents. A process known as optimization is recommended to guide the choice of targets during the remediation and restoration phases of the response, thus providing the best opportunity for decision-makers to gain public confidence through the involvement of stakeholders.

1.2 Audience

The intended audience for this document is Federal, State, tribal, and local government officials, as well as nongovernmental decision-makers, involved in conducting or overseeing response and recovery operations at a site contaminated by a biological agent.

1.3 Scope

This document describes a general risk management framework for decision-makers to use in planning and executing the many activities required for response and recovery from a biological incident in a domestic, civilian setting. The guidance applies to significant incidents involving intentional or accidental releases of biological agents, including unknown and genetically modified organisms. Contamination via air and water is considered in this document. Food production and distribution systems are excluded since they are covered adequately in another guidance document (USDA/FSIS, 2006). Decision makers should use this guidance as a supplement to existing regulations and in the context of *National Response Framework* (NRF) policies and procedures outlined in the Emergency Support Function Annexes (ESF) #8 (Public Health and Medical Services Annex) and ESF #10 (Oil and Hazardous Materials Response Annex), the Worker Safety and Health Support Annex, and the Biological Incident Annex of the NRF (DHS, 2008).

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Although an overall risk management framework covers all phases of a response to a biological incident, this document emphasizes the remediation and restoration phases of a response. For each activity in this component, the decision-making processes and scientifically based methods, practices, and procedures are described, and references are provided as applicable. Each biological incident will have unique site- and organism-specific characteristics associated with remediation. Thus, even though a general framework can be used, final decision-making will be done on a case-by-case basis using an optimization process. Planning and preparedness, critical components of effective site response and recovery, are described elsewhere [e.g., in the National Research Council (NRC) of the National Academies of Science (NAS) study (NRC, 2005) and the Lawrence Livermore National Laboratory (LLNL) airport guidance (Carlsen et al., 2005)], but are not described in depth in this document.

The guidance in this document is applicable to:

- Enclosed facilities and objects, such as commercial and residential buildings, swimming pools, aircraft, vehicles, trains, vessels, and their contents.
- Semi-enclosed facilities and objects, such as subways, public transit facilities, and their contents.
- Outdoor areas and objects, such as building exteriors, streets, parks, water parks, beaches, other open spaces, and items within these areas.
- Drinking water sources, distribution systems, and treatment facilities, and wastewater infrastructures.

A full discussion of all possible scenarios is beyond the scope of this document. This guidance emphasizes the scalable principles of optimization, in which the extent of cleanup efforts and range of considerations will largely be determined by the location, nature, and severity of the biological incident. The processes and decisions employed in the cleanup of a building or facility will differ from those used to clean up a large area, such as a neighborhood or city.

This document emphasizes a framework and activities for decontaminating the first two types of settings because most incidents involving contamination with biological agents to date have involved enclosed and partially enclosed areas. However, this document is also designed to provide basic guidance for contaminated outdoor sites and water-related facilities. Unique problems presented by outdoor contamination pose significant challenges and include: (1) the dynamic and continuing meteorology effects on transport and spread of aerosol; (2) how to take into account the potential presence of naturally occurring biological agents such as *Bacillus anthracis* spores; (3) decontamination of biological agents deposited on common materials such as car metal surfaces, street lights, concrete sidewalks, brick building surfaces, paved roadways, and bridges; (4) decontamination of subsurface and difficult to access infrastructure; (5) determining what areas are contaminated over a large area; and (6) how to deal with potentially very large quantities of contaminated water (see Interim Guidance on Developing Consequence Management Plans for Drinking Water Utilities, EPA, 2008). Additionally, waste disposal continues to be a difficult perception problem even if wastes have been treated and cleared; there are no easy answers in this arena. Currently, there are other efforts in the Federal Government that address the capability gaps in wide-area remediation as well as protecting responders under that scenario.

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Current methodologies for assessing the degree of exposure to and potential risks from biological agents of concern can be used to determine the appropriate degree of cleanup based on the characterization phase and the best available scientific data. However, significant uncertainties exist regarding agent effects and fate, sampling and detection limits, and decontaminant effectiveness (Raber et al., 2001, 2004). Processes for dealing with such uncertainties are emphasized. Guidance is presented in the context of currently available information; as new data are obtained, that information will be incorporated into this decision-making guidance.

1.4 Organization

This document is organized into four chapters:

1. Introduction.
2. Background on Biological Agents.
3. Framework for Decision-Making.
4. Key Activities for Decision-Making.

Chapter 1 provides background on the purpose, audience, scope, and organization of this document. Chapter 2 describes the types and characteristics of biological agents and explains why cleanup of biological contamination substantially differs from cleanup of chemical or radiological contaminants. Chapter 3 describes the risk management framework, roles and responsibilities, phases of a biological response, and a "decision tree" for decision-making. Chapter 4 provides "how-to" guidance for each of the key activities required for a successful cleanup and recovery effort and includes references for further scientific or expert guidance.

In addition to the guidance presented here, there are two scenarios that have been developed to illustrate the principles and application of site-specific optimization. Because of the sensitive response details contained in these scenarios, they are available as a separate, Official Use Only document.

1.5 References

Carlsen, T., L. Berg, D. MacQueen, W. Wilson, G. Brown, S. Mancieri, R. Bishop, K. Folks, R. Kirvel, and V. Vyas (September, 2005), "Restoration Plan for Major International Airports After a Bioterrorist Attack," Lawrence Livermore National Laboratory, Livermore, CA, UCRL-TR-210178.

Department of Homeland Security (DHS) (December, 2008), "National Response Framework," available at http://www.fema.gov/emergency/nrf; available at http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&o=09000064806a5efc

National Research Council (NRC) of the National Academies (2005), "Committee on Standards and Policies for Decontaminating Public Facilities Affected by Exposure to Harmful Biological Agents, How Clean is Safe? *Reopening Public Facilities After a Biological Attack*," National Academies Press, Washington, D.C.; available at http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&o=09000064806a5efc

Raber, E., A. Jin, K. Noonan, R. McGuire, and R. D. Kirvel (2001), "Decontamination Issues for Chemical and Biological Warfare Agents: *How Clean Is Clean Enough*?" *International Journal of Environmental Health Research* **11**, 128–148.

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U.S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) (2006), "Guidelines for the Disposal of Intentionally Contaminated Food Products and the Decontamination of Food Processing Facilities," April 14, 2006, available at http://www.fsis.usda.gov/

U.S. Environmental Protection Agency (EPA) (2002), "Challenges Faced During the Environmental Protection Agency's Response to Anthrax and Recommendations for Enhancing Response Capabilities, A Lessons Learned Report," available from the U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response, Washington, D.C.

U.S. General Accounting Office (GAO) (June, 2003), "Capitol Hill Anthrax Incident, EPA's Cleanup Was Successful. Opportunities Exist to Enhance Oversight," GAO Publication GAO-03-686. (http://www.gao.gov/new.items/d03686.pdf).

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2. Biological Agents

2.1 Types of Biological Agents

Biological agents considered to be likely threats are classified as pathogenic microorganisms (pathogens) and biological toxins (biotoxins). Microorganisms can replicate and are grouped into categories according to their structure and method of replication. Biotoxins are molecules of biological origin that cannot replicate. Some additional information on specific contaminants and general guidance for response and clean-up is available at the websites of the National Response Team (http://www.nrt.org/) and the Centers for Disease Control and Prevention (http://www.cdc.gov/). Specific contaminant information is available in the NRT's Quick Reference Guides (QRG's) located at: http://www.nrt.org/Production/NRT/NRTWeb.nsf/AllPagesByTitle/P-BiologicalHazards?Opendocument (EPA 2006).

Pathogens. Pathogens are disease-causing agents that invade a host and replicate. They are diverse and range from non-cellular organisms (i.e., viruses), to cellular life forms within both the eukaryotic (e.g., protozoa and fungi) and prokaryotic (bacteria) kingdoms. The pathogens of greatest concern in airborne exposures are viruses, bacteria (including Rickettsiae), and fungi (including molds). In waterborne contamination, protozoa and helminths may also be of concern. Some microorganisms have developed specialized life stages designed to resist periods of environmental stress. In general, these are more difficult to disinfect than those microorganisms that have not developed these life cycle stages. Appendix 1 shows a general scheme for hierarchy of environmental resistance and difficulty of disinfection.

Bacteria. Some bacterial species are pathogenic to other organisms. Unlike viruses, the majority of pathogenic bacteria (excluding Rickettsiae and some others) are capable of reproducing outside living cells. A typical bacterial cell is small—approximately 1–2 microns in diameter and approximately 2–10 microns in length (1,000 microns = 1 millimeter). By comparison, a human hair is about 100 microns wide. Bacterial diseases may respond to treatment with antimicrobials, but antimicrobial-resistant bacteria are common. Vaccines are available for some bacteria (e.g., *Bacillus anthracis),* (CDC, 2004b; Dennis et al., 2001; Inglesby et al., 1999, 2000).

Viruses. Viruses are a large group of non-cellular infectious particles that can only multiply within a living cell. Viruses are much smaller than the majority of bacteria, generally ranging from 0.02–0.2 microns, and generally do not respond to antimicrobials. Certain viruses may respond to antiviral compounds. Vaccines are available for certain viral illnesses (e.g., smallpox) (CDC, 2004a; Henderson et al., 1999).

Fungi and molds. Pathogenic fungi and molds are unique organisms in terms of their cellular structure and biochemistry. This highly diverse group of organisms is widely dispersed in the environment. Many molds and fungi are resistant to environmental conditions that kill bacteria, such as sunlight, desiccation, and heat. Many molds and fungi also have life-cycle stages that are environmentally resistant and readily aerosolized. Some organisms in this category are disease-causing agents, including *Coccidioides immitis* and *C. posadasii*, which can cause systemic or lung infections. Specific anti-fungal drugs are available; however, the infections can be difficult to treat. Currently, there are no approved vaccines for human use against any fungus or mold.

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Protozoa and helminths. Pathogenic protozoa are single-celled organisms, whereas helminths (flatworms and roundworms) are multicellular. Both include many parasitic forms. In their infectious stages, protozoa and helminths are generally larger than bacteria, ranging from 2 to 100 microns in diameter. Because of their large size, they are typically only considered a threat to water supplies and are unlikely to be inhaled deeply enough into the lungs to cause an infection. Thus, aerosol dissemination of these pathogens would be an ineffective means of exposure; however, ingestion of these organisms, for example in contaminated water, may be an effective means of dissemination. Many of these organisms are highly resistant to chemical disinfection, and although drug treatment is available for some protozoa and helminths, many infections are difficult to treat. No human vaccines are available for these organisms.

Biotoxins. Biotoxins are toxic substances that are either produced by, or extracted from, living or dead bacteria, fungi, plants, or animals. Although biotoxins can be transferred from person to person on contaminated objects, they are not communicable like the flu and do not replicate within an individual. Biotoxins can be more toxic than chemical warfare agents (CWA). Biotoxins are categorized into groups according to molecular weight and composition or origin. Among biotoxins of concern is the botulinum toxin, which is produced by *Clostridium botulinum* and a few other species of *Clostridium*. There are other toxins of concern as well, including other bacterial toxins (e.g., Staphylococcus enterotoxin B); fungal toxins, also known as mycotoxins (e.g., trichothecenes); and toxins produced by plants and animals (e.g., ricin and tetrodotoxin). Biotoxins may be formulated in a variety of ways, as either liquids or powders. The natural pathway of transmission for most toxins is through contaminated food or water. However, it may be also possible to spread these toxins by aerosol, through hand to mouth exposures, and by direct injection. The symptoms of exposure may vary greatly depending on the toxin and the route of exposure. Medical treatments and vaccinations are available for some toxins, but for many biotoxins, specific treatments or vaccinations have not yet been identified.

2.2 Characteristics of Biological Agents

2.2.1 Pathogens

This section describes the general characteristics of pathogens.

Infectivity. Pathogens act by infecting and replicating within a susceptible host. The infectivity of a pathogen reflects the relative ease with which microorganisms establish themselves and cause disease in a host. Once an individual is infected, the pathogen multiplies, making a dose-response assessment difficult.

Infectious dose. In theory, infectious dose is the number of organisms required to cause an infection. A pathogen is considered highly infective when relatively few organisms can cause disease. Conversely, when numerous pathogens must be present to cause disease, the pathogen is considered to be of low infectivity. High infectivity, the speed of disease onset, and severity of illness are not necessarily related. A minimum infectious dose is the minimum number of organisms required to cause an infection. For most high-consequence pathogens, the minimum infectious dose for some proportion of the population may be a single organism (NRC, 2005). Most pathogens considered to be likely biological weapons are highly infectious with some requiring fewer than 100 organisms to infect an individual.

Infectious dose is the result of complex interactions between host and microorganism, and involves many variable factors. Factors such as age, sex and immune status of the individual

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will affect the susceptibility of the host to an infectious agent. Infectious dose is highly dependent on route of exposure, and may be dependent on the method of preparation of the infectious agent as well. The environmental persistence of various microorganisms is also highly variable. For example, *Yersinia pestis* has been shown to have very limited survival (only hours to days) under certain laboratory conditions, yet has been shown to be capable of persisting in water for days or weeks (Rose et al., 2003; Torosian et al., 2009). In addition, it can be difficult to ascertain whether an infection is present, how an individual has been exposed to a defined dose of microorganisms, or if an exposed individual is either particularly susceptible or resistant to infection. Furthermore, little information is available on cumulative exposures. Because of these and other considerations, the NRC concluded that infectious doses for harmful biological agents cannot be determined with confidence (NRC, 2005). In a jointly-developed white paper, the American Biological Safety Association (ABSA) and the Occupational Safety and Health Administration (OSHA) conclude that there is no clear and universally acceptable definition of the term "infectious dose" (Johnson, 2003). They note that there is no single, standard protocol for testing infectious doses in laboratory animals, making legitimate and controlled comparisons of study results difficult. They also find that extrapolation of infection and toxicity data among animal species and from animals to humans is unreliable for most biological agents (Haas et al., 1999a, 2000).

Viability of pathogens and activity of biotoxins. Pathogens can be present in the environment in both viable and nonviable forms, but they must be viable to exert a pathogenic effect. Toxins, particularly large-protein toxins, also need to be in the appropriate structural configuration (active form) to exhibit toxicity. A pathogen-contaminated environment may be remediated by pathogen removal or by rendering the pathogens nonviable. Physical removal of pathogens can be done by removing contaminated objects and materials, or by direct removal of the contaminant itself by methods such as wet washing or vacuuming (Weis et al., 2002). Disinfection, inactivation, or decontamination can be accomplished by rendering the contaminant nonviable or incapable of infecting or causing disease through the use of disinfectants such as oxidants, through the application of heat, or by other means. Removal and inactivation of pathogens or toxins can be accomplished together through activities such as wiping an area with a disinfectant-saturated cloth. The effectiveness of efforts to remove pathogens or toxins can be evaluated by monitoring for the presence of their signatures or footprints. The effectiveness of disinfection or inactivation must be monitored by methods that test for not only the presence but also the viability or activity of the pathogen or toxin in question. For some contaminants, such as viruses, viability tests are difficult to conduct.

Routes of exposure and infection. Microorganisms must enter a host organism to infect and cause disease. The major routes of exposure to pathogens are inhalation, ingestion, dermal contact, mucous membrane contact, and direct injection by a vector (e.g., mosquito) (Raber et al., 2001). Intentionally introduced contaminants might exploit routes of exposure that are not usually observed in naturally-occurring disease incidents. For example, a pathogen that is usually ingested might be inhaled after being intentionally disseminated as an aerosol. People exposed to a pathogen through a novel pathway may experience symptoms that are uncharacteristic for the natural disease course of that pathogen. Residuals remaining from a release or attack can pose dermal contact, ingestion, or reaerosolization hazards (Weis et al., 2002) that are not normally present in natural disease outbreaks. The potential for reaerosolization from surfaces can depend on a variety of factors, including contaminant formulation, method of dissemination, and the nature of the surfaces involved (Ferro et al., 2004;

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Long et al., 2000; Rodes et al., 2001). Potential exposures to various routes of infection must be considered when planning for decontamination efforts.

Method of dissemination. Dissemination allows access of pathogens to victims through an intended route of infection. Pathogens may be disseminated in wet and dry forms, through contamination of food and water supplies, by release of infected vectors, through aerosol-generation devices, in the mail, or by other novel methods. Dry preparations can range in dispersibility from large, chunky powders with low dispersibility to finely-milled homogenous powders with high dispersibility. Flow-enhancing agents and charge-neutralization techniques can also enhance the dispersibility of dry preparations (Brown et al., 2007). Liquid preparations are easy to manage from a production standpoint and may be used to generate aerosols with a variety of properties ranging from mixed droplet sizes to evenly dispersed and homogenous controlled droplets, or dried particles, depending on the dispersion devices employed. Aerosols can be created with either dry or liquid formulations, and aerosol delivery systems can generate particulate clouds that can remain suspended for long periods and spread over large areas. Contaminated water moving through a water-distribution system can carry a contaminant into a large number of inhabited structures in a city. In the past, pathogens have been intentionally disseminated on contaminated objects or by dispersal of infected vector insects (Kolavic et al., 1997; Carus, 2001; Wheelis, 2004; Torok et al., 1997; Smithson and Levy, 2000). Such methods could be used again in the future. However, certain pathogens are not amenable to particular methods of formulation or dissemination. Methods of dissemination can also create unexpected environmental contamination sites. For example, an outdoor release of agent might contaminate indoor areas or the food supply, and a waterborne release of agent might contaminate indoor areas. The scale and type of remediation for pathogens or biotoxins is determined in large part by the method of formulation and dissemination.

Pathogenicity and virulence. These two related concepts concern a pathogen's ability to cause disease (low to high pathogenicity) and the severity of disease that is produced (low to high virulence). Some pathogens rapidly cause death; others incapacitate individuals. Some disease agents have short courses of infection; others cause illness lasting months, years, or a lifetime. Some diseases are associated with conditions that occur long after initial exposure to the infectious agent.

Availability and effectiveness of prophylaxis and treatment. Some diseases are readily treatable by antimicrobials, antivirals, or other chemotherapeutic agents. In some cases, prophylaxis that provides protection against the disease can be given to individuals before exposure (pre exposure) or before the onset of symptoms (post-exposure). Drug treatments and vaccines exist for several of the diseases of concern. However, drug resistance and vaccine failure are widely known, and engineering drug resistance into bacteria is a standard protocol for certain organisms. In any incident, the existence or lack of effective vaccines, prophylaxis, and treatment will influence decisions on worker protection and other aspects of decontamination efforts.

Communicability. Infectious microorganisms and viruses can be transmitted directly from person to person (e.g., by coughing, sneezing, talking, or touching), indirectly through the environment (e.g., fomites), or via a vector. Microorganisms that are readily transmitted directly from person to person can multiply the effect of an attack. In military terms, most communicable pathogens that are developed for biological warfare are considered strategic weapons because they are capable of sustained transmission that could cause long-term

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debilitation of a population. Furthermore, it is difficult to prevent spread of these pathogens among one's own forces. Some pathogens (e.g., *Variola major* (smallpox virus)) can be readily transmitted person-to-person after initial disseminationwhile others can only do so when a specific form of the disease is present (e.g., pneumonic plague as opposed to bubonic plague). Some agents are generally not transmitted person-to-person (e.g., anthrax).

Availability. Microorganisms are naturally occurring, and some are intentionally cultivated. Many can be cultivated using technology that has been available for more than 50 years (Pepper and Gentry, 2002). However, *Variola major*, the causative agent of smallpox, does not exist outside of a couple of laboratories where research is being conducted.

Incubation period. The time from exposure to onset of a pathological effect is the incubation period. There may be a delay between exposure to a pathogen and the development of a symptomatic infection. This delay is often termed the *latent period*. In addition, there may be a delay between exposure and the ability to detect the pathogen in a host, which is termed the *pre-patent period*. Finally, in some cases exposed individuals may never exhibit symptoms and yet may still be able to pass a disease agent on to others; these individuals are called asymptomatic carriers. Delays between exposure and the recognition of infection or the presence of disease agent may range from hours to days to weeks or more. Such delays may enhance the ability of terrorists to launch a covert attack or multiple attacks. The delay between exposure and recognition that an exposure has occurred also has implications for the remediation required. Because some pathogens do not persist in the environment, the time that may elapse from an initial biological incident to the onset of disease in exposed individuals may mean that viable (i.e., infectious) pathogenic microorganisms are no longer present in the initially contaminated area by the time exposure becomes evident. Alternatively, delayed diagnoses due to long incubation periods or confusion with other more common diagnoses, along with related challenges in detecting a contamination incident, may allow some environmentally-persistent pathogen preparations to spread beyond the initially contaminated area.

Environmental persistence. Some disease agents rapidly inactivate when not in a suitable environment or a host. Others form spores or are adapted for existing long-term in an infectious state in the environment. Temperature, humidity, and ultraviolet radiation are all known to affect the survival of microorganisms in the environment; however, some microbial forms (e.g., bacterial endospores) are less susceptible to these factors than others. The environmental persistence of a particular pathogen or toxin is an important consideration when selecting the type and extent of remediation activities. Pathogens that are exceptionally fragile and persist in some environments for only minutes or hours may require only minimal intervention for decontamination. However, it would still be necessary to confirm that natural attenuation of the pathogen had taken place as expected. The most environmentally persistent agents in dry environments on the Center for Disease Control and Prevention's (CDC, 2005) list of agents of concern for bioterrorism are *Coxiella burnetti* and *Bacillus anthracis* spores. In water-distribution systems, many microorganisms including pathogens can exist in biofilms, creating a persistent contamination problem and necessitating thorough disinfection of the system (see http://www.sciencedirect.com/science/article/pii/S0043135408004089).

Zoonotic potential and environmental reservoirs. Certain pathogens infect domestic or peri-domestic animals or replicate within particular environments. Many of the CDC pathogens of concern, such as *Yersinia pestis* (Inglesby et al., 2000) and *Burkholderia mallei*, cause zoonotic illnesses, which are naturally though infrequently transmitted from animals to humans. Some

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zoonotic pathogens, such as *Francisella tularensis* (Dennis et al., 2001) and *Burkholderia pseudomallei*, can survive and replicate outside of a host organism in specific environmental habitats or in the presence of fee living amoeba (Santic et al., 2011). Microorganisms with the potential to become established in animal hosts or to multiply directly in the environment require special consideration during remediation.

Resistance to decontamination. Disease agents vary considerably in their resistance to decontaminants; some are particularly resistant to disinfection. *Bacillus anthracis* spores, for example, are known to be highly heat resistant. In a water environment, *Cryptosporidium parvum* and *B. anthracis* are is resistant to chlorination (Rose et al., 2005), and some strains of *Burkholderia pseudomallei* may be resistant to routine chlorination (Howard and Inglis, 2003; O'Connell et al., 2009). Even though a particular pathogen might be generally susceptible to a type of disinfectant, specific strains of a pathogen can be more resistant than expected under certain conditions. This principle is well understood in the field of water disinfection, where some organisms that are generally susceptible to chlorine disinfection may be highly resistant under some conditions such as bacteria that grow in a biofilm (Morris et al., 1996). Although less well studied, it is possible that this phenomenon exists in surface contaminants as well. In addition, it is possible that an agent could be intentionally formulated to increase resistance to decontamination.

2.2.2 Biotoxins

Biotoxins are the products or by-products of living organisms. They are nonvolatile, odorless, tasteless, and generally do not affect the skin, with the notable exception of T-2 mycotoxin. Unlike pathogens, biotoxins cannot replicate within the body, therefore the toxic dose of a biotoxin must be delivered by exposure. Non-lethal doses of biotoxin may also have severe medical effects, depending on the biotoxin. Biotoxins may be metabolized and removed from the body at some rate; alternatively, their effects may be cumulative or irreversible. In toxicology, the dose makes the toxin; that is, a critical dose must be ingested or taken in through some route of exposure for it to have a toxic effect. The critical dose, however, may be extremely small and related to the route of entry. Some biotoxins act rapidly; others act over longer times or are progressively incapacitating.

On a weight-for-weight basis, biotoxins tend to be more toxic than chemicals, and because of their diversity in structure and function, they can have more varied adverse effects than chemical agents. Nevertheless, risk assessments of biotoxin- and chemical-contaminated environments can be done in a similar manner.

Small-molecular-mass biotoxins are considerably more environmentally stable than large, globular protein toxins. As such, they may also be resistant to some of the means of inactivation or physical removal that are effective against larger biotoxins. Large-molecular-mass biotoxins are generally more susceptible to heat inactivation, and because of their size, some can be removed from liquid phases by appropriate filtration.

2.2.3 Biological Agents of Concern

Numerous lists of pathogens and biotoxins of concern have been developed for different purposes and according to the needs of various organizations. The U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) have published lists of microorganisms and biotoxins that are regulated as "Select Agents" (see 42 C.F.R. Part

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73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121). Burrows and Renner (1999) present a more thorough discussion on water-safety threats. Another way to determine likely threat agents is to examine their history of use. Carus (2001) and Ecker et al. (2005) have examined pathogens and toxins known or suspected to have been used in bioterrorist, criminal, or warfare incidents. The U.S. Army handbook, *Medical Management of Biological Casualties*, provides several lists of agents and includes a large amount of useful information on each (Darling and Woods, 2004). Intelligence documents and scientific literature contain additional information concerning potential threat agents. It may be important to consider potential novel threat agents from these and other sources, particularly if they might present challenges to a remediation strategy.

2.3 Unique Aspects of Biological Agent Cleanup

Many characteristics of microbial contaminants make them unique from chemical contaminants. The following principles apply primarily to pathogens rather than biotoxins, which are more like chemical contaminants in terms of risk assessment and risk management.

2.3.1 Availability

Most pathogens occur in nature, and many are cultivated as a part of routine human or veterinary diagnostic activities. Techniques for obtaining and propagating pathogens are widely known, practiced, and taught for legitimate purposes. Stock material can be cultured from the environment or from infected humans or animals in hospitals or veterinary clinics worldwide. The availability of many highly pathogenic microorganisms makes them unique from CWAs. Important considerations include the following:

- Most CWAs are uniquely toxic compared to the more widely available toxic industrial chemicals (TICs); therefore, CWAs are generally unavailable to individuals without access to sophisticated chemical manufacturing facilities. Potential BWA, on the other hand, because they are not solely created as BWAs per se, have been cultivated in laboratories using standard laboratory techniques for more than a hundred years in some cases. Good laboratory equipment and biosafety practices are required for safe handling and manufacture of BWAs, and both are readily available.
- A few CWAs can be synthesized in field-expedient laboratories, but these are exceptions. In contrast, BWAs can be generated readily in field-expedient laboratories.
- Available information suggests that CWAs have never been found to occur naturally. CWAs are synthesized from precursor materials that must be generated or purchased. Many of the unique and required precursor chemicals for CWA production are controlled under the Chemical Warfare Convention (CWC) and are difficult to obtain. In contrast, BWAs are much more widely available. At any given time, multiple outbreaks of moderate and high-risk pathogens are occurring somewhere in the world. Outbreaks often occur in areas where terrorist organizations have resources. Natural outbreaks can provide seed material for BWA production.
- CWAs are distinguished by treaty as chemicals with no legitimate civilian purpose; there is no legitimate reason for CWAs to exist outside a closely controlled, treaty-regulated purpose. CWAs must be manufactured under closely monitored conditions in compliance with the CWC, or covertly. Such restrictions should hamper the ability to produce CWAs. On the other hand, BWAs are naturally occurring public health

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threats, and their creation for offensive purposes may be conducted under the cover of legitimate public health or commercial (e.g., vaccine production) activities.

BWAs may be as readily accessible as toxic industrial chemicals, and are as hazardous as, or more hazardous than, CWAs. Their widespread natural occurrence and accessibility make BWAs unique as potential threat agents. [Note: Because this guidance document covers disease outbreaks and intentional or accidental releases of biological agents, henceforth the term "biological agents" will be used rather than "BWA."]

2.3.2 Mechanisms of Dissemination

A significant impact can result from a release of much smaller quantities of biological agent than chemical agent (Rubin, 1987). However, unlike many chemicals, biological agents in a liquid state do not readily aerosolize or vaporize, so some form of dissemination device is usually required.

2.3.3 Delayed Effects

In many scenarios, the first indicator of an incident involving contamination with a biological agent would be an increased number of patients presenting with clinical symptoms caused by exposure to and infection with the pathogen (Darling and Woods, 2004). The time from exposure to onset of clinical signs is generally much longer for pathogens than for acute toxic doses of chemical agents. Onset of clinical signs and symptoms may occur days, weeks, or more after exposure to a pathogen. The result may be delayed identification of a covertly disseminated pathogen, and exposed individuals may unknowingly incubate and disperse the agent if it is capable of human-to-human transmission. This delay in identification that an attack has occurred has wide ramifications to the decontamination process. This may affect the exposure assessment, the design and implementation of the sampling plan, the choice of sampling methods and locations, and other elements of contamination analysis.

2.3.4 Difficulties in Identification

The following difficulties are associated with identifying biological agents:

- Many infectious agents tend to initially produce nonspecific symptoms that mimic more common diseases (e.g. flu-like symptoms, gastrointestinal distress, etc.), thus delaying diagnosis or leading to misdiagnosis.
- Some biological agents are endemic to certain environments and, as a result, could cause naturally occurring infections, complicating recognition of an intentional versus natural biological agent infection.
- Because many pathogens naturally occur in the environment, recovery of specific pathogens or their signatures (e.g., antigens, DNA traces) from an environmental sample may not indicate the presence of an intentionally introduced agent or the source of an environmentally acquired infection.
- Even when pathogen signatures are present, viability assessments on environmental samples can be time-consuming and difficult. Viability information is critical for risk management decisions.
- Many current sample collection and analytical methods are not capable of distinguishing small but biologically significant quantities of pathogens.

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- Some current sample collection and analytical methods are not specific enough to distinguish between organisms that are human pathogens and those closely-related species that produce no human disease.
- Constituents of environmental matrices and, in some instances, constituents of sampling devices may inhibit detection of organisms in the environment. It is not possible to predict all such interactions in advance.
- Techniques that may be applicable for producing pathogens that are difficult to detect are readily available to scientists around the world and have been used and taught in universities for decades.

2.3.5 Potential for Amplification and Significant Numbers of Casualties

Person-to-person transmission of certain biological agents may lead to a rapid, geometric increases in the number of victims and of facilities or areas that require decontamination. Most contagious diseases are spread directly from person to person, and most contagious pathogens do not persist in the environment for extended periods of time, with significant exceptions such as noroviruses and Methicillin-resistant *Staphylococcus aureus*, or MRSA. However, the causative agents of some of these diseases could be treated or disseminated in a manner to cause environmental contamination. The occurrence of person-to-person transmission arising from an initial environmental contamination may give impetus for conducting additional, unwarranted environmental decontamination activities. Conversely, recognition of person-to-person spread may result in a failure to appropriately recognize the role of environmental transmission, leading to an unwarranted lack of environmental decontamination activities. It is important to recognize that mass casualties can also arise from incidents involving dissemination of non-contagious pathogens such as *B. anthracis*.

2.3.6 Public Fear

Increased public fear can be anticipated from potential exposures to biological agents, particularly because exposures are not generally immediately detectable. While rapid, portable contamination detectors are available for radiological and chemical agents, the detection technologies currently available for biological agents have limitations (Fitch et al., 2003). Moreover, since a biological attack or exposure to a biological agent may have occurred days before its recognition, there may be nothing the public can do to prevent themselves from becoming victims, resulting in a sense of helplessness in the wake of the attack or outbreak.

2.3.7 Control Measures

For naturally occurring disease outbreaks, many public health interventions already suffice to control and eliminate the environmental reservoirs for disease agents (e.g., insecticide spraying for mosquitoes that carry equine encephalitis, West Nile virus, etc.). However, deliberate attacks using biological agents as weapons may differ from these naturally-occurring outbreaks. For example, these agents may have been manipulated to be more easily dispersed, or more environmentally stable. Biological agents used as weapons might also be present in locations or scenarios that are unlikely or impossible for the naturally-occurring disease agents. For example, a toxin normally associated with food contamination may have been sprayed in the air. For these reasons, the control measures for naturally occurring diseases may not be sufficient, and novel control measures may be required for the control of biological agents used in an attack by an adversary.

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Sample collection analysis, and remediation of biological incidents may not be achieved as predicted in selected environments. Factors influencing these elements of a response could include the presence of a biofilm (an encapsulated community of microorganisms attached to a living or inert surface), interaction of the surface with the sampling method or decontamination agent, or the characteristics of exposed surfaces (e.g., an environmental surface may be presumed to be hard, but is in fact functionally porous) or the presence of soil. These factors could cause unpredictable failures or discrepancies in persistence, sampling, analysis, and decontamination.

2.3.8 Replication

Chemicals and biotoxins do not replicate within an individual; thus, the dose of a chemical or biotoxin is directly related to its toxicity. Within limits, exposure to greater or lesser amounts of a chemical or biotoxin will predictably have greater or lesser impacts on the health of the exposed individual. This property is used to create safety guidelines, such as permissible exposure limits and acute exposure levels. In contrast, pathogens can replicate (or multiply) within an infected individual, and therefore risk assessments for microorganisms are entirely different from chemical or biotoxin risk assessments. This unique aspect of biological organisms must be considered along with other information to conduct an appropriate assessment of the risk of residual contamination from biological contaminants in the environment.

2.4 Risk Assessment

To make an effective risk management decision, risk managers and other stakeholders need to know what potential harm the situation poses and how likely it is that people or the environment will be harmed. This is accomplished through risk assessment.

Risk is the probability that a substance or situation will produce harm under specified conditions. **Risk assessment** is the gathering and analyzing of information on what potential harm a situation poses and how great the likelihood is that people or the environment will be harmed. (See Section 2.4.1 for a more detailed explanation of risk assessment in the specific context of biological agents.) The nature, extent, and focus of risk assessment are guided by risk management goals. The results of a risk assessment, along with information about public values, statutory requirements, benefits, costs, and cost effectiveness, are used to decide whether and how to manage the risks. Risk assessment can be controversial, reflecting the important role that both science and judgment play in drawing conclusions about the likelihood of effects on human health and the environment. For the reasons described in Section 2.3, risk assessment for biological incidents is highly problematic.

Following are the most salient risk analysis principles from the 1997 Commission report that need to be considered by decision-makers as they plan for and carry out a response to a biological incident:

- Clarify the factual and scientific basis of risks posed by the problem, treating health and ecological risks both qualitatively and quantitatively, where possible.
- Describe the nature, severity, reversibility, or preventability of adverse effects.
- Identify who is potentially at risk and when they are at risk, and explain the possibility of multiple effects.

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- Evaluate the weight of the scientific evidence, and identify the primary sources of uncertainty. For ecological risks, consider indirect effects on human health through disruption of the environment and possible effects on future generations.
- With input from the problem/context stage, place the specific risks posed by the problem into their multi-source, multimedia, multi-chemical, and multi-risk contexts.
- Identify stakeholder perceptions of the risks posed by the problem (Burger, 2002; Jones, 2004; NRC, 1996; Till and Meyer, 2001).
- Combine information on scientific and contextual aspects of risks posed by the problem into a characterization of the problem's risks to human health or the environment.

2.4.1. Risk Assessment in the Context of Biological Agents

Live microorganisms pose a unique challenge because risk assessment of environmental contamination cannot be done with reasonable certainty (NRC, 2005; Canter, 2005). As described earlier, quantitative dose-response assessment is a particular problem. The minimum number of organisms necessary to initiate disease has not been well defined for the various infectious threat agents and depends on many factors related to the agent itself, the person or animal exposed (host), and environmental influences.

Although some methodologies exist for this purpose, in many cases it is not possible to conduct a scientifically sound, quantitative risk assessment to adequately characterize the risks to people from intentional exposures to pathogens. This is especially true when the pathogens themselves or the methods of delivery are novel and may not occur in nature (e.g., exposure to *B. anthracis* spores in the mail) (NRC, 2005). Usually, risks can only be characterized qualitatively and, as such, may be accompanied by significant uncertainty. Nevertheless, sound risk management decisions can be made from qualitative risk assessments by following the risk management framework described in Chapter 3 and the guidance in Chapter 4 when setting clearance goals and determining an appropriate decontamination strategy. Additionally, efforts should still be made to evaluate these risks quantitatively, if possible, and to conduct uncertainty analysis if necessary, which may illuminate areas where additional information could be collected to increase the value of a quantitative assessment if time permits.

Fundamental principles for conducting risk assessments are found in the NAS Risk Assessment/Risk Management Paradigm developed in the late 1970s. Since the development of this paradigm, several enhancements have been made to the initial methods, and new methods have been developed to characterize uncertainties and increase the utility of the resulting quantitative analyses (examples include cancer risk assessment methods, reproductive and developmental toxicity assessment methods, mutagenicity risk assessment methods, and methodologies to assess chemical mixtures).

Using the NAS paradigm, quantitative risk assessment should include four components: **hazard identification, exposure assessment, dose–response assessment,** and **risk characterization**. The methodology used to assess human risk from chemical exposures and to develop standards and guidelines for chemicals may also be used to assess the health effects associated with exposures to biotoxins. However, there is no consensus-based methodology for evaluating human risks specifically posed by environmental exposure to biological agents, and there are no established cleanup goals after biological attacks.

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The World Health Organization (WHO) and the International Life Sciences Institute (ILSI) have developed frameworks to be used as guides in developing risk assessments for pathogens. These frameworks have been used for assessing the risk of exposure to harmful pathogens in certain contexts such as microbial hazards in food safety, drinking water quality, and hospital infection control practices. However, data are lacking to support quantitative risk assessment for pathogens that might be used as biological weapons (NRC, 2005). A more thorough discussion of the issues is provided in the report *Reopening Public Facilities After a Biological Attack: A Decision-Making Framework* (NRC, 2005; see Executive Summary and Chapters 5–8).

Although the basic NAS paradigm was originally developed for chemical risk assessments, it may still be generally followed when assessing risks to humans from environmental exposure to pathogens and biotoxins. Guidance on factors to be considered in each step of the risk assessment paradigm is outlined below.

For biotoxins, the tools currently available for chemical risk assessment may be more relevant. Guidance such as the EPA's Exposure Factors Handbook (USEPA, 1997), Risk Assessment Guidance for Superfund (RAGS) (USEPA, 1989 and 1991), and other guidance for chemical risks and remediation should serve as excellent resources for information on biotoxin remediation. Therefore, the discussion below is focused on pathogens.

2.4.2 Hazard Identification

The first step in determining the risk associated with a biological incident is hazard identification; that is, identifying the pathogen or biotoxin, how the contamination occurred, and the potential adverse health effects to humans through potential routes of exposure to the pathogen or biotoxin. These health effects may have different endpoints. The diseases resulting from exposure to some pathogens have mortality rates approaching 100% when not treated. Meanwhile, exposures to other pathogens or biotoxins may result in far lower mortality rates but have high morbidity rates causing a significant burden on the health care system and the economy. The military divides pathogens into lethal and incapacitating agents, with incapacitating agents requiring perhaps more medical intervention than lethal agents. The effect of certain lethal agents may also be reduced by long-term or significant medical interventions. Data are often readily available on the efficacy and cost effectiveness of various medical responses for infected individuals. Hazard identification is initially a matter of identifying the agent used in an attack. Such information may be derived from clinical, epidemiological, forensic, or environmental sampling data. The hazard assessment must also consider the potential route of exposure for the pathogen or biotoxin. In some cases, novel exposures may cause a change in the hazard inherent from a biological agent. For example, a toxin which is normally ingested may cause much more severe disease if inhaled. These novel pathways of exposure may lead to hazards that would be unanticipated from an examination of natural disease occurrence. Methods for the identification of specific contaminants of concern in biological terrorist incidents may be found in the EPA's Standard Analytical Methods document (EPA, 2007; CDC, 2010).

2.4.3 Exposure Assessment

Exposure assessment is an evaluation of the number of people who have—or could—ingest, inhale, or otherwise come in contact with a pathogen or biotoxin and at what level and frequency. If a pathogen's or biotoxin's formulation is easily dispersible or readily aerosolizable, it poses a risk of aerosol exposure. The characteristics of pathogen and biotoxin

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preparations change over time and with environmental conditions, making it nearly impossible to quantify each of the characteristics in a given situation. Many pathogens and biotoxins also have several routes of infection. *B. anthracis* causes disease from ingestion, cutaneous exposure, and inhalation exposure. Even though inhalational anthrax is the greatest concern posed by this particular pathogen, measures taken to reduce the inhalation risk may not fully address the other risks of exposure and infection. The infectious or toxic dose also varies by the route of exposure. For example, the infectious dose for anthrax by ingestion is considerably higher than through inhalation. Similarly, many pathogens cause different diseases from exposures through different routes of infection. Thus, the route of exposure is an important factor in both hazard identification and subsequent exposure assessment.

Characterizing the viability of a pathogen or activity of a biotoxin is an important aspect of exposure assessment. Exposure to nonviable pathogens and inactivated toxins poses little or no risk. Pathogens die and biotoxins may become inactivated in the environment at different rates, but the specific environmental conditions that result in inactivation vary. Methods of preparing a pathogen or biotoxin for dissemination can also affect the survival in the environment after its release. Thus, determining viability for many pathogens or activity of a biotoxin is may be difficult. In most cases, the ultimate viability test is the ability to cause an infection or toxic effect in a suitable animal or cell culture. In addition, the collection of viable pathogens from the environment is difficult because of such factors as organism inactivation between the release period and the identification of disease; limitations in existing field collection methods, transport techniques, and laboratory processing; and the presence of other co-contaminants in the environment which may inhibit the growth of the pathogen of interest.

If a pathogen is present in a state such that it will not result in exposure to a susceptible individual or initiate infection that is likely to cause disease, then it is not a threat to human health. Similarly, an inactive biotoxin may not be a human health risk. The identity and formulation of the agent, and interactions with environmental matrices, make determining exposure difficult, even in the presence of a known quantity of agent. For example, even if the precise amount of viable or active contaminant present on a floor were known, it would be difficult to predict how much of the contaminant is released in a manner that may result in exposure through inhalation, ingestion, or exposure to broken skin or mucous membranes. It may be possible to design a sampling plan to answer some important exposure questions, but because the variables are so numerous, some of the information must be estimated.

The distribution of contaminants is another crucial variable for exposure assessment. The nature of a large-scale contamination incident may lend itself to developing conceptual distribution models through various modeling tools and an adequate sampling plan. The sampling plan is executed to determine the distribution of contaminant. If the distribution is understood, then the information can be used in risk management decision-making. Even though information on the distribution of a contaminant is necessary to understand the potential for exposure, such information alone does not constitute exposure assessment.

Finally, it is likely that not all pathogens or biotoxins will be detectable in environmental samples. For example, pathogens may no longer be in a sample by the time their presence is suspected, their presence might be masked by other environmental microorganisms, or the methods used for detection may not be sensitive enough to identify pathogens present at low but biologically significant levels. The inability to detect environmental pathogens or biotoxins should not be interpreted as their absence. Other sources of information, including

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epidemiological and forensic evidence, should be interpreted in the context of what is known about the pathogen or biotoxin in question to form a hypothesis about the distribution and concentration of contamination. Such information can then be used to inform the exposure assessment.

2.4.4 Dose–Response Assessment

Dose–response relationships for pathogens are difficult to characterize and describe. Linear relationships in which smaller doses lead to less severe responses cannot be assumed. There may theoretically be some doses of some pathogens that are incapable of causing infection in a given host. There also may be doses of a pathogen that lead to infection (when the organism multiplies within the host) but are unable to cause disease due to elimination of the organism by the host. In other cases, exposure to a small dose may cause an infection leading to a disease state only after sufficient time has elapsed for the number of pathogenic microorganisms to multiply to some threshold level. In such cases, exposure to a higher initial dose may cause an earlier onset of symptoms and more rapid disease progression, but there may be no dose-dependent difference in the final outcome.

There is also a significant and complex interrelationship between dose-response and host factors such as age, immune status, and the presence of other disease conditions. For instance, in some cases, an altered immune status may not change the infectious dose (Miller et al., 2006), but may cause a change in the observable course of the disease (Miller and Schaefer, 2007). Thus the immune status of a given host may make that individual more or less susceptible to infection, or more or less likely to experience a severe outcome from a disease, independent from the infectious dose. Inherent differences in many pathogens may also affect the dose-response relationship. Various strains of the same pathogen may exhibit differences in infectious dose (Messner et al. 2001) or pathogenicity (Welkos et al. 1993). The resulting relationship between the immune status of exposed individuals and the strain or strains to which they are exposed are complicating factors that must be considered in any assessment of dose-response. Most microorganisms that could be used as weapons are not widespread causes of naturally-occurring disease in the U.S.; thus, there may be limited specific immunity in the population.

Estimates of the infectious dose of a specific pathogen can be used to inform risk management decisions related to pathogen remediation. However, infectious dose values are subject to significant uncertainties, and the assumptions defining infectious dose must be taken into consideration when setting clearance goals. Nevertheless, infectious dose may be useful to roughly predict illness in exposed individuals and to serve as a rationale for setting initial clearance goals.

Given the numerous uncertainties regarding published infectious doses for pathogens, it is extremely important to carefully examine what the numbers actually represent, as well as the routes of exposure, selected doses, and the animal species used in the underlying laboratory studies. Models used to extrapolate from animal data to humans should be carefully examined as well. Risk managers should not assume that an infectious dose estimate reflects a "safe" level; that is, the dose below which few people are likely to become ill. Even pathogens that have an infectious dose of 10,000 organisms for 50% of the population may cause infection in 1% of the population with as few as 10 organisms (Peters and Hartley, 2002). The dose response assessment for biotoxins is more similar to that conducted for chemicals.

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2.4.5 Risk Characterization

Hazard information on the virulence and drug resistance of organisms, or toxicity of a biotoxin, may be collected from clinical isolates and epidemiological evidence. Exposure information may be collected from clinical samples taken from people who are thought to have been near exposed individuals, or those present before or after a presumed exposure incident. Law enforcement and intelligence information may also provide information about the potential for environmental contamination. *In the face of potentially serious consequences from contamination, judgments as to the assessment of risks should be based on a weight-of-evidence approach that reflects a qualitative assessment of risks arising from a particular contamination incident.*

The risk characterization synthesizes all available evidence about a hazard to address the needs of decision-makers and interested parties (NRC, 1996; NRC, 2005). In some cases, it is not possible to directly measure environmental contamination. In other cases, direct measurements of environmental contamination may not be related to exposure. Therefore, even though it is imperative to attempt to estimate exposure potential and other elements to inform a risk assessment, it may be necessary to make decisions from a variety of sources of information. This is known as a weight-of-evidence approach.

An overarching goal in any risk assessment is to reduce uncertainty and variability. Because risk assessments for most pathogens are usually qualitative, they inherently contain more uncertainty and variability than quantitative risk assessments performed for chemicals. Nevertheless, following the basic risk assessment principles described above, and collecting and evaluating all relevant information on the pathogen or biotoxin, should provide a sound risk assessment (even if qualitative) that can be used by decision-makers to determine the nature and extent of cleanup needed after a biological incident.

2.5 References

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3. Framework for Decision-Making

This chapter describes basic principles and concepts that provide a sound framework for managing a response to a biological incident. The framework is designed to help decision-makers and officials at the Federal, State, tribal and local levels achieve defensible decisions. Key parts of the framework include a brief description of the overall risk management process, a summary of roles and responsibilities of government agencies and others under the NRF, an overview of the phases and activities involved in responding to a biological incident, and a "decision tree" that outlines key decision points and actions for decision-makers. Key to any decision-making is the application of the site-specific optimization process which is described in this chapter.

3.1 A Starting Point: Presidential/Congressional Commission's Risk Management Framework

In 1997, a Presidential/Congressional Commission on Risk Assessment and Risk Management issued a landmark document entitled *Framework for Environmental Health Risk Management* (Presidential/Congressional Commission, 1997). The Commission's Risk Management Framework is intended to:

- Provide an integrated, holistic approach to solving public health and environmental problems in context.
- Ensure that decisions about the use of risk assessment and economic analysis rely on the best scientific evidence and are made in the context of risk management alternatives.
- Emphasize the importance of collaboration, communication, and negotiation among stakeholders so that public values can influence risk management strategies.
- Produce risk management decisions that are more likely to be successful than decisions made without adequate and early stakeholder involvement.
- Accommodate critical new information that may emerge at any stage of the process.
- Articulate salient risk management principles for consideration by decision-makers as they plan for and carry out a response to a biological incident.
- Base risk management decision-making on a careful analysis of the weight of the scientific evidence that supports conclusions about a problem's potential risks to human health and the environment.
- Make decisions after examining a range of regulatory and non-regulatory risk management options.
- Reduce or eliminate risks in ways that:

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- Are based on the best available scientific, economic, and other technical information.
- Account for their multi-source, multimedia, multi-chemical, and multi-risk contexts.
- Are feasible, with benefits reasonably related to costs.
- Maximize net-benefits. Such approaches should:
  - Give priority to preventing risks, not just controlling them.
  - Use alternatives to command-and-control regulation, where applicable.
  - Be sensitive to social, legal, and cultural factors.
  - Include incentives for innovation, evaluation, and research.

- Implement decisions effectively, expeditiously, flexibly, and with stakeholder support.

- Implement decisions shown to have a significant impact on the risks of concern.

- Revise and change decisions when significant, new information becomes available, but avoid "paralysis by analysis."[1]

The Commission's framework defines a six-stage process for risk management that can be applied to any public health or environmental hazard. As shown in Figure 1, the six stages are:

1. Define the problem, and put it in context.
2. Analyze the risks associated with the problem in context.
3. Examine options for addressing the risks.
4. Make decisions about which options to implement.
5. Take actions to implement the decisions.
6. Conduct an evaluation of the actions.[2]

The level of effort and resources invested in using the Framework can be scaled to the importance of the problem, potential severity and economic impact of the risk, level of controversy surrounding it, and resource constraints. As such, the Framework is particularly appropriate for the type of clean-up decisions associated with the aftermath of intentional attacks.

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[1] http://www.riskworld.com/Nreports/1997/risk-rpt/html/chp1box4.htm
[2] http://www.riskworld.com/Nreports/1997/risk-rpt/html/chp1box2.htm

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Figure 1. Risk management process.

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Every stage of the Framework relies on three key principles:

Broader contexts. Instead of evaluating single risks associated with single chemicals in single environmental media, the Framework puts health and environmental problems in their larger, real-world contexts. The goal of considering problems in their context is to clarify the impact that individual risk management actions are likely to have on public health or the environment and to help direct actions and resources where they will do the most good.

Stakeholder participation. Involvement of stakeholders—parties who are concerned about or affected by the risk management problem—is critical to making and successfully implementing sound, cost-effective, informed risk management decisions. For this reason, the Framework encourages stakeholder involvement to the extent appropriate and feasible during all stages of the risk management process.

Iteration. Valuable information or perspective may emerge during any stage of the risk management process. This Framework is designed so that parts of it may be repeated, giving risk managers and stakeholders the flexibility to revisit early stages of the process when new findings made during later stages shed sufficiently important light on earlier deliberations and decisions ("The Importance of Iteration" on page 47 provides more information.).[3]

The objectives of the Presidential/Congressional Commission's Risk Management Framework and the central role of the stakeholder dovetail with the principles inherent in the optimization processes that currently underlie many State, Federal, and international risk management programs. In the next section we discuss the optimization approach.

3.2 Optimization Approach

The optimization approach is used to help address the uncertainties, gaps in research, and the uniqueness of responding to biological incidents. Responding to biological incidents, particularly, *B. anthracis,* differs from responding to radiological and chemical incidents in which there is a 30 year response history, a range of site-specific cleanup values, and more certainty in doses and concentrations and their impact on human health..

Broadly speaking, optimization is a flexible, multi-attribute decision process that seeks to consider and balance many factors. Optimization analyses are qualitative and quantitative assessments applied at each stage of site remediation decision-making from evaluation of decontamination options to implementation of the chosen alternative. The evaluation of cleanup alternatives, for example, should factor in all relevant variables, including areas impacted (e.g., size and location relative to population), types of contamination (chemical, biological, and/or radioactive), human health, public welfare, technical feasibility, costs and available resources to implement and maintain remedial options, short-term effectiveness, long-term effectiveness, timeliness, public acceptability, and economic effects (e.g., on residents, tourism, business, and industry).

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Optimization is a flexible approach, under which applicable dose and/or risk benchmarks may be identified from State, Federal, and other sources (e.g., national and international advisory organizations); such information may be useful in supporting assessments of site-specific circumstances and balancing other relevant factors. The optimization process is further described in other sections of this chapter.

The principles of site-specific optimization can be applied during several phases of a response to a biological incident. The site-specific optimization process includes quantitative and/or qualitative assessments applied at a particular stage of site cleanup decision making, such as conducting characterization environmental sampling, establishing clearance goals, and selecting decontamination options. The optimization process should consider all of the factors relevant to the issue, such as:

- Areas impacted (e.g., size, location relative to population)
- The identity and characteristics of the contaminant
- Other hazards present
- Human health risk
- Public welfare
- Ecological risks
- Actions already taken
- Projected land uses
- Preservation or destruction of places of historical, national, or regional significance
- Technical feasibility
- Wastes generated and disposal options and costs
- Costs and available resources to implement and maintain remediation options
- Potential adverse impacts (e.g., to human health, the environment, and the economy) of remediation options
- Short-term effectiveness
- Long-term effectiveness
- Timeliness
- Public acceptability, including local cultural sensitivities
- Economic effects (e.g., on employment, tourism, and business)
- Intergenerational equity

The site-specific optimization process provides an opportunity for decision makers to gain public confidence through the involvement of stakeholders. The goals of site specific optimization are:

(1) Transparency—The basis for cleanup decisions should be publicly available.
(2) Inclusiveness—Representative stakeholders should be involved.
(3) Effectiveness—Technical subject matter experts should analyze available options and assess various technologies in order to identify optimal solutions.
(4) Shared accountability—The final decision to proceed will be made jointly by Federal, State, and local officials

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3.3 Roles and Responsibilities

The NRF establishes a comprehensive, all-hazards approach to enhance the ability of the United States to manage domestic incidents (DHS 2008). It forms the basis for how Federal departments and agencies will work together during incidents and how the Federal Government will coordinate with State, tribal, and local governments and the private sector. DHS is the overall Federal coordinator for incidents involving biological terrorism, but many other Federal agencies play key roles in coordinating activities within their areas of expertise. Figures A2-1 and A2-2 in Appendix 2 provide additional information about the structure of the NRF. Table 1 in Appendix 2 shows the roles of individual Federal agencies in decontaminating biological agents. The reader is encouraged to refer to the most current version of these overarching documents, which are available at http://www.fema.gov/nrf/.

Under the NRF, technical and policy issues are addressed at the lowest possible organizational level. In most cases, this is at the level of the Incident Command or Unified Command (IC/UC). Issues that cannot be resolved at the IC/UC level may be elevated to the Joint Field Office (JFO) Unified Coordination Group for resolution. The JFO Unified Coordination Group may also wish to review and provide input on decisions related to extensive contamination (and remediation costs) and in situations where it may be necessary to set priorities among multiple contaminated sites.

In the event of accidental or intentional biological contamination of a facility or area, the appropriate local authority (e.g., fire department, police department, or public health representative) would establish and run an Incident Command, and other local, State, and Federal agencies would join, as needed. As emergency response operations are completed, the lead for remediation/cleanup activities would then be taken by the party responsible for the property involved. For example, the owner of a private building (depending on his/her resources) could oversee the cleanup and restoration of his/her own facility. However, the local or State agencies with authority for protecting public health and/or the environment would also likely exert their regulatory authority (such as by issuing a quarantine for the affected area) to assure that their cleanup and restoration efforts are acceptable. In addition, local, State, tribal, or Federal agencies would have authority for remediating a public building or any private building should the owner not have the resources to remediate it.

The response process will be managed by the IC/UC, who ultimately determines the structure and organization of the Incident Command Post, but the discussion below provides one recommended approach for managing the cleanup process within a NIMS ICS response structure. Decisions will be informed by scientific and technical analyses conducted by the Environmental Unit within the Planning Section of the Incident Command Structure. The Environmental Unit, shown in Figure 2, may be comprised of experts in sampling, decontamination technologies, industrial hygiene, public health and risk assessment, environmental engineers, and waste management. For complex or controversial remediation, the IC/UC or Environmental Unit leader may choose to convene a technical working group (TWG) of additional experts to provide multi-agency, multi-disciplinary input to planning and implementing the remediation, including setting clearance goals. The TWG may include representatives from Federal, State, local, and tribal agencies, and experts from the private sector or universities. The IC/UC or Environmental Unit leader should also meet with representatives of residential communities, building owners, and workers in nearby communities to ensure that they are fully informed about the remediation and their issues are addressed. The IC/UC might also

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consider convening a Stakeholder Work Group to make use of local knowledge and ensure that community concerns are addressed during remediation. The IC/UC command structure shown in Figure 2 is intended to be flexible and expandable in accommodating the groups necessary to address a particular incident. The IC/UC has a number of options available for managing the cleanup process: the Environmental Unit, the Scientific Support Coordinator, or a separate unit under the Planning Section (e.g., a Long-Term Cleanup Planning Unit). The unit with this responsibility will coordinate the work group processes and interactions and report the results of the analysis and working efforts to the IC/UC through the Planning Section Chief. See the *National Incident Management System* (2004) for further discussion of the roles and responsibilities of entities identified in Figure 2.

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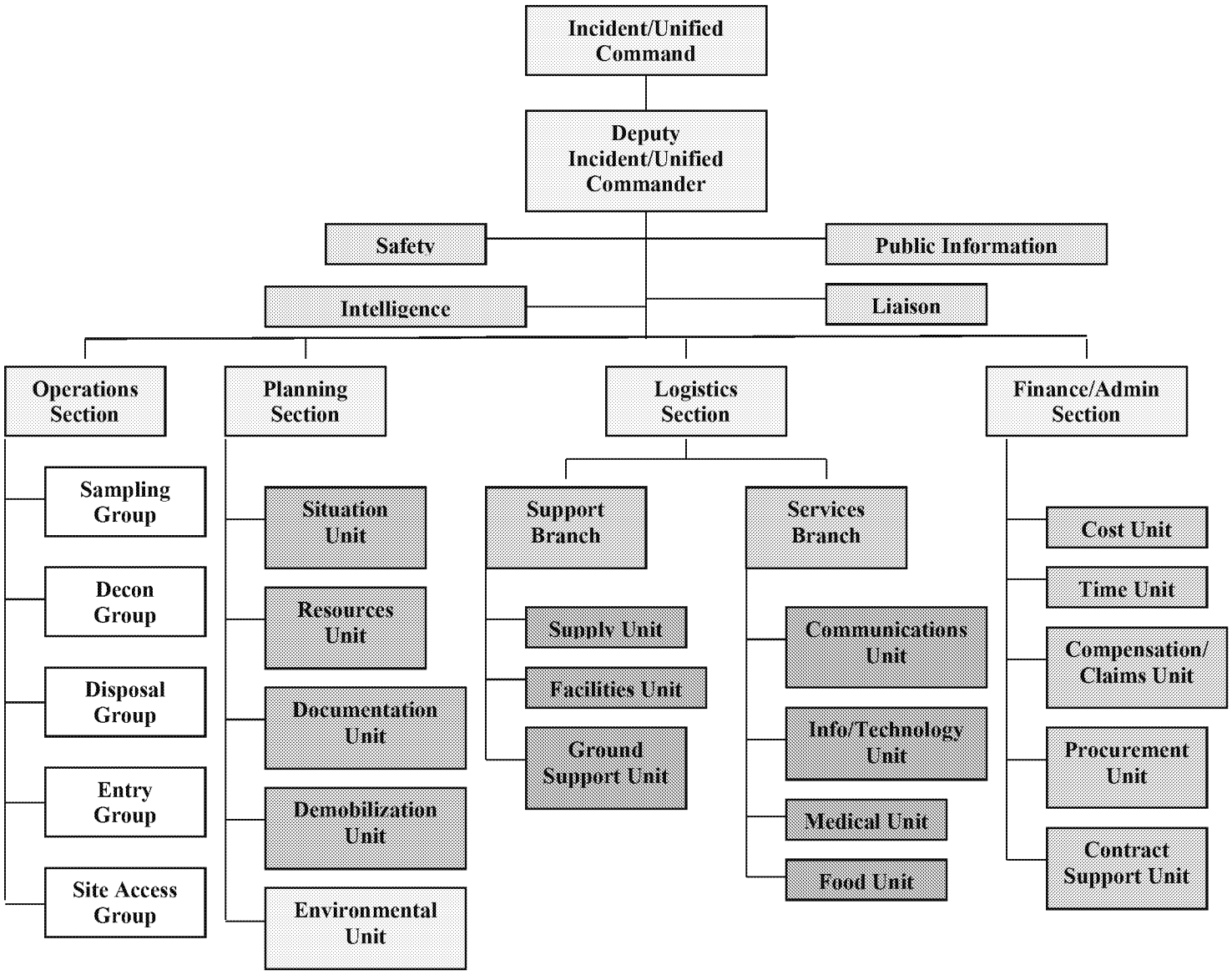

Figure 2. Incident/Unified Command Structure (adapted from DHS, 2008).

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3.3 Overview of a Response to a Biological Incident

Effective and timely decision-making in responding to a biological incident first requires a broad understanding of all the phases and activities involved. Figure 3 provides such an overview and shows the phases and activities, starting with initial notification of a potential or actual biological incident and ending with the completion of restoration/restoration operations that allow a contaminated site to be returned to normal use. Figure 3 has been developed specifically for use in this document, and the terms are defined in the Appendix 9 Glossary based either on existing definitions or on the meaning that best fits within the context of this document. Although the same terms may be defined differently elsewhere, the multi-agency review and approval of this document provides a strong basis for the definitions.

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Response and Recovery					
Crisis Management		**Consequence Management**			
Notification	**First Response**	**Remediation/Cleanup**			**Restoration/ Reoccupancy**
		Characterization	**Decontamination**	**Clearance**	
Receipt of information on biological incident Identification of suspect release sites Notification of appropriate agencies	Initial threat assessment HAZMAT and emergency actions Forensic investigation Public health actions Screening sampling Determination of agent type, concentration, and viability Risk communication	Characterization of biological agent Characterization of affected site Site containment Continue risk communication Characterization environmental sampling and analysis Initial risk assessment Clearance goals	Decontamination strategy Remediation Action Plan Worker health and safety Site preparation Source reduction Waste disposal Decontamination of sites or items Decontamination verification	Clearance environ-mental sampling and analysis Clearance decision	Renovation Reoccupation decision Long-term environmental and public health monitoring

Figure 3. Basic phases of response to a biological incident.

As shown in Figure 3, **Crisis Management** and **Consequence Management** are the two basic phases of response to a biological incident. Crisis Management consists of **Initial Response**, which can be further subdivided into **Notification** and **First Response**. These phases of response to a biological incident are not emphasized in this document, but are the focus of other guidance. Consequence Management consists of **Remediation/Cleanup** (which can be further subdivided into **Characterization**, **Decontamination**, and **Clearance)** and **Restoration/Reoccupancy**. As mentioned previously (Section 1.3), this guidance document emphasizes the remediation and long-term site recovery/restoration phases of a response to a biological incident.

Figure 3 also identifies the principal activities that take place under each of the above categories. For example, under Notification the activities listed are: Receipt of information on biological

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incident, Identification of suspect release sites, and Notification of appropriate agencies. Such activities are briefly described below. *It is important to note that these activities do not necessarily occur in sequential order, but may start at different times, run concurrently, or occur outside the phase in which they are listed in Figure 3.*

3.3.1 Notification

A biological incident may be detected by an environmental detection system, medical surveillance, epidemiologic investigation, or law enforcement investigation. That information will then likely be reported to or collected by a Federal, State or local agency. The responsible person(s) assesses the credibility of information and the degree to which a response is needed. If incoming information of a possible biological incident appears credible and requires a response, the responsible receiving person(s) relays key information to appropriate agencies (e.g., police, fire, public health, Hazmat teams, FBI, and DHS). Suspect release sites are identified, and responders are dispatched to the scene to initiate a First Response (Meehan et al., 2004).

3.3.2 First Response

First-response activities are described briefly in this document (see Section 4.2) to emphasize that such actions will have an effect on remediation activities. Hazmat and emergency actions take place when first responders arrive on the scene to address any immediate threats to life or valuable property necessary for public welfare (e.g., critical infrastructure) and to establish control of the situation. They set up a command post, initiate any needed rescue operations, mitigate any life-threatening or hazardous conditions (e.g., fire or explosion), and conduct preliminary tests to determine whether the threat substance is organic or likely to be a hazard. They also contact law enforcement and other personnel as needed.

To initiate risk communication, a Joint Information Center (JIC) should be established as soon as notification of a biological incident is received to coordinate all public-affairs activities and media releases. Communication activities continue throughout the response (Section 4.6).

If preliminary tests indicate the potential presence of a biological agent, the FBI will likely commence a threat evaluation to determine threat credibility. A forensic investigation will be used to identify the agent and determine its specific genetic, physical, and chemical properties; search for other types of evidence; establish a possible source of the contamination; and determine the responsible party. If a crime scene is established, environmental sampling must be done with explicit approval of the FBI. Initial samples may be sent to a Laboratory Response Network (LRN) (CDC, 2005b) laboratory or the FBI laboratory for analysis and to confirm the identity of the contaminant.

If the laboratory analytical results confirm the presence of a biological agent, the responsible public health agency involved in the response will commence appropriate public health actions, such as treatment (CDC, 2004c) and decontamination of potentially contaminated individuals, distribution of prophylaxis, and medical examinations.

In some instances, additional environmental sampling using methods requiring laboratory processing will commence during First Response to obtain information on agent concentration, viability, potential exposure pathways and drug susceptibility testing; and to generally inform further public health decision making. Environmental sampling may continue in more depth under Characterization.

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3.3.3 Characterization

During Characterization, additional screening sampling and analysis is performed to determine the extent and magnitude of biological agent contamination and approximate location(s) of contamination (Section 4.2). Further detailed characterization of a biological agent includes obtaining viable agent, determining the formulation, and understanding its relevant characteristics (Section 4.3).

Characterization of an affected site includes describing its size, construction, heating, ventilation and air conditioning (HVAC) systems, ambient environmental conditions (such as temperature and relative humidity), structural materials, stored materials, and contents. If decontamination is warranted, the characteristics of the site and its contents may affect selection of a decontamination strategy (Section 4.10) as well as the efficacy of decontamination agents (Section 4.4).

Containment is the set of actions taken to prevent the spread of a contaminant from a particular zone or its movement within the zone (Section 4.5). Workers who exit a contaminated area (the Exclusion Zone or Hot Zone) pass through a decontamination unit erected in a neutral area (Contamination Reduction Zone or Warm Zone) so that they can be decontaminated prior to entering a "clean" area (Support Zone or Cold Zone).

A Characterization Environmental Sampling and Analysis Plan (SAP) is developed to characterize the distribution of biological agent and to obtain semi-quantitative estimates of its concentrations at specific locations. The SAP also assesses the potential of an agent to aerosolize as evaluated by its presence on or in ceiling air ducts, on top of light fixtures, and in other locations (Section 4.7). In case of a water contamination, the SAP would evaluate the source and location of the spread of the contaminant in the water distribution system.

A risk assessment (either qualitative or quantitative) is conducted to determine potential risks posed by a biological agent at a specific site. Risks need to be assessed to assist decision-making about setting clearance goals, formulating a decontamination strategy, and developing a SAP.

There is no simple formula for setting clearance goals. This is especially true for biological agents, which do not have established reference values (like some radiological or chemical agents) or exposure guidelines. The collective, professional judgment of experts, tempered by concerns of the people affected and other factors, are used to set a clearance goal appropriate to the site-specific circumstances (Section 4.9) (EPA, 1997; NRC, 2005). The successful establishment of clearance goals will incorporate optimization (referred to earlier in this chapter).

3.3.4 Decontamination and Clearance

An overall decontamination and clearance strategy is developed through the optimization process and uses agent- and incident-specific information (Section 4.10). After the strategy is determined and the decontamination agent(s) is selected, a Remediation Action Plan (RAP) is prepared that lays out an overall strategy for decontaminating the contaminated site and its contents (Section 4.11).

The OSHA Hazardous Waste Operations and Emergency Response (HAZWOPER) standard (29 CFR 1910.120 and 29 CFR 1926.65) requires a written Worker Health and Safety Plan (HASP),

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to among other things, protect employee health and safety during Remediation/Cleanup activities (Section 4.12).

Before decontamination can proceed, site preparation is necessary (Section 4.13). Source reduction involves removing certain items and/or materials from a contaminated site for further treatment and reuse or disposal. The remaining items and site surfaces may need to be cleaned prior to the main decontamination activity (Section 4.14). Waste disposal runs concurrently with source reduction, but also occurs throughout the entire response and recovery process. In addition to materials or items that are removed from the site as waste, other wastes are created by the decontamination processes themselves, such as water used to rinse personal protective equipment (PPE), employee shower water, and scrubber wastewater (Section 4.15). Source reduction and waste disposal are significant factors that may affect the overall decontamination strategy. Some decontamination methods allow items to be left in place while others do not, and some methods generate waste products themselves.

Once a determination is made that decontamination is necessary to mitigate a biological agent incident, the evaluation, selection, and use of the most appropriate decontamination methods for the biological agent and affected site(s) and item(s) can be carried out (Section 4.16). Decontamination processes are monitored as they are carried out and are evaluated as to whether they have been conducted successfully (Section 4.17).

Clearance sampling and analysis is performed as the ultimate test of whether a remediation process is successful (Section 4.18). The IC/UC or property owner and/or responsible local/State agency (e.g. public health) makes the ultimate clearance decision. This decision is a judgment as to whether the criteria for decontamination verification and clearance have been met (Section 4.19). The local or State agencies with authority for protecting public health and/or the environment would also likely exert their regulatory authority during the response/recovery and cleanup phases (such as by issuing a quarantine for the affected area) to assure that the cleanup and restoration efforts are acceptable. In addition, local, State, tribal, or Federal agencies would have authority for remediating a public building or any private building should the owner not have the resources to remediate it.

3.3.5 Restoration/Reoccupancy

Once a building is cleared for re-use by workers and others without the need for PPE, it may still require extensive work prior to reoccupation by employees and the general public. Site-specific restoration plans would detail any necessary renovations, reoccupancy and reuse criteria. Renovations can include refurbishment, system testing, and inspection before the building is returned to normal use. Upgrading a facility may also take place to make it less vulnerable to future biological agent attack or incident (e.g., installation of biohazard detection systems in U.S. Postal Service Processing and Distribution Centers) (Noller, 2005). Reoccupancy and reuse criteria aimed at longer-term environmental and public health monitoring can vary dramatically depending on who will occupy the site and the extent of the potential residual contamination (Section 4.20). After renovations are completed and monitoring indicates that the established criteria have been met, a reoccupancy decision is made about whether to permit residents and employees to return.

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3.4 Biological Agent Incident-Response Decision Process

The flowchart shown in Figure 4 highlights the critical steps that must be taken during the phases of response to a biological incident (Raber et al., 2002). Whereas Figure 3 in the previous section lists the basic activities that comprise a response, Figure 4 arranges the response activities in a specific sequence and provides the decision-maker (e.g., IC/UC) with a guide to key decisions (diamonds) and tasks (rectangles) that need to be accomplished during a response. The activities in the flowchart are described in more detail in Chapter 4. Thus, a decision-maker can use this chart as a general "map," along with Chapter 4 for details, when determining what needs to be done and in what general order to proceed when responding to a particular incident. Key decisions are within the diamond-shaped boxes, key issues or decisions addressed are in blue boxes, activities are in white boxes, and completion is indicated by green circles. Chapter 4 refers to the various flowchart activities by the number within a box. Just as for Figure 3, in Figure 4 it is important to note that the listed activities may not necessarily occur in sequential order, but may proceed in a different order or in parallel.

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Biological Agent Incident-Response Decision Process (1 of 5)

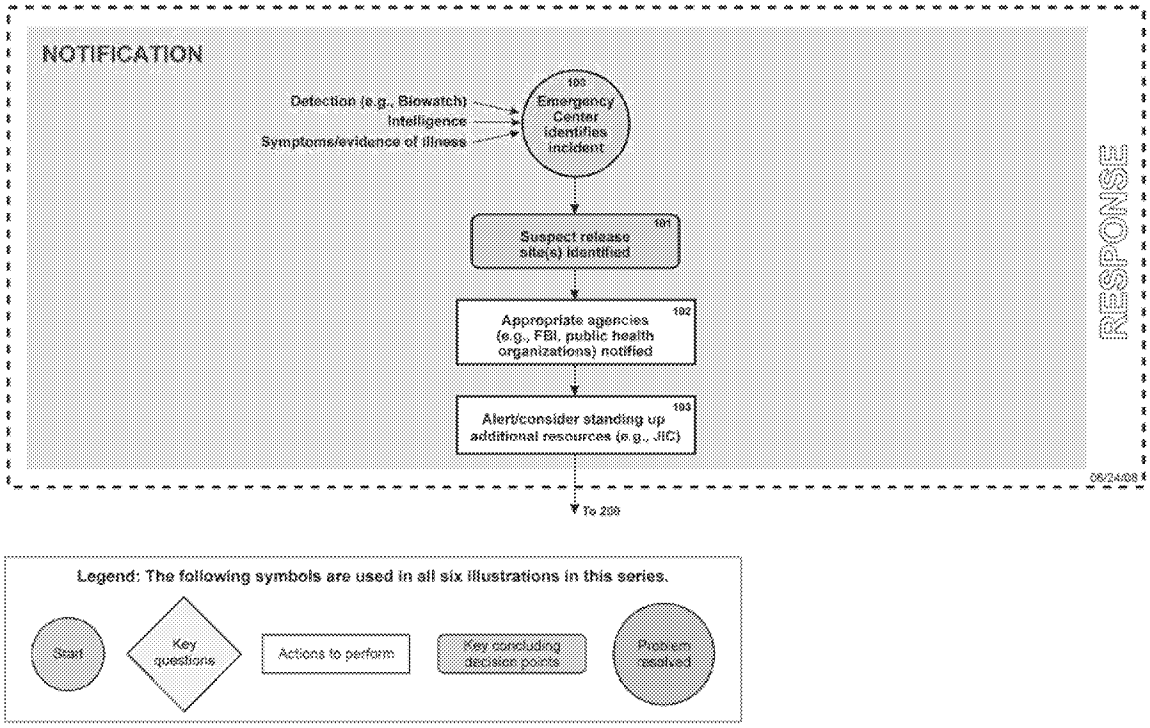

Figure 4. Biological-agent incident response decision process (1 of 5).

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Biological Agent Incident-Response Decision Process (2 of 5)

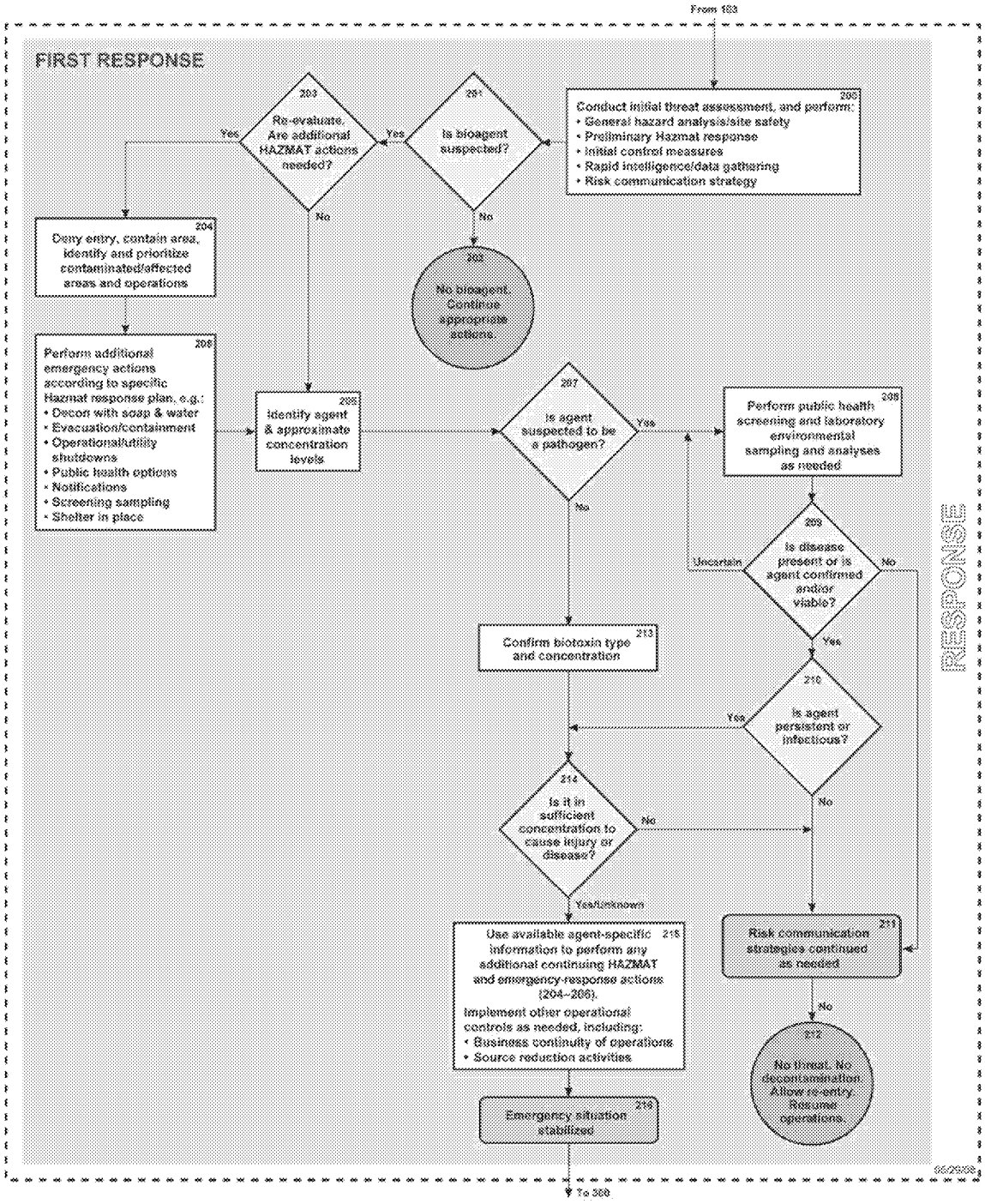

Figure 4. Biological-agent incident response decision process (2 of 5).

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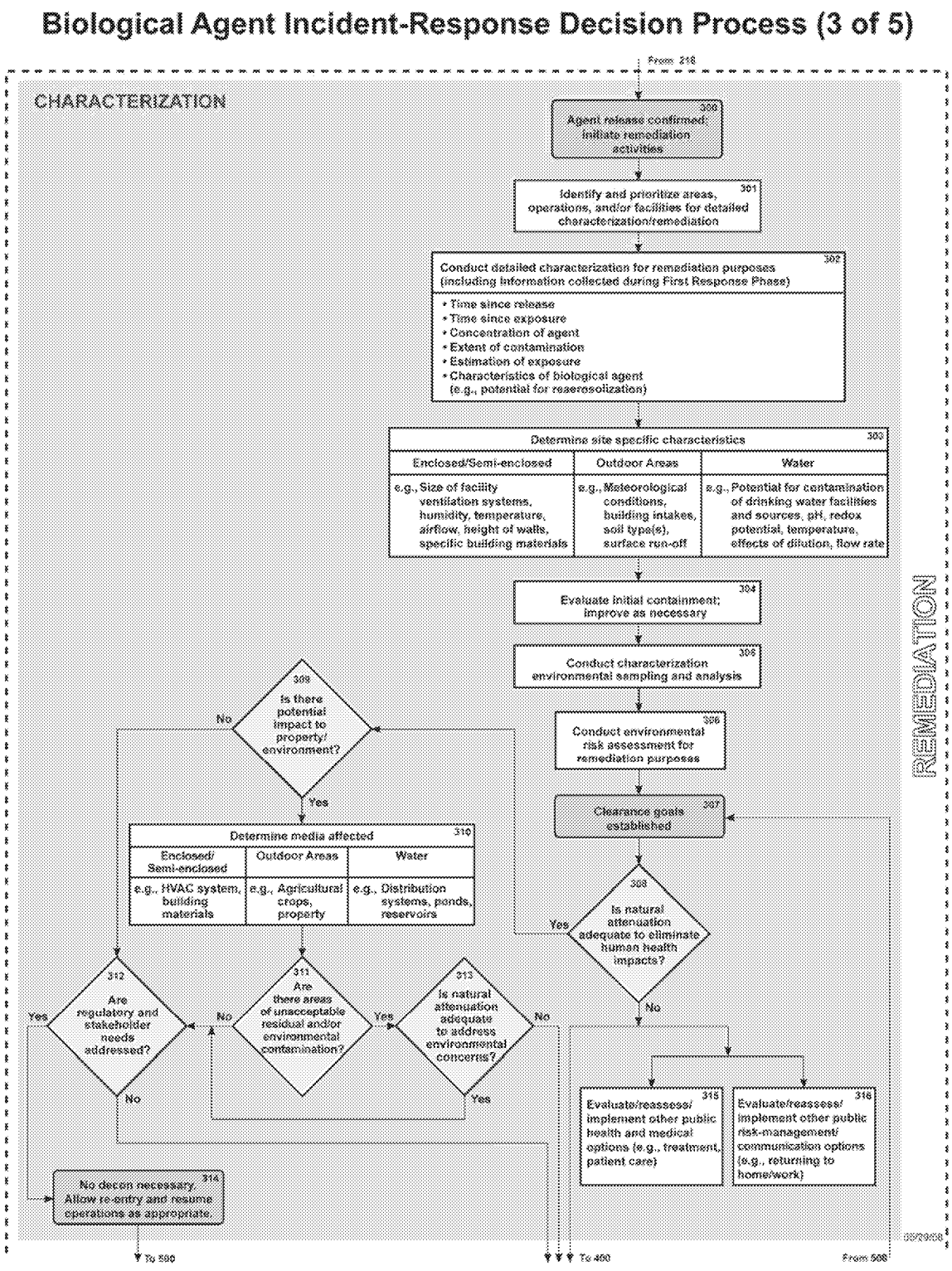

Figure 4. Biological-agent incident response decision process (3 of 5).

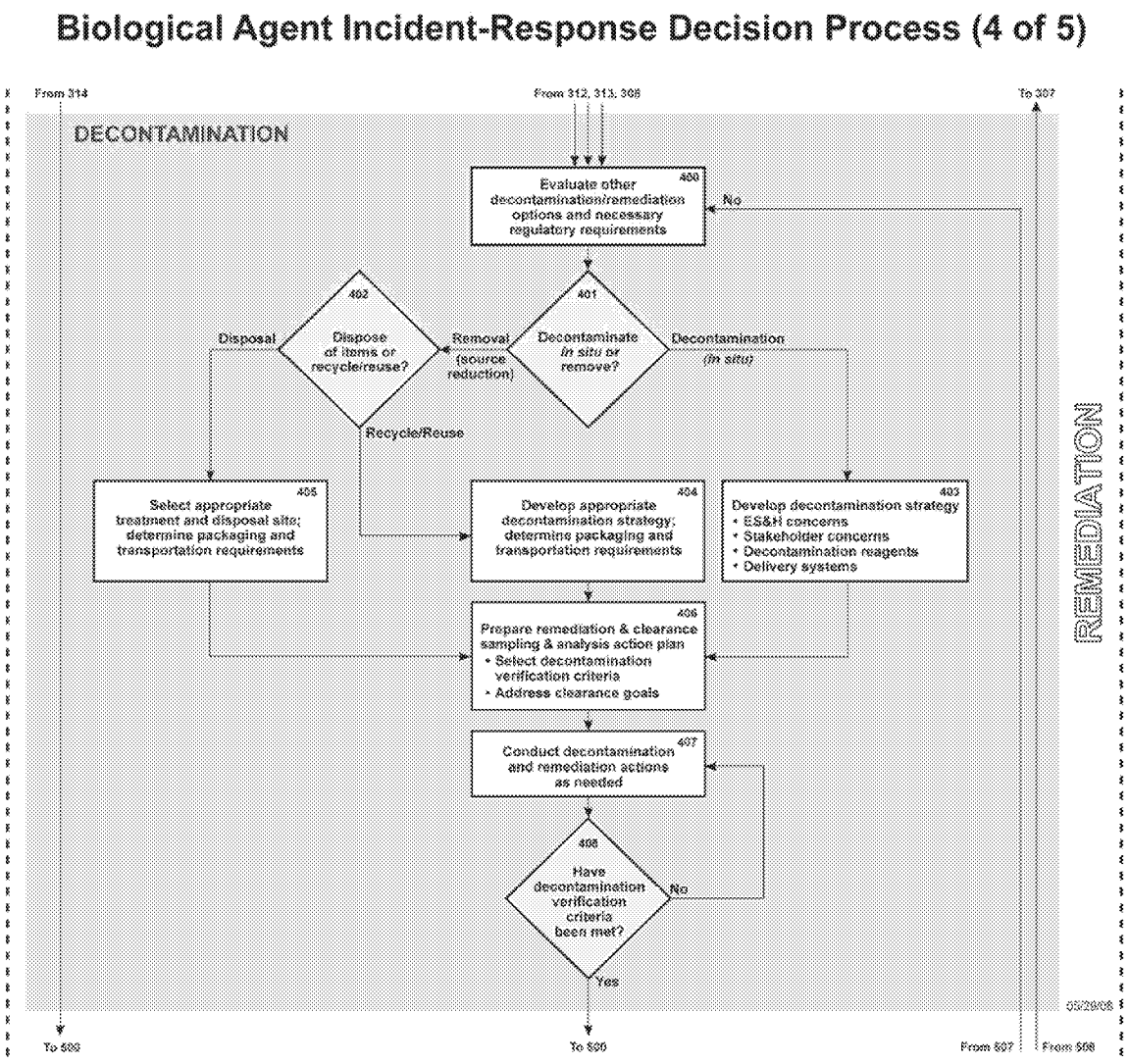

Figure 4. Biological-agent incident response decision process (4 of 5).

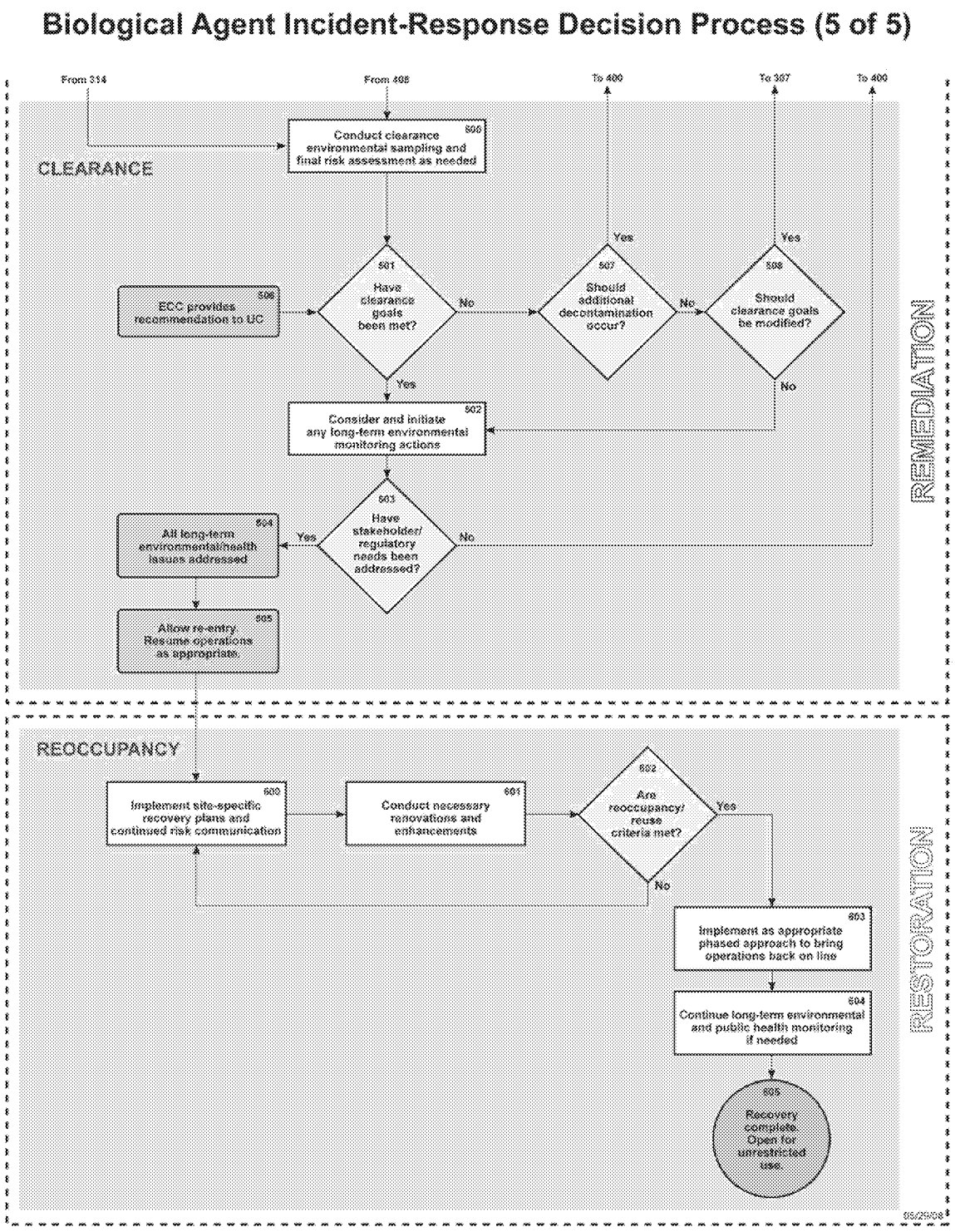

Figure 4. Biological-agent incident response decision process (5 of 5).

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4. Key Activities for Decision-Making

4.1 Introduction

This chapter describes the activities that occur in domestic, civilian settings during a response to a biological incident (Figure 3) and concepts that guide decision-makers in how to accomplish the activities. In planning and executing activities described in this chapter, decision-makers should generally follow the overarching principles of risk management and optimization described in Section 3.1 and establish the IC/UC system described in Section 3.2. The level of effort and resources invested in using the framework should be commensurate with the significance of the problem, the potential severity and economic impact, the level of controversy surrounding the problem, and resource constraints.

As described in Section 1.3, the scope of this guidance includes natural, intentional, or accidental incidents that involve biological agents. The guidance is intended to apply to:

- Enclosed facilities and objects, such as commercial and residential buildings, swimming pools, aircraft, vehicles, trains, vessels, and their contents.
- Semi-enclosed facilities and objects, such as subways, public transit facilities, and their contents.
- Outdoor areas and objects, such as building exteriors, streets, parks, water parks, beaches, other open spaces, and items within these areas.
- Drinking water sources, distribution systems, treatment facilities, and wastewater infrastructures.

Because most experience to date has been with incidents in enclosed and semi-enclosed buildings, much of the guidance pertains to such facilities and their contents. However, as discussed earlier, the framework presented in this document is intended to introduce a scalable cleanup approach based on the principles of site-specific optimization. Where different approaches to response and recovery are needed for outdoor and drinking water facilities or sources, such approaches are discussed in this chapter. In addition, the guidance in this chapter should not prevent the development and use of novel or practical approaches, if those approaches can be implemented safely and effectively. Food production and distribution systems are excluded because they are covered adequately in other guidance (http://www.fda.gov/oc/bioterrorism/role.html).

4.2 Notification and First Response (Boxes 100–217)

Notification of a potential biological incident (see Boxes 100–103 in Figure 4) could be triggered by various sources, such as a detection device (e.g., the U.S. Postal Service Biohazard Detection System for *Bacillus anthracis* spores) (Noller, 2005; see also McBride et al., 2003), a suspicious substance such as a white powder, or the occurrence of disease resulting from an airborne release (i.e., inhalation exposure) of known biological agents or consumption of suspect food or water.

An IC is established (Section 3.2) with the arrival on-scene of the first person of authority (e.g., fire department or police department representative), and a UC may be established—depending on the type and scale of incident—with arrival of representatives from other agencies (e.g.,

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public health or FBI). The coordination of information and resources to support domestic incident management activities (Box 103) typically takes place at an Emergency Operations Center (EOC), which may be a temporary or a permanently established facility. EOCs may be organized by major functional disciplines (e.g., fire, law enforcement, and medical services), by jurisdiction, or some combination. In addition, if a business or government agency has a Continuity of Operations Plan (COOP) prepared for the affected site(s), that plan would be activated.

An initial threat assessment is made of the situation (Box 200). Activities carried out at this early stage would likely include making an initial hazard analysis, performing preliminary Hazmat responses, putting into place control measures, ensuring rapid intelligence and data gathering, and developing a risk-communication strategy. A threat assessment should consider all possible threats, for example ruling out an explosive ordnance device. Of paramount importance during this early stage is the fact that emergency responders initially respond with health-protective actions in an effort to save lives.

Once an incident is known to have occurred, hypotheses concerning the characteristics and risks arising from the contamination are developed. Preliminary hypotheses are developed initially from any available information, including epidemiological, intelligence, or other data, and formulated to facilitate testing and analysis. Realistic, evidence-based first hypotheses are best made by experienced personnel. Public health and other experts make and deliver initial situation assessments to the IC/UC. Initial sampling (sometimes called screening environmental sampling or screening sampling for short) (Box 205) is undertaken to assess the likelihood of the preliminary hypotheses and to develop as complete an understanding of the event as possible.

Screening environmental sampling is the initial collection of a limited number of environmental samples for the purpose of determining the identity, concentration, viability and approximate location of contamination by a purported biological agent, and for informing the IC/UC for decision-making and subsequent remediation actions. The number of samples taken is determined by available resources (collection personnel, equipment, and laboratory surge capacity), the size/complexity/location of the facility, and circumstances. The initial response generally occurs within the first 24 to 48 hours. First responders (Boxes 200–217) in appropriate PPE (National Response Team Technical Assistance Document, 2005) (OSHA Anthrax PPE resource guide, 2008) (CDC Anthrax PPE recommendations, 2001) collect at least the initial sample(s) from any discrete material found and from locations of concern based on the information available. Following notification of a presumptive positive result from the receiving laboratory, first responders, industrial hygienists, or others may collect further initial environmental samples (Box 208), depending on the site to determine approximate location(s) of contamination from the biological agent, semi-quantitative estimates of agent concentrations at those locations, where possible, and understand exposures pathways. Sampling methods used are appropriate to the site or medium from which samples are taken, such as wet wipes or wet swabs from hard, nonporous surfaces and high efficiency particulate air (HEPA) vacuum samples from porous surfaces within the affected areas of the facility, and water samples from drinking water. The results of environmental screening sampling provide important data for the IC/UC to use in decision-making on appropriate public health and subsequent remediation actions. The number of samples taken is determined by available resources (collection personnel, equipment, and laboratory surge capacity), the size/complexity/location of the facility, and circumstances. Current information on available environmental sampling methods may be

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obtained from the CDC web site (http://www.bt.cdc.gov/agent/anthrax/environmental-sampling-apr2002.asp).

Environmental samples are sent to an LRN laboratory (Box 208), which can provide a definitive determination of the identity of pathogenic microbes (Box 207) and certain biotoxins (Box 213) that may be present (CDC 2005). The LRN laboratory runs an appropriate analysis of the sample(s), reports positive and negative results, and confirms the identity of the biological agent, if present. Other laboratory assays may be available at EPA laboratories, or ERLN (Environmental Response Laboratory Network) laboratories, including a rapid viability PCR (RV-PCR) based assay that provides both viability and identification information. The significance of lab test results to the overall sample characterization process depends on the type of test conducted. For example, the first test run on a suspected sample of *Bacillus anthracis* spores is a polymerase chain reaction (PCR) test, which is based on the presence or absence of DNA. In this case, a PCR test provides evidence of the presence of the bacterium but does not indicate viability (Box 209). In this example, a follow-up, culture-based test together with confirmatory biochemical, molecular, or antigenic testing would provide confirmation that spores are capable of producing viable, vegetative bacteria, as well as other information such as strain and antibiotic susceptibility.

Environmental sampling strategies should always be hypothesis-driven. Sampling should not be undertaken if there is no clear idea of what a "positive" sample would mean, or what actions would be taken in the event of a positive result. The hypotheses developed pertain to the identity, presence, persistence (Box 210), concentration, probability of contaminant dispersion, likelihood of exposure, and nature of the site, with respect to factors that may have allowed contaminant to migrate to various locations beyond the point of initial release. Such hypotheses are then tested by collecting environmental samples. It may be necessary to conduct other activities, such as engineering studies (i.e., tracer gas or airflow visualization studies in buildings) to better inform the hypotheses. Given an appropriate hypothesis, a testing strategy can be developed that accounts for uncertainties in the sampling and analytical techniques.

Environmental sampling should always be used with other available information, such as clinical sampling (e.g., blood samples), epidemiologic data (e.g., the occurrence of a disease of concern in humans; see Box 207), and analysis of the original contaminating material to make response and recovery decisions. Clinical sampling can provide definitive identification of the biological agent, which in turn will support elucidation of its characteristics (e.g., virulence and persistence); epidemiologic data can indicate the possible locations at which persons were exposed to the biological agent. Factors such as viability and agent composition can be obtained from the original material, if it is found. If for some reason environmental sampling cannot be effectively employed for a specific biological agent in the affected area (e.g., because of a lack of sensitivity of available sampling methods for a particular agent), then the decision-maker must rely on these other sources of information to evaluate the nature and extent of contamination.

4.3 Characterization of Biological Agents (Boxes 206, 208, 209, 210, 213, 214, 302, 308)

Characterizing biological agents includes not only identifying the particular agent (Boxes 206 and 208) and verifying its presence, but also obtaining information about that agent and the risk potential posed by its presence (e.g., Boxes 209, 210, and 214). Identification typically means establishing the genus and species, and potentially the strain or subspecies. In some instances,

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information on strain or subspecies is necessary to determine the relative risk of illness and transmission of disease. Pathogens may be further tested for virulence, drug resistance, and other conditions that would impact public health recommendations concerning exposures arising from the contamination. Testing biotoxins (Box 213) can help determine whether a particular toxin is present in an active form or may have been inactivated because of handling or environmental degradation.

The viability of agents (Box 209) is an essential piece of information that is required throughout the agent characterization and sampling processes. Simply identifying agent-specific genetic or antigenic material in a location does not confer sufficient information about risk to human health. Only viability testing can provide this information in the context of appropriate identification.

Some of the information about remediation requirements (Box 302), such as time since release and time since exposure, will already have been collected during first-response activities. Characteristics of a biological agent (Box 302) that are critical to the decontamination effort include the environmental persistence of the agent (Boxes 210 and 308) and its susceptibility to inactivation. It is widely thought that there are few environmentally persistent agents of concern among the agents generally considered to have been formulated into weapons-grade agents. There are, however, exceptions to the hypothesis about environmental persistence. It is possible that a terrorist could use a novel agent that was not considered for inclusion by the weapons programs and that is environmentally persistent as well. Several weapons-grade agents may have the potential to persist in the environment. For example, *Bacillus anthracis* spores have been documented to survive in the environment in endemic areas for years (NRC, 2005; Pepper and Gentry, 2002; Sneath, 1962). Furthermore, given appropriate conditions, *Francisella tularensis*, *Burkholderia mallei*, *Burkholderia pseudomallei* and other disease agents of concern may cause naturally occurring outbreaks. The most likely explanation for environmentally transmitted infections is that they are associated with reservoir animal or protist hosts in the environment. However, it is also possible that these agents may persist in the inanimate environment under proper conditions.

Biological agents may be formulated into more environmentally persistent forms. For example, a commercial technique for stabilizing and drying microorganisms so they can be stored might also be used to increase persistence. The time needed for less-persistent, dried agents to undergo monitored natural attenuation can range from days to months.

4.4 Characterization of the Affected Site (Boxes 301–306, 309, 310)

Just as the biological agent is characterized as part of the ongoing assessment of health risks, so is the affected site. Site characterization (Boxes 301–305 and 310) is generally based on the results of environmental sampling and provides important inputs into environmental risk assessment for site-remediation purposes (Box 306; see also Section 4.8). Site characterization includes the activities listed below, as appropriate, for an affected site. Activities that apply to all four types of sites (see Box 303 and Section 1.3 Scope)—namely, enclosed facilities, semi-enclosed facilities, outdoor areas, and drinking water facilities/distribution systems and water sources—are listed first, followed by activities specific to subsets of sites categories. Activities that apply only to water systems are listed last.

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4.4.1 Generic Characterization Activities for All Site Categories

- Develop a detailed description and determine the dimensions of physical areas affected. Areas might include (Box 310) urban or rural environments, outdoor environments, enclosed or semi-enclosed structures, and water systems (natural or man-made).
- Estimate the surface area and volume of materials and surfaces (both contents and structure) that may be potentially contaminated. Detailed maps of the facility, area, or water system will be required to categorize completely the various contents and attributes of a contaminated site (LBL, 2004; NRC, 2005, p. 161).

4.4.2 Enclosed and Semi-Enclosed Facilities

- Identify the types of materials and surfaces comprising the structure and its contents. Surfaces generally fall into one of two categories—hard, nonporous (e.g., walls, hard flooring, and metal surfaces) and porous (e.g., ceiling tile, upholstery, and carpet). The presence of soil or other organic material on the surface should be noted because it could decrease the effectiveness of the decontamination method. Furthermore, the composition of treated material needs to be evaluated (i.e., material compatibility) because of the potential for interference with the decontaminant, the possible production of hazardous by-products that remain after treatment, and the potential effects of the decontaminant or its by-products on sensitive equipment.
- Determine potential routes of exposure to the biological agent (e.g., inhalation, or skin contact) that would be unique to the affected site. Part of this evaluation includes assessing the potential spread of contaminant from point of release, collecting information about a facility's HVAC system (Box 310; DHHS, 2002), and identifying transport systems (e.g., buses or trains between terminals in airports) or other transport mechanisms (e.g., wind, water, humans, fomites) that might facilitate the spread of an airborne biological agent (Box 309). Potential reservoirs of contamination that could contribute to exposure route determinations should also be considered. Desktop computers and other objects with internal fans that draw in air might serve as reservoirs in enclosed facilities.

4.4.3 Outdoor Areas

- Document environmental conditions at the site during and after the contamination incident (Box 303). Conditions such as ambient temperature, humidity, exposure to sunlight, cloud cover, wind speed and direction, rate and directional flow of water, and rainfall may all be important information.
- Determine potential routes of exposure to the biological agent (e.g., inhalation, or skin contact) that would be unique to the affected site. Part of this evaluation includes assessing the potential spread of contaminant from point of release. Transport mechanisms to consider are wind, water, vegetation, and animals. Adhesion to people and clothing, transmission from one person to another, and movement associated with transportation and transit vehicles are also potential means of pathogen movement. Environmental reservoirs could include water, soil, damp

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organic materials, fountains, pools, atriums, crawl spaces, plantings, animals, and insects.

- Use mathematical models (e.g., air movement or plume models), if appropriate, to characterize the fate, spread, and transmission of the agent. Models have inherent limitations and require accurate input and parameters to be useful in the remediation process (Allwine et al., 2002; Lee et al., 2002).

4.4.4 Drinking Water Facilities/Distribution Systems and Water Sources

- Obtain a complete and accurate map of all connections and components of the water distribution system.
- Use modeling to identify the potential locations and level of contamination. A variety of models are in use at many water utilities and are available to assist in predicting flow within distribution systems given a variety of conditions. Ultimately, however, it may be necessary to test the accuracy of predictions with tracer studies, following the distribution of nontoxic tracers as they move through a distribution system.
- Measure residual disinfection levels at or near the point of entry, estimate the transit time to the most distant downstream customer (to determine if the agent has already cleared the system), and look for storage vessels that may have greater water age/residence time than the rest of the system.
- Document the physical–chemical characteristics of the water system. Water may have a wide range of physical and chemical characteristics, some of which can impact the persistence or detectability of pathogens or toxins. Factors such as metal ion content, presence or absence of disinfectant residuals, and temperature should be collected if possible.

4.5 Site Containment (Boxes 204, 205, 304)

Containment (Boxes, 204, 205, and 304) is the set of actions taken to prevent the further spread of a contaminant from a particular area or to prevent its movement within that area. Such actions include:

- Cordoning off any area known or suspected of being contaminated.
- Turning off a facility's HVAC system, if deemed appropriate after considering the specific characteristics of that system (i.e., would shutting down the system decrease exposure to a contaminant that is present in the building?).
- Sealing off all air ducts, windows, doors, conduits, and other vents that might allow contaminants to escape outside a facility.
- Closing valves or segregating stand-alone portions of a water distribution system known to be contaminated (e.g., isolating pressure zones, storage tanks, pump houses, and the like).
- Ensuring site security by establishing procedures to restrict entry of unauthorized personnel (e.g., installing perimeter fencing, posting signs, installing physical barriers, or using guards at all times).
- Establishing standard work zones.

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Site containment should be initiated during first response (Box 204 and 205) and then maintained or expanded during remediation/cleanup (Box 304). For example, in the case of a covert release in an enclosed or semi-enclosed facility, air samplers previously placed throughout the facility should collect data on the presence of biological agents. Once an environmental screening sample is positive for a biological agent (or in the case of an overt release, once a surface sample detects an agent) the immediately-affected area may be evacuated and contained (Box 205).

For outdoor areas, it may be difficult to determine the area contaminated with a biological agent and the boundaries of that contaminated area. For example, a containment decision regarding an incident in which a biological agent is suspected of having been dispersed from an airplane over a wide area would likely require consideration of many factors in addition to environmental sampling. Meteorological data (e.g., wind speed and direction), predictive modeling, data from pre-positioned outdoor samplers (e.g., BioWatch, see Shea and Lister, 2003), and possibly information on the flight pattern of a suspicious aircraft could be useful in informing such a decision.

For drinking water facilities/distribution systems and water sources, water sampling combined with computer modeling of how and where a contaminant may spread through the system would be a practical approach to determine locations that need to be segregated and decontaminated.

Establishing standard work zones at a contaminated site is critical to ensuring that any containment activities and subsequent decontamination activities are safely and effectively conducted. The purpose of work zones is to:

- Reduce the accidental spread of biological agents from contaminated areas to clean areas by natural processes, workers, or equipment.
- Confine work activities to the appropriate areas, thereby minimizing the likelihood of accidental exposures.
- Facilitate the location and evacuation of personnel in case of an emergency.
- Prevent unauthorized personnel from entering controlled areas.

When establishing work zones at a site, the site map may provide a useful format for compiling relevant data. In the absence of sampling results, up-to-date site maps can provide essential information on potential and suspected hazards and potential exposure pathways.

Although a site can be divided into as many zones as necessary to ensure minimal employee exposure to hazardous substances, the three most frequently identified zones are the **Exclusion Zone** ("Hot Zone"), the **Contamination Reduction Zone** ("Warm Zone"), and the **Support Zone** ("Cold Zone") (See Appendix 4 for a detailed description of each zone). In effect, those areas recognized as "cold" have been "cleared" as free from contamination. Movement of personnel and equipment among these zones should be minimized and restricted to specific **access-control points** to prevent cross-contamination. The initial work zones should be monitored through ongoing quality-assurance environmental sampling to determine if the zones are adequate for continued containment of the agent in affected areas and for the safety of workers and other personnel in the immediate vicinity of the release.

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4.6 Risk Communication (Boxes 200, 211)

A Joint Information Center (JIC) should be established immediately (Box 103 and Section 3.3.2) to coordinate all public affairs activities and media releases regarding a biological incident. A Public Information Officer (PIO) who reports to the IC/UC should be appointed to develop and release information (Boxes 200 and 211) about the incident to news media and all agencies and organizations involved.

The PIO establishes information-collection requirements, assists in approving the release of all information, and provides information updates. Multiple phone lines should be provided and staffed by knowledgeable individuals. Other equipment needs for the JIC depend on the size and impact of an incident. Additional guidance can be obtained from the JIC Manual developed by the National Response Team (NRT JIC Manual, 2000, available at http://www.uscg.mil/hq/nsfweb/nsf/onlinedoc.html).

4.6.1 Developing a Public Communication Strategy

Every crisis evolves in phases, as shown in Figure 3. Targeted communication relying on good risk communication principles must evolve in synchrony with the aforementioned phases and must be directed toward phase-specific activities. The JIC staff should be familiar with the basic tenets of risk communication and with the unique informational requirements of each phase. The operational requirements of each phase will vary according to the intensity and longevity of a crisis.

The designated Public Information Officer (PIO) must communicate information the public wants and needs to reduce the incidence of illness and death. It is vital that the spokesperson's communications reduce the likelihood that:

- Scarce public health and safety resources might be misallocated (e.g., through pressures arising from incomplete or misinformation).
- Public health and safety recommendations are ignored or circumvented.

Early during an emergency, the PIO should follow good risk communication principles to describe:

- The incident and its magnitude (who, what, where, when, why, and how).
- What we don't know about the incident.
- Health and safety risks for individuals and communities.
- What is being done to respond to the incident (see Appendix 6).
- What actions the public can take.

4.6.2 Pre-Crisis Communication Planning

A risk communication plan should be developed by the JIC and put into in place before a biological incident occurs. Pre-planned messages should anticipate necessary guidance for target audiences and should relay accurate information to address the public's concerns. Additional steps that can be taken in advance of a potential crisis or emergency include:

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- Identifying regulatory organizations, authorities, and guidance documents.
- Identifying stakeholders and interested parties.
- Developing a public communication strategy.
- Establishing points of communication with local, State, and Federal agencies.
- Deciding how to deliver appropriate risk communication messages.
- Assessing demographic data (e.g., communicating with a non-English-speaking population).

4.6.3 Crisis Communication During the First 48 Hours

During the first few days of an incident, it is necessary to quickly assess the potential response level required in terms of crisis communication, to assemble the facts as they become available, and to secure necessary resources to meet the expected buildup of media interest and demand for public information. Tasks during the initial phase of the crisis include:

- Verifying the incident and its magnitude.
- Notifying the chain of command.
- Coordinating with partner organizations.
- Establishing an initial media response.
- Assessing the level of public information and media response required.
- Assigning individuals to liaison with the media, gather information, translate messages into lay language, and execute support tasks.
- Allocating resources.

Additional information on the topic of risk communication is available at www.hhs.gov/emergency as well as from the CDC's *Crisis and Emergency Risk Communication* (Reynolds, 2002) and in the NRT's document, *Technical Assistance for Anthrax Response* (NRT, 2005). HHS has developed a series of risk communications based messages for use in the first hours of a CBRN incident. These messages address major CBRN events as well as suicide bombs and have been focus-group tested with the public. These messages are available at http://www.bt.cdc.gov/firsthours/

4.7 Characterization Environmental Sampling and Analysis (Box 305)

As explained in Section 4.2, the results of initial screening sampling (Box 205) provide evidence to confirm or reject a *preliminary* hypothesis concerning the distribution and nature of a contaminant, and to inform preliminary public health decisions and actions. Further initial environmental sampling may be conducted to inform potential exposure pathways and identify who may have been exposed (Box 208). More in-depth characterization environmental sampling and analysis (Box 305) is conducted to determine the appropriate public health response and provide input concerning further remediation actions. Thus, during the characterization phase, further hypotheses about the location of contamination are tested by data collection, including environmental characterization sampling. Analysis of the results of such sampling facilitates evaluation of each hypothesis and allows for the development of more advanced hypotheses for

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improved characterization. It is important to note that most current sampling and analytical methods for biological agents are non- or semi-quantitative.

If desired, the IC/UC may appoint an advisory panel of multidisciplinary experts, called a Technical Working Group (TWG), to help develop a Sampling and Analysis Plan (SAP), a Remediation Action Plan (RAP), and other planning documents. As described in Section 4.19, the IC/UC may also form an Environmental Clearance Committee (ECC) of independent experts to review and evaluate relevant clearance data and recommend whether the remediation should be judged successful. State and local planners should ideally identify ECC members as part of their advance planning process for biological incidents and select members who are knowledgeable about regional issues. The ECC will interact early on with the TWG group to a limited extent to be informed of the characterization environmental sampling and the decontamination approaches recommended by the TWG.

A characterization environmental sampling plan should be designed to minimize health risks to the sampling team by minimizing the time spent in the contaminated area. The sampling plan should specify the minimum number of samples needed to provide adequate characterization given the resources available at that time. An additional constraint on sample number is the capacity of laboratory support for sample processing and analysis. Activities such as maintaining chain of custody, archiving, and complicated processing and manipulation of samples may limit the rate and maximum number of samples that can be processed and analyzed to far fewer than what might be predicted from the analytical capacity of a laboratory. Sampling strategies will be site-specific and are determined by the contaminant, presumed level of contamination, location of contamination, and other factors.

Standardized formats for characterization sampling methods and hypothesis testing are not currently available for every condition (e.g., sampling for a particular biological agent on a particular type of surface or environmental matrix). However, a wealth of general information on sampling (Buttner et al., 2004; CDC, 2002; EPA, 2002b; Estill et al., 2009; Hodges et al., 2010; Rose et al., 2011) and analysis is available to guide implementation. Most hypotheses will center on one or two possible notions. For example: (1) contamination is not widespread, and (2) the contamination will have one or more areas of maximum concentration and some distribution, with a gradient of decreasing contamination away from the contaminated zones. Once the hypotheses are formulated and tested—and after the spatial distribution, environmental persistence, and concentration of contamination are better understood—a plan for decontamination can be formulated.

All of the above elements are incorporated into a Characterization Environmental SAP. The Characterization SAP articulates an overall strategy specific to the contaminated site, lists the methods and tools to be employed (e.g., environmental sampling, sampling of animals, and use of tracer studies), and describes how the tools will be applied to implement the strategy. For example, the overall strategy might be to use wipe samples in a targeted area at the suspected point of release of biological agent, along pathways where the agent may have been tracked, and at air-intake vents nearby. From these samples, the locations and amounts of the contaminant can generally be determined. In an interior space, the strategy might include modeling and tracer studies of airflow through the HVAC system and the affected area to determine other possible locations that need to be sampled. In an outdoor space, the strategy might include sampling animals in the area or sampling on unweathered surfaces of vegetation. In a water distribution system, the strategy might include modeling and tracer studies of flow in the distribution system.

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In describing how the tools will be applied, the SAP defines the sampling zones and sampling units; specifies the number and type of samples to be taken in each sampling unit; specifies locations for each type of sample; and describes how samples will be collected, packaged, and transported to the laboratory for analysis. The Characterization SAP also lists the laboratory or laboratories that will analyze samples; the laboratory procedures and protocols that will be followed in handling, processing, and analyzing samples; the laboratory's quality-assurance procedures; and how the laboratory will document and report the results.

Many pieces of information concerning environmental sampling are critical when determining the associated risk. However, some of the information can be difficult to obtain during an incident. In such cases, first approximations or conservative estimates are used. For example, the absolute limit of detection of a sampling-and-analysis method on a given surface for a particular biological agent may never be known because methods are best tested under controlled conditions. In addition, many factors— including humidity, light, temperature, roughness of a surface, pH, and other variables—may affect the resulting analysis (sampling efficiency, extraction of biological agents from a sample collection matrix, or detection in a given assay format). In some cases, internal controls can be used during sampling, processing, and analysis to gauge the performance of detection methods; however, they do not absolutely guarantee an accurate understanding of biological agent levels.

One important aspect of environmental sampling is to collect samples at locations where the biological agent is not detected. The lack of detection is not a guarantee that the agent is not present; rather, it means that the biological agent may be present at or below the limit of detection. Individuals who are unfamiliar with environmental sampling sometimes misinterpret the meaning of the inability to detect a contaminant or negative (nonreactive) assay results. A classic definition of a detection limit is that the method will detect a biological agent at a particular concentration in a defined test protocol some proportion (generally 95%) of the time. This means that at least some times (5% of the time in this example), the presence of the biological agent at the detection limit will result in failure to detect that agent. Many other factors can explain the inability to detect a biological agent. For example, failure to detect can arise from:

- A fault or inconsistency in the application of a protocol.
- Success of the decontamination effort.
- Natural variation in sampling technique.
- A matrix component that interferes with the assay.
- A change in state of contaminant (e.g., loss of a plasmid necessary for detection).
- Assay limitations.
- Actual absence of the biological agent.

A negative assay result for an environmental sample is simply the lack of ability to detect a biological agent, and such a result may not necessarily indicate the absence of target organisms.

The ultimate mass of material or number of organisms released may not be discernable through environmental analysis, or may only become known after the individuals releasing the material are captured and interrogated. It may be possible to estimate the amount of material in a particular release, or to place an upper bound on this number based on the delivery mechanism. However, such information will likely be unavailable during remediation of the affected site.

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The physical and chemical properties of the agent and its subsequent interaction with the environment (e.g., settling, attraction to surfaces, and agglomeration to other materials) also may not be known. Furthermore, most of the bulk material in a recognized, intentional incident will likely have been removed from the scene by law enforcement personnel, and some information about the material (e.g., additives, milling, and delivery systems) may be prosecution-sensitive. This means that the information may be missing from the data sets used to construct remediation plans.

In spite of these possible unknowns, with a good environmental SAP, Hot Zones and contamination gradients (including areas where the contaminant was not detected) can be determined and used to help guide the remediation effort. Even though underlying uncertainties in sampling methodologies are likely, scientifically based decisions can be made.

4.8 Risk Assessment (Box 306)

As part of the risk management paradigm described in Section 3.1, potential risks posed by a biological agent at a specific site need to be assessed to assist decision making about setting clearance goals (Section 4.9), formulating a decontamination strategy (Section 4.10), and developing a RAP (Section 4.11). As previously described, the four basic components of risk assessment are hazard identification, dose-response assessment, exposure assessment, and risk characterization. The overall goal for site-specific environmental risk assessment (Box 306) is to collect and evaluate all relevant information about the biological agent, its characteristics, and potential or measured exposure, and then provide to the decision-maker a scientifically reliable, quantitative or qualitative estimate of the potential level of risk to humans, animals, or the environment.

As discussed in Section 4.3, the identity and characteristics of a biological agent that has been confirmed to be present at a particular site are essential for hazard assessment. Among the most important characteristics to ascertain are the length of time the agent can survive in the contaminated setting (persistence), whether the agent is present in a form that easily disperses, likely routes of exposure, and the degree of resistance to inactivation.

A dose-response assessment is usually based on a review of available animal toxicology and/or human epidemiological data and medical incidence data. Any available data on the specific biological agent of concern needs to be collected and evaluated to ascertain whether a dose-response relation (i.e., an infectious dose) can be established. It is important to remember that infectious dose estimates rely on a "denominator" population. Frequently cited infectious doses are ID_{50}, which is the number of organisms that would cause illness in 50% of the population that was exposed. A minimum infectious dose is the smallest number of organisms administered to an individual (animal), or calculated to have been present in an exposure in a epidemiological study, that resulted in illness in at least one individual; animals or individuals exposed to less than this dose did not become ill in that population. Any given individual exposed to a number of organisms less than the established minimum infectious dose still may become infected if that individual is more susceptible than those in the study population, the exposure mechanism is different (i.e., inhaled in an aerosol versus by nasal lavage), or the organisms are more virulent (either a different strain or prepared with virulence-enhancing materials). The statistical power of many calculated minimum infectious dose studies may also be very small and these calculated doses cannot be extrapolated with known confidence to larger populations.

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Although infectious dose can be useful in qualitatively estimating human health effects, and such information is useful to set preliminary clearance goals, these data depend on the precise conditions present in the study from which the data were generated, and the information may not be directly applicable to the situation at hand. Furthermore, a recent review by the NRC concluded that infectious doses for pathogenic biological agents cannot be determined with confidence because the infectivity and virulence of pathogens can vary by strain, within species, and by the type of preparation used (NRC, 2005). Therefore, available information on infectious dose should not be over-interpreted. Nevertheless, infectious dose and related data are available for biological agents from various sources (USAMRIID, 2005; EPA, 2006; CDC, 1999).

A site-specific exposure assessment is performed by integrating the results of first response screening and assessment (Section 4.2 and Box 205), initial environmental sampling (Section 4.2 and Box 208), characterization of the site (Section 4.4 and Boxes 302–303), and characterization environmental sampling (Section 4.7 and Box 305). Sampling data may also be used to document the locations and levels (if quantitative analyses were performed) of biological agent, and site characterization gives an indication of site structure, the presence of conditions that can spread an agent, and the types of items and environmental matrices at the site. Modeling can also be performed to assess the potential movement of biological agent from one location to another.

For chemical agents and biological toxins, site-specific risk characterization is usually performed by combining the dose-response assessment with the exposure assessment to generate quantitative estimates of the degree of risk that a contaminant may pose to humans or other susceptible species. However, in the case of most biological pathogens, because of the difficulties surrounding infectious doses, the exposure and other risk factors, it is unlikely that a *quantitative* risk characterization can be developed. Nonetheless, a *qualitative* risk characterization still has significant value and needs to be provided to decision-makers. Such a characterization is instrumental in helping decision-makers determine clearance goals and a decontamination strategy. For example, a risk characterization that concludes that the biological agent at a particular site is persistent, easily aerosolizes, and presents a significant risk of disease to humans via inhalation would likely drive the selection of stringent clearance goals and an aggressive decontamination strategy.

4.9 Clearance Goals (Boxes 307, 308, 312, 315, 316)

There is no simple formula for setting clearance goals (Box 307) as part of the risk assessment process (Box 306). The collective, professional judgment of technical experts described in Section 3.2, applied within the context of the concerns of stakeholders, should be used to set clearance goals (Raber et al., 2001) appropriate to the site-specific circumstances (Box 307). The goals may also be influenced by national security, economic, sociological and psychological considerations, available resources, and potentially competing remediation priorities (e.g., in the event of multiple attacks). In cases where contamination is extensive, intermediate goals may be set, complemented by other interventions (Boxes 315, 316), such as prophylaxis, shelter-in-place advisories, administrative controls, medical monitoring, PPE, and other ESF #6 mass-care considerations (see ESF #6 at http://www.nmfi.org/natlresp/files/ESF6.pdf). There may also be separate clearance goals for different locations within a single site. This may happen if the area is sufficiently large and complex to contain variation in terms of parameters such as naturally-occurring background or factors which influence sampling or analysis.

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Fortunately, for most pathogens, the passage of a short time may be sufficient to reduce or dispense with the need for decontamination because many agents do not survive for long in the environment (Box 308). However, certain toxins such as T-2 mycotoxin, and persistent pathogens such as *Bacillus anthracis* spores, pose long-term remediation challenges, as do organisms that have been genetically modified or formulated to be more persistent. Moreover, although certain contaminants are not considered particularly persistent, under appropriate conditions they may persist for days, months, or even years. The risk assessment activities previously described provide the information on which clearance goals will be based.

Risk management considerations, such as potential use of public health interventions, cost and feasibility of available decontamination options, past experience in similar situations, the public's perception of an acceptable level of risk, and regulatory and stakeholder needs (Box 312) also factor into determining the clearance goal. For example, if an epidemiological investigation suggests that an agent was present in a specific area, but no agent can be detected using currently available sampling methods, then a risk management decision may be made to use an effective decontaminant, thus providing some assurance to the public that health risk has been reduced as much as possible.

Setting realistic, site-specific clearance goals should be based on the results of the best possible risk assessments, careful consideration of scientific uncertainties, use of proven technologies wherever possible, verification of decontamination effectiveness, and strong stakeholder involvement throughout the decision-making process. A practical clearance goal is to reduce residual risk (Canter, 2005) to levels that the IC/UC, in coordination with the appropriate authorities, deems consistent with the terms of the risk management principles and the optimization process described in Chapter 3. The aim of such a process is to reduce exposure levels as low as is reasonable while considering potential future land uses, technical feasibility, costs and cost effectiveness, and public acceptability.

4.10 Decontamination Strategy (Boxes 400–404)

The IC/UC develops an overall decontamination strategy (Boxes 400–404) that will guide the development and execution of all remediation activities. The strategy is based on agent- and incident-specific information, such as the following:

- Identity, formulation, and key characteristics of the biological agent (e.g., agent species and subspecies, environmental persistence, and ability to aerosolize).
- Mode of delivery of the biological agent and nature and extent of its spread.
- Results of environmental sampling, including agent location and quantities.
- Epidemiological evidence (human disease cases) and what it shows (e.g., inhalational versus dermal route of exposure).
- Health risks posed by the biological agent.
- Nature of site or items to be decontaminated (Box 310, i.e., an entire facility or just one area within a facility; outdoor environment—rural or urban; an individual water tank or entire multi-jurisdiction metropolitan water distribution system).
- Acute and chronic toxicities of chemical(s) to be used in the decontamination process.
- Public perception, such as acceptance of the process by the public.
- Environmental concerns, such as potential by-products, air emissions, residues, and disinfection by-products.
- Valid test data demonstrating the efficacy of selected decontamination process.

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- Conditions required for effective application of a decontamination process (e.g., specified ranges of relative humidity, temperature, fumigant concentration, and contact time for fumigations, or pH for certain surface treatments).
- Timeframe of the process and associated costs.
- Potential collateral damage caused by the decontamination process (i.e., effects of the process on building infrastructure or equipment).

Considering all relevant information, an overall decontamination strategy is developed and articulated in the RAP. For example, if anthrax spores were delivered to or passed through a mailroom in a letter, and if environmental samples are collected that test positive, and if medical evidence of inhalation exposure is available (e.g., data indicate aerosolizability of spores, or persons exhibit symptoms of inhalational anthrax), then a strategy of decontamination with a gas or vapor fumigant preceded by pre-cleaning of surfaces with a liquid antimicrobial pesticide in heavily contaminated areas may be indicated. As another example, in the case of a contaminated drinking water system, different strategies such as the following could be considered: (a) continue to treat the water by conventional disinfection, (b) increase the level of disinfection for all or part of the system, or (c) issue end-of-pipe treatment devices such as a community supply purification system.

The overall goal of the decontamination strategy should be to achieve the clearance goals while minimizing resources, cost, and time. Such a strategy requires optimizing the balance among source reduction (Section 4.14), waste disposal (Section 4.15), decontamination (Section 4.16), and decontamination verification (Section 4.17) activities.

4.11 Remediation Action Plan (Box 406)

Once a decontamination strategy is developed, a RAP is assembled that spells out an overall plan for decontaminating the contaminated site and its contents (Box 406). The RAP and Clearance SAP (Section 4.18) are generally created at about the same time because the remediation strategy can directly affect characterization and clearance sampling strategies. For example, if contamination is limited to a specific room, and the overall remediation strategy is to treat only the surfaces with a liquid decontamination agent, then the sampling strategy may be to conduct clearance environmental sampling focused on that room and to conduct random/grid samples in rooms that are adjacent or connected by a common HVAC system. The RAP generally includes the following sections, each of which is described elsewhere in this chapter:

- Containment (Box 304).
- Characterization of the biological agent and site, including characterization environmental sampling strategy and results (Box 305).
- Worker safety and health and decontamination (Box 316, 403).
- Clearance goals (Box 307).
- Site preparation (Box 401).
- Source reduction (Box 402).
- Waste disposal (Box 405).
- Decontamination of affected sites (Box 407).
- Offsite decontamination of essential items (Box 404).
- Decontamination verification (Box 408).
- Clearance environmental sampling and analysis plan summary (Box 406).
- Clearance decision-making criteria (Box 406).

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The RAP contains appropriate tables, figures, drawings, references, and appendices of key information from other documents, such as procedures and methods used in the remediation process and the characterization environmental sampling report.

Because the RAP specifies how the remediation activities will be carried out, the IC/UC, in coordination with the appropriate State/local authorities, needs to approve the plan before it is implemented. The IC/UC in coordination with the appropriate State/local authorities must also approve any changes to the RAP as the remediation process progresses. Finally, if any Federal or State agencies have jurisdiction over some or all activities described in the RAP, they should review and approve the RAP as well. For example, the EPA has statutory responsibility under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for registering (licensing) or exempting from registration the sale and use of antimicrobial and other pesticide products in the US (7 U.S.C. 136-136y). Because no antimicrobial pesticide is currently registered by the EPA specifically for the inactivation of *Bacillus anthracis* spores, a Federal or State agency will need to check with EPA about obtaining an emergency exemption from EPA for each specific use of a selected antimicrobial pesticide to decontaminate a facility. EPA has the authority to issue such exemptions (FIFRA section 18) when emergency conditions exist. Most exemptions require an application and quick review from EPA before they can be issued. However, where the discovery of an emergency condition and the need to use a pesticide require quicker action than this would allow, EPA would expect to issue a crisis exemption. After the 2001 bioterrorist attacks, crisis exemptions were issued to permit the sale and use of several antimicrobial pesticides to decontaminate sites, and essential items were removed from the sites and treated in offsite locations, following review and approval of site-specific RAPs.

4.12 Worker Health and Safety (Box 403)

Health and safety requirements must be addressed (Box 403) for all workers involved in the response and recovery following a biological attack. Workers include emergency responders, such as emergency medical personnel, police, firefighters, responders from government agencies, public health officials and volunteers, and those critical workers that may need to report to maintain critical infrastructure and key resources (power, healthcare, etc.). Short- and long-term remediation and restoration workers are also included (e.g., workers from government agencies, decontamination contractors, and employees at the contaminated facility).

The OSHA HAZWOPER standard (29 CFR 1910.120 and 29 CFR 1926.65) applies to each employer of the involved workers. For first/emergency response and remediation operations, this standard requires a written Health and Safety Plan (HASP) that identifies site hazards and appropriate controls to protect employee health and safety. All site hazards should be incorporated into the HASP, including physical, biological, and chemical hazards, as well as any hazards associated with decontamination agents used during remediation. Required elements of the HASP are described in the HAZWOPER standard and include the following:

- Organizational structure.
- Comprehensive workplan.
- Site characterization and job-hazard analysis.
- Engineering and work practice controls
- Site control.
- Training.
- Medical surveillance.

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- PPE.
- Exposure monitoring.
- Spill containment.
- Decontamination.
- Emergency response.
- Standard operating procedures for safety and health.

A site-specific HASP promotes efficiency and enhances completeness, clarity, and coordination among all affected parties. The HASP is a living document that is revised as necessary to reflect changes in site conditions or operations. Because some elements overlap, it may be useful to expand the HASP to include those elements necessary to protect the local community and environment (e.g., disposal of waste from decontamination or monitoring community exposures to fumigants). Additional written programs, plans, or procedures may also be necessary to meet the requirements of other applicable OSHA standards. For example, employees will likely need to use PPE during emergency response and remediation. Pursuant to 29 CFR 1910.132, employers will need to assess the workplace to determine whether and what PPE is necessary to protect workers. In addition, employers will need select appropriate equipment, ensure that it properly fits the workers and train each worker in its use. Moreover, employees will likely need to use respiratory protection during facility decontamination, so a written Respiratory Protection Program also is required in accordance with 29 CFR 1910.134.

Additional OSHA general industry and construction standards may also apply (29 CFR 1910 and 1926). For more information regarding health and safety considerations and OSHA requirements, refer to www.osha.gov. Additional helpful resources include the following:

- Anthrax eTool (OSHA): http://www.osha.gov/SLTC/etools/anthrax/index.html
- *Model Health and Safety Plan (HASP) for Cleanup of Facilities Contaminated with Anthrax Spores* (OSHA): http://www.osha.gov/dep/anthrax/hasp/index.html
- *Safety and Health Topics: Bioterrorism* (OSHA): http://www.osha.gov/SLTC/bioterrorism/index.html
- *Technical Assistance for Anthrax Response* (November 2003), Chapter 5: Health and Safety Considerations (NRT): www.nrt.org
- Safety and Health Topics web page on *Biological Agents*: http://www.osha.gov/LSTC/biologicalagents/index.html
- *Interim Recommendations for Firefighters & Other First Responders for the Selection & Use of Protective Clothing & Respirators Against Biological Agents* (CDC, October 25, 2001): emergency.cdc.gov/documentsapp/Anthrax/Protective/10242001Protect.asp
- *Interim Recommendations for the Selection and Use of Protective Clothing and Respirators Against Biological Agents* (CDC, October 2001): www.bt.cdc.gov/DocumentsApp/Anthrax/Protective/10242001Protect.asp
- *Guide for the Selection of Personal Protection Equipment for Emergency First Responders* National Institute of Justice (NIJ) Guide 102-00 (November 2002): www.ojp.usdoj.gov/nij/pubs-sum/191518.htm
- *Technical Assistance for Anthrax Response - Interim-Final Draft* (National Response Team (NRT), July 2005)
- *Anthrax in the Workplace Risk Reduction Matrix* (OSHA): www.osha.gov/dep/anthrax/matrix/index.html

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- Anthrax eTool "Protecting the Worksite against terrorism" (OSHA): www.osha.gov/SLTC/etools/anthrax/index.html

Some workers will also be involved in the delivery of medical countermeasures. Mail carriers, their security escorts, traditional first responders, and certain personnel working in critical capacities are expected to be working during the first 24 to 48 hours of the response. Separate guidance is currently being developed to address the protection of these responders.

As described in Section 4.5, workers who enter the Hot Zone must wear appropriate PPE, be provided with any recommended medical countermeasures (i.e., antibiotics, antivirals, and vaccines), and be provided with any other forms of preventive care recommended at the time of the response. When exiting a contaminated work area, response personnel and their equipment must be decontaminated. Decontamination of workers in the Warm Zone ensures that they are not contaminated while removing their PPE by materials that they may have contacted in the Hot Zone, and that they do not track contamination into clean areas of the site (Cold Zone). Such procedures can include the following:

- Mechanical decontamination (washing with soap and water to physically remove a potential contaminant) is typically used on workers.
- Chemical decontamination (applying disinfectants or sterilants to inactivate the biological agent) is typically used on PPE or nonsensitive equipment. As described in Section 4.16, only antimicrobial pesticides authorized specifically for the specific biological agent involved should be used.

Procedures for decontaminating equipment are provided in Appendix 5.

4.13 Site Preparation (Boxes 403–404)

Before decontamination methods specified in the RAP can be applied, the site and its contents need to be prepared for the remediation (or cleanup) process. Such preparation can cover a multitude of tasks (Boxes 403–404), such as:

- Assembling a worker decontamination unit.
- Testing a facility for leaks.
- Constructing internal waste-processing and load-out units.
- Installing and testing chemical generation systems.
- Installing and testing chemical, temperature, and humidity monitoring systems.
- Installing and testing negative air units and air scrubbing systems.
- Subdividing existing space with temporary walls.

Where fumigations are performed, some specialized site-preparation tasks may need to be carefully planned, implemented and documented. This preparation may also require some on-site testing prior to full implementation, in some circumstances. Once all components of the decontamination and monitoring system are shown to work independently, some testing may be necessary to demonstrate that they all work together as a system. For example, a low-level performance test may be conducted prior to a large fumigation, which includes the scrubbing system, to show that the system as a whole will likely work when run at full capacity.

Site preparation for a water-distribution system may include isolation of various segments and infrastructure devices. It may also include such activities as installing backflow-prevention

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devices to prevent recontamination of disinfected distribution system segments. Certain distribution system components, such as pressurization and storage tanks, may be drained. Provisions may need to be made for installing additional equipment and to maintain system operations and pressure as various critical system segments are taken off line. Replacement water may need to be provided to critical operations. If protocols such as relining pipes, or aggressive flushing are to be used, supplies must be obtained, and the protocols must be tested to ensure safety and efficacy.

4.14 Source Reduction (Boxes 401–402)

Source reduction (Boxes 401-402) is the process of removing certain items and/or materials from a contaminated site for further treatment and reuse or disposal, of cleaning items remaining on site prior to the main decontamination activity, and of cleaning surfaces. The decision about whether source reduction is needed is made on a case-by-case basis (i.e., considering whether decontamination can be done leaving articles in place). In some cases, source reduction could take place early in the response and recovery process and long before the decontamination phase is underway. If source reduction is performed, the goals are to:

- Reduce the number of potentially contaminated items and/or materials present.
- Ensure that any material that might inhibit decontamination is removed.
- Reduce high levels of contamination before full decontamination, if considered necessary based upon the strategy.

As part of the source reduction process, items to be removed from the site are pre-treated, as appropriate (e.g., essential items to be sent for treatment in ethylene oxide sterilization chambers are not pretreated with diluted bleach), and placed in packaging specified by the Department of Transportation and State and local governments. The packaging is also treated, usually with a 1:10 dilution of pH-adjusted bleach. The packages are then removed from the facility and transported (Box 404) to the appropriate offsite facility for disposal, treatment and disposal (Box 405), recycling, or reuse, depending on the nature of the items.

Exposed surfaces and items remaining in the site may be cleaned by HEPA vacuuming, scrubbing, and/or washing to physically remove dirt, grease, or other inorganic or organic matter, including some potential reduction in the biological agent itself.

Decisions about which items or materials to remove from a contaminated area prior to decontamination depend on many factors, including:

- Sensitivity of essential items to damage by the decontamination chemical.
- Difficulty of decontaminating items onsite (e.g., paper and other porous items).
- Potential for items to absorb or deactivate the decontamination chemical.
- Potential for toxic residues to remain on or in items after treatment.
- Value of items compared to the cost of treatment.

Items or materials that are to be removed can be grouped into the following categories:

- Essential or sensitive items that must be removed, decontaminated elsewhere, and saved or restored for reuse (e.g., art works and valuable papers).
- Items or materials that can be removed, treated elsewhere, and destroyed (e.g., site debris).
- Items or materials that can be removed, treated elsewhere, and recycled (e.g., metals).

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- Items or materials that can be treated and cleared onsite, then sent offsite for recycling (e.g., batteries and fluorescent lights).

Once decisions about the fate of items or materials are made, the source reduction activities are incorporated into the RAP and carried out as specified.

The parallel concept of source reduction in water distribution systems is flushing of water to waste. Such action should reduce the amount of contaminated water, and the flushing action should help to remove contaminants within pipes. The fate of potentially contaminated water must be predetermined before flushing decisions are made.

4.15 Waste Disposal (Box 405)

As part of source reduction, decisions are made about what to do with materials or items to be removed permanently from the site. In addition to such wastes, other wastes are created by decontamination processes, such as water used to rinse PPE, employee shower water, and scrubber wastewater.

A major issue for all types of waste is finding waste disposal sites and/or treatment facilities that will accept either treated or untreated wastes (Box 405). A few facilities have medical-waste incinerators capable of handling sizable quantities of untreated medical waste. Because of uncertainties and negative public perceptions about health risks associated with biological agents, nonmedical waste disposal sites may refuse to accept treated wastes, even if the waste has been shown by sampling not to be contaminated. Nonetheless, to the extent feasible, wastes should be decontaminated on-site in order to minimize the need to transport, treat, and dispose of contaminated wastes off-site.

Although source reduction is generally completed before the main decontamination activity, waste disposal continues until the end of decontamination because of the continuing production of wastewater and other consumables used by onsite workers. Waste is removed from the facility throughout the entire remediation process and transported to an appropriate offsite facility, depending on the nature of the waste. Information on methods of disposal of biologically contaminated waste can be found at: http://www2.ergweb.com/bdrtool/login.asp (Thorneloe 2007).

Wastewater collection and treatment facilities are typically designed to accommodate pathogenic microorganisms. There are, however, circumstances under which a specific wastewater treatment system may not be able to handle wastewater from a particular contamination incident. For example, a rapid influx of a large volume of water, particularly if contaminated with a large quantity of a persistent agent, may challenge a wastewater system beyond its capacity. Many communities have combined waste and storm water collection and treatment systems. Some of these systems maintain combined storm sewer overflow. In the case of a storm water runoff event, or perhaps a large-scale flushing, the system will allow the overflow that exceeds the capacity of the wastewater treatment plant to run directly into receiving rivers or streams. In a biological incident, the potential for environmental contamination, through this and other routes, must be evaluated. The safety of wastewater treatment system workers must also be considered in these decisions. In addition, the wastewater treatment authority must grant permission for the discharge of wastewater into its system.

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4.16 Decontamination of Sites or Items (Box 407)

Once a determination is made that decontamination of any kind is necessary to mitigate a biological agent, the most appropriate decontamination method(s) for the biological agent and affected site and its contents needs to be evaluated and selected (Box 403). A wide array of physical and chemical (antimicrobial) decontamination methods for mitigating biological agents is available for consideration. Physical decontamination either inactivates the agent through physical means, such as heat or radiation, or removes the agent, such as by washing with soap and water or vacuuming with a HEPA filter. Chemical decontamination inactivates the agent through the use of antimicrobial disinfectants or sterilants.

Current technologies for chemical (antimicrobial) decontamination fall into three categories: liquids, foams and gels, and gases and vapors (Fitch et al., 2003 and references therein). Because no single technology is applicable in all situations, the determination to use a particular method is made on a site-specific basis. Liquids are effective against many biological agents when applied to hard, nonporous surfaces, but they can cause corrosion to sensitive equipment. Foams and gels are effective against certain biological contaminants, but some can pose a post-decontamination cleanup issue. Gases and vapor fumigants are effective for inactivation of biological agents under controlled environments and conditions, but they involve complex operations. Certain gas-phase water disinfection systems involve the generation of gas onsite, using chemical or electrochemical processes that offer some advantages in terms of removing the requirement for storage of compressed gases. Difficulties with some such systems include measuring the efficiency of the gas-producing reaction, and establishing that the required contact time and concentration gradients are achieved. Appendix 7 lists some key characteristics of liquid, gas, and vapor chemicals that have been used under FIFRA crisis exemptions to inactivate *Bacillus anthracis* spores in contaminated facilities.

Although many different technologies are available for decontaminating surfaces, enclosed spaces, and water, each has advantages, disadvantages, and limitations when considering the agent and material(s) being decontaminated. No single technology, process, or strategy is effective in every case because decontaminating an area or item contaminated by a biological agent involves numerous and variable issues that are site-specific (Hawley and Kozlovac, 2004; OSHA Anthrax E-tool, 2002; Canter et al., 2005);) also available at www.epa.gov/nhsrc/dcm.htm.

Deciding which decontamination methods to use requires a rigorous evaluation of available methods and consideration of safety, efficacy, cost, and other factors. Following a detailed analysis, and taking into account site-specific details, the IC/UC selects the decontamination method or combination of methods most appropriate to remediate the contaminated site and its contents.

Key considerations for selecting one or more decontamination method(s) includes the following:

Safety

- Adequacy of site containment.
- Physical-chemical properties (e.g., explosivity or sensitivity to ultraviolet light) of the antimicrobial pesticide and potential formation of hazardous degradates.
- Toxicological characteristics and potential risks to humans of the antimicrobial pesticide and its potential chemical degradates.

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- Persistence of the antimicrobial pesticide and degradates.
- Penetration capability of the antimicrobial pesticide.
- Exposure limits applicable to workers in the general population [e.g., Permissible Exposure Limit (PEL), Threshold Limit Value (TLV), and Short Term Exposure Limit (STEL)] of the antimicrobial pesticide.

Efficacy

- History of use in similar decontamination processes.
- Penetration capability of decontaminating agent.
- Availability of acceptable efficacy data.
- Registration and exemption history under FIFRA.
- Capacity of the gas or vapor generation system.
- Methods for evaluating the efficacy of the antimicrobial pesticide (e.g., spore strips and environmental samples).

Generation, Distribution, Monitoring, and Removal

- Mode and capacity of generation of antimicrobial pesticide (i.e., available and ready-to-use versus generation onsite).
- Equipment and chemicals needed to generate and distribute gases, liquids, foams, gels, or vapors.
- Methods for preventing accidental release of decontaminant beyond the area to be decontaminated (e.g., HEPA filters on negative air vents or scrubbers) and to detect or monitor such releases.
- Equipment and methods needed to sample and monitor gas or vapor decontaminant concentrations, temperature, relative humidity, and other parameters required to ensure effective decontamination and that exposure limits are not exceeded for workers or the general public.
- Waste materials created (e.g., wastewater).
- Capacity of the decontamination generation and distribution system.
- Removal or deactivation of residual decontaminant and decontaminant byproducts after decontamination.
- Structure and operation of a facility's HVAC system.

Cost and Timeframe

- Materials (e.g., unit cost and quantity of chemicals needed).
- Equipment for generation, distribution, monitoring, and removal activities; PPE; packaging and containers for removed items and trash; wastewater disposal and treatment costs.
- Labor for planning, constructing, testing, operating, and dismantling equipment and materials.
- Indemnification agreements, if needed.
- Timeframe to set up, perform decontamination, and remove equipment.

Various safety measures may be employed during decontamination. These include, but are not limited to, ambient air monitoring near the building and in nearby neighborhoods to detect any escape of decontaminant; having police, rescue workers, and other staff on standby in the event

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of a catastrophic release of decontaminant or other emergency condition; and precautionary evacuation of nearby businesses or residences, where appropriate.

After the decontamination strategy and methods are selected, the IC/UC must ensure that the products are approved for the target biological agent, which could be either a biotoxin or a pathogenic microorganism. Products used against biotoxins are not Federally regulated, but any substance intended to prevent, destroy, or mitigate any virus, bacteria, fungi, or other microorganisms that are not in or on living man or animals are required by FIFRA, as amended, to be either registered or exempted prior to sale, distribution, and use. If the products selected are not registered for inactivating the specific target microorganism, the IC/UC must consult with the EPA to determine the requirements. Once approval is obtained to use the requested antimicrobial pesticide(s), the site is prepared, source reduction occurs, and decontamination methods are applied (Box 407) according to specific use directions to ensure that the methods are effective against the target pathogen and do not cause adverse effects to human health or the environment. Depending on the specific situation, State and local regulations may also affect the selection and use of particular decontamination strategies (section 4.11 above).

4.17 Decontamination Verification (Box 408)

Decontamination processes are monitored as they are being carried out and then evaluated as to whether they have been conducted according to the specified parameters (Box 408). To be effective, liquid antimicrobial pesticides applied to hard, nonporous surfaces must be applied at a specific concentration, temperature, and contact time. Accordingly, the product must be mixed to the specified use-dilution concentration, the appropriate temperature (normally 20° C) maintained, and the minimum contact time achieved. When these parameters have been met, the decontamination with the liquid antimicrobial pesticide can be judged as likely to have been successful.

For gaseous or vaporized antimicrobial pesticides, four parameters are key to their efficacy--temperature, relative humidity, chemical concentration, and contact time. These parameters are monitored and recorded for each of the four phases of the fumigation process—(de)humidification, conditioning, decontamination, and aeration. Maintaining these variables in the prescribed ranges throughout fumigation is one indicator of the efficacy of the process.

Biological indicators (BI) contain nonpathogenic (surrogate) spores that are selected to be generally more difficult to inactivate than virulent species of spores. A variety of spore preparations can be used such as *Bacillus atrophaeus* and *Geobacillus stearothermophilus*. Usually, a specific number of viable spores (e.g., one million) is dried on filter paper ("spore strips") or stainless-steel discs ("coupons") contained in a glassine or Tyvek pouch. BIs are used during fumigation to provide a general (but not definitive) indication of whether the fumigation was effective. Because the spores on BIs have in some cases been observed to be easier to inactivate than spores on coupons in sporicidal efficacy tests, the BIs may be more indicative of when fumigation is <u>not</u> effective rather than when it is effective. Thus, in a particular fumigation zone, if one or more BIs are positive by culture after treatment, then that zone would need to be re-treated. In addition, the fact that all BIs are negative would not guarantee that all spores have been inactivated.

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BIs are usually placed in various locations at a frequency of one per 100 square feet of floor space, or as otherwise specified in the Clearance SAP. Placing BIs in locations of known or suspected contamination and in spaces hard to reach by the fumigant is the standard practice. Positive and negative control BIs are also employed. After fumigation is complete, treated and control BIs are sent to an analytical laboratory with demonstrated experience in analyzing BIs from biomedical sterilization and other relevant fumigation processes. They are then incubated by culture to determine spore viability.

When the process parameters are met, and all spores on the BIs have been inactivated, the fumigation can be judged as likely to have been effective. If some BIs are positive, then environmental sampling is performed at locations of the positive BIs; if this sampling is positive, additional treatment of the area is required. However, the overall criterion of the success of the remediation is currently based on an indoor environmental clearance sampling which indicates no growth by culture in any sample, as described in section 4.18.

For decontamination of water, the disinfectant concentration, contact time, and temperature parameters must be met. The parameters may vary as a function of different pH or other water-quality parameters. Water treatment residuals may impact the distribution system's ability to establish or maintain appropriate conditions. Treatment chemicals added to enhance flocculation or used for system-wide softening may interact with disinfectants; thus, disinfectant concentration must be carefully monitored during the decontamination process. Rust, pipe tubercles, rough pipe joints, pumps, biofilm, and other pipe features may provide "sinks" or hiding places for pathogenic microorganisms to escape the effects of decontaminant flowing through a distribution system.

4.18 Clearance Environmental Sampling and Analysis (Box 500)

When all decontamination activities have been conducted (Section 4.16) and verified (Section 4.17), clearance environmental sampling is performed (Box 500). Clearance sampling activities may include aggressive air sampling using blowers to potentially aerosolize any remaining agent, and sampling in any area where residual, viable agent could remain after decontamination (Ferro et al., 2004; LBL, 2004; Rodes et al., 2001; Thatcher and Layton, 1995). Clearance sampling should also be designed to continue testing the hypotheses described for initial environmental sampling in Section 4.2.

The strategy for post-remediation environmental sampling (Box 406) depends on the nature and extent of the contamination, as determined by characterization sampling that was conducted prior to remediation. For example, if characterization sampling indicates heavy contamination in one area, some contamination in the surrounding area, and none in remaining areas, the strategy can implement **targeted** surface sampling for the first area (i.e., taking clearance samples at exactly the same locations where positive samples occurred), **biased** surface sampling in the second area, and **random** surface sampling in the remaining areas. If the contaminant is easily aerosolized, the strategy may also include aggressive air sampling to ensure that some of the contaminant is not still suspended in the air or easily re-suspended. The sampling plan must specify what kinds of samples will be taken and in which exact locations.

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For water distribution systems, collection of water samples throughout the system may be supplemented by collecting water in areas where the flow of water is slowed due to hydrological conditions. Locations such as point-of-use filters and water softeners may act as concentration devices for sampling small amounts of water over time. During remediation activities, it may be possible to physically sample the insides of pipe walls, using swabbing techniques similar to those used for sampling moist, hard surfaces. It should be possible to develop a sampling plan that would contain elements of targeted and biased sampling by coupling an understanding of the epidemiology of a disease outbreak with knowledge of the hydrologic functioning of a water distribution system. This approach should enhance the probability of detecting any residual contaminant beyond a simple, randomized sampling strategy.

Clearance sampling determines whether the remediation was successful (i.e., the clearance goals were met) and persons can be allowed to return to the area without PPE. The objective of clearance sampling is to provide the best available scientific evidence that a biological agent is no longer present at a level that poses a significant risk to human health (Box 501). Generally, the clearance goal (Section 4.9 and Boxes 307 and 406) is developed as part of the SAP, before remediation steps are taken, so that the overall criterion for judging the success of remediation is clear from the beginning of the project. The criterion for success is developed specifically for each site and the specific biological agent involved. The criterion must take into account potential risks associated with the agent (estimated using risk assessment methods described in Section 4.8) and the amount and type of sampling needed to provide a high level of confidence in a decision to declare the remediation successful.

Experience to date in decontaminating various agents at different sites indicates that post-remediation clearance sampling is the primary means of demonstrating the absence of biological agent and, therefore, the success of remediation for enclosed or semi-enclosed facilities. The overall criterion for success of a decontamination process that was used in responding to the 2001 attacks with *Bacillus anthracis* spores is "no growth" on any clearance environmental sample processed by culture. However, there is research underway that may help establish a scientific basis for setting a decontamination goal other than "no growth." Future decisions on decontamination effectiveness also factor in better data on agent characteristics/behavior (both indoors and outdoors), improved sampling strategies, and new methods of exposure and risk assessment.

4.19 Clearance Decision (Boxes 501–508)

The IC/UC, in coordination with the appropriate State and local authorities, ultimately makes a clearance decision based on a judgment as to whether the criteria for decontamination verification and clearance have been met (Boxes 501 and 503). The judgment is based on a thorough analysis of all sampling, process, and other data that are pertinent to the criteria for success, as outlined in the SAP and in the RAP. If desired, the IC/UC may appoint an independent advisory panel of multidisciplinary experts, called an Environmental Clearance Committee (ECC), to review and evaluate relevant clearance data and recommend whether the remediation should be judged successful. The ECC is usually formed early so that it can be informed of and have input into the environmental sampling concepts to be used in developing the SAP. If the IC/UC forms a Technical Working Group (TWG), the ECC will likely interact

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with that group to a limited extent to be informed of the characterization environmental sampling and the decontamination approaches recommended by the TWG. To maintain its independence, the ECC does not participate in the decision-making process for decontamination. After decontamination activities and clearance environmental sampling are completed, the ECC reviews all pertinent data (e.g., fumigation results and characterization and clearance environmental sampling data) and, as an advisory group, provides a recommendation (Box 506) to the IC/UC as to whether remediation has been successful (Boxes 503 and 504) and whether people may re-enter the site (Box 505) without using PPE. The IC/UC then makes a clearance decision in coordination with the responsible local, State, or Federal authority. Public health agencies typically makes the final clearance decision, but with input from the IC/UC.

If after review, the clearance goal(s) that were originally established (Box 307) are judged as unmet (Box 501), or decontamination is deemed unsuccessful, or both, then one or more subsequent decisions must be made. If additional decontamination is deemed necessary (Box 507), other decontamination options could be evaluated (Box 400) and possibly implemented (Box 407), or the same decontamination technology could be repeated, and the clearance decision process repeated. Alternatively, decision-makers may opt to modify the originally specified clearance goal(s) (Box 508), in which case the decision process (commencing with Box 307) would be repeated. Clearly, modified clearance goals would require buy-in by stakeholders and regulators (Box 503), and assurance that long-term environmental and health issues have been addressed (Box 504). The incident command system should also communicate these clearance decisions in the context of the risks involved to all stakeholders.

4.20 Restoration/Reoccupancy (Boxes 600–605)

Site-specific restoration (reoccupancy or transitional) plans, developed in the optimization context (Box 600), will vary dramatically, depending on the extent of potential residual contamination, the amount of renovation necessary to meet local safety codes, or any enhancements deemed appropriate (Box 601). An example of an "enhancement" that has been implemented by the U.S. Postal Service is their Bio-Detection System. Before opening a site to the general public (Box 605), decontamination must be judged successful such that no significant risk exists, even with no "control" action on the part of individuals (e.g., PPE, training, standard operating procedures, or medical surveillance). Risk communication (Box 600) continues as part of the restoration/reoccupancy process. It is also possible that a phased restart of business operations (Box 603) might have been planned in parallel with other response and recovery activities. Such a phased approach may be specified in a Continuity-of-Operations Plan (COOP) (Box 216). This phased approach should also be coupled with appropriate risk communication.

Reoccupancy and reuse criteria (Box 602) described in the recovery plans may require the use of longer-term environmental and public health monitoring (such as air monitoring and health monitoring of workers) (see Box 604) if needed to provide evidence that established criteria are met. Occupational (worker) sites have flexibility to use engineering or administrative controls to provide protection as implemented in a site-specific HASP (Section 4.12). With such alternative controls, the HASP can provide adequate protection while providing more flexibility in setting decontamination criteria (i.e., workers can occupy a site that was once and may potentially still be contaminated). Components of a reoccupancy program can include some or all of the elements described in Appendix 8.

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The reuse of a water distribution system might involve a phased approach as well. For example, water service might first be re-established for certain life-essential services, such as fire fighting, then the appropriate authorities might approve certain non-consumption uses, such as washing and sanitation. Finally, the water distribution system would be certified as sanitary for drinking water. Authority to make decisions on the reuse of previously contaminated water systems varies from state to state.

The IC/UC in coordination with the appropriate authority makes the decision to allow re-occupancy of facilities/residences or reuse of distribution system water, given the particular terms for decontamination of individual dwellings, to ensure no new contamination to the distribution system. Reoccupation decisions are also generally overseen by local authorities.

4.21 References

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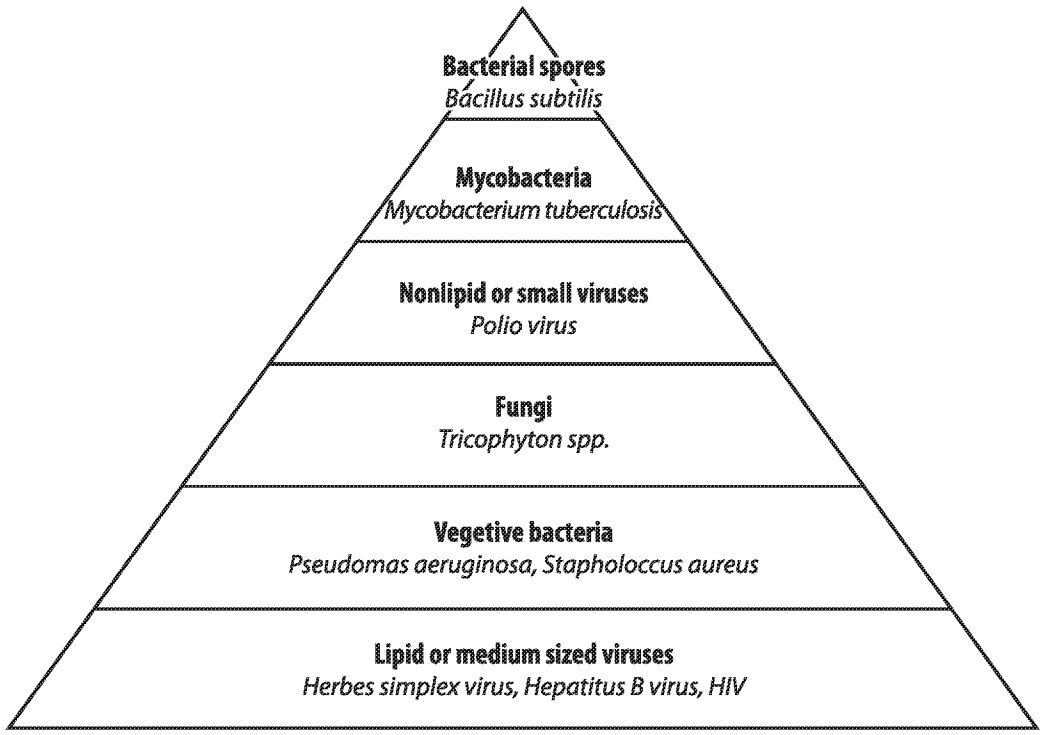
Appendix 1 Microbial Resistance to Disinfectants

Spaulding Hierarchy



Descending order of resistance to germicidal chemicals. This hierarchy considers broad classifications of microbial categories. It is considered a rough guide to general susceptibility of microorganisms to disinfectants. Adapted from Favero, M.S., Bond, W.V., Chemical disinfection of medical and surgical materials. In: Block, S.S., ed. Disinfection, Sterilization, and Preservation. 4th ed. Philadelphia: Lea & Febiger, 1991:621.

Figure A1-1. Spaulding hierarchy. Reprinted from Rutala, W. A. (1996), "APIC Guidelines for Selection and Use of Disinfectants," *American Journal of Infection Control* **24**, 314.

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Appendix 2 National Response Framework Structure and Annexes

The figures in this appendix provide additional information about the structure and content of the *National Response Framework* and its Annexes and Appendices.

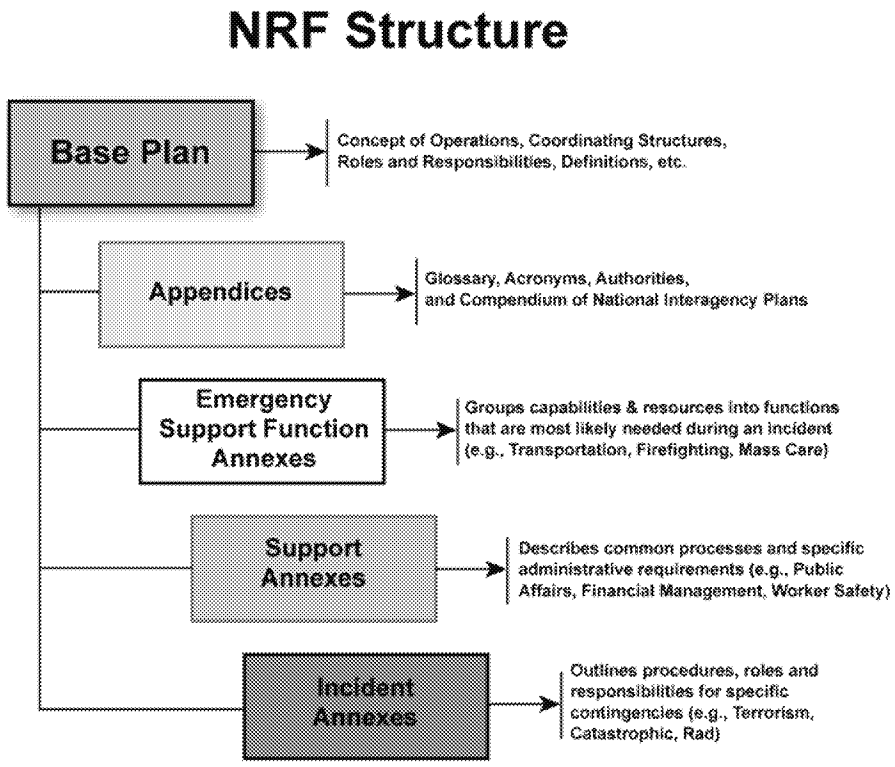

Figure A2-1. Structure of the *National Response Framework*.

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Emergency Support Functions / Annexes

- ESF #1 - Transportation
- ESF #2 - Communications
- ESF #3 - Public Works and Engineering
- ESF #4 - Firefighting
- ESF #5 - Emergency Management
- ESF #6 - Mass Care, Emergency Assistance, Housing and Human Services
- ESF #7 - Logistics Management and Resource Support
- ESF #8 - Public Health and Medical Services
- ESF #9 - Search and Rescue
- ESF #10 - Oil and Hazardous Materials Response
- ESF #11 - Agriculture and Natural Resources
- ESF #12 - Energy
- ESF #13 - Public Safety and Security
- ESF #14 - Long-Term Community Recovery
- ESF #15 - External Affairs

Homeland Security

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Support Annexes

- Critical Infrastructure and Key Resources*
- Financial Management
- International Coordination
- Private Sector Coordination
- Public Affairs
- Tribal Relations
- Volunteer and Donations Management
- Worker Safety and Health

Incident Annexes

- Biological Incident
- Catastrophic Incident
- Cyber Incident
- Food and Agriculture Incident
- Mass Evacuation Incident*
- Nuclear/Radiological Incident
- Terrorism Incident Law Enforcement and Investigation

*New annexes

Homeland Security

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Figure A2-2. *National Response Framework* annexes

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Appendix 3 Federal Agency Roles and Responsibilities for Biological Decontamination

The table below identifies the specific roles and responsibilities of key Federal agencies for various aspects of biological decontamination. Source documents related to the responsibilities are identified in the table.

Table A3-1. Roles and responsibilities of Federal agencies in biological decontamination activities.

BIOLOGICAL INCIDENTS (Page 1 of 3)			
Activity	Activity Description	Key Federal Agencies	Source
Public (victim) decontamination	Public decontamination may include providing technical advice or direct assistance for: – Procedures to protect and decontaminate public – Medical monitoring and decontamination of possibly affected victims – Establishing a registry of potentially exposed individuals	**HHS** – Primary agency responsible for coordinating Federal support* *It is important to note that the NRF provides that victim decontamination is primarily the responsibility of State, local, and tribal governments. Federal assistance is limited.	NRF ESF #8 NRF Biological Incident Annex NRF Catastrophic Incident Annex

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BIOLOGICAL INCIDENTS Continued (Page 2 of 3)			
Activity	**Activity Description**	**Key Federal Agencies**	**Source**
Environmental Decontamination/Cleanup	Environmental decontamination/cleanup generally includes the following types of activities: - Environmental sampling/analysis/monitoring (e.g. for site characterization as well as to verify adequacy of cleanup) - Removal and/or remediation activities (which include decontamination/cleanup) of buildings, residences, open land, etc. - Waste/debris management The agency(ies) conducting these activities will also provide for decontamination of the response worker personnel.	While HHS is the designated overall Federal coordinating agency for biological incidents, then environmental decontamination/cleanup is led by other agencies. Certain agencies have specific roles related to this area as described: **EPA** or **USCG**: - EPA for the Inland Zone - USCG for the Coastal Zone Except for the Federal facilities below. The designation of the lead agencies listed below is not addressed by the NRF but is described in the NCP. **DOD/DOE** – for incidents involving <u>their facilities, vessels, materials</u> Under the NCP, Federal agencies other than EPA/USCG, DOD and DOE are the lead for non-emergency cleanups associated with their facilities, vessels and material. In addition, for decontamination of microorganisms (not toxins), a product must be registered or given a crisis exemption for use by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). **USDA** – in the case of zoonotic agents, HHS will coordinate with USDA for control and management of food supplies **OSHA** will provide technical assistance on worker safety and health issues.	NRF Biological Incident Annex in coordination with ESF #10 NRF Catastrophic Incident Annex NCP Section 300.120 FIFRA NRF Worker Safety and Health Support Annex

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BIOLOGICAL INCIDENTS (Page 3 of 3)			
Activity	**Activity Description**	**Key Federal Agencies**	**Source**
Emergency removal/disposal of contaminated debris	Emergency removal of debris (e.g. clearing public roads and property	[Note: Waste/debris generated from decontamination and remediation is managed under the ESF #10 environmental cleanup/decontamination activities when activated (EPA/USCG)] **OSHA** will provide technical assistance on worker safety and health issues.	NRF ESF #3 (in consultation with ESF #10) NRF Catastrophic Incident Annex
Food/Agricultural/Animal decontamination and waste disposal	Coordination of veterinary and wildlife services in affected area –Inspection, sampling, monitoring, and analysis of food products, livestock, poultry, crops, and associated facilities –Control, de-contamination, and waste management of contaminated food products, livestock, poultry, crops, or related facilities – Control of contaminated material affecting natural and cultural resources including wildlife	If a biological incident primarily involves an attack on the agricultural sector (i.e., agro-terrorism involving livestock, poultry, or crops), the **USDA/APHIS** is the primary agency supporting the DHS under ESF #11. If a biological incident involves natural, cultural or historic resources, the U.S. Department of Interior (**DOI**) is the Primary Agency. For attacks on food already processed and in the food-distribution system (e.g., adulterated packaged foods), **HHS/FDA** or **USDA/FSIS** takes the lead role, depending on which has regulatory authority for the given food. **OSHA** will provide technical assistance on worker safety and health issues.	NRF ESF #11 Public Health Security and Bioterrorism Preparedness and Response Act, 2002 NRF Food and Agricultural Incident Annex is under development and will further clarify roles and responsibilities. In support of HSPD-9 (Food and Agriculture), five Federal agencies developed and issued guidance entitled, "Federal Food and Agriculture Decontamination and Disposal Roles and Responsibilities, November 2005," which provides guidance on how Federal, State and local agencies should coordinate in response to various kinds of biological incidents that may occur in U.S. food and agriculture

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Appendix 4 Standard Work Zones for a Contaminated Site

(See Section 4.5)

Exclusion Zone (Hot Zone)

The Exclusion Zone is the area where contamination is either known or expected to occur and where the greatest potential for exposure exists. The outer boundary of the Exclusion Zone, called the **Hotline**, separates the area of contamination from the Contamination Reduction Zone. The Hotline should initially be established by visually surveying the site and determining the extent of biological agents or related material present with preliminary environmental sampling. Other factors to consider in establishing the Hotline include:

- Providing sufficient space to protect personnel outside the Exclusion Zone from potential fire or explosion.
- Allowing an adequate area within which to conduct site operations.
- Reducing the potential for contaminant migration.

The Hotline should be physically secured (e.g., using chains, fences, or ropes) and/or clearly marked (e.g., using lines, placards, hazard tape, or signs). During subsequent site operations, the boundary may be modified and adjusted as more information becomes available. The Exclusion Zone may also be subdivided into different areas of contamination based on known or expected types and degrees of hazards. If the Exclusion Zone is subdivided in this manner, additional demarcations (e.g., "Hazards Present" or "Protection Required") may be necessary.

Access to and from the Exclusion Zone should be restricted to **Access Control Points** at the Hotline. Access Control Points are used to regulate the flow of personnel and equipment into and out of the contaminated area and to verify that site control procedures are followed. Separate entrances and exits should be established to separate personnel and equipment movement into and out of the Exclusion Zone.

All persons who enter the Exclusion Zone must wear the appropriate level of Personal Protective Equipment (PPE) for the degrees and types of hazards present. PPE should be chosen following a careful risk assessment, and it should be appropriate to the biological agent, as well as any other hazardous material used in the work area. In addition, employers need to ensure that workers entering the Exclusion Zone have received training in the proper use of the PPE they are using (29 CFR 1910.132, 29 CFR 1910.134). If the Exclusion Zone is subdivided, different levels of PPE may be appropriate. Each subdivision of the Exclusion Zone should be clearly marked to identify hazards and the required level of PPE.

Sampling equipment needs to be properly calibrated and clean prior to entering the contaminated area. If electronic communications devices (such as radios) are used, the equipment should be easily decontaminated. Upon exiting the contaminated area, all equipment and gear must be either decontaminated or discarded properly. No contaminated equipment or gear should be allowed to enter the clean area. A change in situation may require a change in containment strategy, including the perimeters. As the situation matures or comes under control, expanding or shrinking the security perimeter and containment zones may be necessary.

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Contamination Reduction Zone (Warm Zone)

The Contamination Reduction Zone is the area in which decontamination of personnel, equipment, and items coming out of the Hot Zone takes place. It is the transition area between the Exclusion Zone and Support Zone. The purpose of the Contamination Reduction Zone is to reduce the possibility that the Support Zone will become contaminated or affected by site hazards.

The Contamination Control Line marks the boundary between the Contamination Reduction Zone and Support Zone and separates clean areas of the site from those areas used to decontaminate workers and equipment. Access Control Points between the Contamination Reduction Zone and Support Zone should be established to ensure workers entering the Contamination Reduction Zone are wearing the proper PPE and that workers exiting the Contamination Reduction Zone to the Support Zone remove or decontaminate all potentially contaminated PPE.

Support Zone (Cold Zone)

The Support Zone is the uncontaminated area where workers are unlikely to be exposed to biological agents or dangerous conditions. Because the Support Zone is free from contamination, personnel working within it may wear normal work clothes. Any potentially contaminated clothing, equipment, and samples (that is, contaminated outer containers for samples) should remain inside the Contamination Reduction Zone or the Exclusion Zone.

Designation of the Support Zone should be based on all available site characterization data and should be located upwind from the Exclusion Zone. The Support Zone should be in an area that is known to be free of elevated (i.e., higher than background) concentrations of hazardous substances.

It is important to evaluate the initial activities to determine if they are adequate for continued containment of the agent in affected areas, and to monitor the safety of remediation workers and other personnel in the immediate vicinity of the release.

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Appendix 5 Decontamination for Workers in Level-C PPE

(See Section 4.12)

Following is a typical decontamination procedure appropriate for workers using Level- A, B or C PPE:

1. Worker proceeds to Exclusion Zone exit.
2. Worker washes the bottom of rubber boots in tub with a soapy water solution.
3. Worker enters the Contamination Reduction Zone.
4. A decontamination assistant or the worker's designated "buddy" inspects the suit for gross contamination in the form of dust and dirt. If dust or dirt is observed, the outer suit is sprayed with a fine mist of soapy water from a pump sprayer. Alternatively, a HEPA vacuum may be used.
5. Worker removes outer suit and discards it into bag/drum, leaving respiratory protection on.
6. Worker removes items such as boots, outer gloves, inner gloves/suit/scrubs, respirator cartridge(s), and discards them in biohazard bag within the Contamination Reduction Zone.
7. Worker proceeds to a separate, delineated equipment-cleaning area to completely submerge and clean all reusable PPE (i.e., respirator, hard hat, rubber boots, etc.) in soapy water or other antimicrobial solution as appropriate for the biological agent and PPE.
8. Worker proceeds to a separate delineated PPE storage area where reusable equipment is dried and stored.
9. Worker proceeds to personnel shower (if appropriate) and/or hand washing facility.
10. If showering, worker thoroughly washes hands, hair, face, and neck.
11. Worker dries and dons street clothes, then exits Contamination Reduction Zone.
12. Worker enters the Support Zone.

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Appendix 6 Basic Tenets of Crisis and Emergency Risk Communication (http://www.bt.cdc.gov/erc/leaders.pdf)

(See Section 4.7)

- **Don't over-reassure.** The objective is not to placate but to elicit accurate, calm concern.
- **Acknowledge uncertainty.** Offer only what you know. Show your distress and acknowledge your audience's distress. "It must be awful to hear …."
- **Emphasize that a process is in place to learn more**. Describe that process in simple terms.
- **Give anticipatory guidance.** If you are aware of future negative outcomes, let people know what to expect (e.g., side effects of antibiotics).
- **Be regretful, not defensive.** Say, "We are sorry…" or "We feel terrible that…" when acknowledging misdeeds or failures from the organization. Don't use "regret," which sounds like you're preparing for a lawsuit.
- **Acknowledge people's fears.** Don't tell people they shouldn't be afraid. They *are* afraid and they have a right to their fears. Don't disparage fear.
- **Acknowledge the shared misery.** Some people will be less frightened than they are miserable, feeling hopeless and defeated. Acknowledge the misery of a catastrophic incident, then help move people toward the future through positive actions.
- **Express wishes.** Say, "I wish we knew more," or "I wish our answers were more definitive."
- **Panic is less common than imagined.** Panic doesn't come from bad news, but from mixed messages. If people are faced with conflicting recommendations and expert advice, they are left with no credible source to turn to for help. Candor protects your credibility and reduces the possibility of panic.
- **Be willing to address "what if" questions.** These are the questions that everyone is thinking about, and they want expert answers. Although it is often impractical to fuel "what ifs" when the crisis is contained and not likely to affect large numbers of people, it is reasonable to answer "what ifs" when people need to be emotionally prepared for them. You may lose credibility by not addressing "what ifs."
- **Give people things to do.** In an emergency, some actions are directed at victims, and those exposed or have the potential to be exposed. However, those who do not need to take immediate action will be engaging in "vicarious rehearsal" regarding those recommendations and may need substitute actions to ensure that they do not prematurely act on recommendations not meant for them. Simple actions in an emergency will give people a sense of control.
- **Ask more of people.** Perhaps the most important role of the spokesperson is to ask people to bear the risk and work toward solutions with you. People can tolerate considerable risk, especially voluntary risk. A spokesperson, especially one who is on the ground and at personal risk, can model the appropriate behavior.

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Appendix 7 Antimicrobial Decontaminants

(See Section 4.16)

Table A7-1. Liquid antimicrobial pesticides used under FIFRA crisis exemptions to inactivate *Bacillus anthracis* spores. Only two antimicrobial pesticides are currently registered for use to inactivate *B. anthracis* spores (see http://www.epa.gov/pesticides/factsheets/chemicals/peridox-eds.html).

Chemical	Generation method	Toxicity	Efficacy	Materials compatibility	Approved uses
Aqueous chlorine dioxide	Must be generated onsite	Acutely toxic; skin and eye irritant.	Sporicidal on nonporous surfaces at 500 ppm and 30 min. contact time	No known problems	EPA registered sanitizer and disinfectant for many uses
Hydrogen peroxide and peracetic acid	Ready to use liquid	Acutely toxic; irreversible eye damage.	Several products are sporicidal on nonporous surfaces with contact times ranging from 15 to 30 minutes.	No known problems	EPA registered sanitizer, disinfectant and sterilant for many uses
Sodium hypochlorite	Dilute 5.25-6% solution to 5,250 to 6,000 ppm; adjust pH to 7.	Acutely toxic; skin and eye irritant.	Sporicidal on nonporous surfaces after 60 minutes contact time.	Corrosive to stainless steel and other metals	EPA registered sanitizer and disinfectant for many uses

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Table A 7-2. Gas and vapor antimicrobial pesticides used under FIFRA crisis exemptions to inactivate *Bacillus anthracis* spores. None of these antimicrobial pesticides is currently registered for use to inactivate *B. anthracis* spores.

Chemical	Generation method	Toxicity	Exposure limits	Materials compatibility	Penetration	Sporicidal uses
Formaldehyde gas	Onsite heating of paraformaldehyde prills (flakes)	Acutely toxic, animal carcinogen, genotoxin	0.75 ppm PEL 2.0 ppm STEL 20 ppm IDLH	Relatively unreactive	High	Biosafety cabinets, clean rooms, mail bags, mail equipment, buildings
Chlorine dioxide gas	Onsite reaction of precursor materials (sodium chlorite & others)	Acutely toxic, respiratory and eye irritant, no cancer data	0.1 ppm PEL 0.3 ppm STEL 5.0 ppm IDLH	May affect metals (Al, Cu, brass), computer parts, carpets and low grade paper at high CT values	High	Buildings
Hydrogen peroxide vapor	Onsite vaporization of liquid hydrogen peroxide	Acutely toxic, respiratory irritant, no cancer data	0.1 ppm PEL 0.2 No STEL 75 ppm IDLH	Relatively unreactive	Medium, does not penetrate paper	Medical equipment, buildings
Methyl bromide gas	Onsite heating & vaporization of liquid MB from cylinder	Acutely toxic, no cancer data	4.0 ppm TLV 20 ppm PEL 250 ppm IDLH	May affect animal fur, leather, natural latex, and sulfur-containing articles	Very high	Experimental (efficacy studies on *Bacillus anthracis* and spore strips)
Ethylene oxide gas	Onsite release of gas from cylinder	Acutely toxic, reproductive toxin, genotoxin, possible human carcinogen	1.0 ppm PEL 5 ppm STEL 800 ppm IDLH	Relatively unreactive	Extremely high	Medical equipment, critical items

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Appendix 8 OSHA Reoccupancy (Transitional) Plans

(See Section 4.20)

Hazard Awareness Training

Hazard awareness training is intended to communicate information concerning hazards of biological agents and appropriate protective measures to employees. The training may include, but is not limited to:

- Elements of the re-occupancy program.
- The health hazards of the biological agent, including routes of entry, signs and symptoms of exposure, synergistic effects, and any medical conditions that would place employees at increased risk.
- Operations in the work area where the biological agent has been identified.
- Dissemination of sampling results, including information on accessing results.
- Any applicable control measures, such as appropriate engineering controls, work practices, housekeeping, or PPE.
- Implementation of interim standard operating procedures to prevent potential exposure during operations, maintenance, cleaning, or the like.
- Frequent updates regarding any ongoing sampling, decontamination, control, medical surveillance, and related activities being performed at the facility, as applicable.

Medical Surveillance

A medical surveillance program may be implemented to ensure that employees receive appropriate preventive care. Medical surveillance includes, but is not limited to:

- Identification of employee populations at risk and establishment of controls for such employees (such as work reassignment, PPE, and prophylactic medication).
- Administrative follow-up on absentees (such as those on sick leave).
- Selection of prophylactic medication, as appropriate.
- Response to symptoms reported by employees.

Reoccupancy (Transitional) Sampling

Additional sampling may be conducted to confirm that occupied areas remain safe for occupancy. Sampling during this period is continued until repeatable results demonstrate that contamination remains insignificant. Elements of reoccupancy sampling include, but are not limited to:

- Determining appropriate sampling techniques. Recommended techniques may include nonaggressive, high-volume, air sampling, HEPA vacuum surface sampling, and if appropriate, bulk sampling (such as bulk samples from HEPA vacuums used to clean surfaces, or ventilation system filters).
- Use of high-volume air sampling as a tool to characterize levels of biological agent in the air and provide exposure information to employees.
- Identification of specific locations and frequency of sampling.

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Personal Protective Equipment

The workplace must be reassessed to select and use appropriate PPE to protect employees from potentially remaining biological agent hazards. The specific types of PPE used depend on the actual operation in question and results from the reassessment. Examples of work operations where modifications to PPE may be necessary are as follows:

- Operating equipment or working on surfaces where the biological agent was previously identified.
- Performing maintenance tasks, such as cleaning equipment or changing HEPA vacuum or ventilation system filters.

Personal Hygiene

A personal hygiene program may be implemented for certain facility areas and operations to reduce the risk of additional exposures and spreading contamination. Procedures that may be required include:

- Assuring that food or beverage is not present or consumed, tobacco products are not present or used, and cosmetics are not applied in specified areas.
- Regular washing of hands and/or face, and before eating, drinking, using tobacco, or applying cosmetics.
- Showering as necessary.

Interim Standard Operating Procedures

Interim standard operating procedures (SOPs) must be developed to address special work activities necessary under the reoccupancy (transitional) program. Affected employees should receive training on the interim SOPs. The SOPs include, but are not limited to, the following topics:

- Maintenance and housekeeping procedures developed or modified to prevent the spread of potential contamination and protect employees. Examples include:
  - Use of HEPA vacuum to clean surfaces instead of sweeping or other methods.
  - Cleaning, maintenance, and filter and bag removal for HEPA vacuums.
  - Maintenance and cleaning of facility equipment.
  - Cleaning floors and other surfaces.
  - Handling and disposal of wastes.
- Changes to regular work operations and equipment, as applicable.
- Modifications to facility-wide mechanical systems, particularly HVAC systems. Examples of HVAC modifications include:
  - Increase in ventilation rates (air changes per hour).
  - Increase in percentage of outside air.
  - Use of HEPA filters to collect dust in circulated air.
- Other applicable major elements implemented as part of the reoccupancy program, as described previously (training, medical surveillance, sampling, PPE, or hygiene).

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Appendix 9 Glossary

ANTIMICROBIAL AGENT

Any agent that kills or suppresses the growth of microorganisms (Block, 2001).

AREA COMMAND (UNIFIED AREA COMMAND)

An organization established (1) to oversee the management of multiple incidents that are each being handled by an ICS organization or (2) to oversee the management of large or multiple incidents to which several Incident Management Teams have been assigned. Area Command becomes Unified Area Command when incidents are multi-jurisdictional. Area Command may be established at an EOC facility or at some location other than an Incident Command Post (DHS, 2008).

ANTHRAX

A non-contagious, infectious, often fatal, naturally occurring disease caused by the bacterium *Bacillus anthracis* that may be contracted by humans or animals via exposure through inhalation, the skin, or the gastrointestinal tract.

BACILLUS ANTHRACIS

A spore-forming bacterium that causes anthrax. The spore form is about 1 by 2 microns in size and can easily be inhaled. In a warm, moist environment (such as the lungs), spores grow into vegetative, rod-shaped cells that multiply and cause hemorrhage, edema, and necrosis in humans and animals.

BIOSAFETY LEVEL (BSL)

Different biosafety levels developed for microbiological and biomedical laboratories provide increasing levels of personnel and environmental protection from pathogenic microorganisms and hazardous subcellular entities (e.g., prions). Accordingly, laboratories may be classified as BSL-1, BSL-2, BSL-3 or BSL-4, ranked from lowest to highest in degree of safety level.

BIOLOGICAL INCIDENT

A natural or human-caused incident involving microbiological organisms (bacteria, fungi, and viruses) or biologically derived toxins that pose a hazard to humans, animals, or plants.

BIOLOGICAL INDICATOR (BI)

A standardized preparation of bacterial spores on or in a carrier serving to demonstrate whether sterilizing conditions have been met. Spores of different organisms are used for different methods of sterilization (Block, 2001).

BIOLOGICAL WARFARE AGENT (BWA)

A microorganism (bacteria, fungi, and viruses) or biologically derived toxin that is intentionally introduced to cause disease or harm in humans, animals, or plants.

BIOTOXIN

A toxic substance that is either produced by, or extracted from, living or dead bacteria, fungi, plants, or animals.

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CERCLA

The Comprehensive Environmental Response, Compensation, and Liability Act (42 USC 9601 et seq.), as amended by the Superfund Amendments and Reauthorization Act of 1986. CERCLA authorizes the President and EPA (by delegation from the President) to respond to releases or substantial threats of releases of hazardous substances or of pollutants or contaminants that may present an imminent and substantial danger to the public health or welfare.

CHARACTERIZATION

The process of obtaining specific information about a biological agent, such as its identity, genetic composition, formulation, physical properties, toxicological properties, ability to aerosolize, and persistence, and about the nature and extent of contamination of the agent, such as locations or items contaminated and the amount of contamination. Characterization of the agent and of the contamination at an affected site generally occurs after First Response and before Decontamination.

CHARACTERIZATION ENVIRONMENTAL SAMPLING

Environmental sampling intended to assess the nature (identity and properties) and extent (location and quantity) of contamination of an area or items. Generally occurs after First Response and before Decontamination.

CHARACTERIZATION ZONE

A discrete section of a contaminated site that is examined for the purpose of determining the potential for exposure to the contaminant in that area.

CLEANUP

The process of characterizing, decontaminating, and clearing a contaminated site or items, including disposal of wastes. Cleanup is a synonym for Remediation. Generally occurs after Characterization and before Clearance.

CLEANUP GOAL

An amount of residual contamination for a specific contaminant in or on an area or item that, once achieved following decontamination, provides acceptable protection to human health and the environment. A cleanup goal specifies criteria for determining the success of decontamination that are measurable and for permitting unprotected reentry.

CLEARANCE

The process of determining that a cleanup goal has been met for a specific contaminant in or on a specific site or item. Generally occurs after Decontamination and before Reoccupancy.

CLEARANCE ENVIRONMENTAL SAMPLING

Environmental sampling that is conducted after the decontamination process is completed for a specific contaminant in an area or on items, and is intended to provide a basis for determining whether the cleanup goal has been met.

CLEARANCE ZONE

A section or sub-section of a contaminated site for which a clearance decision is made.

CONCEPT OF OPERATIONS (CONOPS)

A formal plan that describes the roles, responsibilities, and relationships of organizations involved in a response to a contaminated area or items. Typically, a CONOPS addresses Federal, State, local, and tribal agencies and how they should interact when responding to a potential or actual terrorist threat or incident.

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CONSEQUENCE MANAGEMENT

Predominantly an emergency management function that includes measures to protect public health and safety; restore essential government services; and provide emergency relief to governments, businesses, and individuals affected by the consequences of terrorism (DHS, December 2004). Includes Remediation/Cleanup (i.e., Characterization, Decontamination, and Clearance) and Restoration/Reoccupancy activities (see Figure 3, p. 42).

CONTAINMENT

In the context of this document, includes actions or measures taken to prevent the spread of a contaminant from a particular zone or to prevent the movement of a contaminant within a zone. Compare with Isolation. This term has been used differently by various agencies.

CONTAMINATION REDUCTION ZONE

The transition area between the Exclusion and Support Zones where responders enter and exit the Exclusion Zone and where decontamination activities take place. Also called the Warm Zone (EPA, 2004).

CRISIS EXEMPTION

Under the authority of Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Administrator of EPA may exempt any Federal or State agency from the pesticide registration requirements of FIFRA, if the Administrator determines that emergency conditions exist which require such exemption. As described in EPA's regulations (40 CFR 166.40 – 166.53), a crisis exemption may be issued, subject to specific conditions, when an unpredictable emergency situation exists—that is, an emergency condition exists and there is insufficient time to request and process other types of exemptions or registration. Other types of emergency exemptions require a State or Federal agency to submit an application to EPA for review and approval.

CRISIS MANAGEMENT

Predominantly a law-enforcement function that includes measures to identify, acquire, and plan the use of resources needed to anticipate, prevent, and/or resolve a threat or act of terrorism (DHS, December 2004). Includes Notification and First Response activities (see Figure 3, p. 42).

DECISION-MAKER

A person charged with determining and directing appropriate actions in response to a potential or actual biological incident at a particular site.

DECONTAMINATION

The process of inactivating or reducing a contaminant in or on humans, animals, plants, food, water, soil, air, areas, or items through physical, chemical, or other methods to meet a cleanup goal. Decontamination applies to both disinfection and sterilization processes. Generally occurs as part of Remediation. (Note: Decontamination has been defined in different ways by different Federal agencies and other entities.)

DECONTAMINATION AREA OR ZONE

A section of a contaminated site that can be isolated from other areas and is decontaminated as a unit.

DECONTAMINATION AGENT

A substance that is used to inactivate or reduce a contaminant on humans, animals, plants, or inanimate surfaces or in other media. If the contaminant is a microorganism, the chemical is an antimicrobial pesticide.

DISINFECTANT

A chemical or physical agent that destroys pathogenic or other harmful microorganisms, but not bacterial spores on inanimate surfaces.

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DISINFECTION

The destruction of pathogenic and other kinds of microorganisms by physical (e.g., heat, desiccation, freezing, radiation) or chemical means. Disinfection is a less-lethal process than sterilization because it destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores. Disinfection processes do not ensure the margin of safety associated with sterilization processes (AAMI, 1995).

EMERGENCY OPERATIONS CENTER (EOC)

The physical location at which the coordination of information and resources to support domestic incident management activities normally takes place. An EOC may be a temporary facility or located in a more central or permanently established facility, perhaps at a higher level of organization within a jurisdiction. EOCs may be organized by major functional disciplines (e.g., fire, law enforcement, environment, and medical services), by jurisdiction (e.g., Federal, State, regional, county, city, or tribal), or by some combination thereof (DHS, 2008).

ENVIRONMENTAL CLEARANCE COMMITTEE (ECC)

An independent group of scientific experts from a variety of local, State, and Federal agencies that provides advice, data, process analysis, and recommendations during and after decontamination of a facility. An ECC provides a final recommendation on whether the cleanup was adequate to justify reopening the facility for normal operations and use (Proceedings from the 2nd Civilian-Military Anthrax Response Technical Workshop, 2004).

ENVIRONMENTAL SAMPLING

Sampling conducted on inanimate surfaces or in air, water, or soil for the purpose of detecting the presence of a specific biological agent.

EXCLUSION ZONE

An area with actual or potential contamination and the highest potential for exposure to the contaminant. Entry to this area is permitted only for persons wearing appropriate personal protective equipment (PPE). Equivalent to Hot Zone, Red Zone, Isolation Zone, or Restricted Zone.

FIRST RESPONSE

Actions taken immediately following notification of a biological incident or release. In addition to search and rescue, scene control, and law enforcement activities, first response includes initial site containment, environmental sampling and analysis, and public health activities, such as treatment of potentially exposed persons.

FEDERAL ON-SCENE COORDINATOR (FOSC OR OSC)

The Federal official predesignated by the EPA or the USCG to coordinate responses under subpart D of the National Contingency Plan (NCP); or the government official designated to coordinate and direct removal actions under subpart E of the NCP (DHS, 2008).

FUMIGATION

Use of a chemical gas or vapor in a contained space to inactivate biological contaminants (primarily pathogenic bacteria, fungi, and viruses).

HEALTH AND SAFETY PLAN (HASP)

A written plan required under the Occupational Health and Safety Administration's (OSHA's) Hazardous Waste Operations and Emergency Response (HAZWOPER) standard (29 CFR 1910.120 and 29 CFR 1926.65). This standard requires a written HASP, which identifies site hazards and appropriate controls to protect employee health and safety (NRT, 2003).

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HOTLINE

The outer boundary of the Exclusion Zone (Hot Zone) that separates the area of contamination from the Contamination Reduction Zone (Warm Zone).

INACTIVATION

Removal of the activity of microorganisms by killing or inhibiting reproductive or enzyme activity. When referring to an antimicrobial agent, inactivation means neutralizing its activity by any means (Block, 2001).

INCIDENT

An occurrence or incident, natural or human-caused, that requires an emergency response to protect life or property. Incidents can, for example, include major disasters, emergencies, terrorist attacks, terrorist threats, wildland and urban fires, floods, hazardous materials spills, nuclear accidents, aircraft accidents, earthquakes, hurricanes, tornadoes, tropical storms, war-related disasters, public health and medical emergencies, and other occurrences requiring an emergency response (DHS, 2008).

INCIDENT COMMAND (IC)

The unit responsible for all incident activities, including the development of strategies and tactics and the ordering and release of resources. The IC has overall authority and responsibility for conducting incident operations and is responsible for managing all incident operations at the incident site (National Incident Management System, 2004; DHS, 2008).

INFECTIOUS DOSE (ID)

A dose at which an organism can reproduce in the host and produce a measurable effect (Johnson, 2003).

ISOLATION

For the purposes of this document, action taken to seal a site to permit fumigation and prevent release of fumigant. Compare with containment. This term has been used differently by various agencies.

ISOLATION ZONE

A contaminated area for which entry is permitted only for persons wearing appropriate personal protective equipment (PPE). Equivalent to Hot Zone, Red Zone, Exclusion Zone, and Restricted Zone.

LABORATORY RESPONSE NETWORK (LRN)

An organization of public health laboratories established by the Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) in accordance with Presidential Decision Directive 39, which outlines national anti-terrorism policies and assigns specific missions to Federal departments and agencies. The LRN and its partners maintain an integrated national and international network of laboratories that are fully equipped to respond quickly to acts of chemical or biological terrorism, emerging infectious diseases, and other public health threats and emergencies (CDC, 2005).

LIFE SAFETY ZONES

Zones established at a contaminated site that are intended to reduce the accidental spread of hazardous substances by workers or equipment from contaminated areas to clean areas. Safety zones specify the type of operations that occur in each zone, the degree of hazard at different locations within the release site, and the areas at the site that should be avoided by unauthorized or unprotected employees.

NATURAL ATTENUATION

The destruction or inactivation of a microorganism or products of a microorganism, such as a toxin, via natural, environmental mechanisms such as heat, light, biochemical, or chemical reactions.

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NEGATIVE AIR UNIT (NAU)

A system that subjects an area to a slightly negative pressure to ensure that the contaminant (and decontamination chemical) remains in the contamination zone. NAUs consist of a HEPA filter, chemical scrubber, demister, carbon bed, fan, and stack. Air within a building is exhausted through HEPA filters at a rate sufficient to pull a slightly negative pressure in the contaminated zone. (Carlsen et al., 2005)

NOTIFICATION

The process of communicating the occurrence or potential occurrence of a biological incident through and to designated authorities who initiate First Response actions. Generally occurs as the first step in a response to a suspected or actual biological incident.

OPTIMIZATION

A flexible decision process for biological incidents that addresses multiple aspects of the problem and seeks to analyze, consider, and balance these factors in decontamination and recovery activities .

PATHOGEN

Any disease-producing microorganism (Block, 2001).

PRINCIPAL FEDERAL OFFICIAL (PFO)

The Federal official designated by the Secretary of Homeland Security to act as his/her representative locally to oversee, coordinate, and execute the Secretary's incident management responsibilities under HSPD-5 for major incidents (DHS, 2008).

PROCESS MONITORING

Measuring and recording the key variables of a decontamination process as they occur. For example, during fumigation, the key variables are gas concentration, temperature, contact time, and relative humidity.

QUALITY ASSURANCE

An integrated system of activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence (EPA, 2002c).

RECOMMISSIONING

The process of testing and verifying that equipment is fully functional and may be returned to normal use.

RECOVERY

In the short term, recovery is an extension of the response phase in which basic services and functions are restored. In the long term, recovery is a restoration of both the personal lives of individuals and the livelihood of the community. Recovery can include the development, coordination, and execution of service- and site-restoration plans; the reconstitution of government operations and services; programs to provide housing and to promote restoration; long-term care and treatment of affected individuals; and additional measures for social, environmental, and economic restoration (DHS, 2008). Recovery generally includes actions taken after Notification and First Response activities have been initiated (see Figure 3, p. 42).

REMEDIATION ACTION PLAN (RAP)

A formal plan developed for the Incident Commander that describes actions to remove, reduce, or eliminate contaminants in or on a site and/or items. The RAP is developed during Remediation.

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REMEDIATION

The processes of characterizing, decontaminating, and clearing a contaminated site or items, including disposal of wastes. Generally occurs after the First-Response Phase and before the Restoration Phase (see Figure 3, p. 42). A synonym for cleanup. Remediation is not the same as "remedial action," which is defined below.

REMEDIAL ACTION

Long-term response actions that permanently and significantly reduce the dangers associated with releases or threats of releases of hazardous substances that are serious, but not immediately life threatening. If applicable and with available resources, remedial action may be performed in accordance with the National Oil and Hazardous Substances Pollution Contingency Plan and under the authority of CERCLA (See 40 CFR 300.430 and .435).

REMOVAL ACTION

Response actions taken to address releases or threatened releases of hazardous substances, pollutants, or contaminants that require a prompt response. If applicable and with available resources, removal action may be performed in accordance with the National Oil and Hazardous Substances Pollution Contingency Plan and under the authority of CERCLA (See 40 CFR 300.415).

RENOVATION

The process of reconstructing or refurbishing a facility subsequent to clearance but before allowing occupants to return (see Figure 3, p. 42).

REOCCUPANCY

The process of renovating a facility, monitoring the workers performing the renovation, and deciding when to permit reoccupation. Generally occurs after a facility has been cleared but before occupants are allowed to return (see Figure 3, p. 42).

RESIDUAL CONTAMINATION

The detectable amount of contaminant remaining, if any, after an area has been decontaminated.

RESPONSE

Includes immediate actions to save lives, protect property and the environment, and meet basic human needs. Response also includes the execution of emergency plans and actions to support short-term recovery (DHS, 2008).

RESTORATION

The process of renovating or refurbishing a facility; bringing it to an acceptable condition using the optimization process to determine the appropriate use and associated clearance level at which occupants may return. Generally occurs after the Clearance Phase but before occupants are allowed to return (see Figure 3, p. 42).

RISK

The probability that a substance or situation will produce harm under specified conditions. Risk is a combination of two factors: (1) the probability that an adverse event will occur (such as a specific disease or type of injury), and (2) the consequences of the adverse event (Presidential and Congressional Commission on Risk Assessment and Risk Management, 1997).

RISK ASSESSMENT

Gathering and analyzing information on what potential harm a situation poses and the likelihood that people or the environment will be harmed. (The Presidential and Congressional Commission on Risk Assessment and Risk Management, 1997). A methodological approach to estimate the potential human or environmental risk of a substance that uses hazard identification, dose-response, exposure assessment, and risk characterization.

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RISK MANAGEMENT

The process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems. The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risk while taking into account social, cultural, ethical, and legal considerations (Presidential and Congressional Commission on Risk Assessment and Risk Management, 1997).

SAMPLING AND ANALYSIS PLAN (SAP)

A plan that describes the methods, strategies, and analyses for characterization sampling, verification sampling (if applicable), and clearance sampling for a contaminated site.

SAMPLING UNIT

A sub-section of a sampling zone, such as walls, floors, and furniture surfaces, that can be sampled and evaluated collectively.

SAMPLING ZONE

A discrete section of a contaminated site in which environmental sampling is conducted.

SCREENING ENVIRONMENTAL SAMPLING

The initial collection of a limited number of environmental samples for the purpose of determining the identity, concentration, viability and approximate location of contamination by a purported biological agent, and for informing the IC/UC for decision-making and subsequent remediation actions.

SOURCE REDUCTION

The process of removing certain items and/or materials from a contaminated site for further treatment and reuse or disposal, and of cleaning the remaining site and item surfaces prior to the main decontamination activity. The goals of this process are to (1) reduce the number of items and/or materials present, (2) ensure that any matter that might inhibit decontamination is removed, and (3) generally reduce the levels of contaminant that may be present.

SPORES

The thick-walled resting cells produced by some bacteria and fungi that are capable of survival in unfavorable environments and are more resistant to antimicrobial agents than vegetative cells (Block, 2001).

STAGING AREA

A safety zone established at a hazardous-substance release site that is designated as the Support Zone (or Cold Zone). It is the area of the site that is free from contamination and that may be safely used as a planning and staging area (EPA, 2004).

STERILANT

A substance that destroys all microorganisms on inanimate surfaces, including vegetative and spore forms of bacteria and fungi, as well as viruses. Sterilants registered by the USEPA must be effective on both porous and nonporous surfaces.

STERILIZATION

A process intended to remove or destroy all viable forms of microbial life, including bacterial spores, to achieve an acceptable sterility assurance level (AAMI, 1995).

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SUPPORT ZONE

Area of a site that is free from contamination and that may be safely used as a planning and staging area. Also called the Cold Zone.

SWAB SAMPLING

Collecting environmental samples from nonporous surfaces by rubbing a small area with a wet, absorptive material attached to the end of a wood or plastic stick.

TECHNICAL WORKING GROUP (TWG)

A group of technical experts assembled by the Unified Command to provide guidance during the planning and implementation of remediation operations (Carlsen et al., 2005).

UNIFIED COMMAND

An application of the Incident Command System used when there is more than one agency with incident jurisdiction or when incidents cross jurisdictions. Agencies work together through the designated members of the Unified Command to establish their designated Incident Commander at a single Incident Command Post and to establish a common set of objectives and strategies and a single Incident Action Plan (DHS, 2008).

VACUUM SAMPLING

Collecting environmental samples by suctioning porous or nonporous surfaces with a vacuum cleaner that contains a high-efficiency particulate air (HEPA) filter.

VEGETATIVE CELLS

Microbial cells that are in the growth and reproductive phase of the growth cycle (Block, 2001).

VERIFICATION SAMPLING

Use of chemical and/or biological indicators to document that fumigation has been successful.

WARM ZONE

The transition area between the Exclusion and Support Zones. This area is where responders enter and exit the Exclusion Zone and where decontamination activities take place (EPA, 2004).

WEAPON OF MASS DESTRUCTION (WMD)

Any nuclear, radiological, chemical, or biological substance that is intentionally introduced to cause disease or harm in humans, animal, or plants, or damage to property. (Note: The *National Response Framework* has a longer, legal definition).

WIPE SAMPLING

Collecting environmental surface samples by rubbing a thin, flat piece of wet, absorptive material on a small area of a non-porous surface.

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About this Report

This guidance describes a general risk management framework for decision-makers in planning and executing activities required for response and recovery from a biological incident in a domestic, civilian setting. This report was developed by the Subcommittee on Decontamination Standards and Technology (SDST), and reviewed and approved by the Office of Science and Technology Policy (OSTP) and the National Science and Technology Council (NSTC).

About the National Science and Technology Council

The NSTC, http://www.ostp.gov/cs/nstc, **is the principal** body within **the** executive branch to coordinate **science and technology** policy **across the diverse** entities that make up **the Federal research and development** (R&D) **enterprise.**

About the Office of Science and Technology Policy

The Office of Science and Technology Policy (OSTP) was established by the National Science and Technology Policy, Organization, and Priorities Act of 1976. OSTP's responsibilities include advising the President in policy formulation and budget development on questions in which science and technology are important elements; articulating the President's science and technology policy and programs; and fostering strong partnerships among Federal, State, and local governments, and the scientific communities in industry and academia. The Director of OSTP also manages the NSTC.

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Reference Guide for Developing and Executing *Bacillus anthracis* Sampling Plans in Indoor Settings

Version 4

May 2014

Disclaimer

This document was developed to serve as a reference document for local, state, and federal partners and contractors working within Incident Command who are tasked with sampling and analysis of *Bacillus anthracis* that has been released in or entered an indoor environment. This document serves as a means of standardizing incident response procedures by compiling, in a single volume, common accepted procedures recognized by Federal government agencies as best practices. The document is intended to be a "living" document that will be periodically revised as new methods and processes are developed and validated for use. Wherever possible, citations to locations on the web for the most current recommended methods and procedures are provided and should be referenced in the event of an actual response requirement. This document does not confer legal rights or impose legally binding requirements on any party, nor does it supersede existing practices, guidelines, or authorities of federal, state and local agencies responding to a *Bacillus anthracis* release into the environment. The use of non-mandatory language such as "may" or "should" in this document does not connote a requirement but rather indicates a preferred approach. Mention of commercial products does not constitute endorsement or recommendation of use.

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Acronyms and Abbreviations

AAS	Aggressive Air Sampling
ACIP	Advisory Committee on Immunization Practices
AHJ	Authority Having Jurisdiction
ASTM	American Society for Testing and Materials
BAR	BioWatch Actionable Result
BI	Biological Indicator
BiSKit	Biological Sampling Kit
CBRN	Chemical, Biological, Radiological, and Nuclear
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CITAC	Cooperation on International Traceability in Analytical Chemistry
CJR	Combined Judgmental and Random
ClO2	Chlorine dioxide
COC	Chain of Custody
Ct	Cycle-threshold
DHS	Department of Homeland Security
DMP	Data Management Plan
DoD	Department of Defense
DOE	Department of Energy
DQO	Data Quality Objective
ECC	Environmental Clearance Committee
EPA	U.S. Environmental Protection Agency
ERLN	Environmental Response Laboratory Network
ESF	Emergency Support Function
EURACHEM	A Focus for Analytical Chemistry in Europe
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
GAO	Government Accountability Office
GIS	Geographic Information System
HASP	Health and Safety Plan
HAZMAT	Hazardous Material
HEPA	High Efficiency Particulate Air
HHA	Hand-Held Assay (Based Immunoassay)
HHS	Health and Human Services
HSPD	Homeland Security Presidential Directive
HVAC	Heating, ventilation and air conditioning
IAP	Incident Action Plan
IC	Incident Commander

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ICS/UC	Incident Command System/Unified Command
ICLN	Integrated Consortium of Laboratory Networks
ICS	Incident Command System
IND	Improvised Nuclear Device
ISO	International Organization for Standardization
JLC	Joint Leadership Council
JTTF	Joint Terrorism Task Force
LPM	Liter per minute
LOD	Limit of Detection
LRN	Laboratory Response Network
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
MCE	Mixed cellulose esterase
mL	Milliliter
mm	Millimeter
MOA	Memorandum of Agreement
MPN	Most Probable Number
NCG	Network Coordinating Group
NFPA	National Fire Protection Agency
NIMS	National Incident Management System
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute for Standards and Technology
NMAM	NIOSH Manual of Analytical Methods
NRC	National Research Council
NRF	National Response Framework
NRP	National Response Plan
NRT	National Response Team
NSPD	National Security Presidential Directive
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy
PCR	Polymerase Chain Reaction
PDA	Personal Data Assistant
PEP	Performance Evaluation Procedure
PNNL	Pacific Northwest National Laboratory
PPE	Personal Protective Equipment
QA	Quality Assurance
QC	Quality Control
QUAM	Quantifying Uncertainty in Analytical Measurement
RAP	Remedial Action Plan
RDD	Radiological Dispersal Device
RE	Recovery Efficiency
RV-PCR	Rapid-Viability PCR

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SADA	Spatial Analysis and Decision Assistance
SD	Standard deviation
SMART	Sensitive Membrane Antigen Rapid Test
SNL	Sandia National Laboratories
T_0	Time Zero
TWG	Technical Working Group
UC	Unified Command
VSP	Visual Sample Plan
VSPWG	Validated Sampling Plan Working Group
WMD	Weapons of Mass Destruction

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Section I: Introduction

1.1 Purpose

The purpose of this document is to present a reference document for environmental sampling of *Bacillus anthracis* (spores and vegetative cells), the causative agent of anthrax, during first response and remediation phases following the confirmation of contamination in a facility including large, complex buildings as well as single dwelling buildings. While this document does not address a wide area outdoor release scenario, some of the information provided in this document may be useful in developing an outdoor sampling strategy.

The document presents the tools (including approaches and methodologies) currently available that can be considered by sample planners and technical support staff operating within an Incident Command System/Unified Command (ICS/UC) when developing sampling plans. Most importantly, this document will help sample planners develop a sampling plan specific to each unique *Bacillus anthracis* (*B. anthracis*) contamination site as part of the incident and advise IC/UC decision makers (i.e., stakeholders, federal, state, local, and tribal leaders). A well-executed, site-specific sampling plan will assist decision makers to:

- Determine who may have been potentially exposed during the initial release
- Assess potential risk of exposure to responders entering the site
- Characterize the extent of the contamination
- Remediate/Decontaminate indoor sites of contamination
- Clear the facility for reoccupation or use

1.2 Background

Environmental sampling to determine the presence or absence of *B. anthracis* in indoor environments is an important tool for assessing potential risk of exposure to building occupants at the time of release and responders to the incident. Environmental sampling results can be used to confirm the presence of contamination; determine the extent of contamination; support informed decisions regarding the need for medical interventions and decontamination options; and determine the effectiveness of decontamination and when cleanup is adequate to permit re-entry into an area (OSHA 2002). However, sampling and analysis is just one of many components contributing to a hazard determination. The infectious dose of *B. anthracis* in humans by any route is not well-established, making it difficult to develop risk-based exposure limits. Therefore, sampling results, along with other data inputs (including epidemiological data, intelligence data, and modeling data), and operating parameters are used to make informed decisions regarding public health actions and environmental cleanup. As an outcome of

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meetings among subject matter experts during 2011, EPA and CDC recommended that "no detection of viable spores" be considered the most appropriate clearance goal.

To ensure consistent communication among various agencies during a response to a *B. anthracis* incident, this document uses the Validated Sampling Plan Working Group (VSPWG) definitions of *sampling strategy* and *sampling plan*. The *sampling strategy, sampling approach,* and *sampling plan* definitions were reached by consensus of the VSPWG in 2007.

> **Sampling strategy:** "A set of operating precepts and diagnostic tools (including sample collection methods; packaging and shipping protocols; sample recovery, extraction, and analytical methods; and statistical analysis packages, as appropriate) that are combined to answer specific hypotheses." A sampling strategy includes the approach or combination of approaches to be used to select locations at which to collect samples and provides guidance that is informed by a decision support process. It also includes a compendium of information on relevant methods and the plan for action prescribing their use across multiple potential scenarios. (Using this definition of a *sampling strategy,* this Sampling Reference Guide document is a sampling strategy.)
>
> **Sampling approach**: "A methodology for selecting representative locations and surfaces for collecting samples." A sampling approach provides the structure, when implemented in a sampling plan, for planners to draw conclusions from the sampling results. There are three kinds of sampling approaches discussed in this document: judgmental sampling, hotspot sampling, and combined judgmental and random (CJR) sampling.
>
> **Sampling plan**: "A documented approach for field execution that captures the specific combination of operating precepts and diagnostic tools used for a given scenario to answer a specific hypothesis." A sampling plan is an executable plan of action addressing the sampling and analytical requirements of a specific situation and is formulated in accordance with the guidance of the sampling strategy. The sampling plan must specify the sampling approaches, methods, and analyses, as well as the number, types, and locations of samples to be collected in a given physical space (DHS 2007b).

The VSPWG intends that this reference document align with broader national response guidance, including the National Incident Management System (NIMS) and National Response Framework (NRF), which provides principles of a unified national approach for responding to a *B. anthracis* incident indoors. It is intended to be coupled with the understanding of the authority-having jurisdiction (AHJ) regarding local vulnerabilities and capabilities when developing its plans and guidance documents for response to incidents involving *B. anthracis* contamination. This guidance recognizes NIMS and ICS as an essential part of emergency response planning and response.

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Specific conditions, such as the variation of *B. anthracis* characteristics (e.g., virulence, environmental persistence, and transmissibility), the uniqueness of a given scenario (e.g., mechanism of agent dispersal, exposed population characteristics, micro and macro environmental conditions), and the variety of available response resources make it infeasible to develop a template sampling plan in advance to address all *B. anthracis* incidents. However, this document describes key phases, decision points, and tools to consider when developing a site-specific sampling plan.

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Section II: Response Phases, Coordination, and Roles and Responsibilities

2.1 Basics of a Response

The NRF presents the principles to provide a unified national approach for responding to an incident and provides guidance to all partners in preparing for national emergencies. The NRF is intended to strengthen, organize, and coordinate response actions across all levels. The doctrine of *tiered response* emphasizes response to an incident should be handled at the lowest jurisdictional level capable of handling the work. The NRF addresses incidents of all types, including acts of terrorism, major disasters, and other emergencies (DHS 2008). The NRF uses the same guiding NIMS and ICS principles. These principles are used by first responders through senior decision-makers, and constitute an all-hazard, scalable, flexible, and adaptable approach to response. The NRF provides the structure to align key roles and responsibilities across the nation, linking all levels of government, non-governmental organizations, and the private sector. The framework provides an overarching coordinating mechanism for accessing federal support for response activities and for specific federal departments and agencies to carry out their responsibilities. Currently, fifteen (15) Emergency Support Functions (ESF) and five (5) Incident Annexes address functional capabilities and resources provided by federal departments and agencies. The NRF is always in effect and elements can be implemented as needed.

While an incident is occurring and after, the priorities are to employ resources to save lives; to protect property and the environment; and to preserve the social, economic, and political structure of the jurisdiction. Depending on the size, scope, and magnitude of an incident, communities, states, and the federal government will be called to action (DHS 2008).

Initial information about an incident will depend on whether the release was overt or covert. An overt release is the intentional release of an agent reported by terrorists, observed by witnesses at the scene of the release, or made known at the time of release by other means. A covert release is the intentional release of an agent not observed at the time the release occurs (DHS 2007a). A biological-related incident may be discovered in one of three ways: 1) discovery of either physical or intelligence evidence (law enforcement actions or suspicious package), 2) detection of an agent through environmental surveillance systems (e.g., DHS BioWatch, US Postal Service Biohazard Detection System), or 3) reports of medical symptoms or disease (Emanuel et al. 2008).

2.2 Phases of an Incident

Effective and timely decision-making in responding to a biological agent incident first requires a broad understanding of all the phases and activities involved. As depicted in Table 1, effective response to a biological release incident comprises numerous elements, grouped into two overarching phases: *Crisis management* and *consequence management*. This mapping is

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common in response to all chemical, biological, radiological, and nuclear (CBRN) incidents (NSPD 17/HSPD 4, 2002; and DHS 2004). *It is important to note the activities described below do not necessarily occur in sequential order, but may run concurrently, or occur outside the phase in which they are described. Additionally, this document emphasizes the specific activities for the response and recovery to a B. anthracis incident.*

Table 2-1: Phases of an Effective Response

Response and Recovery*					
Crisis Management		Consequence Management			
Notification	First Response	Remediation/Cleanup			Restoration/ Reoccupancy
		Characterization	Decontamination	Clearance	
Receive information on biological incident Identification of suspect release sites Notification of appropriate agencies	Initial threat assessment HAZMAT and emergency actions Forensic investigation Public health actions Screening sampling Determination of agent type, concentration, and viability Risk communication	Characterization of biological agent Characterization of affected site Site containment Continue risk communication Characterization environmental sampling and analysis Initial risk assessment Clearance goals	Decontamination strategy Remediation Action Plan Worker health and safety Site preparation Source reduction Waste disposal Decontamination of sites or items Decontamination verification	Clearance environmental sampling and analysis Clearance decision	Renovation Reoccupation decision Long-term environmental and public health monitoring
* The optimization decision process is applicable to any phase					

Source: Adapted from NSTC (2009)

2.2.1 Crisis Management

The first phase of response and recovery, the *crisis management* phase, involves law enforcement (local, state and federal), first responders (police, fire, and hazardous materials teams), and public health agencies (local, county, state, and federal health) (DHS 2004). The crisis management phase includes measures to identify and characterize the event, as well as to identify, acquire and plan the use of resources needed to respond to the incident. The crisis management phase of the response consists of the initial response activities, which can be further broken down into the *notification* phase and the *first response* phase (DHS 2004).

Depending on the origin of the event, criminal versus naturally-occurring, different agencies will manage the event and different response actions will take place. Law enforcement manages first responses for criminal responses and may designate the incident location as a crime scene while public health manages responses to naturally-occurring events.

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At the beginning of the response, the data available depends on whether the release was overt or covert. An observed, overt release is likely to prompt an immediate response including site containment. However, even in those circumstances, the causative agent may not be known. The forensic investigation along with epidemiologic and intelligence data will contribute to the identification of the biological agent. The greatest difference between overt and covert scenarios is an overt scenario more quickly yields greater information about the release (e.g., time, location of the release, dispersion methods) and it leads to a response prior to evidence of exposure or infection in the population. An overt scenario also allows the opportunity to implement public safety measures that may mitigate consequences during the first response phase.

2.2.1.1 Notification Phase

During the *notification* phase, tasks include law enforcement and public health receiving and assessing information, identifying suspected release locations, and communicating key information to the appropriate authorities that, in turn, initiate first response actions (DHS 2006b).

2.2.1.2 First Response Phase

This *first response* phase may involve, particularly in an overt release incident, hazardous material (HAZMAT) and emergency actions, public health response, scene control, law enforcement activities, initial site containment, sampling and analysis, personnel decontamination, and risk communication. HAZMAT and emergency actions are conducted to address any immediate threats to life or valuable property necessary for public welfare (e.g., critical infrastructure), and to establish control of the situation (OSTP 2009). A command post is established, and communication and data exchange between law enforcement and other personnel is performed as needed.

During this phase, data regarding the incident most likely have been generated by numerous responding agencies and organizations, such as HAZMAT teams, law enforcement, including the Federal Bureau of Investigation (FBI) Hazardous Materials Response Team, and public health organizations (state/county/local health departments and CDC). Data from these responding agencies involved in the initial response and investigation will be available to members of the IC/UC and may consist of law enforcement, forensic, and incident reports; preliminary environmental laboratory results; and public health case investigation data.

If results from preliminary samples indicate the likely presence of *B. anthracis* or if law enforcement or public health investigations identify a potential contamination location, the FBI will likely commence a criminal investigation. This criminal investigation may include activities

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to determine the agent's specific genetic, physical, and chemical properties; search for other types of evidence; establish a possible source of the contamination; and identify the responsible party. If a crime scene is established, the FBI must approve all environmental sampling within the crime scene through the ICS/UC with the ultimate decision for entry into the crime scene made by the Incident Commander (IC). Initial samples are sent to a Laboratory Response Network (LRN) laboratory for confirmatory testing (OSTP 2009). Additional information about LRN laboratories can be found in Section 2.4.5.1.

The DHS National Bioforensics Analysis Center (NBFAC) may also analyze forensic samples (DHS 2006b). Results from the forensic investigation may not be releasable to all federal entities and may not meet the needs of the public health investigation; therefore additional sampling may be necessary during the *first response* phase to obtain information on the presence of an agent and to determine the agent type, concentration, and viability as well as to determine exposure pathways in the building. These activities may continue in more depth during the first phase of *consequence management, which is characterization*.

2.2.2 Consequence Management

The second phase of response and recovery, the *consequence management* phase, is predominantly an emergency management function and includes measures to protect public health and safety, restore essential government services, and provide emergency relief to governments, businesses, and individuals affected (DHS 2004). As the *crisis management* phase transitions into the *consequence management* phase, in which the U.S. Environmental Protection Agency (EPA) plays a critical role and may step in as a lead federal agency, as directed or requested. The main focuses will be on characterization of the contaminated environment, decontamination, and clearance.

The local or state agencies with authority for protecting public health and/or the environment would also likely exert their regulatory authority to assure consequence management efforts are acceptable. *Consequence management* can be further subdivided into *remediation/cleanup*, which includes *characterization, decontamination*, *clearance,* and *restoration/reoccupancy*. The response and recovery process ends with *restoration/re-occupancy* during which a facility may be renovated, and decisions to allow reoccupation are made by the IC/UC. *However, this phase is not discussed further in this document as environmental sampling does not play a critical role in the restoration process because the building will already have been cleared of contamination.*

2.2.2.1 Characterization

Characterization is the process of obtaining information about a biological agent incident, which is used to determine further action. A sampling plan is developed to characterize the spread of contamination within an area and to obtain semi-quantitative estimates of the biological agent's concentration at specific locations (OSTP 2009). Characterization of an affected site includes

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describing site-specific characteristics such as, size, construction, heating, ventilation and air conditioning (HVAC) systems, ambient environmental conditions (e.g., temperature and relative humidity), structural materials, stored materials, and contents. If decontamination is warranted, the decontamination strategy decision may be affected by characteristics and materials composition of the specific site as well as the efficacy of decontamination approaches (OSTP 2009).

The information generated from the characterization sampling is used to help modify and refine public health actions developed based on the initial assessment. Uses include estimating the potential exposure to the agent, and deciding where, what, and how to decontaminate (DHS 2006b).

A risk assessment is conducted to determine potential risks posed by the threat agent at a specific site. Risks need to be assessed in order to assist decision-makers in setting clearance goals, planning a decontamination strategy, and developing a sampling plan (OSTP 2009).

Clearance goals will need to be established. Setting clearance goals for a biological agent is not an easy process due to the fact that there are no established reference values (unlike some radiological or chemical agents) or exposure guidelines (OSTP 2009). The IC/UC may choose to assemble a Technical Working Group (TWG), to assist in setting clearance goals appropriate to the site-specific circumstances. The TWG is an advisory group of multi-disciplinary technical experts and scientists that provides input on planning and implementing remediation, including setting clearance goals. The TWG may include representatives from federal, state, local, and tribal agencies, and experts from the private sector or universities. The TWG is an advisory group to the IC/UC, and is not a decision-making body. The TWG provides advice and guidance on such issues as interpretation of analytical results; sampling and analysis plans; selection of the appropriate remediation process and conditions for its implementation; development of procedures for a variety of issues that may arise to address releases and other emergencies during the remediation process; and waste management activities.

2.2.2.2 Remediation

During *remediation*, a decontamination strategy is developed and implemented, taking into account specific information about the agent, incident, and materials to be decontaminated. Ambient conditions (temperature and relative humidity) affect decontamination and must also be considered. After the decontamination approach is selected, a Remediation Action Plan (RAP) is prepared for the site specifying the overall strategy for decontaminating impacted areas and their contents. The decontamination strategy will be a guide for the remediation activities.

Site preparation is necessary before decontamination is carried out. Source reduction can be performed to remove certain items and/or materials from a contaminated site for further

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treatment and reuse or disposal. Additionally, items and site surfaces may need to be cleaned prior to the main decontamination activity.

After the RAP is complete and approved by IC/UC, the site is prepared and the specific decontamination methods selected for affected site(s) and/or item(s) can be employed. Decontamination is monitored as it is carried out and evaluated as to whether or not the specific parameters were met, goals were achieved, and the operations were conducted successfully.

2.2.2.3 Clearance

The *clearance* phase includes determining whether the agent has or has not been inactivated to the clearance criteria levels. The IC/UC may establish an Environmental Clearance Committee (ECC), which is a group of experts that functions as an independent peer review group. Members of the ECC may be representatives from the local, county and/or state public health agencies, the facility or property owner, local government, and subject matter experts from the EPA, FBI, OSHA, Food and Drug Administration (FDA) and CDC. The ECC conducts a comprehensive review to make recommendations to the IC/UC on whether the clearance goals have been met.

It is important that the ECC be formed as early as possible in the incident so that committee members can become familiar with the situation, review necessary data which may include agent characteristics, extent of contamination, sampling results, decontamination process, and clearance sampling results. The ECC is an independent body that is not part of the decision-making process on decontamination. Clearance sampling and analysis is the ultimate measure of whether decontamination met the criteria outlined in the RAP. If the clearance criteria are met, then decisions will be made on whether to allow unprotected re-entry to a facility and unrestricted use of items in the facility. The IC/UC makes the ultimate clearance recommendation to the lead local public health agency or private facility owner based on judgment as to whether the criteria for decontamination verification and clearance criteria have been met. Ultimately, the facility is returned to the owner/operator.

2.3 Agency Coordination

All levels of government, the private sector, and non-governmental agencies must be prepared to prevent, protect against, respond to, and recover from a wide spectrum of major incidents that exceed the capabilities of any single entity. These hazards require a unified and coordinated national common approach to planning and responding to an incident management. To address this need, Homeland Security Presidential Directive (HSPD) 5: *Management of Domestic Incidents* required the establishment of the NIMS. In addition, Presidential Policy Directive (PPD) 8: *National Preparedness* provides a comprehensive approach to assess national preparedness that uses consistent methodology to measure the operational readiness of national

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capabilities at the time of assessment, with clear, objective and quantifiable performance measures, against the target capability levels identified in the national preparedness goal.

The NRF specifies what needs to be done to prevent, protect against, respond to, and recover from a major incident. It also specifies how and how well it needs to be done. Together, these related efforts align federal, state, local, tribal, private sector, and non-governmental preparedness, incident management and emergency response plans into an effective and efficient national structure.

2.4 Roles and Responsibilities of Key Agencies, Advisory Groups, and Laboratories

The roles and responsibilities of key agencies, advisory groups, and laboratories are discussed in the following subsections.

2.4.1 Federal Bureau of Investigation

According to the NRF (DHS 2008), the FBI is the lead federal agency for criminal investigation of a terrorism incident. Local law enforcement usually notifies the FBI of a potential Chemical, Biological, Radiological, and Nuclear (CBRN) incident. Other methods of notification can be through local or state public health departments, fire department hazardous material responders, local search warrants where "questionable items" are observed by local law enforcement officers, and the FBI Joint Terrorism Task Force (JTTF) officers.

If initial laboratory results indicate a presumptive positive of *B. anthracis* and/or the circumstances of the incident suggest a credible threat exists, the FBI will commence an investigation including evidence collection. The main objectives for evidence collection are to 1) obtain biological material for further microbiological, chemical, physical and forensic analysis for attribution purposes and 2) locate a dissemination device or other traditional forensic evidence.

If it is a known or suspected biothreat agent incident, the FBI will coordinate with the IC and other entities having jurisdiction (fire department and/or public health department) but will be the lead agency for the criminal investigative response. As part of their investigation, FBI may work with response partners to collect information on the biological agent, including specific genetic, physical, and chemical properties; search for additional items of evidence; establish a possible source of the contamination; and determine the perpetrator(s). For all potential or actual biothreat agent incidents, a Threat Credibility Evaluation teleconference will take place between the local FBI Weapons of Mass Destruction (WMD) Coordinator, the appropriate FBI Headquarters elements (e.g., FBI WMD Directorate, FBI Laboratory, and FBI Critical Incident

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Response Group), and other required elements as necessary such as state, locals or other federal agencies.

The determination of whether or not a credible threat exists may not be made until after the initial detection of *B. anthracis*, therefore law enforcement will coordinate sampling efforts with public safety, public health and environmental agencies to preserve the integrity of the material in case it becomes evidence in a criminal investigation (ASTM 2010b). If a crime scene is established, the FBI may form joint task force sampling teams consisting of FBI and non-law enforcement and will approve all sampling plans until the crime scene is released for environmental remediation. This close working relationship is necessary to ensure both the proper collection of evidentiary samples as well as to protect the public health.

2.4.2 State and Local Public Health

State public health programs have primary responsibility for protecting the health and welfare of the public under their jurisdiction. States vary considerably in the nature and scope of the public health services they provide. State governments are responsible for responding to a public health emergency and play certain key roles in preparedness and response. With exception of the largest metropolitan local public health departments, local public health officials will tend to rely on state personnel and capacity for a number of key functions, including providing advanced laboratory capabilities and capacity, and epidemiological expertise, and serving as a conduit for federal assistance. When resources of state and local authorities are overwhelmed, federal assistance can be requested by the affected state.

2.4.3 Department of Health and Human Services (DHHS)/Centers for Disease Control and Prevention (CDC)

Under the NRF (DHS 2008), the Department of Health and Human Services (DHHS), including the CDC and other HHS agencies, has responsibility for public health and medical services. This responsibility provides the mechanism for coordinated federal assistance to supplement state, tribal, and local resources in response to a public health and medical emergency. The CDC engages in all phases of a biological incident. The CDC's involvement may include:

- Conducting epidemiologic and surveillance activities to identify cases and the populations at risk, and to determine the source of exposure;
- Providing laboratory support for the identification, confirmation, characterization, and drug susceptibility of the biological agent;
- Conducting environmental evaluations to support the epidemiological and surveillance activities and estimate extent of contamination;
- Providing guidance on the identification, diagnosis, and clinical management of human cases;

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- Providing guidance on the use of medical countermeasures (e.g., antimicrobials, vaccines, and immunotherapeutics) that may be utilized in response to an event or incident;
- Developing effective infection control practices for communities and healthcare settings;
- Providing guidance on non-pharmaceutical mitigation strategies to assist with the containment and control of infectious agents;
- Providing technical assistance to SLTT, federal and international partners to support public health activities;
- Disseminating key public health and safety messages to the public to provide timely, accurate, clear, consistent, credible, and easily accessible information relevant to the information needs of all stakeholders.

2.4.4 Environmental Protection Agency (EPA)

Under the NRF (DHS 2008), the EPA's actions can include efforts to detect and assess the extent of contamination (including sampling and analysis and environmental monitoring); actions to stabilize the incident and prevent the spread of contamination; analysis of options for the environmental cleanup and waste disposition; implementation of the environmental cleanup; storage, treatment, and disposal of the hazardous materials; implementation of clearance sampling.

As the *crisis management* phase transitions into the *consequence management* phase, EPA may step in as a lead federal agency. The lead agency during *crisis management* may begin to shift the response to EPA, state environmental agencies, cleanup contractors, and consultants working for the facility owners. The main focus will be on characterization and cleanup work.

2.4.5 Integrated Consortium of Laboratory Networks (ICLN)

The Integrated Consortium of Laboratory Networks (ICLN) was established by a Memorandum of Agreement (MOA) signed in 2012 (ICLN 2012). The ICLN is made up of six established laboratory response networks, including the CDC's LRN and EPA's Environmental Response Laboratory Network (ERLN). The purpose of the ICLN is to enable integrated and coordinated response to, and consequence management of, acts of terrorism and other major incidents requiring laboratory response capabilities. A major outcome of the ICLN is the creation of an Integrated Response Architecture that provides, among other things, a framework for incident notifications and updates, preparedness alerts, and situational reports among networks through a secure web portal. Among the roles of the ICLN are to establish methods for risk-based prioritization and to identify and address key gaps in laboratory capabilities. The ICLN also aims to improve capacity for "surge" requirements and efficiencies in laboratory method development and validation.

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2.4.5.1 Laboratory Response Network (LRN)

Per the NRF's Biological Incident Annex, biological samples for public health and environmental considerations are analyzed by an LRN laboratory. The CDC LRN comprises approximately 140 labs across the U.S. and several foreign countries. LRN member laboratories and their contact information can be obtained from the LRN program Office, accessible through the CDC Emergency Operations Center.

LRN laboratories are designated as either national, reference, or sentinel. The designation depends on the types of tests a laboratory can perform and how it handles infectious agents to protect workers and the public. The *national laboratories* have unique resources to handle highly infectious agents and the ability to identify specific agent strains. The *reference laboratories* can perform tests to detect and confirm the presence of a threat agent. This allows local authorities to respond quickly to emergencies. The *sentinel laboratories* provide routine diagnostic services and have publicly available microbiology procedures that can be used to rule out suspicion of a biological threat agent in clinical specimens. If unable to rule out the presence of a biological threat agent, sentinel labs are able to safely package and refer specimens to an LRN reference laboratory, thus playing a key role in early suspicion of a covert event. They are not equipped to perform the same tests as reference laboratories.

2.4.5.2 Environmental Response Laboratory Network (ERLN)

EPA's ERLN network (part of the ICLN), consists of federal government, state government, water utilities, and commercial laboratories capable of performing environmental sample analyses for chemical, biological, and radiochemical contaminants to support the EPA's homeland security responsibilities. The ERLN's mission is to provide reliable analytical data for environmental samples of known and documented quality to federal, state, and local decision makers. Such data can then be used to mitigate and recover from releases of toxic industrial chemicals, chemical warfare agents, biological agents, and radiochemical contaminants in environmental matrices collected in support of homeland security incidents. In addition to its own resources, the ERLN leverages other networks' capabilities to support responses related to a biological threat release.

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Section III: Sampling Phases during Crisis and Consequence Management

There are four distinct environmental sampling phases during a *B. anthracis* incident: initial response sampling during first response, characterization sampling, verification sampling, and clearance sampling. The purpose and description of each sampling phase are described in this chapter. Sample collection methods used in these sampling phases are described in Section 6 and appendices referenced therein.

3.1 Initial Response Sampling

In situations where release of biothreat agents are suspected, initial response sampling may be conducted by any of a number of entities, such as local HAZMAT or other first response teams, FBI, or public health authorities. The roles these groups may play in initial sampling depend on how the event is uncovered and which group has jurisdictional authority. Most often local HAZMAT or other first response teams are the first on scene. The decision by first responders to collect and submit a sample to the LRN reference laboratory for testing is made at the local level through communication among on-scene responders, the FBI, and the receiving LRN reference laboratory (ASTM 2010b). Their testing typically includes field screening which incorporates field measurements taken early in the site assessment process to identify and delineate the contaminants present (e.g., explosives and radiation), support tactical decision making, and address operational safety measures. Field screening does not include measurements of biological properties. On-site biological assessments to measure properties inherent to biological materials may also be performed in the field using rapid, field-based procedures and assays when a visible powder is present (ASTM 2010b). As a result of the initial risk assessment or first responder testing results, the FBI may determine that there is sufficient indication of a credible threat to assume jurisdiction. The FBI may take immediate tactical actions to contain the threat and mitigate the potential effects until the LRN reference laboratory has received samples and has performed appropriate confirmatory analysis (ASTM 2010b).

The FBI may choose to collect additional samples for forensic purposes; these samples are sent to LRN laboratories or the DHS National Bio Forensics and Analysis Center for definitive analysis (DHS 2006A). The primary objectives of initial response sampling, when conducted by law enforcement personnel, are to identify and confirm if *B. anthracis* is present, and if so, locate the source of the contamination to aid the criminal investigation. Results from the forensic investigation may not be releasable to all federal entities; therefore additional sampling may be necessary. The information from first responders and law enforcement may have important limitations and should be considered with caution (Emanuel et al., 2008), particularly if generated using hand-held assays (see Section 7.1.5 for more information). Also, the forensic investigation is focused on the collection of evidence and the source location and therefore does not involve developing a robust sampling plan. For this reason, a public health sampling plan may be needed to adequately address exposure concerns. If the incident is designated as a crime

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scene, CDC coordinates with the FBI to ensure appropriate samples are collected to meet public health objectives (DHS 2004).

Initial response sampling for public health purposes focuses on identifying areas of contamination to inform who may have been exposed. Such sampling takes place after confirming *B. anthracis* contamination or when contamination is suspected based on epidemiologic investigation. Information and data from first responders and other groups involved in the initial response and investigation are considered in determining if additional sampling is warranted. In order to conduct an initial assessment of who may have been exposed and identify potential pathways of exposure to support appropriate risk assessment and data-driven recommendations for medical countermeasures, further environmental assessment may be necessary prior to transition to the consequence management phase. Public health sampling actions are independent of the magnitude of the incident, or whether it is overt or covert. Thus, the initial environmental investigation must focus on rapidly evaluating the epidemiological information available (e.g., incident timelines and interviews of those involved). Sampling teams typically utilize a judgmental sampling approach (see Section 5.1) that is intended to maximize the possibility of detecting the presence of any contamination. Comprehensive characterization of potentially contaminated spaces is not a goal of initial response sampling for public health purposes.

Sidebar 1 suggests how initial response sampling might be carried out.

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Sidebar 1 – Initial Response Sampling During a Fictional Airport Scenario

A large international airport had a suspicious powder incident associated with a piece of luggage on a baggage carousel giving off a small, steady white cloud of dust. First responders evacuated the baggage claim terminal and cordoned off an area around the baggage carousel. The first responders collected samples that were sent to their local LRN for confirmatory testing. Due to law enforcement intelligence reports, the FBI and local public health responded to the site to conduct additional sampling. Meanwhile, the LRN confirmed a positive sample result for *B. anthracis*. The goal when collecting initial response samples after a confirmed release is to collect samples to evaluate whether contamination is present in other locations and in order to identify who might have been exposed.

It is important to target the location for a plausible pathway that is most likely contaminated. While the immediate area may be perceived to be top priority, other areas and populations should be assessed in order to quickly identify the populations at risk, such as high traffic areas and the area where baggage was offloaded. In addition, *B. anthracis* spores will likely be present on people or baggage in close proximity to the release point and can serve as a fomite to cross-contaminate other areas. For the purposes of this scenario, initial response sampling can determine if the contamination is localized to the baggage claim terminal or if it has spread to other locations (e.g., the taxi stand or food court) (Emanuel et al. 2008). Also, HVAC system return ducts and filters in the immediate vicinity should be sampled in order to assess if contamination spread via aerosol through the HVAC system. Finding surface contamination on the tops of air ducts or rafters that are highly unlikely to have had contact with the contaminated source or finding a dispersion pattern of multiple positive results might suggest that aerosolization occurred during or after the event (CDC2001).

3.2 Characterization Sampling

Characterization sampling is typically used to obtain information concerning the extent and magnitude of contamination to guide remediation. Sampling is used to determine whether an area needs to be decontaminated and what materials need to be decontaminated. The information generated from the characterization sampling is also used to help modify and refine public health actions that were developed based on the initial assessment, if sampling during the characterization phase indicates a different or larger population may have been affected than suggested by initial response sampling.

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Characterization systematically expands on the initial assessment findings to identify other contaminated locations and determine the contamination footprint at the affected locations, in order to better define the boundaries. The strategy for the characterization phase is to supplement the information that has already been collected during the initial assessment. The sampling information, specifics of the scenario, and the data collected during the initial assessment may take on many forms and may come from several different groups involved in the initial response. The initial assessment sampling data will be evaluated and reviewed, and information derived from it will be used by IC/UC to assist in formulating the objectives, strategy, and approach for the characterization phase. The information that results from the characterization affects and shapes the planning and implementation of the remediation phase, as determined by the Incident Commander (DHS 2006b).

3.3 Verification Sampling

Overall clearance of an area or building is a multi-step process that includes application of the decontamination technology, verification sampling and other means to follow progress of the decontamination process, and clearance sampling (discussed in following section).

Verification sampling may be performed during the remediation process to establish whether decontamination was effective or sufficient in neutralizing contamination. Verification sampling may include surface sampling using the same methods that are used during the characterization phase. This type of verification sampling would not take place during decontamination but immediately afterward. These samples are collected adjacent to previously identified contaminated surfaces to determine whether the decontamination process has successfully eliminated viable spores where they were previously found.

Sidebar 2 outlines some of the actions that may be taken to monitor the progress of decontamination.

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Sidebar 2 – Monitoring the Decontamination Process

In order to monitor the progress and adequacy of decontamination using a fumigant or vaporous decontaminant, biological indicators (BIs) may be used to determine that a particular decontamination reagent has been in contact with specified surfaces or distributed throughout a particular area sufficiently. BIs can be porous cellulose filter pads or stainless steel coupons that have been inoculated with a defined titer of non-hazardous bacterial spores, such as *Bacillus atrophaeus*. *Bacillus* spores, including the *B. atrophaeus* species, are recognized as being highly resistant to inactivation by decontamination processes, including gaseous chlorine dioxide (ClO_2) (Leftman 2008). It is important to note that current BIs are more easily decontaminated than building materials such as carpet. Therefore BIs should not be used alone to determine decontamination efficacy. BIs containing *B. atrophaeus* spores are used in medical applications to demonstrate successful ethylene oxide sterilization, as well as in the pharmaceutical industry to document the effectiveness of small-scale ClO_2 treatment. Following the decontamination process, the BIs will be retrieved and sent for analysis at an independent laboratory to ensure that all spores on the BI were inactivated by the treatment process (Sabre 2007).

Other measurements will be used as well to monitor decontamination operating parameters. For example, during fumigation measurements are collected for temperature, humidity, contact time, and fumigant concentration. These data are used to help determine if the fumigation process has met the criteria established in the RAP and whether it is deemed successful. For surface decontamination technologies such as amended bleach, parameters that may be monitored include contact time, pH, and free chlorine concentration.

3.4 Clearance Sampling

Clearance sampling is environmental sampling that provides a determination of whether clearance goals were met and the facility is ready for final preparations for re-occupancy. In this case, clearance sampling is conducted after decontamination activities are completed but before critical barriers are taken down. In addition, clearance sampling could be conducted in areas where no contamination was found during characterization sampling and thus, no remediation was conducted in those areas. The purpose of clearance sampling is to promote confidence in decision-makers and users of the facility that the facility has been adequately remediated. Consequently, analysis of clearance samples should be done using methods that determine viability of any spores remaining.

After all samples are collected and the sample results are reported, the findings and the methods for verification and clearance sampling used to develop those findings will be presented to the IC/UC. If an ECC was created by the IC/UC, the above information will be provided to the ECC, which will review the findings and then prepare a written clearance statement or document

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which is provided to the IC/UC. Depending on the impacted facility, the IC/UC or lead local public health agency makes the final decision on whether or not the building is cleared and ready for re-occupancy.

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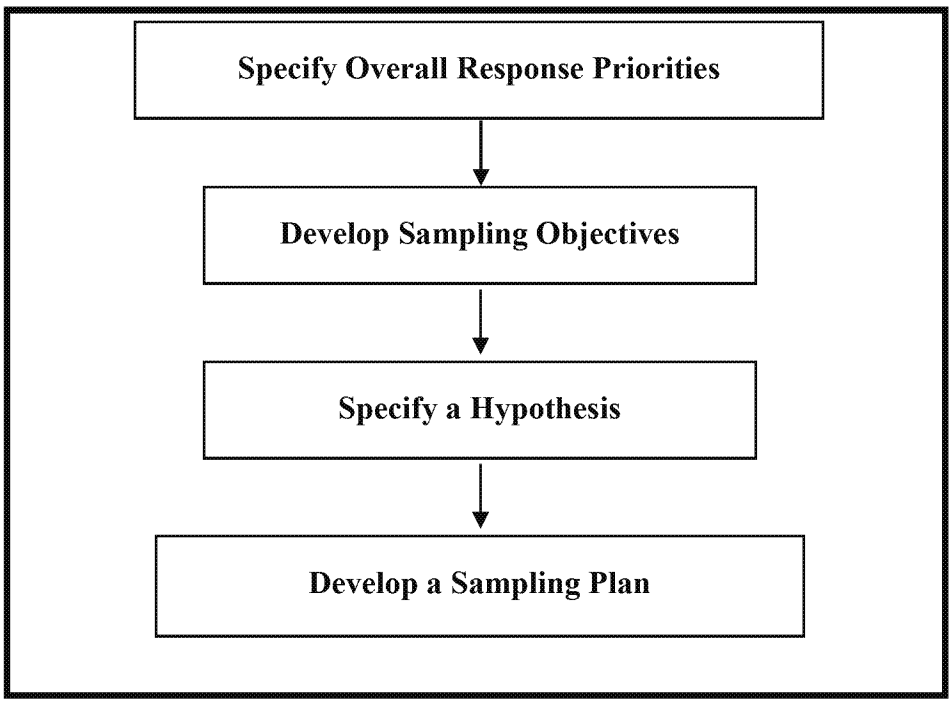
Section IV: Sampling Strategy Roadmap

The first step to produce meaningful sampling data is to understand the basic roadmap for the response (Figure 4-1). The roadmap for the response will include the overall response priorities established by the IC/UC, the sampling objectives, and the sampling approach (Emanuel et al. 2008). The sampling strategy roadmap serves as the framework for developing data of requisite quantity and quality to support an overall process outcome and subsequent decisions.

Figure 4-1. Basic Roadmap for a Sampling Strategy*



*Adapted from Emanuel et al. (2008)

4.1 Specify Overall Response Priorities

Response priorities are set and directed by the IC/UC of an incident. However, the development of these priorities should be made within the context of appropriate information sources. Consideration of critical data streams from law enforcement, intelligence, and epidemiology will help to define the problem, identify what information is lacking, and develop the objectives of environmental sampling. The objectives are met by establishing specific hypotheses and by designing an environmental data collection program that will test the hypotheses.

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4.2 Develop Sampling Objectives

Sampling objectives are derived from the response priorities. Establishing clear and tangible sampling objectives that can be translated into sound test hypotheses is critical to determining the amount of data required to draw conclusions. It is also imperative that the data quality requirements are appropriate to support those conclusions. Decisions that are then made as a result of a careful analysis of the data are considered scientifically-based and therefore, provide greater confidence to those making the decisions and to those affected by the incident with regard to their health and safety.

Specific sampling objectives that may be applicable for an environmental data collection response may include (OSHA 2002):

Initial Response Sampling:

- Immediate Assessment of Potential Contamination**:** Determine, in near real-time, whether a release of spores is occurring or has occurred in a facility. Real-time detection instrumentation, biological agents.
- Identifying Spores in a Bulk Material**:** Determine if a bulk material, such as a powder in an envelope, is contaminated with *B. anthracis*. On-site analysis may be used for preliminary assessment, but laboratory analysis provides confirmation.
- Initial Agent Characterization: Determine the identity of the agent, presence of spores, formulation, toxicological properties, antimicrobial sensitivities, strain sub-typing, persistence, and other physical properties.

Initial Response and Characterization Sampling:

- Determining Contamination Pathway: Determine whether spore contamination resulted from airborne or fomite transport.
- Determining Contamination of an Article**:** Determine whether the surface of an article is contaminated.

Characterization Sampling:

- Determining Extent and Location of Contamination (Characterization Sampling): Determine qualitatively, and if possible, semi-quantitatively, the extent and magnitude of contamination; inform the understanding of spore transport and fate; inform decontamination plans, and compare with future clearance sampling results.

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Verification Sampling:

- Effectiveness of Decontamination (Verification Sampling): Determine whether parameter measurements for the decontamination technology have met criteria established in the RAP.

Clearance Sampling:

- Post-Decontamination Sampling: Develop a body of data of adequate quantity and quality to enable IC/UC to verify that the originally contaminated environment has been sufficiently decontaminated to allow re-occupancy of the area without the use of personal protective equipment (PPE) or other protective measures (OSHA 2002).

4.3 Specify a Hypothesis

Hypothesis-driven sampling plans provide for defensible decisions based on the resulting data, which can be evaluated semi-quantitatively or qualitatively. Hypotheses should specify the principal question(s) of interest, which will then help identify needed information inputs such as epidemiology data or environmental data. Clear hypotheses must be defined before an investigator decides on the number and types of environmental samples to collect and the specific locations to sample. As data are received and interpreted, this new information may be evaluated against the initial intelligence and epidemiologic data and could refine or shift sampling objectives. Subsequently, a new set of hypotheses may be generated and new sampling plans developed to reflect the changing needs.

4.4 Develop a Sampling Plan

A well-designed sampling plan ensures that resulting data can answer the specific hypothesis being tested, thus fulfilling the sampling objectives. The sampling plan, as defined by the VSPWG (see Section 1.2), is a documented approach for field execution that captures the specific combination of operating precepts and diagnostic tools used for a given scenario to answer a specific hypothesis. A sampling plan is an executable plan of action that addresses the sampling and analytical requirements of a specific situation and is formulated in accordance with the guidance of the sampling strategy. This plan should be developed by experts (e.g., industrial hygienists or environmental scientists with microbial sampling expertise) with training and experience in conducting field studies or investigation.

A sampling plan must specify the sampling approaches, methods, and analyses, as well as the number, types, and locations of samples to be collected in a given physical space. The plan also must address quality control considerations (DHS 2007b). A comprehensive sampling plan cannot be developed prior to an incident because its development is governed by the amount of information known about the agent, whether the location of the release is known, and whether the agent has been modified or enhanced. Only after the sampling objectives are determined and

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associated sampling approaches (discussed in Section 5) are selected can an incident-specific sampling plan be written. A sampling plan may develop into several individual plans for multiple locations each with a different objective. A sampling plan may be developed for each task or phase of the response (*first response, characterization, remediation,* and *clearance*) (DHS 2007a). Sampling plans should be documented and describe the basis for all steps, including quality assurance.

Sidebar 3 outlines the process EPA uses to document data quality objectives. The format of an incident-specific sampling plan may vary. Appendix F provides an example sampling plan used in the EPA-funded Bioresponse Operational Testing and Evaluation (BOTE II) project.

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Sidebar 3 – The EPA Data Quality Objectives Process

In order to ensure that the data collected from the exercise of a sampling plan matches the needs of a hypothesis and related decision, a systematic planning process is needed to design the data collection. As an example, the EPA uses the Data Quality Objectives Process to establish performance or acceptance criteria, which serve as the basis for designing a plan for collecting data of sufficient quality and quantity to support the goals of a study (ASTM 2010c). The DQO Process consists of seven iterative steps that are outlined below and explained in detail within the ASTM document.

Elements of the systematic planning process include:

- Organization: Identification and involvement of the sampling plan manager, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, etc. (e.g., all customers and suppliers).
- Sampling Plan Goal: Description of the project goal, objectives, and study questions and issues.
- Schedule: Identification of project schedule, resources (including budget), milestones, and any applicable requirements (e.g., regulatory requirements, contractual requirements).
- Data Needs: Identification of the type of data needed and how the data will be used to support the plan's objectives.
- Criteria: Determination of the quantity of data needed and specification of performance criteria for measuring quality.
- Data Collection: Description of how and where the data will be obtained (including existing data) and identification of any constraints on data collection.
- Quality Assurance (QA): Specification of needed QA and Quality Control (QC) activities to assess the quality performance criteria (e.g., QC samples for field and laboratory examinations, audits, technical assessments, performance evaluations, etc.).
- Analysis: Description of how the acquired data will be analyzed (either in the field or the laboratory), evaluated (i.e., QA review/verification/validation), and assessed against its intended use and the quality performance criteria (EPA 2006a).

While these steps are outlined in a sequential fashion, the iterative nature of the DQO Process allows one or more of these steps to be revisited as more information on the problem is obtained (EPA 2002). A good sampling plan should expend no more resources than are necessary to meet the associated objective (EPA 2002).

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4.4.1 Sampling Approaches

There are three main sampling approaches described in this document: *judgmental sampling*, *hotspot sampling*, and *combined judgmental and random* (CJR) sampling. Judgmental sampling is environmental sampling in which locations having the greatest likelihood of being contaminated are selected using the investigator's expert judgment (Emanuel 2008). Hotspot sampling is a probabilistic (i.e., samples randomly selected) sampling approach that provides for detecting small hotspots of contamination. The CJR sampling approach employs a Bayesian methodology that combines probabilistic samples with a given number of judgmental samples to obtain a specified level of confidence that a building or area has no detectable contamination.

The type of sampling approach selected is based on the response phase, whether the response is covert or overt, the magnitude and type of release, IC/UC objectives, and the available resources. *Judgmental sampling* is virtually always used in initial public health, characterization and clearance sampling, due to its speed, efficiency, and demonstrated effectiveness. For characterization sampling with the majority of contamination scenarios, judgmental sampling will be sufficient to detect the contamination. However, if *B. anthracis* may have been disseminated in one or more small, isolated locations that would typically not be sampled by judgmental samples, then the *hotspot sampling* approach can be used. Although such scenarios are expected to be rare, the hotspot sampling approach is mentioned as an option for completeness. For clearance sampling, judgmental sampling may be sufficient if clearance statements are made with high confidence based on the effectiveness of the decontamination process along with non-detect judgmental samples. The *CJR approach* can be used for clearance sampling if there is a need to generate statistical confidence statements. A more in-depth discussion of these three approaches is found in Section 5.

In selecting a sampling approach for the site-specific sampling plan, the IC/UC must consider many factors, some of which can be in conflict. The IC/UC must consider the level of confidence in the intended outcome of the process needed (i.e., that the facility is free of detectable contamination), the time available to make that determination, the resources available, and the financial investment required. Components of resources available include staff available to collect samples, consumables used in the sampling and analysis process, and analytical resources (laboratories, staff, and equipment) available for processing of environmental samples. Limitations in any resources required to execute the overall sampling response may limit the options available among sampling approaches that can be exercised in the site-specific sampling plan.

Based on the best available science and the most practical approach, EPA and CDC have developed an *Interim Clearance Strategy for Environments Contaminated with Bacillus anthracis* that considers that the available knowledge of the efficacy of decontamination when combined with a reliance on judgmental sampling alone are sufficient generally to inform positive estimations by the IC/UC on clearance of a previously contaminated facility or space.

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4.4.2 Pre-Incident Data

Security camera recordings and eyewitness accounts might provide some information about the extent of contamination. Data on ambient interior conditions (temperature and humidity and time of day) and outdoor conditions (wind speed and direction, temperature, and humidity) contributes to understanding exposure pathways and location of contamination. Such data can be combined with known facility parameters and traffic patterns and used to model the spread of the spores to help estimate exposure of potentially affected individuals. If other environmental sampling systems exist near the site of the incident (i.e., BioWatch collectors), the data from those systems should be obtained and reviewed.

4.4.3 Initial Sampling Plan

Environmental assessment during the initial response phase is a critical component of an overall investigation because it provides important information about the potential exposures to populations who may have been in the release zone. Environmental exposure information along with epidemiological data helps support implementing post-exposure prophylaxis and other public health activities. Knowledge of individuals who have contracted anthrax and whether it is cutaneous or inhalational is important in developing sampling plans. For example, if an individual contracts inhalational anthrax, then that informs the IC/UC that the agent is small enough to enter the deep lung. Thus, the agent may be wide spread throughout the facility. Environmental sampling during the first response phase typically takes place as soon as possible after identifying an incident.

A modular approach provides an effective process for conducting environmental assessment and investigation during the initial response phase as it creates boundaries based on specific questions being asked about the potential incident. Additional benefits include the ability to resolve complex situations, response in the presence of limited resources (on the ground and in the laboratory), and rapid data turnaround resulting from manageable sample numbers. Each module should be designed to address a single hypothesis.

The number and sizes of the modules will depend on the scope and magnitude of exposure. Different modules may exist for:

- Contamination of a closed office environment
- Contaminant drift within an open office environment
- Agent migration via air handling systems

For example, a single individual in an office environment who opens a letter containing a fine powder composed of a *B. anthracis* spores would necessitate a focused investigation of a small area when the interest is exclusively the exposure of one or a few individuals. Environmental

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sampling would be targeted to provide resolution on the release point and to estimate the level of any potential exposure. However, if people work in an open, cubicle office environment, another module should be established that addresses their exposures resulting from spore drift or contact with contaminated fomites. Consideration of biological agent migration to other areas of the building would be addressed through a separate module with sampling targeted to address cross-contamination as a result of people and fomite movement, as well as air transport through the building's ventilation system (VSPWG 2007; VSPWG 2008; Amidan 2009)). Multiple modules may be employed simultaneously, each addressing unique hypotheses. Some overlap may exist in the sampling strategies for each module. This is acceptable as it assures that the data generated by a given module can be integrated from one module to another to create a seamless picture of an incident. However, too much overlap creates duplication and a waste of limited resources.

This is an iterative process of assessing and responding, and of subsequently modifying the response based on assessment. Certain incidents necessitate an initial response to the crisis before appropriate personnel can complete assessment. Such actions as shutting off air handling systems, restricting access to a location, and initiating post-exposure antimicrobial prophylaxis are time-sensitive and must be started immediately.

While there is no scientific evidence supporting correlation of surface contamination resulting from the deposition of an airborne release of a biological agent and the inhalation challenge that may have occurred to the exposed population during the release incident, it does provide context for identifying which areas likely present the highest risk of exposures to building occupants.

4.4.4 Characterization Sampling: Dividing the Building into Zones

Because resources are limited and remediation must proceed quickly, characterization sampling must be centered on well-defined goals. The most efficient characterization of an incident depends on what is known about the incident. Knowledge and understanding of the spore dispersal mechanism, common transport mechanisms, sampling and analysis resources, and the decontamination techniques available for use will help in developing an efficient characterization sampling plan. For example, if there are small areas with high contamination concentrations that must be identified and addressed using a localized decontamination method, then characterization sampling must be designed to yield a high likelihood of discovering all such hotspots. On the other hand, contamination dispersal could result in a very distributed form, with widespread contamination and few hotspots, as was observed during trials at the Idaho National Laboratory in 2007-2008 involving the aerosol dissemination and sampling of a biological simulant in a building.

The potential for contamination within a large building is often not the same across the entire building. Many factors could affect dispersion patterns including distance from release, air

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ventilation systems, traffic patterns, building layout, etc. Therefore, the sampling approach could be different in different parts of the building, depending on the likelihood of contamination. In this case, it is helpful to divide a building into zones. A *zone* is defined as an area within a building that has a similar likelihood of contamination, similar building characteristics and the same sampling objectives. The modular approach utilized in the initial response is not based on similar likelihood of contamination, rather it targets areas anticipated to be contaminated and evaluates potential contamination pathways which may or may not be contaminated. These differences in sample results coupled with the location of the sample aid in understanding any potential exposure pathways and persons most likely at risk of exposure.

If remediation is warranted, the IC/UC should be able to choose the type of remediation method(s) to address contamination in the zone. The sampling approach applicable for different zones may be very different for the following reasons:

- The sampling objectives and decision criteria are based on the amount of prior information available for each part of the building, and
- The different zones have different likelihoods of contamination.

Similar zones should have the same sampling approach. Identifying zones and assigning them zone designations should consider any relevant known information regarding the following:

- Building layout
- Ventilation systems and traffic patterns
- Occupant activities
- Release location
- Initial response results and effects
- Apparent contamination pathways
- Within-room features (furniture, counters, tabletop, shelf configurations)
- Surface materials
- Decontamination technology options and areas of influence

Four types of zones are described in the following subsections.

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4.4.4.1 Zone 1: Extremely High Likelihood of Being Contaminated
(ASTM 2010d, 2010e, 2010f)

This zone includes areas that are confirmed contaminated or are assumed to be contaminated. Examples include the area around a release point, areas adjacent to the release point with a direct flow path from the release point, and areas in which contamination was detected in the initial response phase.

Because this zone of a building is known or assumed to be contaminated, detailed characterization sampling is not required if the entire zone will be decontaminated. If additional information is needed to support selection of decontamination technologies or parameters in order to decontaminate the entire zone, some additional judgmental samples are recommended. These samples should be located using best professional judgment and should take into account any recommended pre-defined sample locations. If areas of very high levels of contamination require a different decontamination technology than areas of lower levels of contamination, then additional sampling may be required to accurately delineate these areas.

4.4.4.2 Zone 2: High Likelihood of Being Contaminated

By definition, the likelihood of contamination in this zone is high, but there is no obvious evidence of contamination here before characterization. The primary objective for sampling within this zone is to identify contamination if it exists or to provide sufficient confidence that it does not exist. If feasible, in order to quickly determine if the zone is contaminated, first collect some judgmental samples in locations that are most likely to be contaminated. If any of those judgmental samples are identified as contaminated, then this zone can be re-classified as Zone 1 and proceed with the recommendations as discussed in Section 4.4.4.1. If all judgmental samples are uncontaminated, but there is reason to believe contamination may only exist in one or more small hotspots, then the hotspot sampling approach (Section 5.2) could be used if warranted. If the hotspots are sufficiently delineated and are small relative to the entire zone, contaminated boundaries within the zone could be established and decontamination could focus on the contaminated areas within the zone.

If no contamination is found in any of the initial judgmental samples, then a more extensive sampling approach (e.g., judgmental or CJR sampling approaches) may be necessary, if feasible and time permits, so that this area can be cleared. The IC/UC will determine if additional samples must be collected to clear the area. The decision will be based on several factors including, but not limited to, time and resource constraints, feasibility, and magnitude of incident (other buildings potentially contaminated). If all samples show no contamination present, then this zone should have limited or no entry in order to be

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protected against potential future cross-contamination.4.4.4.3 Zone 3: Low Likelihood of Being Contaminated

In this zone there is no prior evidence that contamination is present, but there is a low chance of the zone being contaminated. These are areas the IC/UC does not believe are contaminated, but they do not have sufficient evidence to support that conclusion. The characterization sampling objective for this zone is to determine if contamination exists or does not exist. The judgmental sampling approach (see Section 5.1) is recommended.

4.4.4.4 Zone 4: Extremely Low Likelihood of Being Contaminated

This zone includes all remaining areas in the facility that have an extremely low potential of being contaminated because of their location relative to the release point, and the apparent absence of pathways for contamination to travel from the release point. If there is sufficient evidence that there is no known plausible pathway for the contaminant to have entered this zone, then the sampling team is not required to obtain any samples. This zone designation is only included herein for completeness purposes so an entire building or floor plan can be represented, including areas where no samples will be required. If there is some non-negligible chance that contamination is present (albeit a very low chance), then the sampling team should classify the area as a "Zone 3: Low Likelihood of Being Contaminated" and follow the recommended sampling strategy in Section 4.4.4.3.

4.4.5 Clearance Sampling in Designated Zones

The recommended sampling approaches for clearance sampling in Zones 1, 2, and 3 are the same regardless of whether a zone is being cleared after decontamination or after characterization sampling did not detect contamination. The optimum sampling plan for a given incident-specific scenario is a function of various factors, including, at a minimum, the timeframe required for results, the resources available for collecting samples, the resources available to analyze samples, funding available to resolve the situation, and the level of confidence required by the IC/UC and other responsible parties for deciding that a space has been deemed not to be a public health threat.

4.4.5.1 Zone 1: Extremely High Likelihood of Contamination

Zones that were originally classified or reclassified as having an "extremely high likelihood of being contaminated" (Zone 1) require decontamination. After decontamination, such areas

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within a building are assumed to have a "low likelihood of being contaminated" (Zone 3) and are treated as described in the following section.

4.4.5.2 Zones 2 and 3: High and Low Likelihoods of Contamination

For zones that had a high (Zone 2) and low (Zone 3) likelihood of contamination where all characterization sample results were negative, additional samples may be collected to finally clear the area since decontamination was not conducted in those areas. The IC/UC will determine if additional samples should be collected. The decision will be based on a collection of information including epidemiological data, characterization sampling results, and first responder, law enforcement, and public health information, if time permits. Depending on site and incident specifics, the IC/UC may decide to clear a zone based on non-detect characterization sampling results.

For areas that were classified as Zone 1 and decontaminated, clearance sampling is necessary to demonstrate that there is confidence that no detectable contamination remains, and the area can be released for general use. Because information is known about the locations of contamination identified during the characterization phase, judgmental sampling will always be desirable at or near those locations and surfaces along all potentially contaminated pathways (see Section 5.1). It will be up to the IC/UC to decide whether knowledge, control, and verification, of the decontamination method along with judgmental validation samples will be sufficient for clearance with high confidence.

Regardless of whether contamination was detected and decontaminated, or not detected, another option for clearance sampling is the CJR approach (see Section 5.3). This approach makes use of judgmental and statistical ("random") samples, and provides for stating with X% confidence that at least Y% of the decision area does not contain detectable contamination. The advantages and disadvantages of the CJR approach are discussed in Section 5.3.

4.4.6 Sensitive Items versus Non-sensitive Items

Some items are considered sensitive due to the fact that these items may be damaged during sampling when using sample collection methods that involve moistening solutions. It is important to determine what items may be considered sensitive by the property owner at the start of the response. Sensitive items can include items such as artwork, photographs, and equipment such as computers, electronic and electrical circuit boards, high-voltage power lines, and electronic control panels. In addition, personal items such as cellular phones, clothing, and jewelry can be considered sensitive items. Many of these items need to be sampled during characterization and removed prior to decontamination of the facility if possible. Sensitive items

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with a positive characterization sample must be contained before removing so that contamination is not spread. These items can be decontaminated using less destructive methods such as ethylene oxide (only used for small-scale decontamination) at an alternative location. If sensitive items cannot be removed before decontamination, then these items should be protected from the decontaminant. Sensitive items will most likely be sampled using a vacuum sampling technique as was done during the 2001 Amerithrax incident cleanup operations.

4.4.7 Operating Equipment

Decisions must be made on whether equipment (e.g., refrigerators, printers, cash registers, computer screens, typewriters, etc.) present in the contaminated area will be decontaminated and kept after the facility is released for reoccupation, or whether the equipment will be removed and properly disposed. If the equipment is kept, then post-decontamination sampling will be needed to confirm that the equipment has been decontaminated. If there are areas where contamination may have accumulated (such as grease areas or wells, fans, heating or cooling elements, etc.), then samples should be collected in these areas. If there are many small crevices, then vacuum sampling may be in order. If equipment is completely enclosed and air tight, then only wipe sampling of the enclosure will be required.

4.4.8 Optimizing the Sampling Process

At each stage of the response to a contamination incident there are many variables that can be optimized so that only the sampling necessary to achieve the objective(s) is performed. Optimization can be applied in 1) partitioning a facility into designated zones, 2) selecting the sampling approach for each designated zone, and 3) using composite samples where appropriate. The optimization process would be implemented by engaging site workers, technical experts, and key stakeholders to provide the IC/UC with advice on the options, costs and implications of various courses of action.

4.4.8.1 Optimizing via Designated Zones

Sampling can be optimized by partitioning a facility into zone categories, as discussed in Section 4.4.4. Portions of a facility designated as "Zone 1" areas (extremely high likelihood of contamination) may only require minimal judgmental sampling to detect contamination. Spaces designated as "Zone 4" areas (extremely low likelihood of contamination) may require no additional sampling and minimal confirmatory sampling. Areas designated Zone 2 (high likelihood) and Zone 3 (low likelihood of contamination) may receive the most attention during the overall sampling plan development and determination of most appropriate sampling approach

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for those zones. Consideration will be given to the degree to which these areas are distinct from Zone 1 areas, with an emphasis on passageways between them. Such passageways as open doors or connected air flow systems will increase the amount of sampling done and the approach taken.

4.4.8.2 Optimizing Sample Collection

In many response situations, resources are constrained due to 1) limited laboratory capacity to analyze samples, 2) limited number of people to collect, process, and analyze samples, 3) restrictive cost of the sampling or analysis, and 4) limited sampling media and laboratory processing supplies. Additionally, there may be great pressure to have a quick turnaround on the sample results. When planning sample collection, using the optimization process will ensure that the process is efficient and that the data generated are meaningful and applicable. Iterative-based sampling consists of collecting a set of samples, then using the results to determine where to collect another set of samples. Although this may decrease the number of samples collected, it does require more time then collecting samples for the entire area all at once.

Another optimization process is to collect all the samples at once but then prioritize sample submission to laboratories for analysis. Whether samples are collected all at once from an area or iterative-based sampling is conducted, the IC/UC can prioritize sample submission. Samples that are most likely to answer the sampling hypothesis should be chosen for submission to the laboratory for analysis first. Prioritization of sample submission may be based on:

- Knowledge of the incident
    - Contaminant characteristics
    - High probability sample locations like ventilation filter, electrostatic surfaces, high traffic areas, etc.
    - Epidemiologic data
- Time constraints of the incident
- Overall priority of area/building with respect to response objectives

Composite sampling (discussed below) and pooled sample analyses (see Section 7.3) are two other strategies to reduce the number of samples taken and/or analyses performed

4.4.8.3 Composite Samples

Composite sampling involves collecting samples from multiple locations with the same sample collection device and submitting it as a single sample. This might involve wiping more than one

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location with the same wipe, or vacuuming more than one location with the same vacuum filter media. The main advantages of a composite sample are the reduction in the number of samples that require processing and analysis and the reduction in the sample collection materials required. Another advantage to composite sampling is the increase of surface area sampled. With discrete sampling the surface area sampled may by 100 cm^2. With composite sampling the surface area sampled may be up to 400 cm^2 which may increase the likelihood of detecting contamination. During the various phases (public health screening, characterization, and clearance sampling) of past *B. anthracis* incidents, composite sampling was used successfully. An example is provided in Sidebar 4, in which composite sampling is used to verify a cross-contamination pathway. With these conditions, collecting composite samples instead of discrete samples (i.e., collecting one sample from one sampling location) should be considered.

Sidebar 4 – Example of Use of Composite Samples

Initial response sampling of a building's entranceways determined that a three-story office building was cross contaminated due to foot traffic from an adjacent contaminated building that had a *B. anthracis* release. The IC/UC decided in advance that all carpets located in large conference rooms would be replaced if found to be contaminated. Therefore, during characterization sampling, the team decided it would save resources by compositing four vacuum sample locations within a conference room as one sample, instead of collecting four discreet vacuum samples. Four locations to serve as one composite sample is given only as a guide and should depend on the area and amount of debris present. Each floor of the three-story building had a large conference room. The sample team collected one composite sample for each conference room on each floor. Composite sampling was deemed acceptable in this scenario because a similar decision would have been made if discrete sampling had occurred. In other words, if only one of four discrete samples was positive the same decision to replace the carpet would have been made.

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When sampling multiple locations using composite sampling, the decision makers are treating the one analysis of all those locations as one decision. Collecting multiple composite samples from overlapping sample areas should be avoided. In such a case, the areas cannot be distinguished from each other, all spatial information is lost, and useful information is gained only if both samples are positive or negative.

When collecting composite samples, the following guidelines are provided to maximize the utility of this technique:

- Sample vertical and horizontal surfaces separately.
- Group frequently touched surfaces together, like light switches or door handles.
- Keep similar surface type together (e.g., smooth, non-porous desks and filing cabinets).

If there is a desire to delineate contaminant location by room, then a composite sample should not include locations in two or more rooms. Compositing should only be done within each room. This also holds true for delineating contamination by floor, by ventilation systems, etc. The number of locations to collect with a single sampling media should be between two and six. For swabs only two to four locations is appropriate. This prevents the swab from drying out and minimizes overloading the sampling media, both of which will decrease collection efficiency. For wipes, two or four locations should be collected for the same reasons described above. Composite vacuum samples (e.g., filter sock) should only include two to six locations. More composite locations can be collected with a vacuum sample since the filter sock can collect more material, and it is not subject to drying out since it is not wetted. The number of locations and surface area collected for a given sampling media should be consistent throughout all sampling events. This ensures consistency of results for data interpretation. A composite sample collected from four locations with a single sampling media is referred to as a 4-point composite.

One disadvantage of composite sampling is contamination can be spread from contaminated locations to uncontaminated locations. However, this may not be an issue if finding contamination within an area will lead to decontaminating the whole area. Another potential disadvantage is dilution, which would depend on the sample collection method. Composite sampling using the wipe method may reduce the amount of contamination collected on the wipe from a contaminated location by distributing it to subsequent uncontaminated sampling locations. This may cause a composite sample to be reported as non-detect where otherwise a sample of a single contaminated location would be declared positive. However, composite sampling has been exercised in simulated operational scenarios, such as the second sampling test at Idaho National Laboratory (VSPWG, December 2008), with minimal deleterious effects observed.

The decision to collect discrete or composite samples will be based on the types of decisions made with the results, laboratory throughput, resources (sampling media, sampling personnel) and the size of the incident. In most incidents, collection of both composite and discrete samples

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will be conducted. Sidebar 5 presents an example of sample collection optimization in order to make a quick decision to fumigate based on refining the sampling strategy to determine if the pathway of contamination was via aerosol deposition. In this example the sampling process prioritizes samples, expedites the timeline, and saves valuable resources for characterizing other zones.

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Sidebar 5 – Optimizing Characterization Sampling for Making Decontamination Decisions

A sampling team conducted characterization sampling in an area adjacent to the room where a letter containing *B. anthracis* powder was opened and also shared the same HVAC system. Based on this information, the adjacent area was designated as having an extremely high likelihood of contamination (Zone 1). The IC/UC gathered all existing data from any inhalation and/or cutaneous* cases in that vicinity, in order to develop a sampling plan. Based on analysis of the anthrax cases, epidemiological surveillance, and law enforcement evidence, the team determined no anthrax cases were identified from individuals in this area. There was no evidence that the contaminated letter entered this area. However, the IC/UC hypothesized that contamination could still be present due to foot traffic and possibly by transport via the HVAC system. Sampling this area would help inform those most likely to be at highest risk of exposure, and therefore disease, and help with public health decisions for post exposure prophylaxis (PEP).

The IC/UC decided that if any designated areas had evidence of aerosol deposition, then fumigation would be chosen as the method for decontamination. Therefore, the initial characterization sampling efforts would use the judgmental sampling approach to minimize the time and resources needed to make the decision to fumigate.

The sampling team collected samples on surfaces in the HVAC system that had a high probability for aerosolized spore deposition due to inertial impaction. The surfaces included baffles and downstream (supply air) ductwork where airflow made abrupt changes in direction. In addition, the sampling team collected samples on the downstream (supply air) filters where spore deposition may have occurred. This area of the building also had a drop ceiling that acted as the return air plenum. These return air plenums are good locations for some of the larger spores or agglomerated spores to settle due to slower airflow and longer retention time. Therefore, the sampling team removed ceiling tiles and sampled on top of the tiles as well.

Samples were positive for *B. anthracis* on the supply and return vents and one of the ceiling tiles. Therefore, the IC/UC concluded characterization sampling and initiated fumigation of the area.

* Cutaneous cases would show evidence of surface contamination and inhalation cases would show evidence of aerosolization. Anthrax is not known to be communicable (spread from one infected person to another). (Emanuel et al. 2008).

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Section V: Sampling Approaches

Because sampling every surface in a building is not practical, a sampling approach is required to select representative surfaces for sampling. There are three kinds of sampling approaches discussed in this document: judgmental sampling, hotspot sampling, and CJR sampling. Generally, the judgmental sampling approach will be sufficient to detect contamination for first response and characterization sampling. However, the hotspot sampling approach might be needed for characterization sampling to identify smaller, isolated locations of contamination not detected by judgmental sampling. Although the need for hotspot sampling is expected to be rare, it is briefly discussed in this chapter for completeness. The CJR sampling approach employs a Bayesian methodology that combines probabilistic samples with a given number of judgmental samples to obtain a specified level of confidence that a high percentage of a building or area has no detectable contamination. These three sampling approaches are discussed in more detail in the following subsections.

5.1 Judgmental Sampling Approach

Judgmental sampling is environmental sampling in which locations having the greatest likelihood of being contaminated are selected using the investigator's expert judgment (Emanuel 2008). This approach can quickly determine if an area/zone is contaminated, although it is only as good as the information on which sample location selection is based. Using information gathered from the IC/UC, judgmental sampling plans are created with predetermined locations to collect samples. However, sampling teams can also use their judgment to choose new locations while conducting sampling. This approach is commonly utilized during the first response phases involving law enforcement and public health agencies when information to support both the criminal investigation and the implementation of medical countermeasures is needed quickly. Judgmental sampling is also used for the characterization and clearance phases of a response. With judgmental sampling, probability or confidence statements about the absence of contamination are more difficult to make and may require additional assumptions regarding representativeness and likelihood of contamination presence.

Judgmental sampling can be the most efficient way to find contamination if it is either widespread or behaves as expected. Judgmental sampling utilizes expert knowledge on applicable aerosol physics (including particle size, deposition rate, and settling velocity), principles of industrial hygiene, past responses, and epidemiologic and criminal investigations to determine sample locations. It has been successfully used in multiple investigations.

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5.1.1 When to Use Judgmental Sampling

Judgmental sampling is often used during the early phases of an incident as the primary sampling strategy. It is most effective to implement during characterization sampling if the source and characteristics of the contaminant are known from the crisis response phase sampling and when supporting epidemiological or forensic data are available. Critical information to consider from the incident, if available, would include the timeline of the incident, the dissemination mechanism, contaminant characteristics, observable contamination, if the HVAC system was shut down and when, any pathways the contamination source moved along, and any critical forensic evidence collected by law enforcement. Even in situations where very little is known about the release, the IC/UC can use professional judgment and draw upon past experience to select sampling locations. Judgmental sampling is also used during clearance sampling.

5.1.2 Selecting Locations for Initial Public Health and Characterization Sampling

As mentioned in Section 4, judgmental sampling focuses on those areas most likely to be contaminated. Different methods of dispersal would result in different patterns of contamination, and sampling should discover the resultant pattern. If the delivery source is known, investigators can quickly identify sampling locations at the source of the release. However, additional sampling locations will need to be identified to determine the extent of contamination in the building or area. If the source is not known, then identifying locations for sampling will be more challenging.

In addition to information gathered from law enforcement, first responders, building occupants, and public health, investigators may inspect the building for visual information to aid in selecting sample locations. Investigators should utilize current knowledge about contamination pathways resulting in spread of the spores through the building to aid in sample location selection. The four primary contamination pathways include:

- Process pathways
- Foot traffic pathways
- Air movement pathways
- Maintenance and other activity pathways

Process pathways are pathways, either manual or mechanical, associated with a work activity or sequence of steps along a given path (Emanuel et al. 2008). For example, the process by which incoming mail in an office building is processed and delivered to individual occupants can provide information on locations to sample. In this scenario, samples should be collected at

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locations where a contaminated letter or package was known to be present as part of the delivery process (Greene 2002).

Foot traffic movement pathways spread spores from one surface to another or into the air when individuals step in contamination or have contaminated clothing and subsequently move to another location. Samples should be collected along the route individuals took to exit the building (e.g., stairwells, elevators) and the path first responders, law enforcement, and public health took when responding. Paths along which mail carts, equipment, and vehicles moved could also be sampled.

Air movement pathways are pathways associated with the operation of HVAC systems, natural ventilation from open windows, the airflow within affected facilities, and equipment having fans like printers, computers, and refrigerators having a major influence on the spread of the *B. anthracis* spores. The spores can spread quickly throughout the areas served by the same air-handling unit serving the release location, including other floors of the building and all air-handling zones sharing a common return plenum with the release zone. If the HVAC system was operating during the release or was used as the mechanism of dissemination, one can anticipate a greater percentage of the building was contaminated. Specific locations could be sampled including supply air diffusers, return air vent covers, HVAC filters, and equipment fans.

Maintenance and other activity pathways are pathways where actions taken by individuals in these areas can increase or spread contamination in a building. For example, cleaning activities using compressed air or vacuuming can re-aerosolize *B. anthracis* spores. Use of brooms or mops in contaminated areas subsequently used in other areas can cause secondary contamination. In 2006 and 2007, *B. anthracis* contamination was identified in individuals who manually processed imported hides to make drums (Guh 2010, Nguyen 2010). Manually stretching and shaving hairs on contaminated hides resulted in exposure to *B. anthracis* spores.

Sample locations should be selected at sites where *B. anthracis* spores are likely to remain after deposition (repositories). Examples include surfaces with electrostatic charge (e.g., computer screens); tops of light fixtures; tops of signs; air ducts and surfaces near air-supply registers; air return registers, plenums and air-intake grills that are part of equipment cooling systems; ventilation intakes of electronics (e.g., computer tower fans); and HVAC filters.

Knowledge of these four kinds of pathways and likely repositories can assist investigators in identifying sampling locations for judgmental samples.

5.1.3 Selecting Locations for Clearance Sampling

One goal of the sampling approach for clearance purposes is to sample locations where a positive contamination result was found (and/or adjacent locations) in order to verify no detectable spores

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are present. The rationale is that previously sampled locations having a positive result, and nearby locations, represent the most challenging test of remediation effectiveness. Also, locations more likely to have been previously contaminated (such as surfaces along contamination pathways) can be selected for clearance sampling. This rationale can be applied in cases where a limited characterization was performed because the actual contamination boundary may not have been determined and/or the decision to remediate was made based on positive samples at key locations (See Sidebar 5).

5.2 Hotspot Sampling Approach

The *hotspot sampling* approach uses grid sampling with a random start to provide for detecting a small area of contamination (hotspot). This approach may be needed in characterization situations where a hotspot would not be detected by judgmental sampling. Although such situations are expected to be rare, the hotspot sampling approach is briefly discussed for completeness.

The number of grid samples is chosen to provide sufficiently high confidence (Z%) of detecting a hotspot of a given shape (usually circular or elliptical) and size. The type of grid (square, rectangular, or triangular), the hotspot shape and size, and the confidence parameter are chosen by the IC/UC depending on the specifics of the situation. The VSP software (VSP Development Team 2010, Matzke et al. 2010) implements the calculations for the hotspot sampling approach. For more information about the hotspot sampling approach, see Gilbert (1987, Chapter 10).

5.3 Combined Judgmental and Random (CJR) Sampling Approach

The CJR sampling approach employs a Bayesian methodology allowing investigators to combine probabilistic samples[(a)] with a given number of judgmental samples to obtain a specified level of confidence (X%) that a high percentage (Y%) of a building, area, or zone has no detectable contamination (Sego et al. 2007, 2010). The Bayesian approach incorporates prior knowledge about the chances of judgmental samples having contamination, so the combination of judgmental and probabilistic samples allows for statistical inferences about the likelihood of there being no detectable contamination. Increased confidence in the conclusion there is no detectable contamination is important in deciding on the need for further public health or decontamination measures following the initial assessment. The CJR sampling approach ensures samples are obtained from the perceived most-likely-to-be-contaminated locations (via judgmental samples) while protecting against the possibility of contamination existing in less likely areas (via probabilistic samples).

[(a)] Probabilistic sampling applies sampling theory and involves a randomization aspect in selecting sampling locations.

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Probability based sampling applies statistical sampling theory and involves randomized selection of sampling locations. Random sampling locations (or grid samples with a random starting point) can be used to accept or refute statistical hypotheses and to make statistical confidence statements about a decision. However, this approach often requires a large (perhaps impractically large) number of samples to achieve an acceptable level of confidence. The CJR sampling approach, because of using judgmental samples, has the advantage of requiring fewer random samples needed to achieve the same level of confidence. However, this requires making some quantitative statements about the ability of the expert to identify potentially contaminated locations and the likelihood of contamination relative to randomly selected sample locations.

5.3.1 When to Use CJR Sampling

The CJR sampling approach can be used for clearance situations when there is a need to generate statistical confidence statements of the form "There is X% confidence that at least Y% of a decision area does not contain detectable contamination." The clearance situation can be 1) after decontamination of a contaminated area, or 2) without decontamination of an area believed to be uncontaminated. In these cases, the CJR approach selects judgmental samples from locations that are more likely to be contaminated and augments the judgmental samples with probabilistic samples. In the case of clearance after decontamination, locations more likely to be contaminated are those identified as contaminated before decontamination and adjacent locations. In the case of clearance without decontamination, locations more likely to be contaminated include those along contamination pathways based on knowledge of the incident (see Section 5.1).

Sidebars 6 and 7 provide scenarios describing how the CJR approach could be used for clearance sampling after decontamination and without decontamination being judged necessary, respectively. Appendix E provides more information regarding the implementation of combined judgmental and random sampling. *It should be noted that confidence statements as outlined above cannot be directly converted into statements that reflect minimal or no risk to health in the space as there remain no accepted criteria for how clean is safe.*

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Sidebar 6 – Clearance Sampling After Decontamination Using the CJR Approach

A small (18,000 square foot) airport terminal was designated as a zone with a "high likelihood of being contaminated." During characterization, judgmental sampling found that one of the plausible pathways (foot traffic) in this zone was contaminated. Judgmental sampling did not detect contamination in other pathways (luggage areas, touch surfaces). The UC made the decision to surface decontaminate the foot traffic areas by first applying amended bleach solution to the entire carpeted floor and then HEPA vacuuming the entire carpeted floor surface. The UC decided that if decontamination was successful, the carpet would remain in place for reuse. All other fixtures and surfaces in the airport terminal remained and were not remediated.

Now that cleanup was performed, the UC wants to state that they are 95% confident that at least 99% of all surfaces do not have detectable contamination. During clearance sampling, the judgmental sampling accounted for 5% of the carpet being vacuumed and samples were collected in those locations most likely to be contaminated (dense foot traffic areas). The carpet vacuum samples consisted of vacuuming 100 locations each three foot by three foot. All 100 judgmental samples were reported as non-detect for *B. anthracis*. The sample planners believed that any judgment sample on the floor was twice as likely to identify contamination than any uninformed random sample. It was determined that judgmental samples were twice as likely to identify contamination because the characterization sample identified that contamination was most likely spread via foot traffic. Based on the total surface area and the likelihood that judgment samples are twice as likely to identify contamination, the total number of samples collected included 100 judgment and 762 random samples. If all sample results are negative, then the "95% confident that at least 99% of all surfaces do not have detectable contamination" can be stated.

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Sidebar 7 – Clearance Sampling Without Decontamination Using the CJR Approach

A small (1,800 square foot) building was entirely designated as a Zone 3 with a "low likelihood of being contaminated." During characterization, five judgmental samples (three foot by three foot vacuum samples) were reported non-detect for contamination. As a result, no remediation was performed. After characterization sampling the building was protected from becoming contaminated by other nearby operations. This was done in order to use the characterization judgmental samples as part of the clearance sample numbers. The UC wants to state that they are 95% confident that at least 95% of the floor surface does not have detectable contamination.

The sample planners decided not to assume the building was clean and assigned the expected *a priori* probability that all areas have no detectable contamination as 50% (unknown). They believed that any judgment sample collected was twice as likely to be contaminated as any uninformed random sample. The CJR approach resulted in judgmental sampling on 5% of the carpeted floor surface (for a total of ten, three foot by three-foot vacuum samples) and an additional 27 random vacuum floor samples. Combining the five judgmental samples from characterization, a total of 37 vacuum samples were analyzed. If all sample results are negative, then the "95% confident that at least 95% of all surfaces do not have detectable contamination" can be stated. If there were any positive results, then decontamination strategies should be implemented to remediate the area.

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Section VI: Sample Collection

The sampling objectives described in Section 4.2 contribute to deciding on the sample collection method(s) selected. A variety of sampling devices are available and one should be selected based on the location and type of surface to be sampled. The selection of appropriate environmental sample collection methods that can meet the sampling objectives must include consideration of the following factors (OSHA 2002):

- Laboratory capability and capacity to process expected samples
- Recovery efficiency of the sample processing method, specificity and sensitivity of the analytical method, and a determination of the need for quantitative, semi-quantitative, or qualitative results
- Suitability of the sample collection method for the potentially contaminated surface
- Cost effectiveness and efficiency of the sampling plan in meeting stated objectives

Obtaining as much information as possible about the *B. anthracis* spores to be sampled, their physical characteristics, and how they were released will help ensure that the most appropriate sample collection method(s) is employed.

Because the methods for sample processing depend on the analytical laboratory, the LRN laboratory to be used (discussed in detail in Section 7.1) must be contacted during the initial planning stages of sampling to discuss method selection. The final decision to select specific sampling methods, media, and materials should be made in conjunction with the LRN.

6.1 Sample Types

This section describes the following sample types: bulk material, surface, air, liquid, and soil samples. The specific uses and advantages of each sample collection method are also described in this section.

6.1.1 Bulk Samples

Bulk sampling is used to collect a visible solid material to determine the presence of a biological agent including *B. anthracis*. Bulk sampling can be used during any phase of an incident (EPA 2006a). Bulk samples of the source contaminant could be used to determine the characteristics of *B. anthracis* spores (ASTM 2010a).

Bulk samples can be collected in a variety of ways, but must be coordinated with the receiving laboratory. Loose source material (i.e., powder) can be collected by placing material into a sterile vial using a sample spoon, trowel, or spatula. Alternatively, sections of carpet or

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upholstery can be removed and transported to the laboratory for processing and testing (Anderson RL, 1982).Portions of HVAC filter media, or clothing that may be contaminated with *B. anthracis* may also be collected and sent to the lab. A method for collecting bulk samples is described in Appendix C.

6.1.2 Surface Samples

Surface sampling involves collecting microbial contaminants from a surface using an appropriate sampling device to determine the presence of *B. anthracis* spores. Swabs, wipes and vacuum filter socks or cassettes are the primary collection devices for spores on surfaces and are used during all phases (identification, characterization, decontamination, and clearance) of a response (CDC 2012a).

Determining the most appropriate type of surface sample collection method depends on whether porous or non-porous surfaces are to be sampled. Wipes and swabs should be used on non-porous surfaces while vacuum socks or filter cassettes should be used on porous surfaces (DHS 2006A). Examples of non-porous surfaces include: stainless steel, painted wallboard, glass, floor tile, and wood laminate. Examples of porous surfaces include: ceiling tile, fabrics, carpet, clothing, rugs, and upholstered furniture.

When collecting samples for *B. anthracis* on porous surfaces, use of wipes can be considered, because some studies have demonstrated higher recovery efficiencies (RE) when wipes were used to sample carpet and upholstery than when vacuum methods were used (Buttner et al. 2004, Estill et al. 2009, Valentine et al. 2008). Rayon/polyester or cellulose/polyester blends are superior to cotton wipes (Valentine et al. 2008). Vacuum sampling is also effective for spore collection from carpet or upholstery and could be used on these surfaces if high concentrations ($> 10^2$ spores/cm^2) are expected (Brown et al. 2007a).

Certain solutions (wetting agents) can be used to pre-moisten biological collection devices to enhance their overall performance. Common solutions include sterile water, sterile saline, neutralizing buffer, sterile phosphate buffer, and peptone buffer. In addition, surfactants (such as Tween 80, Tween 20, or pleuronic) can be added to these pre-moistening solutions to improve removal of spores from surfaces. Neutralizing solutions block the continued action of a disinfectant after sampling. These neutralizing solutions are important during post-decontamination activities (verification and clearance sampling) to ensure that samples, when analyzed properly, are not falsely negative due to the presence of residual disinfectant. Among available neutralizing solutions are:

- Butterfield's buffer with 0.02% Tween 80 (Tween 80 is effective in neutralizing phenolic compounds and acting as a surfactant);

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- Dey Engley broth (Becton Dickinson, Sparks, MD) [neutralizes chlorine compounds and iodine, but may encourage growth during transport];

- Neutralizing Buffer (Becton Dickinson) [contains sodium thiosulfate to neutralize chlorine compounds and aryl sulfonate complex to neutralize quaternary ammonium compounds];

- Letheen broth (Becton Dickinson [neutralizes quaternary ammonium compounds, but may encourage growth during transport]; and

- Phosphate Buffered Saline, pH 7.2 with 0.02% Tween 80 [Tween 80 is effective at neutralizing phenolic compounds and acts as a surfactant].

Similar recovery efficiencies (26.8 — 39.0%) have been obtained with wipes pre-moistened with each of these neutralizing buffers that were processed by the LRN laboratory processing procedure (see Appendix B). The choice of neutralizing solution depends on the disinfectant used. During the initial identification and characterization of a contaminated building, collection devices with a neutralizing solution are less important.

There are factors that will affect the choice of which wetting solutions to use for pre-moistening swabs and wipes for sampling. For example, phosphate-containing solutions (e.g., Butterfield's buffer and phosphate buffered saline [PBS]) may inhibit polymerase chain reaction (PCR) assays if appropriate DNA extraction and purification is not performed; sterile water could lyse osmotically sensitive vegetative cells; and the use of Dey Engley or Letheen broth may encourage growth during transport. PCR techniques are discussed later in the document in Section 7.1. Sterile saline will not neutralize the action of a sporicide or chemical. However, if it is used during characterization sampling (on surfaces that do not contain sporicides), it may help to preserve the viability of *B. anthracis* spores.

Some of the sampling devices can be purchased pre-moistened or they can be pre-moistened prior to collecting a sample. CDC recommends the use of a neutralizing buffer as the pre-moistening solution in their validated swab and wipe-sampling and analysis methods (CDC 2012a). The CDC developed methods for processing macrofoam swabs and cellulose sponge wipes from samples collected on environmental surfaces. These processing protocols use traditional culture methods and yield semi-quantitative estimates of the amount of *B. anthracis* contamination on a sample The CDC collection procedures for the validated swab and wipe method and a non-validated gauze method are provided on the CDC website at www.cdc.gov/niosh/topics/emres/surface-sampling-bacillus-anthracis.html.

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6.1.2.1 Swab Samples

Swabs are appropriate for sampling small [< 100 square centimeters (cm^2)] non-porous surfaces. Swabs work best for small areas like crevices, corners, supply air diffusers, air return grills, and hard-to-reach places. The CDC currently recommends using synthetic or macrofoam swabs for the collection of *B. anthracis* spores on smooth, non-porous surfaces (CDC 2012a). The LRN laboratories are capable of processing samples collected in accordance with this sample collection protocol using the prescribed swab type.

6.1.2.2 Wipe Samples

Wipes are appropriate for sampling larger (> 100 cm^2) non-porous surfaces, such as walls, desks, and non-carpeted floors. Wipe sampling can be performed using either cellulose sponges or gauze. The CDC currently recommends using a cellulose sponge wipe for the collection of *B. anthracis* spores on smooth, non-porous surfaces (CDC 2012a). The LRN laboratory or laboratories that will be analyzing the sponge wipe samples should be consulted prior to using this collection method to determine if that laboratory is capable of processing and analyzing the sample.

6.1.2.3 Vacuum Samples

The primary sample collection method for sampling large porous surfaces (> 600 cm^2) for *B. anthracis* spores is vacuum sampling. Collecting samples by vacuuming is advantageous for covering large, non-porous surfaces and porous surfaces such as carpeting, ceiling tiles, ventilation systems filters, and upholstered furniture. This type of sampling also works well for capturing bulk powder or dust in hard-to-reach places. Vacuum sampling is also the best choice for sensitive items such as electronics and personal items, since it is less likely to cause damage compared to pre-moistened swabs and wipes. The LRN laboratory or laboratories analyzing the vacuum sampling devices should be consulted prior to using this collection method to determine if that laboratory is capable of processing and analyzing the sample. Currently, vacuum sampling and analysis methods have yet to be validated.

During vacuum sampling, bulk material is trapped by the dry collection media/filter by utilizing a small, HEPA vacuum cleaner or a small sampling pump to draw air through the filter. A number of sampling devices can be used to collect samples from porous materials including filter socks, 3M Forensics Vacuum filters, or 35 mm cassettes. The filter sock method utilizes a filter sock and attachment nozzle that fits onto the inlet nozzle of a HEPA vacuum hose. The 3M Forensics Vacuum filter is favored by law enforcement groups due to its ease of use in evidence collection protocols. This filter also attaches to a HEPA vacuum cleaner hose for sampling, though care should be exercised to regulate the power of the vacuum so the filter integrity is not compromised during sampling. The last option uses micro-vacuuming techniques to collect a

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sample using personal sampling pumps or carbon vane pumps. These pumps utilize a suitable filter contained in a closed-face, conductive sampling cassette to which a short section of plastic tubing cut at a 45° angle is added to the inlet. The EPA method for collecting vacuum sock samples is described in Appendix C. Information on proper packaging and shipping of vacuum socks can be found on the CDC website (CDC 2012b).

Vacuum samples must be collected using only HEPA vacuum cleaners. Conventional home or industrial vacuum cleaners should not be used for sample collection because they can further disperse spores if filtration is insufficient.

6.1.3 Air Samples

Air samples can be taken to determine 1) the extent of airborne contamination, 2) whether *B. anthracis* spores have migrated from the contamination zone, and 3) whether *B. anthracis* spores are still detected in the air after remediation. The primary methods for collecting airborne *B. anthracis* spores include filter media, impactors, and liquid and dry impingers. Sampling using filter media is the type of air sampling most commonly used, whereas the impinger method of sampling is rarely used. The need for data on viable versus non-viable spores should be evaluated prior to selecting an air sampling method (DHS 2006b). Commercially available air samplers and methods for collecting air samples are summarized in Appendix C.

6.1.3.1 Aggressive Air Sampling

AAS is a methodology used to confirm a negative finding of contamination in a space either as part of a public health investigation or as part of the clearance phase process after decontamination of a known contaminated area. The method involves 1) vigorous agitation of the surfaces in a space (using leaf blowers, for example) to aerosolize any particles, and 2) high-volume air samplers to acquire and concentrate aerosolized materials for analysis. The method also uses oscillating fans to keep any *B. anthracis* spores suspended. AAS originated as a testing method for asbestos abatement jobs. AAS is usually only performed after all the surface sampling results have been analyzed and results are negative. However, it is performed before removing critical barriers and negative-air units. As previously mentioned, in some situations, surface sampling may not be conducted for clearance, and AAS may be the only method used. AAS can be an important tool to determine the potential of *B. anthracis* spores to become re-entrained into the air from surfaces following the application of an energy source. Since inhalation is the exposure route of most concern, AAS was used as a final step in demonstrating the effectiveness of the remediation process in many of the 2001 anthrax terrorism incident bio-remediation projects (McKenna and Intrepido 2008). Used correctly, it provides an additional

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level of testing and complements the surface sampling to provide an overall more rigorous test and may add to the preponderance of evidence that a facility is free of detectable contamination.

6.1.4 Liquids and Soil

If applicable, soil and liquid samples can be collected using a variety of methods and equipment to assess whether they are contaminated with spores of *B. anthracis*. The sampling objective is to determine if any soil or liquids (e.g., decorative fountains, potted plants, and plumbing fixtures) are contaminated. This type of sampling can also be used as a tool for initial confirmation of contamination and evidence collection. Various methods for collecting liquid samples are described in Appendix C. When collecting soil, confer with the analytical lab for appropriate methods.

6.2 Sampling Team

Sampling teams should be composed of personnel who are trained to work with hazardous materials in a hot zone (a zone that contains, or is suspected to contain, highly virulent infectious organisms) (NFPA 2008, CFR 1994). The use of experienced investigators to conduct environmental sampling will provide the greatest likelihood of locating and identifying *B. anthracis* spores, if present. Additional information on sample data documentation and data management is found in Appendix D. Personnel should be trained in the appropriate disciplines necessary for sample collection, including sampling methods, equipment, and materials; knowledge of building systems; dissemination pathways; aerosol-generating procedures/equipment; and decontamination methods. As described in Section 6.2.1, a Health and Safety Plan (HASP) should be established at the site. Personnel should also be trained on the use of PPE, safety precautions, and hazards associated with sampling, and included in a medical program.

Personnel and team configurations may vary and should be optimized based on incident-specific requirements. A minimum of two persons is essential for conducting sample collection using aseptic techniques to minimize cross-contamination of the sample and any potential evidence.

6.2.1 Safety and Health

Individuals collecting environmental samples place themselves at substantial risk of exposure. Sample collection personnel work within suspected contaminated environments and their sampling activities may mobilize and even cause re-aerosolization of the *B. anthracis* spores. Therefore, precautions to protect investigators should be implemented prior to conducting an environmental sampling response. A HASP should be developed that includes the following

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elements: medical monitoring, training, and appropriate selection and use of PPE. Elements of a comprehensive medical program include medical countermeasures, medical screening, monitoring, and follow-up care. These recommendations can be found in a number of separate guidance documents that are referenced below. These documents should be reviewed prior to developing and implementing a HASP.

Relevant safety and health guidance documents are:

1. *Use of Anthrax Vaccine in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009* (CDC, 2010) (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5906a1.htm?s_cid=rr5906a1_e)
2. *Protecting Investigators Performing Environmental Sampling for Bacillus anthracis: Personal Protective Equipment* (NIOSH website accessed May 2012) (http://emergency.cdc.gov/agent/anthrax/environment/investigatorppe.asp)
3. *Recommendations for the Selection and Use of Respirators and Protective Clothing for Protection Against Biological Agents* (NIOSH, 2009) (http://www.cdc.gov/niosh/docs/2009-132/default.html)
4. Stern EJ, Uhde KB, Shadomy SV, Messonnier N. Conference report on public health and clinical guidelines for anthrax [conference summary]. Emerg Infect Dis [serial on the Internet]. 2008 Apr. (http://www.cdc.gov/EID/content/14/4/07-0969.htm)
5. *OSHA Anthrax E-Tools* (OSHA website accessed May 2012) (http://www.osha.gov/SLTC/etools/anthrax/index.html)

6.2.2 Aseptic Techniques

Aseptic technique is the operation or performance of a procedure or method under carefully controlled conditions to reduce the risk of exposure and prevent the introduction of unwanted material/matter (contamination) into a sample (ASTM 2010b). Aseptic sampling requires the designation of collector (sampler) and an assistant (assistant sampler or facilitator) who coordinate sample collection, packaging, and documentation. The assistant sampler is responsible for providing the sampler with the appropriate tools and facilitating collection. For example, opening and handing materials to the sampler as required, including sample collection containers, gloves, sampling media, other sampling materials, and packaging materials, as well as performing any administrative functions including communication, photography (FBI Laboratory Publication, Handbook of Forensic Services 2003), as well as ensuring the sample collection sheet is filled out. The sampler should be the only person to come in contact with the suspect *B. anthracis*. The sampler is also responsible for signing the final chain-of custody form outside of the hot zone.

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A critical element of aseptic sampling is the sampler and assistant sampler must have a new pair of non-powdered, nitrile or vinyl examination gloves for each sample collected. This layer of gloves is in addition to the gloves are part of standard PPE ensemble (that is, team members will have three or more layers of gloves on) for each sample collected. During sample collection involving direct contact with the collection media (e.g., gauze wipe), it is recommended for responders to wear sterile gloves to avoid introduction of any other organisms to the sample. The use of sterile gloves is not recommended when using sample collection devices not requiring direct contact with the collection media (e.g., swab or sponge with handle). Regardless of the sampling device selected, the gloves must be changed between samples.

6.3 Sample Collection Quality Assurance/Quality Control

Field blanks and media blanks (also referred to as negative controls) are taken for data authentication (EPA 2002) and should be submitted to the laboratory with other samples. Field blanks are used to identify and estimate sample contamination, which may occur immediately before and after sampling (evaluation of protocols), during shipment, or while awaiting measurement in the laboratory. Field blanks should be collected during sampling to enable determination of any cross-contamination that may occur due to techniques used by the members of the sampling team. It is good practice to collect one field blank for every 10 samples collected. Media blanks are unexposed samples, not taken to the field or shipped, used for background correction of sample readings or for recovery studies. Media blanks should also be submitted with samples for analysis ensuring the sample media had not been contaminated prior to sample collection. A discussion with the laboratory regarding the number of media blanks to include with the samples should also take place. Approximately 1 to 5 media blank samples should be included for each media type or lot number. Media blanks ensure each lot of medium is sterile and free of contamination. Field sampling teams should have standard operating procedures requiring the collection of field and media blanks. The CDC sample collection procedures (CDC 2012a) describe the collection of field and media blanks.

The following quality assurance procedures also apply:

- All instrumentation must be operated in accordance with operating instructions as supplied by the manufacturer unless otherwise specified.
- Equipment checkout/calibration activities occur prior to sampling/operation and must be documented.
- All mechanical equipment should undergo routine maintenance according to manufacturers' specifications.
- A regular schedule for maintenance and equipment upkeep should be coordinated for each piece of equipment.

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- Sampling equipment should be verified to be in working order prior to deploying with the environment sampling teams
- Potential cross-contamination should be minimized between samples.

6.4 Chain of Custody

A Chain of Custody (CoC) form documents transfer of sample custody from one individual to another, from the time the sample is collected until final analytical disposition. Each individual in possession of the sample must be noted by recording their signature on the form. The CoC record should include instructions for the laboratory technician as to analytical methods, potential dangers, and any pertinent handling procedures that should be observed. The CoC form should be kept separate from the sample (i.e., should not be placed with the sample) in order to preserve appropriate CoC. The CoC record must include at least the following information:

- All available information regarding the potential hazards associated with the agent;
- Handling procedures associated with the samples;
- Sample identification number;
- Sample concentration, if known;
- Sampling location;
- Collection date and time;
- Sample matrix;
- Names and signatures of the samplers; and
- Signatures of all individuals who had custody of the samples (EPA 2006a).

6.5 Information on Sample Packaging and Shipping

Environmental samples collected for the purpose of determining whether *B. anthracis* spores are present should be considered "Infectious Substances." As such, the shipper is responsible for establishing protocols to ensure these samples are correctly identified, classified, packaged, labeled, marked, documented, and shipped according to applicable federal and international regulations (ASTM 2010a). These regulations include:

- Public Health Service, 42 CFR Part 72,
- Department of Transportation,
- 49 CFR Parts 171-178,
- United States Postal Service, 39 CFR Part 111, and
- International Civil Aviation Organization (published by the International Air Transport

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Association), Dangerous Goods Regulation.

Investigators who handle and transport infectious substances must receive training on the preceding regulations prior to collecting samples for submission to an LRN laboratory. Triple-layer packaging (consisting of a watertight primary container, watertight secondary packaging, and a durable outer packaging) may be required.

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Section VII: Analytical Considerations

Consulting with the laboratory prior to selecting sampling and analysis methods is essential. When establishing sampling guidelines, an open dialog must be held with the laboratory to determine what requirements and procedures they may have. The samplers should discuss with the laboratory the number of samples expected to be collected, the sample collection methods, and the estimated time of sample delivery (EPA 2006a).

The analytical laboratory should provide information about:

- Names, contact information, directions and any special laboratory-specific instructions (forms, etc.)
- Guidance on preferred media and buffer solutions and discussion on the types and quantity of sample to be collected
- Chain of Custody (CoC) forms and requirements to deliver and drop off samples at the laboratory (EPA 2006a, ASTM 2010a)

The limiting factor in sample collection and analysis is the capacity of the laboratory to process and analyze these samples. Although the sampling team may be able to collect a large number of samples during a single sampling incident, the number of samples collected should be balanced against laboratory capacity and should be spread over a sufficient number of LRN laboratories to ensure adequate turnaround time to results. If it is not feasible to spread sample collection (and hence, sample analyses) out over a few days or to refer samples to a larger number of LRN laboratories, it will be necessary to prioritize samples so they may be processed and analyzed in a staged manner to achieve the result of sequential sampling (Emanuel et al. 2008).

7.1 Analytical Methods

A variety of methods are available for processing and analyzing samples for *B. anthracis*. The method for analysis of samples is selected based on the phase of the incident (purpose of sampling) and the time frame the results are needed. In some cases, multiple methods may be utilized to analyze a sample. It is up to the sampling plan coordinator in conjunction with the laboratory to determine the most appropriate method to suit the needs of the incident. In a bioterrorist attack, detection of *B. anthracis* is performed in a step-by-step manner. An overall response usually involves:

1) Presumptive and rapid analysis of limited, judgmental samples in the hot zone using on-site biological assessments such as hand held assays;
2) Confirmatory analysis of samples in the contaminated area using microbiological culture, biochemical, serological, and PCR to identify *B. anthracis*;

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3) Characterization of the extent of contamination using analytical methods such as PCR, immunoassays, and/or where feasible, culture followed by PCR or immunoassay.
4) Post-decontamination analysis of samples to determine presence or absence of viable (live) *B. anthracis* using a combination of microbiological culture, PCR, Rapid Viability PCR, and immunoassay methods

7.1.1 Standard Microbiological Laboratory Culture Method

Microbiological culture is a method of growing a microorganism for identification and determining concentration in the sample being tested. Culture on solid medium employs Petri dishes containing an agar-based growth medium for the growth of bacteria. Bacteria will grow as colonies on the surface of the medium. In the case of *B. anthracis,* each individual colony represents the growth of a single spore or a clump of spores. Another method is broth culture, in which spores are inoculated into a liquid nutrient medium. The microbe must be viable in order to grow on either solid or liquid medium. These methods usually take days before any confirmatory answer is available.

Culture is the gold standard for determining the presence of viable *B. anthracis*. Therefore, it is used during the initial response phase to confirm the presence of viable spores and during clearance sampling to confirm no viable spores remain after decontamination. Theoretically, culture can detect the presence of a single viable spore within a sample. Thus, culture has a lower limit of detection (LOD) than either an immunoassay (e.g., hand held assay) device or a nucleic acid amplification method (e.g., PCR).

7.1.2 Real-Time PCR-Based Analytical Methods

PCR is a method used for detecting *B. anthracis* DNA, which can provide presumptive results from a direct sample in 3 to 6 hours but does not assess spore viability. DNA amplification methods such as PCR depend on the hybridization of primers to their complementary sequences in the target gene of the test species. Once hybridized, DNA polymerase (e.g., Taq DNA polymerase) amplifies the target sequence millions of times in an hour, so the target gene is detected if present. Although PCR is both sensitive and specific, it is susceptible to inhibition by various compounds found in environmental matrices. This inhibition can result in a false negative result by contaminating DNA from the target organism (Buttner et al. 2004). PCR requires the laboratory to have specific equipment and the necessary supplies (e.g., primers and probes) to conduct the *B. anthracis* analysis. Neither the CDC nor the FBI recommends testing

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samples in the field using commercially available field PCR methods for the detection of *B. anthracis* spores (OSTP 2002).

Due to limitations associated with inhibition to compounds in the environment and the inability to identify viable spores, PCR analysis is not utilized to determine when clearance goals have been met. PCR is primarily utilized during the initial response phase while awaiting culture results which requires additional time for results and during characterization sampling. Characterization sampling is conducted after viable spores are identified during initial public health/law enforcement sampling identifies viable spores. In this case, PCR samples are assumed viable.

7.1.3 Comparison of Culture and Polymerase Chain Reaction Methods

Culture analysis is the principal method for determining quantitative information and is considered to be the definitive method for identifying the presence of viable spores. Culture analysis generally requires days to obtain data when compared to PCR, where results can be obtained within hours. The culture method is less expensive but also requires additional laboratory equipment, such as vacuum manifold systems to perform filter plate testing.

There are numerous advantages of PCR-based methods over traditional culture methods, including: 1) rapid detection, 2) specificity — critical selection of target genes and design of primers and probe provide detection at a single species level, 3) detection of agents in complex environmental samples in collection buffer, 4) detection of difficult-to-grow agents, 5) analysis of inactivated agents — samples suspected of containing highly potent and contagious agents can be inactivated before analysis by PCR, and 6) multiple gene targets per agent and multiple agents can be detected by multiplex PCR assays, thereby allowing high-throughput sample analysis. However, PCR-based analytical methods cannot determine the viability of *B. anthracis*. Additionally, the number (concentration) of spores or cells present in a sample by PCR cannot be determined. Comparison of features of culture versus PCR methods are presented in Table 7-1.

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Table 7-1. Comparison of Culture versus PCR for *B. anthracis*

Culture	PCR
Theoretical sensitivity of one spore	Lower detection limit is 50 - 100 spores
Requires organisms to be viable	Organisms can be viable or non-viable
Growth media has shelf life of 30 - 60 days	Primers and probes for real-time PCR available in LRN laboratories and have a shelf-life of 2 years (dehydrated and stored at 5°C) and 6 months (rehydrated and stored at 4°C)
Results available in 32-40 hours (includes time to subculture for purity)	Results available in 3 to 6 hours but delays may occur depending on the number of samples that are run
Results are considered by CDC to be definitive after PCR confirmation	Results are considered by CDC to be presumptive on direct sample but are confirmatory on pure culture
Growth of contaminating micro-organisms can mask target	Fewer problems with a large number of micro-organisms
Less expensive when compared to PCR	Susceptible to inhibition by compounds found in environmental matrices
No additional laboratory infrastructure required	Additional laboratory infrastructure required (e.g., separate rooms for extraction and amplification)

7.1.4 Rapid Viability PCR (RV-PCR)

The Rapid Viability PCR (RV-PCR) method is most useful for the analysis of samples collected during and after cleanup/decontamination because determining the presence or absence of viable (live) *B. anthracis* spores (in the presence of large number of inactive spores) is a key analytical requirement during this phase of response (Létant 2010, 2011). The method involves extraction of spores from sampling medium, permitting them to germinate in a culture broth, and using real-time PCR to detect the growth of viable bacteria. The RV-PCR method integrates high-throughput sample processing, short-incubation broth culture, and highly sensitive and specific real-time PCR assays to detect low levels of viable *B. anthracis* spores in the presence of challenges including high levels of dead spores, high levels of live, non-target cells and spores, and high levels of dust. This method can be more sensitive than the traditional culture-based method because the whole processed sample is used for analysis. It is relatively rapid, cost-effective, less labor-intensive, less prone to inhibition by environmental matrices, and less prone to interference by outgrowth of other bacteria, fungi, other microbes, and other biological

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material in the sample. It also provides higher-throughput and generates significantly less bio-hazard and other laboratory wastes than the culture-based method.

7.1.5 Hand-Held Assay-Based Immunoassay (HHA)

HHAs, also known as Test Tickets or Smart (Sensitive Membrane Antigen Rapid Test) Tickets, are hand-held devices containing small chromatographic strips. The device exposes the strip to possible contamination, and then indicates whether contamination was detected. They are also known as Immunochromatographic Lateral Flow Assays. They are the most user-friendly assays and mostly used for preliminary screening of samples in the field. Usually, these tests take approximately 15 minutes. However, the detection specificity has been inferior to other detection methods and has led to false positive results. The Executive Branch does not recommend field-testing using commercially available HHAs for the detection of *B. anthracis* spores (OSTP 2002). Results from such on-site biological assessments are not public health actionable, meaning decisions regarding public health action are pending until confirmatory testing is completed. The DHS's Science and Technology Directorate continues to work to improve the specificity and sensitivity of these commercial field test kits and HHAs, and this strategy will be updated as new information becomes available.

7.2 Method Validation

Method validation is the process of proving a sampling method or analytical method is acceptable for its intended purpose (EPA 2002). The International Organization for Standardization (ISO) defines validation as the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. Validation includes the characterization of the method performance parameters including accuracy, precision, ruggedness, robustness, sensitivity, specificity, LOD, limit of quantification, reproducibility, linearity, and range (EPA 2006a). Using validated methods is important because it minimizes inconsistencies in the collection, transport, extraction, and analysis of samples. It enables a better interpretation of results and lends itself to comparison of results between independent incidents.

At present, two methods for sampling and analyzing *B. anthracis* on non-porous surfaces have been validated (Hodges 2010, Hodges 2006, Rose 2004, Rose 2010). These methods utilize a cellulose sampling sponge and a macrofoam swab as the sampling media. The collection protocols are available to the public on the CDC website (CDC 2012a).The laboratory processing protocols have been shared with all of the LRN laboratories via a secure website and these laboratories are trained and equipped to analyze these samples.

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7.3 Optimizing Sample Processing and Analysis

Sample analysis can be optimized depending on the type of information sought from the sample analysis. If qualitative data are acceptable during the initial characterization phase and it is presumed that any *B. anthracis* spores are viable, each sample can be quickly processed and analyzed (within hours) for *B. anthracis* signatures using PCR analytical techniques that provide information on the presence of the DNA of the agent in the sample. Performing such an analysis may require running a second, more specific analysis in order to determine viability by culturing the sample, which generally requires an additional 16-20 hours to obtain results for *B*. anthracis. The IC/UC will determine whether all or a portion of the samples will be analyzed by PCR and/or culture. PCR analysis is regarded as a qualitative analysis method in that results provide the presence or absences of DNA signatures in the sample. Quantitative culture analysis provides an estimate of the magnitude of contamination of viable spores. The magnitude of contamination is important for selection of the decontamination method and evaluating the efficacy of the decontamination technology by comparing pre- and post-decontamination sample results. PCR analysis during characterization sampling can expedite the sample analysis and save the laboratories valuable time and resources.

Another optimization process that can be conducted is batching or pooling sample analyses. The pooling or batching of sample analyses is performed by combining a number of similar discrete samples in the laboratory after individually collected samples have been prepared for analysis. An aliquot of each sample's elution is combined and analyzed as one sample. The main advantage of pooling samples for analysis is the reduction in the number of analyses that must be performed; however, certain laboratory processing steps still occur on each individual sample. The principal disadvantage is that combining the eluent from many samples essentially dilutes the portion that will be cultured from each sample which in turn raises the amount that is needed to be present in positive samples to ensure detection, hence, increases the risk of a false negative result. As a rule of thumb, site characterization sampling (i.e., prior to determining whether to decontaminate a space or not) presents the most beneficial case for pooling samples, since contamination has a higher likelihood of being present. If the result is positive and details about the specific location of the positive sample are needed, individual analysis can be done on each individual sample. Pooling of samples may not be beneficial in the post-decontamination phase, since spore concentrations should be lower after decontamination and the risk of a false negative result due to dilution is substantially increased

While pooling samples for analysis can make best use of available analytical resources, care should be taken when deciding which samples to pool for analysis. It should be done by the IC/UC in a logical manner (similar to composite sampling) that is consistent with the level of delineation desired between areas, surfaces or locations. Additionally, current validated analytical procedures do not consider pooling of samples. Advice and recommendations on the details of procedures for preparing and analyzing pooled samples should be secured from

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technical experts and/or the validating authority to ensure that the process used and the results are rational and comprehensible extensions of validated methods. The decision to pool samples for analysis will be based on the type of information that can be gained from the results.

7.4 Sample Transportation and Storage

Because samples must be transported to the laboratory, and processing and analyzing samples takes time, test results will not be immediately available. Samples should be transported to the laboratory as quickly as possible. Results are reported within hours or days after samples are submitted depending on the type of analysis conducted.

The *B. anthracis* viability and stability when collected with moist samples (swabs, wipes/sponges) depend on the wetting agent. Endospores are not likely to germinate in saline- or buffer-moistened collection media. However, the sample matrix may influence germination if sufficient nutrients are present. In general, samples should be transported to the laboratory at 5° C and analyzed as rapidly as possible to minimize the loss of viability and maintain sample integrity. Samples should be refrigerated upon arrival to the laboratory at 5°C until the sample can be processed. The lower temperature also minimizes endospore germination (DHS 2007b). CDC conducted a shipping integrity study on macrofoam swabs (see Appendices B and C). Based on the findings of the study, CDC recommends sampling media (cellulose sponges and macrofoam swabs) are shipped on ice or on cold packs in order to maintain a temperature between 2° — 8°C (Perry 2010). CDC recommends processing samples within 48 hours of sampling to ensure maximum recovery of spores (Rose 2010).

Dry specimens for determining the presence of *B. anthracis* spores may consist of "bulk" powders or vacuum samples. These specimens should be stable as long as they are kept dry, in the dark (to avoid ultraviolet exposure) and shipped at ambient temperature. Once in the laboratory, they can be stored in a cool, dark, dry place until analyzed. The length of time they can be stored without loss of viability may depend upon the sample matrix and the presence of sporicidal agents (DHS 2007b).

7.5 Laboratory Analysis Quality Assurance/Quality Control

Generation of analytical data of known and documented quality is a critical factor in the accurate assessment of and appropriate response to *B. anthracis* contamination incidents. Generating data of sufficient quality requires analytical laboratories to: 1) have trained personnel, 2) acquire and maintain required supplies, equipment, and reagents, 3) conduct the appropriate quality assurance QA/QC procedures to ensuring all measurement systems are in control and operating, 4) document all analytical results, and 5) document analytical QA/QC procedures and corrective actions.

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In general, analytical QA/QC requirements for pathogen methods include an initial demonstration of measurement system capability, as well as the capability of the laboratory and the analyst to perform the method with the required precision and accuracy. Ongoing analysis of control samples should also be performed to ensure the continued accuracy and reproducibility of the analytical results. QA/QC procedures should be performed each time a test is performed to ensure the quality of analytical results.

7.6 Interpretation of Data

Sample preparation methods have varying extraction efficiencies. This means some methods are better at extracting the *B. anthracis* spores or *B. anthracis* DNA from the sample matrix than other methods. Thus, the efficiency of the sample preparation method should be reviewed with the laboratory so that there is an understanding of the extraction efficiency. This information is crucial when combined with knowledge of the LODs of the analytical method (EURACHEM 1998). A LOD is the smallest amount of analyte that can be distinguished from background with 95% confidence. In addition to extraction efficiency, various sample collection methods have various recovery efficiencies. Recovery and extraction efficiencies may depend on the concentration of contaminant, the type of surface to be sampled, and the sample collection method. Hence, *B. anthracis* could be present in the environment and yet not detectable by the analytical method because of low recovery and/or extraction efficiencies, as well as analytical uncertainties. Ideally, the LODs of the analytical method for the range of samples it will be applied to should be low enough to detect with high confidence levels of a biological agent at or above risk-based exposure limits (DHS 2006b). Currently, there are no data to support a risk-based exposure limit for *B. anthracis* (Hong, T., P. L. Gurian, and N. F. Dudley Ward, 2010.).

After the laboratory has completed analysis of the samples, they must perform appropriate validation testing of their results and evaluate them for data surety and authentication prior to submission (Emanuel et al. 2008).

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Appendix A

CDC Surface Sampling Procedures for *Bacillus anthracis* Spores from Smooth, Non-Porous Surfaces

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Surface sampling procedures for *Bacillus anthracis* spores from smooth, non-porous surfaces

May13, 2010
Revised April 26, 2012

GENERAL

These sampling procedures were prepared by the Centers for Disease Control and Prevention (CDC) to provide standardized methods for industrial hygienists, or other trained samplers under the direction of sampling experts, to use when sampling for *Bacillus anthracis* (*B. anthracis*) spores. These procedures supersede previous CDC procedures for collecting environmental samples for *B. anthracis*, including *Comprehensive Procedures for Collecting Environmental Samples for Culturing Bacillus anthracis*, which were developed during the 2001 anthrax terrorist events. As stated in that guidance, CDC planned to update the guidance as new information becomes available. In particular, one major change is the recent efforts by CDC to validate methods for the laboratory processing and analysis of *B. anthracis* spores.

These procedures are meant to be used for collection of samples on smooth, non-porous surfaces and can be used in both indoor and outdoor environments. Examples of non-porous surfaces are stainless steel, painted wall board, floor tile, or wood laminate. Each sampling method has its specific uses and advantages. Sampling methods must be coordinated with the laboratory to ensure that they are ready to accept and process all the samples. This is particularly important if deviating from the validated sampling procedures.

Swabs are appropriate for sampling small surfaces or hard to reach locations of less than 4 inches square (in^2), like crevices, corners, supply air diffusers, air return grills, and hard-to-reach places. Wipes are appropriate for sampling larger non-porous surfaces including walls, desks, and floors. An interagency effort known as the Validated Sampling Plan Working Group (VSPWG) is currently developing a document titled *Reference Guide for Developing and Executing Bacillus anthracis Sampling Plans in Indoor Settings,* which outlines approaches and methodologies to characterize and guide remediation of indoor sites with potential or actual contamination. The VSPWG document, once published, should be consulted for additional information about strategies and guidance for sampling *B. anthracis*. This document will also assist with the interpretation of results for samples collected with macrofoam swabs and cellulose sponges on smooth, non-porous surfaces following these collection procedures.

Note: Additional information regarding *Bacillus anthracis* sampling, including recommendations for protecting investigators while sampling, are available at emergency.cdc.gov/agent/anthrax/environment/ and www.cdc.gov/niosh/docs/2009-132/default.html.

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The collection of samples associated with a crime scene or suspicion of a criminal event should be coordinated with law enforcement authorities. Sampling teams need to be aware that samples collected may be or become criminal evidence, and certain additional procedures associated with sample collection will be necessary.

MACROFOAM SWAB PROCEDURE

SWAB MATERIALS

1. Gloves, nitrile
2. Ruler, disposable, and masking tape or sample template, disposable, sample area size 4 in^2 (26 cm^2)
3. Macrofoam swab, sterile, 3/16 inch thick medical-grade polyurethane foam head, 100 pores per inch, thermally bonded to a polypropylene stick (such as the Sterile Foam Tipped Applicators Scored with Thumb Stop [Puritan, Guilford, Maine; catalog number 25-1607 1PF SC] or equivalent)
4. General neutralizing buffer that will inactivate halogen disinfectants and quaternary ammonium compounds, 10 milliliter (mL), sterile (such as the Neutralizing Buffer [Hardy Diagnostics, Santa Maria, California; catalog number K105] or equivalent)
5. Screw-cap centrifuge tubes, sterile, 15 mL (such as 15 mL High-Clarity Polypropylene Conical Centrifuge Tube [Becton Dickinson, Franklin Lakes, New Jersey; catalog number 352097] or equivalent)
6. Sample labels or permanent marker
7. Re-sealable plastic bag, 1-quart or smaller
8. Re-sealable plastic bag, 1-gallon or larger

SWAB SAMPLING PROCEDURE

1. Wearing a clean pair of gloves over existing gloves, place the disposable template over the area to be sampled and secure it. If the template cannot be used, measure the sampling area with a disposable ruler, and delineate the area to be sampled with masking tape.
2. Remove the sterile swab from its package. Grasp the swab near the top of the handle. Do not handle below the thumb stop.
3. If the sterile swab is not pre-moistened, moisten the sterile swab by dipping it in the 10 mL container of neutralizing buffer solution. Remove any excess liquid by pressing the swab head on the inside surface of the neutralizing buffer solution container.

> Note: Once a sterile swab has been moistened, the remaining neutralizing buffer solution and container must be discarded.

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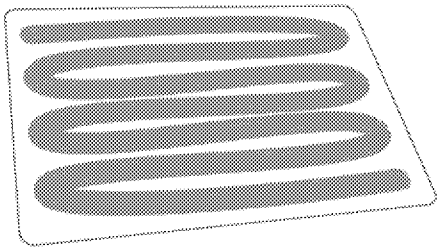
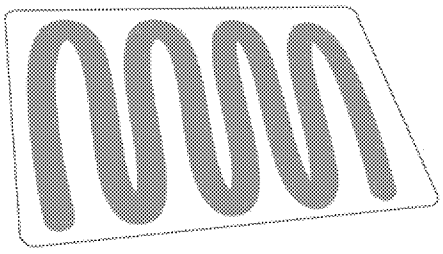
4. Swab the surface to be sampled using the moistened sterile swab. Use an overlapping 'S' pattern to cover the entire surface with horizontal strokes.

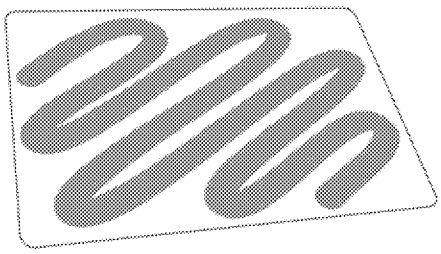


Note: Depending on the design of the swab, a rolling motion can be used when swabbing the surface to maximize swab contact with the surface.

5. Rotate the swab and swab the same area again using vertical 'S'-strokes.



6. Rotate the swab once more and swab the same area using diagonal 'S'-strokes.



7. Place the head of the swab directly into a sterile screw-capped centrifuge tube. Break off the head of the swab by bending the handle. The end of the swab handle, touched by the collector, should not touch the inside of the tube. Securely tighten the screw-cap and label the tube (e.g., unique sample identifier, sample location, initials of collectors and date and time sample was collected). Collection tubes and re-sealable bags may be pre-labeled to assist with sampling efficiency.
8. Place the sample container in a re-sealable 1-quart plastic bag. Securely seal and label the bag (e.g., sample location, date and time sample was collected, and name of individual collecting the sample).

Note:Remove excessive air from the re-sealable plastic bags to increase the number of samples that can be shipped in one container.

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9. Dispose of the template, if used.
10. Remove outer gloves and discard. Clean gloves must be worn for each new sample.

CELLULOSE SPONGE PROCEDURE

CELLULOSE SPONGE MATERIALS

1. Gloves, nitrile
2. Ruler, disposable, and masking tape or sample template, disposable, sample area size 100 in^2 (645 cm^2)
3. Sponge, sterile, pre-moistened with 10 mL neutralizing buffer solution, 1.5 by 3 inches cellulose sponge folded over a handle (such as the 3M™ Sponge-Stick [3M, St. Paul, Minnesota; catalog number SSL-10NB] or equivalent)[a] or sponge, sterile, dry, 1.5 by 3 inches cellulose sponge folded over a handle (such as the 3M™ Sponge-Stick [3M, St. Paul, Minnesota; catalog number SSL-100] or equivalent) and general neutralizing buffer that will inactivate halogen disinfectants and quaternary ammonium compounds, sterile, 10 mL (such as the Neutralizing Buffer [Hardy Diagnostics, Santa Maria, California; catalog number K105] or equivalent)
4. Screw-cap specimen container, sterile, individually wrapped 4 ounce (such as General Purpose Specimen Container [Kendall Healthcare, Mansfield, Massachusetts; catalog number 8889-207026] or equivalent)
5. Sample labels or permanent marker
6. Re-sealable plastic bag, 1-quart or smaller
7. Re-sealable plastic bag, 1-gallon or larger

CELLULOSE SPONGE SAMPLING PROCEDURE

1. Wearing a clean pair of gloves over existing gloves, place the disposable template over the area to be sampled and secure it. If a template cannot be used, measure the sampling area with a disposable ruler, and delineate the area to be sampled with masking tape. The surface area sampled should be less than or equal to 100 in^2 (645 cm^2).
2. Remove the sterile sponge from its package. Grasp the sponge near the top of the handle. Do not handle below the thumb stop.
3. If the sterile sponge is not pre-moistened, moisten the sponge by pouring the 10 mL container of neutralizing buffer solution over the dry sponge.

   Note: The moistened sponge should not be dripping neutralizing buffer solution.
   Note: Any unused neutralizing buffer solution **must** be discarded.

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[a] Additional sponges with limited recovery efficiency data available include the Versalon Non-Woven All-Purpose Gauze Sponge (Kendall Healthcare, Mansfield, Massachusetts; catalog number 8042), Bacti-Sponge (Hardy Diagnostics, Santa Maria, California; catalog number SK711), Cellulose Sponge with DE Broth (Solar Biological, Ogdensburg, New York; catalog number BS-10BPB-1), and Sponge-Wipe (Micronova, Torrance, California; catalog number SWU-99 [cut into 2 by 2 inches).

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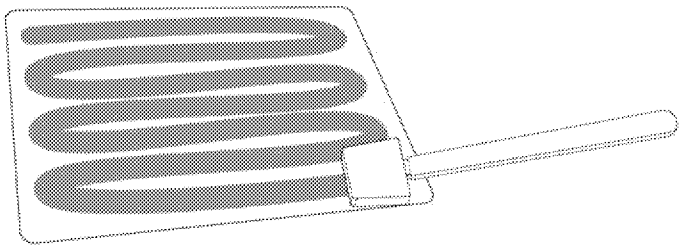
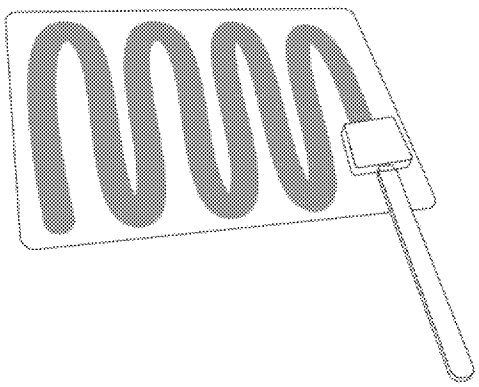
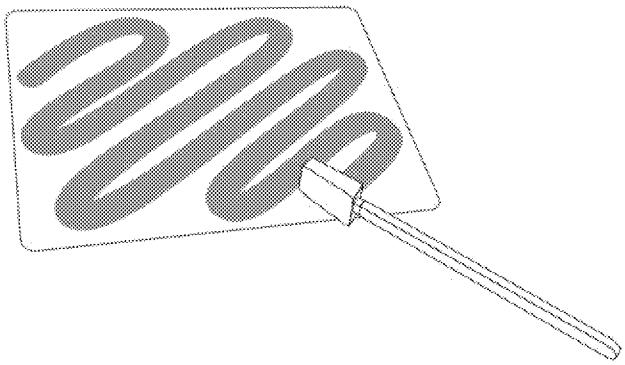
4. Wipe the surface to be sampled using the moistened sterile sponge by laying the widest part of the sponge on the surface, leaving the leading edge slightly lifted. Apply gentle but firm pressure and use an overlapping 'S' pattern to cover the entire surface with horizontal strokes.



5. Turn the sponge over and wipe the same area again using vertical 'S'-strokes.



6. Use the edges of the sponge (narrow sides) to wipe the same area using diagonal 'S'-strokes.



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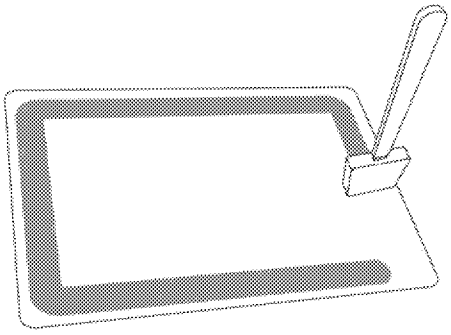
7. Use the tip of the sponge to wipe the perimeter of the sampling area.



8. Place the head of the sponge directly into a sterile specimen container. Break off the head of the sponge by bending the handle. The end of the sponge handle, touched by the collector, should not touch the inside of the specimen container. Securely seal and label the container (e.g., unique sample identifier, sample location, initials of collector and date and time sample was collected).
9. Place the sample container in a re-sealable 1-quart plastic bag. Securely seal and label the bag (e.g., sample location, date and time sample was collected, and name of individual collecting the sample). Specimen containers and re-sealable bags may be pre-labeled to assist with sampling efficiency.

   Note: Remove excessive air from the re-sealable plastic bags to increase the number of samples that can be shipped in one container.

10. Dispose of the template, if used.
11. Remove outer gloves and discard. Clean gloves should be worn for each new sample.

GAUZE PROCEDURE

GAUZE MATERIALS

Note: This sampling and analytical method has not been validated by CDC. A standard sampling procedure is provided in the event that the macrofoam swab or cellulose sponge methods cannot be utilized.

1. Gloves, nitrile
2. Gloves, sterile, nitrile
3. Ruler, disposable, and masking tape or sample template, disposable, sample area between 144 in^2 (929 cm^2)
4. Gauze, sterile, non-cotton, polyester blend sponge or rayon/polyester blend, 2 by 2 inches (such as the Versalon All-Purpose Sponge [Kendall Healthcare, Mansfield, Massachusetts; catalog number 8042; includes two gauze squares/packet] or equivalent)
5. General neutralizing buffer that will inactivate halogen disinfectants and quaternary ammonium compounds solution, 10 mL, sterile (such as the Neutralizing Buffer [Hardy Diagnostics, Santa Maria, California; catalog number K105] or equivalent)

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6. Pipette, 5 mL, sterile, individually wrapped (such as the Greenwood Products' Sterile 5mL Standard Transfer Pipette [Greenwood Products, Inc., Middlesex, New Jersey; catalog number GS137038] or equivalent)
7. Screw-cap specimen container, 4 ounce, sterile, individually wrapped (such as General Purpose Specimen Container [Kendall Healthcare, Mansfield, Massachusetts; catalog number 8889-207026] or equivalent)
8. Sample labels or permanent marker
9. Re-sealable plastic bag, 1-quart or smaller
10. Re-sealable plastic bag, 1-gallon or larger

GAUZE SAMPLING PROCEDURE

1. Wearing a pair of gloves over existing gloves, place the disposable template over the area to be sampled and secure it. If the template cannot be used, measure the sampling area (144 in^2) with a disposable ruler, and delineate the area to be sampled with masking tape.
2. Partially peel open the sterile gauze package carefully exposing the gauze.

   Note: The sterile gauze should not be touched without sterile gloves.

3. Measure 5 mL of neutralizing buffer solution from the 10 mL container using a disposable pipette and apply to sterile gauze in its original packaging. Remove outer gloves.
   Note: The moistened gauze should not be dripping neutralizing buffer solution.
   Note: Any unused neutralizing buffer solution and the pipette **must** be discarded.

4. Don a pair of sterile gloves.

   Note: Sterile gloves are required when sampling with gauze because of the direct contact with the sampling media.

5. Remove one of the sterile gauze (if two per package) and dispose of or retain the other gauze as a field blank (see section 4.1).
6. Completely unfold the remaining moistened sterile gauze, and then fold in half.
7. Wipe the surface to be sampled using the moistened sterile gauze, fingertips should be held together and apply gentle but firm pressure. Use an overlapping 'S' pattern to cover

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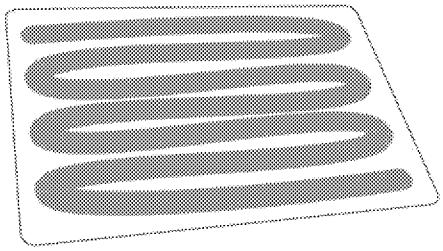
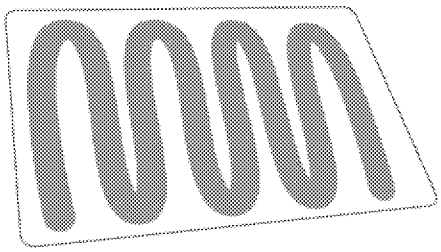
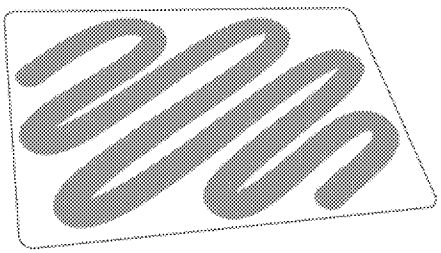
the entire surface with horizontal strokes.



8. Fold the exposed side of the gauze in and wipe the same area again using vertical 'S'-strokes.



9. Fold the exposed side of the gauze in once more and wipe the same area using diagonal 'S'-strokes.



10. Fold the gauze, exposed side in, and place it into a sterile screw-cap specimen container.
11. Securely tighten the screw-cap and label the container (e.g., unique sample identifier, sample location, initials of the collectors and date and time sample was collected).
12. Place the sample container into a re-sealable 1-quart plastic bag. Securely seal and label the bag (e.g., sample location, date and time sample was collected, and name of individual collecting the sample). Specimen containers and re-sealable bags may be pre-labeled to assist with sampling efficiency.

    Note: Remove excessive air from the re-sealable plastic bags to increase the number of samples that can be shipped in one container.

12. Dispose of the template, if used.
13. Remove outer gloves and discard. Clean sterile gloves should be worn for each new sample.

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BLANKS

FIELD BLANKS

Field blanks are samples handled exactly the same as those used to collect field samples, except they are not allowed to come into contact with the contaminated surface. It is used to estimate contamination arising from preparation for sampling, sampler technique, and shipment and storage prior to analysis. The number of field blanks collected should be equal to at least 10% of the samples collected. Field blanks should be collected while in the contaminated area. While wearing clean (sterile gloves for handling gauze), the macrofoam swab, cellulose sponge, or gauze should be removed from its packaging, moistened (as needed, see sections 3.1, 3.2 and 3.3), and then placed in the appropriate container (either a centrifuge tube or specimen container). An aliquot of the unused portion of the opened neutralizing buffer solution should also be collected when using macrofoam swab, cellulose sponge, or gauze media that are not pre-moistened.

MEDIA BLANKS

Media blanks are unexposed samples used for background correction of sample readings or for recovery studies. Provide two unopened sample media (macrofoam swab, cellulose sponge, or gauze) per lot used and provide two unopened, unused samples of the neutralizing buffer solution (if not using pre-moistened media) as media blanks to the processing laboratory.

DECONTAMINATION

SAMPLE BAG DECONTAMINATION

1. Place multiples of the re-sealable 1-quart plastic bags into a 1-gallon re-sealable plastic bag. Securely seal the 1-gallon re-sealable plastic bag and label the bag (e.g., identify samples contained in the re-sealable plastic bag, sample locations, date and time samples were collected, and name of individual collecting the samples).
2. Decontaminate the outer surface of the larger re-sealable plastic bag using a fresh pH-adjusted bleach solution (household bleach diluted 1:9; pH-adjusted to 6.8-8.0) with a 10-minute contact time before the re-sealable plastic bag leaves the contaminated area. This solution can be prepared by:

   Step 1: Mixing one part household bleach (5.25 to 6.0 % sodium hypochlorite) with 5 parts water (v/v);
   Step 2: Adding 1 part white vinegar; and
   Step 3: Adding 3 parts of additional water.

   Note: Additional information about decontamination is available at www.epa.gov/opp00001/factsheets/chemicals/bleachfactsheet.htm.

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3. Thoroughly dry the outside of the re-sealable plastic bag.
4. Complete a chain of custody form.

   Note: Once the outer re-sealable plastic bag is decontaminated, it should not be opened outside of appropriate containment in a laboratory.

5. Place the larger re-sealable plastic bag into an appropriate container for shipping (See Sample Shipment section).

DECONTAMINATION OF BAGS CONTAINING DOCUMENTATION

1. Place sample sheets and other documentation in a separate re-sealable plastic bag. The sheets should be placed two to a bag with the face of each sheet facing out. Securely seal and label the bag (e.g., corresponding sample locations, date and time samples were collected, and name of individual collecting the samples).

   Note: It is important to only write on one side of the paper, the face, when collecting information.
2. Decontaminate the outer surface of the larger re-sealable plastic bag using a fresh pH-adjusted bleach solution (household bleach diluted 1:9; pH-adjusted to 6.8-8.0) with a 10-minute contact time before the re-sealable plastic bag leaves the contaminated area. This solution can be prepared by:

   Step 1: Mixing one part household bleach (5.25 to 6.0 % sodium hypochlorite) with 5 parts water (v/v);
   Step 2: Adding 1 part white vinegar; and
   Step 3: Adding 3 parts of additional water.

   Note: Additional information about decontamination is available at www.epa.gov/opp00001/factsheets/chemicals/bleachfactsheet.htm.
3. Thoroughly dry the outside of the re-sealable plastic bag.
4. Complete a chain of custody form.

   Note: Once the outer re-sealable plastic bag is decontaminated, it should not be opened outside of appropriate containment.
5. Place the larger re-sealable plastic bag into an appropriate container for shipping.

SAMPLE SHIPMENT

1. Transport all samples to the processing laboratory on wet ice or on cold packs.

   Note: Samples may be stored at 2°C–8°C prior to processing and should be processed within 48 hours of collection.

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2. Appropriate chain of custody forms and analytical request forms should be included with each shipment sent to the processing laboratory. Containers used to transport the samples and accompanying contaminated documentation and equipment should be prepared and shipped according to the appropriate regulations for transporting infectious. The most current Code of Federal Regulations, International Air Transport Association guidelines, and other appropriate regulator or guidance publications should be consulted for compete instructions. The shipper is responsible for ensuring adherence to the most current and appropriate regulations.

Note: Do not transport contaminated equipment/supplies in the same container as the samples.

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Appendix B
Swab and Wipe Sample Interpretation

This Appendix provides technical details of sampling studies to guide the interpretation of data resulting from the use of recommended sampling methods. The data reflect variations in sampling efficiency with bacterial surface coverage, with type of surface, and with variations in the sampling device and other characteristics of the recommended sampling method, given that the realities of any response may dictate some variation from recommended procedures.

Information provided in this appendix is used by technical experts in public health and environmental recovery to inform their consultation with incident command or other authoritative decision makers in the response to a contamination event.

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B.1. Swab Sampling Performance

A multi-center validation study involving 12 laboratories was conducted to quantify the performance of a macrofoam swab method using a pure inoculum of *B. anthracis* spores (Hodges 2010). Steel coupons (4-in^2) (26-cm^2) were inoculated with a known concentration of *B. anthracis* spores suspended in 95% ethanol, the inoculum was allowed to dry, and the 26-cm^2 area was sampled with a macrofoam swab pre-moistened with phosphate buffered saline with 0.02% Tween 80 (PBST). To simulate samples with dust and other organisms, some swabs were dipped in a slurry of PBST plus a well characterized dust (A-3, Powder Technology, Inc, Burnsville, MN) before sampling. Laboratories were sent coded swabs in six shipments (three with dust, three without dust). The swabs were processed according to the LRN protocol. Colonies of *B. anthracis* were counted and the numbers compared to the known inoculum level to determine the percent recovery. The results for swabs without dust or other organisms are shown in Table C-1. It should be noted that swabs with dust present yielded recoveries (55,0%, 27.9% and 42.6% for 1, 2, and 4-$\log_{10}$ inocula, respectively), but since the dust content and character will vary from site to site, CDC chose to present the conservative estimate for interpreting contamination on a surface. The macrofoam swabs were pre-moistened with PBST for this study, but in a laboratory comparison, using neutralizing buffer as a pre-moistening liquid was found to result in equivalent recovery efficiency as PBST. Alternate elution buffers may also alter the recovery efficiency of the method; phosphate buffer alone was not as effective at eluting the spores from the swab, though 0.0 5% Tween 20 in buffer was found to be equivalent to 0.02% Tween 80 in buffer.

Table B-1. Recovery Efficiencies Using Macrofoam Swab Sampling and Processing Procedures for *B. anthracis* on Stainless Steel, no dust present.

***B. anthracis* Spores/26 cm^2 Area [Average (SD)][(a)]**	**Number of Swabs**	**Spores Recovered [Average (SD)]**	**% Recovery [Average (SD)]**
49 (7)	118	13 (7)	25.7 (15.2)
506 (86)	120	80 (33)	15.8 (6.6)
41,768 (7415)	116	12,835 (4,392)	31.0 (10.9)
All inoculum levels	354	-	24.2 (13.6)

[(a)] SD= standard deviation

Using other types of swabs for sampling may affect recovery efficiency. This possibility was evaluated by Rose et al. (2004) who inoculated 10^4 spores of *B. anthracis* Sterne in 95% ethanol onto 26 cm^2 stainless steel coupons. After drying, four types of pre-moistened and dry swabs (cotton, foam, polyester, and rayon) were used to remove the spores and were processed according to the LRN method (Rose 2004,). The recovery efficiencies of four swab materials are shown in Table B-2. Pre-moistened macrofoam and cotton swabs were the most efficient of the

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four swab types evaluated; pre-moistened polyester and rayon swabs were significantly less efficient. While all swab materials give biased estimates (under-estimates) of surface concentrations, the pre-moistened macrofoam swab is the preferred swab device. It is important to note that sensitivity, specificity, and limit of detection (LOD) have only been established for macrofoam swabs used to sample stainless steel surfaces.

If samplers choose to use another type of swab, pre-moistened cotton swabs have similar recovery efficiency to that of macrofoam swabs, though cotton may contain substances that inhibit PCR reagents, which should be considered if PCR is performed directly on the swab eluent. The differences in recovery efficiency between swab types may be due to differences in the ability of specific swab materials to remove spores from the surface or due to differences in the ability of the spores to be released from the swab during processing.

Table B-2. Recovery Efficiencies of Four Pre-moistened Swab Materials when Sampling Stainless Steel Surfaces

Swab Material	Cotton	Foam	Polyester	Rayon
Percent Recovery (SD)	41.7 (14.6)	43.6 (11.1)	9.9 (3.8)	11.5 (7.9)

The LRN method for the macrofoam swab has been validated for smooth non-porous surfaces no greater than 4 in^2 (26 cm^2). Both culture and PCR can be used to determine the presence of spores of *B. anthracis*. When viable spores are present, culture results are provided by the LRN laboratory as "*B. anthracis* spores/cm^2 recovered." A result of "No *B. anthracis* spores detected" should be interpreted in the context of the LOD of this assay (the smallest amount of analyte that can be distinguished from background with 95% confidence), which is 20 spores/26cm^2 (ca. 0.8 spores/cm^2) for stainless steel surfaces. One other caveat needs to be mentioned. Reporting the results as spores/cm^2 assumes that each colony on the agar plate results from the growth of a single spore. In reality, it may result from the growth of a single spore or from a clump of spores. Tween 80 and vortexing are used in the LRN method to help disperse clumps of spores that may be present in the samples, but may not do so completely. PCR is used to confirm *B. anthracis* colonies, and the results are reported as "positive" or "negative." PCR does not differentiate between viable or non-viable spores if performed on the sample directly.

B.2. Wipe Sampling Performance

A multi-center validation study involving 9 laboratories was conducted to quantify the performance of an LRN sponge-stick wipe processing protocol (Rose, 2011). Stainless steel coupons (100 in^2) (645 cm^2) were inoculated with known quantities (26, 528, and 33,140 spores) of *B. anthracis* Sterne spores in 95% ethanol. Seven coupons at each spore concentration were sampled with cellulose sponge-wipes pre-moistened with neutralizing buffer (Sponge-Stick, SSL10NB, 3M St. Paul, MN).

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Dust containing a consortia of organisms (A-3, Powder Technology, Inc, Burnsville, MN) were then added to the wipes. A total of 33 wipes were sent to each laboratory in three separate shipments of 11 wipes each. Each shipment consisted of 7 wipes that were used to sample the coupons inoculated with one of the spore quantities, one blank, one dirty blank (background organisms only) and two positive controls (wipes inoculated with the same spore concentration plus background organisms). Upon receipt by the participating laboratory, wipes were stored at 2-8° C until processing. Laboratories processed wipes within 48 hours of sampling according to the LRN protocol. The results are shown in Table B-3. The mean % recovery for all inoculum levels was 29.7% (SD 16.4%).

Table B-3. Recovery Efficiencies using Pre-moistened Sponge-wipes and LRN Processing Procedures for *B. anthracis* on Stainless Steel

B. anthracis Spores/645 cm^2 Area [Average (SD)][a]	Number of Sponge-wipes	Spores Recovered [Average (SD)]	% Recovery [Average (SD)}
26.1 (13.6)	63	9.1 (6.1)	32.4. (24.5)
536.0 (134.1)	63	132.6 (63.0)	24.4 (11.2)
33,140.0 (6,743)	56	9,984.0 (2,707)	30.1 (8.2)

(a) SD= standard deviation

Studies with directly inoculated controls were performed to determine recovery efficiency during wipe processing only. Higher percent recovery for the controls (63.4% (SD 27.5%) vs. 28.9% (SD 16.7%), $p < 0.01$) suggests that a portion of the spores were not removed from the surface with the sponge-stick. The results from sponge-wipes processed by the LRN protocol are given as "*B. anthracis* spores/cm^2 recovered." The results should be interpreted in the context of the LOD of this assay (the smallest amount of analyte that can be distinguished from background with 95% confidence), which is 20 spores/645cm^2 (ca. 0.03 spores/cm^2) for stainless steel surfaces. Reporting the results as spores/cm^2 assumes that each colony on the agar plate results from the growth of a single spore. In reality, it may result from the growth of a single spore or from a clump of spores. Tween 80 and vortexing are used in the LRN method to help disperse clumps of spores that may be present in the samples, but may not do so completely.

Additional evaluations of the validated sponge-wipe protocol were conducted to investigate the effects of validated sponge-wipe protocol with lower spore concentrations and on other surface materials on recovery efficiency, false negative rate, and limit of detection (Krauter 2012). The surrogate spore *Bacillus atrophaeus* var. globigii was employed for these evaluations. The study results show a roughly linear dependence of recovery efficiencies (RE) on surface roughness, where the smoothest surfaces (e.g., stainless steel and ceramic tile) have the higher RE and lower false negative rates. The findings are shown in Table B-4.

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Table B-4. Recovery Efficiency and False Negative Rate of Sponge-wipes (averaged over all *B. atrophaeus* spore concentrations) for Each Surface Material with the Corresponding Roughness Index Measurement

	Recovery efficiency, Mean (%)	False negative rate, Mean	Roughness Index (μm)
Stainless steel	48.1	0.1229	0.13
Ceramic tile	48.9	0.1812	0.59
Vinyl tile	25.6	0.2551	1.63
Faux leather	30.3	0.1417	3.27
Painted wood	25.5	0.2000	4.11
Plastic panel	9.8	0.4792	5.88

Both of the above-mentioned sponge – wipe evaluations (Rose 2011, Krauter 2012) were conducted by eluting the spores from the sponge-wipes with phosphate buffered saline (pH 7.2) containing 0.02% Tween 80 using a stomacher. Deviating from the method by using other elution buffers or elution techniques may lead to different recovery efficiencies, sensitivities, specificities, false negative rates and/or limits of detection.

In a limited study, rayon gauze wipes (2" x 2") pre-moistened with phosphate buffered saline (pH 7.2) containing 0.02% Tween 80, were evaluated as an alternative to Sponge Sticks (Hodges et al 2006b). The mean percent recovery of spores sampled from stainless steel using rayon gauze wipes was 25.4% (SD 18.9%). Thus, pre-moistened gauze wipes may be equivalent to pre-moistened sponge wipes, though validation performance data is not yet available (sensitivity, specificity, reproducibility, precision, LOD).

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Appendix C

Non-Validated Sampling Methods

(Adapted from Emanuel et al. 2008)

The Working Group recognizes that an array of sampling methods beyond those described for smooth surfaces in Appendix A may be used in the characterization of a contaminated space, both prior to and after recovery efforts. While these currently non-validated methods may yield information that is more qualitative than quantitative in nature, their application can provide important indicators of the state of a potentially contaminated space. Accordingly they are included here with general instructions to make their application as uniform as possible, in order to help standardize their application.

Use of these methods should be only be considered after consultation with the on-scene response coordinators and participating analytical laboratories, since interpretation of resulting data from these methods may be difficult.

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Bulk Sampling

Procedure for Bulk Sampling
The method presented below is for collecting a bulk sample.

Materials and Equipment
The following equipment should be available in order to collect bulk samples:

- Non-powdered sampling gloves
- Disposable or decontaminated spade, spatula, scoop or trowel
- Sterile forceps, scissors, scalpel, or sharp knife
- Sterile sample container of proper size
- Sealable plastic bags
- Documentation materials, digital camera, indelible ink pen, and logbook
- Custody seals, tags, and Sample forms

Procedures

1. Ensure that all of the sample equipment is sterile prior to use.
2. Identify the spot to collect the sample.
3. Collect the sample wearing a pair of non-powdered gloves and document the sample area using a camera and in the logbook.
4. For solids, powders, or granular material, collect the laboratory-specified quantity of the bulk sample with a dedicated sterile spoon, trowel, or spatula and place material into a sterile sample container.
5. For large pieces of material or vegetation that require analysis, discuss with the laboratory the material to be sampled. Large pieces may not fit in the sample container and will need to broken, shaved, cut or chipped into a sterile sample container with dedicated sterile scissors, scalpel, or knife.
6. Place item or pieces of the item in an appropriate sterile sample container.
7. Secure the lid, label and attach the custody seal and triple bag the sample container into sealable bags.
8. Change into new gloves prior to collecting the next sample.
9. Decontaminate outer bag prior to leaving hot zone. This is usually done at the entrance of the personnel decontamination line.

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HEPA Vacuum Sampling

Procedure for HEPA Vacuum Sampling on Porous Surfaces

Materials and Equipment

- A portable HEPA vacuum with a nozzle and hose attachment
- Vacuum sample sock assembly with cardboard inlet nozzle
- Power source
- Non-powdered sampling gloves
- Sterile plastic screw-topped sample containers (conical vial or specimen cup)
- Sealable plastic bags
- Small plastic zip tie
- Documentation materials, digital camera, indelible ink pen, and logbook
- Custody seals and tags
- Chain-of-custody forms and shipping paperwork
- Disposable templates to delineate the sample area (optional)
- Isopropyl alcohol wipes

Procedure

1. For each sample collected ensure that a new pair of gloves are worn
2. Determine the location to collect the sample.
3. Wearing a pair of sterile gloves, place a sample template (if using) over the area to be sampled and document the sample area using a camera, and drawing a map in the logbook.
4. Place the cardboard vacuum filter sock inlet assembly securely into the vacuum hose nozzle.
5. With the vacuum on, place cardboard nozzle on the surface to be sampled and vacuum designated area using an overlapping 'S' pattern both in the horizontal and vertical directions. Collect the sample in an area up to several square feet at a rate of 3 – 5 seconds per foot.
6. Once the sample has been collected, turn off the vacuum and remove the cardboard filter sock inlet assembly from the vacuum nozzle.
7. Touching only the blue portion; remove the filter sock from the assembly tube, and zip tie the blue portion of the bag closed. Then place sock into a sterile sample container.
8. Secure the lid, label and attach the custody seal and triple bag the sample container into a sealable bag.
9. To prepare for the next sample, with the vacuum off, wipe the first several inches of the inside and outside of the vacuum nozzle with an isopropyl alcohol wipe and cover with a clean sample glove.
10. Change out the used gloves with new gloves prior to collecting the next sample.
11. Decontaminate outer sample bag prior to leaving hot zone. This is usually done at the entrance of the personnel decontamination line.
12. Package samples for transport.

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13. Fill out Chain-of-Custody form, and make a copy.
14. Secure samples in shipping container with Chain-of-Custody and attach Custody seals.
15. Fill out shipping manifest or contact courier.

Air Filter Samples

Procedures for Air Filter Sampling
Below is procedure for collecting air samples with an open-face filter cassette.

Materials and Equipment

- Calibrated personal sampling pump
- Rotameter (air flow meter) or dry cell calibrator
- 3-piece, 37-milimeter (mm) cassette preloaded with sterile 0.45 micron mixed cellulose ester (MCE), Gelatin or Teflon (PFTE) sample filter
- Flexible Tygon™ tubing
- Sterile tweezers
- Sterile non-powdered sampling gloves
- Cassette opening tool
- Sealable plastic bags
- Documentation materials, digital camera, indelible ink pen, and logbook
- Custody seals and tags
- Chain-of-custody forms and shipping paperwork

Procedure

1. To calibrate the sampling pump, take a 3-piece cassette with a preloaded filter and remove the inlet and outlet plugs. Connect flexible Tygon™ tubing from the inlet of the filter cassette to the outlet of the calibrator. Train by attaching one end of the Tygon™ tubing to the inlet of a dedicated open-faced . Attach another piece of Tygon™ tubing from the outlet of the filter cassette to the pump manifold.
2. Calibrate the pump flow rate to the rate specified by the method: greater than 2.5 liter per minute (LPM) for MCE or Teflon filters and 2.0 LPM for the gelatin filters. If using a rotameter for calibration, then it should be calibrated with a primary standard such as the dry cell calibrator before using. Rotameters are considered secondary standards.
3. When calibration has been completed, remove the filter cassette, cap the inlet and outlet with the plugs, and save the filter cassette for recalibration at the end of sampling. Record initial flow rate of the sample pump from the calibration in the logbook and on the Cain-of-Custody form. The flow rate is used to calculate the airborne concentration of the contaminant.
4. Don sterile non-powdered sampling gloves.
5. To prepare the open-faced cassette for sampling, utilize the cassette opening tool to remove the inlet section of the 3-stage cassette, leaving the other two sections in place.
6. Remove the outlet end plug and attach one end of the flexible Tygon™ tubing to the outlet of the cassette and the other to the pump.

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7. Place the sample cassette and the pump in the desired location and photo-document and map the location.
8. Turn on the pump and record the time. Be sure the sampling cassette is oriented at a 45 degree angle downward. This prevents large particles from being collected that otherwise would not be collected.
9. Document the location and the sample location using a camera, drawing a map, and recording notes in the logbook.
10. Once the sample has run for the specified amount of time, remove the cassette and replace the inlet stage and the outlet and inlet plugs. It is important to note that with gelatin filter sampling times should not exceed 30 minutes since the gelatin can dry out.
11. Triple-bag the sample filter cassette in sealable plastic bags.
12. Check the final flow rate of the sampling train. Place the calibration cassette in the sample train and check with a rotameter or a dry cell calibrator the final flow rate just as in the initial calibration. Record this value in the sample form, on the Chain-of-Custody, and in the logbook.
13. Pre and post sampling train calibration can be done either inside or outside the hot zone. For calibration outside the hot zone the sampling equipment must be protected from contamination or easily decontaminated. Otherwise, pre and post sampling train calibration should be done in the hot zone.
14. Label and attach a custody seal to the cassette.
15. Decontaminate the outer sample bag prior to leaving hot zone. This is usually done at the entrance of the personnel decontamination line.
16. Package samples for transport.
17. Complete the Chain-of-Custody form and any other paperwork and make a copy.
18. Secure samples in shipping container with Chain-of-Custody and attach Custody seals.
19. Fill out shipping manifest or contact courier.

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Air Impactor Samples

Procedures for Impactor Air Sampling

Below is procedure for collecting air impactor samples with petri dishes specific to the contaminant being sampled.

Materials and Equipment

- Calibrated high-flow sampling pump (28.3 LPM)
- Rotameter (air flow meter) or dry cell calibrator
- Calibration adapter for impactors
- Sterile single or six stage impactor
- Sterile Petri dish and agent-specific agar for each stage
- Flexible Tygon™ tubing
- Sterile non-powdered sampling gloves
- Sealable plastic bags
- Parafilm M® wax strips
- Sample labels and wax pencil
- Documentation materials, digital camera, indelible ink pen, and logbook
- Custody seals and tags
- Chain-of-custody forms and shipping paperwork

Procedure

1. For each sample collected, ensure that a new pair of sterile gloves is worn.
2. Set the pump flow rate to 28.3 LPM per minute or as specified in the analytical method, and turn it on.
3. To calibrate the impactor, aseptically remove the lids from the calibration set of Petri dish(es) and keep lids in a clean sealable plastic bag. For the single stage impactor, place each one calibration Petri dish on the stage and reassemble the impactor. For the 6 stage impactor, place one of the calibration Petri dishes on each of the impactor stages and reassemble the stages in the correct numerical order. Attach the calibration adapter to the top of the impactor. Attach flexible Tygon™ tubing from the impactor calibration adapter to the calibrator or rotameter inlet. Attach the second piece of tubing from the outlet of the impactor to the inlet of the sample pump. Turn on the calibrator and record the initial flow rate in the logbook.
4. Calibration of the sampling train can be performed outside the hot zone such as in the sample preparation area. If using a rotameter for calibration, then it should be calibrated with a primary standard such as the dry cell calibrator. Rotameters are considered secondary standards.
5. After calibration, remove the calibration Petri dishes from each stage of the impactor and cover with a lid. These can be reused for calibration several times until they begin to dry out and not more than one day.
6. In preparation to sample, aseptically remove lids from the sample Petri dish(es) and keep in a clean sealable plastic bag. For the single stage impactor, place one Petri dish on the stage and reassemble the impactor. For the 6 stage impactor, place on of the 6 Petri

dishes on each impactor stage and reassemble the impactor ensuring that the stages are in the correct numerical order. Connect the Tygon™ from the outlet of the impactor to the inlet of the pump.

7. Place the impactor and pump in desired sample location and photo document and map the location.
8. Start the pump and record the time sampling began and the time the sampling is completed. Sampling times should be between 10 to 15 minutes. At completion of sample time, don sterile gloves and aseptically remove the petri dish(es), cover with lids and seal each dish with Parafilm M® to secure, label each dish with the wax pencil including the stage number and place into sterile zippered sample bag upside down (agar oriented up).
9. Double bag each sample.
10. Decontaminate outer bag prior to leaving hot zone. This is usually done at the entrance of the personnel decontamination line.
11. For post sampling calibration, aseptically remove lids from each of the pre-calibration sample Petri dishes and place on the impactor stages. Attach the tubing to the calibrator and the pump as in the initial calibration.
12. Turn on pump and record the post sampling flow rate in the log book. Pre and post calibration flow rates are very important in determining final contaminate concentration.
13. Pre and post sampling train calibration can be done either inside or outside the hot zone. For calibration outside the hot zone the sampling equipment must be protected from contamination or easily decontaminated. Otherwise, pre and post sampling train calibration should be done in the hot zone.
14. Package samples for transport.
15. Fill out Chain-of-custody form, and make a copy.
16. Refrigerate samples or package with ice, ensuring agar does not freeze.
17. Secure samples in shipping container with Chain-of-custody and attach Custody seals.
18. Fill out shipping manifest or contact courier.
19. Prior to use to collect another sample, the impactor must be autoclaved.

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Impinger (Wet Method) Air Samples

Procedures for Impinger Air Sampling
Below is procedure for collecting air samples with an impinger using a wet method.

Materials and Equipment

- High Flow Sampling Pump
- Dry cell calibrator and stand
- Two sterile impinger, pump attachment, and sterile impinger fluid
- Teflon or Parafilm M® tape
- Flexible tygon tubing
- Sterile sample container bottle
- Sterile non-powdered sample gloves
- Documentation materials, digital camera and logbook
- Custody seals, sealable plastic bags, and tags
- Sample labels, documentation forms, permanent marker(s)
- Chain-of-custody forms and shipping paperwork

Procedure

1. For each sample collected, ensure that a new pair of sterile gloves is worn.
2. Aseptically fill an impinger with appropriate sterile fluid and attach to pump. This should be done outside the hot zone in a clean area.
3. Set up the sampling train by attaching Tygon™ tubing to outlet of impinger and the other end to inlet of the sample pump.
4. In a clean area, calibrate the sample train by attaching another piece of Tygon ™ tubing to the outlet of the impinger and the other end to a rotameter or dry cell calibrator. Adjust pump to the desired flow rate of 12.5 LPM. If using a rotameter for calibration, then it should be calibrated with a primary standard such as the dry cell calibrator before using. Rotameters are considered secondary standards.
5. After pre-sampling calibration, remove impinger, place caps or Parafilm M® over both the inlet and outlet of the impinger and set aside to use to check the flow rate after the sample is collected.
6. Don a new pair of sterile gloves and attach a second sterile impinger, filled with appropriate sterile fluid, to the sampling train.
7. Place sampling train in desired sample location and turn on pump.
8. Photo document sample location, draw map and record sample start time in the log book.
9. After sampling time has elapsed, turn off pump, don sterile gloves and aseptically remove the impinger.
10. Ascetically transfer impinger fluid to sample container bottle can be done either inside or outside the hot zone. If done outside the hot zone, place a cap or Parafilm M® over the inlet and outlet of the impinger. It is important to keep impingers upright to prevent loss of fluid due to leaking or spillage. Fluid transfer done outside the hot zone must be done in an appropriate fume hood. If impinger fluid will be transferred to sample container bottle in the hot zone, don sterile gloves and aseptically remove the impinger, transfer

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fluid to labeled, sterile sample container and seal the lid with Teflon or Parafilm M® tape.

11. Double bag the sample.
12. For post sampling train calibration, don sterile gloves and attach a fluid filled calibration impinger to the sample train as described in Step 4. Turn on pump and record flow rate. Record flow rate in log book.
13. Pre and post sampling train calibration can be done either inside or outside the hot zone. For calibration outside the hot zone the sampling equipment must have be protected from contamination or easily decontaminated. Otherwise, pre and post sampling train calibration should be done in the hot zone.
14. Decontaminate sample bag before leaving hot zone. This is usually done at the entrance of the personnel decontamination line.
15. Package samples for shipment including ice, if needed.
16. Complete Chain-of-custody form and place in sample shipment container.
17. Secure shipment container and complete shipping manifest.
18. Prior to another use, the impinger used to collect the sample must be autoclaved.

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Liquid Sampling for Biological Agents

Note: For drinking water samples please refer to the sample note at bottom of procedures

Materials and Equipment

- Non-powdered sample gloves
- Plastic or glass 1-liter sample bottle
- Bacon bomb sampler, Kemmerer sampler, Dip sampler, Bailer, or large 100 ml disposable syringe.
- Sealable plastic bags
- Parafilm M® wax strips or
- Teflon tape
- Sample labels and wax pencil
- Documentation materials, digital camera, indelible ink pen, and logbook
- Custody seals and tags
- Chain-of-custody forms and shipping paperwork
- Shipping Manifest

Procedure

1. For each sample collected, ensure a new pair of sterile gloves is worn
2. Ensure all equipment is sterilized or decontaminated prior to use
3. Select appropriate apparatus based on sample depth and locations. For example, in small puddles the syringe may be the best apparatus to use.
4. If a sample collection device was used, transfer the sample to an appropriate sized sterile plastic or glass container
5. To collect the sample directly into a bottle, remove bottle lid and protect from contamination by placing in new sealable plastic bag. Grasp bottle at the base with one hand and plunge bottle mouth down into the water to avoid introducing surface scum. For large sample volumes, the above approach may not be possible; therefore, a sterile transfer container may be needed.
6. If water body is deep and is static, an artificial current can be created, by moving bottle horizontally in the direction it is pointed and away from sampler collector
7. Tip bottle slightly upwards to allow air to exit and the bottle to fill
8. Pour out a small portion of the sample to allow an air space of 2.5-5 cm (1"-2") above each sample for proper mixing of sample before analyses
9. Cap the bottle and seal lid with Parafilm M®, Teflon tape or equivalent
10. Label samples.
11. Photo document sample at the sample location.
12. Double bag sample.
13. Decontaminate outer bag, if needed, in the hot zone.
14. Package sample(s) for shipment, including ice to keep sample cool.
15. Complete Chain-of-custody form and place in sample shipment container.
16. Secure shipment container and complete shipping manifest.

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* U.S. EPA. 2011 Comparison of Ultrafiltration Techniques for Recovering Biothreat Agents in Water. U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-11/103.
http://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=238310&fed_org_id=1253&address=nhsrc/si/&view=desc&sortBy=pubDateYear&showCriteria=1&count=25&searchall='water%20security'%20AND%20'biological'

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Surface Soil Sampling for Biological Agents

Materials and Equipment

- Non-powdered sample gloves
- Sterile stainless steel or plastic scoop or trowel
- Sterile 250 ml sample jar
- Sealable plastic bags
- Chain-of-custody forms and custody seals
- Sample labels, sample documentation form, permanent marker(s)
- Shipping Manifest

Procedure

1. For each sample collected, ensure a new pair of gloves is worn
2. Ensure all equipment is sterilized or decontaminated prior to use
3. Using a scoop or trowel, collect 50-100 g of soil from desired location (fill the container)
4. If possible remove rocks, vegetative matter, or sharp objects from soil
5. Place sample in appropriate sterile plastic container
6. Cap container with the sample jar lid
7. Label samples.
8. Photo document sample at the sample location, draw a map and log information in the logbook.
9. Double bag sample.
10. Decontaminate outer bag, if needed, in the hot zone.
11. Package sample(s) for shipment, including ice to keep sample cool.
12. Complete Chain-of-custody form and place in sample shipment container.
13. Secure shipment container and complete shipping manifest.

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Appendix D
Documentation and Decision Support Tools

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Several different software tools have been designed to manage and document data from sample collection as well as assist in developing grid and statistical sampling plans. Managing the data collected as part of a *consequence management* effort is very important. To ensure the integrity of sample results, various types of documentation need to be completed throughout the sampling process (i.e., from sample collection through sample analysis). The use of decision support tools can support the development of a sampling plan based on statistical sampling theory and the statistical analysis of sample results to support confident decision-making. It is critical to ensure that the information gathered can be easily and quickly shared among the various state, local, and federal agencies.

Since the collection of samples may be associated with a crime scene or suspicion of a criminal incident, the resulting information, the approach utilized to develop the sampling plan, and manner in which samples were collected will be factored into the usability of those samples in a court of law, as well as to ensure process quality. Sampling teams need to be aware that samples collected may be or become criminal evidence, and certain additional procedures associated with sample collection will be necessary.

D. 1 Sample Documentation

In order to provide accurate and high-quality information, it is important for sampling personnel to understand not only what needs to be documented, but also why it needs to be documented (Emanuel et al. 2008). To meet laboratory submission requirements, and to interpret sampling results, information about the sampling process must be documented and should include information about general site details as well as specific information about individual samples. Much of the needed general site information is documented in the sampling plan, described earlier in Section 4.4. Additional documentation and information can also be found in the Incident Action Plan (IAP). The IAP is developed by the IC/UC and describes tactical objectives and support activities for one operational period, generally 12 to 24 hours.

Information that should be documented includes:

- Procedures for collecting and processing the samples;
- Description of the items that may be sampled (e.g., desk, carpet, wallboard, etc.);
- Description of the location where the sample was collected and associated sample number (e.g., Room 110, sample collected from on top of file cabinet in North, East corner and sample number is 1011). This is very important so that a sample result can be associated to a specific item sampled and its location.
- Description of surfaces that must be sampled (e.g., porous, non-porous, rough, smooth, etc.) and surface materials or coating (e.g., plastic, metal, painted surface, etc.);
- Weather conditions, including temperature and wind.

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To meet the documentation needs for individual samples, sample collection, sample analysis request forms, and chain of custody forms should be completed. The information requirements in these forms are described in the next sections. Additional information that may also be important to document in sampler field notes includes:

- Notes regarding the sampling process that might be of interest to future analysis of the data (e.g., surface was noticeably contaminated with particulate material)
- The area that was sampled (e.g., a swab sample using a template with an area of 100 cm^2)
- Information about the photographs taken
- Document the method used to establish the location (e.g., measured with a tape measure, laser positioning system, GPS, manual location on a map, etc.)

The use of handheld data collection devices like a personal data assistant (PDA) improves the quality of the field data collected. A software program can be used to collect information for sample documentation. These programs offer a wide flexibility in managing the information electronically.

- A unique sample identification number, date, and time for each sample
- A detailed description of the matrices that was sampled (e.g., water, air, soil, solids, etc.)
- A COC form must be produced before samples can be transported from the site, and must have a signature confirming the collection and release of the samples
- Establishing a datum for sampling location identification (e.g., the origin location for a local coordinate system, UTM (Universal Transverse Mercator) coordinates, latitude/longitude, etc.)
- Sampling location, in X, Y, Z space relative to the origin location

D.1.1 Sample Collection Form

During sample collection in the hot zone, individual sample information should be recorded. However, recordkeeping should be kept to the minimum necessary as any documentation will have to be decontaminated upon leaving the contaminated area. The sample collection form serves as the documentation for the sampling incident. First, each sample should be given a unique sample identification number. In addition to the unique identification number, the following information should be recorded on the form:

- The date and time collected for each sample
- The type of sample (e.g., surface, air, and bulk, etc.)
- The type of sample collection technique (e.g., swab, wipe, sock vacuum, etc.)
- The orientation of the surface (e.g., horizontal, upwards, vertical, etc.)
- The surface area sampled (e.g., square centimeters wiped)

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- If desired, indicate whether the sample was prescribed as part of a probability-based sampling design, a judgmental sample, or other
- Documentation of sampler's name
- Other sample location information of note (e.g., on what floor the sample was collected, room number, area identifier, etc.)

D.1.2 Sample Analysis Submission Form

After sampling is completed, a sample analysis submission form should be finished and submitted to the LRN along with the samples. Sampling personnel should meet with or contact their local LRN to obtain this form. While individual LRN laboratories may have different required fields, the following information is included in any form:

- Submitter information
- Specimen type, suspect organism, and source
- Date and time collected
- Analytical processing request

D.1.3 Chain of Custody (COC) Form

A COC form documents transfer of sample custody from one individual to another, from the time the sample is collected until final analytical disposition. Each individual in possession of the sample must be noted by recording his or her signature on the form. The COC record should include instructions for the laboratory technician as to analytical methods, potential dangers, and any pertinent handling procedures that should be observed. The COC record must include at least the following information:

- All available information regarding the potential hazards associated with the agent
- Handling procedures associated with the samples
- Sample identification number
- Sample concentration, if known
- Sampling location
- Collection date and time
- Sample matrix
- Names and signatures of the samplers
- Signatures of all individuals who had custody of the samples (EPA 2006a)

An unbroken COC must be maintained for all samples from collection through analysis and archiving. In order to maintain COC, the form must be readily accessible when transferring samples from one individual to another. Therefore, COC forms should not be placed inside the

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primary sample containment. A copy of the record will be kept with the samples until they are analyzed and returned with the analytical results or will be maintained on site at the laboratory if samples are archived for later use or collection by law enforcement.

D.2 Data Management Plan

The Data Management Plan (DMP) establishes an overall plan for the data management requirements for a specific project. The purpose of the DMP is to provide the necessary management, control necessary sample nomenclature, maintain quality control information, Geographic Information System (GIS) information, and control and inventory of all data.

The primary functions of the DMP are as follows:

- record keeping
- data quality control
- storage and retrieval systems
- handling of classified data
- planning, scheduling, and delivery of data

D.2.1 Managing Large Amounts of Data

In managing large amounts of data, the decision makers should pre-plan their data management requirements. With large amounts of data, serious consideration should be given to utilizing a formal database structure for saving and querying data. Databases preserve relationships between sample data. Spreadsheet applications do not provide the same rigor of preservation of sample data attributes. In addition, spreadsheet applications may be too cumbersome to manage large data sets. With more comprehensive database structures, not only will the data associated with sample locations and analysis results be archived, but other spatial information such as facility maps and spatial mapping of results may be maintained as well.

Another consideration for managing large amounts of data is security. With a secure database, access can be managed through login privileges granted by the decision makers thereby limiting access to the data to those with a need-to-know. Data sharing can be managed with a more sophisticated database engine. There can also be allowances to limit which personnel have permission to modify data in the database, in order to preserve integrity of the data. For instance, a secure database will be critical in managing data associated with a terrorist threat response.

The staff that maintains the database should be aware of the structure of the database and the master key identifiers used to manage the data. There is a possibility for corruption of a database if the relationships are not maintained appropriately in the database. Care should be taken to maintain these relationships.

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D.2.2 Electronic Data Format

Whenever possible, data should be stored in an electronic database. There may be a need to export data from a database to a spreadsheet application in order to analyze the data with other tools (e.g., Excel, mapping software, etc.). There may also be a need to establish protocols for saving spatial information, such as CAD drawings, GIS maps, bitmap images, etc. Photographic documentation should also be considered in the specifications for electronic data storage and capture.

D.3 Decision Support Tools

If possible, the use of decision support tools throughout the response phases is recommended to help facilitate the design of a sampling plan. Decision support tools may be used to codify the processes for developing a sampling plan and to document the data and assumptions associated with the plan. These tools should facilitate better defensibility of the assumptions, goals and data associated with the project.

Decision support tools provide users with the following capabilities to:

- Develop DQOs
- Develop defensible sampling design plans (e.g., locating hotspots, testing hypotheses of the confidence in meeting a cleanup goal, etc.)
- Provide sampling locations via spatial representation
- Display building or site layout (e.g., engineering drawings)
- Document information associated with sample collection (e.g., sample collection method, location, surface type, sampling ID number, etc.), including electronic data capture with handheld devices
- Provide sample analyses results via spatial mapping
- Analyze data to determine statistical relationships and information suitable for decision making
- Optimize sampling design if an adaptive sampling strategy is desired

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Appendix E

Details on Application of Combined Judgmental and Random (CJR) Sampling Approach

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For the CJR sampling approach, several input parameters affect the required number of probabilistic samples. These include 1) the percent confidence (X%) desired, 2) the minimum percent (Y%) of the decision area stated to not contain detectable contamination, 3) the number of judgmental samples taken, 4) how much more likely it is a judgmental sample location contains detectable contamination than a probabilistic sample location, and 5) the expected *a priori* probability a judgmental sample will detect contamination. These parameters are discussed and guidance for selecting them is provided after the next paragraph.

An important assumption of the mathematical model used in the CJR approach is that the decision area can be divided into areas of "high" and "low" probabilities of being contaminated (the high probability areas need not be contiguous, and the same for low probability areas). The CJR model assumes all of the high probability areas are sampled judgmentally. In essence, the judgmental sample locations define the high probability areas in the sampling plan. Consequently, fewer probabilistic samples are necessary when more judgmental samples are taken and/or when locations with judgmental samples are more likely to contain detectable contamination. Fewer probabilistic samples are also necessary as the *a priori probability* that a judgmental sample will detect contamination increases.

The key parameters for the CJR sampling approach are briefly explained below with guidance on how to specify a value for each parameter.

- *Desired confidence (X%)*: The CJR sampling approach provides for stating that there is X% confidence that at least Y% of a decision area has no detectable contamination if all of the judgment and random samples obtained are non-detects. There is precedence in environmental regulations for specifying X = 95, but less or greater confidence may be deemed appropriate depending on risk/consequence evaluations.
- *Minimum percent (Y%) of the decision area that can be stated to not contain detectable contamination*: Ideally Y% would be 100%, but that would require sampling 100% of the decision area. When choosing the Y% parameter, the team must balance between resources/cost and risks/uncertainty. Higher Y% values require more samples. Often Y% will range between 90% and 99.5% with 99% often used.
- *Number of Judgment Samples*: The number of judgment samples taken will be determined using expert judgment, knowledge of the event, and previous experience. Judgment samples should be obtained from all areas where contamination is deemed to be most likely.
- *How much more likely it is that a judgment sample location contains detectable contamination than an uninformed random sample*: It is recommended that this parameter be between 1 and 3, unless there is significant evidence that it is higher. This parameter may be derived from expert opinion, knowledge of the event and/or experience from previous studies. If the value of 1 is chosen for this parameter, equal weight is given to the judgment and random samples.

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- *Expected a priori probability (p) that a judgmental sample will contain no detectable contamination:* This parameter is derived from expert opinion and/or results from previous sampling in the decision area. If the CJR sampling approach is being applied after decontaminating the area, information from previous studies regarding the effectiveness of the decontamination process may be used. Where proven, highly effective decontamination technologies are applied, the *a priori* probability might be quite high (0.90 to 0.99). If little is known about the possibility of contamination in the area, an uninformed *a priori* probability of 0.50 is used.

In dealing with contamination incidents, subject matter experts may recommend values of the above parameters, but the ultimate decision is with the IC/UC.

The CJR approach has been incorporated into the freely available Visual Sample Plan (VSP) software (VSP Implementation Team 2010, Matzke et al. 2010) that calculates the required number of random samples given the number of judgmental samples and other parameter values. The VSP software provides for selecting both judgment and random sample locations within the facility. Random samples can be placed either completely at random or using a systematic grid sampling scheme with a random start for the grid. The systematic grid will better protect against a large unsampled area where a large "hotspot" could go undetected. The number of random samples required also depends on the number of possible unique sample locations in the population. For a large facility the number of possible area samples (e.g., 10 cm x 10 cm wipes) can be very large. If a 3-dimensional representation of the facility is constructed in VSP, the number of possible area samples for the surfaces of interest is determined automatically and incorporated in the sample requirements calculations.

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Appendix F
Example of a Site-Specific Sampling Plan

Note: This plan was developed as part of an EPA biological remediation demonstration known as Bio-Response Operational Testing and Evaluation (BOTE II).

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF ENVIRONMENTAL CLEANUP
EMERGENCY RESPONSE UNIT

Site Specific Sampling Plan

Project Name: ___BOTE Phase 2_____ Site ID: _____

Author: _____ Company:_____. Date Completed: ___

This Site Specific Sampling Plan (SSSP) is prepared and used in conjunction with the Quality Assurance Plan (QAP) for the Emergency Response Unit for collecting samples during this Removal Program project. The information contained herein is based on the information available at the time of preparation. As better information becomes available, this SSSP will be adjusted.

When inadequate time is available for preparing the SSSP in advance of the sampling event, a Field Sampling Form may be prepared on-site immediately prior to sampling. This full length version of the SSSP is written after the sampling event and the completed Field Sampling Form attached to it.

1. Approvals

Name, Title	Telephone, Email, Address	Signature
On-Scene Coordinator		
ERU Quality Assurance Coordinator		

I. Project Management and Organization

2. Personnel and Roles involved in the project:

Name	Telephone, Email, Company, Address	Project Role	Data Recipient
		On Scene Coordinator	Yes
		Author of SSSP, START Project Manager	Yes

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		ERU Quality Assurance Coordinator	No
		START Quality Assurance Reviewer	Yes
		Sampling Leader	Yes

3. Physical Description and Site Contact Information:

Site Name	BOTE Phase 2	
Site Location	See Figure 1	
Property Size	See Figure 1	
Site Contact		**Phone Number:**
Nearest Residents		**Direction:**
Primary Land Uses Surrounding the Site	Commercial, university	

4. The proposed schedule of project work follows:

Activity	Estimated Start Date	Estimated Completion Date	Comments
SSSP Review/Approval			
Mobilize to / Demobilize from Site			
Sample Collection			
Laboratory Sample Receipt			Saturday receipt may be requested
Laboratory Analysis			
Data Validation			

5. Historical and Background Information

Describe briefly what you know about the site that is relevant to sampling and analysis for this investigation.

On Wednesday, September 7,2011, a 56 year-old female is admitted to the Eastern Idaho Regional Medical Center (EIRMC) in Idaho Falls, Idaho after experiencing vomiting, confusion, incoherent speech and a severe headache for the past 6 hours. On September 9, the LRN laboratory confirms *B. anthracis* by Polymerase Chain Reaction (PCR) and from a culture of the cerebrospinal fluid. She dies from inhalation anthrax on September 10, 3 days after admission.

On Thursday, September 8,2011, a 64 year-old male is admitted to the Portneuf Medical Center (PMC) in Pocatello, ID with symptoms suggestive of pneumonia. His illness

began on September 6. As of September 10, the patient remains hospitalized with inhalation anthrax and is being treated intravenously with several antibiotics.

On Saturday, September 10,2011, an epidemiological investigation links both patients to the same place of employment in Idaho Falls. The deceased woman, Ann Halation, was identified as the secretary to the President of Southeastern University. Her office is located in the Administration Building on the university campus. The hospitalized male, Austin Powders, was determined to be a janitor employed at the same building.

6. Conceptual Site Model

Example: Contaminant: Mercury
Transport Mechanism: vapor moving on air currents
Receptors: people living in the house

Contaminants: B. anthracis

Transport Mechanisms: Moving on air currents, on surfaces in the building

Receptors: people through inhalation or direct contact of spores

7. Decision Statement

Examples: 1) Determine whether surface contamination exceeds the established action level;
2) Determine appropriate disposal options for contaminated materials.

The decision(s) to be made from this investigation is/are to:

1) Determine extent of contamination within building.
2) Determine the appropriate decontamination method for the building and related items.
3) Determine if contamination is contained to the building or not.

8. Action Level

State the analyte, concentration, and units for each selected action level. Describe the rationale for choosing each action level and its source (i.e. MTCA, PRG, ATSDR, etc.) Example: The action level for total mercury in soil is 6.7 mg/kg (from Regional Screening Level residential).

The Action Level is being determined by the UC.

II. Data Acquisition and Measurement Objectives

9. Site Diagram and Sampling Areas

A Sampling Area is an area within in which a specific action will be performed.
Examples : 1) Each drum on the site is a Sampling Area;
2) Each section of sidewalk in front of the residence is a Sampling Area;

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3) Each sampling grid section is a Sampling Area.

Figure 1, 2, and 3 display the site.
Each room is a decision area.
The outdoors is a decision area.

10. The Decision Rules

These can be written as logical If…, Then.. statements. Describe how the decisions will be made and how to address results falling within the error range of the action level. Examples: 1) In the Old Furnace Sampling Area, the soil in the area around the furnace structure will be excavated until sample analysis with XRF shows no mercury concentrations in surface soil above the lower limit of the error associated with the action level, 18.4 mg/kg. 2) If the concentrations of contaminants in a SA are less than the lower limit of the error associated with the action level, then the area may be characterized as not posing an unacceptable risk to human health or the environment and may be dismissed from additional RP activities. The area may be referred to other Federal, State or Local government agencies.

The following statement(s) describe the decision rules to apply to this investigation:
To be determined by the UC with the help of the TWG. Sample results will be utilized by the TWG to recommend a decon method for the building

11. Information Needed for the Decision Rule

What information needs to be collected to make the decisions – this includes non-sampling info as well: action levels, climate history, direction of water flow, etc. Examples: Current and future on-site and off-site land use; wind direction, humidity and ambient temperature; contaminant concentrations in surface soil.

The following inputs to the decision are necessary to interpret the analytical results:

Action Levels, extent of contamination (areas and concentration), cost effectiveness of each decon technology, dispersal method, status of HVAC system since attack

12. Sampling and Analysis

For each SA, describe:

1. *sampling pattern (random, targeted, scheme for composite)*
2. *number of samples, how many to be collected from where, and why*
3. *sample type (grab, composite)*
4. *matrix (air, water, soil)*
5. *analytes and analytical methods*
6. *name and locations of off-site laboratories, if applicable.*

Non-Impact Rooms: Evaluate if contamination has been tracked into rooms that are not believed to have been impacted by directly by source the source letter. Tracking could be by foot traffic or fomite (i.e. cross contaminated mail, personal belongings). Also, to determine if contamination passed through the HVAC system and impacted the room.

- 1 discrete sample at entry on the floor
- 1 horizontal composite sample (discretionary) floor or surface sample

- 1 ceiling vent sample
- 1 optional discretionary sample (i.e. electro-static surface, mail drop areas, etc)

Total rooms: 23 Total samples: Up to 92

"NIOSH " Rooms: More fully characterize rooms that have had limited sampling from the NIOSH investigation.

- 1 discrete sample at entry on floor
- 1 optional discretionary sample (i.e. electro-static surface, mail drop areas, etc)

Total rooms: 6 Total samples: Up to 12

2nd Floor Exclusion Zone: Provide quantitative analysis of high-spore load areas to potentially support decontamination planning efforts and estimate spore size distribution.

- 2 six-stage impactor samples (Rooms 201 and 201A)
- 2 quantitative discrete samples in each room (discretionary)
- 1 vertical sample per room

Total rooms: 4 Total samples: Up to 24

Hallways / Stairs: To determine if contamination was tracked via movement from source areas.

- One 4-point composite of the upper hallway
- Once HVAC return register
- One 3-point composite from each stairwell

Total areas: 3 Total samples: Up to 4

Outside Evaluation: To determine if contamination has been tracked away from the building

- 4 discretionary discrete samples from concrete areas

Total areas: 1 Total samples: Up to 4

RV-PCR Evaluation: To provide samples to evaluate EPA's rapid viability PCR

Total samples: 12

Field Blanks: Handle samples in the field without collection to support Quality Assurance

Total samples: Up to 15

13. Applicability of Data (place an X in front of the data categories needed, explain with comments)

Do the decisions to be made from the data require that the analytical data be:

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1) definitive data, 2) screening data (with definitive confirmation) or 3) screening data (without definitive confirmation)?

*X___**A) Definitive data** is analytical data of sufficient quality for final decision-making. To produce definitive data on-site or off-site, the field or lab analysis will have passed full Quality Control (QC) requirements (continuing calibration checks, Method Detection Limit (MDL) study, field duplicate samples, field blank, matrix spikes, lab duplicate samples, and other method-specific QC such as surrogates) AND the analyst will have passed a Precision and Recovery (PAR) study AND the instrument will have a valid Performance Evaluation sample on file. This category of data is suitable for: **1) enforcement purposes, 2) determination of extent of contamination, 3) disposal, 4) RP verification or 5) cleanup confirmation.***
Comments:

*___**B) Screening data with definitive confirmation** is analytical data that may be used **to support preliminary or intermediate decision-making** until confirmed by definitive data. However, even after confirmation, this data is often not as precise as definitive data. To produce this category of data, the analyst will have passed a PAR study to determine analytical error AND 10% of the samples are split and analyzed by a method that produced definitive data with a minimum of three samples above the action level and three samples below it.*
Comments:

*___**C) Screening data** is analytical data which has not been confirmed by definitive data. The QC requirements are limited to an MDL study and continuing calibration checks. This data can be used for making decisions: **1) in emergencies, 2) for health and safety screening, 3) to supplement other analytical data, 4) to determine where to collect samples, 5) for waste profiling, and 6) for preliminary identification of pollutants**. This data is not of sufficient quality for final decision-making.*
Comments

14. Special Sampling or Analysis Directions

Describe any special directions for the planned sampling and analysis such as additional quality controls or sample preparation issues. Examples: 1) XRF and Lumex for sediment will be calibrated before each day of use and checked with a second source standard. 2) A field blank will be analyzed with each calibration to confirm the concentration of non-detection. 3) A Method Detection Limit determination will be performed prior to the start of analysis so that the lower quantitation limit can be determined. 4) If particle size is too large for accurate analyses, the samples will be ground prior to analysis. If the sample contains too much moisture for accurate analyses, the sample will be decanted and air dried prior to analysis.

N/A

15. Method Requirements

[Describe the restrictions to be considered in choosing an analytical method due to the need to meet specific regulations, policies, ARARs, and other analytical needs. Examples: 1) Methods must meet USEPA Drinking Water Program requirements. 2) Methods must achieve lower quantitation limits of less than 1/10 the action levels.3) Methods must be performed exactly as written without modification by the analytical laboratory.]

Only CDC approved methods will be used for sampling and analysis.

16. Sample Collection Information

[Describe any activities that will be performed related to sample collection]

The applicable sample collection Standard Operating Procedures (SOPs) or methods will be followed and include:
Field Activity Logbook SOP
Sample Packaging and Shipping SOP
Instrument SOPs:
Other SOPs: Attachment A: CST Sample Collection and QC Sample Collection Protocol, Attachment B: ENVIRONMENTAL SAMPLING GUIDELINES AND ANALYTICAL APPROACH FOR BIOLOGICAL RESPONSE PLANS

17. Optimization of Sampling Plan (Maximizing Data Quality While Minimizing Time and Cost)

[Describe what choices were made to reduce cost of sampling while meeting the needed level of data quality. Example: The XRF will be used in situ whenever possible to achieve accurate results. Reproducibility and accuracy of in situ XRF analyses will be checked by collecting, air drying, analyzing and comparing five in situ samples at the start of sampling. Where interferences are suspected, steps will be taken to eliminate the interferences by mechanisms such as drying, grinding or sieving the samples or analyzing them using the Lumex with soil attachment.]

The format for sample number identification is summarized in Table 1. Sample collection and analysis information is summarized in Table 2.

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Table 1 SAMPLE CODING **Project Name:** ____BOTE Field Exercise_____ **Site ID:** _10ZZ_____		
SAMPLE NUMBER [1]		
Digits	**Description**	**Code (Example)**
1,2,3,4	Year and Month Code	1109
5,6,7,8	Consecutive Sample Number (grouped by SA as appropriate)	0001 (First sample of SA)

SAMPLE NAME / LOCATION ID [2] ***(Optional)***		
1,2,3	Floor and Room number	i.e. 101, 201
4,5	Matrix Code	AR – Air PR – Product QC – Quality Control SB - Swab WP – Wipe WT – Water
6,7	Consecutive number for each area	01

Notes:
(1) The Sample Number is a unique, 8-digit number assigned to each sample.
(2) The Sample Name or Location ID is an optional identifier that can be used to further describe each sample or sample location.

Table 2. Sampling and Analysis

Data Quality	Sampling Area	Matrix	Sampling Pattern	Sample Type	Data Quality	Number of Field Samples	Analyte or Parameter	Method Number	Action Level	Method Quant. Limit	#/type of Sample Containers per Sample	Preservative	Hold Time	Field QC
Lab Analysis	All Decision Areas	Product Wipe Swab Air	Targeted	Grab Composite	Definitive	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	Duplicate Blank

Note: For matrix spike and/or duplicate samples, no extra volume is required for air (unless co-located samples are collected), oil, product, or soil samples except soil VOC or NWTPH-Gx samples (triple volume). Triple volume is also required for organic water samples (double volume for inorganic).

Table 3. Common Sample Handling Information

Analysis Type	Sub Analysis	Matrix	Analytical Method	Container Type	Minimum Volume	Preservative	Temperature/ Storage	Hold Time	Source
Metals	Metals Not including Mercury or Hexachrome. Includes TAL, PP, RCRA lists)	Solid	EPA 6000 / 7000 Series	Glass Jar	200 g	n/a	None	6 months	SW-846 ch. 3
		Aqueous	EPA 6000 / 7000 Series	PTFE or HDPE	600 mL	HNO_3 to pH < 2	Not listed	6 months	SW-846 ch. 3
	Mercury	Solid	EPA 7471B	Glass Jar	200 g	n/a	≤ 6° C	28 days	SW-846 ch. 3
		Aqueous	EPA 7470A	PTFE or HDPE	400 mL	HNO_3 to pH < 2	Not listed	28 days	SW-846 ch. 3
	Hexavalent Chromium, (Hexachrome, Cr+6)	Solid	Lab-specific soil extraction modification, EPA 7196A	Glass Jar	100 g	n/a	≤ 6° C	28 days to extraction	SW-846 ch. 3
		Aqueous	EPA 218.6 (Drinking Water)	PTFE or HDPE	400 mL	n/a	≤ 6° C	24 hours	SW-846 ch. 3
	XRF	Solid (in situ; on the ground surface)	6200	none	n/a	none	none	Analyze Immediately	n/a
		Solid (ex situ)	6200	plastic bag	200 g	none	none	6 months	n/a
VOCs	VOCs / BTEX	Solid	EPA 5035 / 8260B	*	*	*	*	2 days to lab / 14 days	SW-846 ch. 4
		Aqueous	EPA 8260B	Amber Vial with Septa Lid	2 x 40 mL	HCl to pH< 2	≤ 6° C (headspace free)	14 days	SW-846 ch. 4
SVOCs	SVOCs / PAHs	Solid	EPA 8270D	Glass Jar	8 ounces	n/a	≤ 6° C	14 days	SW-846 ch. 4
		Aqueous	EPA 8270D	Amber Glass	2 x 1 L	n/a	≤ 6° C	7 days	SW-846 ch. 4
PCBs and Dioxins/Furans	PCBs	Solid	EPA 8082	Glass Jar	8 ounces	n/a	≤ 6° C	none	SW-846 ch. 4
		Aqueous	EPA 8082	Amber Glass	2 x 1 L	n/a	≤ 6° C	none	SW-846 ch. 4
	Dioxins/Furans	Solid	EPA 8280 or 8290	Glass Jar	8 ounces	n/a	≤ 6° C	none	SW-846 ch. 4
		Aqueous	EPA 8280 or 8290	Amber Glass	2 x 1 L	n/a	≤ 6° C	none	SW-846 ch. 4
Pesticides and Herbicides	Chlorinated Pesticides	Solid	EPA 8081	Glass Jar	8 ounces	n/a	≤ 6° C	14 days	SW-846 ch. 4
		Aqueous	EPA 8081	Amber Glass	2 x 1 L	n/a	≤ 6° C	7 days	SW-846 ch. 4
	Chlorinated Herbicides	Solid	EPA 8151	Glass Jar	8 ounces	n/a	≤ 6° C	14 days	SW-846 ch. 4
		Aqueous	EPA 8151	Amber Glass	2 x 1 L	n/a	≤ 6° C	7 days	SW-846 ch. 4
NWTPH	Gasoline-Range Organics	Solid	TPHs/NWTPH-Gx	Amber Glass Jar with Septa Lid	4 ounces	n/a	≤ 6° C (headspace free)	14 days	Method

Analysis Type	Sub Analysis	Matrix	Analytical Method	Container Type	Minimum Volume	Preservative	Temperature/ Storage	Hold Time	Source
		Aqueous	TPHs/NWTPH-Gx	Amber Vial with Septa Lid	2 x 40 mL	pH < 2 with HCl	≤ 6° C (headspace free)	7 days unpreserved 14 days preserved	Method
	Diesel-Range Organics	Solid	3510, 3540/3550, 8000	Glass Jar	8 ounces	n/a	≤ 6° C	14 days	Method
		Aqueous	3510, 3540/3550, 8000	Glass Amber	2 x 1 L	pH < 2 with HCl	≤ 6° C	7 days unpreserved 14 days preserved	Method
Geotechnical	Particle Size Analysis	Solid	ASTM D-422	Glass Jar or Plastic Bag	2 x 8 ounce	none	n/a	n/a	Method
Miscellaneous	pH	Solid	EPA 9045	Glass Jar	8 ounces	n/a	n/a	Analyze Immediately	SW-846 ch. 3
		Aqueous	EPA 9040	PTFE	25 mL	n/a	n/a	Analyze Immediately	SW-846 ch. 3
	Total Organic Carbon (TOC)	Solid	SW-846 9060	Glass Jar	100 mL	n/a	≤ 6° C	28 days	SW-846
		Aqueous	EPA 415.1	PTFE or HDPE	200 mL	store in dark HCL or H_2SO_4 to pH <2	≤ 6° C	7 days unpreserved 28 days preserved	Method
	Cyanide	Solid	SW-846 9013	Glass Jar	5 g	n/a	≤ 6° C	14 days	SW-846 ch. 3
		Aqueous	SW-846 9010C	PTFE or HDPE	500 mL	NaOH to pH > 12	≤ 6° C	14 days	SW-846 ch. 3
	Conductivity	Aqueous	EPA 120.1	PTFE or HDPE	100 mL	n/a	n/a	Analyze Immediately	Method
	Hardness	Aqueous	EPA 130.1	PTFE or HDPE	1 x 1 L	HNO3 to pH<2	≤ 6° C	28 days	Method
	Total Suspended Solids	Aqueous	EPA 160.2	PTFE or HDPE	100 mL	n/a	≤ 6° C	7 days	Method
	Total Dissolved Solids	Aqueous	EPA 160.1	PTFE or HDPE	100 mL	n/a	≤ 6° C	7 days	Method
	Nitrate/nitrite	Aqueous	EPA 353.2	PTFE or HDPE	1 x 250 mL	H_2SO_4 to pH <2	≤ 6° C	28 days	Method
	Nitrate	Aqueous	SW-846 9210A	PTFE or HDPE	1,000 mL	n/a	≤ 6° C	28 days	SW-846 ch. 3
	Nitrite	Aqueous	SW-846 9216	PTFE or HDPE	25 mL	n/a	≤ 6° C	48 hours	SW-846 ch. 3, Method
	Fluoride	Aqueous	SW-846 9214	PTFE or HDPE	300 mL	n/a	≤ 6° C	28 days	SW-846 ch. 3
	Chloride	Aqueous	SW-846 9250	PTFE or HDPE	50 mL	n/a	≤ 6° C	28 days	SW-846 ch. 3
	Sulfate	Aqueous	SW-846 9035	PTFE or HDPE	50 mL	n/a	≤ 6° C	28 days	SW-846 ch. 3
	Sulfide	Solid	SW-846 9215	Glass Jar	1 x 4 ounces	Fill sample surface with 2N zinc acetate until moistened.	≤ 6° C (headspace free)	7 days	SW-846 ch. 3
		Aqueous	SW-846 9031	PTFE or HDPE	100 mL	4 drops 2N zinc acetate/100 mL sample; NaOH to pH>9.	≤ 6° C (headspace free)	7 days	SW-846 ch. 3

Key:

* = See individual methods. We typically collect 3xEnCore-type samplers and 1x40 mL VOA vial per sample, keep at ≤ 6°C with no chemical preservative, and they must be at the lab within 48 hours of collection.

C = Celsius HNO_3 = nitric acid SVOCs = semivolatile organic compounds

Cr	= chromium	L	= liter	SW-846	= EPA Test Methods for Evaluating Solid Waste, Physical/Chemical Methods
EPA	= Environmental Protection Agency	mL	= milliliter	TAL	= Target Analyte List
g	=grams	n/a	= not applicable	TPH	= total petroleum hydrocarbons
H2SO4	= sulfuric acid	NaOH	= sodium hydroxide	VOA	= Volatile Organic Analysis
HCL	= hydrochloric acid	PCBs	= polychlorinated biphenyls	VOCs	= Volatile Organic Compounds
HDPE	= high-density polyethylene	PTFE	= polytetrafluoroethylene		
Hg	= mercury	RCRA	= Resource Conservation and Recovery Act		

III. Assessment and Response

A Sample Plan Alteration Form (SPAF) will be used to describe project discrepancies (if any) that occur between planned project activities listed in the final SSSP and actual project work. The completed SPAF will be approved by the OSC and QAC and appended to the original SSSP.

A Field Sampling Form (FSF) may be used to capture the sampling and analysis scheme for emergency responses in the field and then the FSF pages can be inserted into the appropriate areas of the final SSSP.

Corrective actions will be assessed by the sampling team and others involved in the sampling and a corrective action report describing the problem, solution, and recommendations will be forwarded to the OSC and the ERU QAC.

IV. Data Validation and Usability

The sample collection data will be entered into Scribe and Scribe will be used to print lab Chains of Custody. Results of field and lab analyses will be entered into Scribe as they are received and uploaded to Scibe.net when the sampling and analysis has been completed.

18. Data Validation or Verification will be performed by:

ERU's general recommendation on validation is that a minimum of CLP-equivalent stage IIA verification and validation be performed for every SSSP involving laboratory analyses. However, stage IIB is preferred if the lab can provide it. Dioxins should be validated at CLP-equivalent stage 4.

	Data Verification and Validation Stages						
Performed by:	I	IIA	IIB	III	IV	Verification	Other:
Contractor QA Reviewer							
Contractor QA Reviewer							
EPA QA Office							
MEL staff							
Other:Unified Command			100%			100%	

BOBBY JINDAL
GOVERNOR

State of Louisiana

Governor's Office of Homeland Security and Emergency Preparedness

KEVIN DAVIS
DIRECTOR

February 20, 2015

Mr. Ron Curry
Regional Administrator (6-RA)
EPA Region VI
1445 Ross Avenue, Suite 1200
Dallas, TX 75202-2733

Dear Mr. Curry,

As you are aware, in November 2014, two non-human primates in the breeding colony at the Tulane National Primate Research center (TNPRC) became ill and one died. Pathology samples were submitted to the CDC which identified *Burkholderia pseudomallei* (BP) as the causative agent. This strain of bacteria is not endemic in the US but was the subject of research at TNPRC. Because BP is a tier 1 agent and the material was considered not in containment, the CDC and USDA conducted a joint investigation of TNPRC on January 20-24, 2015.

Since the January 2015 investigation, four monkeys have been tested positive with burkholderia pseudomallei. A second primate was euthanized on February 19, 2015 due to infection with burkholderia pseudomallei. One of the federal investigators has fallen ill and has tested positive with possible recent exposure to the BP strain. Human serology has expanded to the investigative tour group and TPNRC staff. Safety protcols have been enhanced for all those participating in the investigation proceedings. A second investigation was conducted on February 9 – 12, 2015 with the intent of conducting more in-depth review of TNPRC processes to determine route of transmission.

As the investigation continues on the TNPRC compound regarding route of exposure, it is also pressing to answer questions regarding whether the organism has escaped the compound and whether livestock and domestic animals are at risk.

It is come to our attention, that EPA requires a letter to ask for their active participation in this investigative process. To this end, Louisiana is formally requesting EPA's assistance with the following:

7667 Independence Boulevard • Baton Rouge, Louisiana 70806 • (225) 925-7500 • Fax (225) 925-7501

1. **Active Engagement:** EPA is requested to provide strategic direction, technical guidance, and/or solicit guidance from appropriate agencies and sections within CDC or other members of the federal family with regards to environmental testing – air, water, soil sampling. Outcomes would determine subsequent steps in remediation of TNPRC and the breeding colony site.

2. ***Mitigation/Remediation Plans:*** We are requesting EPA provide direct assistance and active engagement in the development of the following mitigation/remediation plans. The intent of these plans is to reduce – if not eliminate – the risk of BP outside the TNPRC compound and to indicate remediation steps if BP infection is indicated.
    - *Surrounding Environmental Testing Plan and Sampling* – to include environmental sampling and evaluation in the surrounding surveillance zone to include air, water, and soil testing and to indicate remediation if BP infection is indicated.
    - *Affected Environmental Remediation in high*-risk area—to perform soil remediation in area(s) identified as high-risk as soon as possible to prevent further transmission/transference
    - *Longterm Monitoring and Surveillance Plan and Sampling* – to perform risk assessment within a meaningful vicinity of the area; to indicate longterm monitoring, surveillance, and on-going lab testing for soil and water sampling.

We understand that this remains an evolving event. Planning and response are essential to our joint responsibility to protect the health and safety of our citizens. We look forward to the immediate identification of a federal lead, and timely action plan so that we can be more effective in the consequence management activities for this unfolding event.

If you have any questions, please contact me at (225) 925-7345 or by email at Kevin.Davis@la.gov.

Sincerely,

Kevin Davis

Smith, Monica

From: Martin, John
Sent: Wednesday, March 25, 2015 4:28 PM
To: Smith, Monica
Subject: FW: Tulane primate center

Follow Up Flag: Flag for follow up
Flag Status: Flagged

-----Original Message-----
From: Kevin Davis [mailto:Kevin.Davis@LA.GOV]
Sent: Saturday, January 31, 2015 11:53 AM
To: Canzler, Erica; Martin, John
Cc: Jimmy Guidry (DHH); Dexter Accardo; Christina Dayries; Christopher Guilbeaux; Rosanne Prats; Vernie McNamee; Scott Deitchman
Subject: Tulane primate center

I am requesting EPA to send both Erica and John to our response in Louisiana. CDC will be arriving Monday evening and begin discussions Tuesday morning at site. I would hope you both could assist and arrive Monday evening.
Thank you,
Kevin Davis
Director
Gov. Office Of Homeland Security
Sent from my iPhone

Message

From: Smith, Monica [smith.monica@epa.gov]
Sent: 4/7/2015 9:14:29 PM
To: Crossland, Ronnie [Crossland.Ronnie@epa.gov]; Petersen, Chris [petersen.chris@epa.gov]; Martin, John [martin.john@epa.gov]; Rhotenberry, William [Rhotenberry.William@epa.gov]; Edlund, Carl [Edlund.Carl@epa.gov]; Phillips, Pam [phillips.pam@epa.gov]; Gray, David [gray.david@epa.gov]; Thomas, LaWanda [Thomas.LaWanda@epa.gov]; Braden, Dana [Braden.Dana@epa.gov]
CC: Horner, Jo [Horner.Jo@epa.gov]
Subject: FW: revised final response - Tulane 4-3-2015 1pm
Attachments: Joint Env Sampling Guidelines_27 April 2014_CLEAN.docx; Planning Guidance for Recovery Following Biological Incidents final 0211 .docx; EPA Letter - February 20 2015.pdf; january 31 2015 gohsep email requesting EPA assistance.pdf; Ron Curry - EPA Letter - March 13 2015.pdf; Tulane University ER QASP - v2.pdf; FINAL 472015.docx

Was not sure who would print the letter for signature – so I am sending this out to several people. Please let me know when the letter is printed and signed. Also, it is my understanding that the attachments are to be sent electronically to the Senators.

Here is the final letter (FINAL472015.docx) and the attachments.

I reviewed the comments we received from CDC and deleted the paragraph referencing pending enforcement action as per CDC's request. All other changes/ comments were not accepted.

This email may contain material that is confidential, privileged and/or attorney work product and is for the sole use of the intended recipient. Any review, reliance, or distribution by others or forwarding without express permission is strictly prohibited. If you are not the intended recipient, please contact the sender and delete all copies.

Reference Guide for Developing and Executing *Bacillus anthracis* Sampling Plans in Indoor Settings

Version 4

May 2014

Disclaimer

This document was developed to serve as a reference document for local, state, and federal partners and contractors working within Incident Command who are tasked with sampling and analysis of *Bacillus anthracis* that has been released in or entered an indoor environment. This document serves as a means of standardizing incident response procedures by compiling, in a single volume, common accepted procedures recognized by Federal government agencies as best practices. The document is intended to be a "living" document that will be periodically revised as new methods and processes are developed and validated for use. Wherever possible, citations to locations on the web for the most current recommended methods and procedures are provided and should be referenced in the event of an actual response requirement. This document does not confer legal rights or impose legally binding requirements on any party, nor does it supersede existing practices, guidelines, or authorities of federal, state and local agencies responding to a *Bacillus anthracis* release into the environment. The use of non-mandatory language such as "may" or "should" in this document does not connote a requirement but rather indicates a preferred approach. Mention of commercial products does not constitute endorsement or recommendation of use.

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Acknowledgments

This document was prepared by an interagency workgroup known as the Validated Sampling Plan Working Group (VSPWG). This workgroup is chaired by the Department of Homeland Security (DHS), and includes technical and scientific experts from the Centers for Disease Control and Prevention (CDC), U.S. Environmental Protection Agency (EPA), Department of Defense (DoD), Federal Bureau of Investigation (FBI), National Institute for Standards and Technology (NIST), and Department of Energy (DOE) National Laboratories, including Pacific Northwest National Laboratory (PNNL) and Sandia National Laboratories (SNL).

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Acronyms and Abbreviations

AAS	Aggressive Air Sampling
ACIP	Advisory Committee on Immunization Practices
AHJ	Authority Having Jurisdiction
ASTM	American Society for Testing and Materials
BAR	BioWatch Actionable Result
BI	Biological Indicator
BiSKit	Biological Sampling Kit
CBRN	Chemical, Biological, Radiological, and Nuclear
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CITAC	Cooperation on International Traceability in Analytical Chemistry
CJR	Combined Judgmental and Random
ClO2	Chlorine dioxide
COC	Chain of Custody
Ct	Cycle-threshold
DHS	Department of Homeland Security
DMP	Data Management Plan
DoD	Department of Defense
DOE	Department of Energy
DQO	Data Quality Objective
ECC	Environmental Clearance Committee
EPA	U.S. Environmental Protection Agency
ERLN	Environmental Response Laboratory Network
ESF	Emergency Support Function
EURACHEM	A Focus for Analytical Chemistry in Europe
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
GAO	Government Accountability Office
GIS	Geographic Information System
HASP	Health and Safety Plan
HAZMAT	Hazardous Material
HEPA	High Efficiency Particulate Air
HHA	Hand-Held Assay (Based Immunoassay)
HHS	Health and Human Services
HSPD	Homeland Security Presidential Directive
HVAC	Heating, ventilation and air conditioning
IAP	Incident Action Plan
IC	Incident Commander

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ICS/UC	Incident Command System/Unified Command
ICLN	Integrated Consortium of Laboratory Networks
ICS	Incident Command System
IND	Improvised Nuclear Device
ISO	International Organization for Standardization
JLC	Joint Leadership Council
JTTF	Joint Terrorism Task Force
LPM	Liter per minute
LOD	Limit of Detection
LRN	Laboratory Response Network
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
MCE	Mixed cellulose esterase
mL	Milliliter
mm	Millimeter
MOA	Memorandum of Agreement
MPN	Most Probable Number
NCG	Network Coordinating Group
NFPA	National Fire Protection Agency
NIMS	National Incident Management System
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute for Standards and Technology
NMAM	NIOSH Manual of Analytical Methods
NRC	National Research Council
NRF	National Response Framework
NRP	National Response Plan
NRT	National Response Team
NSPD	National Security Presidential Directive
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy
PCR	Polymerase Chain Reaction
PDA	Personal Data Assistant
PEP	Performance Evaluation Procedure
PNNL	Pacific Northwest National Laboratory
PPE	Personal Protective Equipment
QA	Quality Assurance
QC	Quality Control
QUAM	Quantifying Uncertainty in Analytical Measurement
RAP	Remedial Action Plan
RDD	Radiological Dispersal Device
RE	Recovery Efficiency
RV-PCR	Rapid-Viability PCR

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SADA	Spatial Analysis and Decision Assistance
SD	Standard deviation
SMART	Sensitive Membrane Antigen Rapid Test
SNL	Sandia National Laboratories
T_0	Time Zero
TWG	Technical Working Group
UC	Unified Command
VSP	Visual Sample Plan
VSPWG	Validated Sampling Plan Working Group
WMD	Weapons of Mass Destruction

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Section I: Introduction

1.1 Purpose

The purpose of this document is to present a reference document for environmental sampling of *Bacillus anthracis* (spores and vegetative cells), the causative agent of anthrax, during first response and remediation phases following the confirmation of contamination in a facility including large, complex buildings as well as single dwelling buildings. While this document does not address a wide area outdoor release scenario, some of the information provided in this document may be useful in developing an outdoor sampling strategy.

The document presents the tools (including approaches and methodologies) currently available that can be considered by sample planners and technical support staff operating within an Incident Command System/Unified Command (ICS/UC) when developing sampling plans. Most importantly, this document will help sample planners develop a sampling plan specific to each unique *Bacillus anthracis* (*B. anthracis*) contamination site as part of the incident and advise IC/UC decision makers (i.e., stakeholders, federal, state, local, and tribal leaders). A well-executed, site-specific sampling plan will assist decision makers to:

- Determine who may have been potentially exposed during the initial release
- Assess potential risk of exposure to responders entering the site
- Characterize the extent of the contamination
- Remediate/Decontaminate indoor sites of contamination
- Clear the facility for reoccupation or use

1.2 Background

Environmental sampling to determine the presence or absence of *B. anthracis* in indoor environments is an important tool for assessing potential risk of exposure to building occupants at the time of release and responders to the incident. Environmental sampling results can be used to confirm the presence of contamination; determine the extent of contamination; support informed decisions regarding the need for medical interventions and decontamination options; and determine the effectiveness of decontamination and when cleanup is adequate to permit re-entry into an area (OSHA 2002). However, sampling and analysis is just one of many components contributing to a hazard determination. The infectious dose of *B. anthracis* in humans by any route is not well-established, making it difficult to develop risk-based exposure limits. Therefore, sampling results, along with other data inputs (including epidemiological data, intelligence data, and modeling data), and operating parameters are used to make informed decisions regarding public health actions and environmental cleanup. As an outcome of

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meetings among subject matter experts during 2011, EPA and CDC recommended that "no detection of viable spores" be considered the most appropriate clearance goal.

To ensure consistent communication among various agencies during a response to a *B. anthracis* incident, this document uses the Validated Sampling Plan Working Group (VSPWG) definitions of *sampling strategy* and *sampling plan*. The *sampling strategy, sampling approach,* and *sampling plan* definitions were reached by consensus of the VSPWG in 2007.

> **Sampling strategy:** "A set of operating precepts and diagnostic tools (including sample collection methods; packaging and shipping protocols; sample recovery, extraction, and analytical methods; and statistical analysis packages, as appropriate) that are combined to answer specific hypotheses." A sampling strategy includes the approach or combination of approaches to be used to select locations at which to collect samples and provides guidance that is informed by a decision support process. It also includes a compendium of information on relevant methods and the plan for action prescribing their use across multiple potential scenarios. (Using this definition of a *sampling strategy,* this Sampling Reference Guide document is a sampling strategy.)
>
> **Sampling approach**: "A methodology for selecting representative locations and surfaces for collecting samples." A sampling approach provides the structure, when implemented in a sampling plan, for planners to draw conclusions from the sampling results. There are three kinds of sampling approaches discussed in this document: judgmental sampling, hotspot sampling, and combined judgmental and random (CJR) sampling.
>
> **Sampling plan**: "A documented approach for field execution that captures the specific combination of operating precepts and diagnostic tools used for a given scenario to answer a specific hypothesis." A sampling plan is an executable plan of action addressing the sampling and analytical requirements of a specific situation and is formulated in accordance with the guidance of the sampling strategy. The sampling plan must specify the sampling approaches, methods, and analyses, as well as the number, types, and locations of samples to be collected in a given physical space (DHS 2007b).

The VSPWG intends that this reference document align with broader national response guidance, including the National Incident Management System (NIMS) and National Response Framework (NRF), which provides principles of a unified national approach for responding to a *B. anthracis* incident indoors. It is intended to be coupled with the understanding of the authority-having jurisdiction (AHJ) regarding local vulnerabilities and capabilities when developing its plans and guidance documents for response to incidents involving *B. anthracis* contamination. This guidance recognizes NIMS and ICS as an essential part of emergency response planning and response.

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Specific conditions, such as the variation of *B. anthracis* characteristics (e.g., virulence, environmental persistence, and transmissibility), the uniqueness of a given scenario (e.g., mechanism of agent dispersal, exposed population characteristics, micro and macro environmental conditions), and the variety of available response resources make it infeasible to develop a template sampling plan in advance to address all *B. anthracis* incidents. However, this document describes key phases, decision points, and tools to consider when developing a site-specific sampling plan.

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Section II: Response Phases, Coordination, and Roles and Responsibilities

2.1 Basics of a Response

The NRF presents the principles to provide a unified national approach for responding to an incident and provides guidance to all partners in preparing for national emergencies. The NRF is intended to strengthen, organize, and coordinate response actions across all levels. The doctrine of *tiered response* emphasizes response to an incident should be handled at the lowest jurisdictional level capable of handling the work. The NRF addresses incidents of all types, including acts of terrorism, major disasters, and other emergencies (DHS 2008). The NRF uses the same guiding NIMS and ICS principles. These principles are used by first responders through senior decision-makers, and constitute an all-hazard, scalable, flexible, and adaptable approach to response. The NRF provides the structure to align key roles and responsibilities across the nation, linking all levels of government, non-governmental organizations, and the private sector. The framework provides an overarching coordinating mechanism for accessing federal support for response activities and for specific federal departments and agencies to carry out their responsibilities. Currently, fifteen (15) Emergency Support Functions (ESF) and five (5) Incident Annexes address functional capabilities and resources provided by federal departments and agencies. The NRF is always in effect and elements can be implemented as needed.

While an incident is occurring and after, the priorities are to employ resources to save lives; to protect property and the environment; and to preserve the social, economic, and political structure of the jurisdiction. Depending on the size, scope, and magnitude of an incident, communities, states, and the federal government will be called to action (DHS 2008).

Initial information about an incident will depend on whether the release was overt or covert. An overt release is the intentional release of an agent reported by terrorists, observed by witnesses at the scene of the release, or made known at the time of release by other means. A covert release is the intentional release of an agent not observed at the time the release occurs (DHS 2007a). A biological-related incident may be discovered in one of three ways: 1) discovery of either physical or intelligence evidence (law enforcement actions or suspicious package), 2) detection of an agent through environmental surveillance systems (e.g., DHS BioWatch, US Postal Service Biohazard Detection System), or 3) reports of medical symptoms or disease (Emanuel et al. 2008).

2.2 Phases of an Incident

Effective and timely decision-making in responding to a biological agent incident first requires a broad understanding of all the phases and activities involved. As depicted in Table 1, effective response to a biological release incident comprises numerous elements, grouped into two overarching phases: *Crisis management* and *consequence management*. This mapping is

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common in response to all chemical, biological, radiological, and nuclear (CBRN) incidents (NSPD 17/HSPD 4, 2002; and DHS 2004). *It is important to note the activities described below do not necessarily occur in sequential order, but may run concurrently, or occur outside the phase in which they are described. Additionally, this document emphasizes the specific activities for the response and recovery to a B. anthracis incident.*

Table 2-1: Phases of an Effective Response

Response and Recovery*					
Crisis Management		Consequence Management			
Notification	First Response	Remediation/Cleanup			Restoration/ Reoccupancy
		Characterization	Decontamination	Clearance	
Receive information on biological incident Identification of suspect release sites Notification of appropriate agencies	Initial threat assessment HAZMAT and emergency actions Forensic investigations Public health actions Screening sampling Determination of agent type, concentration, and viability Risk communication	Characterization of biological agent Characterization of affected site Site containment Continue risk communication Characterization environmental sampling and analysis Initial risk assessment Clearance goals	Decontamination strategy Remediation Action Plan Worker health and safety Site preparation Source reduction Waste disposal Decontamination of sites or items Decontamination verification	Clearance environmental sampling and analysis Clearance decision	Restoration Reoccupation decision Long-term environmental and public health monitoring
* The optimization decision process is applicable to any phase					

Source: Adapted from NSTC (2009)

2.2.1 Crisis Management

The first phase of response and recovery, the *crisis management* phase, involves law enforcement (local, state and federal), first responders (police, fire, and hazardous materials teams), and public health agencies (local, county, state, and federal health) (DHS 2004). The crisis management phase includes measures to identify and characterize the event, as well as to identify, acquire and plan the use of resources needed to respond to the incident. The crisis management phase of the response consists of the initial response activities, which can be further broken down into the *notification* phase and the *first response* phase (DHS 2004).

Depending on the origin of the event, criminal versus naturally-occurring, different agencies will manage the event and different response actions will take place. Law enforcement manages first responses for criminal responses and may designate the incident location as a crime scene while public health manages responses to naturally-occurring events.

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At the beginning of the response, the data available depends on whether the release was overt or covert. An observed, overt release is likely to prompt an immediate response including site containment. However, even in those circumstances, the causative agent may not be known. The forensic investigation along with epidemiologic and intelligence data will contribute to the identification of the biological agent. The greatest difference between overt and covert scenarios is an overt scenario more quickly yields greater information about the release (e.g., time, location of the release, dispersion methods) and it leads to a response prior to evidence of exposure or infection in the population. An overt scenario also allows the opportunity to implement public safety measures that may mitigate consequences during the first response phase.

2.2.1.1 Notification Phase

During the *notification* phase, tasks include law enforcement and public health receiving and assessing information, identifying suspected release locations, and communicating key information to the appropriate authorities that, in turn, initiate first response actions (DHS 2006b).

2.2.1.2 First Response Phase

This *first response* phase may involve, particularly in an overt release incident, hazardous material (HAZMAT) and emergency actions, public health response, scene control, law enforcement activities, initial site containment, sampling and analysis, personnel decontamination, and risk communication. HAZMAT and emergency actions are conducted to address any immediate threats to life or valuable property necessary for public welfare (e.g., critical infrastructure), and to establish control of the situation (OSTP 2009). A command post is established, and communication and data exchange between law enforcement and other personnel is performed as needed.

During this phase, data regarding the incident most likely have been generated by numerous responding agencies and organizations, such as HAZMAT teams, law enforcement, including the Federal Bureau of Investigation (FBI) Hazardous Materials Response Team, and public health organizations (state/county/local health departments and CDC). Data from these responding agencies involved in the initial response and investigation will be available to members of the IC/UC and may consist of law enforcement, forensic, and incident reports; preliminary environmental laboratory results; and public health case investigation data.

If results from preliminary samples indicate the likely presence of *B. anthracis* or if law enforcement or public health investigations identify a potential contamination location, the FBI will likely commence a criminal investigation. This criminal investigation may include activities

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to determine the agent's specific genetic, physical, and chemical properties; search for other types of evidence; establish a possible source of the contamination; and identify the responsible party. If a crime scene is established, the FBI must approve all environmental sampling within the crime scene through the ICS/UC with the ultimate decision for entry into the crime scene made by the Incident Commander (IC). Initial samples are sent to a Laboratory Response Network (LRN) laboratory for confirmatory testing (OSTP 2009). Additional information about LRN laboratories can be found in Section 2.4.5.1.

The DHS National Bioforensics Analysis Center (NBFAC) may also analyze forensic samples (DHS 2006b). Results from the forensic investigation may not be releasable to all federal entities and may not meet the needs of the public health investigation; therefore additional sampling may be necessary during the *first response* phase to obtain information on the presence of an agent and to determine the agent type, concentration, and viability as well as to determine exposure pathways in the building. These activities may continue in more depth during the first phase of *consequence management, which is characterization.*

2.2.2 Consequence Management

The second phase of response and recovery, the *consequence management* phase, is predominantly an emergency management function and includes measures to protect public health and safety, restore essential government services, and provide emergency relief to governments, businesses, and individuals affected (DHS 2004). As the *crisis management* phase transitions into the *consequence management* phase, in which the U.S. Environmental Protection Agency (EPA) plays a critical role and may step in as a lead federal agency, as directed or requested. The main focuses will be on characterization of the contaminated environment, decontamination, and clearance.

The local or state agencies with authority for protecting public health and/or the environment would also likely exert their regulatory authority to assure consequence management efforts are acceptable. *Consequence management* can be further subdivided into *remediation/cleanup*, which includes *characterization, decontamination*, *clearance,* and *restoration/reoccupancy*. The response and recovery process ends with *restoration/re-occupancy* during which a facility may be renovated, and decisions to allow reoccupation are made by the IC/UC. *However, this phase is not discussed further in this document as environmental sampling does not play a critical role in the restoration process because the building will already have been cleared of contamination.*

2.2.2.1 Characterization

Characterization is the process of obtaining information about a biological agent incident, which is used to determine further action. A sampling plan is developed to characterize the spread of contamination within an area and to obtain semi-quantitative estimates of the biological agent's concentration at specific locations (OSTP 2009). Characterization of an affected site includes

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describing site-specific characteristics such as, size, construction, heating, ventilation and air conditioning (HVAC) systems, ambient environmental conditions (e.g., temperature and relative humidity), structural materials, stored materials, and contents. If decontamination is warranted, the decontamination strategy decision may be affected by characteristics and materials composition of the specific site as well as the efficacy of decontamination approaches (OSTP 2009).

The information generated from the characterization sampling is used to help modify and refine public health actions developed based on the initial assessment. Uses include estimating the potential exposure to the agent, and deciding where, what, and how to decontaminate (DHS 2006b).

A risk assessment is conducted to determine potential risks posed by the threat agent at a specific site. Risks need to be assessed in order to assist decision-makers in setting clearance goals, planning a decontamination strategy, and developing a sampling plan (OSTP 2009).

Clearance goals will need to be established. Setting clearance goals for a biological agent is not an easy process due to the fact that there are no established reference values (unlike some radiological or chemical agents) or exposure guidelines (OSTP 2009). The IC/UC may choose to assemble a Technical Working Group (TWG), to assist in setting clearance goals appropriate to the site-specific circumstances. The TWG is an advisory group of multi-disciplinary technical experts and scientists that provides input on planning and implementing remediation, including setting clearance goals. The TWG may include representatives from federal, state, local, and tribal agencies, and experts from the private sector or universities. The TWG is an advisory group to the IC/UC, and is not a decision-making body. The TWG provides advice and guidance on such issues as interpretation of analytical results; sampling and analysis plans; selection of the appropriate remediation process and conditions for its implementation; development of procedures for a variety of issues that may arise to address releases and other emergencies during the remediation process; and waste management activities.

2.2.2.2 Remediation

During *remediation*, a decontamination strategy is developed and implemented, taking into account specific information about the agent, incident, and materials to be decontaminated. Ambient conditions (temperature and relative humidity) affect decontamination and must also be considered. After the decontamination approach is selected, a Remediation Action Plan (RAP) is prepared for the site specifying the overall strategy for decontaminating impacted areas and their contents. The decontamination strategy will be a guide for the remediation activities.

Site preparation is necessary before decontamination is carried out. Source reduction can be performed to remove certain items and/or materials from a contaminated site for further

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treatment and reuse or disposal. Additionally, items and site surfaces may need to be cleaned prior to the main decontamination activity.

After the RAP is complete and approved by IC/UC, the site is prepared and the specific decontamination methods selected for affected site(s) and/or item(s) can be employed. Decontamination is monitored as it is carried out and evaluated as to whether or not the specific parameters were met, goals were achieved, and the operations were conducted successfully.

2.2.2.3 Clearance

The *clearance* phase includes determining whether the agent has or has not been inactivated to the clearance criteria levels. The IC/UC may establish an Environmental Clearance Committee (ECC), which is a group of experts that functions as an independent peer review group. Members of the ECC may be representatives from the local, county and/or state public health agencies, the facility or property owner, local government, and subject matter experts from the EPA, FBI, OSHA, Food and Drug Administration (FDA) and CDC. The ECC conducts a comprehensive review to make recommendations to the IC/UC on whether the clearance goals have been met.

It is important that the ECC be formed as early as possible in the incident so that committee members can become familiar with the situation, review necessary data which may include agent characteristics, extent of contamination, sampling results, decontamination process, and clearance sampling results. The ECC is an independent body that is not part of the decision-making process on decontamination. Clearance sampling and analysis is the ultimate measure of whether decontamination met the criteria outlined in the RAP. If the clearance criteria are met, then decisions will be made on whether to allow unprotected re-entry to a facility and unrestricted use of items in the facility. The IC/UC makes the ultimate clearance recommendation to the lead local public health agency or private facility owner based on judgment as to whether the criteria for decontamination verification and clearance criteria have been met. Ultimately, the facility is returned to the owner/operator.

2.3 Agency Coordination

All levels of government, the private sector, and non-governmental agencies must be prepared to prevent, protect against, respond to, and recover from a wide spectrum of major incidents that exceed the capabilities of any single entity. These hazards require a unified and coordinated national common approach to planning and responding to an incident management. To address this need, Homeland Security Presidential Directive (HSPD) 5: *Management of Domestic Incidents* required the establishment of the NIMS. In addition, Presidential Policy Directive (PPD) 8: *National Preparedness* provides a comprehensive approach to assess national preparedness that uses consistent methodology to measure the operational readiness of national

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capabilities at the time of assessment, with clear, objective and quantifiable performance measures, against the target capability levels identified in the national preparedness goal.

The NRF specifies what needs to be done to prevent, protect against, respond to, and recover from a major incident. It also specifies how and how well it needs to be done. Together, these related efforts align federal, state, local, tribal, private sector, and non-governmental preparedness, incident management and emergency response plans into an effective and efficient national structure.

2.4 Roles and Responsibilities of Key Agencies, Advisory Groups, and Laboratories

The roles and responsibilities of key agencies, advisory groups, and laboratories are discussed in the following subsections.

2.4.1 Federal Bureau of Investigation

According to the NRF (DHS 2008), the FBI is the lead federal agency for criminal investigation of a terrorism incident. Local law enforcement usually notifies the FBI of a potential Chemical, Biological, Radiological, and Nuclear (CBRN) incident. Other methods of notification can be through local or state public health departments, fire department hazardous material responders, local search warrants where "questionable items" are observed by local law enforcement officers, and the FBI Joint Terrorism Task Force (JTTF) officers.

If initial laboratory results indicate a presumptive positive of *B. anthracis* and/or the circumstances of the incident suggest a credible threat exists, the FBI will commence an investigation including evidence collection. The main objectives for evidence collection are to 1) obtain biological material for further microbiological, chemical, physical and forensic analysis for attribution purposes and 2) locate a dissemination device or other traditional forensic evidence.

If it is a known or suspected biothreat agent incident, the FBI will coordinate with the IC and other entities having jurisdiction (fire department and/or public health department) but will be the lead agency for the criminal investigative response. As part of their investigation, FBI may work with response partners to collect information on the biological agent, including specific genetic, physical, and chemical properties; search for additional items of evidence; establish a possible source of the contamination; and determine the perpetrator(s). For all potential or actual biothreat agent incidents, a Threat Credibility Evaluation teleconference will take place between the local FBI Weapons of Mass Destruction (WMD) Coordinator, the appropriate FBI Headquarters elements (e.g., FBI WMD Directorate, FBI Laboratory, and FBI Critical Incident

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Response Group), and other required elements as necessary such as state, locals or other federal agencies.

The determination of whether or not a credible threat exists may not be made until after the initial detection of *B. anthracis*, therefore law enforcement will coordinate sampling efforts with public safety, public health and environmental agencies to preserve the integrity of the material in case it becomes evidence in a criminal investigation (ASTM 2010b). If a crime scene is established, the FBI may form joint task force sampling teams consisting of FBI and non-law enforcement and will approve all sampling plans until the crime scene is released for environmental remediation. This close working relationship is necessary to ensure both the proper collection of evidentiary samples as well as to protect the public health.

2.4.2 State and Local Public Health

State public health programs have primary responsibility for protecting the health and welfare of the public under their jurisdiction. States vary considerably in the nature and scope of the public health services they provide. State governments are responsible for responding to a public health emergency and play certain key roles in preparedness and response. With exception of the largest metropolitan local public health departments, local public health officials will tend to rely on state personnel and capacity for a number of key functions, including providing advanced laboratory capabilities and capacity, and epidemiological expertise, and serving as a conduit for federal assistance. When resources of state and local authorities are overwhelmed, federal assistance can be requested by the affected state.

2.4.3 Department of Health and Human Services (DHHS)/Centers for Disease Control and Prevention (CDC)

Under the NRF (DHS 2008), the Department of Health and Human Services (DHHS), including the CDC and other HHS agencies, has responsibility for public health and medical services. This responsibility provides the mechanism for coordinated federal assistance to supplement state, tribal, and local resources in response to a public health and medical emergency. The CDC engages in all phases of a biological incident. The CDC's involvement may include:

- Conducting epidemiologic and surveillance activities to identify cases and the populations at risk, and to determine the source of exposure;
- Providing laboratory support for the identification, confirmation, characterization, and drug susceptibility of the biological agent;
- Conducting environmental evaluations to support the epidemiological and surveillance activities and estimate extent of contamination;
- Providing guidance on the identification, diagnosis, and clinical management of human cases;

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- Providing guidance on the use of medical countermeasures (e.g., antimicrobials, vaccines, and immunotherapeutics) that may be utilized in response to an event or incident;
- Developing effective infection control practices for communities and healthcare settings;
- Providing guidance on non-pharmaceutical mitigation strategies to assist with the containment and control of infectious agents;
- Providing technical assistance to SLTT, federal and international partners to support public health activities;
- Disseminating key public health and safety messages to the public to provide timely, accurate, clear, consistent, credible, and easily accessible information relevant to the information needs of all stakeholders.

2.4.4 Environmental Protection Agency (EPA)

Under the NRF (DHS 2008), the EPA's actions can include efforts to detect and assess the extent of contamination (including sampling and analysis and environmental monitoring); actions to stabilize the incident and prevent the spread of contamination; analysis of options for the environmental cleanup and waste disposition; implementation of the environmental cleanup; storage, treatment, and disposal of the hazardous materials; implementation of clearance sampling.

As the *crisis management* phase transitions into the *consequence management* phase, EPA may step in as a lead federal agency. The lead agency during *crisis management* may begin to shift the response to EPA, state environmental agencies, cleanup contractors, and consultants working for the facility owners. The main focus will be on characterization and cleanup work.

2.4.5 Integrated Consortium of Laboratory Networks (ICLN)

The Integrated Consortium of Laboratory Networks (ICLN) was established by a [HYPERLINK "http://www.icln.org/docs/moa.pdf" \t "_blank"] signed in 2012 (ICLN 2012). The ICLN is made up of six established laboratory response networks, including the CDC's LRN and EPA's Environmental Response Laboratory Network (ERLN). The purpose of the ICLN is to enable integrated and coordinated response to, and consequence management of, acts of terrorism and other major incidents requiring laboratory response capabilities. A major outcome of the ICLN is the creation of an Integrated Response Architecture that provides, among other things, a framework for incident notifications and updates, preparedness alerts, and situational reports among networks through a secure web portal. Among the roles of the ICLN are to establish methods for risk-based prioritization and to identify and address key gaps in laboratory capabilities. The ICLN also aims to improve capacity for "surge" requirements and efficiencies in laboratory method development and validation.

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2.4.5.1 Laboratory Response Network (LRN)

Per the NRF's Biological Incident Annex, biological samples for public health and environmental considerations are analyzed by an LRN laboratory. The CDC LRN comprises approximately 140 labs across the U.S. and several foreign countries. LRN member laboratories and their contact information can be obtained from the LRN program Office, accessible through the CDC Emergency Operations Center.

LRN laboratories are designated as either national, reference, or sentinel. The designation depends on the types of tests a laboratory can perform and how it handles infectious agents to protect workers and the public. The *national laboratories* have unique resources to handle highly infectious agents and the ability to identify specific agent strains. The *reference laboratories* can perform tests to detect and confirm the presence of a threat agent. This allows local authorities to respond quickly to emergencies. The *sentinel laboratories* provide routine diagnostic services and have publicly available microbiology procedures that can be used to rule out suspicion of a biological threat agent in clinical specimens. If unable to rule out the presence of a biological threat agent, sentinel labs are able to safely package and refer specimens to an LRN reference laboratory, thus playing a key role in early suspicion of a covert event. They are not equipped to perform the same tests as reference laboratories.

2.4.5.2 Environmental Response Laboratory Network (ERLN)

EPA's ERLN network (part of the ICLN), consists of federal government, state government, water utilities, and commercial laboratories capable of performing environmental sample analyses for chemical, biological, and radiochemical contaminants to support the EPA's homeland security responsibilities. The ERLN's mission is to provide reliable analytical data for environmental samples of known and documented quality to federal, state, and local decision makers. Such data can then be used to mitigate and recover from releases of toxic industrial chemicals, chemical warfare agents, biological agents, and radiochemical contaminants in environmental matrices collected in support of homeland security incidents. In addition to its own resources, the ERLN leverages other networks' capabilities to support responses related to a biological threat release.

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Section III: Sampling Phases during Crisis and Consequence Management

There are four distinct environmental sampling phases during a *B. anthracis* incident: initial response sampling during first response, characterization sampling, verification sampling, and clearance sampling. The purpose and description of each sampling phase are described in this chapter. Sample collection methods used in these sampling phases are described in Section 6 and appendices referenced therein.

3.1 Initial Response Sampling

In situations where release of biothreat agents are suspected, initial response sampling may be conducted by any of a number of entities, such as local HAZMAT or other first response teams, FBI, or public health authorities. The roles these groups may play in initial sampling depend on how the event is uncovered and which group has jurisdictional authority. Most often local HAZMAT or other first response teams are the first on scene. The decision by first responders to collect and submit a sample to the LRN reference laboratory for testing is made at the local level through communication among on-scene responders, the FBI, and the receiving LRN reference laboratory (ASTM 2010b). Their testing typically includes field screening which incorporates field measurements taken early in the site assessment process to identify and delineate the contaminants present (e.g., explosives and radiation), support tactical decision making, and address operational safety measures. Field screening does not include measurements of biological properties. On-site biological assessments to measure properties inherent to biological materials may also be performed in the field using rapid, field-based procedures and assays when a visible powder is present (ASTM 2010b). As a result of the initial risk assessment or first responder testing results, the FBI may determine that there is sufficient indication of a credible threat to assume jurisdiction. The FBI may take immediate tactical actions to contain the threat and mitigate the potential effects until the LRN reference laboratory has received samples and has performed appropriate confirmatory analysis (ASTM 2010b).

The FBI may choose to collect additional samples for forensic purposes; these samples are sent to LRN laboratories or the DHS National Bio Forensics and Analysis Center for definitive analysis (DHS 2006A). The primary objectives of initial response sampling, when conducted by law enforcement personnel, are to identify and confirm if *B. anthracis* is present, and if so, locate the source of the contamination to aid the criminal investigation. Results from the forensic investigation may not be releasable to all federal entities; therefore additional sampling may be necessary. The information from first responders and law enforcement may have important limitations and should be considered with caution (Emanuel et al., 2008), particularly if generated using hand-held assays (see Section 7.1.5 for more information). Also, the forensic investigation is focused on the collection of evidence and the source location and therefore does not involve developing a robust sampling plan. For this reason, a public health sampling plan may be needed to adequately address exposure concerns. If the incident is designated as a crime

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scene, CDC coordinates with the FBI to ensure appropriate samples are collected to meet public health objectives (DHS 2004).

Initial response sampling for public health purposes focuses on identifying areas of contamination to inform who may have been exposed. Such sampling takes place after confirming *B. anthracis* contamination or when contamination is suspected based on epidemiologic investigation. Information and data from first responders and other groups involved in the initial response and investigation are considered in determining if additional sampling is warranted. In order to conduct an initial assessment of who may have been exposed and identify potential pathways of exposure to support appropriate risk assessment and data-driven recommendations for medical countermeasures, further environmental assessment may be necessary prior to transition to the consequence management phase. Public health sampling actions are independent of the magnitude of the incident, or whether it is overt or covert. Thus, the initial environmental investigation must focus on rapidly evaluating the epidemiological information available (e.g., incident timelines and interviews of those involved). Sampling teams typically utilize a judgmental sampling approach (see Section 5.1) that is intended to maximize the possibility of detecting the presence of any contamination. Comprehensive characterization of potentially contaminated spaces is not a goal of initial response sampling for public health purposes.

Sidebar 1 suggests how initial response sampling might be carried out.

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Sidebar 1 – Initial Response Sampling During a Fictional Airport Scenario

A large international airport had a suspicious powder incident associated with a piece of luggage on a baggage carousel giving off a small, steady white cloud of dust. First responders evacuated the baggage claim terminal and cordoned off an area around the baggage carousel. The first responders collected samples that were sent to their local LRN for confirmatory testing. Due to law enforcement intelligence reports, the FBI and local public health responded to the site to conduct additional sampling. Meanwhile, the LRN confirmed a positive sample result for *B. anthracis*. The goal when collecting initial response samples after a confirmed release is to collect samples to evaluate whether contamination is present in other locations and in order to identify who might have been exposed.

It is important to target the location for a plausible pathway that is most likely contaminated. While the immediate area may be perceived to be top priority, other areas and populations should be assessed in order to quickly identify the populations at risk, such as high traffic areas and the area where baggage was offloaded. In addition, *B. anthracis* spores will likely be present on people or baggage in close proximity to the release point and can serve as a fomite to cross-contaminate other areas. For the purposes of this scenario, initial response sampling can determine if the contamination is localized to the baggage claim terminal or if it has spread to other locations (e.g., the taxi stand or food court) (Emanuel et al. 2008). Also, HVAC system return ducts and filters in the immediate vicinity should be sampled in order to assess if contamination spread via aerosol through the HVAC system. Finding surface contamination on the tops of air ducts or rafters that are highly unlikely to have had contact with the contaminated source or finding a dispersion pattern of multiple positive results might suggest that aerosolization occurred during or after the event (CDC2001).

3.2 Characterization Sampling

Characterization sampling is typically used to obtain information concerning the extent and magnitude of contamination to guide remediation. Sampling is used to determine whether an area needs to be decontaminated and what materials need to be decontaminated. The information generated from the characterization sampling is also used to help modify and refine public health actions that were developed based on the initial assessment, if sampling during the characterization phase indicates a different or larger population may have been affected than suggested by initial response sampling.

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Characterization systematically expands on the initial assessment findings to identify other contaminated locations and determine the contamination footprint at the affected locations, in order to better define the boundaries. The strategy for the characterization phase is to supplement the information that has already been collected during the initial assessment. The sampling information, specifics of the scenario, and the data collected during the initial assessment may take on many forms and may come from several different groups involved in the initial response. The initial assessment sampling data will be evaluated and reviewed, and information derived from it will be used by IC/UC to assist in formulating the objectives, strategy, and approach for the characterization phase. The information that results from the characterization affects and shapes the planning and implementation of the remediation phase, as determined by the Incident Commander (DHS 2006b).

3.3 Verification Sampling

Overall clearance of an area or building is a multi-step process that includes application of the decontamination technology, verification sampling and other means to follow progress of the decontamination process, and clearance sampling (discussed in following section).

Verification sampling may be performed during the remediation process to establish whether decontamination was effective or sufficient in neutralizing contamination. Verification sampling may include surface sampling using the same methods that are used during the characterization phase. This type of verification sampling would not take place during decontamination but immediately afterward. These samples are collected adjacent to previously identified contaminated surfaces to determine whether the decontamination process has successfully eliminated viable spores where they were previously found.

Sidebar 2 outlines some of the actions that may be taken to monitor the progress of decontamination.

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Sidebar 2 – Monitoring the Decontamination Process

In order to monitor the progress and adequacy of decontamination using a fumigant or vaporous decontaminant, biological indicators (BIs) may be used to determine that a particular decontamination reagent has been in contact with specified surfaces or distributed throughout a particular area sufficiently. BIs can be porous cellulose filter pads or stainless steel coupons that have been inoculated with a defined titer of non-hazardous bacterial spores, such as *Bacillus atrophaeus*. *Bacillus* spores, including the *B. atrophaeus* species, are recognized as being highly resistant to inactivation by decontamination processes, including gaseous chlorine dioxide (ClO_2) (Leftman 2008). It is important to note that current BIs are more easily decontaminated than building materials such as carpet. Therefore BIs should not be used alone to determine decontamination efficacy. BIs containing *B. atrophaeus* spores are used in medical applications to demonstrate successful ethylene oxide sterilization, as well as in the pharmaceutical industry to document the effectiveness of small-scale ClO_2 treatment. Following the decontamination process, the BIs will be retrieved and sent for analysis at an independent laboratory to ensure that all spores on the BI were inactivated by the treatment process (Sabre 2007).

Other measurements will be used as well to monitor decontamination operating parameters. For example, during fumigation measurements are collected for temperature, humidity, contact time, and fumigant concentration. These data are used to help determine if the fumigation process has met the criteria established in the RAP and whether it is deemed successful. For surface decontamination technologies such as amended bleach, parameters that may be monitored include contact time, pH, and free chlorine concentration.

3.4 Clearance Sampling

Clearance sampling is environmental sampling that provides a determination of whether clearance goals were met and the facility is ready for final preparations for re-occupancy. In this case, clearance sampling is conducted after decontamination activities are completed but before critical barriers are taken down. In addition, clearance sampling could be conducted in areas where no contamination was found during characterization sampling and thus, no remediation was conducted in those areas. The purpose of clearance sampling is to promote confidence in decision-makers and users of the facility that the facility has been adequately remediated. Consequently, analysis of clearance samples should be done using methods that determine viability of any spores remaining.

After all samples are collected and the sample results are reported, the findings and the methods for verification and clearance sampling used to develop those findings will be presented to the IC/UC. If an ECC was created by the IC/UC, the above information will be provided to the ECC, which will review the findings and then prepare a written clearance statement or document

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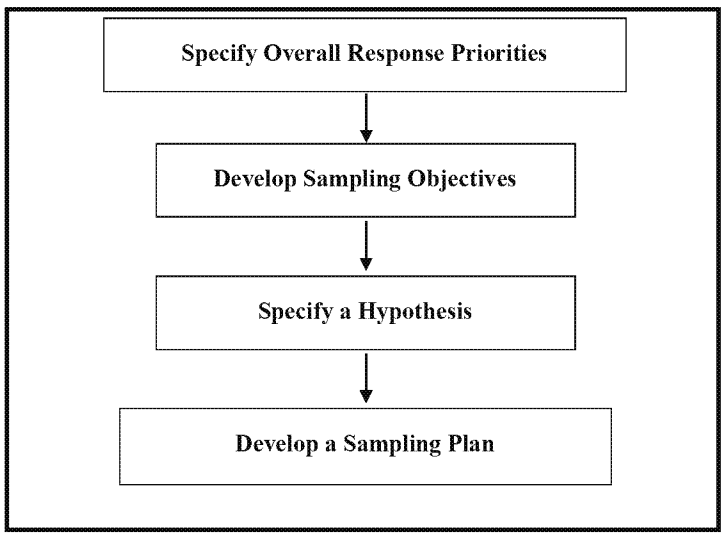
which is provided to the IC/UC. Depending on the impacted facility, the IC/UC or lead local public health agency makes the final decision on whether or not the building is cleared and ready for re-occupancy.

Section IV: Sampling Strategy Roadmap

The first step to produce meaningful sampling data is to understand the basic roadmap for the response (Figure 4-1). The roadmap for the response will include the overall response priorities established by the IC/UC, the sampling objectives, and the sampling approach (Emanuel et al. 2008). The sampling strategy roadmap serves as the framework for developing data of requisite quantity and quality to support an overall process outcome and subsequent decisions.

Figure 4-1. Basic Roadmap for a Sampling Strategy*



*Adapted from Emanuel et al. (2008)

4.1 Specify Overall Response Priorities

Response priorities are set and directed by the IC/UC of an incident. However, the development of these priorities should be made within the context of appropriate information sources. Consideration of critical data streams from law enforcement, intelligence, and epidemiology will help to define the problem, identify what information is lacking, and develop the objectives of environmental sampling. The objectives are met by establishing specific hypotheses and by designing an environmental data collection program that will test the hypotheses.

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4.2 Develop Sampling Objectives

Sampling objectives are derived from the response priorities. Establishing clear and tangible sampling objectives that can be translated into sound test hypotheses is critical to determining the amount of data required to draw conclusions. It is also imperative that the data quality requirements are appropriate to support those conclusions. Decisions that are then made as a result of a careful analysis of the data are considered scientifically-based and therefore, provide greater confidence to those making the decisions and to those affected by the incident with regard to their health and safety.

Specific sampling objectives that may be applicable for an environmental data collection response may include (OSHA 2002):

Initial Response Sampling:

- Immediate Assessment of Potential Contamination**:** Determine, in near real-time, whether a release of spores is occurring or has occurred in a facility. Real-time detection instrumentation, biological agents.
- Identifying Spores in a Bulk Material**:** Determine if a bulk material, such as a powder in an envelope, is contaminated with *B. anthracis*. On-site analysis may be used for preliminary assessment, but laboratory analysis provides confirmation.
- Initial Agent Characterization: Determine the identity of the agent, presence of spores, formulation, toxicological properties, antimicrobial sensitivities, strain sub-typing, persistence, and other physical properties.

Initial Response and Characterization Sampling:

- Determining Contamination Pathway: Determine whether spore contamination resulted from airborne or fomite transport.
- Determining Contamination of an Article**:** Determine whether the surface of an article is contaminated.

Characterization Sampling:

- Determining Extent and Location of Contamination (Characterization Sampling): Determine qualitatively, and if possible, semi-quantitatively, the extent and magnitude of contamination; inform the understanding of spore transport and fate; inform decontamination plans, and compare with future clearance sampling results.

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Verification Sampling:

- Effectiveness of Decontamination (Verification Sampling): Determine whether parameter measurements for the decontamination technology have met criteria established in the RAP.

Clearance Sampling:

- Post-Decontamination Sampling: Develop a body of data of adequate quantity and quality to enable IC/UC to verify that the originally contaminated environment has been sufficiently decontaminated to allow re-occupancy of the area without the use of personal protective equipment (PPE) or other protective measures (OSHA 2002).

4.3 Specify a Hypothesis

Hypothesis-driven sampling plans provide for defensible decisions based on the resulting data, which can be evaluated semi-quantitatively or qualitatively. Hypotheses should specify the principal question(s) of interest, which will then help identify needed information inputs such as epidemiology data or environmental data. Clear hypotheses must be defined before an investigator decides on the number and types of environmental samples to collect and the specific locations to sample. As data are received and interpreted, this new information may be evaluated against the initial intelligence and epidemiologic data and could refine or shift sampling objectives. Subsequently, a new set of hypotheses may be generated and new sampling plans developed to reflect the changing needs.

4.4 Develop a Sampling Plan

A well-designed sampling plan ensures that resulting data can answer the specific hypothesis being tested, thus fulfilling the sampling objectives. The sampling plan, as defined by the VSPWG (see Section 1.2), is a documented approach for field execution that captures the specific combination of operating precepts and diagnostic tools used for a given scenario to answer a specific hypothesis. A sampling plan is an executable plan of action that addresses the sampling and analytical requirements of a specific situation and is formulated in accordance with the guidance of the sampling strategy. This plan should be developed by experts (e.g., industrial hygienists or environmental scientists with microbial sampling expertise) with training and experience in conducting field studies or investigation.

A sampling plan must specify the sampling approaches, methods, and analyses, as well as the number, types, and locations of samples to be collected in a given physical space. The plan also must address quality control considerations (DHS 2007b). A comprehensive sampling plan cannot be developed prior to an incident because its development is governed by the amount of information known about the agent, whether the location of the release is known, and whether the agent has been modified or enhanced. Only after the sampling objectives are determined and

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associated sampling approaches (discussed in Section 5) are selected can an incident-specific sampling plan be written. A sampling plan may develop into several individual plans for multiple locations each with a different objective. A sampling plan may be developed for each task or phase of the response (*first response, characterization, remediation,* and *clearance*) (DHS 2007a*)*. Sampling plans should be documented and describe the basis for all steps, including quality assurance.

Sidebar 3 outlines the process EPA uses to document data quality objectives. The format of an incident-specific sampling plan may vary. Appendix F provides an example sampling plan used in the EPA-funded Bioresponse Operational Testing and Evaluation (BOTE II) project.

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Sidebar 3 – The EPA Data Quality Objectives Process

In order to ensure that the data collected from the exercise of a sampling plan matches the needs of a hypothesis and related decision, a systematic planning process is needed to design the data collection. As an example, the EPA uses the Data Quality Objectives Process to establish performance or acceptance criteria, which serve as the basis for designing a plan for collecting data of sufficient quality and quantity to support the goals of a study (ASTM 2010c). The DQO Process consists of seven iterative steps that are outlined below and explained in detail within the ASTM document.

Elements of the systematic planning process include:

- Organization: Identification and involvement of the sampling plan manager, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, etc. (e.g., all customers and suppliers).
- Sampling Plan Goal: Description of the project goal, objectives, and study questions and issues.
- Schedule: Identification of project schedule, resources (including budget), milestones, and any applicable requirements (e.g., regulatory requirements, contractual requirements).
- Data Needs: Identification of the type of data needed and how the data will be used to support the plan's objectives.
- Criteria: Determination of the quantity of data needed and specification of performance criteria for measuring quality.
- Data Collection: Description of how and where the data will be obtained (including existing data) and identification of any constraints on data collection.
- Quality Assurance (QA): Specification of needed QA and Quality Control (QC) activities to assess the quality performance criteria (e.g., QC samples for field and laboratory examinations, audits, technical assessments, performance evaluations, etc.).
- Analysis: Description of how the acquired data will be analyzed (either in the field or the laboratory), evaluated (i.e., QA review/verification/validation), and assessed against its intended use and the quality performance criteria (EPA 2006a).

While these steps are outlined in a sequential fashion, the iterative nature of the DQO Process allows one or more of these steps to be revisited as more information on the problem is obtained (EPA 2002). A good sampling plan should expend no more resources than are necessary to meet the associated objective (EPA 2002).

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4.4.1 Sampling Approaches

There are three main sampling approaches described in this document: *judgmental sampling*, *hotspot sampling*, and *combined judgmental and random* (CJR) sampling. Judgmental sampling is environmental sampling in which locations having the greatest likelihood of being contaminated are selected using the investigator's expert judgment (Emanuel 2008). Hotspot sampling is a probabilistic (i.e., samples randomly selected) sampling approach that provides for detecting small hotspots of contamination. The CJR sampling approach employs a Bayesian methodology that combines probabilistic samples with a given number of judgmental samples to obtain a specified level of confidence that a building or area has no detectable contamination.

The type of sampling approach selected is based on the response phase, whether the response is covert or overt, the magnitude and type of release, IC/UC objectives, and the available resources. *Judgmental sampling* is virtually always used in initial public health, characterization and clearance sampling, due to its speed, efficiency, and demonstrated effectiveness. For characterization sampling with the majority of contamination scenarios, judgmental sampling will be sufficient to detect the contamination. However, if *B. anthracis* may have been disseminated in one or more small, isolated locations that would typically not be sampled by judgmental samples, then the *hotspot sampling* approach can be used. Although such scenarios are expected to be rare, the hotspot sampling approach is mentioned as an option for completeness. For clearance sampling, judgmental sampling may be sufficient if clearance statements are made with high confidence based on the effectiveness of the decontamination process along with non-detect judgmental samples. The *CJR approach* can be used for clearance sampling if there is a need to generate statistical confidence statements. A more in-depth discussion of these three approaches is found in Section 5.

In selecting a sampling approach for the site-specific sampling plan, the IC/UC must consider many factors, some of which can be in conflict. The IC/UC must consider the level of confidence in the intended outcome of the process needed (i.e., that the facility is free of detectable contamination), the time available to make that determination, the resources available, and the financial investment required. Components of resources available include staff available to collect samples, consumables used in the sampling and analysis process, and analytical resources (laboratories, staff, and equipment) available for processing of environmental samples. Limitations in any resources required to execute the overall sampling response may limit the options available among sampling approaches that can be exercised in the site-specific sampling plan.

Based on the best available science and the most practical approach, EPA and CDC have developed an *Interim Clearance Strategy for Environments Contaminated with Bacillus anthracis* that considers that the available knowledge of the efficacy of decontamination when combined with a reliance on judgmental sampling alone are sufficient generally to inform positive estimations by the IC/UC on clearance of a previously contaminated facility or space.

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4.4.2 Pre-Incident Data

Security camera recordings and eyewitness accounts might provide some information about the extent of contamination. Data on ambient interior conditions (temperature and humidity and time of day) and outdoor conditions (wind speed and direction, temperature, and humidity) contributes to understanding exposure pathways and location of contamination. Such data can be combined with known facility parameters and traffic patterns and used to model the spread of the spores to help estimate exposure of potentially affected individuals. If other environmental sampling systems exist near the site of the incident (i.e., BioWatch collectors), the data from those systems should be obtained and reviewed.

4.4.3 Initial Sampling Plan

Environmental assessment during the initial response phase is a critical component of an overall investigation because it provides important information about the potential exposures to populations who may have been in the release zone. Environmental exposure information along with epidemiological data helps support implementing post-exposure prophylaxis and other public health activities. Knowledge of individuals who have contracted anthrax and whether it is cutaneous or inhalational is important in developing sampling plans. For example, if an individual contracts inhalational anthrax, then that informs the IC/UC that the agent is small enough to enter the deep lung. Thus, the agent may be wide spread throughout the facility. Environmental sampling during the first response phase typically takes place as soon as possible after identifying an incident.

A modular approach provides an effective process for conducting environmental assessment and investigation during the initial response phase as it creates boundaries based on specific questions being asked about the potential incident. Additional benefits include the ability to resolve complex situations, response in the presence of limited resources (on the ground and in the laboratory), and rapid data turnaround resulting from manageable sample numbers. Each module should be designed to address a single hypothesis.

The number and sizes of the modules will depend on the scope and magnitude of exposure. Different modules may exist for:

- Contamination of a closed office environment
- Contaminant drift within an open office environment
- Agent migration via air handling systems

For example, a single individual in an office environment who opens a letter containing a fine powder composed of a *B. anthracis* spores would necessitate a focused investigation of a small area when the interest is exclusively the exposure of one or a few individuals. Environmental

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sampling would be targeted to provide resolution on the release point and to estimate the level of any potential exposure. However, if people work in an open, cubicle office environment, another module should be established that addresses their exposures resulting from spore drift or contact with contaminated fomites. Consideration of biological agent migration to other areas of the building would be addressed through a separate module with sampling targeted to address cross-contamination as a result of people and fomite movement, as well as air transport through the building's ventilation system (VSPWG 2007; VSPWG 2008; Amidan 2009)). Multiple modules may be employed simultaneously, each addressing unique hypotheses. Some overlap may exist in the sampling strategies for each module. This is acceptable as it assures that the data generated by a given module can be integrated from one module to another to create a seamless picture of an incident. However, too much overlap creates duplication and a waste of limited resources.

This is an iterative process of assessing and responding, and of subsequently modifying the response based on assessment. Certain incidents necessitate an initial response to the crisis before appropriate personnel can complete assessment. Such actions as shutting off air handling systems, restricting access to a location, and initiating post-exposure antimicrobial prophylaxis are time-sensitive and must be started immediately.

While there is no scientific evidence supporting correlation of surface contamination resulting from the deposition of an airborne release of a biological agent and the inhalation challenge that may have occurred to the exposed population during the release incident, it does provide context for identifying which areas likely present the highest risk of exposures to building occupants.

4.4.4 Characterization Sampling: Dividing the Building into Zones

Because resources are limited and remediation must proceed quickly, characterization sampling must be centered on well-defined goals. The most efficient characterization of an incident depends on what is known about the incident. Knowledge and understanding of the spore dispersal mechanism, common transport mechanisms, sampling and analysis resources, and the decontamination techniques available for use will help in developing an efficient characterization sampling plan. For example, if there are small areas with high contamination concentrations that must be identified and addressed using a localized decontamination method, then characterization sampling must be designed to yield a high likelihood of discovering all such hotspots. On the other hand, contamination dispersal could result in a very distributed form, with widespread contamination and few hotspots, as was observed during trials at the Idaho National Laboratory in 2007-2008 involving the aerosol dissemination and sampling of a biological simulant in a building.

The potential for contamination within a large building is often not the same across the entire building. Many factors could affect dispersion patterns including distance from release, air

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ventilation systems, traffic patterns, building layout, etc. Therefore, the sampling approach could be different in different parts of the building, depending on the likelihood of contamination. In this case, it is helpful to divide a building into zones. A *zone* is defined as an area within a building that has a similar likelihood of contamination, similar building characteristics and the same sampling objectives. The modular approach utilized in the initial response is not based on similar likelihood of contamination, rather it targets areas anticipated to be contaminated and evaluates potential contamination pathways which may or may not be contaminated. These differences in sample results coupled with the location of the sample aid in understanding any potential exposure pathways and persons most likely at risk of exposure.

If remediation is warranted, the IC/UC should be able to choose the type of remediation method(s) to address contamination in the zone. The sampling approach applicable for different zones may be very different for the following reasons:

- The sampling objectives and decision criteria are based on the amount of prior information available for each part of the building, and
- The different zones have different likelihoods of contamination.

Similar zones should have the same sampling approach. Identifying zones and assigning them zone designations should consider any relevant known information regarding the following:

- Building layout
- Ventilation systems and traffic patterns
- Occupant activities
- Release location
- Initial response results and effects
- Apparent contamination pathways
- Within-room features (furniture, counters, tabletop, shelf configurations)
- Surface materials
- Decontamination technology options and areas of influence

Four types of zones are described in the following subsections.

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4.4.4.1 Zone 1: Extremely High Likelihood of Being Contaminated
(ASTM 2010d, 2010e, 2010f)

This zone includes areas that are confirmed contaminated or are assumed to be contaminated. Examples include the area around a release point, areas adjacent to the release point with a direct flow path from the release point, and areas in which contamination was detected in the initial response phase.

Because this zone of a building is known or assumed to be contaminated, detailed characterization sampling is not required if the entire zone will be decontaminated. If additional information is needed to support selection of decontamination technologies or parameters in order to decontaminate the entire zone, some additional judgmental samples are recommended. These samples should be located using best professional judgment and should take into account any recommended pre-defined sample locations. If areas of very high levels of contamination require a different decontamination technology than areas of lower levels of contamination, then additional sampling may be required to accurately delineate these areas.

4.4.4.2 Zone 2: High Likelihood of Being Contaminated

By definition, the likelihood of contamination in this zone is high, but there is no obvious evidence of contamination here before characterization. The primary objective for sampling within this zone is to identify contamination if it exists or to provide sufficient confidence that it does not exist. If feasible, in order to quickly determine if the zone is contaminated, first collect some judgmental samples in locations that are most likely to be contaminated. If any of those judgmental samples are identified as contaminated, then this zone can be re-classified as Zone 1 and proceed with the recommendations as discussed in Section 4.4.4.1. If all judgmental samples are uncontaminated, but there is reason to believe contamination may only exist in one or more small hotspots, then the hotspot sampling approach (Section 5.2) could be used if warranted. If the hotspots are sufficiently delineated and are small relative to the entire zone, contaminated boundaries within the zone could be established and decontamination could focus on the contaminated areas within the zone.

If no contamination is found in any of the initial judgmental samples, then a more extensive sampling approach (e.g., judgmental or CJR sampling approaches) may be necessary, if feasible and time permits, so that this area can be cleared. The IC/UC will determine if additional samples must be collected to clear the area. The decision will be based on several factors including, but not limited to, time and resource constraints, feasibility, and magnitude of incident (other buildings potentially contaminated). If all samples show no contamination present, then this zone should have limited or no entry in order to be

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protected against potential future cross-contamination.4.4.4.3 Zone 3: Low Likelihood of Being Contaminated

In this zone there is no prior evidence that contamination is present, but there is a low chance of the zone being contaminated. These are areas the IC/UC does not believe are contaminated, but they do not have sufficient evidence to support that conclusion. The characterization sampling objective for this zone is to determine if contamination exists or does not exist. The judgmental sampling approach (see Section 5.1) is recommended.

4.4.4.4 Zone 4: Extremely Low Likelihood of Being Contaminated

This zone includes all remaining areas in the facility that have an extremely low potential of being contaminated because of their location relative to the release point, and the apparent absence of pathways for contamination to travel from the release point. If there is sufficient evidence that there is no known plausible pathway for the contaminant to have entered this zone, then the sampling team is not required to obtain any samples. This zone designation is only included herein for completeness purposes so an entire building or floor plan can be represented, including areas where no samples will be required. If there is some non-negligible chance that contamination is present (albeit a very low chance), then the sampling team should classify the area as a "Zone 3: Low Likelihood of Being Contaminated" and follow the recommended sampling strategy in Section 4.4.4.3.

4.4.5 Clearance Sampling in Designated Zones

The recommended sampling approaches for clearance sampling in Zones 1, 2, and 3 are the same regardless of whether a zone is being cleared after decontamination or after characterization sampling did not detect contamination. The optimum sampling plan for a given incident-specific scenario is a function of various factors, including, at a minimum, the timeframe required for results, the resources available for collecting samples, the resources available to analyze samples, funding available to resolve the situation, and the level of confidence required by the IC/UC and other responsible parties for deciding that a space has been deemed not to be a public health threat.

4.4.5.1 Zone 1: Extremely High Likelihood of Contamination

Zones that were originally classified or reclassified as having an "extremely high likelihood of being contaminated" (Zone 1) require decontamination. After decontamination, such areas

within a building are assumed to have a "low likelihood of being contaminated" (Zone 3) and are treated as described in the following section.

4.4.5.2 Zones 2 and 3: High and Low Likelihoods of Contamination

For zones that had a high (Zone 2) and low (Zone 3) likelihood of contamination where all characterization sample results were negative, additional samples may be collected to finally clear the area since decontamination was not conducted in those areas. The IC/UC will determine if additional samples should be collected. The decision will be based on a collection of information including epidemiological data, characterization sampling results, and first responder, law enforcement, and public health information, if time permits. Depending on site and incident specifics, the IC/UC may decide to clear a zone based on non-detect characterization sampling results.

For areas that were classified as Zone 1 and decontaminated, clearance sampling is necessary to demonstrate that there is confidence that no detectable contamination remains, and the area can be released for general use. Because information is known about the locations of contamination identified during the characterization phase, judgmental sampling will always be desirable at or near those locations and surfaces along all potentially contaminated pathways (see Section 5.1). It will be up to the IC/UC to decide whether knowledge, control, and verification, of the decontamination method along with judgmental validation samples will be sufficient for clearance with high confidence.

Regardless of whether contamination was detected and decontaminated, or not detected, another option for clearance sampling is the CJR approach (see Section 5.3). This approach makes use of judgmental and statistical ("random") samples, and provides for stating with X% confidence that at least Y% of the decision area does not contain detectable contamination. The advantages and disadvantages of the CJR approach are discussed in Section 5.3.

4.4.6 Sensitive Items versus Non-sensitive Items

Some items are considered sensitive due to the fact that these items may be damaged during sampling when using sample collection methods that involve moistening solutions. It is important to determine what items may be considered sensitive by the property owner at the start of the response. Sensitive items can include items such as artwork, photographs, and equipment such as computers, electronic and electrical circuit boards, high-voltage power lines, and electronic control panels. In addition, personal items such as cellular phones, clothing, and jewelry can be considered sensitive items. Many of these items need to be sampled during characterization and removed prior to decontamination of the facility if possible. Sensitive items

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with a positive characterization sample must be contained before removing so that contamination is not spread. These items can be decontaminated using less destructive methods such as ethylene oxide (only used for small-scale decontamination) at an alternative location. If sensitive items cannot be removed before decontamination, then these items should be protected from the decontaminant. Sensitive items will most likely be sampled using a vacuum sampling technique as was done during the 2001 Amerithrax incident cleanup operations.

4.4.7 Operating Equipment

Decisions must be made on whether equipment (e.g., refrigerators, printers, cash registers, computer screens, typewriters, etc.) present in the contaminated area will be decontaminated and kept after the facility is released for reoccupation, or whether the equipment will be removed and properly disposed. If the equipment is kept, then post-decontamination sampling will be needed to confirm that the equipment has been decontaminated. If there are areas where contamination may have accumulated (such as grease areas or wells, fans, heating or cooling elements, etc.), then samples should be collected in these areas. If there are many small crevices, then vacuum sampling may be in order. If equipment is completely enclosed and air tight, then only wipe sampling of the enclosure will be required.

4.4.8 Optimizing the Sampling Process

At each stage of the response to a contamination incident there are many variables that can be optimized so that only the sampling necessary to achieve the objective(s) is performed. Optimization can be applied in 1) partitioning a facility into designated zones, 2) selecting the sampling approach for each designated zone, and 3) using composite samples where appropriate. The optimization process would be implemented by engaging site workers, technical experts, and key stakeholders to provide the IC/UC with advice on the options, costs and implications of various courses of action.

4.4.8.1 Optimizing via Designated Zones

Sampling can be optimized by partitioning a facility into zone categories, as discussed in Section 4.4.4. Portions of a facility designated as “Zone 1” areas (extremely high likelihood of contamination) may only require minimal judgmental sampling to detect contamination. Spaces designated as “Zone 4” areas (extremely low likelihood of contamination) may require no additional sampling and minimal confirmatory sampling. Areas designated Zone 2 (high likelihood) and Zone 3 (low likelihood of contamination) may receive the most attention during the overall sampling plan development and determination of most appropriate sampling approach

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for those zones. Consideration will be given to the degree to which these areas are distinct from Zone 1 areas, with an emphasis on passageways between them. Such passageways as open doors or connected air flow systems will increase the amount of sampling done and the approach taken.

4.4.8.2 Optimizing Sample Collection

In many response situations, resources are constrained due to 1) limited laboratory capacity to analyze samples, 2) limited number of people to collect, process, and analyze samples, 3) restrictive cost of the sampling or analysis, and 4) limited sampling media and laboratory processing supplies. Additionally, there may be great pressure to have a quick turnaround on the sample results. When planning sample collection, using the optimization process will ensure that the process is efficient and that the data generated are meaningful and applicable. Iterative-based sampling consists of collecting a set of samples, then using the results to determine where to collect another set of samples. Although this may decrease the number of samples collected, it does require more time then collecting samples for the entire area all at once.

Another optimization process is to collect all the samples at once but then prioritize sample submission to laboratories for analysis. Whether samples are collected all at once from an area or iterative-based sampling is conducted, the IC/UC can prioritize sample submission. Samples that are most likely to answer the sampling hypothesis should be chosen for submission to the laboratory for analysis first. Prioritization of sample submission may be based on:

- Knowledge of the incident
    - Contaminant characteristics
    - High probability sample locations like ventilation filter, electrostatic surfaces, high traffic areas, etc.
    - Epidemiologic data
- Time constraints of the incident
- Overall priority of area/building with respect to response objectives

Composite sampling (discussed below) and pooled sample analyses (see Section 7.3) are two other strategies to reduce the number of samples taken and/or analyses performed

4.4.8.3 Composite Samples

Composite sampling involves collecting samples from multiple locations with the same sample collection device and submitting it as a single sample. This might involve wiping more than one

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location with the same wipe, or vacuuming more than one location with the same vacuum filter media. The main advantages of a composite sample are the reduction in the number of samples that require processing and analysis and the reduction in the sample collection materials required. Another advantage to composite sampling is the increase of surface area sampled. With discrete sampling the surface area sampled may by 100 cm^2. With composite sampling the surface area sampled may be up to 400 cm^2 which may increase the likelihood of detecting contamination. During the various phases (public health screening, characterization, and clearance sampling) of past *B. anthracis* incidents, composite sampling was used successfully. An example is provided in Sidebar 4, in which composite sampling is used to verify a cross-contamination pathway. With these conditions, collecting composite samples instead of discrete samples (i.e., collecting one sample from one sampling location) should be considered.

Sidebar 4 – Example of Use of Composite Samples

Initial response sampling of a building's entranceways determined that a three-story office building was cross contaminated due to foot traffic from an adjacent contaminated building that had a *B. anthracis* release. The IC/UC decided in advance that all carpets located in large conference rooms would be replaced if found to be contaminated. Therefore, during characterization sampling, the team decided it would save resources by compositing four vacuum sample locations within a conference room as one sample, instead of collecting four discreet vacuum samples. Four locations to serve as one composite sample is given only as a guide and should depend on the area and amount of debris present. Each floor of the three-story building had a large conference room. The sample team collected one composite sample for each conference room on each floor. Composite sampling was deemed acceptable in this scenario because a similar decision would have been made if discrete sampling had occurred. In other words, if only one of four discrete samples was positive the same decision to replace the carpet would have been made.

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When sampling multiple locations using composite sampling, the decision makers are treating the one analysis of all those locations as one decision. Collecting multiple composite samples from overlapping sample areas should be avoided. In such a case, the areas cannot be distinguished from each other, all spatial information is lost, and useful information is gained only if both samples are positive or negative.

When collecting composite samples, the following guidelines are provided to maximize the utility of this technique:

- Sample vertical and horizontal surfaces separately.
- Group frequently touched surfaces together, like light switches or door handles.
- Keep similar surface type together (e.g., smooth, non-porous desks and filing cabinets).

If there is a desire to delineate contaminant location by room, then a composite sample should not include locations in two or more rooms. Compositing should only be done within each room. This also holds true for delineating contamination by floor, by ventilation systems, etc. The number of locations to collect with a single sampling media should be between two and six. For swabs only two to four locations is appropriate. This prevents the swab from drying out and minimizes overloading the sampling media, both of which will decrease collection efficiency. For wipes, two or four locations should be collected for the same reasons described above. Composite vacuum samples (e.g., filter sock) should only include two to six locations. More composite locations can be collected with a vacuum sample since the filter sock can collect more material, and it is not subject to drying out since it is not wetted. The number of locations and surface area collected for a given sampling media should be consistent throughout all sampling events. This ensures consistency of results for data interpretation. A composite sample collected from four locations with a single sampling media is referred to as a 4-point composite.

One disadvantage of composite sampling is contamination can be spread from contaminated locations to uncontaminated locations. However, this may not be an issue if finding contamination within an area will lead to decontaminating the whole area. Another potential disadvantage is dilution, which would depend on the sample collection method. Composite sampling using the wipe method may reduce the amount of contamination collected on the wipe from a contaminated location by distributing it to subsequent uncontaminated sampling locations. This may cause a composite sample to be reported as non-detect where otherwise a sample of a single contaminated location would be declared positive. However, composite sampling has been exercised in simulated operational scenarios, such as the second sampling test at Idaho National Laboratory (VSPWG, December 2008), with minimal deleterious effects observed.

The decision to collect discrete or composite samples will be based on the types of decisions made with the results, laboratory throughput, resources (sampling media, sampling personnel) and the size of the incident. In most incidents, collection of both composite and discrete samples

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will be conducted. Sidebar 5 presents an example of sample collection optimization in order to make a quick decision to fumigate based on refining the sampling strategy to determine if the pathway of contamination was via aerosol deposition. In this example the sampling process prioritizes samples, expedites the timeline, and saves valuable resources for characterizing other zones.

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Sidebar 5 – Optimizing Characterization Sampling for Making Decontamination Decisions

A sampling team conducted characterization sampling in an area adjacent to the room where a letter containing *B. anthracis* powder was opened and also shared the same HVAC system. Based on this information, the adjacent area was designated as having an extremely high likelihood of contamination (Zone 1). The IC/UC gathered all existing data from any inhalation and/or cutaneous* cases in that vicinity, in order to develop a sampling plan. Based on analysis of the anthrax cases, epidemiological surveillance, and law enforcement evidence, the team determined no anthrax cases were identified from individuals in this area. There was no evidence that the contaminated letter entered this area. However, the IC/UC hypothesized that contamination could still be present due to foot traffic and possibly by transport via the HVAC system. Sampling this area would help inform those most likely to be at highest risk of exposure, and therefore disease, and help with public health decisions for post exposure prophylaxis (PEP).

The IC/UC decided that if any designated areas had evidence of aerosol deposition, then fumigation would be chosen as the method for decontamination. Therefore, the initial characterization sampling efforts would use the judgmental sampling approach to minimize the time and resources needed to make the decision to fumigate.

The sampling team collected samples on surfaces in the HVAC system that had a high probability for aerosolized spore deposition due to inertial impaction. The surfaces included baffles and downstream (supply air) ductwork where airflow made abrupt changes in direction. In addition, the sampling team collected samples on the downstream (supply air) filters where spore deposition may have occurred. This area of the building also had a drop ceiling that acted as the return air plenum. These return air plenums are good locations for some of the larger spores or agglomerated spores to settle due to slower airflow and longer retention time. Therefore, the sampling team removed ceiling tiles and sampled on top of the tiles as well.

Samples were positive for *B. anthracis* on the supply and return vents and one of the ceiling tiles. Therefore, the IC/UC concluded characterization sampling and initiated fumigation of the area.

* Cutaneous cases would show evidence of surface contamination and inhalation cases would show evidence of aerosolization. Anthrax is not known to be communicable (spread from one infected person to another). (Emanuel et al. 2008).

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Section V: Sampling Approaches

Because sampling every surface in a building is not practical, a sampling approach is required to select representative surfaces for sampling. There are three kinds of sampling approaches discussed in this document: judgmental sampling, hotspot sampling, and CJR sampling. Generally, the judgmental sampling approach will be sufficient to detect contamination for first response and characterization sampling. However, the hotspot sampling approach might be needed for characterization sampling to identify smaller, isolated locations of contamination not detected by judgmental sampling. Although the need for hotspot sampling is expected to be rare, it is briefly discussed in this chapter for completeness. The CJR sampling approach employs a Bayesian methodology that combines probabilistic samples with a given number of judgmental samples to obtain a specified level of confidence that a high percentage of a building or area has no detectable contamination. These three sampling approaches are discussed in more detail in the following subsections.

5.1 Judgmental Sampling Approach

Judgmental sampling is environmental sampling in which locations having the greatest likelihood of being contaminated are selected using the investigator's expert judgment (Emanuel 2008). This approach can quickly determine if an area/zone is contaminated, although it is only as good as the information on which sample location selection is based. Using information gathered from the IC/UC, judgmental sampling plans are created with predetermined locations to collect samples. However, sampling teams can also use their judgment to choose new locations while conducting sampling. This approach is commonly utilized during the first response phases involving law enforcement and public health agencies when information to support both the criminal investigation and the implementation of medical countermeasures is needed quickly. Judgmental sampling is also used for the characterization and clearance phases of a response. With judgmental sampling, probability or confidence statements about the absence of contamination are more difficult to make and may require additional assumptions regarding representativeness and likelihood of contamination presence.

Judgmental sampling can be the most efficient way to find contamination if it is either widespread or behaves as expected. Judgmental sampling utilizes expert knowledge on applicable aerosol physics (including particle size, deposition rate, and settling velocity), principles of industrial hygiene, past responses, and epidemiologic and criminal investigations to determine sample locations. It has been successfully used in multiple investigations.

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5.1.1 When to Use Judgmental Sampling

Judgmental sampling is often used during the early phases of an incident as the primary sampling strategy. It is most effective to implement during characterization sampling if the source and characteristics of the contaminant are known from the crisis response phase sampling and when supporting epidemiological or forensic data are available. Critical information to consider from the incident, if available, would include the timeline of the incident, the dissemination mechanism, contaminant characteristics, observable contamination, if the HVAC system was shut down and when, any pathways the contamination source moved along, and any critical forensic evidence collected by law enforcement. Even in situations where very little is known about the release, the IC/UC can use professional judgment and draw upon past experience to select sampling locations. Judgmental sampling is also used during clearance sampling.

5.1.2 Selecting Locations for Initial Public Health and Characterization Sampling

As mentioned in Section 4, judgmental sampling focuses on those areas most likely to be contaminated. Different methods of dispersal would result in different patterns of contamination, and sampling should discover the resultant pattern. If the delivery source is known, investigators can quickly identify sampling locations at the source of the release. However, additional sampling locations will need to be identified to determine the extent of contamination in the building or area. If the source is not known, then identifying locations for sampling will be more challenging.

In addition to information gathered from law enforcement, first responders, building occupants, and public health, investigators may inspect the building for visual information to aid in selecting sample locations. Investigators should utilize current knowledge about contamination pathways resulting in spread of the spores through the building to aid in sample location selection. The four primary contamination pathways include:

- Process pathways
- Foot traffic pathways
- Air movement pathways
- Maintenance and other activity pathways

Process pathways are pathways, either manual or mechanical, associated with a work activity or sequence of steps along a given path (Emanuel et al. 2008). For example, the process by which incoming mail in an office building is processed and delivered to individual occupants can provide information on locations to sample. In this scenario, samples should be collected at

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locations where a contaminated letter or package was known to be present as part of the delivery process (Greene 2002).

Foot traffic movement pathways spread spores from one surface to another or into the air when individuals step in contamination or have contaminated clothing and subsequently move to another location. Samples should be collected along the route individuals took to exit the building (e.g., stairwells, elevators) and the path first responders, law enforcement, and public health took when responding. Paths along which mail carts, equipment, and vehicles moved could also be sampled.

Air movement pathways are pathways associated with the operation of HVAC systems, natural ventilation from open windows, the airflow within affected facilities, and equipment having fans like printers, computers, and refrigerators having a major influence on the spread of the *B. anthracis* spores. The spores can spread quickly throughout the areas served by the same air-handling unit serving the release location, including other floors of the building and all air-handling zones sharing a common return plenum with the release zone. If the HVAC system was operating during the release or was used as the mechanism of dissemination, one can anticipate a greater percentage of the building was contaminated. Specific locations could be sampled including supply air diffusers, return air vent covers, HVAC filters, and equipment fans.

Maintenance and other activity pathways are pathways where actions taken by individuals in these areas can increase or spread contamination in a building. For example, cleaning activities using compressed air or vacuuming can re-aerosolize *B. anthracis* spores. Use of brooms or mops in contaminated areas subsequently used in other areas can cause secondary contamination. In 2006 and 2007, *B. anthracis* contamination was identified in individuals who manually processed imported hides to make drums (Guh 2010, Nguyen 2010). Manually stretching and shaving hairs on contaminated hides resulted in exposure to *B. anthracis* spores.

Sample locations should be selected at sites where *B. anthracis* spores are likely to remain after deposition (repositories). Examples include surfaces with electrostatic charge (e.g., computer screens); tops of light fixtures; tops of signs; air ducts and surfaces near air-supply registers; air return registers, plenums and air-intake grills that are part of equipment cooling systems; ventilation intakes of electronics (e.g., computer tower fans); and HVAC filters.

Knowledge of these four kinds of pathways and likely repositories can assist investigators in identifying sampling locations for judgmental samples.

5.1.3 Selecting Locations for Clearance Sampling

One goal of the sampling approach for clearance purposes is to sample locations where a positive contamination result was found (and/or adjacent locations) in order to verify no detectable spores

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are present. The rationale is that previously sampled locations having a positive result, and nearby locations, represent the most challenging test of remediation effectiveness. Also, locations more likely to have been previously contaminated (such as surfaces along contamination pathways) can be selected for clearance sampling. This rationale can be applied in cases where a limited characterization was performed because the actual contamination boundary may not have been determined and/or the decision to remediate was made based on positive samples at key locations (See Sidebar 5).

5.2 Hotspot Sampling Approach

The *hotspot sampling* approach uses grid sampling with a random start to provide for detecting a small area of contamination (hotspot). This approach may be needed in characterization situations where a hotspot would not be detected by judgmental sampling. Although such situations are expected to be rare, the hotspot sampling approach is briefly discussed for completeness.

The number of grid samples is chosen to provide sufficiently high confidence (Z%) of detecting a hotspot of a given shape (usually circular or elliptical) and size. The type of grid (square, rectangular, or triangular), the hotspot shape and size, and the confidence parameter are chosen by the IC/UC depending on the specifics of the situation. The VSP software (VSP Development Team 2010, Matzke et al. 2010) implements the calculations for the hotspot sampling approach. For more information about the hotspot sampling approach, see Gilbert (1987, Chapter 10).

5.3 Combined Judgmental and Random (CJR) Sampling Approach

The CJR sampling approach employs a Bayesian methodology allowing investigators to combine probabilistic samples[a] with a given number of judgmental samples to obtain a specified level of confidence (X%) that a high percentage (Y%) of a building, area, or zone has no detectable contamination (Sego et al. 2007, 2010). The Bayesian approach incorporates prior knowledge about the chances of judgmental samples having contamination, so the combination of judgmental and probabilistic samples allows for statistical inferences about the likelihood of there being no detectable contamination. Increased confidence in the conclusion there is no detectable contamination is important in deciding on the need for further public health or decontamination measures following the initial assessment. The CJR sampling approach ensures samples are obtained from the perceived most-likely-to-be-contaminated locations (via judgmental samples) while protecting against the possibility of contamination existing in less likely areas (via probabilistic samples).

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[a] Probabilistic sampling applies sampling theory and involves a randomization aspect in selecting sampling locations.

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Probability based sampling applies statistical sampling theory and involves randomized selection of sampling locations. Random sampling locations (or grid samples with a random starting point) can be used to accept or refute statistical hypotheses and to make statistical confidence statements about a decision. However, this approach often requires a large (perhaps impractically large) number of samples to achieve an acceptable level of confidence. The CJR sampling approach, because of using judgmental samples, has the advantage of requiring fewer random samples needed to achieve the same level of confidence. However, this requires making some quantitative statements about the ability of the expert to identify potentially contaminated locations and the likelihood of contamination relative to randomly selected sample locations.

5.3.1 When to Use CJR Sampling

The CJR sampling approach can be used for clearance situations when there is a need to generate statistical confidence statements of the form "There is X% confidence that at least Y% of a decision area does not contain detectable contamination." The clearance situation can be 1) after decontamination of a contaminated area, or 2) without decontamination of an area believed to be uncontaminated. In these cases, the CJR approach selects judgmental samples from locations that are more likely to be contaminated and augments the judgmental samples with probabilistic samples. In the case of clearance after decontamination, locations more likely to be contaminated are those identified as contaminated before decontamination and adjacent locations. In the case of clearance without decontamination, locations more likely to be contaminated include those along contamination pathways based on knowledge of the incident (see Section 5.1).

Sidebars 6 and 7 provide scenarios describing how the CJR approach could be used for clearance sampling after decontamination and without decontamination being judged necessary, respectively. Appendix E provides more information regarding the implementation of combined judgmental and random sampling. *It should be noted that confidence statements as outlined above cannot be directly converted into statements that reflect minimal or no risk to health in the space as there remain no accepted criteria for how clean is safe.*

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Sidebar 6 – Clearance Sampling After Decontamination Using the CJR Approach

A small (18,000 square foot) airport terminal was designated as a zone with a "high likelihood of being contaminated." During characterization, judgmental sampling found that one of the plausible pathways (foot traffic) in this zone was contaminated. Judgmental sampling did not detect contamination in other pathways (luggage areas, touch surfaces). The UC made the decision to surface decontaminate the foot traffic areas by first applying amended bleach solution to the entire carpeted floor and then HEPA vacuuming the entire carpeted floor surface. The UC decided that if decontamination was successful, the carpet would remain in place for reuse. All other fixtures and surfaces in the airport terminal remained and were not remediated.

Now that cleanup was performed, the UC wants to state that they are 95% confident that at least 99% of all surfaces do not have detectable contamination. During clearance sampling, the judgmental sampling accounted for 5% of the carpet being vacuumed and samples were collected in those locations most likely to be contaminated (dense foot traffic areas). The carpet vacuum samples consisted of vacuuming 100 locations each three foot by three foot. All 100 judgmental samples were reported as non-detect for *B. anthracis*. The sample planners believed that any judgment sample on the floor was twice as likely to identify contamination than any uninformed random sample. It was determined that judgmental samples were twice as likely to identify contamination because the characterization sample identified that contamination was most likely spread via foot traffic. Based on the total surface area and the likelihood that judgment samples are twice as likely to identify contamination, the total number of samples collected included 100 judgment and 762 random samples. If all sample results are negative, then the "95% confident that at least 99% of all surfaces do not have detectable contamination" can be stated.

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Sidebar 7 – Clearance Sampling Without Decontamination Using the CJR Approach

A small (1,800 square foot) building was entirely designated as a Zone 3 with a "low likelihood of being contaminated." During characterization, five judgmental samples (three foot by three foot vacuum samples) were reported non-detect for contamination. As a result, no remediation was performed. After characterization sampling the building was protected from becoming contaminated by other nearby operations. This was done in order to use the characterization judgmental samples as part of the clearance sample numbers. The UC wants to state that they are 95% confident that at least 95% of the floor surface does not have detectable contamination.

The sample planners decided not to assume the building was clean and assigned the expected *a priori* probability that all areas have no detectable contamination as 50% (unknown). They believed that any judgment sample collected was twice as likely to be contaminated as any uninformed random sample. The CJR approach resulted in judgmental sampling on 5% of the carpeted floor surface (for a total of ten, three foot by three-foot vacuum samples) and an additional 27 random vacuum floor samples. Combining the five judgmental samples from characterization, a total of 37 vacuum samples were analyzed. If all sample results are negative, then the "95% confident that at least 95% of all surfaces do not have detectable contamination" can be stated. If there were any positive results, then decontamination strategies should be implemented to remediate the area.

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Section VI: Sample Collection

The sampling objectives described in Section 4.2 contribute to deciding on the sample collection method(s) selected. A variety of sampling devices are available and one should be selected based on the location and type of surface to be sampled. The selection of appropriate environmental sample collection methods that can meet the sampling objectives must include consideration of the following factors (OSHA 2002):

- Laboratory capability and capacity to process expected samples
- Recovery efficiency of the sample processing method, specificity and sensitivity of the analytical method, and a determination of the need for quantitative, semi-quantitative, or qualitative results
- Suitability of the sample collection method for the potentially contaminated surface
- Cost effectiveness and efficiency of the sampling plan in meeting stated objectives

Obtaining as much information as possible about the *B. anthracis* spores to be sampled, their physical characteristics, and how they were released will help ensure that the most appropriate sample collection method(s) is employed.

Because the methods for sample processing depend on the analytical laboratory, the LRN laboratory to be used (discussed in detail in Section 7.1) must be contacted during the initial planning stages of sampling to discuss method selection. The final decision to select specific sampling methods, media, and materials should be made in conjunction with the LRN.

6.1 Sample Types

This section describes the following sample types: bulk material, surface, air, liquid, and soil samples. The specific uses and advantages of each sample collection method are also described in this section.

6.1.1 Bulk Samples

Bulk sampling is used to collect a visible solid material to determine the presence of a biological agent including *B. anthracis*. Bulk sampling can be used during any phase of an incident (EPA 2006a). Bulk samples of the source contaminant could be used to determine the characteristics of *B. anthracis* spores (ASTM 2010a).

Bulk samples can be collected in a variety of ways, but must be coordinated with the receiving laboratory. Loose source material (i.e., powder) can be collected by placing material into a sterile vial using a sample spoon, trowel, or spatula. Alternatively, sections of carpet or

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upholstery can be removed and transported to the laboratory for processing and testing [ADDIN EN.CITE <EndNote><Cite><Author>Anderson RL</Author><Year>1982</Year><RecNum>1532</RecNum><record><rec-number>1532</rec-number><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Anderson RL, Mackel DC, Stoler BS, Mallison GF</author></authors></contributors><titles><title>Carpeting in hospitals: an epidemiological evaluation</title><secondary-title>Journal of Clinical Microbiology</secondary-title></titles><periodical><full-title>Journal of Clinical Microbiology</full-title></periodical><pages>408-415</pages><volume>15</volume><number>3</number><dates><year>1982</year></dates><urls></urls></record></Cite></EndNote>].Portions of HVAC filter media, or clothing that may be contaminated with *B. anthracis* may also be collected and sent to the lab. A method for collecting bulk samples is described in Appendix C.

6.1.2 Surface Samples

Surface sampling involves collecting microbial contaminants from a surface using an appropriate sampling device to determine the presence of *B. anthracis* spores. Swabs, wipes and vacuum filter socks or cassettes are the primary collection devices for spores on surfaces and are used during all phases (identification, characterization, decontamination, and clearance) of a response (CDC 2012a).

Determining the most appropriate type of surface sample collection method depends on whether porous or non-porous surfaces are to be sampled. Wipes and swabs should be used on non-porous surfaces while vacuum socks or filter cassettes should be used on porous surfaces (DHS 2006A). Examples of non-porous surfaces include: stainless steel, painted wallboard, glass, floor tile, and wood laminate. Examples of porous surfaces include: ceiling tile, fabrics, carpet, clothing, rugs, and upholstered furniture.

When collecting samples for *B. anthracis* on porous surfaces, use of wipes can be considered, because some studies have demonstrated higher recovery efficiencies (RE) when wipes were used to sample carpet and upholstery than when vacuum methods were used [ADDIN EN.CITE <EndNote><Cite><Author>Buttner</Author><Year>2007</Year><RecNum>1500</RecNum><record><rec-number>1500</rec-number><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Buttner, Mark P.</author><author>Cruz, Patricia</author><author>Stetzenbach, Linda D.</author><author>Cronin, Tracy</author></authors></contributors><titles><title>Evaluation of Two Surface Sampling Methods for Detection of Erwinia herbicola on a Variety of Materials by Culture and Quantitative PCR</title><secondary-title>Appl. Environ. Microbiol.</secondary-title></titles><periodical><full-title>Appl. Environ. Microbiol.</full-title></periodical><pages>3505-

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3510</pages><volume>73</volume><number>11</number><dates><year>2007</year><pub-dates><date>June 1, 2007</date></pub-dates></dates><urls><related-urls><url>http://aem.asm.org/cgi/content/abstract/73/11/3505 </url></related-urls></urls><electronic-resource-num>10.1128/aem.01825-06</electronic-resource-num></record></Cite><Cite><Author>Estill</Author><Year>2009</Year><RecNum>1569</RecNum><record><rec-number>1569</rec-number><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Estill, CF, </author><author>Baron PA, Beard JK, Hein MJ, Larsen LD, Rose L, Schaefer FW 3rd, Noble-Wang J, Hodges L, Lindquist HD, Deye GJ, Arduino MJ.</author></authors></contributors><titles><title>Recovery efficiency and limit of detection of aerosolized Bacillus anthracis Sterne from environmental surface samples</title><secondary-title>Applied and Environmental Microbiology</secondary-title></titles><periodical><full-title>Applied and Environmental Microbiology</full-title></periodical><volume>May 8</volume><dates><year>2009</year></dates><urls></urls></record></Cite><Cite><Author>Valentine</Author><Year>2008</Year><RecNum>1471</RecNum><record><rec-number>1471</rec-number><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Valentine, N. B.</author><author>Butcher, M. G.</author><author>Su, Y. F.</author><author>Jarman, K. H.</author><author>Matzke, M.</author><author>Webb-Robertson, B. J.</author><author>Panisko, E. A.</author><author>Seiders, B. A. B.</author><author>Wahl, K. L.</author></authors></contributors><auth-address>Valentine, NB
POB 999,Battelle Blvd, Richland, WA 99352 USA
Pacific NW Natl Lab, Richland, WA 99352 USA</auth-address><titles><title>Evaluation of sampling tools for environmental sampling of bacterial endospores from porous and nonporous surfaces</title><secondary-title>J Appl Microbiol</secondary-title></titles><pages>1107-1113</pages><volume>105</volume><number>4</number><keywords><keyword>bacillus</keyword><keyword>detection</keyword><keyword>environmental health</keyword><keyword>identification</keyword><keyword>spores (inc. endospores)</keyword><keyword>microbial forensics</keyword><keyword>bacillus-anthracis</keyword><keyword>collection</keyword><keyword>spores</keyword><keyword>contamination</keyword><keyword>recovery</keyword></keywords><dates><year>2008</year><pub-dates><date>Oct</date></pub-dates></dates><isbn>1364-5072</isbn><accession-num>ISI:000259270500020</accession-num><urls><related-urls><url><Go to ISI>://000259270500020</url></related-urls></urls><language>English</language></record></Cite></EndNote>]. Rayon/polyester or cellulose/polyester blends are superior to cotton wipes [ADDIN EN.CITE <EndNote><Cite><Author>Valentine</Author><Year>2008</Year><RecNum>1471</RecNum><record><rec-number>1471</rec-number><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Valentine, N. B.</author><author>Butcher, M. G.</author><author>Su, Y. F.</author><author>Jarman, K. H.</author><author>Matzke, M.</author><author>Webb-Robertson, B. J.</author><author>Panisko, E. A.</author><author>Seiders, B. A. B.

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Pacific NW Natl Lab, Richland, WA 99352 USA</auth-address><titles><title>Evaluation of sampling tools for environmental sampling of bacterial endospores from porous and nonporous surfaces</title><secondary-title>J Appl Microbiol</secondary-title></titles><pages>1107-1113</pages><volume>105</volume><number>4</number><keywords><keyword>bacillus</keyword><keyword>detection</keyword><keyword>environmental health</keyword><keyword>identification</keyword><keyword>spores (inc. endospores)</keyword><keyword>microbial forensics</keyword><keyword>bacillus-anthracis</keyword><keyword>collection</keyword><keyword>spores</keyword><keyword>contamination</keyword><keyword>recovery</keyword></keywords><dates><year>2008</year><pub-dates><date>Oct</date></pub-dates></dates><isbn>1364-5072</isbn><accession-num>ISI:000259270500020</accession-num><urls><related-urls><url><Go to ISI>://000259270500020</url></related-urls></urls><language>English</language></record></Cite></EndNote>]. Vacuum sampling is also effective for spore collection from carpet or upholstery and could be used on these surfaces if high concentrations (> 10^2 spores/cm^2) are expected [ADDIN EN.CITE <EndNote><Cite><Author>Brown</Author><Year>2007</Year><RecNum>1485</RecNum><record><rec-number>1485</rec-number><ref-type name="Journal Article">17</ref-type><contributors><authors><author> Brown, Gary S., </author><author>Rita G. Betty, </author><author>John E. Brockmann, </author><author>Daniel A. Lucero, </author><author>Caroline A. Souza, </author><author>Kathryn S. Walsh, </author><author>Raymond M. Boucher, </author><author>Matthew S. Tezak, </author><author>Mollye C. Wilson</author></authors></contributors><titles><title> Evaluation of vacuum filter sock surface sample collection method for Bacillus spores from porous and non-porous surfaces</title><secondary-title>Journal of Environmental Monitoring</secondary-title></titles><periodical><full-title>Journal of Environmental Monitoring</full-title></periodical><pages>666 - 671</pages><volume>9</volume><number>7</number><dates><year>2007</year></dates><urls></urls></record></Cite></EndNote>].

Certain solutions (wetting agents) can be used to pre-moisten biological collection devices to enhance their overall performance. Common solutions include sterile water, sterile saline, neutralizing buffer, sterile phosphate buffer, and peptone buffer. In addition, surfactants (such as Tween 80, Tween 20, or pleuronic) can be added to these pre-moistening solutions to improve removal of spores from surfaces. Neutralizing solutions block the continued action of a disinfectant after sampling. These neutralizing solutions are important during post-decontamination activities (verification and clearance sampling) to ensure that samples, when analyzed properly, are not falsely negative due to the presence of residual disinfectant. Among available neutralizing solutions are:

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- Butterfield's buffer with 0.02% Tween 80 (Tween 80 is effective in neutralizing phenolic compounds and acting as a surfactant);

- Dey Engley broth (Becton Dickinson, Sparks, MD) [neutralizes chlorine compounds and iodine, but may encourage growth during transport];

- Neutralizing Buffer (Becton Dickinson) [contains sodium thiosulfate to neutralize chlorine compounds and aryl sulfonate complex to neutralize quaternary ammonium compounds];

- Letheen broth (Becton Dickinson [neutralizes quaternary ammonium compounds, but may encourage growth during transport]; and

- Phosphate Buffered Saline, pH 7.2 with 0.02% Tween 80 [Tween 80 is effective at neutralizing phenolic compounds and acts as a surfactant].

Similar recovery efficiencies (26.8 – 39.0%) have been obtained with wipes pre-moistened with each of these neutralizing buffers that were processed by the LRN laboratory processing procedure (see Appendix B). The choice of neutralizing solution depends on the disinfectant used. During the initial identification and characterization of a contaminated building, collection devices with a neutralizing solution are less important.

There are factors that will affect the choice of which wetting solutions to use for pre-moistening swabs and wipes for sampling. For example, phosphate-containing solutions (e.g., Butterfield's buffer and phosphate buffered saline [PBS]) may inhibit polymerase chain reaction (PCR) assays if appropriate DNA extraction and purification is not performed; sterile water could lyse osmotically sensitive vegetative cells; and the use of Dey Engley or Letheen broth may encourage growth during transport. PCR techniques are discussed later in the document in Section 7.1. Sterile saline will not neutralize the action of a sporicide or chemical. However, if it is used during characterization sampling (on surfaces that do not contain sporicides), it may help to preserve the viability of *B. anthracis* spores.

Some of the sampling devices can be purchased pre-moistened or they can be pre-moistened prior to collecting a sample. CDC recommends the use of a neutralizing buffer as the pre-moistening solution in their validated swab and wipe-sampling and analysis methods (CDC 2012a). The CDC developed methods for processing macrofoam swabs and cellulose sponge wipes from samples collected on environmental surfaces. These processing protocols use traditional culture methods and yield semi-quantitative estimates of the amount of *B. anthracis* contamination on a sample The CDC collection procedures for the validated swab and wipe

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method and a non-validated gauze method are provided on the CDC website at www.cdc.gov/niosh/topics/emres/surface-sampling-bacillus-anthracis.html.

6.1.2.1 Swab Samples

Swabs are appropriate for sampling small [< 100 square centimeters (cm^2)] non-porous surfaces. Swabs work best for small areas like crevices, corners, supply air diffusers, air return grills, and hard-to-reach places. The CDC currently recommends using synthetic or macrofoam swabs for the collection of *B. anthracis* spores on smooth, non-porous surfaces (CDC 2012a). The LRN laboratories are capable of processing samples collected in accordance with this sample collection protocol using the prescribed swab type.

6.1.2.2 Wipe Samples

Wipes are appropriate for sampling larger (> 100 cm^2) non-porous surfaces, such as walls, desks, and non-carpeted floors. Wipe sampling can be performed using either cellulose sponges or gauze. The CDC currently recommends using a cellulose sponge wipe for the collection of *B. anthracis* spores on smooth, non-porous surfaces (CDC 2012a). The LRN laboratory or laboratories that will be analyzing the sponge wipe samples should be consulted prior to using this collection method to determine if that laboratory is capable of processing and analyzing the sample.

6.1.2.3 Vacuum Samples

The primary sample collection method for sampling large porous surfaces (> 600 cm^2) for *B. anthracis* spores is vacuum sampling. Collecting samples by vacuuming is advantageous for covering large, non-porous surfaces and porous surfaces such as carpeting, ceiling tiles, ventilation systems filters, and upholstered furniture. This type of sampling also works well for capturing bulk powder or dust in hard-to-reach places. Vacuum sampling is also the best choice for sensitive items such as electronics and personal items, since it is less likely to cause damage compared to pre-moistened swabs and wipes. The LRN laboratory or laboratories analyzing the vacuum sampling devices should be consulted prior to using this collection method to determine if that laboratory is capable of processing and analyzing the sample. Currently, vacuum sampling and analysis methods have yet to be validated.

During vacuum sampling, bulk material is trapped by the dry collection media/filter by utilizing a small, HEPA vacuum cleaner or a small sampling pump to draw air through the filter. A number of sampling devices can be used to collect samples from porous materials including filter socks, 3M Forensics Vacuum filters, or 35 mm cassettes. The filter sock method utilizes a filter sock and attachment nozzle that fits onto the inlet nozzle of a HEPA vacuum hose. The 3M

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Forensics Vacuum filter is favored by law enforcement groups due to its ease of use in evidence collection protocols. This filter also attaches to a HEPA vacuum cleaner hose for sampling, though care should be exercised to regulate the power of the vacuum so the filter integrity is not compromised during sampling. The last option uses micro-vacuuming techniques to collect a sample using personal sampling pumps or carbon vane pumps. These pumps utilize a suitable filter contained in a closed-face, conductive sampling cassette to which a short section of plastic tubing cut at a 45° angle is added to the inlet. The EPA method for collecting vacuum sock samples is described in Appendix C. Information on proper packaging and shipping of vacuum socks can be found on the CDC website (CDC 2012b).

Vacuum samples must be collected using only HEPA vacuum cleaners. Conventional home or industrial vacuum cleaners should not be used for sample collection because they can further disperse spores if filtration is insufficient.

6.1.3 Air Samples

Air samples can be taken to determine 1) the extent of airborne contamination, 2) whether *B. anthracis* spores have migrated from the contamination zone, and 3) whether *B. anthracis* spores are still detected in the air after remediation. The primary methods for collecting airborne *B. anthracis* spores include filter media, impactors, and liquid and dry impingers. Sampling using filter media is the type of air sampling most commonly used, whereas the impinger method of sampling is rarely used. The need for data on viable versus non-viable spores should be evaluated prior to selecting an air sampling method (DHS 2006b). Commercially available air samplers and methods for collecting air samples are summarized in Appendix C.

6.1.3.1 Aggressive Air Sampling

AAS is a methodology used to confirm a negative finding of contamination in a space either as part of a public health investigation or as part of the clearance phase process after decontamination of a known contaminated area. The method involves 1) vigorous agitation of the surfaces in a space (using leaf blowers, for example) to aerosolize any particles, and 2) high-volume air samplers to acquire and concentrate aerosolized materials for analysis. The method also uses oscillating fans to keep any *B. anthracis* spores suspended. AAS originated as a testing method for asbestos abatement jobs. AAS is usually only performed after all the surface sampling results have been analyzed and results are negative. However, it is performed before removing critical barriers and negative-air units. As previously mentioned, in some situations, surface sampling may not be conducted for clearance, and AAS may be the only method used. AAS can be an important tool to determine the potential of *B. anthracis* spores to become re-entrained into the air from surfaces following the application of an energy source. Since

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inhalation is the exposure route of most concern, AAS was used as a final step in demonstrating the effectiveness of the remediation process in many of the 2001 anthrax terrorism incident bio-remediation projects (McKenna and Intrepido 2008). Used correctly, it provides an additional level of testing and complements the surface sampling to provide an overall more rigorous test and may add to the preponderance of evidence that a facility is free of detectable contamination.

6.1.4 Liquids and Soil

If applicable, soil and liquid samples can be collected using a variety of methods and equipment to assess whether they are contaminated with spores of *B. anthracis*. The sampling objective is to determine if any soil or liquids (e.g., decorative fountains, potted plants, and plumbing fixtures) are contaminated. This type of sampling can also be used as a tool for initial confirmation of contamination and evidence collection. Various methods for collecting liquid samples are described in Appendix C. When collecting soil, confer with the analytical lab for appropriate methods.

6.2 Sampling Team

Sampling teams should be composed of personnel who are trained to work with hazardous materials in a hot zone (a zone that contains, or is suspected to contain, highly virulent infectious organisms) (NFPA 2008, CFR 1994). The use of experienced investigators to conduct environmental sampling will provide the greatest likelihood of locating and identifying *B. anthracis* spores, if present. Additional information on sample data documentation and data management is found in Appendix D. Personnel should be trained in the appropriate disciplines necessary for sample collection, including sampling methods, equipment, and materials; knowledge of building systems; dissemination pathways; aerosol-generating procedures/equipment; and decontamination methods. As described in Section 6.2.1, a Health and Safety Plan (HASP) should be established at the site. Personnel should also be trained on the use of PPE, safety precautions, and hazards associated with sampling, and included in a medical program.

Personnel and team configurations may vary and should be optimized based on incident-specific requirements. A minimum of two persons is essential for conducting sample collection using aseptic techniques to minimize cross-contamination of the sample and any potential evidence.

6.2.1 Safety and Health

Individuals collecting environmental samples place themselves at substantial risk of exposure. Sample collection personnel work within suspected contaminated environments and their

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sampling activities may mobilize and even cause re-aerosolization of the *B. anthracis* spores. Therefore, precautions to protect investigators should be implemented prior to conducting an environmental sampling response. A HASP should be developed that includes the following elements: medical monitoring, training, and appropriate selection and use of PPE. Elements of a comprehensive medical program include medical countermeasures, medical screening, monitoring, and follow-up care. These recommendations can be found in a number of separate guidance documents that are referenced below. These documents should be reviewed prior to developing and implementing a HASP.

Relevant safety and health guidance documents are:

1. *Use of Anthrax Vaccine in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009* (CDC, 2010) ([HYPERLINK "http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5906a1.htm?s_cid=rr5906a1_e"])
2. [HYPERLINK "http://emergency.cdc.gov/agent/anthrax/environment/investigatorppe.asp"] (NIOSH website accessed May 2012) ([HYPERLINK "http://emergency.cdc.gov/agent/anthrax/environment/investigatorppe.asp"])
3. [HYPERLINK "http://www.cdc.gov/niosh/docs/2009-132/default.html"] (NIOSH, 2009) ([HYPERLINK "http://www.cdc.gov/niosh/docs/2009-132/default.html"])
4. Stern EJ, Uhde KB, Shadomy SV, Messonnier N. Conference report on public health and clinical guidelines for anthrax [conference summary]. Emerg Infect Dis [serial on the Internet]. 2008 Apr. (http://www.cdc.gov/EID/content/14/4/07-0969.htm)
5. [HYPERLINK "http://www.osha.gov/SLTC/etools/anthrax/index.html"] (OSHA website accessed May 2012) ([HYPERLINK "http://www.osha.gov/SLTC/etools/anthrax/index.html"])

6.2.2 Aseptic Techniques

Aseptic technique is the operation or performance of a procedure or method under carefully controlled conditions to reduce the risk of exposure and prevent the introduction of unwanted material/matter (contamination) into a sample (ASTM 2010b). Aseptic sampling requires the designation of collector (sampler) and an assistant (assistant sampler or facilitator) who coordinate sample collection, packaging, and documentation. The assistant sampler is responsible for providing the sampler with the appropriate tools and facilitating collection. For example, opening and handing materials to the sampler as required, including sample collection containers, gloves, sampling media, other sampling materials, and packaging materials, as well as performing any administrative functions including communication, photography (FBI Laboratory Publication, Handbook of Forensic Services 2003), as well as ensuring the sample collection sheet is filled out. The sampler should be the only person to come in contact with the

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suspect *B. anthracis*. The sampler is also responsible for signing the final chain-of custody form outside of the hot zone.

A critical element of aseptic sampling is the sampler and assistant sampler must have a new pair of non-powdered, nitrile or vinyl examination gloves for each sample collected. This layer of gloves is in addition to the gloves are part of standard PPE ensemble (that is, team members will have three or more layers of gloves on) for each sample collected. During sample collection involving direct contact with the collection media (e.g., gauze wipe), it is recommended for responders to wear sterile gloves to avoid introduction of any other organisms to the sample. The use of sterile gloves is not recommended when using sample collection devices not requiring direct contact with the collection media (e.g., swab or sponge with handle). Regardless of the sampling device selected, the gloves must be changed between samples.

6.3 Sample Collection Quality Assurance/Quality Control

Field blanks and media blanks (also referred to as negative controls) are taken for data authentication (EPA 2002) and should be submitted to the laboratory with other samples. Field blanks are used to identify and estimate sample contamination, which may occur immediately before and after sampling (evaluation of protocols), during shipment, or while awaiting measurement in the laboratory. Field blanks should be collected during sampling to enable determination of any cross-contamination that may occur due to techniques used by the members of the sampling team. It is good practice to collect one field blank for every 10 samples collected. Media blanks are unexposed samples, not taken to the field or shipped, used for background correction of sample readings or for recovery studies. Media blanks should also be submitted with samples for analysis ensuring the sample media had not been contaminated prior to sample collection. A discussion with the laboratory regarding the number of media blanks to include with the samples should also take place. Approximately 1 to 5 media blank samples should be included for each media type or lot number. Media blanks ensure each lot of medium is sterile and free of contamination. Field sampling teams should have standard operating procedures requiring the collection of field and media blanks. The CDC sample collection procedures (CDC 2012a) describe the collection of field and media blanks.

The following quality assurance procedures also apply:

- All instrumentation must be operated in accordance with operating instructions as supplied by the manufacturer unless otherwise specified.
- Equipment checkout/calibration activities occur prior to sampling/operation and must be documented.
- All mechanical equipment should undergo routine maintenance according to manufacturers' specifications.

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- A regular schedule for maintenance and equipment upkeep should be coordinated for each piece of equipment.
- Sampling equipment should be verified to be in working order prior to deploying with the environment sampling teams
- Potential cross-contamination should be minimized between samples.

6.4 Chain of Custody

A Chain of Custody (CoC) form documents transfer of sample custody from one individual to another, from the time the sample is collected until final analytical disposition. Each individual in possession of the sample must be noted by recording their signature on the form. The CoC record should include instructions for the laboratory technician as to analytical methods, potential dangers, and any pertinent handling procedures that should be observed. The CoC form should be kept separate from the sample (i.e., should not be placed with the sample) in order to preserve appropriate CoC. The CoC record must include at least the following information:

- All available information regarding the potential hazards associated with the agent;
- Handling procedures associated with the samples;
- Sample identification number;
- Sample concentration, if known;
- Sampling location;
- Collection date and time;
- Sample matrix;
- Names and signatures of the samplers; and
- Signatures of all individuals who had custody of the samples (EPA 2006a).

6.5 Information on Sample Packaging and Shipping

Environmental samples collected for the purpose of determining whether *B. anthracis* spores are present should be considered "Infectious Substances." As such, the shipper is responsible for establishing protocols to ensure these samples are correctly identified, classified, packaged, labeled, marked, documented, and shipped according to applicable federal and international regulations (ASTM 2010a). These regulations include:

- Public Health Service, 42 CFR Part 72,
- Department of Transportation,
- 49 CFR Parts 171-178,

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- United States Postal Service, 39 CFR Part 111, and
- International Civil Aviation Organization (published by the International Air Transport Association), Dangerous Goods Regulation.

Investigators who handle and transport infectious substances must receive training on the preceding regulations prior to collecting samples for submission to an LRN laboratory. Triple-layer packaging (consisting of a watertight primary container, watertight secondary packaging, and a durable outer packaging) may be required.

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Section VII: Analytical Considerations

Consulting with the laboratory prior to selecting sampling and analysis methods is essential. When establishing sampling guidelines, an open dialog must be held with the laboratory to determine what requirements and procedures they may have. The samplers should discuss with the laboratory the number of samples expected to be collected, the sample collection methods, and the estimated time of sample delivery (EPA 2006a).

The analytical laboratory should provide information about:

- Names, contact information, directions and any special laboratory-specific instructions (forms, etc.)
- Guidance on preferred media and buffer solutions and discussion on the types and quantity of sample to be collected
- Chain of Custody (CoC) forms and requirements to deliver and drop off samples at the laboratory (EPA 2006a, ASTM 2010a)

The limiting factor in sample collection and analysis is the capacity of the laboratory to process and analyze these samples. Although the sampling team may be able to collect a large number of samples during a single sampling incident, the number of samples collected should be balanced against laboratory capacity and should be spread over a sufficient number of LRN laboratories to ensure adequate turnaround time to results. If it is not feasible to spread sample collection (and hence, sample analyses) out over a few days or to refer samples to a larger number of LRN laboratories, it will be necessary to prioritize samples so they may be processed and analyzed in a staged manner to achieve the result of sequential sampling (Emanuel et al. 2008).

7.1 Analytical Methods

A variety of methods are available for processing and analyzing samples for *B. anthracis*. The method for analysis of samples is selected based on the phase of the incident (purpose of sampling) and the time frame the results are needed. In some cases, multiple methods may be utilized to analyze a sample. It is up to the sampling plan coordinator in conjunction with the laboratory to determine the most appropriate method to suit the needs of the incident. In a bioterrorist attack, detection of *B. anthracis* is performed in a step-by-step manner. An overall response usually involves:

1) Presumptive and rapid analysis of limited, judgmental samples in the hot zone using on-site biological assessments such as hand held assays;
2) Confirmatory analysis of samples in the contaminated area using microbiological culture, biochemical, serological, and PCR to identify *B. anthracis*;

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3) Characterization of the extent of contamination using analytical methods such as PCR, immunoassays, and/or where feasible, culture followed by PCR or immunoassay.
4) Post-decontamination analysis of samples to determine presence or absence of viable (live) *B. anthracis* using a combination of microbiological culture, PCR, Rapid Viability PCR, and immunoassay methods

7.1.1 Standard Microbiological Laboratory Culture Method

Microbiological culture is a method of growing a microorganism for identification and determining concentration in the sample being tested. Culture on solid medium employs Petri dishes containing an agar-based growth medium for the growth of bacteria. Bacteria will grow as colonies on the surface of the medium. In the case of *B. anthracis,* each individual colony represents the growth of a single spore or a clump of spores. Another method is broth culture, in which spores are inoculated into a liquid nutrient medium. The microbe must be viable in order to grow on either solid or liquid medium. These methods usually take days before any confirmatory answer is available.

Culture is the gold standard for determining the presence of viable *B. anthracis*. Therefore, it is used during the initial response phase to confirm the presence of viable spores and during clearance sampling to confirm no viable spores remain after decontamination. Theoretically, culture can detect the presence of a single viable spore within a sample. Thus, culture has a lower limit of detection (LOD) than either an immunoassay (e.g., hand held assay) device or a nucleic acid amplification method (e.g., PCR).

7.1.2 Real-Time PCR-Based Analytical Methods

PCR is a method used for detecting *B. anthracis* DNA, which can provide presumptive results from a direct sample in 3 to 6 hours but does not assess spore viability. DNA amplification methods such as PCR depend on the hybridization of primers to their complementary sequences in the target gene of the test species. Once hybridized, DNA polymerase (e.g., Taq DNA polymerase) amplifies the target sequence millions of times in an hour, so the target gene is detected if present. Although PCR is both sensitive and specific, it is susceptible to inhibition by various compounds found in environmental matrices. This inhibition can result in a false negative result by contaminating DNA from the target organism (Buttner et al. 2004). PCR requires the laboratory to have specific equipment and the necessary supplies (e.g., primers and probes) to conduct the *B. anthracis* analysis. Neither the CDC nor the FBI recommends testing

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samples in the field using commercially available field PCR methods for the detection of *B. anthracis* spores (OSTP 2002).

Due to limitations associated with inhibition to compounds in the environment and the inability to identify viable spores, PCR analysis is not utilized to determine when clearance goals have been met. PCR is primarily utilized during the initial response phase while awaiting culture results which requires additional time for results and during characterization sampling. Characterization sampling is conducted after viable spores are identified during initial public health/law enforcement sampling identifies viable spores. In this case, PCR samples are assumed viable.

7.1.3 Comparison of Culture and Polymerase Chain Reaction Methods

Culture analysis is the principal method for determining quantitative information and is considered to be the definitive method for identifying the presence of viable spores. Culture analysis generally requires days to obtain data when compared to PCR, where results can be obtained within hours. The culture method is less expensive but also requires additional laboratory equipment, such as vacuum manifold systems to perform filter plate testing.

There are numerous advantages of PCR-based methods over traditional culture methods, including: 1) rapid detection, 2) specificity – critical selection of target genes and design of primers and probe provide detection at a single species level, 3) detection of agents in complex environmental samples in collection buffer, 4) detection of difficult-to-grow agents, 5) analysis of inactivated agents – samples suspected of containing highly potent and contagious agents can be inactivated before analysis by PCR, and 6) multiple gene targets per agent and multiple agents can be detected by multiplex PCR assays, thereby allowing high-throughput sample analysis. However, PCR-based analytical methods cannot determine the viability of *B. anthracis*. Additionally, the number (concentration) of spores or cells present in a sample by PCR cannot be determined. Comparison of features of culture versus PCR methods are presented in Table 7-1.

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Table 7-1. Comparison of Culture versus PCR for *B. anthracis*

Culture	PCR
Theoretical sensitivity of one spore	Lower detection limit is 50 - 100 spores
Requires organisms to be viable	Organisms can be viable or non-viable
Growth media has shelf life of 30 - 60 days	Primers and probes for real-time PCR available in LRN laboratories and have a shelf-life of 2 years (dehydrated and stored at 5°C) and 6 months (rehydrated and stored at 4°C)
Results available in 32-40 hours (includes time to subculture for purity)	Results available in 3 to 6 hours but delays may occur depending on the number of samples that are run
Results are considered by CDC to be definitive after PCR confirmation	Results are considered by CDC to be presumptive on direct sample but are confirmatory on pure culture
Growth of contaminating micro-organisms can mask target	Fewer problems with a large number of micro-organisms
Less expensive when compared to PCR	Susceptible to inhibition by compounds found in environmental matrices
No additional laboratory infrastructure required	Additional laboratory infrastructure required (e.g., separate rooms for extraction and amplification)

7.1.4 Rapid Viability PCR (RV-PCR)

The Rapid Viability PCR (RV-PCR) method is most useful for the analysis of samples collected during and after cleanup/decontamination because determining the presence or absence of viable (live) *B. anthracis* spores (in the presence of large number of inactive spores) is a key analytical requirement during this phase of response (Létant 2010, 2011). The method involves extraction of spores from sampling medium, permitting them to germinate in a culture broth, and using real-time PCR to detect the growth of viable bacteria. The RV-PCR method integrates high-throughput sample processing, short-incubation broth culture, and highly sensitive and specific real-time PCR assays to detect low levels of viable *B. anthracis* spores in the presence of challenges including high levels of dead spores, high levels of live, non-target cells and spores, and high levels of dust. This method can be more sensitive than the traditional culture-based method because the whole processed sample is used for analysis. It is relatively rapid, cost-effective, less labor-intensive, less prone to inhibition by environmental matrices, and less prone to interference by outgrowth of other bacteria, fungi, other microbes, and other biological

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material in the sample. It also provides higher-throughput and generates significantly less bio-hazard and other laboratory wastes than the culture-based method.

7.1.5 Hand-Held Assay-Based Immunoassay (HHA)

HHAs, also known as Test Tickets or Smart (Sensitive Membrane Antigen Rapid Test) Tickets, are hand-held devices containing small chromatographic strips. The device exposes the strip to possible contamination, and then indicates whether contamination was detected. They are also known as Immunochromatographic Lateral Flow Assays. They are the most user-friendly assays and mostly used for preliminary screening of samples in the field. Usually, these tests take approximately 15 minutes. However, the detection specificity has been inferior to other detection methods and has led to false positive results. The Executive Branch does not recommend field-testing using commercially available HHAs for the detection of *B. anthracis* spores (OSTP 2002). Results from such on-site biological assessments are not public health actionable, meaning decisions regarding public health action are pending until confirmatory testing is completed. The DHS's Science and Technology Directorate continues to work to improve the specificity and sensitivity of these commercial field test kits and HHAs, and this strategy will be updated as new information becomes available.

7.2 Method Validation

Method validation is the process of proving a sampling method or analytical method is acceptable for its intended purpose (EPA 2002). The International Organization for Standardization (ISO) defines validation as the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. Validation includes the characterization of the method performance parameters including accuracy, precision, ruggedness, robustness, sensitivity, specificity, LOD, limit of quantification, reproducibility, linearity, and range (EPA 2006a). Using validated methods is important because it minimizes inconsistencies in the collection, transport, extraction, and analysis of samples. It enables a better interpretation of results and lends itself to comparison of results between independent incidents.

At present, two methods for sampling and analyzing *B. anthracis* on non-porous surfaces have been validated (Hodges 2010, Hodges 2006, Rose 2004, Rose 2010). These methods utilize a cellulose sampling sponge and a macrofoam swab as the sampling media. The collection protocols are available to the public on the CDC website (CDC 2012a).The laboratory processing protocols have been shared with all of the LRN laboratories via a secure website and these laboratories are trained and equipped to analyze these samples.

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7.3 Optimizing Sample Processing and Analysis

Sample analysis can be optimized depending on the type of information sought from the sample analysis. If qualitative data are acceptable during the initial characterization phase and it is presumed that any *B. anthracis* spores are viable, each sample can be quickly processed and analyzed (within hours) for *B. anthracis* signatures using PCR analytical techniques that provide information on the presence of the DNA of the agent in the sample. Performing such an analysis may require running a second, more specific analysis in order to determine viability by culturing the sample, which generally requires an additional 16-20 hours to obtain results for *B.* anthracis. The IC/UC will determine whether all or a portion of the samples will be analyzed by PCR and/or culture. PCR analysis is regarded as a qualitative analysis method in that results provide the presence or absences of DNA signatures in the sample. Quantitative culture analysis provides an estimate of the magnitude of contamination of viable spores. The magnitude of contamination is important for selection of the decontamination method and evaluating the efficacy of the decontamination technology by comparing pre- and post-decontamination sample results. PCR analysis during characterization sampling can expedite the sample analysis and save the laboratories valuable time and resources.

Another optimization process that can be conducted is batching or pooling sample analyses. The pooling or batching of sample analyses is performed by combining a number of similar discrete samples in the laboratory after individually collected samples have been prepared for analysis. An aliquot of each sample's elution is combined and analyzed as one sample. The main advantage of pooling samples for analysis is the reduction in the number of analyses that must be performed; however, certain laboratory processing steps still occur on each individual sample. The principal disadvantage is that combining the eluent from many samples essentially dilutes the portion that will be cultured from each sample which in turn raises the amount that is needed to be present in positive samples to ensure detection, hence, increases the risk of a false negative result. As a rule of thumb, site characterization sampling (i.e., prior to determining whether to decontaminate a space or not) presents the most beneficial case for pooling samples, since contamination has a higher likelihood of being present. If the result is positive and details about the specific location of the positive sample are needed, individual analysis can be done on each individual sample. Pooling of samples may not be beneficial in the post-decontamination phase, since spore concentrations should be lower after decontamination and the risk of a false negative result due to dilution is substantially increased

While pooling samples for analysis can make best use of available analytical resources, care should be taken when deciding which samples to pool for analysis. It should be done by the IC/UC in a logical manner (similar to composite sampling) that is consistent with the level of delineation desired between areas, surfaces or locations. Additionally, current validated analytical procedures do not consider pooling of samples. Advice and recommendations on the details of procedures for preparing and analyzing pooled samples should be secured from

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technical experts and/or the validating authority to ensure that the process used and the results are rational and comprehensible extensions of validated methods. The decision to pool samples for analysis will be based on the type of information that can be gained from the results.

7.4 Sample Transportation and Storage

Because samples must be transported to the laboratory, and processing and analyzing samples takes time, test results will not be immediately available. Samples should be transported to the laboratory as quickly as possible. Results are reported within hours or days after samples are submitted depending on the type of analysis conducted.

The *B. anthracis* viability and stability when collected with moist samples (swabs, wipes/sponges) depend on the wetting agent. Endospores are not likely to germinate in saline- or buffer-moistened collection media. However, the sample matrix may influence germination if sufficient nutrients are present. In general, samples should be transported to the laboratory at 5° C and analyzed as rapidly as possible to minimize the loss of viability and maintain sample integrity. Samples should be refrigerated upon arrival to the laboratory at 5°C until the sample can be processed. The lower temperature also minimizes endospore germination (DHS 2007b). CDC conducted a shipping integrity study on macrofoam swabs (see Appendices B and C). Based on the findings of the study, CDC recommends sampling media (cellulose sponges and macrofoam swabs) are shipped on ice or on cold packs in order to maintain a temperature between 2° – 8°C (Perry 2010). CDC recommends processing samples within 48 hours of sampling to ensure maximum recovery of spores (Rose 2010).

Dry specimens for determining the presence of *B. anthracis* spores may consist of "bulk" powders or vacuum samples. These specimens should be stable as long as they are kept dry, in the dark (to avoid ultraviolet exposure) and shipped at ambient temperature. Once in the laboratory, they can be stored in a cool, dark, dry place until analyzed. The length of time they can be stored without loss of viability may depend upon the sample matrix and the presence of sporicidal agents (DHS 2007b).

7.5 Laboratory Analysis Quality Assurance/Quality Control

Generation of analytical data of known and documented quality is a critical factor in the accurate assessment of and appropriate response to *B. anthracis* contamination incidents. Generating data of sufficient quality requires analytical laboratories to: 1) have trained personnel, 2) acquire and maintain required supplies, equipment, and reagents, 3) conduct the appropriate quality assurance QA/QC procedures to ensuring all measurement systems are in control and operating, 4) document all analytical results, and 5) document analytical QA/QC procedures and corrective actions.

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In general, analytical QA/QC requirements for pathogen methods include an initial demonstration of measurement system capability, as well as the capability of the laboratory and the analyst to perform the method with the required precision and accuracy. Ongoing analysis of control samples should also be performed to ensure the continued accuracy and reproducibility of the analytical results. QA/QC procedures should be performed each time a test is performed to ensure the quality of analytical results.

7.6 Interpretation of Data

Sample preparation methods have varying extraction efficiencies. This means some methods are better at extracting the *B. anthracis* spores or *B. anthracis* DNA from the sample matrix than other methods. Thus, the efficiency of the sample preparation method should be reviewed with the laboratory so that there is an understanding of the extraction efficiency. This information is crucial when combined with knowledge of the LODs of the analytical method (EURACHEM 1998). A LOD is the smallest amount of analyte that can be distinguished from background with 95% confidence. In addition to extraction efficiency, various sample collection methods have various recovery efficiencies. Recovery and extraction efficiencies may depend on the concentration of contaminant, the type of surface to be sampled, and the sample collection method. Hence, *B. anthracis* could be present in the environment and yet not detectable by the analytical method because of low recovery and/or extraction efficiencies, as well as analytical uncertainties. Ideally, the LODs of the analytical method for the range of samples it will be applied to should be low enough to detect with high confidence levels of a biological agent at or above risk-based exposure limits (DHS 2006b). Currently, there are no data to support a risk-based exposure limit for *B. anthracis* (Hong, T., P. L. Gurian, and N. F. Dudley Ward, 2010.).

After the laboratory has completed analysis of the samples, they must perform appropriate validation testing of their results and evaluate them for data surety and authentication prior to submission (Emanuel et al. 2008).

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Appendix A

CDC Surface Sampling Procedures for *Bacillus anthracis* Spores from Smooth, Non-Porous Surfaces

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Surface sampling procedures for *Bacillus anthracis* spores from smooth, non-porous surfaces

May 13, 2010
Revised April 26, 2012

GENERAL

These sampling procedures were prepared by the Centers for Disease Control and Prevention (CDC) to provide standardized methods for industrial hygienists, or other trained samplers under the direction of sampling experts, to use when sampling for *Bacillus anthracis* (*B. anthracis*) spores. These procedures supersede previous CDC procedures for collecting environmental samples for *B. anthracis*, including *Comprehensive Procedures for Collecting Environmental Samples for Culturing Bacillus anthracis*, which were developed during the 2001 anthrax terrorist events. As stated in that guidance, CDC planned to update the guidance as new information becomes available. In particular, one major change is the recent efforts by CDC to validate methods for the laboratory processing and analysis of *B. anthracis* spores.

These procedures are meant to be used for collection of samples on smooth, non-porous surfaces and can be used in both indoor and outdoor environments. Examples of non-porous surfaces are stainless steel, painted wall board, floor tile, or wood laminate. Each sampling method has its specific uses and advantages. Sampling methods must be coordinated with the laboratory to ensure that they are ready to accept and process all the samples. This is particularly important if deviating from the validated sampling procedures.

Swabs are appropriate for sampling small surfaces or hard to reach locations of less than 4 inches square (in^2), like crevices, corners, supply air diffusers, air return grills, and hard-to-reach places. Wipes are appropriate for sampling larger non-porous surfaces including walls, desks, and floors. An interagency effort known as the Validated Sampling Plan Working Group (VSPWG) is currently developing a document titled *Reference Guide for Developing and Executing Bacillus anthracis Sampling Plans in Indoor Settings,* which outlines approaches and methodologies to characterize and guide remediation of indoor sites with potential or actual contamination. The VSPWG document, once published, should be consulted for additional information about strategies and guidance for sampling *B. anthracis*. This document will also assist with the interpretation of results for samples collected with macrofoam swabs and cellulose sponges on smooth, non-porous surfaces following these collection procedures.

Note: Additional information regarding *Bacillus anthracis* sampling, including recommendations for protecting investigators while sampling, are available at [HYPERLINK "http://emergency.cdc.gov/agent/anthrax/environment/"] and [HYPERLINK "http://www.cdc.gov/niosh/docs/2009-132/default.html"].

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The collection of samples associated with a crime scene or suspicion of a criminal event should be coordinated with law enforcement authorities. Sampling teams need to be aware that samples collected may be or become criminal evidence, and certain additional procedures associated with sample collection will be necessary.

MACROFOAM SWAB PROCEDURE

SWAB MATERIALS

1. Gloves, nitrile
2. Ruler, disposable, and masking tape or sample template, disposable, sample area size 4 in^2 (26 cm^2)
3. Macrofoam swab, sterile, 3/16 inch thick medical-grade polyurethane foam head, 100 pores per inch, thermally bonded to a polypropylene stick (such as the Sterile Foam Tipped Applicators Scored with Thumb Stop [Puritan, Guilford, Maine; catalog number 25-1607 1PF SC] or equivalent)
4. General neutralizing buffer that will inactivate halogen disinfectants and quaternary ammonium compounds, 10 milliliter (mL), sterile (such as the Neutralizing Buffer [Hardy Diagnostics, Santa Maria, California; catalog number K105] or equivalent)
5. Screw-cap centrifuge tubes, sterile, 15 mL (such as 15 mL High-Clarity Polypropylene Conical Centrifuge Tube [Becton Dickinson, Franklin Lakes, New Jersey; catalog number 352097] or equivalent)
6. Sample labels or permanent marker
7. Re-sealable plastic bag, 1-quart or smaller
8. Re-sealable plastic bag, 1-gallon or larger

SWAB SAMPLING PROCEDURE

1. Wearing a clean pair of gloves over existing gloves, place the disposable template over the area to be sampled and secure it. If the template cannot be used, measure the sampling area with a disposable ruler, and delineate the area to be sampled with masking tape.
2. Remove the sterile swab from its package. Grasp the swab near the top of the handle. Do not handle below the thumb stop.
3. If the sterile swab is not pre-moistened, moisten the sterile swab by dipping it in the 10 mL container of neutralizing buffer solution. Remove any excess liquid by pressing the swab head on the inside surface of the neutralizing buffer solution container.

   Note: Once a sterile swab has been moistened, the remaining neutralizing buffer solution and container must be discarded.

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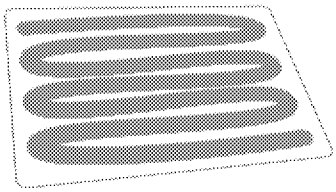
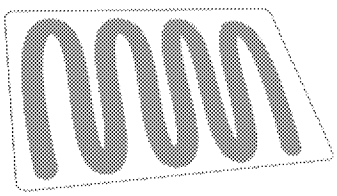
4. Swab the surface to be sampled using the moistened sterile swab. Use an overlapping 'S' pattern to cover the entire surface with horizontal strokes.

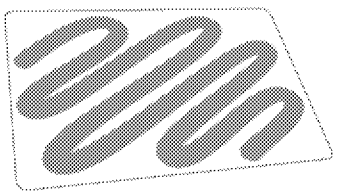


Note: Depending on the design of the swab, a rolling motion can be used when swabbing the surface to maximize swab contact with the surface.

5. Rotate the swab and swab the same area again using vertical 'S'-strokes.



6. Rotate the swab once more and swab the same area using diagonal 'S'-strokes.



7. Place the head of the swab directly into a sterile screw-capped centrifuge tube. Break off the head of the swab by bending the handle. The end of the swab handle, touched by the collector, should not touch the inside of the tube. Securely tighten the screw-cap and label the tube (e.g., unique sample identifier, sample location, initials of collectors and date and time sample was collected). Collection tubes and re-sealable bags may be pre-labeled to assist with sampling efficiency.
8. Place the sample container in a re-sealable 1-quart plastic bag. Securely seal and label the bag (e.g., sample location, date and time sample was collected, and name of individual collecting the sample).

Note:Remove excessive air from the re-sealable plastic bags to increase the number of samples that can be shipped in one container.

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9. Dispose of the template, if used.
10. Remove outer gloves and discard. Clean gloves must be worn for each new sample.

CELLULOSE SPONGE PROCEDURE

CELLULOSE SPONGE MATERIALS

1. Gloves, nitrile
2. Ruler, disposable, and masking tape or sample template, disposable, sample area size 100 in^2 (645 cm^2)
3. Sponge, sterile, pre-moistened with 10 mL neutralizing buffer solution, 1.5 by 3 inches cellulose sponge folded over a handle (such as the 3M™ Sponge-Stick [3M, St. Paul, Minnesota; catalog number SSL-10NB] or equivalent)[a] or sponge, sterile, dry, 1.5 by 3 inches cellulose sponge folded over a handle (such as the 3M™ Sponge-Stick [3M, St. Paul, Minnesota; catalog number SSL-100] or equivalent) and general neutralizing buffer that will inactivate halogen disinfectants and quaternary ammonium compounds, sterile, 10 mL (such as the Neutralizing Buffer [Hardy Diagnostics, Santa Maria, California; catalog number K105] or equivalent)
4. Screw-cap specimen container, sterile, individually wrapped 4 ounce (such as General Purpose Specimen Container [Kendall Healthcare, Mansfield, Massachusetts; catalog number 8889-207026] or equivalent)
5. Sample labels or permanent marker
6. Re-sealable plastic bag, 1-quart or smaller
7. Re-sealable plastic bag, 1-gallon or larger

CELLULOSE SPONGE SAMPLING PROCEDURE

1. Wearing a clean pair of gloves over existing gloves, place the disposable template over the area to be sampled and secure it. If a template cannot be used, measure the sampling area with a disposable ruler, and delineate the area to be sampled with masking tape. The surface area sampled should be less than or equal to 100 in^2 (645 cm^2).
2. Remove the sterile sponge from its package. Grasp the sponge near the top of the handle. Do not handle below the thumb stop.
3. If the sterile sponge is not pre-moistened, moisten the sponge by pouring the 10 mL container of neutralizing buffer solution over the dry sponge.

   Note: The moistened sponge should not be dripping neutralizing buffer solution.
   Note: Any unused neutralizing buffer solution **must** be discarded.

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[a] Additional sponges with limited recovery efficiency data available include the Versalon Non-Woven All-Purpose Gauze Sponge (Kendall Healthcare, Mansfield, Massachusetts; catalog number 8042), Bacti-Sponge (Hardy Diagnostics, Santa Maria, California; catalog number SK711), Cellulose Sponge with DE Broth (Solar Biological, Ogdensburg, New York; catalog number BS-10BPB-1), and Sponge-Wipe (Micronova, Torrance, California; catalog number SWU-99 [cut into 2 by 2 inches).

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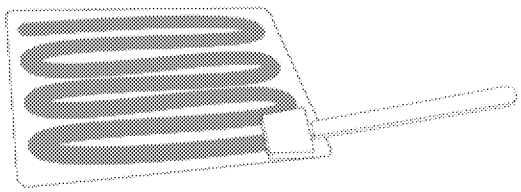
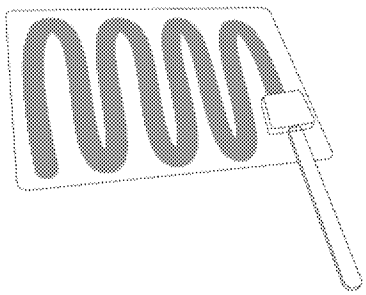
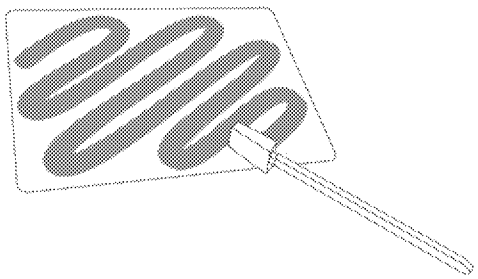
4. Wipe the surface to be sampled using the moistened sterile sponge by laying the widest part of the sponge on the surface, leaving the leading edge slightly lifted. Apply gentle but firm pressure and use an overlapping 'S' pattern to cover the entire surface with horizontal strokes.



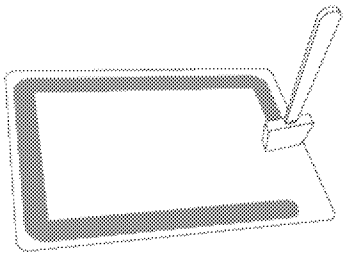
5. Turn the sponge over and wipe the same area again using vertical 'S'-strokes.



6. Use the edges of the sponge (narrow sides) to wipe the same area using diagonal 'S'-strokes.



7. Use the tip of the sponge to wipe the perimeter of the sampling area.



8. Place the head of the sponge directly into a sterile specimen container. Break off the head of the sponge by bending the handle. The end of the sponge handle, touched by the collector, should not touch the inside of the specimen container. Securely seal and label the container (e.g., unique sample identifier, sample location, initials of collector and date and time sample was collected).
9. Place the sample container in a re-sealable 1-quart plastic bag. Securely seal and label the bag (e.g., sample location, date and time sample was collected, and name of individual collecting the sample). Specimen containers and re-sealable bags may be pre-labeled to assist with sampling efficiency.

   Note: Remove excessive air from the re-sealable plastic bags to increase the number of samples that can be shipped in one container.

10. Dispose of the template, if used.
11. Remove outer gloves and discard. Clean gloves should be worn for each new sample.

GAUZE PROCEDURE

GAUZE MATERIALS

Note: This sampling and analytical method has not been validated by CDC. A standard sampling procedure is provided in the event that the macrofoam swab or cellulose sponge methods cannot be utilized.

1. Gloves, nitrile
2. Gloves, sterile, nitrile
3. Ruler, disposable, and masking tape or sample template, disposable, sample area between 144 in^2 (929 cm^2)
4. Gauze, sterile, non-cotton, polyester blend sponge or rayon/polyester blend, 2 by 2 inches (such as the Versalon All-Purpose Sponge [Kendall Healthcare, Mansfield, Massachusetts; catalog number 8042; includes two gauze squares/packet] or equivalent)
5. General neutralizing buffer that will inactivate halogen disinfectants and quaternary ammonium compounds solution, 10 mL, sterile (such as the Neutralizing Buffer [Hardy Diagnostics, Santa Maria, California; catalog number K105] or equivalent)

6. Pipette, 5 mL, sterile, individually wrapped (such as the Greenwood Products' Sterile 5mL Standard Transfer Pipette [Greenwood Products, Inc., Middlesex, New Jersey; catalog number GS137038] or equivalent)
7. Screw-cap specimen container, 4 ounce, sterile, individually wrapped (such as General Purpose Specimen Container [Kendall Healthcare, Mansfield, Massachusetts; catalog number 8889-207026] or equivalent)
8. Sample labels or permanent marker
9. Re-sealable plastic bag, 1-quart or smaller
10. Re-sealable plastic bag, 1-gallon or larger

GAUZE SAMPLING PROCEDURE

1. Wearing a pair of gloves over existing gloves, place the disposable template over the area to be sampled and secure it. If the template cannot be used, measure the sampling area (144 in^2) with a disposable ruler, and delineate the area to be sampled with masking tape.
2. Partially peel open the sterile gauze package carefully exposing the gauze.

   Note: The sterile gauze should not be touched without sterile gloves.

3. Measure 5 mL of neutralizing buffer solution from the 10 mL container using a disposable pipette and apply to sterile gauze in its original packaging. Remove outer gloves.
   Note: The moistened gauze should not be dripping neutralizing buffer solution.
   Note: Any unused neutralizing buffer solution and the pipette **must** be discarded.

4. Don a pair of sterile gloves.

   Note: Sterile gloves are required when sampling with gauze because of the direct contact with the sampling media.

5. Remove one of the sterile gauze (if two per package) and dispose of or retain the other gauze as a field blank (see section 4.1).
6. Completely unfold the remaining moistened sterile gauze, and then fold in half.
7. Wipe the surface to be sampled using the moistened sterile gauze, fingertips should be held together and apply gentle but firm pressure. Use an overlapping 'S' pattern to cover

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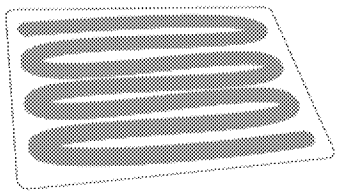
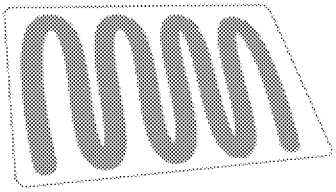
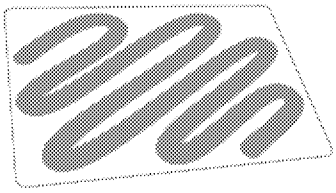
the entire surface with horizontal strokes.



8. Fold the exposed side of the gauze in and wipe the same area again using vertical 'S'-strokes.



9. Fold the exposed side of the gauze in once more and wipe the same area using diagonal 'S'-strokes.



10. Fold the gauze, exposed side in, and place it into a sterile screw-cap specimen container.
11. Securely tighten the screw-cap and label the container (e.g., unique sample identifier, sample location, initials of the collectors and date and time sample was collected).
12. Place the sample container into a re-sealable 1-quart plastic bag. Securely seal and label the bag (e.g., sample location, date and time sample was collected, and name of individual collecting the sample). Specimen containers and re-sealable bags may be pre-labeled to assist with sampling efficiency.

    Note: Remove excessive air from the re-sealable plastic bags to increase the number of samples that can be shipped in one container.

12. Dispose of the template, if used.
13. Remove outer gloves and discard. Clean sterile gloves should be worn for each new sample.

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BLANKS

FIELD BLANKS

Field blanks are samples handled exactly the same as those used to collect field samples, except they are not allowed to come into contact with the contaminated surface. It is used to estimate contamination arising from preparation for sampling, sampler technique, and shipment and storage prior to analysis. The number of field blanks collected should be equal to at least 10% of the samples collected. Field blanks should be collected while in the contaminated area. While wearing clean (sterile gloves for handling gauze), the macrofoam swab, cellulose sponge, or gauze should be removed from its packaging, moistened (as needed, see sections 3.1, 3.2 and 3.3), and then placed in the appropriate container (either a centrifuge tube or specimen container). An aliquot of the unused portion of the opened neutralizing buffer solution should also be collected when using macrofoam swab, cellulose sponge, or gauze media that are not pre-moistened.

MEDIA BLANKS

Media blanks are unexposed samples used for background correction of sample readings or for recovery studies. Provide two unopened sample media (macrofoam swab, cellulose sponge, or gauze) per lot used and provide two unopened, unused samples of the neutralizing buffer solution (if not using pre-moistened media) as media blanks to the processing laboratory.

DECONTAMINATION

SAMPLE BAG DECONTAMINATION

1. Place multiples of the re-sealable 1-quart plastic bags into a 1-gallon re-sealable plastic bag. Securely seal the 1-gallon re-sealable plastic bag and label the bag (e.g., identify samples contained in the re-sealable plastic bag, sample locations, date and time samples were collected, and name of individual collecting the samples).
2. Decontaminate the outer surface of the larger re-sealable plastic bag using a fresh pH-adjusted bleach solution (household bleach diluted 1:9; pH-adjusted to 6.8-8.0) with a 10-minute contact time before the re-sealable plastic bag leaves the contaminated area. This solution can be prepared by:

   Step 1: Mixing one part household bleach (5.25 to 6.0 % sodium hypochlorite) with 5 parts water (v/v);
   Step 2: Adding 1 part white vinegar; and
   Step 3: Adding 3 parts of additional water.

   Note: Additional information about decontamination is available at [HYPERLINK "http://www.epa.gov/opp00001/factsheets/chemicals/bleachfactsheet.htm"].

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3. Thoroughly dry the outside of the re-sealable plastic bag.
4. Complete a chain of custody form.

   Note: Once the outer re-sealable plastic bag is decontaminated, it should not be opened outside of appropriate containment in a laboratory.

5. Place the larger re-sealable plastic bag into an appropriate container for shipping (See Sample Shipment section).

DECONTAMINATION OF BAGS CONTAINING DOCUMENTATION

1. Place sample sheets and other documentation in a separate re-sealable plastic bag. The sheets should be placed two to a bag with the face of each sheet facing out. Securely seal and label the bag (e.g., corresponding sample locations, date and time samples were collected, and name of individual collecting the samples).

   Note: It is important to only write on one side of the paper, the face, when collecting information.
2. Decontaminate the outer surface of the larger re-sealable plastic bag using a fresh pH-adjusted bleach solution (household bleach diluted 1:9; pH-adjusted to 6.8-8.0) with a 10-minute contact time before the re-sealable plastic bag leaves the contaminated area. This solution can be prepared by:

   Step 1: Mixing one part household bleach (5.25 to 6.0 % sodium hypochlorite) with 5 parts water (v/v);
   Step 2: Adding 1 part white vinegar; and
   Step 3: Adding 3 parts of additional water.

   Note: Additional information about decontamination is available at [HYPERLINK "http://www.epa.gov/opp00001/factsheets/chemicals/bleachfactsheet.htm"].
3. Thoroughly dry the outside of the re-sealable plastic bag.
4. Complete a chain of custody form.

   Note: Once the outer re-sealable plastic bag is decontaminated, it should not be opened outside of appropriate containment.
5. Place the larger re-sealable plastic bag into an appropriate container for shipping.

SAMPLE SHIPMENT

1. Transport all samples to the processing laboratory on wet ice or on cold packs.

   Note: Samples may be stored at 2°C–8°C prior to processing and should be processed within 48 hours of collection.

2. Appropriate chain of custody forms and analytical request forms should be included with each shipment sent to the processing laboratory. Containers used to transport the samples and accompanying contaminated documentation and equipment should be prepared and shipped according to the appropriate regulations for transporting infectious. The most current Code of Federal Regulations, International Air Transport Association guidelines, and other appropriate regulator or guidance publications should be consulted for compete instructions. The shipper is responsible for ensuring adherence to the most current and appropriate regulations.

Note: Do not transport contaminated equipment/supplies in the same container as the samples.

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Appendix B
Swab and Wipe Sample Interpretation

This Appendix provides technical details of sampling studies to guide the interpretation of data resulting from the use of recommended sampling methods. The data reflect variations in sampling efficiency with bacterial surface coverage, with type of surface, and with variations in the sampling device and other characteristics of the recommended sampling method, given that the realities of any response may dictate some variation from recommended procedures.

Information provided in this appendix is used by technical experts in public health and environmental recovery to inform their consultation with incident command or other authoritative decision makers in the response to a contamination event.

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B.1. Swab Sampling Performance

A multi-center validation study involving 12 laboratories was conducted to quantify the performance of a macrofoam swab method using a pure inoculum of *B. anthracis* spores (Hodges 2010). Steel coupons (4-in^2) (26-cm^2) were inoculated with a known concentration of *B. anthracis* spores suspended in 95% ethanol, the inoculum was allowed to dry, and the 26-cm^2 area was sampled with a macrofoam swab pre-moistened with phosphate buffered saline with 0.02% Tween 80 (PBST). To simulate samples with dust and other organisms, some swabs were dipped in a slurry of PBST plus a well characterized dust (A-3, Powder Technology, Inc, Burnsville, MN) before sampling. Laboratories were sent coded swabs in six shipments (three with dust, three without dust). The swabs were processed according to the LRN protocol. Colonies of *B. anthracis* were counted and the numbers compared to the known inoculum level to determine the percent recovery. The results for swabs without dust or other organisms are shown in Table C-1. It should be noted that swabs with dust present yielded recoveries (55,0%, 27.9% and 42.6% for 1, 2, and 4-$\log_{10}$ inocula, respectively), but since the dust content and character will vary from site to site, CDC chose to present the conservative estimate for interpreting contamination on a surface. The macrofoam swabs were pre-moistened with PBST for this study, but in a laboratory comparison, using neutralizing buffer as a pre-moistening liquid was found to result in equivalent recovery efficiency as PBST. Alternate elution buffers may also alter the recovery efficiency of the method; phosphate buffer alone was not as effective at eluting the spores from the swab, though 0.0 5% Tween 20 in buffer was found to be equivalent to 0.02% Tween 80 in buffer.

Table B-1. Recovery Efficiencies Using Macrofoam Swab Sampling and Processing Procedures for *B. anthracis* on Stainless Steel, no dust present.

B. anthracis Spores/26 cm^2 Area [Average (SD)][(a)]	Number of Swabs	Spores Recovered [Average (SD)]	% Recovery [Average (SD)]
49 (7)	118	13 (7)	25.7 (15.2)
506 (86)	120	80 (33)	15.8 (6.6)
41,768 (7415)	116	12,835 (4,392)	31.0 (10.9)
All inoculum levels	354	-	24.2 (13.6)

[(a)] SD= standard deviation

Using other types of swabs for sampling may affect recovery efficiency. This possibility was evaluated by Rose et al. (2004) who inoculated 10^4 spores of *B. anthracis* Sterne in 95% ethanol onto 26 cm^2 stainless steel coupons. After drying, four types of pre-moistened and dry swabs (cotton, foam, polyester, and rayon) were used to remove the spores and were processed according to the LRN method (Rose 2004,). The recovery efficiencies of four swab materials are shown in Table B-2. Pre-moistened macrofoam and cotton swabs were the most efficient of the

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four swab types evaluated; pre-moistened polyester and rayon swabs were significantly less efficient. While all swab materials give biased estimates (under-estimates) of surface concentrations, the pre-moistened macrofoam swab is the preferred swab device. It is important to note that sensitivity, specificity, and limit of detection (LOD) have only been established for macrofoam swabs used to sample stainless steel surfaces.

If samplers choose to use another type of swab, pre-moistened cotton swabs have similar recovery efficiency to that of macrofoam swabs, though cotton may contain substances that inhibit PCR reagents, which should be considered if PCR is performed directly on the swab eluent. The differences in recovery efficiency between swab types may be due to differences in the ability of specific swab materials to remove spores from the surface or due to differences in the ability of the spores to be released from the swab during processing.

Table B-2. Recovery Efficiencies of Four Pre-moistened Swab Materials when Sampling Stainless Steel Surfaces

Swab Material	Cotton	Foam	Polyester	Rayon
Percent Recovery (SD)	41.7 (14.6)	43.6 (11.1)	9.9 (3.8)	11.5 (7.9)

The LRN method for the macrofoam swab has been validated for smooth non-porous surfaces no greater than 4 in^2 (26 cm^2). Both culture and PCR can be used to determine the presence of spores of *B. anthracis*. When viable spores are present, culture results are provided by the LRN laboratory as "*B. anthracis* spores/cm^2 recovered." A result of "No *B. anthracis* spores detected" should be interpreted in the context of the LOD of this assay (the smallest amount of analyte that can be distinguished from background with 95% confidence), which is 20 spores/26cm^2 (ca. 0.8 spores/cm^2) for stainless steel surfaces. One other caveat needs to be mentioned. Reporting the results as spores/cm^2 assumes that each colony on the agar plate results from the growth of a single spore. In reality, it may result from the growth of a single spore or from a clump of spores. Tween 80 and vortexing are used in the LRN method to help disperse clumps of spores that may be present in the samples, but may not do so completely. PCR is used to confirm *B. anthracis* colonies, and the results are reported as "positive" or "negative." PCR does not differentiate between viable or non-viable spores if performed on the sample directly.

B.2. Wipe Sampling Performance

A multi-center validation study involving 9 laboratories was conducted to quantify the performance of an LRN sponge-stick wipe processing protocol (Rose, 2011). Stainless steel coupons (100 in^2) (645 cm^2) were inoculated with known quantities (26, 528, and 33,140 spores) of *B. anthracis* Sterne spores in 95% ethanol. Seven coupons at each spore concentration were sampled with cellulose sponge-wipes pre-moistened with neutralizing buffer (Sponge-Stick, SSL10NB, 3M St. Paul, MN).

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Dust containing a consortia of organisms (A-3, Powder Technology, Inc, Burnsville, MN) were then added to the wipes. A total of 33 wipes were sent to each laboratory in three separate shipments of 11 wipes each. Each shipment consisted of 7 wipes that were used to sample the coupons inoculated with one of the spore quantities, one blank, one dirty blank (background organisms only) and two positive controls (wipes inoculated with the same spore concentration plus background organisms). Upon receipt by the participating laboratory, wipes were stored at 2-8° C until processing. Laboratories processed wipes within 48 hours of sampling according to the LRN protocol. The results are shown in Table B-3. The mean % recovery for all inoculum levels was 29.7% (SD 16.4%).

Table B-3. Recovery Efficiencies using Pre-moistened Sponge-wipes and LRN Processing Procedures for *B. anthracis* on Stainless Steel

***B. anthracis* Spores/645 cm² Area [Average (SD)][a]**	**Number of Sponge-wipes**	**Spores Recovered [Average (SD)]**	**% Recovery [Average (SD)}**
26.1 (13.6)	**63**	**9.1 (6.1)**	**32.4. (24.5)**
536.0 (134.1)	**63**	**132.6 (63.0)**	**24.4 (11.2)**
33,140.0 (6,743)	**56**	**9,984.0 (2,707)**	**30.1 (8.2)**

(a) SD= standard deviation

Studies with directly inoculated controls were performed to determine recovery efficiency during wipe processing only. Higher percent recovery for the controls (63.4% (SD 27.5%) vs. 28.9% (SD 16.7%), $p < 0.01$) suggests that a portion of the spores were not removed from the surface with the sponge-stick. The results from sponge-wipes processed by the LRN protocol are given as "*B. anthracis* spores/cm² recovered." The results should be interpreted in the context of the LOD of this assay (the smallest amount of analyte that can be distinguished from background with 95% confidence), which is 20 spores/645cm² (ca. 0.03 spores/cm²) for stainless steel surfaces. Reporting the results as spores/cm² assumes that each colony on the agar plate results from the growth of a single spore. In reality, it may result from the growth of a single spore or from a clump of spores. Tween 80 and vortexing are used in the LRN method to help disperse clumps of spores that may be present in the samples, but may not do so completely.

Additional evaluations of the validated sponge-wipe protocol were conducted to investigate the effects of validated sponge-wipe protocol with lower spore concentrations and on other surface materials on recovery efficiency, false negative rate, and limit of detection (Krauter 2012). The surrogate spore *Bacillus atrophaeus* var. globigii was employed for these evaluations. The study results show a roughly linear dependence of recovery efficiencies (RE) on surface roughness, where the smoothest surfaces (e.g., stainless steel and ceramic tile) have the higher RE and lower false negative rates. The findings are shown in Table B-4.

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Table B-4. Recovery Efficiency and False Negative Rate of Sponge-wipes (averaged over all *B. atrophaeus* spore concentrations) for Each Surface Material with the Corresponding Roughness Index Measurement

	Recovery efficiency, Mean (%)	False negative rate, Mean	Roughness Index (μm)
Stainless steel	48.1	0.1229	0.13
Ceramic tile	48.9	0.1812	0.59
Vinyl tile	25.6	0.2551	1.63
Faux leather	30.3	0.1417	3.27
Painted wood	25.5	0.2000	4.11
Plastic panel	9.8	0.4792	5.88

Both of the above-mentioned sponge – wipe evaluations (Rose 2011, Krauter 2012) were conducted by eluting the spores from the sponge-wipes with phosphate buffered saline (pH 7.2) containing 0.02% Tween 80 using a stomacher. Deviating from the method by using other elution buffers or elution techniques may lead to different recovery efficiencies, sensitivities, specificities, false negative rates and/or limits of detection.

In a limited study, rayon gauze wipes (2" x 2") pre-moistened with phosphate buffered saline (pH 7.2) containing 0.02% Tween 80, were evaluated as an alternative to Sponge Sticks (Hodges et al 2006b). The mean percent recovery of spores sampled from stainless steel using rayon gauze wipes was 25.4% (SD 18.9%). Thus, pre-moistened gauze wipes may be equivalent to pre-moistened sponge wipes, though validation performance data is not yet available (sensitivity, specificity, reproducibility, precision, LOD).

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Appendix C

Non-Validated Sampling Methods

(Adapted from Emanuel et al. 2008)

The Working Group recognizes that an array of sampling methods beyond those described for smooth surfaces in Appendix A may be used in the characterization of a contaminated space, both prior to and after recovery efforts. While these currently non-validated methods may yield information that is more qualitative than quantitative in nature, their application can provide important indicators of the state of a potentially contaminated space. Accordingly they are included here with general instructions to make their application as uniform as possible, in order to help standardize their application.

Use of these methods should be only be considered after consultation with the on-scene response coordinators and participating analytical laboratories, since interpretation of resulting data from these methods may be difficult.

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Bulk Sampling

Procedure for Bulk Sampling
The method presented below is for collecting a bulk sample.

Materials and Equipment
The following equipment should be available in order to collect bulk samples:

- Non-powdered sampling gloves
- Disposable or decontaminated spade, spatula, scoop or trowel
- Sterile forceps, scissors, scalpel, or sharp knife
- Sterile sample container of proper size
- Sealable plastic bags
- Documentation materials, digital camera, indelible ink pen, and logbook
- Custody seals, tags, and Sample forms

Procedures

1. Ensure that all of the sample equipment is sterile prior to use.
2. Identify the spot to collect the sample.
3. Collect the sample wearing a pair of non-powdered gloves and document the sample area using a camera and in the logbook.
4. For solids, powders, or granular material, collect the laboratory-specified quantity of the bulk sample with a dedicated sterile spoon, trowel, or spatula and place material into a sterile sample container.
5. For large pieces of material or vegetation that require analysis, discuss with the laboratory the material to be sampled. Large pieces may not fit in the sample container and will need to broken, shaved, cut or chipped into a sterile sample container with dedicated sterile scissors, scalpel, or knife.
6. Place item or pieces of the item in an appropriate sterile sample container.
7. Secure the lid, label and attach the custody seal and triple bag the sample container into sealable bags.
8. Change into new gloves prior to collecting the next sample.
9. Decontaminate outer bag prior to leaving hot zone. This is usually done at the entrance of the personnel decontamination line.

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HEPA Vacuum Sampling

Procedure for HEPA Vacuum Sampling on Porous Surfaces

Materials and Equipment

- A portable HEPA vacuum with a nozzle and hose attachment
- Vacuum sample sock assembly with cardboard inlet nozzle
- Power source
- Non-powdered sampling gloves
- Sterile plastic screw-topped sample containers (conical vial or specimen cup)
- Sealable plastic bags
- Small plastic zip tie
- Documentation materials, digital camera, indelible ink pen, and logbook
- Custody seals and tags
- Chain-of-custody forms and shipping paperwork
- Disposable templates to delineate the sample area (optional)
- Isopropyl alcohol wipes

Procedure

1. For each sample collected ensure that a new pair of gloves are worn
2. Determine the location to collect the sample.
3. Wearing a pair of sterile gloves, place a sample template (if using) over the area to be sampled and document the sample area using a camera, and drawing a map in the logbook.
4. Place the cardboard vacuum filter sock inlet assembly securely into the vacuum hose nozzle.
5. With the vacuum on, place cardboard nozzle on the surface to be sampled and vacuum designated area using an overlapping 'S' pattern both in the horizontal and vertical directions. Collect the sample in an area up to several square feet at a rate of 3 – 5 seconds per foot.
6. Once the sample has been collected, turn off the vacuum and remove the cardboard filter sock inlet assembly from the vacuum nozzle.
7. Touching only the blue portion; remove the filter sock from the assembly tube, and zip tie the blue portion of the bag closed. Then place sock into a sterile sample container.
8. Secure the lid, label and attach the custody seal and triple bag the sample container into a sealable bag.
9. To prepare for the next sample, with the vacuum off, wipe the first several inches of the inside and outside of the vacuum nozzle with an isopropyl alcohol wipe and cover with a clean sample glove.
10. Change out the used gloves with new gloves prior to collecting the next sample.
11. Decontaminate outer sample bag prior to leaving hot zone. This is usually done at the entrance of the personnel decontamination line.
12. Package samples for transport.

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13. Fill out Chain-of-Custody form, and make a copy.
14. Secure samples in shipping container with Chain-of-Custody and attach Custody seals.
15. Fill out shipping manifest or contact courier.

Air Filter Samples

Procedures for Air Filter Sampling
Below is procedure for collecting air samples with an open-face filter cassette.

Materials and Equipment

- Calibrated personal sampling pump
- Rotameter (air flow meter) or dry cell calibrator
- 3-piece, 37-milimeter (mm) cassette preloaded with sterile 0.45 micron mixed cellulose ester (MCE), Gelatin or Teflon (PFTE) sample filter
- Flexible Tygon™ tubing
- Sterile tweezers
- Sterile non-powdered sampling gloves
- Cassette opening tool
- Sealable plastic bags
- Documentation materials, digital camera, indelible ink pen, and logbook
- Custody seals and tags
- Chain-of-custody forms and shipping paperwork

Procedure

1. To calibrate the sampling pump, take a 3-piece cassette with a preloaded filter and remove the inlet and outlet plugs. Connect flexible Tygon™ tubing from the inlet of the filter cassette to the outlet of the calibrator. Train by attaching one end of the Tygon™ tubing to the inlet of a dedicated open-faced . Attach another piece of Tygon™ tubing from the outlet of the filter cassette to the pump manifold.
2. Calibrate the pump flow rate to the rate specified by the method: greater than 2.5 liter per minute (LPM) for MCE or Teflon filters and 2.0 LPM for the gelatin filters. If using a rotameter for calibration, then it should be calibrated with a primary standard such as the dry cell calibrator before using. Rotameters are considered secondary standards.
3. When calibration has been completed, remove the filter cassette, cap the inlet and outlet with the plugs, and save the filter cassette for recalibration at the end of sampling. Record initial flow rate of the sample pump from the calibration in the logbook and on the Cain-of-Custody form. The flow rate is used to calculate the airborne concentration of the contaminant.
4. Don sterile non-powdered sampling gloves.
5. To prepare the open-faced cassette for sampling, utilize the cassette opening tool to remove the inlet section of the 3-stage cassette, leaving the other two sections in place.
6. Remove the outlet end plug and attach one end of the flexible Tygon™ tubing to the outlet of the cassette and the other to the pump.

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7. Place the sample cassette and the pump in the desired location and photo-document and map the location.
8. Turn on the pump and record the time. Be sure the sampling cassette is oriented at a 45 degree angle downward. This prevents large particles from being collected that otherwise would not be collected.
9. Document the location and the sample location using a camera, drawing a map, and recording notes in the logbook.
10. Once the sample has run for the specified amount of time, remove the cassette and replace the inlet stage and the outlet and inlet plugs. It is important to note that with gelatin filter sampling times should not exceed 30 minutes since the gelatin can dry out.
11. Triple-bag the sample filter cassette in sealable plastic bags.
12. Check the final flow rate of the sampling train. Place the calibration cassette in the sample train and check with a rotameter or a dry cell calibrator the final flow rate just as in the initial calibration. Record this value in the sample form, on the Chain-of-Custody, and in the logbook.
13. Pre and post sampling train calibration can be done either inside or outside the hot zone. For calibration outside the hot zone the sampling equipment must be protected from contamination or easily decontaminated. Otherwise, pre and post sampling train calibration should be done in the hot zone.
14. Label and attach a custody seal to the cassette.
15. Decontaminate the outer sample bag prior to leaving hot zone. This is usually done at the entrance of the personnel decontamination line.
16. Package samples for transport.
17. Complete the Chain-of-Custody form and any other paperwork and make a copy.
18. Secure samples in shipping container with Chain-of-Custody and attach Custody seals.
19. Fill out shipping manifest or contact courier.

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Air Impactor Samples

Procedures for Impactor Air Sampling

Below is procedure for collecting air impactor samples with petri dishes specific to the contaminant being sampled.

Materials and Equipment

- Calibrated high-flow sampling pump (28.3 LPM)
- Rotameter (air flow meter) or dry cell calibrator
- Calibration adapter for impactors
- Sterile single or six stage impactor
- Sterile Petri dish and agent-specific agar for each stage
- Flexible Tygon™ tubing
- Sterile non-powdered sampling gloves
- Sealable plastic bags
- Parafilm M® wax strips
- Sample labels and wax pencil
- Documentation materials, digital camera, indelible ink pen, and logbook
- Custody seals and tags
- Chain-of-custody forms and shipping paperwork

Procedure

1. For each sample collected, ensure that a new pair of sterile gloves is worn.
2. Set the pump flow rate to 28.3 LPM per minute or as specified in the analytical method, and turn it on.
3. To calibrate the impactor, aseptically remove the lids from the calibration set of Petri dish(es) and keep lids in a clean sealable plastic bag. For the single stage impactor, place each one calibration Petri dish on the stage and reassemble the impactor. For the 6 stage impactor, place one of the calibration Petri dishes on each of the impactor stages and reassemble the stages in the correct numerical order. Attach the calibration adapter to the top of the impactor. Attach flexible Tygon™ tubing from the impactor calibration adapter to the calibrator or rotameter inlet. Attach the second piece of tubing from the outlet of the impactor to the inlet of the sample pump. Turn on the calibrator and record the initial flow rate in the logbook.
4. Calibration of the sampling train can be performed outside the hot zone such as in the sample preparation area. If using a rotameter for calibration, then it should be calibrated with a primary standard such as the dry cell calibrator. Rotameters are considered secondary standards.
5. After calibration, remove the calibration Petri dishes from each stage of the impactor and cover with a lid. These can be reused for calibration several times until they begin to dry out and not more than one day.
6. In preparation to sample, aseptically remove lids from the sample Petri dish(es) and keep in a clean sealable plastic bag. For the single stage impactor, place one Petri dish on the stage and reassemble the impactor. For the 6 stage impactor, place on of the 6 Petri

dishes on each impactor stage and reassemble the impactor ensuring that the stages are in the correct numerical order. Connect the Tygon™ from the outlet of the impactor to the inlet of the pump.

7. Place the impactor and pump in desired sample location and photo document and map the location.
8. Start the pump and record the time sampling began and the time the sampling is completed. Sampling times should be between 10 to 15 minutes. At completion of sample time, don sterile gloves and aseptically remove the petri dish(es), cover with lids and seal each dish with Parafilm M® to secure, label each dish with the wax pencil including the stage number and place into sterile zippered sample bag upside down (agar oriented up).
9. Double bag each sample.
10. Decontaminate outer bag prior to leaving hot zone. This is usually done at the entrance of the personnel decontamination line.
11. For post sampling calibration, aseptically remove lids from each of the pre-calibration sample Petri dishes and place on the impactor stages. Attach the tubing to the calibrator and the pump as in the initial calibration.
12. Turn on pump and record the post sampling flow rate in the log book. Pre and post calibration flow rates are very important in determining final contaminate concentration.
13. Pre and post sampling train calibration can be done either inside or outside the hot zone. For calibration outside the hot zone the sampling equipment must be protected from contamination or easily decontaminated. Otherwise, pre and post sampling train calibration should be done in the hot zone.
14. Package samples for transport.
15. Fill out Chain-of-custody form, and make a copy.
16. Refrigerate samples or package with ice, ensuring agar does not freeze.
17. Secure samples in shipping container with Chain-of-custody and attach Custody seals.
18. Fill out shipping manifest or contact courier.
19. Prior to use to collect another sample, the impactor must be autoclaved.

Impinger (Wet Method) Air Samples

Procedures for Impinger Air Sampling
Below is procedure for collecting air samples with an impinger using a wet method.

Materials and Equipment

- High Flow Sampling Pump
- Dry cell calibrator and stand
- Two sterile impinger, pump attachment, and sterile impinger fluid
- Teflon or Parafilm M® tape
- Flexible tygon tubing
- Sterile sample container bottle
- Sterile non-powdered sample gloves
- Documentation materials, digital camera and logbook
- Custody seals, sealable plastic bags, and tags
- Sample labels, documentation forms, permanent marker(s)
- Chain-of-custody forms and shipping paperwork

Procedure

1. For each sample collected, ensure that a new pair of sterile gloves is worn.
2. Aseptically fill an impinger with appropriate sterile fluid and attach to pump. This should be done outside the hot zone in a clean area.
3. Set up the sampling train by attaching Tygon™ tubing to outlet of impinger and the other end to inlet of the sample pump.
4. In a clean area, calibrate the sample train by attaching another piece of Tygon ™ tubing to the outlet of the impinger and the other end to a rotameter or dry cell calibrator. Adjust pump to the desired flow rate of 12.5 LPM. If using a rotameter for calibration, then it should be calibrated with a primary standard such as the dry cell calibrator before using. Rotameters are considered secondary standards.
5. After pre-sampling calibration, remove impinger, place caps or Parafilm M® over both the inlet and outlet of the impinger and set aside to use to check the flow rate after the sample is collected.
6. Don a new pair of sterile gloves and attach a second sterile impinger, filled with appropriate sterile fluid, to the sampling train.
7. Place sampling train in desired sample location and turn on pump.
8. Photo document sample location, draw map and record sample start time in the log book.
9. After sampling time has elapsed, turn off pump, don sterile gloves and aseptically remove the impinger.
10. Ascetically transfer impinger fluid to sample container bottle can be done either inside or outside the hot zone. If done outside the hot zone, place a cap or Parafilm M® over the inlet and outlet of the impinger. It is important to keep impingers upright to prevent loss of fluid due to leaking or spillage. Fluid transfer done outside the hot zone must be done in an appropriate fume hood. If impinger fluid will be transferred to sample container bottle in the hot zone, don sterile gloves and aseptically remove the impinger, transfer

fluid to labeled, sterile sample container and seal the lid with Teflon or Parafilm M® tape.

11. Double bag the sample.
12. For post sampling train calibration, don sterile gloves and attach a fluid filled calibration impinger to the sample train as described in Step 4. Turn on pump and record flow rate. Record flow rate in log book.
13. Pre and post sampling train calibration can be done either inside or outside the hot zone. For calibration outside the hot zone the sampling equipment must have be protected from contamination or easily decontaminated. Otherwise, pre and post sampling train calibration should be done in the hot zone.
14. Decontaminate sample bag before leaving hot zone. This is usually done at the entrance of the personnel decontamination line.
15. Package samples for shipment including ice, if needed.
16. Complete Chain-of-custody form and place in sample shipment container.
17. Secure shipment container and complete shipping manifest.
18. Prior to another use, the impinger used to collect the sample must be autoclaved.

Liquid Sampling for Biological Agents

Note: For drinking water samples please refer to the sample note at bottom of procedures

Materials and Equipment

- Non-powdered sample gloves
- Plastic or glass 1-liter sample bottle
- Bacon bomb sampler, Kemmerer sampler, Dip sampler, Bailer, or large 100 ml disposable syringe.
- Sealable plastic bags
- Parafilm M® wax strips or
- Teflon tape
- Sample labels and wax pencil
- Documentation materials, digital camera, indelible ink pen, and logbook
- Custody seals and tags
- Chain-of-custody forms and shipping paperwork
- Shipping Manifest

Procedure

1. For each sample collected, ensure a new pair of sterile gloves is worn
2. Ensure all equipment is sterilized or decontaminated prior to use
3. Select appropriate apparatus based on sample depth and locations. For example, in small puddles the syringe may be the best apparatus to use.
4. If a sample collection device was used, transfer the sample to an appropriate sized sterile plastic or glass container
5. To collect the sample directly into a bottle, remove bottle lid and protect from contamination by placing in new sealable plastic bag. Grasp bottle at the base with one hand and plunge bottle mouth down into the water to avoid introducing surface scum. For large sample volumes, the above approach may not be possible; therefore, a sterile transfer container may be needed.
6. If water body is deep and is static, an artificial current can be created, by moving bottle horizontally in the direction it is pointed and away from sampler collector
7. Tip bottle slightly upwards to allow air to exit and the bottle to fill
8. Pour out a small portion of the sample to allow an air space of 2.5-5 cm (1"-2") above each sample for proper mixing of sample before analyses
9. Cap the bottle and seal lid with Parafilm M®, Teflon tape or equivalent
10. Label samples.
11. Photo document sample at the sample location.
12. Double bag sample.
13. Decontaminate outer bag, if needed, in the hot zone.
14. Package sample(s) for shipment, including ice to keep sample cool.
15. Complete Chain-of-custody form and place in sample shipment container.
16. Secure shipment container and complete shipping manifest.

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* U.S. EPA. 2011 Comparison of Ultrafiltration Techniques for Recovering Biothreat Agents in Water. U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-11/103. http://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=238310&fed_org_id=1253&address=nhsrc/si/&view=desc&sortBy=pubDateYear&showCriteria=1&count=25&searchall='water%20security'%20AND%20'biological'

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Surface Soil Sampling for Biological Agents

Materials and Equipment

- Non-powdered sample gloves
- Sterile stainless steel or plastic scoop or trowel
- Sterile 250 ml sample jar
- Sealable plastic bags
- Chain-of-custody forms and custody seals
- Sample labels, sample documentation form, permanent marker(s)
- Shipping Manifest

Procedure

1. For each sample collected, ensure a new pair of gloves is worn
2. Ensure all equipment is sterilized or decontaminated prior to use
3. Using a scoop or trowel, collect 50-100 g of soil from desired location (fill the container)
4. If possible remove rocks, vegetative matter, or sharp objects from soil
5. Place sample in appropriate sterile plastic container
6. Cap container with the sample jar lid
7. Label samples.
8. Photo document sample at the sample location, draw a map and log information in the logbook.
9. Double bag sample.
10. Decontaminate outer bag, if needed, in the hot zone.
11. Package sample(s) for shipment, including ice to keep sample cool.
12. Complete Chain-of-custody form and place in sample shipment container.
13. Secure shipment container and complete shipping manifest.

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Appendix D
Documentation and Decision Support Tools

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Several different software tools have been designed to manage and document data from sample collection as well as assist in developing grid and statistical sampling plans. Managing the data collected as part of a *consequence management* effort is very important. To ensure the integrity of sample results, various types of documentation need to be completed throughout the sampling process (i.e., from sample collection through sample analysis). The use of decision support tools can support the development of a sampling plan based on statistical sampling theory and the statistical analysis of sample results to support confident decision-making. It is critical to ensure that the information gathered can be easily and quickly shared among the various state, local, and federal agencies.

Since the collection of samples may be associated with a crime scene or suspicion of a criminal incident, the resulting information, the approach utilized to develop the sampling plan, and manner in which samples were collected will be factored into the usability of those samples in a court of law, as well as to ensure process quality. Sampling teams need to be aware that samples collected may be or become criminal evidence, and certain additional procedures associated with sample collection will be necessary.

D. 1 Sample Documentation

In order to provide accurate and high-quality information, it is important for sampling personnel to understand not only what needs to be documented, but also why it needs to be documented (Emanuel et al. 2008). To meet laboratory submission requirements, and to interpret sampling results, information about the sampling process must be documented and should include information about general site details as well as specific information about individual samples. Much of the needed general site information is documented in the sampling plan, described earlier in Section 4.4. Additional documentation and information can also be found in the Incident Action Plan (IAP). The IAP is developed by the IC/UC and describes tactical objectives and support activities for one operational period, generally 12 to 24 hours.

Information that should be documented includes:

- Procedures for collecting and processing the samples;
- Description of the items that may be sampled (e.g., desk, carpet, wallboard, etc.);
- Description of the location where the sample was collected and associated sample number (e.g., Room 110, sample collected from on top of file cabinet in North, East corner and sample number is 1011). This is very important so that a sample result can be associated to a specific item sampled and its location.
- Description of surfaces that must be sampled (e.g., porous, non-porous, rough, smooth, etc.) and surface materials or coating (e.g., plastic, metal, painted surface, etc.);
- Weather conditions, including temperature and wind.

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To meet the documentation needs for individual samples, sample collection, sample analysis request forms, and chain of custody forms should be completed. The information requirements in these forms are described in the next sections. Additional information that may also be important to document in sampler field notes includes:

- Notes regarding the sampling process that might be of interest to future analysis of the data (e.g., surface was noticeably contaminated with particulate material)
- The area that was sampled (e.g., a swab sample using a template with an area of 100 cm^2)
- Information about the photographs taken
- Document the method used to establish the location (e.g., measured with a tape measure, laser positioning system, GPS, manual location on a map, etc.)

The use of handheld data collection devices like a personal data assistant (PDA) improves the quality of the field data collected. A software program can be used to collect information for sample documentation. These programs offer a wide flexibility in managing the information electronically.

- A unique sample identification number, date, and time for each sample
- A detailed description of the matrices that was sampled (e.g., water, air, soil, solids, etc.)
- A COC form must be produced before samples can be transported from the site, and must have a signature confirming the collection and release of the samples
- Establishing a datum for sampling location identification (e.g., the origin location for a local coordinate system, UTM (Universal Transverse Mercator) coordinates, latitude/longitude, etc.)
- Sampling location, in X, Y, Z space relative to the origin location

D.1.1 Sample Collection Form

During sample collection in the hot zone, individual sample information should be recorded. However, recordkeeping should be kept to the minimum necessary as any documentation will have to be decontaminated upon leaving the contaminated area. The sample collection form serves as the documentation for the sampling incident. First, each sample should be given a unique sample identification number. In addition to the unique identification number, the following information should be recorded on the form:

- The date and time collected for each sample
- The type of sample (e.g., surface, air, and bulk, etc.)
- The type of sample collection technique (e.g., swab, wipe, sock vacuum, etc.)
- The orientation of the surface (e.g., horizontal, upwards, vertical, etc.)
- The surface area sampled (e.g., square centimeters wiped)

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- If desired, indicate whether the sample was prescribed as part of a probability-based sampling design, a judgmental sample, or other
- Documentation of sampler's name
- Other sample location information of note (e.g., on what floor the sample was collected, room number, area identifier, etc.)

D.1.2 Sample Analysis Submission Form

After sampling is completed, a sample analysis submission form should be finished and submitted to the LRN along with the samples. Sampling personnel should meet with or contact their local LRN to obtain this form. While individual LRN laboratories may have different required fields, the following information is included in any form:

- Submitter information
- Specimen type, suspect organism, and source
- Date and time collected
- Analytical processing request

D.1.3 Chain of Custody (COC) Form

A COC form documents transfer of sample custody from one individual to another, from the time the sample is collected until final analytical disposition. Each individual in possession of the sample must be noted by recording his or her signature on the form. The COC record should include instructions for the laboratory technician as to analytical methods, potential dangers, and any pertinent handling procedures that should be observed. The COC record must include at least the following information:

- All available information regarding the potential hazards associated with the agent
- Handling procedures associated with the samples
- Sample identification number
- Sample concentration, if known
- Sampling location
- Collection date and time
- Sample matrix
- Names and signatures of the samplers
- Signatures of all individuals who had custody of the samples (EPA 2006a)

An unbroken COC must be maintained for all samples from collection through analysis and archiving. In order to maintain COC, the form must be readily accessible when transferring samples from one individual to another. Therefore, COC forms should not be placed inside the

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primary sample containment. A copy of the record will be kept with the samples until they are analyzed and returned with the analytical results or will be maintained on site at the laboratory if samples are archived for later use or collection by law enforcement.

D.2 Data Management Plan

The Data Management Plan (DMP) establishes an overall plan for the data management requirements for a specific project. The purpose of the DMP is to provide the necessary management, control necessary sample nomenclature, maintain quality control information, Geographic Information System (GIS) information, and control and inventory of all data.

The primary functions of the DMP are as follows:

- record keeping
- data quality control
- storage and retrieval systems
- handling of classified data
- planning, scheduling, and delivery of data

D.2.1 Managing Large Amounts of Data

In managing large amounts of data, the decision makers should pre-plan their data management requirements. With large amounts of data, serious consideration should be given to utilizing a formal database structure for saving and querying data. Databases preserve relationships between sample data. Spreadsheet applications do not provide the same rigor of preservation of sample data attributes. In addition, spreadsheet applications may be too cumbersome to manage large data sets. With more comprehensive database structures, not only will the data associated with sample locations and analysis results be archived, but other spatial information such as facility maps and spatial mapping of results may be maintained as well.

Another consideration for managing large amounts of data is security. With a secure database, access can be managed through login privileges granted by the decision makers thereby limiting access to the data to those with a need-to-know. Data sharing can be managed with a more sophisticated database engine. There can also be allowances to limit which personnel have permission to modify data in the database, in order to preserve integrity of the data. For instance, a secure database will be critical in managing data associated with a terrorist threat response.

The staff that maintains the database should be aware of the structure of the database and the master key identifiers used to manage the data. There is a possibility for corruption of a database if the relationships are not maintained appropriately in the database. Care should be taken to maintain these relationships.

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D.2.2 Electronic Data Format

Whenever possible, data should be stored in an electronic database. There may be a need to export data from a database to a spreadsheet application in order to analyze the data with other tools (e.g., Excel, mapping software, etc.). There may also be a need to establish protocols for saving spatial information, such as CAD drawings, GIS maps, bitmap images, etc. Photographic documentation should also be considered in the specifications for electronic data storage and capture.

D.3 Decision Support Tools

If possible, the use of decision support tools throughout the response phases is recommended to help facilitate the design of a sampling plan. Decision support tools may be used to codify the processes for developing a sampling plan and to document the data and assumptions associated with the plan. These tools should facilitate better defensibility of the assumptions, goals and data associated with the project.

Decision support tools provide users with the following capabilities to:

- Develop DQOs
- Develop defensible sampling design plans (e.g., locating hotspots, testing hypotheses of the confidence in meeting a cleanup goal, etc.)
- Provide sampling locations via spatial representation
- Display building or site layout (e.g., engineering drawings)
- Document information associated with sample collection (e.g., sample collection method, location, surface type, sampling ID number, etc.), including electronic data capture with handheld devices
- Provide sample analyses results via spatial mapping
- Analyze data to determine statistical relationships and information suitable for decision making
- Optimize sampling design if an adaptive sampling strategy is desired

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Appendix E

Details on Application of Combined Judgmental and Random (CJR) Sampling Approach

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For the CJR sampling approach, several input parameters affect the required number of probabilistic samples. These include 1) the percent confidence (X%) desired, 2) the minimum percent (Y%) of the decision area stated to not contain detectable contamination, 3) the number of judgmental samples taken, 4) how much more likely it is a judgmental sample location contains detectable contamination than a probabilistic sample location, and 5) the expected *a priori* probability a judgmental sample will detect contamination. These parameters are discussed and guidance for selecting them is provided after the next paragraph.

An important assumption of the mathematical model used in the CJR approach is that the decision area can be divided into areas of "high" and "low" probabilities of being contaminated (the high probability areas need not be contiguous, and the same for low probability areas). The CJR model assumes all of the high probability areas are sampled judgmentally. In essence, the judgmental sample locations define the high probability areas in the sampling plan. Consequently, fewer probabilistic samples are necessary when more judgmental samples are taken and/or when locations with judgmental samples are more likely to contain detectable contamination. Fewer probabilistic samples are also necessary as the *a priori probability* that a judgmental sample will detect contamination increases.

The key parameters for the CJR sampling approach are briefly explained below with guidance on how to specify a value for each parameter.

- *Desired confidence (X%)*: The CJR sampling approach provides for stating that there is X% confidence that at least Y% of a decision area has no detectable contamination if all of the judgment and random samples obtained are non-detects. There is precedence in environmental regulations for specifying X = 95, but less or greater confidence may be deemed appropriate depending on risk/consequence evaluations.
- *Minimum percent (Y%) of the decision area that can be stated to not contain detectable contamination*: Ideally Y% would be 100%, but that would require sampling 100% of the decision area. When choosing the Y% parameter, the team must balance between resources/cost and risks/uncertainty. Higher Y% values require more samples. Often Y% will range between 90% and 99.5% with 99% often used.
- *Number of Judgment Samples*: The number of judgment samples taken will be determined using expert judgment, knowledge of the event, and previous experience. Judgment samples should be obtained from all areas where contamination is deemed to be most likely.
- *How much more likely it is that a judgment sample location contains detectable contamination than an uninformed random sample*: It is recommended that this parameter be between 1 and 3, unless there is significant evidence that it is higher. This parameter may be derived from expert opinion, knowledge of the event and/or experience from previous studies. If the value of 1 is chosen for this parameter, equal weight is given to the judgment and random samples.

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- *Expected a priori probability (p) that a judgmental sample will contain no detectable contamination:* This parameter is derived from expert opinion and/or results from previous sampling in the decision area. If the CJR sampling approach is being applied after decontaminating the area, information from previous studies regarding the effectiveness of the decontamination process may be used. Where proven, highly effective decontamination technologies are applied, the *a priori* probability might be quite high (0.90 to 0.99). If little is known about the possibility of contamination in the area, an uninformed *a priori* probability of 0.50 is used.

In dealing with contamination incidents, subject matter experts may recommend values of the above parameters, but the ultimate decision is with the IC/UC.

The CJR approach has been incorporated into the freely available Visual Sample Plan (VSP) software (VSP Implementation Team 2010, Matzke et al. 2010) that calculates the required number of random samples given the number of judgmental samples and other parameter values. The VSP software provides for selecting both judgment and random sample locations within the facility. Random samples can be placed either completely at random or using a systematic grid sampling scheme with a random start for the grid. The systematic grid will better protect against a large unsampled area where a large "hotspot" could go undetected. The number of random samples required also depends on the number of possible unique sample locations in the population. For a large facility the number of possible area samples (e.g., 10 cm x 10 cm wipes) can be very large. If a 3-dimensional representation of the facility is constructed in VSP, the number of possible area samples for the surfaces of interest is determined automatically and incorporated in the sample requirements calculations.

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Appendix F
Example of a Site-Specific Sampling Plan

Note: This plan was developed as part of an EPA biological remediation demonstration known as Bio-Response Operational Testing and Evaluation (BOTE II).

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF ENVIRONMENTAL CLEANUP
EMERGENCY RESPONSE UNIT

Site Specific Sampling Plan

Project Name: ___BOTE Phase 2_____ Site ID: _____

Author: _____ Company:_____. Date Completed: ___

This Site Specific Sampling Plan (SSSP) is prepared and used in conjunction with the Quality Assurance Plan (QAP) for the Emergency Response Unit for collecting samples during this Removal Program project. The information contained herein is based on the information available at the time of preparation. As better information becomes available, this SSSP will be adjusted.

When inadequate time is available for preparing the SSSP in advance of the sampling event, a Field Sampling Form may be prepared on-site immediately prior to sampling. This full length version of the SSSP is written after the sampling event and the completed Field Sampling Form attached to it.

1. Approvals

Name, Title	Telephone, Email, Address	Signature
On-Scene Coordinator		
ERU Quality Assurance Coordinator		

I. Project Management and Organization

2. Personnel and Roles involved in the project:

Name	Telephone, Email, Company, Address	Project Role	Data Recipient
		On Scene Coordinator	Yes
		Author of SSSP, START Project Manager	Yes

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		ERU Quality Assurance Coordinator	No
		START Quality Assurance Reviewer	Yes
		Sampling Leader	Yes

3. Physical Description and Site Contact Information:

Site Name	BOTE Phase 2		
Site Location	See Figure 1		
Property Size	See Figure 1		
Site Contact		**Phone Number:**	
Nearest Residents		**Direction:**	
Primary Land Uses Surrounding the Site	Commercial, university		

4. The proposed schedule of project work follows:

Activity	Estimated Start Date	Estimated Completion Date	Comments
SSSP Review/Approval			
Mobilize to / Demobilize from Site			
Sample Collection			
Laboratory Sample Receipt			Saturday receipt may be requested
Laboratory Analysis			
Data Validation			

5. Historical and Background Information

Describe briefly what you know about the site that is relevant to sampling and analysis for this investigation.

On Wednesday, September 7,2011, a 56 year-old female is admitted to the Eastern Idaho Regional Medical Center (EIRMC) in Idaho Falls, Idaho after experiencing vomiting, confusion, incoherent speech and a severe headache for the past 6 hours. On September 9, the LRN laboratory confirms *B. anthracis* by Polymerase Chain Reaction (PCR) and from a culture of the cerebrospinal fluid. She dies from inhalation anthrax on September 10, 3 days after admission.

On Thursday, September 8,2011, a 64 year-old male is admitted to the Portneuf Medical Center (PMC) in Pocatello, ID with symptoms suggestive of pneumonia. His illness

began on September 6. As of September 10, the patient remains hospitalized with inhalation anthrax and is being treated intravenously with several antibiotics.

On Saturday, September 10,2011, an epidemiological investigation links both patients to the same place of employment in Idaho Falls. The deceased woman, Ann Halation, was identified as the secretary to the President of Southeastern University. Her office is located in the Administration Building on the university campus. The hospitalized male, Austin Powders, was determined to be a janitor employed at the same building.

6. Conceptual Site Model

Example: Contaminant: Mercury
Transport Mechanism: vapor moving on air currents
Receptors: people living in the house

Contaminants: B. anthracis

Transport Mechanisms: Moving on air currents, on surfaces in the building

Receptors: people through inhalation or direct contact of spores

7. Decision Statement

Examples: 1) Determine whether surface contamination exceeds the established action level;
2) Determine appropriate disposal options for contaminated materials.

The decision(s) to be made from this investigation is/are to:

1) Determine extent of contamination within building.
2) Determine the appropriate decontamination method for the building and related items.
3) Determine if contamination is contained to the building or not.

8. Action Level

State the analyte, concentration, and units for each selected action level. Describe the rationale for choosing each action level and its source (i.e. MTCA, PRG, ATSDR, etc.) Example: The action level for total mercury in soil is 6.7 mg/kg (from Regional Screening Level residential).

The Action Level is being determined by the UC.

II. Data Acquisition and Measurement Objectives

9. Site Diagram and Sampling Areas

A Sampling Area is an area within in which a specific action will be performed.
Examples : 1) Each drum on the site is a Sampling Area;
2) Each section of sidewalk in front of the residence is a Sampling Area;

3) Each sampling grid section is a Sampling Area.

Figure 1, 2, and 3 display the site. Each room is a decision area. The outdoors is a decision area.

10. The Decision Rules

These can be written as logical If…, Then.. statements. Describe how the decisions will be made and how to address results falling within the error range of the action level. Examples: 1) In the Old Furnace Sampling Area, the soil in the area around the furnace structure will be excavated until sample analysis with XRF shows no mercury concentrations in surface soil above the lower limit of the error associated with the action level, 18.4 mg/kg. 2) If the concentrations of contaminants in a SA are less than the lower limit of the error associated with the action level, then the area may be characterized as not posing an unacceptable risk to human health or the environment and may be dismissed from additional RP activities. The area may be referred to other Federal, State or Local government agencies.

The following statement(s) describe the decision rules to apply to this investigation: To be determined by the UC with the help of the TWG. Sample results will be utilized by the TWG to recommend a decon method for the building

11. Information Needed for the Decision Rule

What information needs to be collected to make the decisions – this includes non-sampling info as well: action levels, climate history, direction of water flow, etc. Examples: Current and future on-site and off-site land use; wind direction, humidity and ambient temperature; contaminant concentrations in surface soil.

The following inputs to the decision are necessary to interpret the analytical results: Action Levels, extent of contamination (areas and concentration), cost effectiveness of each decon technology, dispersal method, status of HVAC system since attack

12. Sampling and Analysis

For each SA, describe:

1. *sampling pattern (random, targeted, scheme for composite)*
2. *number of samples, how many to be collected from where, and why*
3. *sample type (grab, composite)*
4. *matrix (air, water, soil)*
5. *analytes and analytical methods*
6. *name and locations of off-site laboratories, if applicable.*

Non-Impact Rooms: Evaluate if contamination has been tracked into rooms that are not believed to have been impacted by directly by source the source letter. Tracking could be by foot traffic or fomite (i.e. cross contaminated mail, personal belongings). Also, to determine if contamination passed through the HVAC system and impacted the room. - 1 discrete sample at entry on the floor - 1 horizontal composite sample (discretionary) floor or surface sample

- 1 ceiling vent sample
- 1 optional discretionary sample (i.e. electro-static surface, mail drop areas, etc)

Total rooms: 23 Total samples: Up to 92

"NIOSH " Rooms: More fully characterize rooms that have had limited sampling from the NIOSH investigation.

- 1 discrete sample at entry on floor
- 1 optional discretionary sample (i.e. electro-static surface, mail drop areas, etc)

Total rooms: 6 Total samples: Up to 12

2nd Floor Exclusion Zone: Provide quantitative analysis of high-spore load areas to potentially support decontamination planning efforts and estimate spore size distribution.

- 2 six-stage impactor samples (Rooms 201 and 201A)
- 2 quantitative discrete samples in each room (discretionary)
- 1 vertical sample per room

Total rooms: 4 Total samples: Up to 24

Hallways / Stairs: To determine if contamination was tracked via movement from source areas.

- One 4-point composite of the upper hallway
- Once HVAC return register
- One 3-point composite from each stairwell

Total areas: 3 Total samples: Up to 4

Outside Evaluation: To determine if contamination has been tracked away from the building

- 4 discretionary discrete samples from concrete areas

Total areas: 1 Total samples: Up to 4

RV-PCR Evaluation: To provide samples to evaluate EPA's rapid viability PCR

Total samples: 12

Field Blanks: Handle samples in the field without collection to support Quality Assurance

Total samples: Up to 15

13. Applicability of Data (place an X in front of the data categories needed, explain with comments)

Do the decisions to be made from the data require that the analytical data be:

1) definitive data, 2) screening data (with definitive confirmation) or 3) screening data (without definitive confirmation)?

*X___**A) Definitive data** is analytical data of sufficient quality for final decision-making. To produce definitive data on-site or off-site, the field or lab analysis will have passed full Quality Control (QC) requirements (continuing calibration checks, Method Detection Limit (MDL) study, field duplicate samples, field blank, matrix spikes, lab duplicate samples, and other method-specific QC such as surrogates) AND the analyst will have passed a Precision and Recovery (PAR) study AND the instrument will have a valid Performance Evaluation sample on file. This category of data is suitable for: **1) enforcement purposes, 2) determination of extent of contamination, 3) disposal, 4) RP verification or 5) cleanup confirmation.***
Comments:

*___**B) Screening data with definitive confirmation** is analytical data that may be used **to support preliminary or intermediate decision-making** until confirmed by definitive data. However, even after confirmation, this data is often not as precise as definitive data. To produce this category of data, the analyst will have passed a PAR study to determine analytical error AND 10% of the samples are split and analyzed by a method that produced definitive data with a minimum of three samples above the action level and three samples below it.*
Comments:

*___**C) Screening data** is analytical data which has not been confirmed by definitive data. The QC requirements are limited to an MDL study and continuing calibration checks. This data can be used for making decisions: **1) in emergencies, 2) for health and safety screening, 3) to supplement other analytical data, 4) to determine where to collect samples, 5) for waste profiling, and 6) for preliminary identification of pollutants**. This data is not of sufficient quality for final decision-making.*
Comments

14. Special Sampling or Analysis Directions

Describe any special directions for the planned sampling and analysis such as additional quality controls or sample preparation issues. Examples: 1) XRF and Lumex for sediment will be calibrated before each day of use and checked with a second source standard. 2) A field blank will be analyzed with each calibration to confirm the concentration of non-detection. 3) A Method Detection Limit determination will be performed prior to the start of analysis so that the lower quantitation limit can be determined. 4) If particle size is too large for accurate analyses, the samples will be ground prior to analysis. If the sample contains too much moisture for accurate analyses, the sample will be decanted and air dried prior to analysis.

N/A

15. Method Requirements

[Describe the restrictions to be considered in choosing an analytical method due to the need to meet specific regulations, policies, ARARs, and other analytical needs. Examples: 1) Methods must meet USEPA Drinking Water Program requirements. 2) Methods must achieve lower quantitation limits of less than 1/10 the action levels.3) Methods must be performed exactly as written without modification by the analytical laboratory.]

Only CDC approved methods will be used for sampling and analysis.

16. Sample Collection Information

[Describe any activities that will be performed related to sample collection]

The applicable sample collection Standard Operating Procedures (SOPs) or methods will be followed and include:
Field Activity Logbook SOP
Sample Packaging and Shipping SOP
Instrument SOPs:
Other SOPs: Attachment A: CST Sample Collection and QC Sample Collection Protocol, Attachment B: ENVIRONMENTAL SAMPLING GUIDELINES AND ANALYTICAL APPROACH FOR BIOLOGICAL RESPONSE PLANS

17. Optimization of Sampling Plan (Maximizing Data Quality While Minimizing Time and Cost)

[Describe what choices were made to reduce cost of sampling while meeting the needed level of data quality. Example: The XRF will be used in situ whenever possible to achieve accurate results. Reproducibility and accuracy of in situ XRF analyses will be checked by collecting, air drying, analyzing and comparing five in situ samples at the start of sampling. Where interferences are suspected, steps will be taken to eliminate the interferences by mechanisms such as drying, grinding or sieving the samples or analyzing them using the Lumex with soil attachment.]

The format for sample number identification is summarized in Table 1. Sample collection and analysis information is summarized in Table 2.

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Table 1
SAMPLE CODING

Project Name: ____BOTE Field Exercise_____ **Site ID:** _10ZZ_____

SAMPLE NUMBER [1]		
Digits	**Description**	**Code (Example)**
1,2,3,4	Year and Month Code	1109
5,6,7,8	Consecutive Sample Number (grouped by SA as appropriate)	0001 (First sample of SA)

SAMPLE NAME / LOCATION ID [2] ***(Optional)***		
1,2,3	Floor and Room number	i.e. 101, 201
4,5	Matrix Code	AR – Air PR – Product QC – Quality Control SB - Swab WP – Wipe WT – Water
6,7	Consecutive number for each area	01

Notes:
(1) The Sample Number is a unique, 8-digit number assigned to each sample.
(2) The Sample Name or Location ID is an optional identifier that can be used to further describe each sample or sample location.

Table 2. Sampling and Analysis

Data Quality	Sampling Area	Matrix	Sampling Pattern	Sample Type	Data Quality	Number of Field Samples	Analyte or Parameter	Method Number	Action Level	Method Quant. Limit	#/type of Sample Containers per Sample	Preservative	Hold Time	Field QC
Lab Analysis	All Decision Areas	Product Wipe Swab Air	Targeted	Grab Composite	Definitive	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	Duplicate Blank

Note: For matrix spike and/or duplicate samples, no extra volume is required for air (unless co-located samples are collected), oil, product, or soil samples except soil VOC or NWTPH-Gx samples (triple volume). Triple volume is also required for organic water samples (double volume for inorganic).

Table 3. Common Sample Handling Information

Analysis Type	Sub Analysis	Matrix	Analytical Method	Container Type	Minimum Volume	Preservative	Temperature/ Storage	Hold Time	Source
Metals	Metals Not including Mercury or Hexachrome. Includes TAL, PP, RCRA lists)	Solid	EPA 6000 / 7000 Series	Glass Jar	200 g	n/a	None	6 months	SW-846 ch. 3
		Aqueous	EPA 6000 / 7000 Series	PTFE or HDPE	600 mL	HNO_3 to pH < 2	Not listed	6 months	SW-846 ch. 3
	Mercury	Solid	EPA 7471B	Glass Jar	200 g	n/a	≤ 6° C	28 days	SW-846 ch. 3
		Aqueous	EPA 7470A	PTFE or HDPE	400 mL	HNO_3 to pH < 2	Not listed	28 days	SW-846 ch. 3
	Hexavalent Chromium, (Hexachrome, Cr+6)	Solid	Lab-specific soil extraction modification, EPA 7196A	Glass Jar	100 g	n/a	≤ 6° C	28 days to extraction	SW-846 ch. 3
		Aqueous	EPA 218.6 (Drinking Water)	PTFE or HDPE	400 mL	n/a	≤ 6° C	24 hours	SW-846 ch. 3
	XRF	Solid (in situ; on the ground surface)	6200	none	n/a	none	none	Analyze Immediately	n/a
		Solid (ex situ)	6200	plastic bag	200 g	none	none	6 months	n/a
VOCs	VOCs / BTEX	Solid	EPA 5035 / 8260B	*	*	*	*	2 days to lab / 14 days	SW-846 ch. 4
		Aqueous	EPA 8260B	Amber Vial with Septa Lid	2 x 40 mL	HCl to pH< 2	≤ 6° C (headspace free)	14 days	SW-846 ch. 4
SVOCs	SVOCs / PAHs	Solid	EPA 8270D	Glass Jar	8 ounces	n/a	≤ 6° C	14 days	SW-846 ch. 4
		Aqueous	EPA 8270D	Amber Glass	2 x 1 L	n/a	≤ 6° C	7 days	SW-846 ch. 4
PCBs and Dioxins/Furans	PCBs	Solid	EPA 8082	Glass Jar	8 ounces	n/a	≤ 6° C	none	SW-846 ch. 4
		Aqueous	EPA 8082	Amber Glass	2 x 1 L	n/a	≤ 6° C	none	SW-846 ch. 4
	Dioxins/Furans	Solid	EPA 8280 or 8290	Glass Jar	8 ounces	n/a	≤ 6° C	none	SW-846 ch. 4
		Aqueous	EPA 8280 or 8290	Amber Glass	2 x 1 L	n/a	≤ 6° C	none	SW-846 ch. 4
Pesticides and Herbicides	Chlorinated Pesticides	Solid	EPA 8081	Glass Jar	8 ounces	n/a	≤ 6° C	14 days	SW-846 ch. 4
		Aqueous	EPA 8081	Amber Glass	2 x 1 L	n/a	≤ 6° C	7 days	SW-846 ch. 4
	Chlorinated Herbicides	Solid	EPA 8151	Glass Jar	8 ounces	n/a	≤ 6° C	14 days	SW-846 ch. 4
		Aqueous	EPA 8151	Amber Glass	2 x 1 L	n/a	≤ 6° C	7 days	SW-846 ch. 4
NWTPH	Gasoline-Range Organics	Solid	TPHs/NWTPH-Gx	Amber Glass Jar with Septa Lid	4 ounces	n/a	≤ 6° C (headspace free)	14 days	Method

Analysis Type	Sub Analysis	Matrix	Analytical Method	Container Type	Minimum Volume	Preservative	Temperature/ Storage	Hold Time	Source
		Aqueous	TPHs/NWTPH-Gx	Amber Vial with Septa Lid	2 x 40 mL	pH < 2 with HCl	≤ 6° C (headspace free)	7 days unpreserved 14 days preserved	Method
	Diesel-Range Organics	Solid	3510, 3540/3550, 8000	Glass Jar	8 ounces	n/a	≤ 6° C	14 days	Method
		Aqueous	3510, 3540/3550, 8000	Glass Amber	2 x 1 L	pH < 2 with HCl	≤ 6° C	7 days unpreserved 14 days preserved	Method
Geotechnical	Particle Size Analysis	Solid	ASTM D-422	Glass Jar or Plastic Bag	2 x 8 ounce	none	n/a	n/a	Method
Miscellaneous	pH	Solid	EPA 9045	Glass Jar	8 ounces	n/a	n/a	Analyze Immediately	SW-846 ch. 3
		Aqueous	EPA 9040	PTFE	25 mL	n/a	n/a	Analyze Immediately	SW-846 ch. 3
	Total Organic Carbon (TOC)	Solid	SW-846 9060	Glass Jar	100 mL	n/a	≤ 6° C	28 days	SW-846
		Aqueous	EPA 415.1	PTFE or HDPE	200 mL	store in dark HCL or H_2SO_4 to pH <2	≤ 6° C	7 days unpreserved 28 days preserved	Method
	Cyanide	Solid	SW-846 9013	Glass Jar	5 g	n/a	≤ 6° C	14 days	SW-846 ch. 3
		Aqueous	SW-846 9010C	PTFE or HDPE	500 mL	NaOH to pH > 12	≤ 6° C	14 days	SW-846 ch. 3
	Conductivity	Aqueous	EPA 120.1	PTFE or HDPE	100 mL	n/a	n/a	Analyze Immediately	Method
	Hardness	Aqueous	EPA 130.1	PTFE or HDPE	1 x 1 L	HNO3 to pH<2	≤ 6° C	28 days	Method
	Total Suspended Solids	Aqueous	EPA 160.2	PTFE or HDPE	100 mL	n/a	≤ 6° C	7 days	Method
	Total Dissolved Solids	Aqueous	EPA 160.1	PTFE or HDPE	100 mL	n/a	≤ 6° C	7 days	Method
	Nitrate/nitrite	Aqueous	EPA 353.2	PTFE or HDPE	1 x 250 mL	H_2SO_4 to pH <2	≤ 6° C	28 days	Method
	Nitrate	Aqueous	SW-846 9210A	PTFE or HDPE	1,000 mL	n/a	≤ 6° C	28 days	SW-846 ch. 3
	Nitrite	Aqueous	SW-846 9216	PTFE or HDPE	25 mL	n/a	≤ 6° C	48 hours	SW-846 ch. 3, Method
	Fluoride	Aqueous	SW-846 9214	PTFE or HDPE	300 mL	n/a	≤ 6° C	28 days	SW-846 ch. 3
	Chloride	Aqueous	SW-846 9250	PTFE or HDPE	50 mL	n/a	≤ 6° C	28 days	SW-846 ch. 3
	Sulfate	Aqueous	SW-846 9035	PTFE or HDPE	50 mL	n/a	≤ 6° C	28 days	SW-846 ch. 3
	Sulfide	Solid	SW-846 9215	Glass Jar	1 x 4 ounces	Fill sample surface with 2N zinc acetate until moistened.	≤ 6° C (headspace free)	7 days	SW-846 ch. 3
		Aqueous	SW-846 9031	PTFE or HDPE	100 mL	4 drops 2N zinc acetate/100 mL sample; NaOH to pH>9.	≤ 6° C (headspace free)	7 days	SW-846 ch. 3

Key:

* = See individual methods. We typically collect 3xEnCore-type samplers and 1x40 mL VOA vial per sample, keep at ≤ 6°C with no chemical preservative, and they must be at the lab within 48 hours of collection.

C = Celsius HNO_3 = nitric acid SVOCs = semivolatile organic compounds

Cr	= chromium	L	= liter	SW-846	= EPA Test Methods for Evaluating Solid Waste, Physical/Chemical Methods
EPA	= Environmental Protection Agency	mL	= milliliter	TAL	= Target Analyte List
g	=grams	n/a	= not applicable	TPH	= total petroleum hydrocarbons
H2SO4	= sulfuric acid	NaOH	= sodium hydroxide	VOA	= Volatile Organic Analysis
HCL	= hydrochloric acid	PCBs	= polychlorinated biphenyls	VOCs	= Volatile Organic Compounds
HDPE	= high-density polyethylene	PTFE	= polytetrafluoroethylene		
Hg	= mercury	RCRA	= Resource Conservation and Recovery Act		

III. Assessment and Response

A Sample Plan Alteration Form (SPAF) will be used to describe project discrepancies (if any) that occur between planned project activities listed in the final SSSP and actual project work. The completed SPAF will be approved by the OSC and QAC and appended to the original SSSP.

A Field Sampling Form (FSF) may be used to capture the sampling and analysis scheme for emergency responses in the field and then the FSF pages can be inserted into the appropriate areas of the final SSSP.

Corrective actions will be assessed by the sampling team and others involved in the sampling and a corrective action report describing the problem, solution, and recommendations will be forwarded to the OSC and the ERU QAC.

IV. Data Validation and Usability

The sample collection data will be entered into Scribe and Scribe will be used to print lab Chains of Custody. Results of field and lab analyses will be entered into Scribe as they are received and uploaded to Scibe.net when the sampling and analysis has been completed.

18. Data Validation or Verification will be performed by:

ERU's general recommendation on validation is that a minimum of CLP-equivalent stage IIA verification and validation be performed for every SSSP involving laboratory analyses. However, stage IIB is preferred if the lab can provide it. Dioxins should be validated at CLP-equivalent stage 4.

	Data Verification and Validation Stages						
Performed by:	I	IIA	IIB	III	IV	Verification	Other:
Contractor QA Reviewer							
Contractor QA Reviewer							
EPA QA Office							
MEL staff							
Other:Unified Command			100%			100%	

Final Planning Guidance for Recovery Following Biological Incidents

Subcommittee on Chemical, Biological, Radiological, Nuclear, and Explosives Standards
Formerly, Biological Decontamination Standards Working Group
Subcommittee on Decontamination Standards & Technology

Committee on Homeland and National Security

National Science and Technology Council

February 2014

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[TOC \o "1-3" \h \z \u]

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Executive Summary

This guidance describes a general risk management framework for government and nongovernmental decision-makers, at all levels, in planning and executing activities required for response and recovery from a biological incident in a domestic, civilian setting. The objective of this guidance is to provide Federal, State, local, and tribal decision makers with uniform Federal guidance to protect the public, emergency responders, and surrounding environments and to ensure that local and Federal first responders can prepare for an incident involving biological contamination. This guidance was developed by an interagency working group of the White House National Science and Technology Council (NSTC), Committee on Homeland and National Security, Subcommittee on Decontamination Standards and Technology (SDST).

Although an overall risk management framework covers all phases of a response to a biological incident, this document emphasizes the remediation/cleanup and restoration phases of a response. This guidance is intended to achieve effective cleanup following a biological incident while minimizing the expected total social cost, which includes human health costs, ecological and environmental damage, loss of site utility, and the economic costs of the actions taken. The guidance does not address critical public health (such as antibiotic distribution) or public safety (security) aspects of the First Response portion of Crisis Management. This Guidance is not intended to impact site cleanups occurring under other statutory authorities such as the Environmental Protection Agency's (EPA) Superfund program, or other Federal and State cleanup programs. Companion documents have also been developed and are under modification for both radiological and chemical response.

This guidance applies to characterization, decontamination, clearance, and restoration/reoccupancy of a variety of public facility types, drinking water infrastructure, and open areas. Principal topics include the unique characteristics and hazards of biological agents, a risk management framework for responding to a biological incident, and all remediation and restoration activities. A process is identified for making timely and effective decisions despite incomplete data and uncertainties associated with potential risks posed by biological agents.

Chapter 1 summarizes the purpose, audience, and scope of this document.

Chapter 2 focuses on pathogenic microorganisms and biotoxins considered likely threats and the unique aspects of each relevant to cleanup. There is no consensus-based methodology for evaluating human health risks posed by environmental exposure to biological agents or standard cleanup goals to be employed after biological attacks. Risk assessments for most biological agents are qualitative and inherently contain significant uncertainty and variability. This document emphasizes that in the face of potentially serious consequences from contamination, judgments concerning the assessment of risks should be based on a weight-of-evidence approach that reflects a qualitative assessment of all risks arising from a particular contamination incident. This process is known as "optimization" and is recommended to guide the choice of targets during the remediation and restoration phases of the response. Through the use of this process, many different considerations are taken into account, including societal objectives for expected land or structure uses with the goal being to balance achievable and practical results.

Hazard information on the virulence and drug resistance of organisms may be collected from clinical isolates and epidemiological evidence. Exposure information may be collected from clinical samples taken from people who are thought to have been near exposed individuals or

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those present before or after a presumed exposure incident. Law enforcement and intelligence information may also provide information about the potential for environmental contamination.

Chapter 3 is the framework for decision-making, which consists of four principal components:

(1) A risk management process: Risk management is the process of identifying, evaluating, and implementing actions to reduce risk to human health and ecosystems.

(2) A clear delineation of roles and responsibilities of relevant agencies and responders: The *National Response Framework* establishes a comprehensive, all-hazards approach to manage domestic incidents and delineates the roles and responsibilities of the numerous agencies that work together during incidents.

(3) The phases of response: The basic phases of response to a biological incident are notification, first response, characterization, decontamination, clearance, and restoration, which incorporates site-specific optimization into the response effort. (Figure 3).

(4) A decision tree that defines key decision points and actions for decision-makers.

Chapter 4 explains the decision process, namely, all actions required during response to a biological incident. Beginning with notification and screening environmental sampling, each step in the decision-making process is described, and the various actions are explicitly linked to numbered boxes in a five-page decision-tree flowchart (Figure 4).

An important step in the decision process is setting a clearance (or cleanup) goal for determining whether a remediation is successful and the treated area may be returned to normal use. No formula is available for setting a clearance goal for biological agents. The collective, professional judgment of experts, considered within the context of the concerns of a broad range of local, regional, and Federal stakeholders, should be used to set a clearance goal appropriate to the site-specific circumstances. A practical clearance goal is to reduce residual risk to levels acceptable by employing an optimization process. The aim of such a process is to reduce exposure levels, as low as is reasonable, while considering potential future land uses, technical feasibility, costs and cost effectiveness, and public acceptability. After the remediation is carried out, a clearance decision is made based on a judgment whether decontamination verification criteria and the clearance goals have been met. This judgment is based on a thorough analysis of all sampling, processes, and other pertinent data.

This document focuses on the decision making framework in response to a biological event; it is designed to be consistent with the *National Response Framework* (NRF) and our scientific understanding of the characteristics of biological agents. Neither of these areas are static. We expect both our response planning and our scientific understanding of the characteristics of biological agents to evolve over time.

In addition to the guidance presented here, there are two scenarios that have been developed to illustrate the principles and application of site specific optimization. Because of the response details contained in these scenarios, they are sensitive and contained in a separate, Official Use Only document.

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Planning Guidance for Recovery Following Biological Incidents

1. Introduction

The Homeland Security Act of 2002 (PL 107-296 Section 301) directs DHS, in partnership with other Federal agencies, to develop and implement countermeasures to prepare for and respond to chemical, biological, radiological, and nuclear threats. Homeland Security Presidential Directive - 10: Biodefense for the 21st Century, describes the interagency activity required to meet this charge. This document is part of a series of guidance being prepared by the Federal Government. Response and recovery following an incident involving a biological agent is likely to be a complex, resource-intensive, and challenging undertaking. Biological contamination presents a unique cleanup challenge because of the ability of certain pathogenic microorganisms to persist in the environment. Clear, consistent Federal decontamination guidance is needed to address all phases and activities involved in response and recovery following a biological incident (Government Accountability Office [GAO], 2003). The National Science and Technology Council (NSTC) is the principal means by which the President coordinates science, space, and technology policies across the Federal government.

To develop coordinated Federal guidance, the NSTC Committee on Homeland and National Security convened a Subcommittee on Decontamination Standards and Technologies (SDST). The Subcommittee chartered an interagency Biological Decontamination Standards Working Group (BDSWG) to develop risk management guidance for safe recovery from an incident involving biological contamination in a domestic, civilian setting. The interagency working group included participants from the Departments of Homeland Security, Agriculture, Commerce, Defense, Energy, Labor, Health and Human Services, Transportation, and the Environmental Protection Agency.

This guidance describes a general risk management framework and activities for decision-makers, at all levels, in planning and executing activities required for response and recovery from a biological incident in a domestic, civilian setting. The objective is to provide uniform Federal guidance that enhances the ability of Federal, State, local and tribal emergency responders and decision makers to prepare for and respond to an incident involving biological contamination. This Guidance is not intended to impact site cleanups occurring under other statutory authorities such as the Environmental Protection Agency's (EPA) Superfund program, or other Federal and State cleanup programs.

In developing the guidance, the Federal Government recognized that experience and scientific knowledge from existing programs such as EPA's Superfund and research programs, from multi-agency cleanups of sites contaminated with *Bacillus anthracis* spores (EPA, 2002), and from other national recommendations will be useful in planning response and recovery efforts following a biological incident. This guidance allows the consideration and incorporation, as appropriate, of any or all of this existing experience and knowledge, and does not alter existing

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programs. It is sufficiently flexible to address the extremely broad range of situations that can occur under various biological contamination scenarios, more than most existing programs or recommendations address. Finally, this guidance will enable State and local officials, working with Federal counterparts, to make informed decisions with the best available information to decide what is best for their community.

1.1 Purpose

This document provides guidance that focuses primarily on remediation and restoration activities associated with a domestic, civilian site that has been contaminated, intentionally or otherwise, with a biological agent. This guidance document covers intentional or accidental releases of biological agents; henceforth the term "biological agents" will be used rather than "biological warfare agent" (BWA), except where noted. Throughout the overall response and recovery process, remediation activities conducted to clean up facilities take place in parallel with other activities such as risk communications and addressing public health issues. The document explains the unique characteristics and hazards of biological agents (i.e., pathogenic microorganisms and biotoxins); provides a risk management framework for responding to a biological incident in a domestic, civilian setting; and addresses the environmental remediation and restoration activities necessary for successful cleanup and reoccupation.

Most importantly, this document describes the process for making timely and effective decisions despite incomplete data and uncertainties associated with characterizing the potential risks posed by biological agents. A process known as optimization is recommended to guide the choice of targets during the remediation and restoration phases of the response, thus providing the best opportunity for decision-makers to gain public confidence through the involvement of stakeholders.

1.2 Audience

The intended audience for this document is Federal, State, tribal, and local government officials, as well as nongovernmental decision-makers, involved in conducting or overseeing response and recovery operations at a site contaminated by a biological agent.

1.3 Scope

This document describes a general risk management framework for decision-makers to use in planning and executing the many activities required for response and recovery from a biological incident in a domestic, civilian setting. The guidance applies to significant incidents involving intentional or accidental releases of biological agents, including unknown and genetically modified organisms. Contamination via air and water is considered in this document. Food production and distribution systems are excluded since they are covered adequately in another guidance document (USDA/FSIS, 2006). Decision makers should use this guidance as a supplement to existing regulations and in the context of *National Response Framework* (NRF) policies and procedures outlined in the Emergency Support Function Annexes (ESF) #8 (Public Health and Medical Services Annex) and ESF #10 (Oil and Hazardous Materials Response Annex), the Worker Safety and Health Support Annex, and the Biological Incident Annex of the NRF (DHS, 2008).

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Although an overall risk management framework covers all phases of a response to a biological incident, this document emphasizes the remediation and restoration phases of a response. For each activity in this component, the decision-making processes and scientifically based methods, practices, and procedures are described, and references are provided as applicable. Each biological incident will have unique site- and organism-specific characteristics associated with remediation. Thus, even though a general framework can be used, final decision-making will be done on a case-by-case basis using an optimization process. Planning and preparedness, critical components of effective site response and recovery, are described elsewhere [e.g., in the National Research Council (NRC) of the National Academies of Science (NAS) study (NRC, 2005) and the Lawrence Livermore National Laboratory (LLNL) airport guidance (Carlsen et al., 2005)], but are not described in depth in this document.

The guidance in this document is applicable to:

- Enclosed facilities and objects, such as commercial and residential buildings, swimming pools, aircraft, vehicles, trains, vessels, and their contents.
- Semi-enclosed facilities and objects, such as subways, public transit facilities, and their contents.
- Outdoor areas and objects, such as building exteriors, streets, parks, water parks, beaches, other open spaces, and items within these areas.
- Drinking water sources, distribution systems, and treatment facilities, and wastewater infrastructures.

A full discussion of all possible scenarios is beyond the scope of this document. This guidance emphasizes the scalable principles of optimization, in which the extent of cleanup efforts and range of considerations will largely be determined by the location, nature, and severity of the biological incident. The processes and decisions employed in the cleanup of a building or facility will differ from those used to clean up a large area, such as a neighborhood or city.

This document emphasizes a framework and activities for decontaminating the first two types of settings because most incidents involving contamination with biological agents to date have involved enclosed and partially enclosed areas. However, this document is also designed to provide basic guidance for contaminated outdoor sites and water-related facilities. Unique problems presented by outdoor contamination pose significant challenges and include: (1) the dynamic and continuing meteorology effects on transport and spread of aerosol; (2) how to take into account the potential presence of naturally occurring biological agents such as *Bacillus anthracis* spores; (3) decontamination of biological agents deposited on common materials such as car metal surfaces, street lights, concrete sidewalks, brick building surfaces, paved roadways, and bridges; (4) decontamination of subsurface and difficult to access infrastructure; (5) determining what areas are contaminated over a large area; and (6) how to deal with potentially very large quantities of contaminated water (see Interim Guidance on Developing Consequence Management Plans for Drinking Water Utilities, EPA, 2008). Additionally, waste disposal continues to be a difficult perception problem even if wastes have been treated and cleared; there are no easy answers in this arena. Currently, there are other efforts in the Federal Government that address the capability gaps in wide-area remediation as well as protecting responders under that scenario.

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Current methodologies for assessing the degree of exposure to and potential risks from biological agents of concern can be used to determine the appropriate degree of cleanup based on the characterization phase and the best available scientific data. However, significant uncertainties exist regarding agent effects and fate, sampling and detection limits, and decontaminant effectiveness (Raber et al., 2001, 2004). Processes for dealing with such uncertainties are emphasized. Guidance is presented in the context of currently available information; as new data are obtained, that information will be incorporated into this decision-making guidance.

1.4 Organization

This document is organized into four chapters:

1. Introduction.
2. Background on Biological Agents.
3. Framework for Decision-Making.
4. Key Activities for Decision-Making.

Chapter 1 provides background on the purpose, audience, scope, and organization of this document. Chapter 2 describes the types and characteristics of biological agents and explains why cleanup of biological contamination substantially differs from cleanup of chemical or radiological contaminants. Chapter 3 describes the risk management framework, roles and responsibilities, phases of a biological response, and a "decision tree" for decision-making. Chapter 4 provides "how-to" guidance for each of the key activities required for a successful cleanup and recovery effort and includes references for further scientific or expert guidance.

In addition to the guidance presented here, there are two scenarios that have been developed to illustrate the principles and application of site-specific optimization. Because of the sensitive response details contained in these scenarios, they are available as a separate, Official Use Only document.

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2. Biological Agents

2.1 Types of Biological Agents

Biological agents considered to be likely threats are classified as pathogenic microorganisms (pathogens) and biological toxins (biotoxins). Microorganisms can replicate and are grouped into categories according to their structure and method of replication. Biotoxins are molecules of biological origin that cannot replicate. Some additional information on specific contaminants and general guidance for response and clean-up is available at the websites of the National Response Team ([HYPERLINK "http://www.nrt.org/"]) and the Centers for Disease Control and Prevention ([HYPERLINK "http://www.cdc.gov/"]). Specific contaminant information is available in the NRT's Quick Reference Guides (QRG's) located at: [HYPERLINK "http://www.nrt.org/Production/NRT/NRTWeb.nsf/AllPagesByTitle/P-BiologicalHazards?Opendocument"] (EPA 2006).

Pathogens. Pathogens are disease-causing agents that invade a host and replicate. They are diverse and range from non-cellular organisms (i.e., viruses), to cellular life forms within both the eukaryotic (e.g., protozoa and fungi) and prokaryotic (bacteria) kingdoms. The pathogens of greatest concern in airborne exposures are viruses, bacteria (including Rickettsiae), and fungi (including molds). In waterborne contamination, protozoa and helminths may also be of concern. Some microorganisms have developed specialized life stages designed to resist periods of environmental stress. In general, these are more difficult to disinfect than those microorganisms that have not developed these life cycle stages. Appendix 1 shows a general scheme for hierarchy of environmental resistance and difficulty of disinfection.

Bacteria. Some bacterial species are pathogenic to other organisms. Unlike viruses, the majority of pathogenic bacteria (excluding Rickettsiae and some others) are capable of reproducing outside living cells. A typical bacterial cell is small—approximately 1–2 microns in diameter and approximately 2–10 microns in length (1,000 microns = 1 millimeter). By comparison, a human hair is about 100 microns wide. Bacterial diseases may respond to treatment with antimicrobials, but antimicrobial-resistant bacteria are common. Vaccines are available for some bacteria (e.g., *Bacillus anthracis),* (CDC, 2004b; Dennis et al., 2001; Inglesby et al., 1999, 2000).

Viruses. Viruses are a large group of non-cellular infectious particles that can only multiply within a living cell. Viruses are much smaller than the majority of bacteria, generally ranging from 0.02–0.2 microns, and generally do not respond to antimicrobials. Certain viruses may respond to antiviral compounds. Vaccines are available for certain viral illnesses (e.g., smallpox) (CDC, 2004a; Henderson et al., 1999).

Fungi and molds. Pathogenic fungi and molds are unique organisms in terms of their cellular structure and biochemistry. This highly diverse group of organisms is widely dispersed in the environment. Many molds and fungi are resistant to environmental conditions that kill bacteria, such as sunlight, desiccation, and heat. Many molds and fungi also have life-cycle stages that are environmentally resistant and readily aerosolized. Some organisms in this category are disease-causing agents, including *Coccidioides immiti*s and *C. posadasii*, which can cause systemic or lung infections. Specific anti-fungal drugs are available; however, the infections can be difficult to treat. Currently, there are no approved vaccines for human use against any fungus or mold.

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Protozoa and helminths. Pathogenic protozoa are single-celled organisms, whereas helminths (flatworms and roundworms) are multicellular. Both include many parasitic forms. In their infectious stages, protozoa and helminths are generally larger than bacteria, ranging from 2 to 100 microns in diameter. Because of their large size, they are typically only considered a threat to water supplies and are unlikely to be inhaled deeply enough into the lungs to cause an infection. Thus, aerosol dissemination of these pathogens would be an ineffective means of exposure; however, ingestion of these organisms, for example in contaminated water, may be an effective means of dissemination. Many of these organisms are highly resistant to chemical disinfection, and although drug treatment is available for some protozoa and helminths, many infections are difficult to treat. No human vaccines are available for these organisms.

Biotoxins. Biotoxins are toxic substances that are either produced by, or extracted from, living or dead bacteria, fungi, plants, or animals. Although biotoxins can be transferred from person to person on contaminated objects, they are not communicable like the flu and do not replicate within an individual. Biotoxins can be more toxic than chemical warfare agents (CWA). Biotoxins are categorized into groups according to molecular weight and composition or origin. Among biotoxins of concern is the botulinum toxin, which is produced by *Clostridium botulinum* and a few other species of *Clostridium*. There are other toxins of concern as well, including other bacterial toxins (e.g., Staphylococcus enterotoxin B); fungal toxins, also known as mycotoxins (e.g., trichothecenes); and toxins produced by plants and animals (e.g., ricin and tetrodotoxin). Biotoxins may be formulated in a variety of ways, as either liquids or powders. The natural pathway of transmission for most toxins is through contaminated food or water. However, it may be also possible to spread these toxins by aerosol, through hand to mouth exposures, and by direct injection. The symptoms of exposure may vary greatly depending on the toxin and the route of exposure. Medical treatments and vaccinations are available for some toxins, but for many biotoxins, specific treatments or vaccinations have not yet been identified.

2.2 Characteristics of Biological Agents

2.2.1 Pathogens

This section describes the general characteristics of pathogens.

Infectivity. Pathogens act by infecting and replicating within a susceptible host. The infectivity of a pathogen reflects the relative ease with which microorganisms establish themselves and cause disease in a host. Once an individual is infected, the pathogen multiplies, making a dose-response assessment difficult.

Infectious dose. In theory, infectious dose is the number of organisms required to cause an infection. A pathogen is considered highly infective when relatively few organisms can cause disease. Conversely, when numerous pathogens must be present to cause disease, the pathogen is considered to be of low infectivity. High infectivity, the speed of disease onset, and severity of illness are not necessarily related. A minimum infectious dose is the minimum number of organisms required to cause an infection. For most high-consequence pathogens, the minimum infectious dose for some proportion of the population may be a single organism (NRC, 2005). Most pathogens considered to be likely biological weapons are highly infectious with some requiring fewer than 100 organisms to infect an individual.

Infectious dose is the result of complex interactions between host and microorganism, and involves many variable factors. Factors such as age, sex and immune status of the individual

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will affect the susceptibility of the host to an infectious agent. Infectious dose is highly dependent on route of exposure, and may be dependent on the method of preparation of the infectious agent as well. The environmental persistence of various microorganisms is also highly variable. For example, *Yersinia pestis* has been shown to have very limited survival (only hours to days) under certain laboratory conditions, yet has been shown to be capable of persisting in water for days or weeks (Rose et al., 2003; Torosian et al., 2009). In addition, it can be difficult to ascertain whether an infection is present, how an individual has been exposed to a defined dose of microorganisms, or if an exposed individual is either particularly susceptible or resistant to infection. Furthermore, little information is available on cumulative exposures. Because of these and other considerations, the NRC concluded that infectious doses for harmful biological agents cannot be determined with confidence (NRC, 2005). In a jointly-developed white paper, the American Biological Safety Association (ABSA) and the Occupational Safety and Health Administration (OSHA) conclude that there is no clear and universally acceptable definition of the term "infectious dose" (Johnson, 2003). They note that there is no single, standard protocol for testing infectious doses in laboratory animals, making legitimate and controlled comparisons of study results difficult. They also find that extrapolation of infection and toxicity data among animal species and from animals to humans is unreliable for most biological agents (Haas et al., 1999a, 2000).

Viability of pathogens and activity of biotoxins. Pathogens can be present in the environment in both viable and nonviable forms, but they must be viable to exert a pathogenic effect. Toxins, particularly large-protein toxins, also need to be in the appropriate structural configuration (active form) to exhibit toxicity. A pathogen-contaminated environment may be remediated by pathogen removal or by rendering the pathogens nonviable. Physical removal of pathogens can be done by removing contaminated objects and materials, or by direct removal of the contaminant itself by methods such as wet washing or vacuuming (Weis et al., 2002). Disinfection, inactivation, or decontamination can be accomplished by rendering the contaminant nonviable or incapable of infecting or causing disease through the use of disinfectants such as oxidants, through the application of heat, or by other means. Removal and inactivation of pathogens or toxins can be accomplished together through activities such as wiping an area with a disinfectant-saturated cloth. The effectiveness of efforts to remove pathogens or toxins can be evaluated by monitoring for the presence of their signatures or footprints. The effectiveness of disinfection or inactivation must be monitored by methods that test for not only the presence but also the viability or activity of the pathogen or toxin in question. For some contaminants, such as viruses, viability tests are difficult to conduct.

Routes of exposure and infection. Microorganisms must enter a host organism to infect and cause disease. The major routes of exposure to pathogens are inhalation, ingestion, dermal contact, mucous membrane contact, and direct injection by a vector (e.g., mosquito) (Raber et al., 2001). Intentionally introduced contaminants might exploit routes of exposure that are not usually observed in naturally-occurring disease incidents. For example, a pathogen that is usually ingested might be inhaled after being intentionally disseminated as an aerosol. People exposed to a pathogen through a novel pathway may experience symptoms that are uncharacteristic for the natural disease course of that pathogen. Residuals remaining from a release or attack can pose dermal contact, ingestion, or reaerosolization hazards (Weis et al., 2002) that are not normally present in natural disease outbreaks. The potential for reaerosolization from surfaces can depend on a variety of factors, including contaminant formulation, method of dissemination, and the nature of the surfaces involved (Ferro et al., 2004;

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Long et al., 2000; Rodes et al., 2001). Potential exposures to various routes of infection must be considered when planning for decontamination efforts.

Method of dissemination. Dissemination allows access of pathogens to victims through an intended route of infection. Pathogens may be disseminated in wet and dry forms, through contamination of food and water supplies, by release of infected vectors, through aerosol-generation devices, in the mail, or by other novel methods. Dry preparations can range in dispersibility from large, chunky powders with low dispersibility to finely-milled homogenous powders with high dispersibility. Flow-enhancing agents and charge-neutralization techniques can also enhance the dispersibility of dry preparations (Brown et al., 2007). Liquid preparations are easy to manage from a production standpoint and may be used to generate aerosols with a variety of properties ranging from mixed droplet sizes to evenly dispersed and homogenous controlled droplets, or dried particles, depending on the dispersion devices employed. Aerosols can be created with either dry or liquid formulations, and aerosol delivery systems can generate particulate clouds that can remain suspended for long periods and spread over large areas. Contaminated water moving through a water-distribution system can carry a contaminant into a large number of inhabited structures in a city. In the past, pathogens have been intentionally disseminated on contaminated objects or by dispersal of infected vector insects (Kolavic et al., 1997; Carus, 2001; Wheelis, 2004; Torok et al., 1997; Smithson and Levy, 2000). Such methods could be used again in the future. However, certain pathogens are not amenable to particular methods of formulation or dissemination. Methods of dissemination can also create unexpected environmental contamination sites. For example, an outdoor release of agent might contaminate indoor areas or the food supply, and a waterborne release of agent might contaminate indoor areas. The scale and type of remediation for pathogens or biotoxins is determined in large part by the method of formulation and dissemination.

Pathogenicity and virulence. These two related concepts concern a pathogen's ability to cause disease (low to high pathogenicity) and the severity of disease that is produced (low to high virulence). Some pathogens rapidly cause death; others incapacitate individuals. Some disease agents have short courses of infection; others cause illness lasting months, years, or a lifetime. Some diseases are associated with conditions that occur long after initial exposure to the infectious agent.

Availability and effectiveness of prophylaxis and treatment. Some diseases are readily treatable by antimicrobials, antivirals, or other chemotherapeutic agents. In some cases, prophylaxis that provides protection against the disease can be given to individuals before exposure (pre exposure) or before the onset of symptoms (post-exposure). Drug treatments and vaccines exist for several of the diseases of concern. However, drug resistance and vaccine failure are widely known, and engineering drug resistance into bacteria is a standard protocol for certain organisms. In any incident, the existence or lack of effective vaccines, prophylaxis, and treatment will influence decisions on worker protection and other aspects of decontamination efforts.

Communicability. Infectious microorganisms and viruses can be transmitted directly from person to person (e.g., by coughing, sneezing, talking, or touching), indirectly through the environment (e.g., fomites), or via a vector. Microorganisms that are readily transmitted directly from person to person can multiply the effect of an attack. In military terms, most communicable pathogens that are developed for biological warfare are considered strategic weapons because they are capable of sustained transmission that could cause long-term

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debilitation of a population. Furthermore, it is difficult to prevent spread of these pathogens among one's own forces. Some pathogens (e.g., *Variola major* (smallpox virus)) can be readily transmitted person-to-person after initial disseminationwhile others can only do so when a specific form of the disease is present (e.g., pneumonic plague as opposed to bubonic plague). Some agents are generally not transmitted person-to-person (e.g., anthrax).

Availability. Microorganisms are naturally occurring, and some are intentionally cultivated. Many can be cultivated using technology that has been available for more than 50 years (Pepper and Gentry, 2002). However, *Variola major*, the causative agent of smallpox, does not exist outside of a couple of laboratories where research is being conducted.

Incubation period. The time from exposure to onset of a pathological effect is the incubation period. There may be a delay between exposure to a pathogen and the development of a symptomatic infection. This delay is often termed the *latent period*. In addition, there may be a delay between exposure and the ability to detect the pathogen in a host, which is termed the *pre-patent period*. Finally, in some cases exposed individuals may never exhibit symptoms and yet may still be able to pass a disease agent on to others; these individuals are called asymptomatic carriers. Delays between exposure and the recognition of infection or the presence of disease agent may range from hours to days to weeks or more. Such delays may enhance the ability of terrorists to launch a covert attack or multiple attacks. The delay between exposure and recognition that an exposure has occurred also has implications for the remediation required. Because some pathogens do not persist in the environment, the time that may elapse from an initial biological incident to the onset of disease in exposed individuals may mean that viable (i.e., infectious) pathogenic microorganisms are no longer present in the initially contaminated area by the time exposure becomes evident. Alternatively, delayed diagnoses due to long incubation periods or confusion with other more common diagnoses, along with related challenges in detecting a contamination incident, may allow some environmentally-persistent pathogen preparations to spread beyond the initially contaminated area.

Environmental persistence. Some disease agents rapidly inactivate when not in a suitable environment or a host. Others form spores or are adapted for existing long-term in an infectious state in the environment. Temperature, humidity, and ultraviolet radiation are all known to affect the survival of microorganisms in the environment; however, some microbial forms (e.g., bacterial endospores) are less susceptible to these factors than others. The environmental persistence of a particular pathogen or toxin is an important consideration when selecting the type and extent of remediation activities. Pathogens that are exceptionally fragile and persist in some environments for only minutes or hours may require only minimal intervention for decontamination. However, it would still be necessary to confirm that natural attenuation of the pathogen had taken place as expected. The most environmentally persistent agents in dry environments on the Center for Disease Control and Prevention's (CDC, 2005) list of agents of concern for bioterrorism are *Coxiella burnetti* and *Bacillus anthracis* spores. In water-distribution systems, many microorganisms including pathogens can exist in biofilms, creating a persistent contamination problem and necessitating thorough disinfection of the system (see [HYPERLINK "http://www.sciencedirect.com/science/article/pii/S0043135408004089"]).

Zoonotic potential and environmental reservoirs. Certain pathogens infect domestic or peri-domestic animals or replicate within particular environments. Many of the CDC pathogens of concern, such as *Yersinia pestis* (Inglesby et al., 2000) and *Burkholderia mallei*, cause zoonotic illnesses, which are naturally though infrequently transmitted from animals to humans. Some

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zoonotic pathogens, such as *Francisella tularensis* (Dennis et al., 2001) and *Burkholderia pseudomallei*, can survive and replicate outside of a host organism in specific environmental habitats or in the presence of fee living amoeba (Santic et al., 2011). Microorganisms with the potential to become established in animal hosts or to multiply directly in the environment require special consideration during remediation.

Resistance to decontamination. Disease agents vary considerably in their resistance to decontaminants; some are particularly resistant to disinfection. *Bacillus anthracis* spores, for example, are known to be highly heat resistant. In a water environment, *Cryptosporidium parvum* and *B. anthracis* are is resistant to chlorination (Rose et al., 2005), and some strains of *Burkholderia pseudomallei* may be resistant to routine chlorination (Howard and Inglis, 2003; O'Connell et al., 2009). Even though a particular pathogen might be generally susceptible to a type of disinfectant, specific strains of a pathogen can be more resistant than expected under certain conditions. This principle is well understood in the field of water disinfection, where some organisms that are generally susceptible to chlorine disinfection may be highly resistant under some conditions such as bacteria that grow in a biofilm (Morris et al., 1996). Although less well studied, it is possible that this phenomenon exists in surface contaminants as well. In addition, it is possible that an agent could be intentionally formulated to increase resistance to decontamination.

2.2.2 Biotoxins

Biotoxins are the products or by-products of living organisms. They are nonvolatile, odorless, tasteless, and generally do not affect the skin, with the notable exception of T-2 mycotoxin. Unlike pathogens, biotoxins cannot replicate within the body, therefore the toxic dose of a biotoxin must be delivered by exposure. Non-lethal doses of biotoxin may also have severe medical effects, depending on the biotoxin. Biotoxins may be metabolized and removed from the body at some rate; alternatively, their effects may be cumulative or irreversible. In toxicology, the dose makes the toxin; that is, a critical dose must be ingested or taken in through some route of exposure for it to have a toxic effect. The critical dose, however, may be extremely small and related to the route of entry. Some biotoxins act rapidly; others act over longer times or are progressively incapacitating.

On a weight-for-weight basis, biotoxins tend to be more toxic than chemicals, and because of their diversity in structure and function, they can have more varied adverse effects than chemical agents. Nevertheless, risk assessments of biotoxin- and chemical-contaminated environments can be done in a similar manner.

Small-molecular-mass biotoxins are considerably more environmentally stable than large, globular protein toxins. As such, they may also be resistant to some of the means of inactivation or physical removal that are effective against larger biotoxins. Large-molecular-mass biotoxins are generally more susceptible to heat inactivation, and because of their size, some can be removed from liquid phases by appropriate filtration.

2.2.3 Biological Agents of Concern

Numerous lists of pathogens and biotoxins of concern have been developed for different purposes and according to the needs of various organizations. The U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) have published lists of microorganisms and biotoxins that are regulated as "Select Agents" (see 42 C.F.R. Part

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73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121). Burrows and Renner (1999) present a more thorough discussion on water-safety threats. Another way to determine likely threat agents is to examine their history of use. Carus (2001) and Ecker et al. (2005) have examined pathogens and toxins known or suspected to have been used in bioterrorist, criminal, or warfare incidents. The U.S. Army handbook, *Medical Management of Biological Casualties*, provides several lists of agents and includes a large amount of useful information on each (Darling and Woods, 2004). Intelligence documents and scientific literature contain additional information concerning potential threat agents. It may be important to consider potential novel threat agents from these and other sources, particularly if they might present challenges to a remediation strategy.

2.3 Unique Aspects of Biological Agent Cleanup

Many characteristics of microbial contaminants make them unique from chemical contaminants. The following principles apply primarily to pathogens rather than biotoxins, which are more like chemical contaminants in terms of risk assessment and risk management.

2.3.1 Availability

Most pathogens occur in nature, and many are cultivated as a part of routine human or veterinary diagnostic activities. Techniques for obtaining and propagating pathogens are widely known, practiced, and taught for legitimate purposes. Stock material can be cultured from the environment or from infected humans or animals in hospitals or veterinary clinics worldwide. The availability of many highly pathogenic microorganisms makes them unique from CWAs. Important considerations include the following:

- Most CWAs are uniquely toxic compared to the more widely available toxic industrial chemicals (TICs); therefore, CWAs are generally unavailable to individuals without access to sophisticated chemical manufacturing facilities. Potential BWA, on the other hand, because they are not solely created as BWAs per se, have been cultivated in laboratories using standard laboratory techniques for more than a hundred years in some cases. Good laboratory equipment and biosafety practices are required for safe handling and manufacture of BWAs, and both are readily available.
- A few CWAs can be synthesized in field-expedient laboratories, but these are exceptions. In contrast, BWAs can be generated readily in field-expedient laboratories.
- Available information suggests that CWAs have never been found to occur naturally. CWAs are synthesized from precursor materials that must be generated or purchased. Many of the unique and required precursor chemicals for CWA production are controlled under the Chemical Warfare Convention (CWC) and are difficult to obtain. In contrast, BWAs are much more widely available. At any given time, multiple outbreaks of moderate and high-risk pathogens are occurring somewhere in the world. Outbreaks often occur in areas where terrorist organizations have resources. Natural outbreaks can provide seed material for BWA production.
- CWAs are distinguished by treaty as chemicals with no legitimate civilian purpose; there is no legitimate reason for CWAs to exist outside a closely controlled, treaty-regulated purpose. CWAs must be manufactured under closely monitored conditions in compliance with the CWC, or covertly. Such restrictions should hamper the ability to produce CWAs. On the other hand, BWAs are naturally occurring public health

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threats, and their creation for offensive purposes may be conducted under the cover of legitimate public health or commercial (e.g., vaccine production) activities.

BWAs may be as readily accessible as toxic industrial chemicals, and are as hazardous as, or more hazardous than, CWAs. Their widespread natural occurrence and accessibility make BWAs unique as potential threat agents. [Note: Because this guidance document covers disease outbreaks and intentional or accidental releases of biological agents, henceforth the term "biological agents" will be used rather than "BWA."]

2.3.2 Mechanisms of Dissemination

A significant impact can result from a release of much smaller quantities of biological agent than chemical agent (Rubin, 1987). However, unlike many chemicals, biological agents in a liquid state do not readily aerosolize or vaporize, so some form of dissemination device is usually required.

2.3.3 Delayed Effects

In many scenarios, the first indicator of an incident involving contamination with a biological agent would be an increased number of patients presenting with clinical symptoms caused by exposure to and infection with the pathogen (Darling and Woods, 2004). The time from exposure to onset of clinical signs is generally much longer for pathogens than for acute toxic doses of chemical agents. Onset of clinical signs and symptoms may occur days, weeks, or more after exposure to a pathogen. The result may be delayed identification of a covertly disseminated pathogen, and exposed individuals may unknowingly incubate and disperse the agent if it is capable of human-to-human transmission. This delay in identification that an attack has occurred has wide ramifications to the decontamination process. This may affect the exposure assessment, the design and implementation of the sampling plan, the choice of sampling methods and locations, and other elements of contamination analysis.

2.3.4 Difficulties in Identification

The following difficulties are associated with identifying biological agents:

- Many infectious agents tend to initially produce nonspecific symptoms that mimic more common diseases (e.g. flu-like symptoms, gastrointestinal distress, etc.), thus delaying diagnosis or leading to misdiagnosis.
- Some biological agents are endemic to certain environments and, as a result, could cause naturally occurring infections, complicating recognition of an intentional versus natural biological agent infection.
- Because many pathogens naturally occur in the environment, recovery of specific pathogens or their signatures (e.g., antigens, DNA traces) from an environmental sample may not indicate the presence of an intentionally introduced agent or the source of an environmentally acquired infection.
- Even when pathogen signatures are present, viability assessments on environmental samples can be time-consuming and difficult. Viability information is critical for risk management decisions.
- Many current sample collection and analytical methods are not capable of distinguishing small but biologically significant quantities of pathogens.

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- Some current sample collection and analytical methods are not specific enough to distinguish between organisms that are human pathogens and those closely-related species that produce no human disease.
- Constituents of environmental matrices and, in some instances, constituents of sampling devices may inhibit detection of organisms in the environment. It is not possible to predict all such interactions in advance.
- Techniques that may be applicable for producing pathogens that are difficult to detect are readily available to scientists around the world and have been used and taught in universities for decades.

2.3.5 Potential for Amplification and Significant Numbers of Casualties

Person-to-person transmission of certain biological agents may lead to a rapid, geometric increases in the number of victims and of facilities or areas that require decontamination. Most contagious diseases are spread directly from person to person, and most contagious pathogens do not persist in the environment for extended periods of time, with significant exceptions such as noroviruses and Methicillin-resistant *Staphylococcus aureus*, or MRSA. However, the causative agents of some of these diseases could be treated or disseminated in a manner to cause environmental contamination. The occurrence of person-to-person transmission arising from an initial environmental contamination may give impetus for conducting additional, unwarranted environmental decontamination activities. Conversely, recognition of person-to-person spread may result in a failure to appropriately recognize the role of environmental transmission, leading to an unwarranted lack of environmental decontamination activities. It is important to recognize that mass casualties can also arise from incidents involving dissemination of non-contagious pathogens such as *B. anthracis*.

2.3.6 Public Fear

Increased public fear can be anticipated from potential exposures to biological agents, particularly because exposures are not generally immediately detectable. While rapid, portable contamination detectors are available for radiological and chemical agents, the detection technologies currently available for biological agents have limitations (Fitch et al., 2003). Moreover, since a biological attack or exposure to a biological agent may have occurred days before its recognition, there may be nothing the public can do to prevent themselves from becoming victims, resulting in a sense of helplessness in the wake of the attack or outbreak.

2.3.7 Control Measures

For naturally occurring disease outbreaks, many public health interventions already suffice to control and eliminate the environmental reservoirs for disease agents (e.g., insecticide spraying for mosquitoes that carry equine encephalitis, West Nile virus, etc.). However, deliberate attacks using biological agents as weapons may differ from these naturally-occurring outbreaks. For example, these agents may have been manipulated to be more easily dispersed, or more environmentally stable. Biological agents used as weapons might also be present in locations or scenarios that are unlikely or impossible for the naturally-occurring disease agents. For example, a toxin normally associated with food contamination may have been sprayed in the air. For these reasons, the control measures for naturally occurring diseases may not be sufficient, and novel control measures may be required for the control of biological agents used in an attack by an adversary.

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Sample collection analysis, and remediation of biological incidents may not be achieved as predicted in selected environments. Factors influencing these elements of a response could include the presence of a biofilm (an encapsulated community of microorganisms attached to a living or inert surface), interaction of the surface with the sampling method or decontamination agent, or the characteristics of exposed surfaces (e.g., an environmental surface may be presumed to be hard, but is in fact functionally porous) or the presence of soil. These factors could cause unpredictable failures or discrepancies in persistence, sampling, analysis, and decontamination.

2.3.8 Replication

Chemicals and biotoxins do not replicate within an individual; thus, the dose of a chemical or biotoxin is directly related to its toxicity. Within limits, exposure to greater or lesser amounts of a chemical or biotoxin will predictably have greater or lesser impacts on the health of the exposed individual. This property is used to create safety guidelines, such as permissible exposure limits and acute exposure levels. In contrast, pathogens can replicate (or multiply) within an infected individual, and therefore risk assessments for microorganisms are entirely different from chemical or biotoxin risk assessments. This unique aspect of biological organisms must be considered along with other information to conduct an appropriate assessment of the risk of residual contamination from biological contaminants in the environment.

2.4 Risk Assessment

To make an effective risk management decision, risk managers and other stakeholders need to know what potential harm the situation poses and how likely it is that people or the environment will be harmed. This is accomplished through risk assessment.

Risk is the probability that a substance or situation will produce harm under specified conditions. **Risk assessment** is the gathering and analyzing of information on what potential harm a situation poses and how great the likelihood is that people or the environment will be harmed. (See Section 2.4.1 for a more detailed explanation of risk assessment in the specific context of biological agents.) The nature, extent, and focus of risk assessment are guided by risk management goals. The results of a risk assessment, along with information about public values, statutory requirements, benefits, costs, and cost effectiveness, are used to decide whether and how to manage the risks. Risk assessment can be controversial, reflecting the important role that both science and judgment play in drawing conclusions about the likelihood of effects on human health and the environment. For the reasons described in Section 2.3, risk assessment for biological incidents is highly problematic.

Following are the most salient risk analysis principles from the 1997 Commission report that need to be considered by decision-makers as they plan for and carry out a response to a biological incident:

- Clarify the factual and scientific basis of risks posed by the problem, treating health and ecological risks both qualitatively and quantitatively, where possible.
- Describe the nature, severity, reversibility, or preventability of adverse effects.
- Identify who is potentially at risk and when they are at risk, and explain the possibility of multiple effects.

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- Evaluate the weight of the scientific evidence, and identify the primary sources of uncertainty. For ecological risks, consider indirect effects on human health through disruption of the environment and possible effects on future generations.
- With input from the problem/context stage, place the specific risks posed by the problem into their multi-source, multimedia, multi-chemical, and multi-risk contexts.
- Identify stakeholder perceptions of the risks posed by the problem (Burger, 2002; Jones, 2004; NRC, 1996; Till and Meyer, 2001).
- Combine information on scientific and contextual aspects of risks posed by the problem into a characterization of the problem's risks to human health or the environment.

2.4.1. Risk Assessment in the Context of Biological Agents

Live microorganisms pose a unique challenge because risk assessment of environmental contamination cannot be done with reasonable certainty (NRC, 2005; Canter, 2005). As described earlier, quantitative dose-response assessment is a particular problem. The minimum number of organisms necessary to initiate disease has not been well defined for the various infectious threat agents and depends on many factors related to the agent itself, the person or animal exposed (host), and environmental influences.

Although some methodologies exist for this purpose, in many cases it is not possible to conduct a scientifically sound, quantitative risk assessment to adequately characterize the risks to people from intentional exposures to pathogens. This is especially true when the pathogens themselves or the methods of delivery are novel and may not occur in nature (e.g., exposure to *B. anthracis* spores in the mail) (NRC, 2005). Usually, risks can only be characterized qualitatively and, as such, may be accompanied by significant uncertainty. Nevertheless, sound risk management decisions can be made from qualitative risk assessments by following the risk management framework described in Chapter 3 and the guidance in Chapter 4 when setting clearance goals and determining an appropriate decontamination strategy. Additionally, efforts should still be made to evaluate these risks quantitatively, if possible, and to conduct uncertainty analysis if necessary, which may illuminate areas where additional information could be collected to increase the value of a quantitative assessment if time permits.

Fundamental principles for conducting risk assessments are found in the NAS Risk Assessment/Risk Management Paradigm developed in the late 1970s. Since the development of this paradigm, several enhancements have been made to the initial methods, and new methods have been developed to characterize uncertainties and increase the utility of the resulting quantitative analyses (examples include cancer risk assessment methods, reproductive and developmental toxicity assessment methods, mutagenicity risk assessment methods, and methodologies to assess chemical mixtures).

Using the NAS paradigm, quantitative risk assessment should include four components: **hazard identification, exposure assessment, dose–response assessment,** and **risk characterization**. The methodology used to assess human risk from chemical exposures and to develop standards and guidelines for chemicals may also be used to assess the health effects associated with exposures to biotoxins. However, there is no consensus-based methodology for evaluating human risks specifically posed by environmental exposure to biological agents, and there are no established cleanup goals after biological attacks.

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The World Health Organization (WHO) and the International Life Sciences Institute (ILSI) have developed frameworks to be used as guides in developing risk assessments for pathogens. These frameworks have been used for assessing the risk of exposure to harmful pathogens in certain contexts such as microbial hazards in food safety, drinking water quality, and hospital infection control practices. However, data are lacking to support quantitative risk assessment for pathogens that might be used as biological weapons (NRC, 2005). A more thorough discussion of the issues is provided in the report *Reopening Public Facilities After a Biological Attack: A Decision-Making Framework* (NRC, 2005; see Executive Summary and Chapters 5–8).

Although the basic NAS paradigm was originally developed for chemical risk assessments, it may still be generally followed when assessing risks to humans from environmental exposure to pathogens and biotoxins. Guidance on factors to be considered in each step of the risk assessment paradigm is outlined below.

For biotoxins, the tools currently available for chemical risk assessment may be more relevant. Guidance such as the EPA's Exposure Factors Handbook (USEPA, 1997), Risk Assessment Guidance for Superfund (RAGS) (USEPA, 1989 and 1991), and other guidance for chemical risks and remediation should serve as excellent resources for information on biotoxin remediation. Therefore, the discussion below is focused on pathogens.

2.4.2 Hazard Identification

The first step in determining the risk associated with a biological incident is hazard identification; that is, identifying the pathogen or biotoxin, how the contamination occurred, and the potential adverse health effects to humans through potential routes of exposure to the pathogen or biotoxin. These health effects may have different endpoints. The diseases resulting from exposure to some pathogens have mortality rates approaching 100% when not treated. Meanwhile, exposures to other pathogens or biotoxins may result in far lower mortality rates but have high morbidity rates causing a significant burden on the health care system and the economy. The military divides pathogens into lethal and incapacitating agents, with incapacitating agents requiring perhaps more medical intervention than lethal agents. The effect of certain lethal agents may also be reduced by long-term or significant medical interventions. Data are often readily available on the efficacy and cost effectiveness of various medical responses for infected individuals. Hazard identification is initially a matter of identifying the agent used in an attack. Such information may be derived from clinical, epidemiological, forensic, or environmental sampling data. The hazard assessment must also consider the potential route of exposure for the pathogen or biotoxin. In some cases, novel exposures may cause a change in the hazard inherent from a biological agent. For example, a toxin which is normally ingested may cause much more severe disease if inhaled. These novel pathways of exposure may lead to hazards that would be unanticipated from an examination of natural disease occurrence. Methods for the identification of specific contaminants of concern in biological terrorist incidents may be found in the EPA's Standard Analytical Methods document (EPA, 2007; CDC, 2010).

2.4.3 Exposure Assessment

Exposure assessment is an evaluation of the number of people who have—or could—ingest, inhale, or otherwise come in contact with a pathogen or biotoxin and at what level and frequency. If a pathogen's or biotoxin's formulation is easily dispersible or readily aerosolizable, it poses a risk of aerosol exposure. The characteristics of pathogen and biotoxin

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preparations change over time and with environmental conditions, making it nearly impossible to quantify each of the characteristics in a given situation. Many pathogens and biotoxins also have several routes of infection. *B. anthracis* causes disease from ingestion, cutaneous exposure, and inhalation exposure. Even though inhalational anthrax is the greatest concern posed by this particular pathogen, measures taken to reduce the inhalation risk may not fully address the other risks of exposure and infection. The infectious or toxic dose also varies by the route of exposure. For example, the infectious dose for anthrax by ingestion is considerably higher than through inhalation. Similarly, many pathogens cause different diseases from exposures through different routes of infection. Thus, the route of exposure is an important factor in both hazard identification and subsequent exposure assessment.

Characterizing the viability of a pathogen or activity of a biotoxin is an important aspect of exposure assessment. Exposure to nonviable pathogens and inactivated toxins poses little or no risk. Pathogens die and biotoxins may become inactivated in the environment at different rates, but the specific environmental conditions that result in inactivation vary. Methods of preparing a pathogen or biotoxin for dissemination can also affect the survival in the environment after its release. Thus, determining viability for many pathogens or activity of a biotoxin is may be difficult. In most cases, the ultimate viability test is the ability to cause an infection or toxic effect in a suitable animal or cell culture. In addition, the collection of viable pathogens from the environment is difficult because of such factors as organism inactivation between the release period and the identification of disease; limitations in existing field collection methods, transport techniques, and laboratory processing; and the presence of other co-contaminants in the environment which may inhibit the growth of the pathogen of interest.

If a pathogen is present in a state such that it will not result in exposure to a susceptible individual or initiate infection that is likely to cause disease, then it is not a threat to human health. Similarly, an inactive biotoxin may not be a human health risk. The identity and formulation of the agent, and interactions with environmental matrices, make determining exposure difficult, even in the presence of a known quantity of agent. For example, even if the precise amount of viable or active contaminant present on a floor were known, it would be difficult to predict how much of the contaminant is released in a manner that may result in exposure through inhalation, ingestion, or exposure to broken skin or mucous membranes. It may be possible to design a sampling plan to answer some important exposure questions, but because the variables are so numerous, some of the information must be estimated.

The distribution of contaminants is another crucial variable for exposure assessment. The nature of a large-scale contamination incident may lend itself to developing conceptual distribution models through various modeling tools and an adequate sampling plan. The sampling plan is executed to determine the distribution of contaminant. If the distribution is understood, then the information can be used in risk management decision-making. Even though information on the distribution of a contaminant is necessary to understand the potential for exposure, such information alone does not constitute exposure assessment.

Finally, it is likely that not all pathogens or biotoxins will be detectable in environmental samples. For example, pathogens may no longer be in a sample by the time their presence is suspected, their presence might be masked by other environmental microorganisms, or the methods used for detection may not be sensitive enough to identify pathogens present at low but biologically significant levels. The inability to detect environmental pathogens or biotoxins should not be interpreted as their absence. Other sources of information, including

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epidemiological and forensic evidence, should be interpreted in the context of what is known about the pathogen or biotoxin in question to form a hypothesis about the distribution and concentration of contamination. Such information can then be used to inform the exposure assessment.

2.4.4 Dose–Response Assessment

Dose–response relationships for pathogens are difficult to characterize and describe. Linear relationships in which smaller doses lead to less severe responses cannot be assumed. There may theoretically be some doses of some pathogens that are incapable of causing infection in a given host. There also may be doses of a pathogen that lead to infection (when the organism multiplies within the host) but are unable to cause disease due to elimination of the organism by the host. In other cases, exposure to a small dose may cause an infection leading to a disease state only after sufficient time has elapsed for the number of pathogenic microorganisms to multiply to some threshold level. In such cases, exposure to a higher initial dose may cause an earlier onset of symptoms and more rapid disease progression, but there may be no dose-dependent difference in the final outcome.

There is also a significant and complex interrelationship between dose-response and host factors such as age, immune status, and the presence of other disease conditions. For instance, in some cases, an altered immune status may not change the infectious dose (Miller et al., 2006), but may cause a change in the observable course of the disease (Miller and Schaefer, 2007). Thus the immune status of a given host may make that individual more or less susceptible to infection, or more or less likely to experience a severe outcome from a disease, independent from the infectious dose. Inherent differences in many pathogens may also affect the dose-response relationship. Various strains of the same pathogen may exhibit differences in infectious dose (Messner et al. 2001) or pathogenicity (Welkos et al. 1993). The resulting relationship between the immune status of exposed individuals and the strain or strains to which they are exposed are complicating factors that must be considered in any assessment of dose-response. Most microorganisms that could be used as weapons are not widespread causes of naturally-occurring disease in the U.S.; thus, there may be limited specific immunity in the population.

Estimates of the infectious dose of a specific pathogen can be used to inform risk management decisions related to pathogen remediation. However, infectious dose values are subject to significant uncertainties, and the assumptions defining infectious dose must be taken into consideration when setting clearance goals. Nevertheless, infectious dose may be useful to roughly predict illness in exposed individuals and to serve as a rationale for setting initial clearance goals.

Given the numerous uncertainties regarding published infectious doses for pathogens, it is extremely important to carefully examine what the numbers actually represent, as well as the routes of exposure, selected doses, and the animal species used in the underlying laboratory studies. Models used to extrapolate from animal data to humans should be carefully examined as well. Risk managers should not assume that an infectious dose estimate reflects a "safe" level; that is, the dose below which few people are likely to become ill. Even pathogens that have an infectious dose of 10,000 organisms for 50% of the population may cause infection in 1% of the population with as few as 10 organisms (Peters and Hartley, 2002). The dose response assessment for biotoxins is more similar to that conducted for chemicals.

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2.4.5 Risk Characterization

Hazard information on the virulence and drug resistance of organisms, or toxicity of a biotoxin, may be collected from clinical isolates and epidemiological evidence. Exposure information may be collected from clinical samples taken from people who are thought to have been near exposed individuals, or those present before or after a presumed exposure incident. Law enforcement and intelligence information may also provide information about the potential for environmental contamination. *In the face of potentially serious consequences from contamination, judgments as to the assessment of risks should be based on a weight-of-evidence approach that reflects a qualitative assessment of risks arising from a particular contamination incident.*

The risk characterization synthesizes all available evidence about a hazard to address the needs of decision-makers and interested parties (NRC, 1996; NRC, 2005). In some cases, it is not possible to directly measure environmental contamination. In other cases, direct measurements of environmental contamination may not be related to exposure. Therefore, even though it is imperative to attempt to estimate exposure potential and other elements to inform a risk assessment, it may be necessary to make decisions from a variety of sources of information. This is known as a weight-of-evidence approach.

An overarching goal in any risk assessment is to reduce uncertainty and variability. Because risk assessments for most pathogens are usually qualitative, they inherently contain more uncertainty and variability than quantitative risk assessments performed for chemicals. Nevertheless, following the basic risk assessment principles described above, and collecting and evaluating all relevant information on the pathogen or biotoxin, should provide a sound risk assessment (even if qualitative) that can be used by decision-makers to determine the nature and extent of cleanup needed after a biological incident.

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3. Framework for Decision-Making

This chapter describes basic principles and concepts that provide a sound framework for managing a response to a biological incident. The framework is designed to help decision-makers and officials at the Federal, State, tribal and local levels achieve defensible decisions. Key parts of the framework include a brief description of the overall risk management process, a summary of roles and responsibilities of government agencies and others under the NRF, an overview of the phases and activities involved in responding to a biological incident, and a "decision tree" that outlines key decision points and actions for decision-makers. Key to any decision-making is the application of the site-specific optimization process which is described in this chapter.

3.1 A Starting Point: Presidential/Congressional Commission's Risk Management Framework

In 1997, a Presidential/Congressional Commission on Risk Assessment and Risk Management issued a landmark document entitled *Framework for Environmental Health Risk Management* (Presidential/Congressional Commission, 1997). The Commission's Risk Management Framework is intended to:

- Provide an integrated, holistic approach to solving public health and environmental problems in context.
- Ensure that decisions about the use of risk assessment and economic analysis rely on the best scientific evidence and are made in the context of risk management alternatives.
- Emphasize the importance of collaboration, communication, and negotiation among stakeholders so that public values can influence risk management strategies.
- Produce risk management decisions that are more likely to be successful than decisions made without adequate and early stakeholder involvement.
- Accommodate critical new information that may emerge at any stage of the process.
- Articulate salient risk management principles for consideration by decision-makers as they plan for and carry out a response to a biological incident.
- Base risk management decision-making on a careful analysis of the weight of the scientific evidence that supports conclusions about a problem's potential risks to human health and the environment.
- Make decisions after examining a range of regulatory and non-regulatory risk management options.
- Reduce or eliminate risks in ways that:

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- Are based on the best available scientific, economic, and other technical information.
- Account for their multi-source, multimedia, multi-chemical, and multi-risk contexts.
- Are feasible, with benefits reasonably related to costs.
- Maximize net-benefits. Such approaches should:
  - Give priority to preventing risks, not just controlling them.
  - Use alternatives to command-and-control regulation, where applicable.
  - Be sensitive to social, legal, and cultural factors.
  - Include incentives for innovation, evaluation, and research.

- Implement decisions effectively, expeditiously, flexibly, and with stakeholder support.

- Implement decisions shown to have a significant impact on the risks of concern.

- Revise and change decisions when significant, new information becomes available, but avoid "paralysis by analysis." [1]

The Commission's framework defines a six-stage process for risk management that can be applied to any public health or environmental hazard. As shown in Figure 1, the six stages are:

1. Define the problem, and put it in context.
2. Analyze the risks associated with the problem in context.
3. Examine options for addressing the risks.
4. Make decisions about which options to implement.
5. Take actions to implement the decisions.
6. Conduct an evaluation of the actions.[2]

The level of effort and resources invested in using the Framework can be scaled to the importance of the problem, potential severity and economic impact of the risk, level of controversy surrounding it, and resource constraints. As such, the Framework is particularly appropriate for the type of clean-up decisions associated with the aftermath of intentional attacks.

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[1] http://www.riskworld.com/Nreports/1997/risk-rpt/html/chp1box4.htm
[2] http://www.riskworld.com/Nreports/1997/risk-rpt/html/chp1box2.htm

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Figure 1. Risk management process.

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Every stage of the Framework relies on three key principles:

Broader contexts. Instead of evaluating single risks associated with single chemicals in single environmental media, the Framework puts health and environmental problems in their larger, real-world contexts. The goal of considering problems in their context is to clarify the impact that individual risk management actions are likely to have on public health or the environment and to help direct actions and resources where they will do the most good.

Stakeholder participation. Involvement of stakeholders—parties who are concerned about or affected by the risk management problem—is critical to making and successfully implementing sound, cost-effective, informed risk management decisions. For this reason, the Framework encourages stakeholder involvement to the extent appropriate and feasible during all stages of the risk management process.

Iteration. Valuable information or perspective may emerge during any stage of the risk management process. This Framework is designed so that parts of it may be repeated, giving risk managers and stakeholders the flexibility to revisit early stages of the process when new findings made during later stages shed sufficiently important light on earlier deliberations and decisions ([HYPERLINK "http://www.riskworld.com/Nreports/1997/risk-rpt/html/epajan7.htm" \l "7impt"] on page 47 provides more information.).[3]

The objectives of the Presidential/Congressional Commission's Risk Management Framework and the central role of the stakeholder dovetail with the principles inherent in the optimization processes that currently underlie many State, Federal, and international risk management programs. In the next section we discuss the optimization approach.

3.2 Optimization Approach

The optimization approach is used to help address the uncertainties, gaps in research, and the uniqueness of responding to biological incidents. Responding to biological incidents, particularly, *B. anthracis,* differs from responding to radiological and chemical incidents in which there is a 30 year response history, a range of site-specific cleanup values, and more certainty in doses and concentrations and their impact on human health..

Broadly speaking, optimization is a flexible, multi-attribute decision process that seeks to consider and balance many factors. Optimization analyses are qualitative and quantitative assessments applied at each stage of site remediation decision-making from evaluation of decontamination options to implementation of the chosen alternative. The evaluation of cleanup alternatives, for example, should factor in all relevant variables, including areas impacted (e.g., size and location relative to population), types of contamination (chemical, biological, and/or radioactive), human health, public welfare, technical feasibility, costs and available resources to implement and maintain remedial options, short-term effectiveness, long-term effectiveness, timeliness, public acceptability, and economic effects (e.g., on residents, tourism, business, and industry).

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Optimization is a flexible approach, under which applicable dose and/or risk benchmarks may be identified from State, Federal, and other sources (e.g., national and international advisory organizations); such information may be useful in supporting assessments of site-specific circumstances and balancing other relevant factors. The optimization process is further described in other sections of this chapter.

The principles of site-specific optimization can be applied during several phases of a response to a biological incident. The site-specific optimization process includes quantitative and/or qualitative assessments applied at a particular stage of site cleanup decision making, such as conducting characterization environmental sampling, establishing clearance goals, and selecting decontamination options. The optimization process should consider all of the factors relevant to the issue, such as:

- Areas impacted (e.g., size, location relative to population)
- The identity and characteristics of the contaminant
- Other hazards present
- Human health risk
- Public welfare
- Ecological risks
- Actions already taken
- Projected land uses
- Preservation or destruction of places of historical, national, or regional significance
- Technical feasibility
- Wastes generated and disposal options and costs
- Costs and available resources to implement and maintain remediation options
- Potential adverse impacts (e.g., to human health, the environment, and the economy) of remediation options
- Short-term effectiveness
- Long-term effectiveness
- Timeliness
- Public acceptability, including local cultural sensitivities
- Economic effects (e.g., on employment, tourism, and business)
- Intergenerational equity

The site-specific optimization process provides an opportunity for decision makers to gain public confidence through the involvement of stakeholders. The goals of site specific optimization are:

(1) Transparency—The basis for cleanup decisions should be publicly available.
(2) Inclusiveness—Representative stakeholders should be involved.
(3) Effectiveness—Technical subject matter experts should analyze available options and assess various technologies in order to identify optimal solutions.
(4) Shared accountability—The final decision to proceed will be made jointly by Federal, State, and local officials

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3.3 Roles and Responsibilities

The NRF establishes a comprehensive, all-hazards approach to enhance the ability of the United States to manage domestic incidents (DHS 2008). It forms the basis for how Federal departments and agencies will work together during incidents and how the Federal Government will coordinate with State, tribal, and local governments and the private sector. DHS is the overall Federal coordinator for incidents involving biological terrorism, but many other Federal agencies play key roles in coordinating activities within their areas of expertise. Figures A2-1 and A2-2 in Appendix 2 provide additional information about the structure of the NRF. Table 1 in Appendix 2 shows the roles of individual Federal agencies in decontaminating biological agents. The reader is encouraged to refer to the most current version of these overarching documents, which are available at [HYPERLINK "http://www.fema.gov/nrf/"].

Under the NRF, technical and policy issues are addressed at the lowest possible organizational level. In most cases, this is at the level of the Incident Command or Unified Command (IC/UC). Issues that cannot be resolved at the IC/UC level may be elevated to the Joint Field Office (JFO) Unified Coordination Group for resolution. The JFO Unified Coordination Group may also wish to review and provide input on decisions related to extensive contamination (and remediation costs) and in situations where it may be necessary to set priorities among multiple contaminated sites.

In the event of accidental or intentional biological contamination of a facility or area, the appropriate local authority (e.g., fire department, police department, or public health representative) would establish and run an Incident Command, and other local, State, and Federal agencies would join, as needed. As emergency response operations are completed, the lead for remediation/cleanup activities would then be taken by the party responsible for the property involved. For example, the owner of a private building (depending on his/her resources) could oversee the cleanup and restoration of his/her own facility. However, the local or State agencies with authority for protecting public health and/or the environment would also likely exert their regulatory authority (such as by issuing a quarantine for the affected area) to assure that their cleanup and restoration efforts are acceptable. In addition, local, State, tribal, or Federal agencies would have authority for remediating a public building or any private building should the owner not have the resources to remediate it.

The response process will be managed by the IC/UC, who ultimately determines the structure and organization of the Incident Command Post, but the discussion below provides one recommended approach for managing the cleanup process within a NIMS ICS response structure. Decisions will be informed by scientific and technical analyses conducted by the Environmental Unit within the Planning Section of the Incident Command Structure. The Environmental Unit, shown in Figure 2, may be comprised of experts in sampling, decontamination technologies, industrial hygiene, public health and risk assessment, environmental engineers, and waste management. For complex or controversial remediation, the IC/UC or Environmental Unit leader may choose to convene a technical working group (TWG) of additional experts to provide multi-agency, multi-disciplinary input to planning and implementing the remediation, including setting clearance goals. The TWG may include representatives from Federal, State, local, and tribal agencies, and experts from the private sector or universities. The IC/UC or Environmental Unit leader should also meet with representatives of residential communities, building owners, and workers in nearby communities to ensure that they are fully informed about the remediation and their issues are addressed. The IC/UC might also

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consider convening a Stakeholder Work Group to make use of local knowledge and ensure that community concerns are addressed during remediation. The IC/UC command structure shown in Figure 2 is intended to be flexible and expandable in accommodating the groups necessary to address a particular incident. The IC/UC has a number of options available for managing the cleanup process: the Environmental Unit, the Scientific Support Coordinator, or a separate unit under the Planning Section (e.g., a Long-Term Cleanup Planning Unit). The unit with this responsibility will coordinate the work group processes and interactions and report the results of the analysis and working efforts to the IC/UC through the Planning Section Chief. See the *National Incident Management System* (2004) for further discussion of the roles and responsibilities of entities identified in Figure 2.

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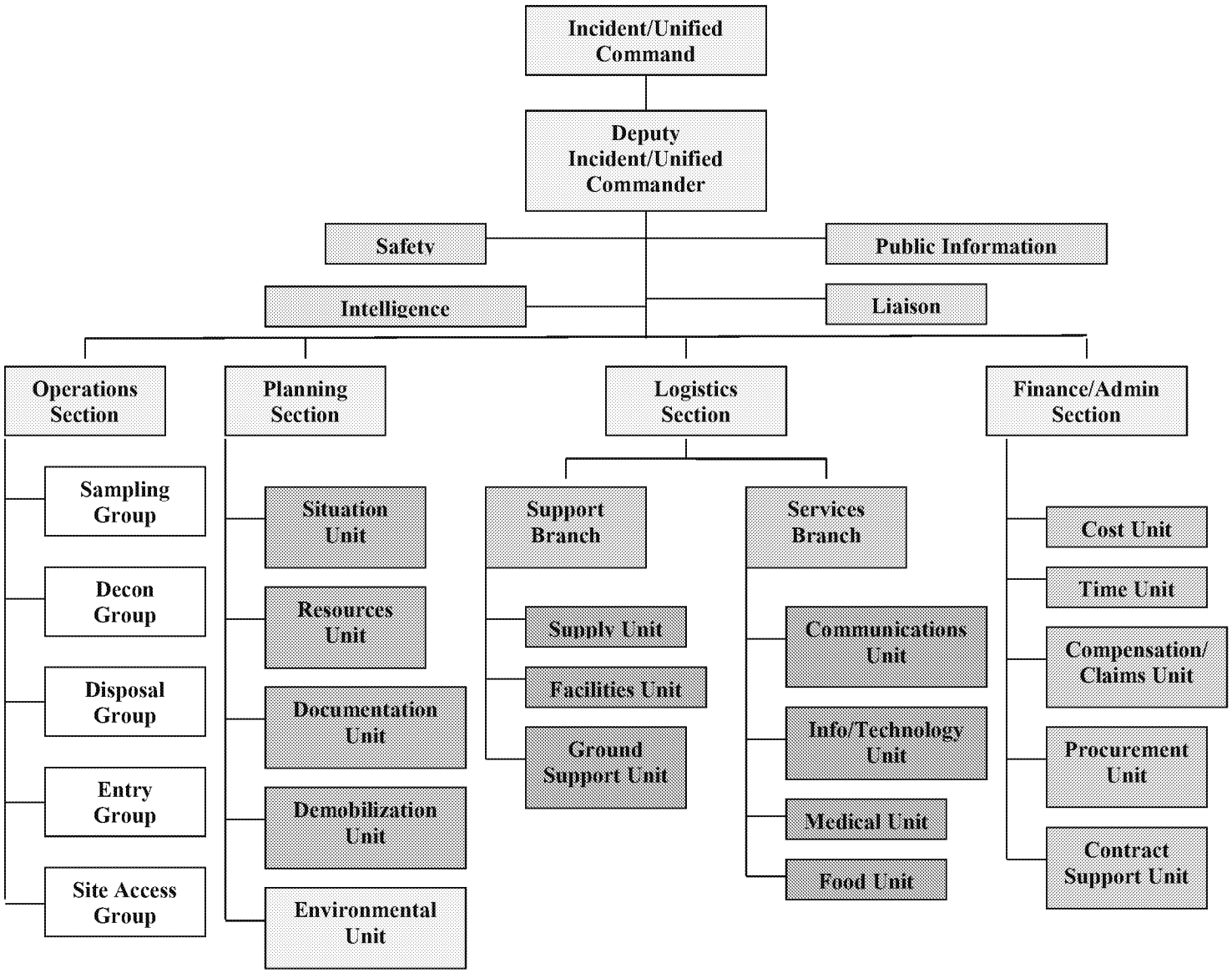

Figure 2. Incident/Unified Command Structure (adapted from DHS, 2008).

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3.3 Overview of a Response to a Biological Incident

Effective and timely decision-making in responding to a biological incident first requires a broad understanding of all the phases and activities involved. Figure 3 provides such an overview and shows the phases and activities, starting with initial notification of a potential or actual biological incident and ending with the completion of restoration/restoration operations that allow a contaminated site to be returned to normal use. Figure 3 has been developed specifically for use in this document, and the terms are defined in the Appendix 9 Glossary based either on existing definitions or on the meaning that best fits within the context of this document. Although the same terms may be defined differently elsewhere, the multi-agency review and approval of this document provides a strong basis for the definitions.

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Response and Recovery					
Crisis Management		**Consequence Management**			
Notification	**First Response**	**Remediation/Cleanup**			**Restoration/ Reoccupancy**
		Characterization	**Decontamination**	**Clearance**	
Receipt of information on biological incident Identification of suspect release sites Notification of appropriate agencies	Initial threat assessment HAZMAT and emergency actions Forensic investigation Public health actions Screening sampling Determination of agent type, concentration, and viability Risk communication	Characterization of biological agent Characterization of affected site Site containment Continue risk communication Characterization environmental sampling and analysis Initial risk assessment Clearance goals	Decontamination strategy Remediation Action Plan Worker health and safety Site preparation Source reduction Waste disposal Decontamination of sites or items Decontamination verification	Clearance environ-mental sampling and analysis Clearance decision	Renovation Reoccupation decision Long-term environmental and public health monitoring

Figure 3. Basic phases of response to a biological incident.

As shown in Figure 3, **Crisis Management** and **Consequence Management** are the two basic phases of response to a biological incident. Crisis Management consists of **Initial Response**, which can be further subdivided into **Notification** and **First Response**. These phases of response to a biological incident are not emphasized in this document, but are the focus of other guidance. Consequence Management consists of **Remediation/Cleanup** (which can be further subdivided into **Characterization**, **Decontamination**, and **Clearance)** and **Restoration/Reoccupancy**. As mentioned previously (Section 1.3), this guidance document emphasizes the remediation and long-term site recovery/restoration phases of a response to a biological incident.

Figure 3 also identifies the principal activities that take place under each of the above categories. For example, under Notification the activities listed are: Receipt of information on biological

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incident, Identification of suspect release sites, and Notification of appropriate agencies. Such activities are briefly described below. *It is important to note that these activities do not necessarily occur in sequential order, but may start at different times, run concurrently, or occur outside the phase in which they are listed in Figure 3.*

3.3.1 Notification

A biological incident may be detected by an environmental detection system, medical surveillance, epidemiologic investigation, or law enforcement investigation. That information will then likely be reported to or collected by a Federal, State or local agency. The responsible person(s) assesses the credibility of information and the degree to which a response is needed. If incoming information of a possible biological incident appears credible and requires a response, the responsible receiving person(s) relays key information to appropriate agencies (e.g., police, fire, public health, Hazmat teams, FBI, and DHS). Suspect release sites are identified, and responders are dispatched to the scene to initiate a First Response (Meehan et al., 2004).

3.3.2 First Response

First-response activities are described briefly in this document (see Section 4.2) to emphasize that such actions will have an effect on remediation activities. Hazmat and emergency actions take place when first responders arrive on the scene to address any immediate threats to life or valuable property necessary for public welfare (e.g., critical infrastructure) and to establish control of the situation. They set up a command post, initiate any needed rescue operations, mitigate any life-threatening or hazardous conditions (e.g., fire or explosion), and conduct preliminary tests to determine whether the threat substance is organic or likely to be a hazard. They also contact law enforcement and other personnel as needed.

To initiate risk communication, a Joint Information Center (JIC) should be established as soon as notification of a biological incident is received to coordinate all public-affairs activities and media releases. Communication activities continue throughout the response (Section 4.6).

If preliminary tests indicate the potential presence of a biological agent, the FBI will likely commence a threat evaluation to determine threat credibility. A forensic investigation will be used to identify the agent and determine its specific genetic, physical, and chemical properties; search for other types of evidence; establish a possible source of the contamination; and determine the responsible party. If a crime scene is established, environmental sampling must be done with explicit approval of the FBI. Initial samples may be sent to a Laboratory Response Network (LRN) (CDC, 2005b) laboratory or the FBI laboratory for analysis and to confirm the identity of the contaminant.

If the laboratory analytical results confirm the presence of a biological agent, the responsible public health agency involved in the response will commence appropriate public health actions, such as treatment (CDC, 2004c) and decontamination of potentially contaminated individuals, distribution of prophylaxis, and medical examinations.

In some instances, additional environmental sampling using methods requiring laboratory processing will commence during First Response to obtain information on agent concentration, viability, potential exposure pathways and drug susceptibility testing; and to generally inform further public health decision making. Environmental sampling may continue in more depth under Characterization.

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3.3.3 Characterization

During Characterization, additional screening sampling and analysis is performed to determine the extent and magnitude of biological agent contamination and approximate location(s) of contamination (Section 4.2). Further detailed characterization of a biological agent includes obtaining viable agent, determining the formulation, and understanding its relevant characteristics (Section 4.3).

Characterization of an affected site includes describing its size, construction, heating, ventilation and air conditioning (HVAC) systems, ambient environmental conditions (such as temperature and relative humidity), structural materials, stored materials, and contents. If decontamination is warranted, the characteristics of the site and its contents may affect selection of a decontamination strategy (Section 4.10) as well as the efficacy of decontamination agents (Section 4.4).

Containment is the set of actions taken to prevent the spread of a contaminant from a particular zone or its movement within the zone (Section 4.5). Workers who exit a contaminated area (the Exclusion Zone or Hot Zone) pass through a decontamination unit erected in a neutral area (Contamination Reduction Zone or Warm Zone) so that they can be decontaminated prior to entering a "clean" area (Support Zone or Cold Zone).

A Characterization Environmental Sampling and Analysis Plan (SAP) is developed to characterize the distribution of biological agent and to obtain semi-quantitative estimates of its concentrations at specific locations. The SAP also assesses the potential of an agent to aerosolize as evaluated by its presence on or in ceiling air ducts, on top of light fixtures, and in other locations (Section 4.7). In case of a water contamination, the SAP would evaluate the source and location of the spread of the contaminant in the water distribution system.

A risk assessment (either qualitative or quantitative) is conducted to determine potential risks posed by a biological agent at a specific site. Risks need to be assessed to assist decision-making about setting clearance goals, formulating a decontamination strategy, and developing a SAP.

There is no simple formula for setting clearance goals. This is especially true for biological agents, which do not have established reference values (like some radiological or chemical agents) or exposure guidelines. The collective, professional judgment of experts, tempered by concerns of the people affected and other factors, are used to set a clearance goal appropriate to the site-specific circumstances (Section 4.9) (EPA, 1997; NRC, 2005). The successful establishment of clearance goals will incorporate optimization (referred to earlier in this chapter).

3.3.4 Decontamination and Clearance

An overall decontamination and clearance strategy is developed through the optimization process and uses agent- and incident-specific information (Section 4.10). After the strategy is determined and the decontamination agent(s) is selected, a Remediation Action Plan (RAP) is prepared that lays out an overall strategy for decontaminating the contaminated site and its contents (Section 4.11).

The OSHA Hazardous Waste Operations and Emergency Response (HAZWOPER) standard (29 CFR 1910.120 and 29 CFR 1926.65) requires a written Worker Health and Safety Plan (HASP),

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to among other things, protect employee health and safety during Remediation/Cleanup activities (Section 4.12).

Before decontamination can proceed, site preparation is necessary (Section 4.13). Source reduction involves removing certain items and/or materials from a contaminated site for further treatment and reuse or disposal. The remaining items and site surfaces may need to be cleaned prior to the main decontamination activity (Section 4.14). Waste disposal runs concurrently with source reduction, but also occurs throughout the entire response and recovery process. In addition to materials or items that are removed from the site as waste, other wastes are created by the decontamination processes themselves, such as water used to rinse personal protective equipment (PPE), employee shower water, and scrubber wastewater (Section 4.15). Source reduction and waste disposal are significant factors that may affect the overall decontamination strategy. Some decontamination methods allow items to be left in place while others do not, and some methods generate waste products themselves.

Once a determination is made that decontamination is necessary to mitigate a biological agent incident, the evaluation, selection, and use of the most appropriate decontamination methods for the biological agent and affected site(s) and item(s) can be carried out (Section 4.16). Decontamination processes are monitored as they are carried out and are evaluated as to whether they have been conducted successfully (Section 4.17).

Clearance sampling and analysis is performed as the ultimate test of whether a remediation process is successful (Section 4.18). The IC/UC or property owner and/or responsible local/State agency (e.g. public health) makes the ultimate clearance decision. This decision is a judgment as to whether the criteria for decontamination verification and clearance have been met (Section 4.19). The local or State agencies with authority for protecting public health and/or the environment would also likely exert their regulatory authority during the response/recovery and cleanup phases (such as by issuing a quarantine for the affected area) to assure that the cleanup and restoration efforts are acceptable. In addition, local, State, tribal, or Federal agencies would have authority for remediating a public building or any private building should the owner not have the resources to remediate it.

3.3.5 Restoration/Reoccupancy

Once a building is cleared for re-use by workers and others without the need for PPE, it may still require extensive work prior to reoccupation by employees and the general public. Site-specific restoration plans would detail any necessary renovations, reoccupancy and reuse criteria. Renovations can include refurbishment, system testing, and inspection before the building is returned to normal use. Upgrading a facility may also take place to make it less vulnerable to future biological agent attack or incident (e.g., installation of biohazard detection systems in U.S. Postal Service Processing and Distribution Centers) (Noller, 2005). Reoccupancy and reuse criteria aimed at longer-term environmental and public health monitoring can vary dramatically depending on who will occupy the site and the extent of the potential residual contamination (Section 4.20). After renovations are completed and monitoring indicates that the established criteria have been met, a reoccupancy decision is made about whether to permit residents and employees to return.

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3.4 Biological Agent Incident-Response Decision Process

The flowchart shown in Figure 4 highlights the critical steps that must be taken during the phases of response to a biological incident (Raber et al., 2002). Whereas Figure 3 in the previous section lists the basic activities that comprise a response, Figure 4 arranges the response activities in a specific sequence and provides the decision-maker (e.g., IC/UC) with a guide to key decisions (diamonds) and tasks (rectangles) that need to be accomplished during a response. The activities in the flowchart are described in more detail in Chapter 4. Thus, a decision-maker can use this chart as a general "map," along with Chapter 4 for details, when determining what needs to be done and in what general order to proceed when responding to a particular incident. Key decisions are within the diamond-shaped boxes, key issues or decisions addressed are in blue boxes, activities are in white boxes, and completion is indicated by green circles. Chapter 4 refers to the various flowchart activities by the number within a box. Just as for Figure 3, in Figure 4 it is important to note that the listed activities may not necessarily occur in sequential order, but may proceed in a different order or in parallel.

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Biological Agent Incident-Response Decision Process (1 of 5)

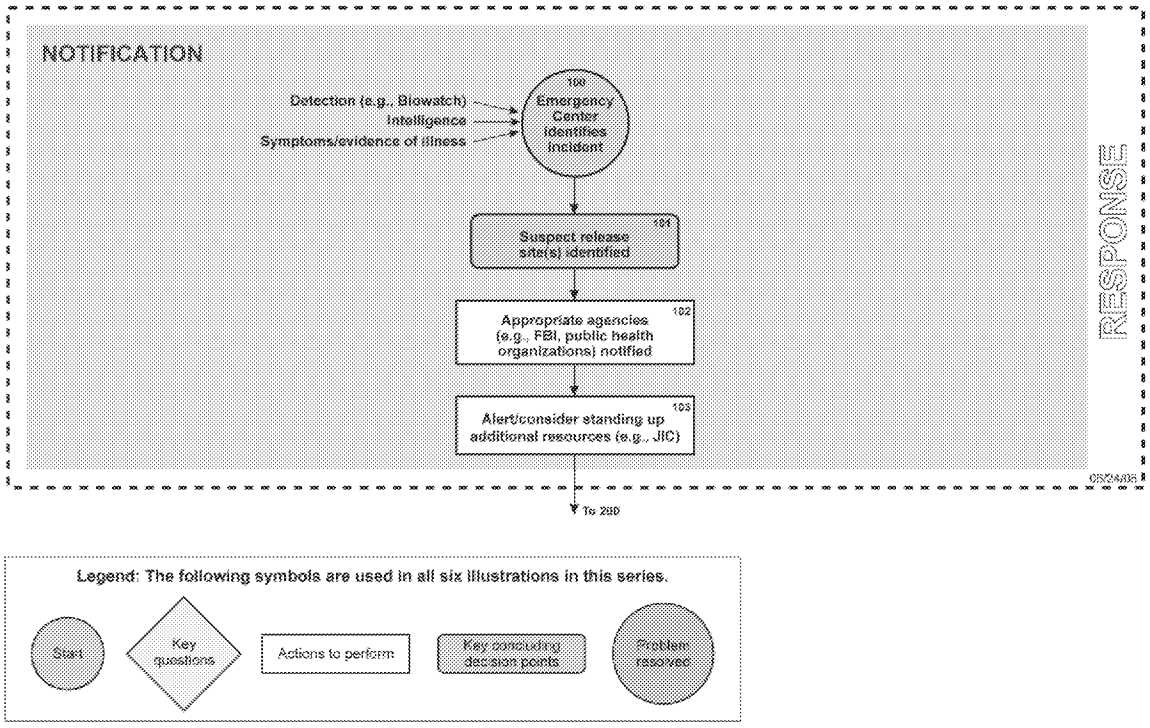

Figure 4. Biological-agent incident response decision process (1 of 5).

Biological Agent Incident-Response Decision Process (2 of 5)

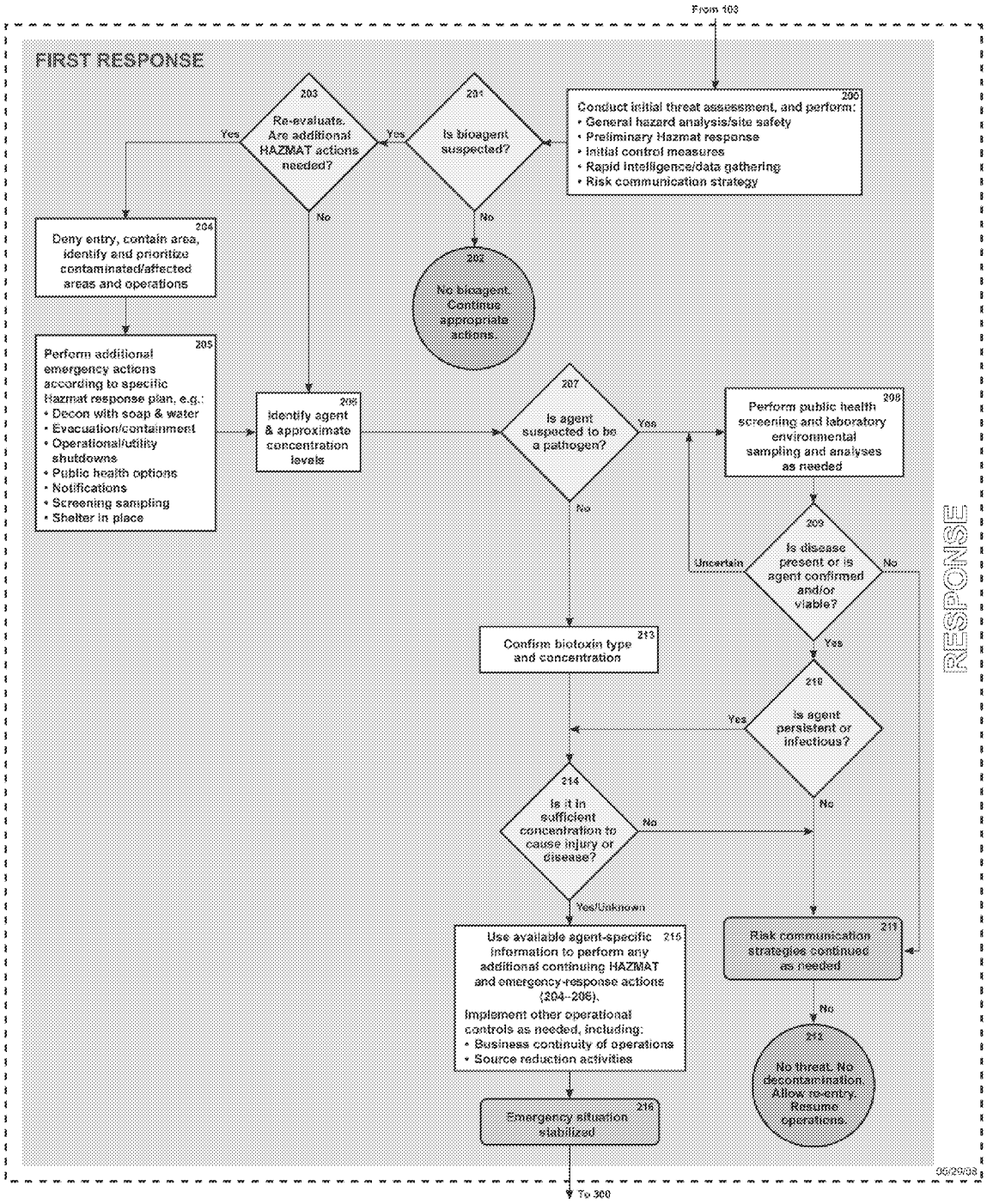

Figure 4. Biological-agent incident response decision process (2 of 5).

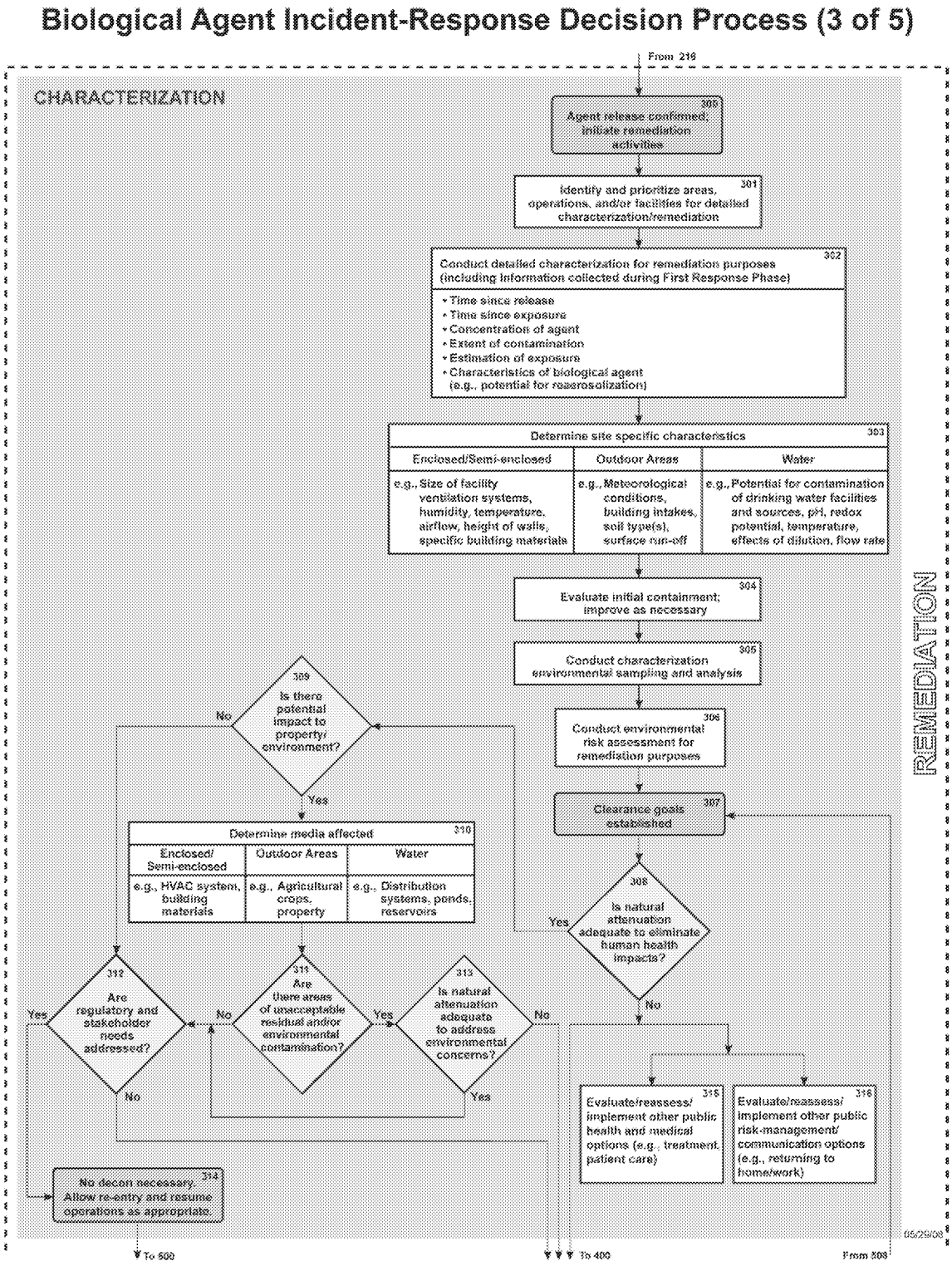

Figure 4. Biological-agent incident response decision process (3 of 5).

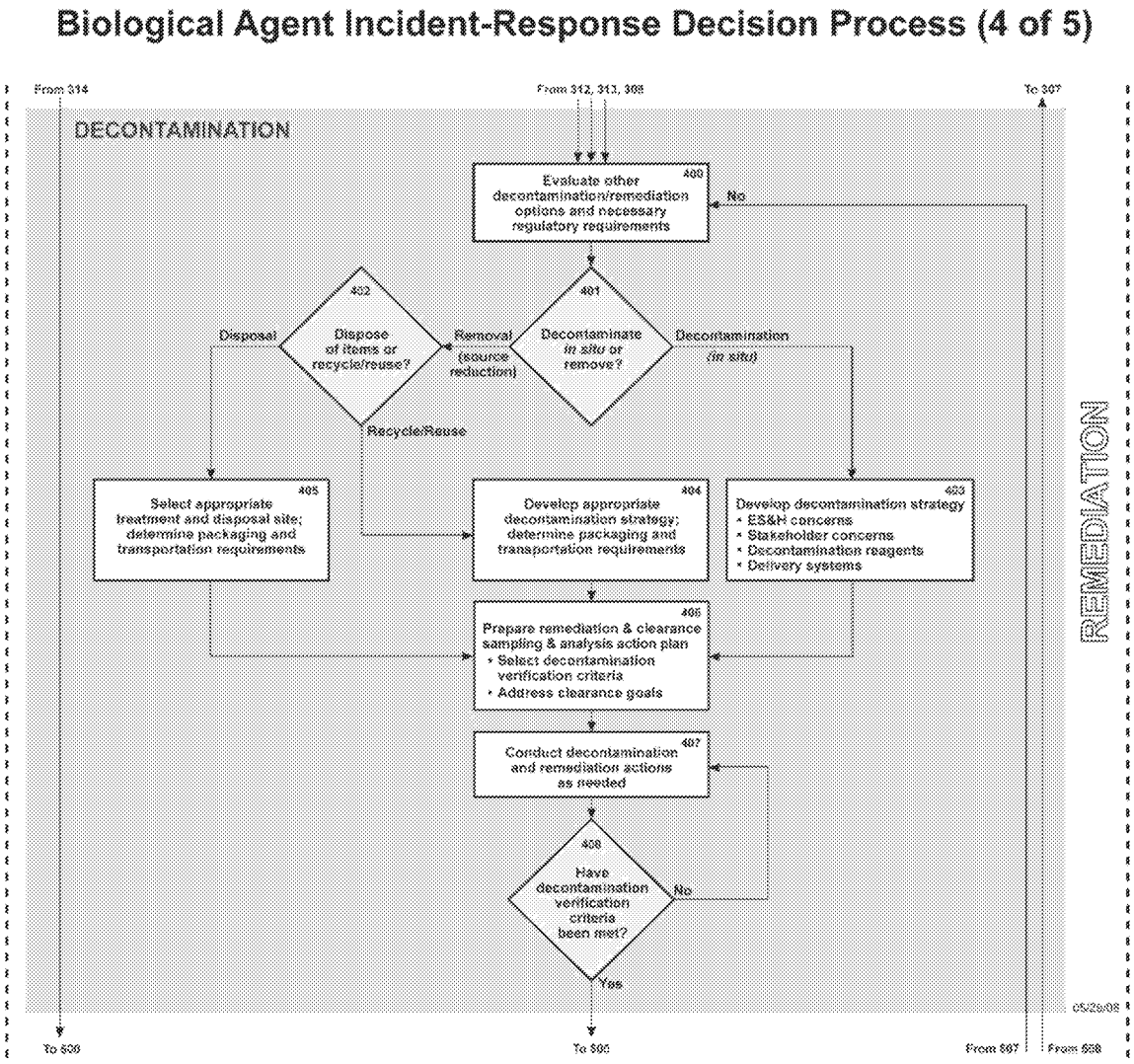

Figure 4. Biological-agent incident response decision process (4 of 5).

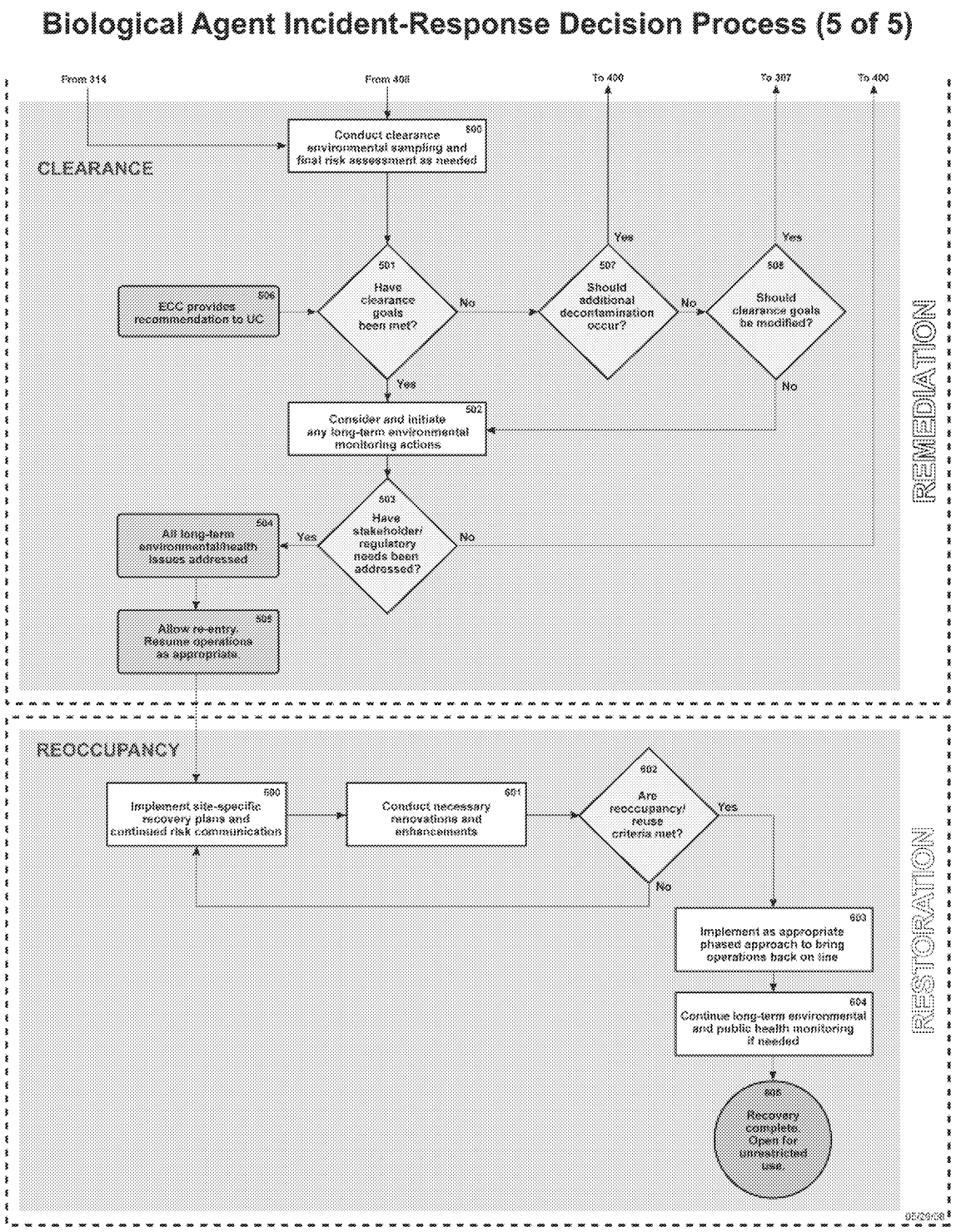

Figure 4. Biological-agent incident response decision process (5 of 5).

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4. Key Activities for Decision-Making

4.1 Introduction

This chapter describes the activities that occur in domestic, civilian settings during a response to a biological incident (Figure 3) and concepts that guide decision-makers in how to accomplish the activities. In planning and executing activities described in this chapter, decision-makers should generally follow the overarching principles of risk management and optimization described in Section 3.1 and establish the IC/UC system described in Section 3.2. The level of effort and resources invested in using the framework should be commensurate with the significance of the problem, the potential severity and economic impact, the level of controversy surrounding the problem, and resource constraints.

As described in Section 1.3, the scope of this guidance includes natural, intentional, or accidental incidents that involve biological agents. The guidance is intended to apply to:

- Enclosed facilities and objects, such as commercial and residential buildings, swimming pools, aircraft, vehicles, trains, vessels, and their contents.
- Semi-enclosed facilities and objects, such as subways, public transit facilities, and their contents.
- Outdoor areas and objects, such as building exteriors, streets, parks, water parks, beaches, other open spaces, and items within these areas.
- Drinking water sources, distribution systems, treatment facilities, and wastewater infrastructures.

Because most experience to date has been with incidents in enclosed and semi-enclosed buildings, much of the guidance pertains to such facilities and their contents. However, as discussed earlier, the framework presented in this document is intended to introduce a scalable cleanup approach based on the principles of site-specific optimization. Where different approaches to response and recovery are needed for outdoor and drinking water facilities or sources, such approaches are discussed in this chapter. In addition, the guidance in this chapter should not prevent the development and use of novel or practical approaches, if those approaches can be implemented safely and effectively. Food production and distribution systems are excluded because they are covered adequately in other guidance ([HYPERLINK "http://www.fda.gov/oc/bioterrorism/role.html"]).

4.2 Notification and First Response (Boxes 100–217)

Notification of a potential biological incident (see Boxes 100–103 in Figure 4) could be triggered by various sources, such as a detection device (e.g., the U.S. Postal Service Biohazard Detection System for *Bacillus anthracis* spores) (Noller, 2005; see also McBride et al., 2003), a suspicious substance such as a white powder, or the occurrence of disease resulting from an airborne release (i.e., inhalation exposure) of known biological agents or consumption of suspect food or water.

An IC is established (Section 3.2) with the arrival on-scene of the first person of authority (e.g., fire department or police department representative), and a UC may be established—depending on the type and scale of incident—with arrival of representatives from other agencies (e.g.,

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public health or FBI). The coordination of information and resources to support domestic incident management activities (Box 103) typically takes place at an Emergency Operations Center (EOC), which may be a temporary or a permanently established facility. EOCs may be organized by major functional disciplines (e.g., fire, law enforcement, and medical services), by jurisdiction, or some combination. In addition, if a business or government agency has a Continuity of Operations Plan (COOP) prepared for the affected site(s), that plan would be activated.

An initial threat assessment is made of the situation (Box 200). Activities carried out at this early stage would likely include making an initial hazard analysis, performing preliminary Hazmat responses, putting into place control measures, ensuring rapid intelligence and data gathering, and developing a risk-communication strategy. A threat assessment should consider all possible threats, for example ruling out an explosive ordnance device. Of paramount importance during this early stage is the fact that emergency responders initially respond with health-protective actions in an effort to save lives.

Once an incident is known to have occurred, hypotheses concerning the characteristics and risks arising from the contamination are developed. Preliminary hypotheses are developed initially from any available information, including epidemiological, intelligence, or other data, and formulated to facilitate testing and analysis. Realistic, evidence-based first hypotheses are best made by experienced personnel. Public health and other experts make and deliver initial situation assessments to the IC/UC. Initial sampling (sometimes called screening environmental sampling or screening sampling for short) (Box 205) is undertaken to assess the likelihood of the preliminary hypotheses and to develop as complete an understanding of the event as possible.

Screening environmental sampling is the initial collection of a limited number of environmental samples for the purpose of determining the identity, concentration, viability and approximate location of contamination by a purported biological agent, and for informing the IC/UC for decision-making and subsequent remediation actions. The number of samples taken is determined by available resources (collection personnel, equipment, and laboratory surge capacity), the size/complexity/location of the facility, and circumstances. The initial response generally occurs within the first 24 to 48 hours. First responders (Boxes 200–217) in appropriate PPE (National Response Team Technical Assistance Document, 2005) (OSHA Anthrax PPE resource guide, 2008) (CDC Anthrax PPE recommendations, 2001) collect at least the initial sample(s) from any discrete material found and from locations of concern based on the information available. Following notification of a presumptive positive result from the receiving laboratory, first responders, industrial hygienists, or others may collect further initial environmental samples (Box 208), depending on the site to determine approximate location(s) of contamination from the biological agent, semi-quantitative estimates of agent concentrations at those locations, where possible, and understand exposures pathways. Sampling methods used are appropriate to the site or medium from which samples are taken, such as wet wipes or wet swabs from hard, nonporous surfaces and high efficiency particulate air (HEPA) vacuum samples from porous surfaces within the affected areas of the facility, and water samples from drinking water. The results of environmental screening sampling provide important data for the IC/UC to use in decision-making on appropriate public health and subsequent remediation actions. The number of samples taken is determined by available resources (collection personnel, equipment, and laboratory surge capacity), the size/complexity/location of the facility, and circumstances. Current information on available environmental sampling methods may be

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obtained from the CDC web site ([HYPERLINK "http://www.bt.cdc.gov/agent/anthrax/environmental-sampling-apr2002.asp"]).

Environmental samples are sent to an LRN laboratory (Box 208), which can provide a definitive determination of the identity of pathogenic microbes (Box 207) and certain biotoxins (Box 213) that may be present (CDC 2005). The LRN laboratory runs an appropriate analysis of the sample(s), reports positive and negative results, and confirms the identity of the biological agent, if present. Other laboratory assays may be available at EPA laboratories, or ERLN (Environmental Response Laboratory Network) laboratories, including a rapid viability PCR (RV-PCR) based assay that provides both viability and identification information. The significance of lab test results to the overall sample characterization process depends on the type of test conducted. For example, the first test run on a suspected sample of *Bacillus anthracis* spores is a polymerase chain reaction (PCR) test, which is based on the presence or absence of DNA. In this case, a PCR test provides evidence of the presence of the bacterium but does not indicate viability (Box 209). In this example, a follow-up, culture-based test together with confirmatory biochemical, molecular, or antigenic testing would provide confirmation that spores are capable of producing viable, vegetative bacteria, as well as other information such as strain and antibiotic susceptibility.

Environmental sampling strategies should always be hypothesis-driven. Sampling should not be undertaken if there is no clear idea of what a "positive" sample would mean, or what actions would be taken in the event of a positive result. The hypotheses developed pertain to the identity, presence, persistence (Box 210), concentration, probability of contaminant dispersion, likelihood of exposure, and nature of the site, with respect to factors that may have allowed contaminant to migrate to various locations beyond the point of initial release. Such hypotheses are then tested by collecting environmental samples. It may be necessary to conduct other activities, such as engineering studies (i.e., tracer gas or airflow visualization studies in buildings) to better inform the hypotheses. Given an appropriate hypothesis, a testing strategy can be developed that accounts for uncertainties in the sampling and analytical techniques.

Environmental sampling should always be used with other available information, such as clinical sampling (e.g., blood samples), epidemiologic data (e.g., the occurrence of a disease of concern in humans; see Box 207), and analysis of the original contaminating material to make response and recovery decisions. Clinical sampling can provide definitive identification of the biological agent, which in turn will support elucidation of its characteristics (e.g., virulence and persistence); epidemiologic data can indicate the possible locations at which persons were exposed to the biological agent. Factors such as viability and agent composition can be obtained from the original material, if it is found. If for some reason environmental sampling cannot be effectively employed for a specific biological agent in the affected area (e.g., because of a lack of sensitivity of available sampling methods for a particular agent), then the decision-maker must rely on these other sources of information to evaluate the nature and extent of contamination.

4.3 Characterization of Biological Agents (Boxes 206, 208, 209, 210, 213, 214, 302, 308)

Characterizing biological agents includes not only identifying the particular agent (Boxes 206 and 208) and verifying its presence, but also obtaining information about that agent and the risk potential posed by its presence (e.g., Boxes 209, 210, and 214). Identification typically means establishing the genus and species, and potentially the strain or subspecies. In some instances,

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information on strain or subspecies is necessary to determine the relative risk of illness and transmission of disease. Pathogens may be further tested for virulence, drug resistance, and other conditions that would impact public health recommendations concerning exposures arising from the contamination. Testing biotoxins (Box 213) can help determine whether a particular toxin is present in an active form or may have been inactivated because of handling or environmental degradation.

The viability of agents (Box 209) is an essential piece of information that is required throughout the agent characterization and sampling processes. Simply identifying agent-specific genetic or antigenic material in a location does not confer sufficient information about risk to human health. Only viability testing can provide this information in the context of appropriate identification.

Some of the information about remediation requirements (Box 302), such as time since release and time since exposure, will already have been collected during first-response activities. Characteristics of a biological agent (Box 302) that are critical to the decontamination effort include the environmental persistence of the agent (Boxes 210 and 308) and its susceptibility to inactivation. It is widely thought that there are few environmentally persistent agents of concern among the agents generally considered to have been formulated into weapons-grade agents. There are, however, exceptions to the hypothesis about environmental persistence. It is possible that a terrorist could use a novel agent that was not considered for inclusion by the weapons programs and that is environmentally persistent as well. Several weapons-grade agents may have the potential to persist in the environment. For example, *Bacillus anthracis* spores have been documented to survive in the environment in endemic areas for years (NRC, 2005; Pepper and Gentry, 2002; Sneath, 1962). Furthermore, given appropriate conditions, *Francisella tularensis*, *Burkholderia mallei*, *Burkholderia pseudomallei* and other disease agents of concern may cause naturally occurring outbreaks. The most likely explanation for environmentally transmitted infections is that they are associated with reservoir animal or protist hosts in the environment. However, it is also possible that these agents may persist in the inanimate environment under proper conditions.

Biological agents may be formulated into more environmentally persistent forms. For example, a commercial technique for stabilizing and drying microorganisms so they can be stored might also be used to increase persistence. The time needed for less-persistent, dried agents to undergo monitored natural attenuation can range from days to months.

4.4 Characterization of the Affected Site (Boxes 301–306, 309, 310)

Just as the biological agent is characterized as part of the ongoing assessment of health risks, so is the affected site. Site characterization (Boxes 301–305 and 310) is generally based on the results of environmental sampling and provides important inputs into environmental risk assessment for site-remediation purposes (Box 306; see also Section 4.8). Site characterization includes the activities listed below, as appropriate, for an affected site. Activities that apply to all four types of sites (see Box 303 and Section 1.3 Scope)—namely, enclosed facilities, semi-enclosed facilities, outdoor areas, and drinking water facilities/distribution systems and water sources—are listed first, followed by activities specific to subsets of sites categories. Activities that apply only to water systems are listed last.

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4.4.1 Generic Characterization Activities for All Site Categories

- Develop a detailed description and determine the dimensions of physical areas affected. Areas might include (Box 310) urban or rural environments, outdoor environments, enclosed or semi-enclosed structures, and water systems (natural or man-made).
- Estimate the surface area and volume of materials and surfaces (both contents and structure) that may be potentially contaminated. Detailed maps of the facility, area, or water system will be required to categorize completely the various contents and attributes of a contaminated site (LBL, 2004; NRC, 2005, p. 161).

4.4.2 Enclosed and Semi-Enclosed Facilities

- Identify the types of materials and surfaces comprising the structure and its contents. Surfaces generally fall into one of two categories—hard, nonporous (e.g., walls, hard flooring, and metal surfaces) and porous (e.g., ceiling tile, upholstery, and carpet). The presence of soil or other organic material on the surface should be noted because it could decrease the effectiveness of the decontamination method. Furthermore, the composition of treated material needs to be evaluated (i.e., material compatibility) because of the potential for interference with the decontaminant, the possible production of hazardous by-products that remain after treatment, and the potential effects of the decontaminant or its by-products on sensitive equipment.
- Determine potential routes of exposure to the biological agent (e.g., inhalation, or skin contact) that would be unique to the affected site. Part of this evaluation includes assessing the potential spread of contaminant from point of release, collecting information about a facility's HVAC system (Box 310; DHHS, 2002), and identifying transport systems (e.g., buses or trains between terminals in airports) or other transport mechanisms (e.g., wind, water, humans, fomites) that might facilitate the spread of an airborne biological agent (Box 309). Potential reservoirs of contamination that could contribute to exposure route determinations should also be considered. Desktop computers and other objects with internal fans that draw in air might serve as reservoirs in enclosed facilities.

4.4.3 Outdoor Areas

- Document environmental conditions at the site during and after the contamination incident (Box 303). Conditions such as ambient temperature, humidity, exposure to sunlight, cloud cover, wind speed and direction, rate and directional flow of water, and rainfall may all be important information.
- Determine potential routes of exposure to the biological agent (e.g., inhalation, or skin contact) that would be unique to the affected site. Part of this evaluation includes assessing the potential spread of contaminant from point of release. Transport mechanisms to consider are wind, water, vegetation, and animals. Adhesion to people and clothing, transmission from one person to another, and movement associated with transportation and transit vehicles are also potential means of pathogen movement. Environmental reservoirs could include water, soil, damp

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organic materials, fountains, pools, atriums, crawl spaces, plantings, animals, and insects.

- Use mathematical models (e.g., air movement or plume models), if appropriate, to characterize the fate, spread, and transmission of the agent. Models have inherent limitations and require accurate input and parameters to be useful in the remediation process (Allwine et al., 2002; Lee et al., 2002).

4.4.4 Drinking Water Facilities/Distribution Systems and Water Sources

- Obtain a complete and accurate map of all connections and components of the water distribution system.
- Use modeling to identify the potential locations and level of contamination. A variety of models are in use at many water utilities and are available to assist in predicting flow within distribution systems given a variety of conditions. Ultimately, however, it may be necessary to test the accuracy of predictions with tracer studies, following the distribution of nontoxic tracers as they move through a distribution system.
- Measure residual disinfection levels at or near the point of entry, estimate the transit time to the most distant downstream customer (to determine if the agent has already cleared the system), and look for storage vessels that may have greater water age/residence time than the rest of the system.
- Document the physical–chemical characteristics of the water system. Water may have a wide range of physical and chemical characteristics, some of which can impact the persistence or detectability of pathogens or toxins. Factors such as metal ion content, presence or absence of disinfectant residuals, and temperature should be collected if possible.

4.5 Site Containment (Boxes 204, 205, 304)

Containment (Boxes, 204, 205, and 304) is the set of actions taken to prevent the further spread of a contaminant from a particular area or to prevent its movement within that area. Such actions include:

- Cordoning off any area known or suspected of being contaminated.
- Turning off a facility's HVAC system, if deemed appropriate after considering the specific characteristics of that system (i.e., would shutting down the system decrease exposure to a contaminant that is present in the building?).
- Sealing off all air ducts, windows, doors, conduits, and other vents that might allow contaminants to escape outside a facility.
- Closing valves or segregating stand-alone portions of a water distribution system known to be contaminated (e.g., isolating pressure zones, storage tanks, pump houses, and the like).
- Ensuring site security by establishing procedures to restrict entry of unauthorized personnel (e.g., installing perimeter fencing, posting signs, installing physical barriers, or using guards at all times).
- Establishing standard work zones.

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Site containment should be initiated during first response (Box 204 and 205) and then maintained or expanded during remediation/cleanup (Box 304). For example, in the case of a covert release in an enclosed or semi-enclosed facility, air samplers previously placed throughout the facility should collect data on the presence of biological agents. Once an environmental screening sample is positive for a biological agent (or in the case of an overt release, once a surface sample detects an agent) the immediately-affected area may be evacuated and contained (Box 205).

For outdoor areas, it may be difficult to determine the area contaminated with a biological agent and the boundaries of that contaminated area. For example, a containment decision regarding an incident in which a biological agent is suspected of having been dispersed from an airplane over a wide area would likely require consideration of many factors in addition to environmental sampling. Meteorological data (e.g., wind speed and direction), predictive modeling, data from pre-positioned outdoor samplers (e.g., BioWatch, see Shea and Lister, 2003), and possibly information on the flight pattern of a suspicious aircraft could be useful in informing such a decision.

For drinking water facilities/distribution systems and water sources, water sampling combined with computer modeling of how and where a contaminant may spread through the system would be a practical approach to determine locations that need to be segregated and decontaminated.

Establishing standard work zones at a contaminated site is critical to ensuring that any containment activities and subsequent decontamination activities are safely and effectively conducted. The purpose of work zones is to:

- Reduce the accidental spread of biological agents from contaminated areas to clean areas by natural processes, workers, or equipment.
- Confine work activities to the appropriate areas, thereby minimizing the likelihood of accidental exposures.
- Facilitate the location and evacuation of personnel in case of an emergency.
- Prevent unauthorized personnel from entering controlled areas.

When establishing work zones at a site, the site map may provide a useful format for compiling relevant data. In the absence of sampling results, up-to-date site maps can provide essential information on potential and suspected hazards and potential exposure pathways.

Although a site can be divided into as many zones as necessary to ensure minimal employee exposure to hazardous substances, the three most frequently identified zones are the **Exclusion Zone** ("Hot Zone"), the **Contamination Reduction Zone** ("Warm Zone"), and the **Support Zone** ("Cold Zone") (See Appendix 4 for a detailed description of each zone). In effect, those areas recognized as "cold" have been "cleared" as free from contamination. Movement of personnel and equipment among these zones should be minimized and restricted to specific **access-control points** to prevent cross-contamination. The initial work zones should be monitored through ongoing quality-assurance environmental sampling to determine if the zones are adequate for continued containment of the agent in affected areas and for the safety of workers and other personnel in the immediate vicinity of the release.

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4.6 Risk Communication (Boxes 200, 211)

A Joint Information Center (JIC) should be established immediately (Box 103 and Section 3.3.2) to coordinate all public affairs activities and media releases regarding a biological incident. A Public Information Officer (PIO) who reports to the IC/UC should be appointed to develop and release information (Boxes 200 and 211) about the incident to news media and all agencies and organizations involved.

The PIO establishes information-collection requirements, assists in approving the release of all information, and provides information updates. Multiple phone lines should be provided and staffed by knowledgeable individuals. Other equipment needs for the JIC depend on the size and impact of an incident. Additional guidance can be obtained from the JIC Manual developed by the National Response Team (NRT JIC Manual, 2000, available at [HYPERLINK "http://www.uscg.mil/hq/nsfweb/nsf/onlinedoc.html"]).

4.6.1 Developing a Public Communication Strategy

Every crisis evolves in phases, as shown in Figure 3. Targeted communication relying on good risk communication principles must evolve in synchrony with the aforementioned phases and must be directed toward phase-specific activities. The JIC staff should be familiar with the basic tenets of risk communication and with the unique informational requirements of each phase. The operational requirements of each phase will vary according to the intensity and longevity of a crisis.

The designated Public Information Officer (PIO) must communicate information the public wants and needs to reduce the incidence of illness and death. It is vital that the spokesperson's communications reduce the likelihood that:

- Scarce public health and safety resources might be misallocated (e.g., through pressures arising from incomplete or misinformation).
- Public health and safety recommendations are ignored or circumvented.

Early during an emergency, the PIO should follow good risk communication principles to describe:

- The incident and its magnitude (who, what, where, when, why, and how).
- What we don't know about the incident.
- Health and safety risks for individuals and communities.
- What is being done to respond to the incident (see Appendix 6).
- What actions the public can take.

4.6.2 Pre-Crisis Communication Planning

A risk communication plan should be developed by the JIC and put into in place before a biological incident occurs. Pre-planned messages should anticipate necessary guidance for target audiences and should relay accurate information to address the public's concerns. Additional steps that can be taken in advance of a potential crisis or emergency include:

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- Identifying regulatory organizations, authorities, and guidance documents.
- Identifying stakeholders and interested parties.
- Developing a public communication strategy.
- Establishing points of communication with local, State, and Federal agencies.
- Deciding how to deliver appropriate risk communication messages.
- Assessing demographic data (e.g., communicating with a non-English-speaking population).

4.6.3 Crisis Communication During the First 48 Hours

During the first few days of an incident, it is necessary to quickly assess the potential response level required in terms of crisis communication, to assemble the facts as they become available, and to secure necessary resources to meet the expected buildup of media interest and demand for public information. Tasks during the initial phase of the crisis include:

- Verifying the incident and its magnitude.
- Notifying the chain of command.
- Coordinating with partner organizations.
- Establishing an initial media response.
- Assessing the level of public information and media response required.
- Assigning individuals to liaison with the media, gather information, translate messages into lay language, and execute support tasks.
- Allocating resources.

Additional information on the topic of risk communication is available at [HYPERLINK "http://www.hhs.gov/emergency"] as well as from the CDC's *Crisis and Emergency Risk Communication* (Reynolds, 2002) and in the NRT's document, *Technical Assistance for Anthrax Response* (NRT, 2005). HHS has developed a series of risk communications based messages for use in the first hours of a CBRN incident. These messages address major CBRN events as well as suicide bombs and have been focus-group tested with the public. These messages are available at http://www.bt.cdc.gov/firsthours/

4.7 Characterization Environmental Sampling and Analysis (Box 305)

As explained in Section 4.2, the results of initial screening sampling (Box 205) provide evidence to confirm or reject a *preliminary* hypothesis concerning the distribution and nature of a contaminant, and to inform preliminary public health decisions and actions. Further initial environmental sampling may be conducted to inform potential exposure pathways and identify who may have been exposed (Box 208). More in-depth characterization environmental sampling and analysis (Box 305) is conducted to determine the appropriate public health response and provide input concerning further remediation actions. Thus, during the characterization phase, further hypotheses about the location of contamination are tested by data collection, including environmental characterization sampling. Analysis of the results of such sampling facilitates evaluation of each hypothesis and allows for the development of more advanced hypotheses for

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improved characterization. It is important to note that most current sampling and analytical methods for biological agents are non- or semi-quantitative.

If desired, the IC/UC may appoint an advisory panel of multidisciplinary experts, called a Technical Working Group (TWG), to help develop a Sampling and Analysis Plan (SAP), a Remediation Action Plan (RAP), and other planning documents. As described in Section 4.19, the IC/UC may also form an Environmental Clearance Committee (ECC) of independent experts to review and evaluate relevant clearance data and recommend whether the remediation should be judged successful. State and local planners should ideally identify ECC members as part of their advance planning process for biological incidents and select members who are knowledgeable about regional issues. The ECC will interact early on with the TWG group to a limited extent to be informed of the characterization environmental sampling and the decontamination approaches recommended by the TWG.

A characterization environmental sampling plan should be designed to minimize health risks to the sampling team by minimizing the time spent in the contaminated area. The sampling plan should specify the minimum number of samples needed to provide adequate characterization given the resources available at that time. An additional constraint on sample number is the capacity of laboratory support for sample processing and analysis. Activities such as maintaining chain of custody, archiving, and complicated processing and manipulation of samples may limit the rate and maximum number of samples that can be processed and analyzed to far fewer than what might be predicted from the analytical capacity of a laboratory. Sampling strategies will be site-specific and are determined by the contaminant, presumed level of contamination, location of contamination, and other factors.

Standardized formats for characterization sampling methods and hypothesis testing are not currently available for every condition (e.g., sampling for a particular biological agent on a particular type of surface or environmental matrix). However, a wealth of general information on sampling (Buttner et al., 2004; CDC, 2002; EPA, 2002b; Estill et al., 2009; Hodges et al., 2010; Rose et al., 2011) and analysis is available to guide implementation. Most hypotheses will center on one or two possible notions. For example: (1) contamination is not widespread, and (2) the contamination will have one or more areas of maximum concentration and some distribution, with a gradient of decreasing contamination away from the contaminated zones. Once the hypotheses are formulated and tested—and after the spatial distribution, environmental persistence, and concentration of contamination are better understood—a plan for decontamination can be formulated.

All of the above elements are incorporated into a Characterization Environmental SAP. The Characterization SAP articulates an overall strategy specific to the contaminated site, lists the methods and tools to be employed (e.g., environmental sampling, sampling of animals, and use of tracer studies), and describes how the tools will be applied to implement the strategy. For example, the overall strategy might be to use wipe samples in a targeted area at the suspected point of release of biological agent, along pathways where the agent may have been tracked, and at air-intake vents nearby. From these samples, the locations and amounts of the contaminant can generally be determined. In an interior space, the strategy might include modeling and tracer studies of airflow through the HVAC system and the affected area to determine other possible locations that need to be sampled. In an outdoor space, the strategy might include sampling animals in the area or sampling on unweathered surfaces of vegetation. In a water distribution system, the strategy might include modeling and tracer studies of flow in the distribution system.

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In describing how the tools will be applied, the SAP defines the sampling zones and sampling units; specifies the number and type of samples to be taken in each sampling unit; specifies locations for each type of sample; and describes how samples will be collected, packaged, and transported to the laboratory for analysis. The Characterization SAP also lists the laboratory or laboratories that will analyze samples; the laboratory procedures and protocols that will be followed in handling, processing, and analyzing samples; the laboratory's quality-assurance procedures; and how the laboratory will document and report the results.

Many pieces of information concerning environmental sampling are critical when determining the associated risk. However, some of the information can be difficult to obtain during an incident. In such cases, first approximations or conservative estimates are used. For example, the absolute limit of detection of a sampling-and-analysis method on a given surface for a particular biological agent may never be known because methods are best tested under controlled conditions. In addition, many factors— including humidity, light, temperature, roughness of a surface, pH, and other variables—may affect the resulting analysis (sampling efficiency, extraction of biological agents from a sample collection matrix, or detection in a given assay format). In some cases, internal controls can be used during sampling, processing, and analysis to gauge the performance of detection methods; however, they do not absolutely guarantee an accurate understanding of biological agent levels.

One important aspect of environmental sampling is to collect samples at locations where the biological agent is not detected. The lack of detection is not a guarantee that the agent is not present; rather, it means that the biological agent may be present at or below the limit of detection. Individuals who are unfamiliar with environmental sampling sometimes misinterpret the meaning of the inability to detect a contaminant or negative (nonreactive) assay results. A classic definition of a detection limit is that the method will detect a biological agent at a particular concentration in a defined test protocol some proportion (generally 95%) of the time. This means that at least some times (5% of the time in this example), the presence of the biological agent at the detection limit will result in failure to detect that agent. Many other factors can explain the inability to detect a biological agent. For example, failure to detect can arise from:

- A fault or inconsistency in the application of a protocol.
- Success of the decontamination effort.
- Natural variation in sampling technique.
- A matrix component that interferes with the assay.
- A change in state of contaminant (e.g., loss of a plasmid necessary for detection).
- Assay limitations.
- Actual absence of the biological agent.

A negative assay result for an environmental sample is simply the lack of ability to detect a biological agent, and such a result may not necessarily indicate the absence of target organisms.

The ultimate mass of material or number of organisms released may not be discernable through environmental analysis, or may only become known after the individuals releasing the material are captured and interrogated. It may be possible to estimate the amount of material in a particular release, or to place an upper bound on this number based on the delivery mechanism. However, such information will likely be unavailable during remediation of the affected site.

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The physical and chemical properties of the agent and its subsequent interaction with the environment (e.g., settling, attraction to surfaces, and agglomeration to other materials) also may not be known. Furthermore, most of the bulk material in a recognized, intentional incident will likely have been removed from the scene by law enforcement personnel, and some information about the material (e.g., additives, milling, and delivery systems) may be prosecution-sensitive. This means that the information may be missing from the data sets used to construct remediation plans.

In spite of these possible unknowns, with a good environmental SAP, Hot Zones and contamination gradients (including areas where the contaminant was not detected) can be determined and used to help guide the remediation effort. Even though underlying uncertainties in sampling methodologies are likely, scientifically based decisions can be made.

4.8 Risk Assessment (Box 306)

As part of the risk management paradigm described in Section 3.1, potential risks posed by a biological agent at a specific site need to be assessed to assist decision making about setting clearance goals (Section 4.9), formulating a decontamination strategy (Section 4.10), and developing a RAP (Section 4.11). As previously described, the four basic components of risk assessment are hazard identification, dose-response assessment, exposure assessment, and risk characterization. The overall goal for site-specific environmental risk assessment (Box 306) is to collect and evaluate all relevant information about the biological agent, its characteristics, and potential or measured exposure, and then provide to the decision-maker a scientifically reliable, quantitative or qualitative estimate of the potential level of risk to humans, animals, or the environment.

As discussed in Section 4.3, the identity and characteristics of a biological agent that has been confirmed to be present at a particular site are essential for hazard assessment. Among the most important characteristics to ascertain are the length of time the agent can survive in the contaminated setting (persistence), whether the agent is present in a form that easily disperses, likely routes of exposure, and the degree of resistance to inactivation.

A dose-response assessment is usually based on a review of available animal toxicology and/or human epidemiological data and medical incidence data. Any available data on the specific biological agent of concern needs to be collected and evaluated to ascertain whether a dose-response relation (i.e., an infectious dose) can be established. It is important to remember that infectious dose estimates rely on a "denominator" population. Frequently cited infectious doses are ID_{50}, which is the number of organisms that would cause illness in 50% of the population that was exposed. A minimum infectious dose is the smallest number of organisms administered to an individual (animal), or calculated to have been present in an exposure in a epidemiological study, that resulted in illness in at least one individual; animals or individuals exposed to less than this dose did not become ill in that population. Any given individual exposed to a number of organisms less than the established minimum infectious dose still may become infected if that individual is more susceptible than those in the study population, the exposure mechanism is different (i.e., inhaled in an aerosol versus by nasal lavage), or the organisms are more virulent (either a different strain or prepared with virulence-enhancing materials). The statistical power of many calculated minimum infectious dose studies may also be very small and these calculated doses cannot be extrapolated with known confidence to larger populations.

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Although infectious dose can be useful in qualitatively estimating human health effects, and such information is useful to set preliminary clearance goals, these data depend on the precise conditions present in the study from which the data were generated, and the information may not be directly applicable to the situation at hand. Furthermore, a recent review by the NRC concluded that infectious doses for pathogenic biological agents cannot be determined with confidence because the infectivity and virulence of pathogens can vary by strain, within species, and by the type of preparation used (NRC, 2005). Therefore, available information on infectious dose should not be over-interpreted. Nevertheless, infectious dose and related data are available for biological agents from various sources (USAMRIID, 2005; EPA, 2006; CDC, 1999).

A site-specific exposure assessment is performed by integrating the results of first response screening and assessment (Section 4.2 and Box 205), initial environmental sampling (Section 4.2 and Box 208), characterization of the site (Section 4.4 and Boxes 302–303), and characterization environmental sampling (Section 4.7 and Box 305). Sampling data may also be used to document the locations and levels (if quantitative analyses were performed) of biological agent, and site characterization gives an indication of site structure, the presence of conditions that can spread an agent, and the types of items and environmental matrices at the site. Modeling can also be performed to assess the potential movement of biological agent from one location to another.

For chemical agents and biological toxins, site-specific risk characterization is usually performed by combining the dose-response assessment with the exposure assessment to generate quantitative estimates of the degree of risk that a contaminant may pose to humans or other susceptible species. However, in the case of most biological pathogens, because of the difficulties surrounding infectious doses, the exposure and other risk factors, it is unlikely that a *quantitative* risk characterization can be developed. Nonetheless, a *qualitative* risk characterization still has significant value and needs to be provided to decision-makers. Such a characterization is instrumental in helping decision-makers determine clearance goals and a decontamination strategy. For example, a risk characterization that concludes that the biological agent at a particular site is persistent, easily aerosolizes, and presents a significant risk of disease to humans via inhalation would likely drive the selection of stringent clearance goals and an aggressive decontamination strategy.

4.9 Clearance Goals (Boxes 307, 308, 312, 315, 316)

There is no simple formula for setting clearance goals (Box 307) as part of the risk assessment process (Box 306). The collective, professional judgment of technical experts described in Section 3.2, applied within the context of the concerns of stakeholders, should be used to set clearance goals (Raber et al., 2001) appropriate to the site-specific circumstances (Box 307). The goals may also be influenced by national security, economic, sociological and psychological considerations, available resources, and potentially competing remediation priorities (e.g., in the event of multiple attacks). In cases where contamination is extensive, intermediate goals may be set, complemented by other interventions (Boxes 315, 316), such as prophylaxis, shelter-in-place advisories, administrative controls, medical monitoring, PPE, and other ESF #6 mass-care considerations (see ESF #6 at [HYPERLINK "http://www.nmfi.org/natlresp/files/ESF6.pdf"]). There may also be separate clearance goals for different locations within a single site. This may happen if the area is sufficiently large and complex to contain variation in terms of parameters such as naturally-occurring background or factors which influence sampling or analysis.

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Fortunately, for most pathogens, the passage of a short time may be sufficient to reduce or dispense with the need for decontamination because many agents do not survive for long in the environment (Box 308). However, certain toxins such as T-2 mycotoxin, and persistent pathogens such as *Bacillus anthracis* spores, pose long-term remediation challenges, as do organisms that have been genetically modified or formulated to be more persistent. Moreover, although certain contaminants are not considered particularly persistent, under appropriate conditions they may persist for days, months, or even years. The risk assessment activities previously described provide the information on which clearance goals will be based.

Risk management considerations, such as potential use of public health interventions, cost and feasibility of available decontamination options, past experience in similar situations, the public's perception of an acceptable level of risk, and regulatory and stakeholder needs (Box 312) also factor into determining the clearance goal. For example, if an epidemiological investigation suggests that an agent was present in a specific area, but no agent can be detected using currently available sampling methods, then a risk management decision may be made to use an effective decontaminant, thus providing some assurance to the public that health risk has been reduced as much as possible.

Setting realistic, site-specific clearance goals should be based on the results of the best possible risk assessments, careful consideration of scientific uncertainties, use of proven technologies wherever possible, verification of decontamination effectiveness, and strong stakeholder involvement throughout the decision-making process. A practical clearance goal is to reduce residual risk (Canter, 2005) to levels that the IC/UC, in coordination with the appropriate authorities, deems consistent with the terms of the risk management principles and the optimization process described in Chapter 3. The aim of such a process is to reduce exposure levels as low as is reasonable while considering potential future land uses, technical feasibility, costs and cost effectiveness, and public acceptability.

4.10 Decontamination Strategy (Boxes 400–404)

The IC/UC develops an overall decontamination strategy (Boxes 400–404) that will guide the development and execution of all remediation activities. The strategy is based on agent- and incident-specific information, such as the following:

- Identity, formulation, and key characteristics of the biological agent (e.g., agent species and subspecies, environmental persistence, and ability to aerosolize).
- Mode of delivery of the biological agent and nature and extent of its spread.
- Results of environmental sampling, including agent location and quantities.
- Epidemiological evidence (human disease cases) and what it shows (e.g., inhalational versus dermal route of exposure).
- Health risks posed by the biological agent.
- Nature of site or items to be decontaminated (Box 310, i.e., an entire facility or just one area within a facility; outdoor environment—rural or urban; an individual water tank or entire multi-jurisdiction metropolitan water distribution system).
- Acute and chronic toxicities of chemical(s) to be used in the decontamination process.
- Public perception, such as acceptance of the process by the public.
- Environmental concerns, such as potential by-products, air emissions, residues, and disinfection by-products.
- Valid test data demonstrating the efficacy of selected decontamination process.

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- Conditions required for effective application of a decontamination process (e.g., specified ranges of relative humidity, temperature, fumigant concentration, and contact time for fumigations, or pH for certain surface treatments).
- Timeframe of the process and associated costs.
- Potential collateral damage caused by the decontamination process (i.e., effects of the process on building infrastructure or equipment).

Considering all relevant information, an overall decontamination strategy is developed and articulated in the RAP. For example, if anthrax spores were delivered to or passed through a mailroom in a letter, and if environmental samples are collected that test positive, and if medical evidence of inhalation exposure is available (e.g., data indicate aerosolizability of spores, or persons exhibit symptoms of inhalational anthrax), then a strategy of decontamination with a gas or vapor fumigant preceded by pre-cleaning of surfaces with a liquid antimicrobial pesticide in heavily contaminated areas may be indicated. As another example, in the case of a contaminated drinking water system, different strategies such as the following could be considered: (a) continue to treat the water by conventional disinfection, (b) increase the level of disinfection for all or part of the system, or (c) issue end-of-pipe treatment devices such as a community supply purification system.

The overall goal of the decontamination strategy should be to achieve the clearance goals while minimizing resources, cost, and time. Such a strategy requires optimizing the balance among source reduction (Section 4.14), waste disposal (Section 4.15), decontamination (Section 4.16), and decontamination verification (Section 4.17) activities.

4.11 Remediation Action Plan (Box 406)

Once a decontamination strategy is developed, a RAP is assembled that spells out an overall plan for decontaminating the contaminated site and its contents (Box 406). The RAP and Clearance SAP (Section 4.18) are generally created at about the same time because the remediation strategy can directly affect characterization and clearance sampling strategies. For example, if contamination is limited to a specific room, and the overall remediation strategy is to treat only the surfaces with a liquid decontamination agent, then the sampling strategy may be to conduct clearance environmental sampling focused on that room and to conduct random/grid samples in rooms that are adjacent or connected by a common HVAC system. The RAP generally includes the following sections, each of which is described elsewhere in this chapter:

- Containment (Box 304).
- Characterization of the biological agent and site, including characterization environmental sampling strategy and results (Box 305).
- Worker safety and health and decontamination (Box 316, 403).
- Clearance goals (Box 307).
- Site preparation (Box 401).
- Source reduction (Box 402).
- Waste disposal (Box 405).
- Decontamination of affected sites (Box 407).
- Offsite decontamination of essential items (Box 404).
- Decontamination verification (Box 408).
- Clearance environmental sampling and analysis plan summary (Box 406).
- Clearance decision-making criteria (Box 406).

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The RAP contains appropriate tables, figures, drawings, references, and appendices of key information from other documents, such as procedures and methods used in the remediation process and the characterization environmental sampling report.

Because the RAP specifies how the remediation activities will be carried out, the IC/UC, in coordination with the appropriate State/local authorities, needs to approve the plan before it is implemented. The IC/UC in coordination with the appropriate State/local authorities must also approve any changes to the RAP as the remediation process progresses. Finally, if any Federal or State agencies have jurisdiction over some or all activities described in the RAP, they should review and approve the RAP as well. For example, the EPA has statutory responsibility under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for registering (licensing) or exempting from registration the sale and use of antimicrobial and other pesticide products in the US (7 U.S.C. 136-136y). Because no antimicrobial pesticide is currently registered by the EPA specifically for the inactivation of *Bacillus anthracis* spores, a Federal or State agency will need to check with EPA about obtaining an emergency exemption from EPA for each specific use of a selected antimicrobial pesticide to decontaminate a facility. EPA has the authority to issue such exemptions (FIFRA section 18) when emergency conditions exist. Most exemptions require an application and quick review from EPA before they can be issued. However, where the discovery of an emergency condition and the need to use a pesticide require quicker action than this would allow, EPA would expect to issue a crisis exemption. After the 2001 bioterrorist attacks, crisis exemptions were issued to permit the sale and use of several antimicrobial pesticides to decontaminate sites, and essential items were removed from the sites and treated in offsite locations, following review and approval of site-specific RAPs.

4.12 Worker Health and Safety (Box 403)

Health and safety requirements must be addressed (Box 403) for all workers involved in the response and recovery following a biological attack. Workers include emergency responders, such as emergency medical personnel, police, firefighters, responders from government agencies, public health officials and volunteers, and those critical workers that may need to report to maintain critical infrastructure and key resources (power, healthcare, etc.). Short- and long-term remediation and restoration workers are also included (e.g., workers from government agencies, decontamination contractors, and employees at the contaminated facility).

The OSHA HAZWOPER standard (29 CFR 1910.120 and 29 CFR 1926.65) applies to each employer of the involved workers. For first/emergency response and remediation operations, this standard requires a written Health and Safety Plan (HASP) that identifies site hazards and appropriate controls to protect employee health and safety. All site hazards should be incorporated into the HASP, including physical, biological, and chemical hazards, as well as any hazards associated with decontamination agents used during remediation. Required elements of the HASP are described in the HAZWOPER standard and include the following:

- Organizational structure.
- Comprehensive workplan.
- Site characterization and job-hazard analysis.
- Engineering and work practice controls
- Site control.
- Training.
- Medical surveillance.

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- PPE.
- Exposure monitoring.
- Spill containment.
- Decontamination.
- Emergency response.
- Standard operating procedures for safety and health.

A site-specific HASP promotes efficiency and enhances completeness, clarity, and coordination among all affected parties. The HASP is a living document that is revised as necessary to reflect changes in site conditions or operations. Because some elements overlap, it may be useful to expand the HASP to include those elements necessary to protect the local community and environment (e.g., disposal of waste from decontamination or monitoring community exposures to fumigants). Additional written programs, plans, or procedures may also be necessary to meet the requirements of other applicable OSHA standards. For example, employees will likely need to use PPE during emergency response and remediation. Pursuant to 29 CFR 1910.132, employers will need to assess the workplace to determine whether and what PPE is necessary to protect workers. In addition, employers will need select appropriate equipment, ensure that it properly fits the workers and train each worker in its use. Moreover, employees will likely need to use respiratory protection during facility decontamination, so a written Respiratory Protection Program also is required in accordance with 29 CFR 1910.134.

Additional OSHA general industry and construction standards may also apply (29 CFR 1910 and 1926). For more information regarding health and safety considerations and OSHA requirements, refer to [HYPERLINK "http://www.osha.gov"]. Additional helpful resources include the following:

- Anthrax eTool (OSHA): [HYPERLINK "http://www.osha.gov/SLTC/etools/anthrax/index.html"]
- *Model Health and Safety Plan (HASP) for Cleanup of Facilities Contaminated with Anthrax Spores* (OSHA): [HYPERLINK "http://www.osha.gov/dep/anthrax/hasp/index.html"]
- *Safety and Health Topics: Bioterrorism* (OSHA): [HYPERLINK "http://www.osha.gov/SLTC/bioterrorism/index.html"]
- *Technical Assistance for Anthrax Response* (November 2003), Chapter 5: Health and Safety Considerations (NRT): [HYPERLINK "http://www.nrt.org"]
- Safety and Health Topics web page on *Biological Agents*: [HYPERLINK "http://www.osha.gov/LSTC/biologicalagents/index.html"]
- *Interim Recommendations for Firefighters & Other First Responders for the Selection & Use of Protective Clothing & Respirators Against Biological Agents* (CDC, October 25, 2001): [HYPERLINK "http://emergency.cdc.gov/documentsapp/Anthrax/Protective/10242001Protect.asp"]
- *Interim Recommendations for the Selection and Use of Protective Clothing and Respirators Against Biological Agents* (CDC, October 2001): [HYPERLINK "http://www.bt.cdc.gov/DocumentsApp/Anthrax/Protective/10242001Protect.asp"]
- *Guide for the Selection of Personal Protection Equipment for Emergency First Responders* National Institute of Justice (NIJ) Guide 102-00 (November 2002): [HYPERLINK "http://www.ojp.usdoj.gov/nij/pubs-sum/191518.htm"]

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- *Technical Assistance for Anthrax Response - Interim-Final Draft* (National Response Team (NRT), July 2005)
- [HYPERLINK "file:///D:\\Documents%20and%20Settings\\tod.companion\\SDST\\bio%20doc%20versions\\Anthrax%20in%20the%20Workplace%20Risk%20Reduction%20Matrix"] (OSHA): [HYPERLINK "http://www.osha.gov/dep/anthrax/matrix/index.html"]
- Anthrax eTool "Protecting the Worksite against terrorism" (OSHA): [HYPERLINK "http://www.osha.gov/SLTC/etools/anthrax/index.html"]

Some workers will also be involved in the delivery of medical countermeasures. Mail carriers, their security escorts, traditional first responders, and certain personnel working in critical capacities are expected to be working during the first 24 to 48 hours of the response. Separate guidance is currently being developed to address the protection of these responders.

As described in Section 4.5, workers who enter the Hot Zone must wear appropriate PPE, be provided with any recommended medical countermeasures (i.e., antibiotics, antivirals, and vaccines), and be provided with any other forms of preventive care recommended at the time of the response. When exiting a contaminated work area, response personnel and their equipment must be decontaminated. Decontamination of workers in the Warm Zone ensures that they are not contaminated while removing their PPE by materials that they may have contacted in the Hot Zone, and that they do not track contamination into clean areas of the site (Cold Zone). Such procedures can include the following:

- Mechanical decontamination (washing with soap and water to physically remove a potential contaminant) is typically used on workers.
- Chemical decontamination (applying disinfectants or sterilants to inactivate the biological agent) is typically used on PPE or nonsensitive equipment. As described in Section 4.16, only antimicrobial pesticides authorized specifically for the specific biological agent involved should be used.

Procedures for decontaminating equipment are provided in Appendix 5.

4.13 Site Preparation (Boxes 403–404)

Before decontamination methods specified in the RAP can be applied, the site and its contents need to be prepared for the remediation (or cleanup) process. Such preparation can cover a multitude of tasks (Boxes 403–404), such as:

- Assembling a worker decontamination unit.
- Testing a facility for leaks.
- Constructing internal waste-processing and load-out units.
- Installing and testing chemical generation systems.
- Installing and testing chemical, temperature, and humidity monitoring systems.
- Installing and testing negative air units and air scrubbing systems.
- Subdividing existing space with temporary walls.

Where fumigations are performed, some specialized site-preparation tasks may need to be carefully planned, implemented and documented. This preparation may also require some on-site testing prior to full implementation, in some circumstances. Once all components of the decontamination and monitoring system are shown to work independently, some testing may be

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necessary to demonstrate that they all work together as a system. For example, a low-level performance test may be conducted prior to a large fumigation, which includes the scrubbing system, to show that the system as a whole will likely work when run at full capacity.

Site preparation for a water-distribution system may include isolation of various segments and infrastructure devices. It may also include such activities as installing backflow-prevention devices to prevent recontamination of disinfected distribution system segments. Certain distribution system components, such as pressurization and storage tanks, may be drained. Provisions may need to be made for installing additional equipment and to maintain system operations and pressure as various critical system segments are taken off line. Replacement water may need to be provided to critical operations. If protocols such as relining pipes, or aggressive flushing are to be used, supplies must be obtained, and the protocols must be tested to ensure safety and efficacy.

4.14 Source Reduction (Boxes 401–402)

Source reduction (Boxes 401-402) is the process of removing certain items and/or materials from a contaminated site for further treatment and reuse or disposal, of cleaning items remaining on site prior to the main decontamination activity, and of cleaning surfaces. The decision about whether source reduction is needed is made on a case-by-case basis (i.e., considering whether decontamination can be done leaving articles in place). In some cases, source reduction could take place early in the response and recovery process and long before the decontamination phase is underway. If source reduction is performed, the goals are to:

- Reduce the number of potentially contaminated items and/or materials present.
- Ensure that any material that might inhibit decontamination is removed.
- Reduce high levels of contamination before full decontamination, if considered necessary based upon the strategy.

As part of the source reduction process, items to be removed from the site are pre-treated, as appropriate (e.g., essential items to be sent for treatment in ethylene oxide sterilization chambers are not pretreated with diluted bleach), and placed in packaging specified by the Department of Transportation and State and local governments. The packaging is also treated, usually with a 1:10 dilution of pH-adjusted bleach. The packages are then removed from the facility and transported (Box 404) to the appropriate offsite facility for disposal, treatment and disposal (Box 405), recycling, or reuse, depending on the nature of the items.

Exposed surfaces and items remaining in the site may be cleaned by HEPA vacuuming, scrubbing, and/or washing to physically remove dirt, grease, or other inorganic or organic matter, including some potential reduction in the biological agent itself.

Decisions about which items or materials to remove from a contaminated area prior to decontamination depend on many factors, including:

- Sensitivity of essential items to damage by the decontamination chemical.
- Difficulty of decontaminating items onsite (e.g., paper and other porous items).
- Potential for items to absorb or deactivate the decontamination chemical.
- Potential for toxic residues to remain on or in items after treatment.
- Value of items compared to the cost of treatment.

Items or materials that are to be removed can be grouped into the following categories:

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- Essential or sensitive items that must be removed, decontaminated elsewhere, and saved or restored for reuse (e.g., art works and valuable papers).
- Items or materials that can be removed, treated elsewhere, and destroyed (e.g., site debris).
- Items or materials that can be removed, treated elsewhere, and recycled (e.g., metals).
- Items or materials that can be treated and cleared onsite, then sent offsite for recycling (e.g., batteries and fluorescent lights).

Once decisions about the fate of items or materials are made, the source reduction activities are incorporated into the RAP and carried out as specified.

The parallel concept of source reduction in water distribution systems is flushing of water to waste. Such action should reduce the amount of contaminated water, and the flushing action should help to remove contaminants within pipes. The fate of potentially contaminated water must be predetermined before flushing decisions are made.

4.15 Waste Disposal (Box 405)

As part of source reduction, decisions are made about what to do with materials or items to be removed permanently from the site. In addition to such wastes, other wastes are created by decontamination processes, such as water used to rinse PPE, employee shower water, and scrubber wastewater.

A major issue for all types of waste is finding waste disposal sites and/or treatment facilities that will accept either treated or untreated wastes (Box 405). A few facilities have medical-waste incinerators capable of handling sizable quantities of untreated medical waste. Because of uncertainties and negative public perceptions about health risks associated with biological agents, nonmedical waste disposal sites may refuse to accept treated wastes, even if the waste has been shown by sampling not to be contaminated. Nonetheless, to the extent feasible, wastes should be decontaminated on-site in order to minimize the need to transport, treat, and dispose of contaminated wastes off-site.

Although source reduction is generally completed before the main decontamination activity, waste disposal continues until the end of decontamination because of the continuing production of wastewater and other consumables used by onsite workers. Waste is removed from the facility throughout the entire remediation process and transported to an appropriate offsite facility, depending on the nature of the waste. Information on methods of disposal of biologically contaminated waste can be found at: [HYPERLINK "http://www2.ergweb.com/bdrtool/login.asp"] (Thorneloe 2007).

Wastewater collection and treatment facilities are typically designed to accommodate pathogenic microorganisms. There are, however, circumstances under which a specific wastewater treatment system may not be able to handle wastewater from a particular contamination incident. For example, a rapid influx of a large volume of water, particularly if contaminated with a large quantity of a persistent agent, may challenge a wastewater system beyond its capacity. Many communities have combined waste and storm water collection and treatment systems. Some of these systems maintain combined storm sewer overflow. In the case of a storm water runoff event, or perhaps a large-scale flushing, the system will allow the overflow that exceeds the capacity of the wastewater treatment plant to run directly into receiving rivers or streams. In a biological incident, the potential for environmental contamination, through this and other routes,

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must be evaluated. The safety of wastewater treatment system workers must also be considered in these decisions. In addition, the wastewater treatment authority must grant permission for the discharge of wastewater into its system.

4.16 Decontamination of Sites or Items (Box 407)

Once a determination is made that decontamination of any kind is necessary to mitigate a biological agent, the most appropriate decontamination method(s) for the biological agent and affected site and its contents needs to be evaluated and selected (Box 403). A wide array of physical and chemical (antimicrobial) decontamination methods for mitigating biological agents is available for consideration. Physical decontamination either inactivates the agent through physical means, such as heat or radiation, or removes the agent, such as by washing with soap and water or vacuuming with a HEPA filter. Chemical decontamination inactivates the agent through the use of antimicrobial disinfectants or sterilants.

Current technologies for chemical (antimicrobial) decontamination fall into three categories: liquids, foams and gels, and gases and vapors (Fitch et al., 2003 and references therein). Because no single technology is applicable in all situations, the determination to use a particular method is made on a site-specific basis. Liquids are effective against many biological agents when applied to hard, nonporous surfaces, but they can cause corrosion to sensitive equipment. Foams and gels are effective against certain biological contaminants, but some can pose a post-decontamination cleanup issue. Gases and vapor fumigants are effective for inactivation of biological agents under controlled environments and conditions, but they involve complex operations. Certain gas-phase water disinfection systems involve the generation of gas onsite, using chemical or electrochemical processes that offer some advantages in terms of removing the requirement for storage of compressed gases. Difficulties with some such systems include measuring the efficiency of the gas-producing reaction, and establishing that the required contact time and concentration gradients are achieved. Appendix 7 lists some key characteristics of liquid, gas, and vapor chemicals that have been used under FIFRA crisis exemptions to inactivate *Bacillus anthracis* spores in contaminated facilities.

Although many different technologies are available for decontaminating surfaces, enclosed spaces, and water, each has advantages, disadvantages, and limitations when considering the agent and material(s) being decontaminated. No single technology, process, or strategy is effective in every case because decontaminating an area or item contaminated by a biological agent involves numerous and variable issues that are site-specific (Hawley and Kozlovac, 2004; OSHA Anthrax E-tool, 2002; Canter et al., 2005);) also available at [HYPERLINK "file:///D:\\Documents%20and%20Settings\\tod.companion\\Local%20Settings\\Temporary%20Internet%20Files\\Content.Outlook\\LET9QJ1H\\www.epa.gov\\nhsrc\\dcm.htm"].

Deciding which decontamination methods to use requires a rigorous evaluation of available methods and consideration of safety, efficacy, cost, and other factors. Following a detailed analysis, and taking into account site-specific details, the IC/UC selects the decontamination method or combination of methods most appropriate to remediate the contaminated site and its contents.

Key considerations for selecting one or more decontamination method(s) includes the following:

Safety

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- Adequacy of site containment.
- Physical-chemical properties (e.g., explosivity or sensitivity to ultraviolet light) of the antimicrobial pesticide and potential formation of hazardous degradates.
- Toxicological characteristics and potential risks to humans of the antimicrobial pesticide and its potential chemical degradates.
- Persistence of the antimicrobial pesticide and degradates.
- Penetration capability of the antimicrobial pesticide.
- Exposure limits applicable to workers in the general population [e.g., Permissible Exposure Limit (PEL), Threshold Limit Value (TLV), and Short Term Exposure Limit (STEL)] of the antimicrobial pesticide.

Efficacy

- History of use in similar decontamination processes.
- Penetration capability of decontaminating agent.
- Availability of acceptable efficacy data.
- Registration and exemption history under FIFRA.
- Capacity of the gas or vapor generation system.
- Methods for evaluating the efficacy of the antimicrobial pesticide (e.g., spore strips and environmental samples).

Generation, Distribution, Monitoring, and Removal

- Mode and capacity of generation of antimicrobial pesticide (i.e., available and ready-to-use versus generation onsite).
- Equipment and chemicals needed to generate and distribute gases, liquids, foams, gels, or vapors.
- Methods for preventing accidental release of decontaminant beyond the area to be decontaminated (e.g., HEPA filters on negative air vents or scrubbers) and to detect or monitor such releases.
- Equipment and methods needed to sample and monitor gas or vapor decontaminant concentrations, temperature, relative humidity, and other parameters required to ensure effective decontamination and that exposure limits are not exceeded for workers or the general public.
- Waste materials created (e.g., wastewater).
- Capacity of the decontamination generation and distribution system.
- Removal or deactivation of residual decontaminant and decontaminant byproducts after decontamination.
- Structure and operation of a facility's HVAC system.

Cost and Timeframe

- Materials (e.g., unit cost and quantity of chemicals needed).
- Equipment for generation, distribution, monitoring, and removal activities; PPE; packaging and containers for removed items and trash; wastewater disposal and treatment costs.
- Labor for planning, constructing, testing, operating, and dismantling equipment and materials.
- Indemnification agreements, if needed.
- Timeframe to set up, perform decontamination, and remove equipment.

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Various safety measures may be employed during decontamination. These include, but are not limited to, ambient air monitoring near the building and in nearby neighborhoods to detect any escape of decontaminant; having police, rescue workers, and other staff on standby in the event of a catastrophic release of decontaminant or other emergency condition; and precautionary evacuation of nearby businesses or residences, where appropriate.

After the decontamination strategy and methods are selected, the IC/UC must ensure that the products are approved for the target biological agent, which could be either a biotoxin or a pathogenic microorganism. Products used against biotoxins are not Federally regulated, but any substance intended to prevent, destroy, or mitigate any virus, bacteria, fungi, or other microorganisms that are not in or on living man or animals are required by FIFRA, as amended, to be either registered or exempted prior to sale, distribution, and use. If the products selected are not registered for inactivating the specific target microorganism, the IC/UC must consult with the EPA to determine the requirements. Once approval is obtained to use the requested antimicrobial pesticide(s), the site is prepared, source reduction occurs, and decontamination methods are applied (Box 407) according to specific use directions to ensure that the methods are effective against the target pathogen and do not cause adverse effects to human health or the environment. Depending on the specific situation, State and local regulations may also affect the selection and use of particular decontamination strategies (section 4.11 above).

4.17 Decontamination Verification (Box 408)

Decontamination processes are monitored as they are being carried out and then evaluated as to whether they have been conducted according to the specified parameters (Box 408). To be effective, liquid antimicrobial pesticides applied to hard, nonporous surfaces must be applied at a specific concentration, temperature, and contact time. Accordingly, the product must be mixed to the specified use-dilution concentration, the appropriate temperature (normally 20° C) maintained, and the minimum contact time achieved. When these parameters have been met, the decontamination with the liquid antimicrobial pesticide can be judged as likely to have been successful.

For gaseous or vaporized antimicrobial pesticides, four parameters are key to their efficacy--temperature, relative humidity, chemical concentration, and contact time. These parameters are monitored and recorded for each of the four phases of the fumigation process—(de)humidification, conditioning, decontamination, and aeration. Maintaining these variables in the prescribed ranges throughout fumigation is one indicator of the efficacy of the process.

Biological indicators (BI) contain nonpathogenic (surrogate) spores that are selected to be generally more difficult to inactivate than virulent species of spores. A variety of spore preparations can be used such as *Bacillus atrophaeus* and *Geobacillus stearothermophilus*. Usually, a specific number of viable spores (e.g., one million) is dried on filter paper ("spore strips") or stainless-steel discs ("coupons") contained in a glassine or Tyvek pouch. BIs are used during fumigation to provide a general (but not definitive) indication of whether the fumigation was effective. Because the spores on BIs have in some cases been observed to be easier to inactivate than spores on coupons in sporicidal efficacy tests, the BIs may be more indicative of when fumigation is <u>not</u> effective rather than when it is effective. Thus, in a particular fumigation zone, if one or more BIs are positive by culture after treatment, then that zone would need to be re-treated. In addition, the fact that all BIs are negative would not guarantee that all spores have been inactivated.

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BIs are usually placed in various locations at a frequency of one per 100 square feet of floor space, or as otherwise specified in the Clearance SAP. Placing BIs in locations of known or suspected contamination and in spaces hard to reach by the fumigant is the standard practice. Positive and negative control BIs are also employed. After fumigation is complete, treated and control BIs are sent to an analytical laboratory with demonstrated experience in analyzing BIs from biomedical sterilization and other relevant fumigation processes. They are then incubated by culture to determine spore viability.

When the process parameters are met, and all spores on the BIs have been inactivated, the fumigation can be judged as likely to have been effective. If some BIs are positive, then environmental sampling is performed at locations of the positive BIs; if this sampling is positive, additional treatment of the area is required. However, the overall criterion of the success of the remediation is currently based on an indoor environmental clearance sampling which indicates no growth by culture in any sample, as described in section 4.18.

For decontamination of water, the disinfectant concentration, contact time, and temperature parameters must be met. The parameters may vary as a function of different pH or other water-quality parameters. Water treatment residuals may impact the distribution system's ability to establish or maintain appropriate conditions. Treatment chemicals added to enhance flocculation or used for system-wide softening may interact with disinfectants; thus, disinfectant concentration must be carefully monitored during the decontamination process. Rust, pipe tubercles, rough pipe joints, pumps, biofilm, and other pipe features may provide "sinks" or hiding places for pathogenic microorganisms to escape the effects of decontaminant flowing through a distribution system.

4.18 Clearance Environmental Sampling and Analysis (Box 500)

When all decontamination activities have been conducted (Section 4.16) and verified (Section 4.17), clearance environmental sampling is performed (Box 500). Clearance sampling activities may include aggressive air sampling using blowers to potentially aerosolize any remaining agent, and sampling in any area where residual, viable agent could remain after decontamination (Ferro et al., 2004; LBL, 2004; Rodes et al., 2001; Thatcher and Layton, 1995). Clearance sampling should also be designed to continue testing the hypotheses described for initial environmental sampling in Section 4.2.

The strategy for post-remediation environmental sampling (Box 406) depends on the nature and extent of the contamination, as determined by characterization sampling that was conducted prior to remediation. For example, if characterization sampling indicates heavy contamination in one area, some contamination in the surrounding area, and none in remaining areas, the strategy can implement **targeted** surface sampling for the first area (i.e., taking clearance samples at exactly the same locations where positive samples occurred), **biased** surface sampling in the second area, and **random** surface sampling in the remaining areas. If the contaminant is easily aerosolized, the strategy may also include aggressive air sampling to ensure that some of the contaminant is not still suspended in the air or easily re-suspended. The sampling plan must specify what kinds of samples will be taken and in which exact locations.

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For water distribution systems, collection of water samples throughout the system may be supplemented by collecting water in areas where the flow of water is slowed due to hydrological conditions. Locations such as point-of-use filters and water softeners may act as concentration devices for sampling small amounts of water over time. During remediation activities, it may be possible to physically sample the insides of pipe walls, using swabbing techniques similar to those used for sampling moist, hard surfaces. It should be possible to develop a sampling plan that would contain elements of targeted and biased sampling by coupling an understanding of the epidemiology of a disease outbreak with knowledge of the hydrologic functioning of a water distribution system. This approach should enhance the probability of detecting any residual contaminant beyond a simple, randomized sampling strategy.

Clearance sampling determines whether the remediation was successful (i.e., the clearance goals were met) and persons can be allowed to return to the area without PPE. The objective of clearance sampling is to provide the best available scientific evidence that a biological agent is no longer present at a level that poses a significant risk to human health (Box 501). Generally, the clearance goal (Section 4.9 and Boxes 307 and 406) is developed as part of the SAP, before remediation steps are taken, so that the overall criterion for judging the success of remediation is clear from the beginning of the project. The criterion for success is developed specifically for each site and the specific biological agent involved. The criterion must take into account potential risks associated with the agent (estimated using risk assessment methods described in Section 4.8) and the amount and type of sampling needed to provide a high level of confidence in a decision to declare the remediation successful.

Experience to date in decontaminating various agents at different sites indicates that post-remediation clearance sampling is the primary means of demonstrating the absence of biological agent and, therefore, the success of remediation for enclosed or semi-enclosed facilities. The overall criterion for success of a decontamination process that was used in responding to the 2001 attacks with *Bacillus anthracis* spores is "no growth" on any clearance environmental sample processed by culture. However, there is research underway that may help establish a scientific basis for setting a decontamination goal other than "no growth." Future decisions on decontamination effectiveness also factor in better data on agent characteristics/behavior (both indoors and outdoors), improved sampling strategies, and new methods of exposure and risk assessment.

4.19 Clearance Decision (Boxes 501–508)

The IC/UC, in coordination with the appropriate State and local authorities, ultimately makes a clearance decision based on a judgment as to whether the criteria for decontamination verification and clearance have been met (Boxes 501 and 503). The judgment is based on a thorough analysis of all sampling, process, and other data that are pertinent to the criteria for success, as outlined in the SAP and in the RAP. If desired, the IC/UC may appoint an independent advisory panel of multidisciplinary experts, called an Environmental Clearance Committee (ECC), to review and evaluate relevant clearance data and recommend whether the remediation should be judged successful. The ECC is usually formed early so that it can be informed of and have input into the environmental sampling concepts to be used in developing the SAP. If the IC/UC forms a Technical Working Group (TWG), the ECC will likely interact

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with that group to a limited extent to be informed of the characterization environmental sampling and the decontamination approaches recommended by the TWG. To maintain its independence, the ECC does not participate in the decision-making process for decontamination. After decontamination activities and clearance environmental sampling are completed, the ECC reviews all pertinent data (e.g., fumigation results and characterization and clearance environmental sampling data) and, as an advisory group, provides a recommendation (Box 506) to the IC/UC as to whether remediation has been successful (Boxes 503 and 504) and whether people may re-enter the site (Box 505) without using PPE. The IC/UC then makes a clearance decision in coordination with the responsible local, State, or Federal authority. Public health agencies typically makes the final clearance decision, but with input from the IC/UC.

If after review, the clearance goal(s) that were originally established (Box 307) are judged as unmet (Box 501), or decontamination is deemed unsuccessful, or both, then one or more subsequent decisions must be made. If additional decontamination is deemed necessary (Box 507), other decontamination options could be evaluated (Box 400) and possibly implemented (Box 407), or the same decontamination technology could be repeated, and the clearance decision process repeated. Alternatively, decision-makers may opt to modify the originally specified clearance goal(s) (Box 508), in which case the decision process (commencing with Box 307) would be repeated. Clearly, modified clearance goals would require buy-in by stakeholders and regulators (Box 503), and assurance that long-term environmental and health issues have been addressed (Box 504). The incident command system should also communicate these clearance decisions in the context of the risks involved to all stakeholders.

4.20 Restoration/Reoccupancy (Boxes 600–605)

Site-specific restoration (reoccupancy or transitional) plans, developed in the optimization context (Box 600), will vary dramatically, depending on the extent of potential residual contamination, the amount of renovation necessary to meet local safety codes, or any enhancements deemed appropriate (Box 601). An example of an "enhancement" that has been implemented by the U.S. Postal Service is their Bio-Detection System. Before opening a site to the general public (Box 605), decontamination must be judged successful such that no significant risk exists, even with no "control" action on the part of individuals (e.g., PPE, training, standard operating procedures, or medical surveillance). Risk communication (Box 600) continues as part of the restoration/reoccupancy process. It is also possible that a phased restart of business operations (Box 603) might have been planned in parallel with other response and recovery activities. Such a phased approach may be specified in a Continuity-of-Operations Plan (COOP) (Box 216). This phased approach should also be coupled with appropriate risk communication.

Reoccupancy and reuse criteria (Box 602) described in the recovery plans may require the use of longer-term environmental and public health monitoring (such as air monitoring and health monitoring of workers) (see Box 604) if needed to provide evidence that established criteria are met. Occupational (worker) sites have flexibility to use engineering or administrative controls to provide protection as implemented in a site-specific HASP (Section 4.12). With such alternative controls, the HASP can provide adequate protection while providing more flexibility in setting decontamination criteria (i.e., workers can occupy a site that was once and may potentially still be contaminated). Components of a reoccupancy program can include some or all of the elements described in Appendix 8.

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The reuse of a water distribution system might involve a phased approach as well. For example, water service might first be re-established for certain life-essential services, such as fire fighting, then the appropriate authorities might approve certain non-consumption uses, such as washing and sanitation. Finally, the water distribution system would be certified as sanitary for drinking water. Authority to make decisions on the reuse of previously contaminated water systems varies from state to state.

The IC/UC in coordination with the appropriate authority makes the decision to allow re-occupancy of facilities/residences or reuse of distribution system water, given the particular terms for decontamination of individual dwellings, to ensure no new contamination to the distribution system. Reoccupation decisions are also generally overseen by local authorities.

4.21 References

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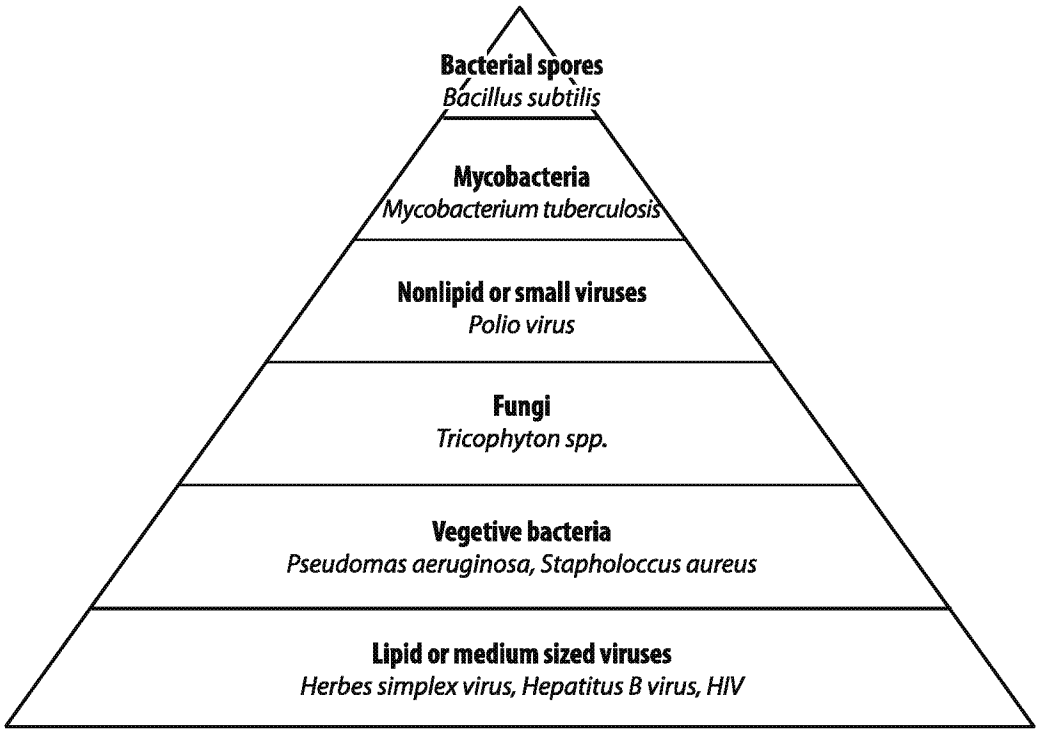
Appendix 1 Microbial Resistance to Disinfectants

Spaulding Hierarchy



Descending order of resistance to germicidal chemicals. This hierarchy considers broad classifications of microbial categories. It is considered a rough guide to general susceptibility of microorganisms to disinfectants. Adapted from Favero, M.S., Bond, W.V., Chemical disinfection of medical and surgical materials. In: Block, S.S., ed. Disinfection, Sterilization, and Preservation. 4th ed. Philadelphia: Lea & Febiger, 1991:621.

Figure A1-1. Spaulding hierarchy. Reprinted from Rutala, W. A. (1996), "APIC Guidelines for Selection and Use of Disinfectants," *American Journal of Infection Control* **24**, 314.

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Appendix 2 National Response Framework Structure and Annexes

The figures in this appendix provide additional information about the structure and content of the *National Response Framework* and its Annexes and Appendices.

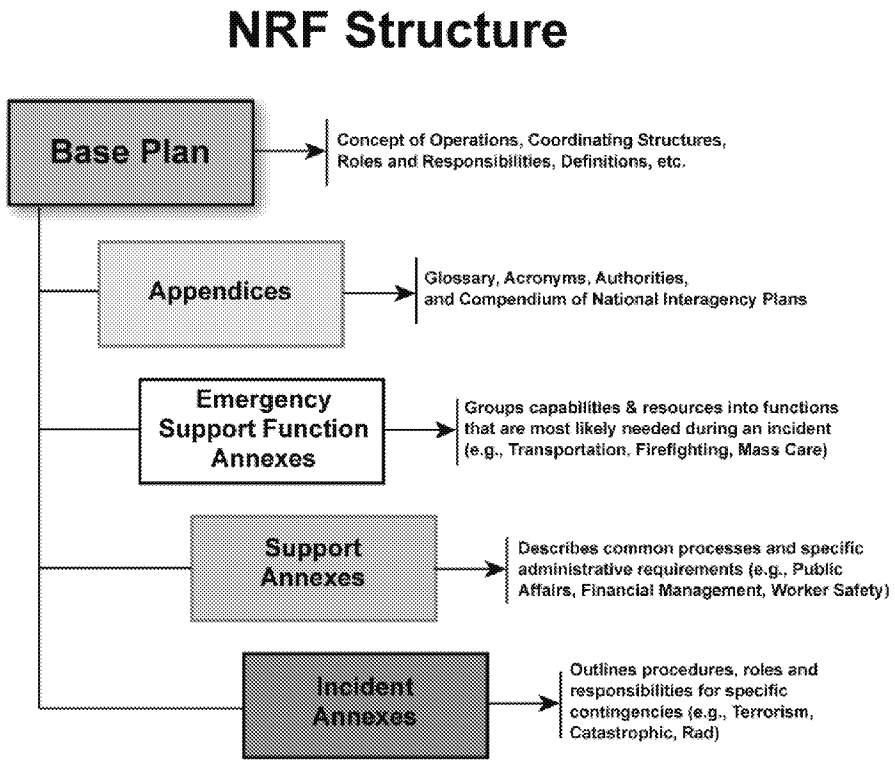

Figure A2-1. Structure of the *National Response Framework*.

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Emergency Support Functions / Annexes

- ESF #1 - Transportation
- ESF #2 - Communications
- ESF #3 - Public Works and Engineering
- ESF #4 - Firefighting
- ESF #5 - Emergency Management
- ESF #6 - Mass Care, Emergency Assistance, Housing and Human Services
- ESF #7 - Logistics Management and Resource Support
- ESF #8 - Public Health and Medical Services
- ESF #9 - Search and Rescue
- ESF #10 - Oil and Hazardous Materials Response
- ESF #11 - Agriculture and Natural Resources
- ESF #12 - Energy
- ESF #13 - Public Safety and Security
- ESF #14 - Long-Term Community Recovery
- ESF #15 - External Affairs

Homeland Security

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Support Annexes

- Critical Infrastructure and Key Resources*
- Financial Management
- International Coordination
- Private Sector Coordination
- Public Affairs
- Tribal Relations
- Volunteer and Donations Management
- Worker Safety and Health

Incident Annexes

- Biological Incident
- Catastrophic Incident
- Cyber Incident
- Food and Agriculture Incident
- Mass Evacuation Incident*
- Nuclear/Radiological Incident
- Terrorism Incident Law Enforcement and Investigation

*New annexes.

Homeland Security

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Figure A2-2. *National Response Framework* annexes

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Appendix 3 Federal Agency Roles and Responsibilities for Biological Decontamination

The table below identifies the specific roles and responsibilities of key Federal agencies for various aspects of biological decontamination. Source documents related to the responsibilities are identified in the table.

Table A3-1. Roles and responsibilities of Federal agencies in biological decontamination activities.

BIOLOGICAL INCIDENTS (Page 1 of 3)			
Activity	Activity Description	Key Federal Agencies	Source
Public (victim) decontamination	Public decontamination may include providing technical advice or direct assistance for: – Procedures to protect and decontaminate public – Medical monitoring and decontamination of possibly affected victims – Establishing a registry of potentially exposed individuals	**HHS** – Primary agency responsible for coordinating Federal support* *It is important to note that the NRF provides that victim decontamination is primarily the responsibility of State, local, and tribal governments. Federal assistance is limited.	NRF ESF #8 NRF Biological Incident Annex NRF Catastrophic Incident Annex

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BIOLOGICAL INCIDENTS Continued (Page 2 of 3)			
Activity	**Activity Description**	**Key Federal Agencies**	**Source**
Environmental Decontamination/Cleanup	Environmental decontamination/cleanup generally includes the following types of activities: - Environmental sampling/analysis/monitoring (e.g. for site characterization as well as to verify adequacy of cleanup) - Removal and/or remediation activities (which include decontamination/cleanup) of buildings, residences, open land, etc. - Waste/debris management The agency(ies) conducting these activities will also provide for decontamination of the response worker personnel.	While HHS is the designated overall Federal coordinating agency for biological incidents, then environmental decontamination/cleanup is led by other agencies. Certain agencies have specific roles related to this area as described: **EPA** or **USCG**: - EPA for the Inland Zone - USCG for the Coastal Zone Except for the Federal facilities below. The designation of the lead agencies listed below is not addressed by the NRF but is described in the NCP. **DOD/DOE** – for incidents involving <u>their facilities, vessels, materials</u> Under the NCP, Federal agencies other than EPA/USCG, DOD and DOE are the lead for non-emergency cleanups associated with their facilities, vessels and material. In addition, for decontamination of microorganisms (not toxins), a product must be registered or given a crisis exemption for use by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). **USDA** – in the case of zoonotic agents, HHS will coordinate with USDA for control and management of food supplies **OSHA** will provide technical assistance on worker safety and health issues.	NRF Biological Incident Annex in coordination with ESF #10 NRF Catastrophic Incident Annex NCP Section 300.120 FIFRA NRF Worker Safety and Health Support Annex

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BIOLOGICAL INCIDENTS (Page 3 of 3)			
Activity	**Activity Description**	**Key Federal Agencies**	**Source**
Emergency removal/disposal of contaminated debris	Emergency removal of debris (e.g. clearing public roads and property	[Note: Waste/debris generated from decontamination and remediation is managed under the ESF #10 environmental cleanup/decontamination activities when activated (EPA/USCG)] **OSHA** will provide technical assistance on worker safety and health issues.	NRF ESF #3 (in consultation with ESF #10) NRF Catastrophic Incident Annex
Food/Agricultural/Animal decontamination and waste disposal	Coordination of veterinary and wildlife services in affected area –Inspection, sampling, monitoring, and analysis of food products, livestock, poultry, crops, and associated facilities –Control, de-contamination, and waste management of contaminated food products, livestock, poultry, crops, or related facilities – Control of contaminated material affecting natural and cultural resources including wildlife	If a biological incident primarily involves an attack on the agricultural sector (i.e., agro-terrorism involving livestock, poultry, or crops), the **USDA/APHIS** is the primary agency supporting the DHS under ESF #11. If a biological incident involves natural, cultural or historic resources, the U.S. Department of Interior (**DOI**) is the Primary Agency. For attacks on food already processed and in the food-distribution system (e.g., adulterated packaged foods), **HHS/FDA** or **USDA/FSIS** takes the lead role, depending on which has regulatory authority for the given food. **OSHA** will provide technical assistance on worker safety and health issues.	NRF ESF #11 Public Health Security and Bioterrorism Preparedness and Response Act, 2002 NRF Food and Agricultural Incident Annex is under development and will further clarify roles and responsibilities. In support of HSPD-9 (Food and Agriculture), five Federal agencies developed and issued guidance entitled, "Federal Food and Agriculture Decontamination and Disposal Roles and Responsibilities, November 2005," which provides guidance on how Federal, State and local agencies should coordinate in response to various kinds of biological incidents that may occur in U.S. food and agriculture

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Appendix 4 Standard Work Zones for a Contaminated Site

(See Section 4.5)

Exclusion Zone (Hot Zone)

The Exclusion Zone is the area where contamination is either known or expected to occur and where the greatest potential for exposure exists. The outer boundary of the Exclusion Zone, called the **Hotline**, separates the area of contamination from the Contamination Reduction Zone. The Hotline should initially be established by visually surveying the site and determining the extent of biological agents or related material present with preliminary environmental sampling. Other factors to consider in establishing the Hotline include:

- Providing sufficient space to protect personnel outside the Exclusion Zone from potential fire or explosion.
- Allowing an adequate area within which to conduct site operations.
- Reducing the potential for contaminant migration.

The Hotline should be physically secured (e.g., using chains, fences, or ropes) and/or clearly marked (e.g., using lines, placards, hazard tape, or signs). During subsequent site operations, the boundary may be modified and adjusted as more information becomes available. The Exclusion Zone may also be subdivided into different areas of contamination based on known or expected types and degrees of hazards. If the Exclusion Zone is subdivided in this manner, additional demarcations (e.g., "Hazards Present" or "Protection Required") may be necessary.

Access to and from the Exclusion Zone should be restricted to **Access Control Points** at the Hotline. Access Control Points are used to regulate the flow of personnel and equipment into and out of the contaminated area and to verify that site control procedures are followed. Separate entrances and exits should be established to separate personnel and equipment movement into and out of the Exclusion Zone.

All persons who enter the Exclusion Zone must wear the appropriate level of Personal Protective Equipment (PPE) for the degrees and types of hazards present. PPE should be chosen following a careful risk assessment, and it should be appropriate to the biological agent, as well as any other hazardous material used in the work area. In addition, employers need to ensure that workers entering the Exclusion Zone have received training in the proper use of the PPE they are using (29 CFR 1910.132, 29 CFR 1910.134). If the Exclusion Zone is subdivided, different levels of PPE may be appropriate. Each subdivision of the Exclusion Zone should be clearly marked to identify hazards and the required level of PPE.

Sampling equipment needs to be properly calibrated and clean prior to entering the contaminated area. If electronic communications devices (such as radios) are used, the equipment should be easily decontaminated. Upon exiting the contaminated area, all equipment and gear must be either decontaminated or discarded properly. No contaminated equipment or gear should be allowed to enter the clean area. A change in situation may require a change in containment strategy, including the perimeters. As the situation matures or comes under control, expanding or shrinking the security perimeter and containment zones may be necessary.

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Contamination Reduction Zone (Warm Zone)

The Contamination Reduction Zone is the area in which decontamination of personnel, equipment, and items coming out of the Hot Zone takes place. It is the transition area between the Exclusion Zone and Support Zone. The purpose of the Contamination Reduction Zone is to reduce the possibility that the Support Zone will become contaminated or affected by site hazards.

The Contamination Control Line marks the boundary between the Contamination Reduction Zone and Support Zone and separates clean areas of the site from those areas used to decontaminate workers and equipment. Access Control Points between the Contamination Reduction Zone and Support Zone should be established to ensure workers entering the Contamination Reduction Zone are wearing the proper PPE and that workers exiting the Contamination Reduction Zone to the Support Zone remove or decontaminate all potentially contaminated PPE.

Support Zone (Cold Zone)

The Support Zone is the uncontaminated area where workers are unlikely to be exposed to biological agents or dangerous conditions. Because the Support Zone is free from contamination, personnel working within it may wear normal work clothes. Any potentially contaminated clothing, equipment, and samples (that is, contaminated outer containers for samples) should remain inside the Contamination Reduction Zone or the Exclusion Zone.

Designation of the Support Zone should be based on all available site characterization data and should be located upwind from the Exclusion Zone. The Support Zone should be in an area that is known to be free of elevated (i.e., higher than background) concentrations of hazardous substances.

It is important to evaluate the initial activities to determine if they are adequate for continued containment of the agent in affected areas, and to monitor the safety of remediation workers and other personnel in the immediate vicinity of the release.

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Appendix 5 Decontamination for Workers in Level-C PPE

(See Section 4.12)

Following is a typical decontamination procedure appropriate for workers using Level- A, B or C PPE:

1. Worker proceeds to Exclusion Zone exit.
2. Worker washes the bottom of rubber boots in tub with a soapy water solution.
3. Worker enters the Contamination Reduction Zone.
4. A decontamination assistant or the worker's designated "buddy" inspects the suit for gross contamination in the form of dust and dirt. If dust or dirt is observed, the outer suit is sprayed with a fine mist of soapy water from a pump sprayer. Alternatively, a HEPA vacuum may be used.
5. Worker removes outer suit and discards it into bag/drum, leaving respiratory protection on.
6. Worker removes items such as boots, outer gloves, inner gloves/suit/scrubs, respirator cartridge(s), and discards them in biohazard bag within the Contamination Reduction Zone.
7. Worker proceeds to a separate, delineated equipment-cleaning area to completely submerge and clean all reusable PPE (i.e., respirator, hard hat, rubber boots, etc.) in soapy water or other antimicrobial solution as appropriate for the biological agent and PPE.
8. Worker proceeds to a separate delineated PPE storage area where reusable equipment is dried and stored.
9. Worker proceeds to personnel shower (if appropriate) and/or hand washing facility.
10. If showering, worker thoroughly washes hands, hair, face, and neck.
11. Worker dries and dons street clothes, then exits Contamination Reduction Zone.
12. Worker enters the Support Zone.

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Appendix 6 Basic Tenets of Crisis and Emergency Risk Communication ([HYPERLINK "http://www.bt.cdc.gov/erc/leaders.pdf"])

(See Section 4.7)

- **Don't over-reassure.** The objective is not to placate but to elicit accurate, calm concern.
- **Acknowledge uncertainty.** Offer only what you know. Show your distress and acknowledge your audience's distress. "It must be awful to hear …."
- **Emphasize that a process is in place to learn more**. Describe that process in simple terms.
- **Give anticipatory guidance.** If you are aware of future negative outcomes, let people know what to expect (e.g., side effects of antibiotics).
- **Be regretful, not defensive.** Say, "We are sorry…" or "We feel terrible that…" when acknowledging misdeeds or failures from the organization. Don't use "regret," which sounds like you're preparing for a lawsuit.
- **Acknowledge people's fears.** Don't tell people they shouldn't be afraid. They *are* afraid and they have a right to their fears. Don't disparage fear.
- **Acknowledge the shared misery.** Some people will be less frightened than they are miserable, feeling hopeless and defeated. Acknowledge the misery of a catastrophic incident, then help move people toward the future through positive actions.
- **Express wishes.** Say, "I wish we knew more," or "I wish our answers were more definitive."
- **Panic is less common than imagined.** Panic doesn't come from bad news, but from mixed messages. If people are faced with conflicting recommendations and expert advice, they are left with no credible source to turn to for help. Candor protects your credibility and reduces the possibility of panic.
- **Be willing to address "what if" questions.** These are the questions that everyone is thinking about, and they want expert answers. Although it is often impractical to fuel "what ifs" when the crisis is contained and not likely to affect large numbers of people, it is reasonable to answer "what ifs" when people need to be emotionally prepared for them. You may lose credibility by not addressing "what ifs."
- **Give people things to do.** In an emergency, some actions are directed at victims, and those exposed or have the potential to be exposed. However, those who do not need to take immediate action will be engaging in "vicarious rehearsal" regarding those recommendations and may need substitute actions to ensure that they do not prematurely act on recommendations not meant for them. Simple actions in an emergency will give people a sense of control.
- **Ask more of people.** Perhaps the most important role of the spokesperson is to ask people to bear the risk and work toward solutions with you. People can tolerate considerable risk, especially voluntary risk. A spokesperson, especially one who is on the ground and at personal risk, can model the appropriate behavior.

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Appendix 7 Antimicrobial Decontaminants

(See Section 4.16)

Table A7-1. Liquid antimicrobial pesticides used under FIFRA crisis exemptions to inactivate *Bacillus anthracis* spores. Only two antimicrobial pesticides are currently registered for use to inactivate *B. anthracis* spores (see http://www.epa.gov/pesticides/factsheets/chemicals/peridox-eds.html).

Chemical	Generation method	Toxicity	Efficacy	Materials compatibility	Approved uses
Aqueous chlorine dioxide	Must be generated onsite	Acutely toxic; skin and eye irritant.	Sporicidal on nonporous surfaces at 500 ppm and 30 min. contact time	No known problems	EPA registered sanitizer and disinfectant for many uses
Hydrogen peroxide and peracetic acid	Ready to use liquid	Acutely toxic; irreversible eye damage.	Several products are sporicidal on nonporous surfaces with contact times ranging from 15 to 30 minutes.	No known problems	EPA registered sanitizer, disinfectant and sterilant for many uses
Sodium hypochlorite	Dilute 5.25-6% solution to 5,250 to 6,000 ppm; adjust pH to 7.	Acutely toxic; skin and eye irritant.	Sporicidal on nonporous surfaces after 60 minutes contact time.	Corrosive to stainless steel and other metals	EPA registered sanitizer and disinfectant for many uses

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Table A 7-2. Gas and vapor antimicrobial pesticides used under FIFRA crisis exemptions to inactivate *Bacillus anthracis* spores. None of these antimicrobial pesticides is currently registered for use to inactivate *B. anthracis* spores.

Chemical	Generation method	Toxicity	Exposure limits	Materials compatibility	Penetration	Sporicidal uses
Formaldehyde gas	Onsite heating of paraformaldehyde prills (flakes)	Acutely toxic, animal carcinogen, genotoxin	0.75 ppm PEL 2.0 ppm STEL 20 ppm IDLH	Relatively unreactive	High	Biosafety cabinets, clean rooms, mail bags, mail equipment, buildings
Chlorine dioxide gas	Onsite reaction of precursor materials (sodium chlorite & others)	Acutely toxic, respiratory and eye irritant, no cancer data	0.1 ppm PEL 0.3 ppm STEL 5.0 ppm IDLH	May affect metals (Al, Cu, brass), computer parts, carpets and low grade paper at high CT values	High	Buildings
Hydrogen peroxide vapor	Onsite vaporization of liquid hydrogen peroxide	Acutely toxic, respiratory irritant, no cancer data	0.1 ppm PEL 0.2 No STEL 75 ppm IDLH	Relatively unreactive	Medium, does not penetrate paper	Medical equipment, buildings
Methyl bromide gas	Onsite heating & vaporization of liquid MB from cylinder	Acutely toxic, no cancer data	4.0 ppm TLV 20 ppm PEL 250 ppm IDLH	May affect animal fur, leather, natural latex, and sulfur-containing articles	Very high	Experimental (efficacy studies on *Bacillus anthracis* and spore strips)
Ethylene oxide gas	Onsite release of gas from cylinder	Acutely toxic, reproductive toxin, genotoxin, possible human carcinogen	1.0 ppm PEL 5 ppm STEL 800 ppm IDLH	Relatively unreactive	Extremely high	Medical equipment, critical items

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Appendix 8 OSHA Reoccupancy (Transitional) Plans

(See Section 4.20)

Hazard Awareness Training

Hazard awareness training is intended to communicate information concerning hazards of biological agents and appropriate protective measures to employees. The training may include, but is not limited to:

- Elements of the re-occupancy program.
- The health hazards of the biological agent, including routes of entry, signs and symptoms of exposure, synergistic effects, and any medical conditions that would place employees at increased risk.
- Operations in the work area where the biological agent has been identified.
- Dissemination of sampling results, including information on accessing results.
- Any applicable control measures, such as appropriate engineering controls, work practices, housekeeping, or PPE.
- Implementation of interim standard operating procedures to prevent potential exposure during operations, maintenance, cleaning, or the like.
- Frequent updates regarding any ongoing sampling, decontamination, control, medical surveillance, and related activities being performed at the facility, as applicable.

Medical Surveillance

A medical surveillance program may be implemented to ensure that employees receive appropriate preventive care. Medical surveillance includes, but is not limited to:

- Identification of employee populations at risk and establishment of controls for such employees (such as work reassignment, PPE, and prophylactic medication).
- Administrative follow-up on absentees (such as those on sick leave).
- Selection of prophylactic medication, as appropriate.
- Response to symptoms reported by employees.

Reoccupancy (Transitional) Sampling

Additional sampling may be conducted to confirm that occupied areas remain safe for occupancy. Sampling during this period is continued until repeatable results demonstrate that contamination remains insignificant. Elements of reoccupancy sampling include, but are not limited to:

- Determining appropriate sampling techniques. Recommended techniques may include nonaggressive, high-volume, air sampling, HEPA vacuum surface sampling, and if appropriate, bulk sampling (such as bulk samples from HEPA vacuums used to clean surfaces, or ventilation system filters).
- Use of high-volume air sampling as a tool to characterize levels of biological agent in the air and provide exposure information to employees.
- Identification of specific locations and frequency of sampling.

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Personal Protective Equipment

The workplace must be reassessed to select and use appropriate PPE to protect employees from potentially remaining biological agent hazards. The specific types of PPE used depend on the actual operation in question and results from the reassessment. Examples of work operations where modifications to PPE may be necessary are as follows:

- Operating equipment or working on surfaces where the biological agent was previously identified.
- Performing maintenance tasks, such as cleaning equipment or changing HEPA vacuum or ventilation system filters.

Personal Hygiene

A personal hygiene program may be implemented for certain facility areas and operations to reduce the risk of additional exposures and spreading contamination. Procedures that may be required include:

- Assuring that food or beverage is not present or consumed, tobacco products are not present or used, and cosmetics are not applied in specified areas.
- Regular washing of hands and/or face, and before eating, drinking, using tobacco, or applying cosmetics.
- Showering as necessary.

Interim Standard Operating Procedures

Interim standard operating procedures (SOPs) must be developed to address special work activities necessary under the reoccupancy (transitional) program. Affected employees should receive training on the interim SOPs. The SOPs include, but are not limited to, the following topics:

- Maintenance and housekeeping procedures developed or modified to prevent the spread of potential contamination and protect employees. Examples include:
  - Use of HEPA vacuum to clean surfaces instead of sweeping or other methods.
  - Cleaning, maintenance, and filter and bag removal for HEPA vacuums.
  - Maintenance and cleaning of facility equipment.
  - Cleaning floors and other surfaces.
  - Handling and disposal of wastes.
- Changes to regular work operations and equipment, as applicable.
- Modifications to facility-wide mechanical systems, particularly HVAC systems. Examples of HVAC modifications include:
  - Increase in ventilation rates (air changes per hour).
  - Increase in percentage of outside air.
  - Use of HEPA filters to collect dust in circulated air.
- Other applicable major elements implemented as part of the reoccupancy program, as described previously (training, medical surveillance, sampling, PPE, or hygiene).

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Appendix 9 Glossary

ANTIMICROBIAL AGENT

Any agent that kills or suppresses the growth of microorganisms (Block, 2001).

AREA COMMAND (UNIFIED AREA COMMAND)

An organization established (1) to oversee the management of multiple incidents that are each being handled by an ICS organization or (2) to oversee the management of large or multiple incidents to which several Incident Management Teams have been assigned. Area Command becomes Unified Area Command when incidents are multi-jurisdictional. Area Command may be established at an EOC facility or at some location other than an Incident Command Post (DHS, 2008).

ANTHRAX

A non-contagious, infectious, often fatal, naturally occurring disease caused by the bacterium *Bacillus anthracis* that may be contracted by humans or animals via exposure through inhalation, the skin, or the gastrointestinal tract.

BACILLUS ANTHRACIS

A spore-forming bacterium that causes anthrax. The spore form is about 1 by 2 microns in size and can easily be inhaled. In a warm, moist environment (such as the lungs), spores grow into vegetative, rod-shaped cells that multiply and cause hemorrhage, edema, and necrosis in humans and animals.

BIOSAFETY LEVEL (BSL)

Different biosafety levels developed for microbiological and biomedical laboratories provide increasing levels of personnel and environmental protection from pathogenic microorganisms and hazardous subcellular entities (e.g., prions). Accordingly, laboratories may be classified as BSL-1, BSL-2, BSL-3 or BSL-4, ranked from lowest to highest in degree of safety level.

BIOLOGICAL INCIDENT

A natural or human-caused incident involving microbiological organisms (bacteria, fungi, and viruses) or biologically derived toxins that pose a hazard to humans, animals, or plants.

BIOLOGICAL INDICATOR (BI)

A standardized preparation of bacterial spores on or in a carrier serving to demonstrate whether sterilizing conditions have been met. Spores of different organisms are used for different methods of sterilization (Block, 2001).

BIOLOGICAL WARFARE AGENT (BWA)

A microorganism (bacteria, fungi, and viruses) or biologically derived toxin that is intentionally introduced to cause disease or harm in humans, animals, or plants.

BIOTOXIN

A toxic substance that is either produced by, or extracted from, living or dead bacteria, fungi, plants, or animals.

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CERCLA

The Comprehensive Environmental Response, Compensation, and Liability Act (42 USC 9601 et seq.), as amended by the Superfund Amendments and Reauthorization Act of 1986. CERCLA authorizes the President and EPA (by delegation from the President) to respond to releases or substantial threats of releases of hazardous substances or of pollutants or contaminants that may present an imminent and substantial danger to the public health or welfare.

CHARACTERIZATION

The process of obtaining specific information about a biological agent, such as its identity, genetic composition, formulation, physical properties, toxicological properties, ability to aerosolize, and persistence, and about the nature and extent of contamination of the agent, such as locations or items contaminated and the amount of contamination. Characterization of the agent and of the contamination at an affected site generally occurs after First Response and before Decontamination.

CHARACTERIZATION ENVIRONMENTAL SAMPLING

Environmental sampling intended to assess the nature (identity and properties) and extent (location and quantity) of contamination of an area or items. Generally occurs after First Response and before Decontamination.

CHARACTERIZATION ZONE

A discrete section of a contaminated site that is examined for the purpose of determining the potential for exposure to the contaminant in that area.

CLEANUP

The process of characterizing, decontaminating, and clearing a contaminated site or items, including disposal of wastes. Cleanup is a synonym for Remediation. Generally occurs after Characterization and before Clearance.

CLEANUP GOAL

An amount of residual contamination for a specific contaminant in or on an area or item that, once achieved following decontamination, provides acceptable protection to human health and the environment. A cleanup goal specifies criteria for determining the success of decontamination that are measurable and for permitting unprotected reentry.

CLEARANCE

The process of determining that a cleanup goal has been met for a specific contaminant in or on a specific site or item. Generally occurs after Decontamination and before Reoccupancy.

CLEARANCE ENVIRONMENTAL SAMPLING

Environmental sampling that is conducted after the decontamination process is completed for a specific contaminant in an area or on items, and is intended to provide a basis for determining whether the cleanup goal has been met.

CLEARANCE ZONE

A section or sub-section of a contaminated site for which a clearance decision is made.

CONCEPT OF OPERATIONS (CONOPS)

A formal plan that describes the roles, responsibilities, and relationships of organizations involved in a response to a contaminated area or items. Typically, a CONOPS addresses Federal, State, local, and tribal agencies and how they should interact when responding to a potential or actual terrorist threat or incident.

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CONSEQUENCE MANAGEMENT

Predominantly an emergency management function that includes measures to protect public health and safety; restore essential government services; and provide emergency relief to governments, businesses, and individuals affected by the consequences of terrorism (DHS, December 2004). Includes Remediation/Cleanup (i.e., Characterization, Decontamination, and Clearance) and Restoration/Reoccupancy activities (see Figure 3, p. 42).

CONTAINMENT

In the context of this document, includes actions or measures taken to prevent the spread of a contaminant from a particular zone or to prevent the movement of a contaminant within a zone. Compare with Isolation. This term has been used differently by various agencies.

CONTAMINATION REDUCTION ZONE

The transition area between the Exclusion and Support Zones where responders enter and exit the Exclusion Zone and where decontamination activities take place. Also called the Warm Zone (EPA, 2004).

CRISIS EXEMPTION

Under the authority of Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Administrator of EPA may exempt any Federal or State agency from the pesticide registration requirements of FIFRA, if the Administrator determines that emergency conditions exist which require such exemption. As described in EPA's regulations (40 CFR 166.40 – 166.53), a crisis exemption may be issued, subject to specific conditions, when an unpredictable emergency situation exists—that is, an emergency condition exists and there is insufficient time to request and process other types of exemptions or registration. Other types of emergency exemptions require a State or Federal agency to submit an application to EPA for review and approval.

CRISIS MANAGEMENT

Predominantly a law-enforcement function that includes measures to identify, acquire, and plan the use of resources needed to anticipate, prevent, and/or resolve a threat or act of terrorism (DHS, December 2004). Includes Notification and First Response activities (see Figure 3, p. 42).

DECISION-MAKER

A person charged with determining and directing appropriate actions in response to a potential or actual biological incident at a particular site.

DECONTAMINATION

The process of inactivating or reducing a contaminant in or on humans, animals, plants, food, water, soil, air, areas, or items through physical, chemical, or other methods to meet a cleanup goal. Decontamination applies to both disinfection and sterilization processes. Generally occurs as part of Remediation. (Note: Decontamination has been defined in different ways by different Federal agencies and other entities.)

DECONTAMINATION AREA OR ZONE

A section of a contaminated site that can be isolated from other areas and is decontaminated as a unit.

DECONTAMINATION AGENT

A substance that is used to inactivate or reduce a contaminant on humans, animals, plants, or inanimate surfaces or in other media. If the contaminant is a microorganism, the chemical is an antimicrobial pesticide.

DISINFECTANT

A chemical or physical agent that destroys pathogenic or other harmful microorganisms, but not bacterial spores on inanimate surfaces.

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DISINFECTION

The destruction of pathogenic and other kinds of microorganisms by physical (e.g., heat, desiccation, freezing, radiation) or chemical means. Disinfection is a less-lethal process than sterilization because it destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores. Disinfection processes do not ensure the margin of safety associated with sterilization processes (AAMI, 1995).

EMERGENCY OPERATIONS CENTER (EOC)

The physical location at which the coordination of information and resources to support domestic incident management activities normally takes place. An EOC may be a temporary facility or located in a more central or permanently established facility, perhaps at a higher level of organization within a jurisdiction. EOCs may be organized by major functional disciplines (e.g., fire, law enforcement, environment, and medical services), by jurisdiction (e.g., Federal, State, regional, county, city, or tribal), or by some combination thereof (DHS, 2008).

ENVIRONMENTAL CLEARANCE COMMITTEE (ECC)

An independent group of scientific experts from a variety of local, State, and Federal agencies that provides advice, data, process analysis, and recommendations during and after decontamination of a facility. An ECC provides a final recommendation on whether the cleanup was adequate to justify reopening the facility for normal operations and use (Proceedings from the 2nd Civilian-Military Anthrax Response Technical Workshop, 2004).

ENVIRONMENTAL SAMPLING

Sampling conducted on inanimate surfaces or in air, water, or soil for the purpose of detecting the presence of a specific biological agent.

EXCLUSION ZONE

An area with actual or potential contamination and the highest potential for exposure to the contaminant. Entry to this area is permitted only for persons wearing appropriate personal protective equipment (PPE). Equivalent to Hot Zone, Red Zone, Isolation Zone, or Restricted Zone.

FIRST RESPONSE

Actions taken immediately following notification of a biological incident or release. In addition to search and rescue, scene control, and law enforcement activities, first response includes initial site containment, environmental sampling and analysis, and public health activities, such as treatment of potentially exposed persons.

FEDERAL ON-SCENE COORDINATOR (FOSC OR OSC)

The Federal official predesignated by the EPA or the USCG to coordinate responses under subpart D of the National Contingency Plan (NCP); or the government official designated to coordinate and direct removal actions under subpart E of the NCP (DHS, 2008).

FUMIGATION

Use of a chemical gas or vapor in a contained space to inactivate biological contaminants (primarily pathogenic bacteria, fungi, and viruses).

HEALTH AND SAFETY PLAN (HASP)

A written plan required under the Occupational Health and Safety Administration's (OSHA's) Hazardous Waste Operations and Emergency Response (HAZWOPER) standard (29 CFR 1910.120 and 29 CFR 1926.65). This standard requires a written HASP, which identifies site hazards and appropriate controls to protect employee health and safety (NRT, 2003).

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HOTLINE

The outer boundary of the Exclusion Zone (Hot Zone) that separates the area of contamination from the Contamination Reduction Zone (Warm Zone).

INACTIVATION

Removal of the activity of microorganisms by killing or inhibiting reproductive or enzyme activity. When referring to an antimicrobial agent, inactivation means neutralizing its activity by any means (Block, 2001).

INCIDENT

An occurrence or incident, natural or human-caused, that requires an emergency response to protect life or property. Incidents can, for example, include major disasters, emergencies, terrorist attacks, terrorist threats, wildland and urban fires, floods, hazardous materials spills, nuclear accidents, aircraft accidents, earthquakes, hurricanes, tornadoes, tropical storms, war-related disasters, public health and medical emergencies, and other occurrences requiring an emergency response (DHS, 2008).

INCIDENT COMMAND (IC)

The unit responsible for all incident activities, including the development of strategies and tactics and the ordering and release of resources. The IC has overall authority and responsibility for conducting incident operations and is responsible for managing all incident operations at the incident site (National Incident Management System, 2004; DHS, 2008).

INFECTIOUS DOSE (ID)

A dose at which an organism can reproduce in the host and produce a measurable effect (Johnson, 2003).

ISOLATION

For the purposes of this document, action taken to seal a site to permit fumigation and prevent release of fumigant. Compare with containment. This term has been used differently by various agencies.

ISOLATION ZONE

A contaminated area for which entry is permitted only for persons wearing appropriate personal protective equipment (PPE). Equivalent to Hot Zone, Red Zone, Exclusion Zone, and Restricted Zone.

LABORATORY RESPONSE NETWORK (LRN)

An organization of public health laboratories established by the Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) in accordance with Presidential Decision Directive 39, which outlines national anti-terrorism policies and assigns specific missions to Federal departments and agencies. The LRN and its partners maintain an integrated national and international network of laboratories that are fully equipped to respond quickly to acts of chemical or biological terrorism, emerging infectious diseases, and other public health threats and emergencies (CDC, 2005).

LIFE SAFETY ZONES

Zones established at a contaminated site that are intended to reduce the accidental spread of hazardous substances by workers or equipment from contaminated areas to clean areas. Safety zones specify the type of operations that occur in each zone, the degree of hazard at different locations within the release site, and the areas at the site that should be avoided by unauthorized or unprotected employees.

NATURAL ATTENUATION

The destruction or inactivation of a microorganism or products of a microorganism, such as a toxin, via natural, environmental mechanisms such as heat, light, biochemical, or chemical reactions.

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NEGATIVE AIR UNIT (NAU)

A system that subjects an area to a slightly negative pressure to ensure that the contaminant (and decontamination chemical) remains in the contamination zone. NAUs consist of a HEPA filter, chemical scrubber, demister, carbon bed, fan, and stack. Air within a building is exhausted through HEPA filters at a rate sufficient to pull a slightly negative pressure in the contaminated zone. (Carlsen et al., 2005)

NOTIFICATION

The process of communicating the occurrence or potential occurrence of a biological incident through and to designated authorities who initiate First Response actions. Generally occurs as the first step in a response to a suspected or actual biological incident.

OPTIMIZATION

A flexible decision process for biological incidents that addresses multiple aspects of the problem and seeks to analyze, consider, and balance these factors in decontamination and recovery activities .

PATHOGEN

Any disease-producing microorganism (Block, 2001).

PRINCIPAL FEDERAL OFFICIAL (PFO)

The Federal official designated by the Secretary of Homeland Security to act as his/her representative locally to oversee, coordinate, and execute the Secretary's incident management responsibilities under HSPD-5 for major incidents (DHS, 2008).

PROCESS MONITORING

Measuring and recording the key variables of a decontamination process as they occur. For example, during fumigation, the key variables are gas concentration, temperature, contact time, and relative humidity.

QUALITY ASSURANCE

An integrated system of activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence (EPA, 2002c).

RECOMMISSIONING

The process of testing and verifying that equipment is fully functional and may be returned to normal use.

RECOVERY

In the short term, recovery is an extension of the response phase in which basic services and functions are restored. In the long term, recovery is a restoration of both the personal lives of individuals and the livelihood of the community. Recovery can include the development, coordination, and execution of service- and site-restoration plans; the reconstitution of government operations and services; programs to provide housing and to promote restoration; long-term care and treatment of affected individuals; and additional measures for social, environmental, and economic restoration (DHS, 2008). Recovery generally includes actions taken after Notification and First Response activities have been initiated (see Figure 3, p. 42).

REMEDIATION ACTION PLAN (RAP)

A formal plan developed for the Incident Commander that describes actions to remove, reduce, or eliminate contaminants in or on a site and/or items. The RAP is developed during Remediation.

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REMEDIATION

The processes of characterizing, decontaminating, and clearing a contaminated site or items, including disposal of wastes. Generally occurs after the First-Response Phase and before the Restoration Phase (see Figure 3, p. 42). A synonym for cleanup. Remediation is not the same as "remedial action," which is defined below.

REMEDIAL ACTION

Long-term response actions that permanently and significantly reduce the dangers associated with releases or threats of releases of hazardous substances that are serious, but not immediately life threatening. If applicable and with available resources, remedial action may be performed in accordance with the National Oil and Hazardous Substances Pollution Contingency Plan and under the authority of CERCLA (See 40 CFR 300.430 and .435).

REMOVAL ACTION

Response actions taken to address releases or threatened releases of hazardous substances, pollutants, or contaminants that require a prompt response. If applicable and with available resources, removal action may be performed in accordance with the National Oil and Hazardous Substances Pollution Contingency Plan and under the authority of CERCLA (See 40 CFR 300.415).

RENOVATION

The process of reconstructing or refurbishing a facility subsequent to clearance but before allowing occupants to return (see Figure 3, p. 42).

REOCCUPANCY

The process of renovating a facility, monitoring the workers performing the renovation, and deciding when to permit reoccupation. Generally occurs after a facility has been cleared but before occupants are allowed to return (see Figure 3, p. 42).

RESIDUAL CONTAMINATION

The detectable amount of contaminant remaining, if any, after an area has been decontaminated.

RESPONSE

Includes immediate actions to save lives, protect property and the environment, and meet basic human needs. Response also includes the execution of emergency plans and actions to support short-term recovery (DHS, 2008).

RESTORATION

The process of renovating or refurbishing a facility; bringing it to an acceptable condition using the optimization process to determine the appropriate use and associated clearance level at which occupants may return. Generally occurs after the Clearance Phase but before occupants are allowed to return (see Figure 3, p. 42).

RISK

The probability that a substance or situation will produce harm under specified conditions. Risk is a combination of two factors: (1) the probability that an adverse event will occur (such as a specific disease or type of injury), and (2) the consequences of the adverse event (Presidential and Congressional Commission on Risk Assessment and Risk Management, 1997).

RISK ASSESSMENT

Gathering and analyzing information on what potential harm a situation poses and the likelihood that people or the environment will be harmed. (The Presidential and Congressional Commission on Risk Assessment and Risk Management, 1997). A methodological approach to estimate the potential human or environmental risk of a substance that uses hazard identification, dose-response, exposure assessment, and risk characterization.

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RISK MANAGEMENT

The process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems. The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risk while taking into account social, cultural, ethical, and legal considerations (Presidential and Congressional Commission on Risk Assessment and Risk Management, 1997).

SAMPLING AND ANALYSIS PLAN (SAP)

A plan that describes the methods, strategies, and analyses for characterization sampling, verification sampling (if applicable), and clearance sampling for a contaminated site.

SAMPLING UNIT

A sub-section of a sampling zone, such as walls, floors, and furniture surfaces, that can be sampled and evaluated collectively.

SAMPLING ZONE

A discrete section of a contaminated site in which environmental sampling is conducted.

SCREENING ENVIRONMENTAL SAMPLING

The initial collection of a limited number of environmental samples for the purpose of determining the identity, concentration, viability and approximate location of contamination by a purported biological agent, and for informing the IC/UC for decision-making and subsequent remediation actions.

SOURCE REDUCTION

The process of removing certain items and/or materials from a contaminated site for further treatment and reuse or disposal, and of cleaning the remaining site and item surfaces prior to the main decontamination activity. The goals of this process are to (1) reduce the number of items and/or materials present, (2) ensure that any matter that might inhibit decontamination is removed, and (3) generally reduce the levels of contaminant that may be present.

SPORES

The thick-walled resting cells produced by some bacteria and fungi that are capable of survival in unfavorable environments and are more resistant to antimicrobial agents than vegetative cells (Block, 2001).

STAGING AREA

A safety zone established at a hazardous-substance release site that is designated as the Support Zone (or Cold Zone). It is the area of the site that is free from contamination and that may be safely used as a planning and staging area (EPA, 2004).

STERILANT

A substance that destroys all microorganisms on inanimate surfaces, including vegetative and spore forms of bacteria and fungi, as well as viruses. Sterilants registered by the USEPA must be effective on both porous and nonporous surfaces.

STERILIZATION

A process intended to remove or destroy all viable forms of microbial life, including bacterial spores, to achieve an acceptable sterility assurance level (AAMI, 1995).

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SUPPORT ZONE

Area of a site that is free from contamination and that may be safely used as a planning and staging area. Also called the Cold Zone.

SWAB SAMPLING

Collecting environmental samples from nonporous surfaces by rubbing a small area with a wet, absorptive material attached to the end of a wood or plastic stick.

TECHNICAL WORKING GROUP (TWG)

A group of technical experts assembled by the Unified Command to provide guidance during the planning and implementation of remediation operations (Carlsen et al., 2005).

UNIFIED COMMAND

An application of the Incident Command System used when there is more than one agency with incident jurisdiction or when incidents cross jurisdictions. Agencies work together through the designated members of the Unified Command to establish their designated Incident Commander at a single Incident Command Post and to establish a common set of objectives and strategies and a single Incident Action Plan (DHS, 2008).

VACUUM SAMPLING

Collecting environmental samples by suctioning porous or nonporous surfaces with a vacuum cleaner that contains a high-efficiency particulate air (HEPA) filter.

VEGETATIVE CELLS

Microbial cells that are in the growth and reproductive phase of the growth cycle (Block, 2001).

VERIFICATION SAMPLING

Use of chemical and/or biological indicators to document that fumigation has been successful.

WARM ZONE

The transition area between the Exclusion and Support Zones. This area is where responders enter and exit the Exclusion Zone and where decontamination activities take place (EPA, 2004).

WEAPON OF MASS DESTRUCTION (WMD)

Any nuclear, radiological, chemical, or biological substance that is intentionally introduced to cause disease or harm in humans, animal, or plants, or damage to property. (Note: The *National Response Framework* has a longer, legal definition).

WIPE SAMPLING

Collecting environmental surface samples by rubbing a thin, flat piece of wet, absorptive material on a small area of a non-porous surface.

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About this Report

This guidance describes a general risk management framework for decision-makers in planning and executing activities required for response and recovery from a biological incident in a domestic, civilian setting. This report was developed by the Subcommittee on Decontamination Standards and Technology (SDST), and reviewed and approved by the Office of Science and Technology Policy (OSTP) and the National Science and Technology Council (NSTC).

About the National Science and Technology Council

The NSTC, [HYPERLINK "http://www.ostp.gov/cs/nstc"], is the principal body within **the** executive branch to coordinate **science and technology** policy **across the diverse** entities that make up **the Federal research and development** (R&D) **enterprise.**

About the Office of Science and Technology Policy

The Office of Science and Technology Policy (OSTP) was established by the National Science and Technology Policy, Organization, and Priorities Act of 1976. OSTP's responsibilities include advising the President in policy formulation and budget development on questions in which science and technology are important elements; articulating the President's science and technology policy and programs; and fostering strong partnerships among Federal, State, and local governments, and the scientific communities in industry and academia. The Director of OSTP also manages the NSTC.

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BOBBY JINDAL
GOVERNOR

State of Louisiana

Governor's Office of Homeland Security and Emergency Preparedness

KEVIN DAVIS
DIRECTOR

February 20, 2015

Mr. Ron Curry
Regional Administrator (6-RA)
EPA Region VI
1445 Ross Avenue, Suite 1200
Dallas, TX 75202-2733

Dear Mr. Curry,

As you are aware, in November 2014, two non-human primates in the breeding colony at the Tulane National Primate Research center (TNPRC) became ill and one died. Pathology samples were submitted to the CDC which identified *Burkholderia pseudomallei* (BP) as the causative agent. This strain of bacteria is not endemic in the US but was the subject of research at TNPRC. Because BP is a tier 1 agent and the material was considered not in containment, the CDC and USDA conducted a joint investigation of TNPRC on January 20-24, 2015.

Since the January 2015 investigation, four monkeys have been tested positive with burkholderia pseudomallei. A second primate was euthanized on February 19, 2015 due to infection with burkholderia pseudomallei. One of the federal investigators has fallen ill and has tested positive with possible recent exposure to the BP strain. Human serology has expanded to the investigative tour group and TPNRC staff. Safety protcols have been enhanced for all those participating in the investigation proceedings. A second investigation was conducted on February 9 – 12, 2015 with the intent of conducting more in-depth review of TNPRC processes to determine route of transmission.

As the investigation continues on the TNPRC compound regarding route of exposure, it is also pressing to answer questions regarding whether the organism has escaped the compound and whether livestock and domestic animals are at risk.

It is come to our attention, that EPA requires a letter to ask for their active participation in this investigative process. To this end, Louisiana is formally requesting EPA's assistance with the following:

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1. **Active Engagement:** EPA is requested to provide strategic direction, technical guidance, and/or solicit guidance from appropriate agencies and sections within CDC or other members of the federal family with regards to environmental testing – air, water, soil sampling. Outcomes would determine subsequent steps in remediation of TNPRC and the breeding colony site.

2. ***Mitigation/Remediation Plans:*** We are requesting EPA provide direct assistance and active engagement in the development of the following mitigation/remediation plans. The intent of these plans is to reduce – if not eliminate – the risk of BP outside the TNPRC compound and to indicate remediation steps if BP infection is indicated.
    - *Surrounding Environmental Testing Plan and Sampling* – to include environmental sampling and evaluation in the surrounding surveillance zone to include air, water, and soil testing and to indicate remediation if BP infection is indicated.
    - *Affected Environmental Remediation in high*-risk area—to perform soil remediation in area(s) identified as high-risk as soon as possible to prevent further transmission/transference
    - *Longterm Monitoring and Surveillance Plan and Sampling* – to perform risk assessment within a meaningful vicinity of the area; to indicate longterm monitoring, surveillance, and on-going lab testing for soil and water sampling.

We understand that this remains an evolving event. Planning and response are essential to our joint responsibility to protect the health and safety of our citizens. We look forward to the immediate identification of a federal lead, and timely action plan so that we can be more effective in the consequence management activities for this unfolding event.

If you have any questions, please contact me at (225) 925-7345 or by email at Kevin.Davis@la.gov.

Sincerely,

Kevin Davis

Smith, Monica

From: Martin, John
Sent: Wednesday, March 25, 2015 4:28 PM
To: Smith, Monica
Subject: FW: Tulane primate center

Follow Up Flag: Flag for follow up
Flag Status: Flagged

-----Original Message-----
From: Kevin Davis [mailto:Kevin.Davis@LA.GOV]
Sent: Saturday, January 31, 2015 11:53 AM
To: Canzler, Erica; Martin, John
Cc: Jimmy Guidry (DHH); Dexter Accardo; Christina Dayries; Christopher Guilbeaux; Rosanne Prats; Vernie McNamee; Scott Deitchman
Subject: Tulane primate center

I am requesting EPA to send both Erica and John to our response in Louisiana. CDC will be arriving Monday evening and begin discussions Tuesday morning at site. I would hope you both could assist and arrive Monday evening.
Thank you,
Kevin Davis
Director
Gov. Office Of Homeland Security
Sent from my iPhone

BOBBY JINDAL
GOVERNOR

State of Louisiana

Governor's Office of Homeland Security and Emergency Preparedness

KEVIN DAVIS
DIRECTOR

March 13, 2015

Mr. Ron Curry
Regional Administrator (6-RA)
EPA Region VI
1445 Ross Avenue, Suite 1200
Dallas, TX 75202-2733

Re: Tulane National Primate Research Center (TNPRC) Incident
(Reference previous letter dated February 20, 2015 – copy attached)

Dear Mr. Curry:

Please consider this email my official request on behalf of the State of Louisiana to have appropriate representatives from your agency continue to participate and assist in activities related to the Tulane National Primate Research Center (TNPRC) investigation as previously detailed in my email to you dated February 20, 2015, including but not limited to:

- Working with TNPRC, Louisiana Department of Environmental Quality (LDEQ), U.S. Department of Agriculture (USDA), Center for Disease Control (CD), and other local, state and federal agencies involved in the response to this incident, in developing and coordinating **short term and long term environmental monitoring plans** for possible contamination of the environment with *Burkholderia pseudomallei (Bp),* both on and off the TNPRC site, by sampling of air, water, soil, or by whatever other means your agency, in coordination with other agencies, deems appropriate.
- In furtherance of the efforts listed above, to coordinate and lead conference calls among TNPRC, and other federal, state and local agencies that have created a "Science Working Group" to develop short term and long term environmental monitoring plans, decontamination plans, remediation plans, and other action plans in the event test results come back positive for Bp.
- Attendance by an appropriate representative from your agency at a town hall meeting in St. Tammany Parish on March 31, 2015 at 6:00pm, in conjunction with TNPRC and other federal, state and local agencies, to address and answer questions from the public concerning your agency's participation in the response to this incident.

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- Continued representation and participation by your agency in the regular activities of the Unified Command as this incident evolves, and until such time as the Unified Command determines such assistance from your agency is no longer needed on a regular (daily) basis.

Effective planning and response are essential to our joint responsibility to protect the health and safety of our citizens. We appreciate your agency's ongoing assistance in achieving these objective through our unified response to this incident.

If you have any questions, please contact me at (225) 925-7345 or by email at Kevin.Davis@la.gov

Sincerely,

Kevin Davis,

cc: RADM Scott Deitchman, CDC (Unified Commander)
Dr. Jimmy Guidry, DHH (Unified Commander)
Mr. Dexter Accardo, St. Tammany Parish OHSEP, (Unified Commander)
Mr. John Martin, EPA
Mr. Chris Petersen, EPC

NOTE: Each member receives a letter

Honorable Ron Johnson
Chairman
US Senate Committee on Homeland Security and Governmental Affairs
Washington, DC 20510-6250

Honorable Thomas R. Carper
Ranking Member
US Senate Committee on Homeland Security and Governmental Affairs
Washington, DC 20510-6250

Dear Senator XXX:

Thank you for your interest in the EPA's role in the Centers for Disease Control (CDC) and U.S. Department of Agriculture (USDA) lead investigation into how the exposure to the *Burkholderia pseudomallei* (Bp) occurred at the Tulane National Primate Research Center (TNPRC). Below is a summary of EPA activities and attached are responses to your specific requests.

On January 27, 2015, CDC requested EPA, as an assisting agency, to provide technical assistance on the development of a rapid response environmental sampling plan and on possible methods to decontaminate soil in the TNPRC non-human primate enclosures that could be implemented on an emergency basis. The EPA drafted and presented a sampling plan to the Unified Command which included the Saint Tammany Parish, Louisiana Governor's Office of Homeland Security and Emergency Preparedness (GOHSEP), Louisiana Department of Health and Hospitals (LDHH) and CDC on February 6, 2015. EPA also provided assistance to TNPRC in the development of options for their consideration regarding the decontamination of primate cages. The Unified Command adopted the sampling plan and EPA initiated air sampling on February 8, 2015, and TNPRC initiated soil and water sampling on February 9, 2015. TNPRC shipped all of the samples (air, soil and water) to CDC for analysis and interpretation. On February 20, 2015, CDC informed the Unified Command that none of the environmental samples contained live or dead traces of Bp. On March 13, 2015, CDC announced that there was no evidence at that time to suggest that Bp was released into the surrounding environment and that it was unlikely there was any threat to the general population. CDC also found that the cause of the bacteria transmission was due to lapses of internal controls.

I hope that this letter and attachments are helpful in your inquiry regarding the public and private sector response to this incident.

Sincerely yours,

Ron Curry
Regional Administrator
Environmental Protection Agency

Attachments

Attachment 1
RESPONSE TO SPECIFIC REQUEST

1. ***An explanation of the EPA's scientific justification for the soil sampling plan used in the federal investigation at the Tulane National Primate Research Center, particularly as it pertains to the number of soil samples taken at the site, and whether the agency has sought outside input or consultation about that plan (if so, please provide us with a list of those partners).***

   - **Explain the justification for the number of soil samples taken:** EPA was requested to design a sampling plan for the Unified Command's consideration, for Tulane National Primate Research Center (TNPRC) to implement and for CDC to analyze and interpret. The purpose of this plan was to develop an approach to determine if *Burkholderia pseudomallei* (Bp) had been released from primate cages. Following the DHS and EPA's Planning Guidance for Recovery Following Biological Incidents and the joint CDC, DHS and EPA's interim final Reference Guide for Developing and Executing *Bacillus anthracis* Sampling Plans in Indoor Settings, EPA used known site factors like the source location and potential release direction to determine the sample locations and optimize the possibility of detecting Bp during the February sampling effort. EPA also included sampling protocols for TNPRC to follow during the implementation of the sampling plan. Attachment 2 is a copy of the sampling plan. During implementation, at the request of CDC, the plan was adjusted in the field to add sampling locations on the north campus.

   - **Did EPA seek outside consultation on the sampling plan?** EPA briefed the Unified Command and included all input received in the sampling plan. Unified Command included: St Tammy Parish, GOHSEP, Louisiana Department of Health and Hospitals and CDC. In addition, EPA also consulted with the Louisiana Department of Environmental Quality, Louisiana Department of Agriculture and Forestry, USDA, and EPA Office of Research and Development's National Homeland Security Research Center for input on the sampling strategy, sampling procedures, and decontamination options.

2. ***A description of the procedure and specific equipment used by the EPA for air sampling pursuant to this investigation.***

   The Portable Sampling Units (PSUs) utilized at the Tulane National Primate Research Center (TNPRC) were units designed and used for the Department of Homeland Security BioWatch program. All air samples were collected utilizing PSUs. Three PSUs were used in the air sampling conducted at TNPRC. They were initially deployed throughout the South Campus in the following areas around the non-human primate enclosures; 1) The fence line nearest the Northlake Christian School, 2) Near the sewage aeration pond and 3) Near the gravel filter. The PSU's were activated on Sunday February 8th and collected data on a 24 hour basis until Thursday February 12th. The samples were sent to CDC for analysis and interpretation. CDC found that all twelve of the samples collected from the 4 days of sampling were negative for the presence of Bp or any other biological agents.

Additional details are included in the Quality Assurance Sampling Plan for Tulane University National Primate Research Center date February 2015 Section 3 Response Activities. (See Attachment 2)

3. A ***copy of the State of Louisiana's letter to the EPA requesting assistance in testing soil for B. pseudomallei.***

   See attached files
   - Copy of January 31, 2015, email request from GOHSEP requesting EPA staff to assist (Attachment 3)
   - 2/20 letter to EPA from GOHSEP (Attachment 4)
   - 3/13 letter to EPA from GOHSEP (Attachment 5)

4. ***A delineation of responsibilities among federal agencies for soil and air sampling in the wake of this and other events involving potential bioterrorism agents or infectious diseases.***

   Under the Biological Incident Annex to the National Response Framework, the coordinating agency is the Department of Health and Human Services which includes CDC. Under this annex, EPA is considered a cooperating agency. In the TNPRC event, EPA fulfilled this role when on January 27, 2015, CDC asked EPA to provide technical assistance on how to sample air, soil and water and methods to decontaminate soil in the non-human primate enclosures that could be implemented on an emergency basis. EPA then drafted and presented a plan to the Unified Command which included the St Tammany Parish, Louisiana Governor's Office of Homeland Security and Emergency Preparedness (GOHSEP), Louisiana Department of Health and Hospitals (LDHH) and CDC on February 6, 2015. The Unified Command approved the sampling plan and EPA initiated air sampling on February 8, 2015, and TNPRC initiated soil and water sampling on February 9, 2015. TNPRC shipped all of the samples (air, soil, and water) to CDC for analysis and interpretation. On March 13, 2015, CDC announced that there was no evidence at that time to suggest the organism was released into the surrounding environment and it was unlikely there was any threat to the general population.

   EPA has authority under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), Pursuant to CERCLA, disease causing agents are considered pollutants or contaminants and EPA may take action to contain or mitigate a threatened or actual release. In addition, under the National Response Framework, Emergency Support Function (ESF) #10, EPA is the ESF coordinator for Oil and Hazardous Material Response which includes chemical, biological and radiological substances, whether accidentally or intentionally released. The Homeland Security Presidential Directive #10 directs EPA to, among other items, develop "specific standards, protocols, capabilities to address the risks of contamination following a biological weapons attack and develop strategies, guidelines, and plans for decontamination of persons, equipment, and facilities."

Message

From: Crossland, Ronnie [Crossland.Ronnie@epa.gov]
Sent: 4/7/2015 5:16:11 PM
To: Smith, Monica [smith.monica@epa.gov]
CC: Petersen, Chris [petersen.chris@epa.gov]; Rhotenberry, William [Rhotenberry.William@epa.gov]; Martin, John [martin.john@epa.gov]
Subject: FW: information

From: Coleman, Sam
Sent: Tuesday, April 07, 2015 12:08 PM
To: Natarajan, Nitin; Cheatham, Reggie; Tulis, Dana
Cc: Edlund, Carl; Crossland, Ronnie
Subject: RE: information

Carl Edlund, Ronnie Crossland

Samuel Coleman, P.E.,
Deputy Regional Administrator
coleman.sam@epa.gov
214.665.2100
214.665.3110 Direct
214.789.2016 Cell

From: Natarajan, Nitin
Sent: Tuesday, April 07, 2015 12:04 PM
To: Coleman, Sam; Cheatham, Reggie; Tulis, Dana
Subject: FW: information

I've suggested to CDC that we setup a call later this week to discuss. Who from your shops should we include?

N

Nitin Natarajan
Deputy Assistant Administrator
Office of Solid Waste and Emergency Response
Environmental Protection Agency
202-566-0200 Office

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: 4/7/2015 12:50
To: Natarajan, Nitin
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: FW: information

Nitin: in case you are not aware, it appears that Tulane is acting on its own to convene a panel of independent experts to weigh in on the environmental sampling needs. The deliberations of this group should be helpful for considering additional USG-sponsored deliberations on sampling for biological threats in the environment.

It will be good to have a suitable lab or two in mind to conduct the testing should Tulane and the local authorities decide to do more testing.

Best regards,

Dan

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: Tuesday, April 07, 2015 12:47 PM
To: Helfand, Rita (CDC/OID/NCEZID); Deitchman, Scott (CDC/ONDIEH/NCEH); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: RE: information

Thank you Rita ... based on where we are in this response and our position on environmental testing, it seems best to be responsive to this panel's information requests regarding how we tested samples (as you are), and be particularly careful not to offer a contrary position to the EPA sampling methods as provided initially on request of the state.

It may be helpful to the community members to have an independent panel offer advice on further sampling at this point as long as Tulane is prepared to act on the input. The results of this panel should be informative of the need to further USG planning work for future events as well.

Dan

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Helfand, Rita (CDC/OID/NCEZID)
Sent: Tuesday, April 07, 2015 12:38 PM
To: Deitchman, Scott (CDC/ONDIEH/NCEH); Sosin, Dan (CDC/OPHPR/OD); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: FW: information

Fyi too

From: Hoffmaster, Alex (CDC/OID/NCEZID)
Sent: Tuesday, April 07, 2015 6:51 AM
To: Gee, Jay (CDC/OID/NCEZID); Glass Elrod, Mindy (CDC/OID/NCEZID); Blaney, David (CDC/OID/NCEZID); Nolen, Leisha

(CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID)
Cc: Belay, Ermias (CDC/OID/NCEZID); Helfand, Rita (CDC/OID/NCEZID); Damon, Inger K. (CDC/OID/NCEZID)
Subject: FW: information

See below regarding Tulane panel. Henry, Dave and I were just talking about this yesterday.

Mindy – well just send the consensus document along with any modifications done short description of how water was processed.
Alex

From: Lackner, Andrew A [mailto:alackner@tulane.edu]
Sent: Tuesday, April 07, 2015 6:17 AM
To: Hoffmaster, Alex (CDC/OID/NCEZID); Gee, Jay (CDC/OID/NCEZID)
Cc: Bohm, Rudolf P; Sibley, Don A
Subject: information

Alex,

As part of our response to the Burkholderia pseudomallei incident at Tulane an expert panel has been put together to help us work through the various issues that this has brought up. Among the members are David Wagner, Paul Keim and David Dance. Among the issues to consider is additional environmental testing. A question that came up in the discussion involved the methods used for environmental analyses to be sure that any future testing, if done, would be comparable with prior work. Thus, I would appreciate it if you could share details of how the analyses were performed.

best regards

Andrew
****
Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu
****

CONFIDENTIALITY NOTICE

This communication and any attachments may contain confidential and privileged information for the use of the designated recipient/s named above. Distribution, reproduction or any other use of this transmission by any party other than the intended recipient(s) is prohibited.

Message

From: Smith, Monica [smith.monica@epa.gov]
Sent: 4/3/2015 6:10:16 PM
To: Crossland, Ronnie [Crossland.Ronnie@epa.gov]; Petersen, Chris [petersen.chris@epa.gov]; Martin, John [martin.john@epa.gov]; Rhotenberry, William [Rhotenberry.William@epa.gov]
Subject: revised final response - Tulane 4-3-2015 1pm
Attachments: Joint Env Sampling Guidelines_27 April 2014_CLEAN.docx; Planning Guidance for Recovery Following Biological Incidents final 0211 .docx; EPA Letter - February 20 2015.pdf; january 31 2015 gohsep email requesting EPA assistance.pdf; Ron Curry - EPA Letter - March 13 2015.pdf; Tulane University ER QASP - v2.pdf; draft 12 432015 1pm.docx

I incorporated Nittin's comments

Monica Smith
US EPA Region 6
Superfund Division
1445 Ross Avenue
Dallas, TX 75202-2733
214-665-6780 office
469-766-3398 cell
214-665-6660 fax

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NOTE: Each member receives a letter

Honorable Ron Johnson
Chairman
US Senate Committee on Homeland Security and Governmental Affairs
Washington, DC 20510-6250

Honorable Thomas R. Carper
Ranking Member
US Senate Committee on Homeland Security and Governmental Affairs
Washington, DC 20510-6250

Dear Senator XXX:

Thank you for your interest in the EPA's role in the Centers for Disease Control (CDC) and U.S. Department of Agriculture (USDA) lead investigation into how the exposure to the Burkholderia pseudomallei (Bp) occurred at the Tulane National Primate Research Center (TNPRC). Below is a summary of EPA activities and attached are responses to your specific requests.

On January 27, 2015, CDC requested EPA, as an assisting agency, to provide technical assistance on the development of a rapid response environmental sampling plan and on possible methods to decontaminate soil in the TNPRC non-human primate enclosures that could be implemented on an emergency basis. The EPA drafted and presented a sampling plan to the Unified Command which included the Saint Tammany Parish, Louisiana Governor's Office of Homeland Security and Emergency Preparedness (GOHSEP), Louisiana Department of Health and Hospitals (LDHH) and CDC on February 6, 2015. EPA also provided the Unified Command with specific options for their consideration regarding the decontamination of primate cages. The Unified Command adopted the sampling plan and EPA initiated air sampling on February 8, 2015, and TNPRC initiated soil and water sampling on February 9, 2015. TNPRC shipped all of the samples (air, soil and water) to CDC for analysis and interpretation. On February 20, 2015, CDC informed the Unified Command that none of the environmental samples contained live or dead traces of Bp. On March 13, 2015, CDC announced that there was no evidence at that time to suggest that Bp was released into the surrounding environment and that it was unlikely there was any threat to the general population. CDC also found that the cause of the bacteria transmission was due to lapses of internal controls.

On March 13, 2015, the CDC/USDA Federal Special Agent Program investigators referred this matter to the enforcement bodies within USDA and/or HHS (on behalf of CDC) for consideration of civil penalties and other actions. Any additional actions would be expected to be conducted by the TNPRC, the independent owner and operator of the research laboratory, as a result of

enforcement requirements by the appropriate federal and state agencies. A decision to decontaminate primate cages will remain the responsibility of the TNPRC and local authorities.

I hope that this letter and attachments are helpful in your inquiry regarding the public and private sector response to this incident.

Sincerely yours,

Ron Curry
Regional Administrator
Environmental Protection Agency

Attachments

Attachment 1
RESPONSE TO SPECIFIC REQUEST

1. ***An explanation of the EPA's scientific justification for the soil sampling plan used in the federal investigation at the Tulane National Primate Research Center, particularly as it pertains to the number of soil samples taken at the site, and whether the agency has sought outside input or consultation about that plan (if so, please provide us with a list of those partners).***

   - **Explain the justification for the number of soil samples taken:** EPA was requested to design a sampling plan for the Unified Command's consideration, for TNPRC to implement and for CDC to analyze and interpret. The purpose of this plan was to develop an approach to determine if Burkholderia pseudomallei (Bp) had been released from primate cages. Following the DHS and EPA's Planning Guidance for Recovery Following Biological Incidents and the joint CDC, DHS and EPA's interim final Reference Guide for Developing and Executing *Bacillus Anthracis* Sampling Plans in Indoor Settings, EPA used known site factors like the source location and potential release direction to determine the sample locations and optimize the possibility of detecting Bp during the February sampling effort. EPA also included sampling protocols for TNPRC to follow during the implementation of the sampling plan. Attachment 2 is a copy of the sampling plan. During implementation, at the request of CDC, the plan was adjusted in the field to add sampling locations on the north campus.

   - **Did EPA seek outside consultation on the sampling plan?** EPA briefed the Unified Command and included all input received in the sampling plan. Unified Command included: St Tammy Parish, GOHSEP, Louisiana Department of Health and Hospitals and CDC. In addition, EPA also consulted with the Louisiana Department of Environmental Quality, Louisiana Department of Agriculture and Forestry, USDA, and EPA Office of Research and Development's National Homeland Security Research Center for input on the sampling strategy, sampling procedures, and decontamination options.

2. ***A description of the procedure and specific equipment used by the EPA for air sampling pursuant to this investigation.***

   The Portable Sampling Units (PSUs) utilized at the Tulane National Primate Research Center (TNPRC) were units designed and used for the Department of Homeland Security BioWatch program. All air samples were collected utilizing PSUs. Three PSUs were used in the air sampling conducted at TNPRC. They were initially deployed throughout the South Campus in the following areas around the non-human primate enclosures; 1)The fence line nearest the Northlake Christian School, 2) Near the sewage aeration pond and 3) Near the gravel filter. The PSU's were activated on Sunday February 8th and collected data on a 24 hour basis until Thursday February 12th. The samples were sent to CDC for analysis and interpretation. CDC found that all twelve of the samples collected from the 4 days of sampling were negative for the presence of Bp or any other biological agents.

Additional details are included in the Quality Assurance Sampling Plan for Tulane University National Primate Research Center date February 2015 Section 3 Response Activities. (See Attachment 2)

3. A ***copy of the State of Louisiana's letter to the EPA requesting assistance in testing soil for B. pseudomallei.***

   See attached files
   - Copy of January 31, 2015, email request from GOHSEP requesting EPA staff to assist (Attachment 3)
   - 2/20 letter to EPA from GOHSEP (Attachment 4)
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4. ***A delineation of responsibilities among federal agencies for soil and air sampling in the wake of this and other events involving potential bioterrorism agents or infectious diseases.***

   Under the Biological Incident Annex to the National Response Framework, the coordinating agency is the Department of Health and Human Services which includes CDC. Under this annex, EPA is considered a cooperating agency. In the TNPRC event, EPA fulfilled this role when on January 27, 2015, CDC asked EPA to provide technical assistance on how to sample air, soil and water and methods to decontaminate soil in the non-human primate enclosures that could be implemented on an emergency basis. EPA then drafted and presented a plan to the Unified Command which included the Saint Tammany Parish, Louisiana Governor's Office of Homeland Security and Emergency Preparedness (GOHSEP), Louisiana Department of Health and Hospitals (LDHH) and CDC on February 6, 2015. The Unified Command approved the sampling plan and EPA initiated air sampling on February 8, 2015, and TNPRC initiated soil and water sampling on February 9, 2015. TNPRC shipped all of the samples (air, soil, and water) to CDC for analysis and interpretation. On March 13, 2015, CDC announced that there was no evidence at that time to suggest the organism was released into the surrounding environment and it was unlikely there was any threat to the general population.

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Message

From: Crossland, Ronnie [Crossland.Ronnie@epa.gov]
Sent: 4/3/2015 8:03:39 PM
To: Edlund, Carl [Edlund.Carl@epa.gov]
CC: Phillips, Pam [phillips.pam@epa.gov]; Coleman, Sam [Coleman.Sam@epa.gov]; Gray, David [gray.david@epa.gov]; Rhotenberry, William [Rhotenberry.William@epa.gov]; Smith, Monica [smith.monica@epa.gov]; Martin, John [martin.john@epa.gov]; Petersen, Chris [petersen.chris@epa.gov]
Subject: FW: revised final response - Tulane 4-3-2015 1pm
Attachments: Joint Env Sampling Guidelines_27 April 2014_CLEAN.docx; Planning Guidance for Recovery Following Biological Incidents final 0211 .docx; EPA Letter - February 20 2015.pdf; january 31 2015 gohsep email requesting EPA assistance.pdf; Ron Curry - EPA Letter - March 13 2015.pdf; Tulane University ER QASP - v2.pdf; draft 12 432015 1pm.docx

Carl and David,

We made the suggested changes from Nitin and coordinated with OEM on the names of the reference documents.

Ronnie

Message

From: Crossland, Ronnie [Crossland.Ronnie@epa.gov]
Sent: 4/2/2015 1:04:10 PM
To: Edlund, Carl [Edlund.Carl@epa.gov]
CC: Phillips, Pam [phillips.pam@epa.gov]; Coleman, Sam [Coleman.Sam@epa.gov]; Gray, David [gray.david@epa.gov]; Smith, Monica [smith.monica@epa.gov]; Rhotenberry, William [Rhotenberry.William@epa.gov]; Martin, John [martin.john@epa.gov]; Crossland, Ronnie [Crossland.Ronnie@epa.gov]
Subject: Revised Draft Tulane Response
Attachments: Tulane University ER QASP - v2.pdf; january 31 2015 gohsep email requesting EPA assistance.pdf; Ron Curry - EPA Letter - March 13 2015.pdf; EPA Letter - February 20 2015.pdf; draft response 11 3-31-15.docx

Flag: Follow up

Here is the letter and all of the attachments.

From: Crossland, Ronnie
Sent: Tuesday, March 31, 2015 4:39 PM
To: Edlund, Carl
Cc: Phillips, Pam; Coleman, Sam; Gray, David; Smith, Monica; Rhotenberry, William; Martin, John
Subject: Revised Draft Tulane Response

Attached is a revised draft response to the senators. I incorporated Sam and David's revisions and I also took out the reference to the ERT Sampling Guidelines. So this should be the most current draft.

Ronnie

DRAFT
3/31/2015 4:00 PM

NOTE: Each member receives a letter

Honorable Ron Johnson
Chairman
US Senate Committee on Homeland Security and Governmental Affairs
Washington, DC 20510-6250

Honorable Thomas R. Carper
Ranking Member
US Senate Committee on Homeland Security and Governmental Affairs
Washington, DC 20510-6250

Dear Senator XXX:

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Primate Center, the independent owner and operator of the research laboratory, as a result of binding enforcement requirements by the appropriate federal and state agencies. The decision to decontaminate primate cages is left to TNPRC and local authorities.

I hope that this and the attached information is helpful in demonstrating the efficiency and effectiveness of not only EPA's, but also the entire Federal Government's response to this incident.

Sincerely yours,

Ron Curry
Regional Administrator
Environmental Protection Agency

Attachments

DRAFT

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   The Portable Sampling Units (PSUs) utilized at the Tulane National Primate Research Center (TNPRC) were units designed and used for the Department of Homeland Security BioWatch program. All air samples were collected utilizing PSUs. Three PSUs were used in the air sampling conducted at TNPRC. They were initially deployed throughout the South Campus in the following areas around the non-human primate enclosures; 1) The fence line nearest the Northlake Christian School, 2) Near the sewage aeration pond and 3) Near the gravel filter. The PSU's were activated on Sunday February 8th and collected data on a 24 hour basis until Thursday February 12th. The samples were sent to CDC for analysis and interpretation. CDC found that all twelve of the samples collected from the 4 days of sampling were negative for the presence of Bp or any other biological agents.

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Message

From: Nalipinski, Mike [Nalipinski.Mike@epa.gov]
Sent: 3/30/2015 5:39:53 PM
To: Alise, Mark A [malise@tulane.edu]
CC: Ryan, Shawn [Ryan.Shawn@epa.gov]; Martin, John [martin.john@epa.gov]; Lackner, Andrew A [alackner@tulane.edu]; Bohm, Rudolf P [bohm@tulane.edu]; Blanchard, James L [jblanch1@tulane.edu]
Subject: RE: Soil remediation options TNPRC Conf call Tues 3/31 0900 eastern

Importance: High

Mark --

Please call in tomorrow at 866-299-3188 pass code 617 918 1228 at 0900 hrs eastern time to discuss decontamination options for the TNPRC field cages. The objective of the meeting will be to discuss various possible technologies and ideally agree on an acceptable technical approach. The next step would be for the TNPRC to prepare a proposal (based on our conversation) that would be submitted to the Unified Command for their review and approval.

Talk to you tomorrow.

Michael Nalipinski, Associate Director
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Monday, March 30, 2015 1:30 PM
To: Nalipinski, Mike
Cc: Ryan, Shawn; Martin, John; Lackner, Andrew A; Bohm, Rudolf P; Blanchard, James L
Subject: Re: Soil remediation options TNPRC Conf call
Importance: High

Mike,

Thanks for you call. Can we set up the conference call for 8:00 am CDT, 9:00 am EDT tomorrow March 31?

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

From: <Alise>, Mark Alise <malise@tulane.edu>
Date: Monday, March 30, 2015 at 10:27 AM
To: "Nalipinski, Mike" <Nalipinski.Mike@epa.gov>
Cc: "Ryan, Shawn" <Ryan.Shawn@epa.gov>, "Martin, John" <martin.john@epa.gov>, Andrew Lackner

<alackner@tulane.edu>, Rudolf Bohm <bohm@tulane.edu>
Subject: Re: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time

Subsequent to the Unified Command meeting this morning, when can we re-schedule this call?

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

From: <Nalipinski>, Mike <Nalipinski.Mike@epa.gov>
Date: Tuesday, March 17, 2015 at 3:23 PM
To: Mark Alise <malise@tulane.edu>
Cc: "Ryan, Shawn" <Ryan.Shawn@epa.gov>, "Martin, John" <martin.john@epa.gov>
Subject: RE: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time

Mark –

Thanks for accommodating a call tomorrow at 1500 hrs Eastern Standard Time. We can use the following call in number:

877-299-3188 pass code 202 564 2359

Note that I've invited OSC John Martin Region 6 and Dr. Shawn Ryan NHSRC to the call. As you know John is the EPA lead out of Dallas and Shawn is the Director of EPA's Office of Research and Development National Homeland Security Research Center. Shawn's group has conducted extensive laboratory and field studies on different decontamination technologies.

The goal of tomorrow's meeting is to hopefully down select one or two technologies that the group could support and that would merit more detailed evaluation/consideration. In my previous e-mails EPA has offered several options and those, or if you have other alternatives, could be a framework for our conversation.

Have a good evening and looking forward to a productive discussion tomorrow.

Cheers,

V/R

Michael Nalipinski
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Tuesday, March 17, 2015 3:07 PM
To: Nalipinski, Mike
Cc: Lackner, Andrew A; Blanchard, James L
Subject: FW: Soil remediation options TNPRC

Mike,

Thanks for the information. I would like Dr. Lackner to join in our conversation tomorrow afternoon and I am copying him on this response.

We can talk at 2:00 pm CDT, 3:00 pm EDT if that works for you. If not we can work around other afternoon times.

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

TULANE NATIONAL PRIMATE RESEARCH CENTER

From: <Nalipinski>, Mike <Nalipinski.Mike@epa.gov>
Date: Tuesday, March 17, 2015 at 1:34 PM
To: Mark Alise <malise@tulane.edu>
Cc: "Martin, John" <martin.john@epa.gov>, "Ryan, Shawn" <Ryan.Shawn@epa.gov>, "Petersen, Chris" <petersen.chris@epa.gov>, "Smith, Monica" <smith.monica@epa.gov>
Subject: FW: Soil remediation options TNPRC

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I hope the above information will be thought provoking and can guide our conversations as we continue to evaluate options to decontaminate the field cages. Please let me know if you would be available tomorrow March 18th to continue our discussion. I am available any time after noon eastern standard time.

Cheers,

V/R

Michael Nalipinski, Associate Director
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

Message

From: Alise, Mark A [malise@tulane.edu]
Sent: 3/30/2015 3:27:47 PM
To: Nalipinski, Mike [Nalipinski.Mike@epa.gov]
CC: Ryan, Shawn [Ryan.Shawn@epa.gov]; Martin, John [martin.john@epa.gov]; Lackner, Andrew A [alackner@tulane.edu]; Bohm, Rudolf P [bohm@tulane.edu]
Subject: Re: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time
Attachments: image002.png

Importance: High

Subsequent to the Unified Command meeting this morning, when can we re-schedule this call?

Mark

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From: <Nalipinski>, Mike <Nalipinski.Mike@epa.gov>
Date: Tuesday, March 17, 2015 at 3:23 PM
To: Mark Alise <malise@tulane.edu>
Cc: "Ryan, Shawn" <Ryan.Shawn@epa.gov>, "Martin, John" <martin.john@epa.gov>
Subject: RE: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time

Mark –

Thanks for accommodating a call tomorrow at 1500 hrs Eastern Standard Time. We can use the following call in number:

877-299-3188 pass code 202 564 2359

Note that I've invited OSC John Martin Region 6 and Dr. Shawn Ryan NHSRC to the call. As you know John is the EPA lead out of Dallas and Shawn is the Director of EPA's Office of Research and Development National Homeland Security Research Center. Shawn's group has conducted extensive laboratory and field studies on different decontamination technologies.

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From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Tuesday, March 17, 2015 3:07 PM
To: Nalipinski, Mike
Cc: Lackner, Andrew A; Blanchard, James L
Subject: FW: Soil remediation options TNPRC

Mike,

Thanks for the information. I would like Dr. Lackner to join in our conversation tomorrow afternoon and I am copying him on this response.

We can talk at 2:00 pm CDT, 3:00 pm EDT if that works for you. If not we can work around other afternoon times.

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Message

From: Alise, Mark A [malise@tulane.edu]
Sent: 3/30/2015 5:30:16 PM
To: Nalipinski, Mike [Nalipinski.Mike@epa.gov]
CC: Ryan, Shawn [Ryan.Shawn@epa.gov]; Martin, John [martin.john@epa.gov]; Lackner, Andrew A [alackner@tulane.edu]; Bohm, Rudolf P [bohm@tulane.edu]; Blanchard, James L [jblanch1@tulane.edu]
Subject: Re: Soil remediation options TNPRC Conf call
Attachments: image002.png

Importance: High

Mike,

Thanks for you call. Can we set up the conference call for 8:00 am CDT, 9:00 am EDT tomorrow March 31?

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

From: <Alise>, Mark Alise <malise@tulane.edu>
Date: Monday, March 30, 2015 at 10:27 AM
To: "Nalipinski, Mike" <Nalipinski.Mike@epa.gov>
Cc: "Ryan, Shawn" <Ryan.Shawn@epa.gov>, "Martin, John" <martin.john@epa.gov>, Andrew Lackner <alackner@tulane.edu>, Rudolf Bohm <bohm@tulane.edu>
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Message

From: Smith, Monica [smith.monica@epa.gov]
Sent: 3/26/2015 11:15:30 PM
To: Edlund, Carl [Edlund.Carl@epa.gov]; Crossland, Ronnie [Crossland.Ronnie@epa.gov]; Petersen, Chris [petersen.chris@epa.gov]; Martin, John [martin.john@epa.gov]; Rhotenberry, William [Rhotenberry.William@epa.gov]; Phillips, Pam [phillips.pam@epa.gov]
Subject: draft version 5
Attachments: EPA Letter - February 20 2015.pdf; january 31 2015 gohsep email requesting EPA assistance.pdf; Ron Curry - EPA Letter - March 13 2015.pdf; Tulane University ER QASP - v2 (2).pdf; draft response 5.docx; Incident Action Plan - 01.pdf

Here is the latest version of the letter. It includes the following paragraph which was taken out of an update John Martin received from GOSHEP in February.

In late November 2014, two non-human primates in the breeding colony at TNPRC became ill. In mid-December 2014, samples submitted to the CDC identified Burkholderia Pseudomallei as the causative agent. This strain of bacteria is not endemic in the US but was the subject of research at TNPRC. Because Burkholderia Pseudomallei is a tier 1 agent and the material was considered not in containment, the CDC and U.S. Department of Agriculture (USDA) initiated a joint investigation of TNPRC in January 2015. As part of the investigation conducted January 20-24, federal and state scientists visited the TNPRC site to conduct epidemiological study and to review lab practices to determine possible route of transmission. (This language in this paragraph is from GOHSEP update on 2/19/2015)

The attachments to this email are in support of the response to the 4 requests with the exception of the Incident action plan which is being provided to show the structure of the organization.

Attachments:
1 – incident action plan dated February 9, 2015
2- quality assurance sampling plan to support soil and air sampling
3 – January 31, 2015 email from GOHSEP requesting assistance
4– February 20, 2015 letter from GOHSEP requesting assistance
5- March 13 , 2015 letter from GOHSEP requesting assistance

For ease in reading on your mobile device, I have included the letter as part of the text of this message. Let me know if you have any changes to make. Thanks - Monica

Thank you for your interest in the EPA's role in the Centers for Disease Control (CDC) and U.S. Department of Agriculture's (USDA) investigation into how the exposure to the Burkholderia pseudomallei (Bp) occurred at the Tulane National Primate Research Center (TNPRC)
In late November 2014, two non-human primates in the breeding colony at TNPRC became ill. In mid-December 2014, samples submitted to the CDC identified Burkholderia Pseudomallei as the causative agent. This strain of bacteria is not endemic in the US but was the subject of research at TNPRC. Because Burkholderia Pseudomallei is a tier 1 agent and the material was considered not in containment, the CDC and U.S. Department of Agriculture (USDA) initiated a joint investigation of TNPRC in January 2015. As part of the investigation conducted January 20-24, federal and state scientists visited the TNPRC site to conduct epidemiological study and to review lab practices to determine possible route of transmission. (This language in this paragraph is from GOHSEP update on 2/19/2015)

As a result of their joint investigation CDC and USDA concluded they needed assistance and technical advice from EPA. CDC reached out to EPA on January 27, 2015, requesting EPA's assistance and advice in developing soil sampling plans and remediation plans. As indicated in the Incident Action Plan (see Attachment 1) produced by the Governor's Office of Homeland Security and Emergency Preparedness (GOHSEP), EPA's response role for this incident is to provide assistance to the Unified Command comprised of local and state response agencies and the CDC. EPA is considered an Assisting Agency, an agency directly contributing tactical and other resources to the incident but not part of the Unified Command. (UC). In response this incident, CDC has been the lead federal agency and has been an active participant in the UC.

At CDC's request, EPA developed environmental sampling plans to aid in determining the presence or absence of Bp in the environment. EPA developed submitted sampling plans for air, water and soil on February 6, 2015. The sampling plans were implemented by TNPRC scientists. For the environmental sampling that occurred from February 8 to February 12, EPA arranged for portable sampling units to be provided to collect air samples. The air, soil and water sampling locations were targeted locations that had the highest likelihood of finding the bacteria. TNRPC staff collected the soil and water samples. EPA provided advice to TNPRC, the Potential Responsible Party, to ensure compliance with the plans. TNPRC shipped the samples to the CDC for laboratory analysis and interpretation. EPA completed these tasks and demobilized its staff on February 13, 2015. On February 20, 2015, CDC informed Unified Command that none of the screening environmental samples contained live or dead traces of the bacteria.

Unified Command initially indicated that the two field cages would be decontaminated and requested that EPA assisted TRNPC with the development of a decontamination strategy plan for two field cages that housed the first two infected monkeys. As the extent of exposure and the nature of the problem continued to evolve, additional cages which might require decontamination were identified. On March 13, 2015 CDC announced that it closed its investigation and had determined that the cause of contamination was due to poor internal controls in the research center. CDC also concluded that there was no evidence to suggest that the organism was released into the surrounding environment based on their analysis of field samples collected by Tulane under EPA's sampling plan. Seeing that CDC had concluded that it is unlikely that Bp is a threat to the general population, EPA discontinued its assistance to CDC with respect to the response at TNPRC.

RESPONSE TO SPECIFIC REQUEST

1. ***An explanation of the EPA's scientific justification for the soil sampling plan used in the federal investigation at the Tulane National Primate Research Center, particularly as it pertains to the number of soil samples taken at the site, and whether the agency has sought outside input or consultation about that plan (if so, please provide us with a list of those partners).***

   - **Explain the justification for the number of soil samples taken:** EPA was requested to design a sampling plan which TNRPC would implement to evaluate if Bp may be present in the environment. The UC required a rapid evaluation of the environmental conditions. Thus, TNRPC conducted targeted sampling at locations having the greatest probability of identifying Bp based on the available epidemiological information and environmental conditions.

   - **Did EPA seek outside consultation on the sampling plan?** EPA worked within the Incident Command System and sought input, and approval of the plan prior to implementation, from the members of the Incident Management Team. Those included: GOHSEP, St Tammy Parish, Louisiana Department of Environmental Quality, Louisiana Department of Agriculture and Forestry, USDA, and CDC, EPA also coordinated internally with our Office of Research and Development's National Homeland Security Research Center for input on the sampling strategy, sampling procedures, and decontamination options.

     Additional details are included in the Quality Assurance Sampling Plan for Tulane University National Primate Research Center date February 2015 Section 3 Response Activities. (See Attachment 2)

2. ***A description of the procedure and specific equipment used by the EPA for air sampling pursuant to this investigation.***

   Air samples were collected utilizing Portable Sampling Units (PSUs). The PSUs utilized at the Tulane National Primate Research Center (TNPRC) were units used for the BioWatch program. The PSU is an aerosol monitor which draws in air and passes it through a filter. The filters are then manually collected, typically every 24 hours and shipped to a laboratory for analysis. CDC was responsible for coordinating the laboratory analysis and result interpretation of the filters at the Georgia Public Health Laboratory collected during the TNPRC sampling event. The filters were analyzed using standardized Bio Watch program polymerase chain reaction (PCR) techniques specific for *Burkholderia pseudomallei* (Bp). If a biological agent is detected, lab analysts will then perform a secondary test. A positive secondary test result is considered a PCR-verified positive and indicates the presence of a biological material in the air.
   Three PSUs were used in the air sampling conducted at TNPRC. They were initially deployed throughout the South Campus in the following areas around the non-human primate enclosures; 1) The fence line nearest the Northlake Christian School, 2) Near the sewage aeration pond and 3) Near the gravel filter. The flow rate of the PSU's was set at 100 liters per minute (L/m). The PSU's were activated on Sunday February 8th and collected data on a 24 hour basis until Thursday February 12th. All twelve of the samples collected from the 4 days of sampling were negative for the presence of Bp or any other biological agents.

   Additional details are included in the Quality Assurance Sampling Plan for Tulane University National Primate Research Center date February 2015 Section 3 Response Activities. (See Attachment 2)

3. A ***copy of the State of Louisiana's letter to the EPA requesting assistance in testing soil for B. pseudomallei.***

   See attached files

- Copy of January 31, 2015, email request from GOHSEP requesting EPA staff to assist (Attachment 3)
- 2/20 letter to EPA from GOHSEP (Attachment 4)
- 3/13 letter to EPA from GOHSEP (Attachment 5)

4. ***A delineation of responsibilities among federal agencies for soil and air sampling in the wake of this and other events involving potential bioterrorism agents or infectious diseases.***

CDC and USDA conducted a joint investigation of TNPRC on January 20-24, 2015. As a result of their joint investigation CDC and USDA concluded they needed assistance and technical advice from EPA. CDC reached out to EPA on January 27, 2015, requesting EPA's assistance and advice in developing soil sampling plans and remediation plans. EPA worked closely with our federal partners to provide air, soil, and water sampling advice to TNPRC. CDC is the federal lead for the epidemiological investigation and protection of public health

However, EPA has various response authorities. Under EPA's CERCLA authority, biological agents are considered pollutants or contaminants and EPA has the authority to take action to contain or mitigate a threat. Under the National Response Framework, Emergency Support Function #10, EPA is the ESF coordinator for Oil and Hazardous Material Response which includes chemical, biological and radiological substances, whether accidentally or intentionally released. HSPD 10 directs EPA to develop "specific standards, protocols, capabilities to address the risks of contamination following a biological weapons attack and develop strategies, guidelines, and plans for decontamination of persons, equipment, and facilities."

EPA also ensures "enforcement first," whereas (potentially) responsible parties are required to comply with CERCLA and other relevant authorities. The Tulane National Primate Research Center (TNPRC) is considered a potentially responsible party. Tulane was conducting their work for CDC, CDC is in charge of the Federal Select Agent Program. The Unified Command noted that the investigation has identified lapses in personal protective equipment (PPE) and implementation of biosafety practices and security procedures in the Tulane building.

In past biological events, EPA has conducted the following activities:

- Capitol Hill Anthrax – this clearly was a terrorist event without an identified responsible party. EPA collected surface and air samples, developed a decontamination plan, and provided technical oversight of the contractor hired to conduct the decontamination. EPA provided technical assistance to the lead federal agency;
- Danbury, CT Anthrax Case – The home owner (responsible party) did not have the resources to respond the contamination. EPA was the lead federal agency for this response and collected environmental samples and conducted the decontamination;
- University of New Hampshire Anthrax Case – EPA served in a technical advisory role to the State of New Hampshire who was working with the responsible party (a nonprofit religious ministry), and to the State and federal public health officials; EPA collected one round of characterization samples to determine the extent of contamination in support the epidemiological and environmental evaluations. EPA advised the public health officials on decontamination options.
- Ricin – there have been several ricin cases over the last three years; EPA has provided technical advice on the sampling, analysis, and decontamination to the state public health officials. In some cases, EPA has collected samples and conducted decontamination whereas in other cases EPA has reviewed plans and provided technical consultation (dependent upon the local and state capabilities).
- Ebola – Since Ebola has been a primary concern in a healthcare setting, CDC has been the lead federal agency. However, EPA did prepare plans for clean-up outside of a health care setting should it be necessary. Thus far, Ebola cases in the US have not required EPA to consult or assist with clean up outside of a health care setting.

As indicated in the responses above, EPA has various authorities, and can provide various levels of assistance during a biological response ranging from advice to leading a response. Each incident is unique and EPA has the option to use its response authorities as appropriate.

.

Monica Smith
US EPA Region 6
Superfund Division
1445 Ross Avenue
Dallas, TX 75202-2733
214-665-6780 office
469-766-3398 cell
214-665-6660 fax

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EMERGENCY RESPONSE
QUALITY ASSURANCE SAMPLING PLAN

FOR

TULANE UNIVERSITY - NATIONAL PRIMATE RESEARCH CENTER
18703 THREE RIVERS ROAD
COVINGTON, ST TAMMANY PARISH, LOUISIANA

Prepared for

U.S. Environmental Protection Agency Region 6
Will LaBombard, Project Officer
1445 Ross Avenue
Dallas, Texas 75202

Contract No. EP-W-06-042
Technical Direction Document No. 1/WESTON-042-15-008
WESTON Work Order No. 20406.012.001.0933.01
NRC No: N/A
CERCLIS ID: N/A
FPN: N/A
EPA TM: John Martin
START-3 PTL: Sam Cheek

Prepared by

Weston Solutions, Inc.
Cecilia H. Shappee P.E., Program Manager
5599 San Felipe, Suite 700
Houston, Texas 77056
(713) 985-6600

February 2015

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1. INTRODUCTION

Weston Solutions, Inc. (WESTON®), the Superfund Technical Assessment and Response Team (START-3) contractor, has been tasked by U.S. Environmental Protection Agency (EPA) Region 6 Prevention and Response Branch (PRB) under Contract Number EP-W-06-042 and Technical Direction Document (TDD) No. 1/WESTON-042-15-008 to conduct an Emergency Response (ER) at the National Primate Research Center, located in Covington, St Tammany Parish, Louisiana.

The EPA Team has prepared this ER Quality Assurance Sampling Plan (QASP) to describe the field investigation activities, sampling, and analytical scope of work to be conducted as part of the response.

1.1 PROJECT OBJECTIVES

The EPA Team is providing technical assistance to EPA Region 6 for the performance of the biological assessment as part of the ER. EPA will be responsible for coordinating the collection and analysis of environmental samples. However, personnel from the Tulane National Primate Research Center (TNPRC) will collect the on-site soil, sediment, and water samples with EPA oversight. The EPA Team will collect the air samples.

1.2 PROJECT TEAM

The EPA Team will consist of EPA Task Monitor (TM), John Martin; Sam Cheek, the EPA Team Project Team Leader (PTL); Jose Ojeda, the Field Team Leader (FTL); Jeff Wright, Project Chemist; Janine Latham, IT and Data Manager (DM); and additional EPA Team members as necessary to assist with sample preparation, packing, and shipment.

The EPA Team PTL will be responsible for the technical quality of work performed in the field and will serve as the EPA team liaison to the EPA TM during the field activities. The PTL will log the activities at each sample location in the field logbook and verify the sample

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documentation. The DM will be responsible for entering all samples collected into the Scribe Environmental Sampling Data Management System (SCRIBE), for producing accurate chain-of-custody documentation for the samples during the ER, and for entering daily operations and sample collection data into EPA Response Manager. The PTL will oversee the packaging and shipping of samples to the designated laboratory. The PTL will also be responsible for providing overall site health and safety support during field activities.

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2. SITE BACKGROUND

Two macaques at TNPRC were potentially infected with the bacteria Burkholderia pseudomallei (abbreviated Bp, the cause of Melioidosis). One animal was euthanized on 26 November 2014, and the second macaque has reportedly recovered. According to the Center for Disease Control (CDC) Burkholderia pseudomallei is a bacterium endemic to Southeast Asia and Northern Australia, and is typically found in contaminated water and soil. The bacterium spreads through direct contact with the contaminated source. The manner in which the macaques were exposed to the Bp is not known at this time.

An Inspector for the U.S. Department of Agriculture was reported to have become sick after performing an inspection at the facility. However, it has not been determined if the Inspector's illness is related to or is the result of exposure to Bp.

2.1 SITE LOCATION AND DESCRIPTION

The TNPRC is divided into a "North Campus" and a "South Campus." The North Campus is located north of Three Rivers Road and contains the offices and laboratories. The South Campus is located south of Three Rivers Road and contains the macaque breeding colonies, the storm-water treatment system, and the sewage treatment system. The macaques were located in cages in the South Campus when they were discovered to be sick.

2.2 OPERATIONAL HISTORY AND OWNERSHIP

The TNPRC has a national mission to improve human and animal health through basic and applied biomedical research. The TNPRC website states their purpose is the following:

- Conduct basic and applied biomedical research on human health problems using nonhuman primate models.
- Investigate nonhuman primate biology and diseases with particular regard to the study of human health problems.
- Serve as a regional and national resource and center of excellence for biomedical research using nonhuman primates.

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- Provide training for graduate students, postdoctoral fellows, veterinarians, undergraduates, veterinary students, and visiting scientists.
- Educate the general public about the critical link between basic research with animal models and improvements in human health.

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3. RESPONSE ACTIVITIES

The activities that will be conducted during the response are discussed in this section. Sampling of surface water, sediment and waste sampling procedures, locations, analytical approach, and quality assurance (QA) that will be conducted during the response are also discussed.

3.1 SAMPLING STRATEGY

A sampling strategy was developed by TNPRC and EPA representatives to collect the data necessary to evaluate and meet the objectives of the response. The sampling strategy focuses on the collection of soil, water, and air samples by employees of the TNPRC. Sampling Standard Operating Procedures (SOPs) for naturally occurring Bp in the soils of Southeast Asia call for a sample depth of 30 centimeters. However, for this response the source of the Bp is believed to be runoff of waste products from the macaque cages which could have been deposited onto the top of the soil or sediment. Therefore, soil and sediment samples will be collected in the top 2 inches of soil. Samples may be collected at a greater depth as the project progresses.

Table 3-1 has been prepared to include a summary of Sample Locations and Sampling Rationale as part of the ER field effort.

3.2 DATA QUALITY OBJECTIVE

The objective of sampling activities is to determine if Bp is present in the soil, sediment, water, and air at the facility. Soil, sediment, and water sampling will be conducted by TNPRC personnel. The EPA Team will conduct air sampling. The sampling will be conducted under direction of the EPA TM and TNPRC representatives. Media specific data quality objectives (DQOs) are not applicable. If DQOs are determined to be applicable, they will be developed using the seven-step process set out in the *EPA Guidance for Quality Assurance Project Plans: EPA QA/G-5*.

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3.3 PRELIMINARY FIELD ACTIVITIES

Mobilization and preliminary field activities for the ER are discussed in the following subsections.

3.3.1 Field Activities Review Meeting

The EPA Team FTL will conduct a meeting with the entire field team to familiarize them with the ER Scope of Work; to discuss EPA TM expectations, including planned field investigation activities; and to review the project Health and Safety Plan (HASP) and other relevant EPA team operating procedures. This meeting will be conducted in the WESTON Houston, Texas, office or via video conferencing for team members in other offices prior to mobilizing to the field.

3.3.2 Mobilization and Command Post Establishment

The EPA Team will mobilize the equipment required for the response from the EPA warehouse in Addison, Texas, and the WESTON equipment stores in Dallas and Houston, Texas. The field team will utilize the EPA mobile Logistics Response Vehicle (LRV) as a command post. Equipment used during the ER will be stored in the command post. Dedicated (nondisposable and disposable) sampling equipment will be used to collect samples in a manner minimizing the number of times that decontamination is performed on a daily basis.

Prior to demobilization, field supplies and equipment will be transported back to the EPA warehouse and WESTON equipment stores.

3.3.3 Health and Safety Plan Implementation

The ER field activities will be conducted in accordance with the site-specific HASP prepared for this investigation. In general, the HASP specifies that work on the North Campus will proceed in Level D personal protective equipment (PPE). During sampling events on the South Campus the EPA will be teamed with TNPRC personnel and follow TNPRC protocols wearing a modified Level C consisting of Tyvek coveralls, nitrile gloves, boot covers, surgical caps, face shields, and N95 masks. The EPA Team FTL will serve as the Field Safety Officer (FSO) and

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will be responsible for implementation of the HASP during field investigation activities. Daily tailgate safety meetings will be held prior to initiation of each work day.

In accordance with the EPA Team's general health and safety operating procedures, the field team will also drive the route to the hospital specified in the HASP prior to initiating sampling activities.

3.3.3 Documentation of Field Sampling Activities

The EPA Team will document the ER field activities in bound field logbooks. At a minimum, the information documented in the field logbook for each sample location will include the following:

- The sample location number and the depths of sample collection.
- A description of the sample location at the site.
- The sample matrix and sample description.
- The analyses for which the samples were collected.
- The date and time of sample collection.

Locations where samples are collected will be documented using a global positioning system (GPS) to obtain horizontal control.

3.3.4 Decontamination and Investigation-Derived Wastes (IDW)

The nondisposable sampling equipment (portable sampling unit) used during the sample collection process will be thoroughly decontaminated before initial use, between locations, and at the end of the response before leaving the Site. Decontamination activities will be conducted at a designated decontamination area. Equipment decontamination will be completed in the following steps:

- High-pressure water spray or brush, if needed, to remove soil from the equipment.
- Nonphosphate detergent and potable water wash to clean the equipment.
- Final potable water rinse.
- Equipment air dried.

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The fluids and excess soil/sediment generated as a result of equipment decontamination will be containerized and disposed of by TNPRC personnel according to facility protocols.

3.4 SAMPLING/MONITORING APPROACH

Air sampling will be conducted by the EPA Team. Soil/sediment sampling and water sampling will be conducted by the TNPRC with supervision by the EPA Team. The specific sampling, decontamination, sample handling procedures, and disposition of IDW are described in the following subsections.

3.4.1 Soil Sampling

Soil/sediment samples will be collected by employees of the TNPRC with supervision and documentation by the EPA Team. Sampling SOPs for naturally occurring Bp in the soils of Southeast Asia call for a sample depth of 30 centimeters. However, for this response the source of the Bp is believed to be runoff of waste products from the macaque cages which could have been deposited onto the top of the soil or sediment. Therefore, soil and sediment samples will be collected in the top 2 inches of soil. Soil sampling procedures include:

- Wear modified Level C PPE protective gear including Tyvek coveralls, nitrile gloves, boot covers, surgical caps, face shields, and N95 respirators, according to TNPRC safety protocols.
- Dig a hole using a clean, disposable shovel to collect a soil sample in the top 2 inches of soil.
- Transfer approximately 30 to 40 grams of soil to sterile containers.
- Upon collection of the sample, the outside of the jar will be cleaned with disinfecting wipes, placed in a resealable plastic bag, and placed into a cooler or other container out of direct sunlight.
- Deliver samples to the laboratory at ambient temperature without exposure to direct sunlight and process as quickly as possible.

Soil sample locations and the sampling order will be determined by the EPA Team while on-site. Sample locations will initially include areas associated with the storm-water treatment system and the sewage treatment system. As the project progresses, samples will be collected from

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other locations on the South Campus working from outer areas and moving inward to the cages that contained the affected macaques. Samplers will coordinate with the laboratory to determine how many samples can be shipped each day. Generally, samples will be collected from areas as follows:

- All four sides of macaque cage G12.
- South and east side of macaque cage R24.
- Next to any potential waste streams from impacted field cages.
- Background (near front entrance gate).
- Wetlands sludge.
- Near the outfall 003 and 004.
- Outfall sludge.

Table 3-1 presents a summary of the samples and the sample rational associated with each. Information regarding sample analysis is presented in Section 4.

3.4.2 Water Sampling

Water samples will be collected on-site from within drainage ditches, the sewage treatment system, and the storm-water treatment system. Water samples will be collected by employees of the TNPRC with supervision and documentation by the EPA Team. Sampling procedures include the following:

- Wear modified Level C PPE protective gear including Tyvek coveralls, nitrile gloves, boot covers, surgical caps, face shields, and N95 respirators, according to TNPRC safety protocols.

- Transfer approximately 1 liter of water into sterile containers (two 1-liter containers per sample). Surface water can be "dipped" directly from the water and transferred into the sample jars using a funnel.

- Upon collection of the sample, the outside of the jar will be cleaned with disinfecting wipes, placed into a resealable plastic bag, and placed into a container or cooler out of direct sunlight.

- Deliver samples to the laboratory at ambient temperature without exposure to direct sunlight and process as quickly as possible.

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Table 3-1 presents a summary of the samples and the sample rational associated with each. Information regarding sample analysis is presented in Section 4.

3.4.3 Air Sampling

Air samples will be collected by the EPA Team using Portable Sampling Units (PSUs). Three PSUs will be deployed throughout the site. PSUs will initially be deployed on the South Campus at the fence line closest to Northlake Christian School, near the aerator on the sewage treatment system, and at the gravel filter near water outlet 3. The locations of the samplers may change due to changes in weather or changes in work activities. Samples will be collected for 24-hour periods.

1. PSU-247: Fenceline near Northlake Christian School (east side of South Campus).
2. PSU-465: Near sewage aeration pond (west side of South Campus).
3. PSU-340: Near gravel filter (center of South Campus).

The flow rate will be set to 100 liters per minute (L/min) at the beginning of the run. The flow rate will be noted at the completion of the run. The flow rate for the run will be the average of the flow rates at the beginning and end of the run. The reading on the time counter will be noted at the beginning of the sample run and at the end of the run. The difference on the time counter from the end of the run and the beginning of the run will be the sample run time. The sample counter is more accurate than elapsed time in that it will correct for any down time due to power outages.

The sampling head from the PSUs will be collected, bagged, and sent to the laboratory for analysis.

At the completion of the project, the PSU will be decontaminated with antiseptic wipes. After decontamination, the EPA Team will collect swab samples at the PSU inlet hood and on the lid of the PSU. The swab samples will be sent to the laboratory for QA/QC analysis.

Table 3-1 presents a summary of the samples and the sample rational associated with each. Information regarding sample analysis is presented in Section 4.

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3.4.4 Wipe Sampling

The EPA Team will collect wipe samples from flat surfaces using sterile swabs made of synthetic fibers. Wipe samples will be collected from the vans that were used to transport macaques from the South Campus to the North Campus and from the PSUs at the completion of the project.

3.4.5 Investigation-Derived Wastes

Any used PPE, excess fluids generated as a result of equipment decontamination, and non-dedicated sampling equipment will be stored on-site and be disposed by the TNPRC.

3.4.6 Quality Assurance/Quality Control Samples

The EPA Team will observe collection of field duplicates of soil samples, water and air samples and document preparation of QA/QC samples as needed during the response sampling activities. QA/QC samples may include but not be limited to the following:

- Blind field duplicate soil samples and sediment samples may be collected to assist in the QA of the sampling procedures and laboratory analytical data by allowing an evaluation of reproducibility of results. Efforts will be made to collect duplicate samples in locations where there is visual evidence of contamination or where contamination is suspected. Blind field duplicate samples will be collected at the rate of one duplicate for every 10 samples collected.

- Equipment rinsate blanks may be prepared by pouring laboratory-grade de-ionized water over non-disposable sampling equipment after it has been decontaminated and by collecting the rinse water in sample containers for analyses.

- Field blanks may be prepared by pouring laboratory-grade de-ionized water into pre-cleaned laboratory-grade sample containers for analysis. These samples will be prepared to demonstrate the impact the surrounding environment is having on the samples being collected. Field blank samples will be collected for this particular scope of work at a rate of one per day.

- Wipe (swab) samples will be collected during decontamination activities of the PSU units. These samples will be prepared to demonstrate that the equipment decontamination

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procedures for the sampling equipment were performed effectively. The wipe samples will be collected at the end of each air sample collection period.

Specific laboratory information is included in Section 4 of this QASP.

3.5 DEVIATIONS FROM THE SAMPLING PLAN

Deviations from the sample locations may occur at the EPA TM direction due to new observations made prior to sampling, information obtained in the field that warrants an altered sampling point, difficulty in sample collection, or limited access. The EPA TM will be notified, and concurrence will be obtained should significant deviations from the planned sampling points be proposed. Details regarding deviations of the QASP will be documented in the site logbook and reported in the final ER report to EPA.

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Table 3-1
Sample Locations and Sampling Rationale
Tulane University – National Primate Research Center
Covington, Louisiana

Sample Name	Sample Matrix	Sample Location (refer to Figure 3-1)	Rationale
SW01-G-150209-N-01	Surface Water	Pond 9	Part of the storm water treatment system.
SW02-G-150209-N-01	Surface Water	Pond 8	Storm water collects here.
SW03-G-150209-N-01	Surface Water	Outfall 004	Confluence of site storm water.
SW03-G-150209-D-01	Surface Water	Outfall 004 - Duplicate	Duplicate -- collected for QA/QC
SW04-G-150209-N-01	Surface Water	Outfall 003	Outlet of water treatment system. All sewage and storm water exits here.
SW05-G-150209-N-01	Surface Water	Field Blank	Tap Water -- collected for QA/QC
SW06-G-150209-N-01	Surface Water	Contact Basin	Part of water treatment system. Sewage and storm water flow through here.
SW07-G-150209-N-01	Surface Water	Rock Filter	Part of water treatment system. Sewage and storm water flow through here.
SW08-G-150209-N-01	Surface Water	Wetlands – South	Part of water treatment system. Sewage and storm water flow through here.
SW09-G-150209-N-01	Surface Water	Wetlands – West	Part of water treatment system. Sewage and storm water flow through here.
SW10-G-150209-N-01	Surface Water	Wetlands – North	Part of water treatment system. Sewage and storm water flow through here.
SW11-G-150209-N-01	Surface Water	Ditch near Macaque Cage - G12	G12 was a cage that held an affected macaque. Determine if waste products spread Bp into the ditch near the cage.
SW12-G-150209-N-01	Surface Water	Ditch near Macaque Cage - R24	R24 was a cage that held an affected macaque. Determine if waste products spread Bp into the ditch near the cage.
SW13-G-150209-N-01	Surface Water	Aeration Pond	Part of water treatment system. Sewage passes through here.
WW14-G-150212-N-01	Waste Water	Lift Station	Part of water treatment system. Sewage from North Campus passes here.
PSU01-C-YYMMDD-N-01	Air	Fenceline near Northlake Christian School (East side of South Campus)	Collected to document air monitoring – one sample per day

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Sample Name	Sample Matrix	Sample Location (refer to Figure 3-1)	Rationale
PSU02-C-YYMMDD-N-01	Air	Near sewage aeration pond (West side of South Campus)	Collected to document air monitoring – one sample per day
PSU03-C-YYMMDD-N-01	Air	Near gravel filter (Middle of South Campus)	Collected to document air monitoring – one sample per day
PSU04-C-150212-N-01	Air	Near maintenance building (North Campus)	Collected to document air monitoring – one sample only
SWAB01-G-150212-N-01	Swab	Steering wheel of van 1 TPC09 Lic# V340918	Vehicle used to transfer macaques
SWAB02-G-150212-N-01	Swab	Front of bed of van 1 TPC09 Lic# V340918	Vehicle used to transfer macaques
SWAB03-G-150212-N-01	Swab	Middle of bed of van 1 TPC09 Lic# V340918	Vehicle used to transfer macaques
SWAB04-G-150212-N-01	Swab	Back of bed of van 1 TPC09 Lic# V340918	Vehicle used to transfer macaques
SWAB05-G-150212-N-01	Swab	Steering wheel of van 2 TPC22 Lic# KIB568	Vehicle used to transfer macaques
SWAB06-G-150212-N-01	Swab	Bed of van 2 TPC22 Lic# KIB568	Vehicle used to transfer macaques
SWAB07-G-150212-N-01	Swab	Head of PSU247	PSU was used inside of South Campus
SWAB08-G-150212-N-01	Swab	Lid of PSU247	PSU was used inside of South Campus
SWAB09-G-150212-N-01	Swab	Head of PSU340	PSU was used inside of South Campus
SWAB10-G-150212-N-01	Swab	Lid of PSU340	PSU was used inside of South Campus
SWAB11-G-150212-N-01	Swab	Head of PSU465	PSU was used inside of South Campus
SWAB12-G-150212-N-01	Swab	Lid of PSU465	PSU was used inside of South Campus

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Table 3-1
Sample Locations and Sampling Rationale
Tulane University – National Primate Research Center
Covington, Louisiana
(Continued)

Sample Name	Sample Matrix	Sample Location (refer to Figure 3-1)	Rationale
SS01-G- 150210-N-01 through SS10-G- 150210-N-01	Soil/Sediment	Near cage G12	G12 was a cage that held an affected macaque. Samples will determine if waste products spread Bp into the soil near the cage.
SS11-G- 150210-N-01 through SS16-G- 150210-N-01	Soil/Sediment	Near cage R24	R24 was a cage that held an affected macaque. Samples will determine if waste products spread Bp into the soil near the cage.
SS17-G- 150210-N-01	Soil/Sediment	Outfall 003	Outlet of water treatment system. All sewage and storm water exits here.
SS18-G- 150210-N-01	Soil/Sediment	Outfall 004	Collection of all storm water on the site.
SS19-G- 150210-N-01 through SS22-G- 150210-N-01	Soil/Sediment	Ditches near G12	Col G12 was a cage that held an affected macaque. Samples will determine if waste products spread Bp into the soil near the cage.
SS23-G- 150210-N-01 through SS28-G- 150210-N-01	Soil/Sediment	Ditches near R24	R24 was a cage that held an affected macaque. Samples will determine if waste products spread Bp into the soil near the cage.
SS29-G- 150210-N-01	Soil/Sediment	Outfall 004 Ditch	Collection of all storm water on the site.
SS30-G- 150210-N-01 through SS32-G- 150210-N-01	Soil/Sediment	Wetland area, North, Middle, and South	Part of the water treatment system. All sewage and storm water passes through here.
SS33-G- 150210-N-01 through SS35-G-150210-N-01	Soil/Sediment	Duplicates, TBD	Duplicate -- collected for QA/QC
SS36-C- 150211-N-01	Soil/Sediment	Surface composite from inside of cage G12 – 4 points under perches	Cage held an affected macaque
SS37-C- 150211-N-01	Soil/Sediment	Grab depth sample inside of cage G12 – under a perch	Cage held an affected macaque
SS38-G- 150211-N-01	Soil/Sediment	Surface composite from inside of cage G12 – 4 points not under perches	Cage held an affected macaque
SS39-C- 150211-N-01	Soil/Sediment	Grab depth sample inside of cage G12 – not under a perch	Cage held an affected macaque

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SS40-G- 150211-N-01	Soil/Sediment	Surface composite from inside of cage R24	Cage held an affected macaque
SS41-G- 150212-N-01	Soil/Sediment	Surface grab from van parking area	Vans used to transport macaques
SS42-G- 150212-N-01	Soil/Sediment	Surface grab from van parking area	Vans used to transport macaques

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4. ANALYTICAL APPROACH

Samples collected as part of the response will be prepared for shipment and shipped by TNPRC personnel who have training and certification in the proper shipment of biological samples. The EPA team will prepare chain-of-custody (COC) documentation and will assist TNPRC personnel with the sample packaging. Samples will be sent to the CDC laboratory in Atlanta, Georgia.

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Table 4-1
Requirements for Containers, Preservation Techniques, Sample Volumes, and Holding Times
Tulane University – National Primate Research Center
Covington, Louisiana

Name	Analytical Methods	Container	Preservation	Sample Containers	Maximum Holding Time
Bp bacteria in soil	CDC methods	Glass	None. Keep at ambient temperature and out of UV light	One 8 oz jar	N/A
Bp bacteria in water	CDC methods	Glass	None. Keep at ambient temperature and out of UV light	Two 1-liter jars	N/A
Bp bacteria in air	CDC methods	PTFE Filter	None. Keep at ambient temperature and out of UV light	One sample filter assembly	N/A
Bp bacteria on a surface	CDC methods		None. Keep at ambient temperature and out of UV light		N/A

oz = ounce
PTFE = Polytetrafluoroethylene
Note: Information on containers, preservation, and holding times provided by CDC.

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5. QUALITY ASSURANCE

Quality assurance will be conducted in accordance with the WESTON Corporate Quality Management Manual, dated March 2014, and the WESTON Programmatic Quality Assurance Project Plan (QAPP). Following receipt of the TDD from EPA, a Quality Control (QC) officer is assigned and monitors work conducted throughout the entire project including reviewing interim report deliverables and field audits. The EPA Team FTL will be responsible for QA/QC of the field investigation activities. The designated laboratory utilized during the investigation will be responsible for QA/QC related to the analytical work. The EPA Team will also collect samples to verify that laboratory QA/QC is consistent with the required standards and to validate the laboratory data received as described above.

All sampling will be conducted following SOPs, which are found in Appendix A.

5.1 SAMPLE CUSTODY PROCEDURES

After sample collection and identification, samples will be maintained under COC procedures. If the sample collected is to be split (laboratory QC), the sample will be allocated into similar sample containers. Sample labels completed with the same information as that on the original sample container will be attached to each of the split samples. Personnel required to package and ship coolers containing potentially hazardous material will be trained accordingly.

The EPA Team will prepare and complete COC forms using SCRIBE for samples sent to an off-site laboratory. The COC procedures are documented and will be made available to personnel involved with the sampling. A typical COC record will be completed each time a sample or group of samples is prepared for shipment to the laboratory. The record will repeat the information on each sample label and will serve as documentation of handling during shipment. A copy of this record will remain with the shipped samples at all times, and another copy will be retained by the member of the sampling team who originally relinquished the samples. At the completion of the project, the DM will export the SCRIBE COC documentation to the Analytical Service Tracking System (ANSETS) database.

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Samples relinquished to the participating laboratories will be subject to the following procedures for transfer of custody and shipment:

- Samples will be accompanied by the COC record. When transferring possession of samples, the individuals relinquishing and receiving the samples will sign, date, and note the time of the sample transfer on the record. This custody records document transfer of sample custody from the sampler to another person or to the laboratory.
- Samples will be properly packed for shipment and dispatched to the appropriate laboratory for analysis with separate, signed custody records enclosed in each sample box or cooler. Sample shipping containers will be custody-sealed for shipment to the laboratory. The preferred procedure includes use of a custody seal wrapped across filament tape that is wrapped around the package at least twice. The custody seal will then be folded over and adhered to seal and ensure that the only access to the package is by cutting the filament tape or breaking the seal to unwrap the tape.
- If sent by common carrier, a bill of lading or airbill will be used. Bill of lading and airbill receipts will be retained in the project file as part of the permanent documentation of sample shipping and transfer.

5.2 PROJECT DOCUMENTATION

Documents will be completed legibly in ink and by entry into field logbooks and SCRIBE as described above. Response Manager will be used based on direction of the EPA TM.

5.2.1 Custody Seal

Custody seals demonstrate that a sample container has not been tampered with or opened. The individual who has custody of the samples will sign and date the seal and affix it to the container in such a manner that it cannot be opened without breaking the seal.

5.2.2 Photographic Documentation

The EPA Team will take photographs to document site conditions and activities as site work progresses. Initial conditions should be well documented by photographing features that define the working conditions. Representative photographs should be taken of each type of site activity. The photographs should show typical operations and operating conditions as well as special

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situations and conditions that may arise during site activities. Site final conditions should also be documented as a record of how the site appeared at completion of the work.

Photographs will be taken using digital cameras capable of recording the date, time, and location. Each photograph will be recorded in the logbook with the location of the photographer, direction the photograph was taken, the subject of the photograph, and its significance (i.e., why the picture was taken).

5.2.3 Report Preparation

At the completion of the project, the EPA Team will review and validate laboratory data and prepare a draft report of field activities and analytical results for EPA TM review. Draft deliverable documents will be uploaded to the EPA TeamLink Web-site for EPA TM review and comment.

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Thank you for your interest in the EPA's role in the Centers for Disease Control (CDC) and U.S. Department of Agriculture's (USDA) investigation into how the exposure to the Burkholderia pseudomallei (Bp) occurred at the Tulane National Primate Research Center (TNPRC)

In late November 2014, two non-human primates in the breeding colony at TNPRC became ill. In mid- December 2014, samples submitted to the CDC identified Burkholderia Pseudomallei as the causative agent. This strain of bacteria is not endemic in the US but was the subject of research at TNPRC. Because Burkholderia Pseudomallei is a tier 1 agent and the material was considered not in containment, the CDC and U.S. Department of Agriculture (USDA) initiated a joint investigation of TNPRC in January 2015. As part of the investigation conducted January 20-24, federal and state scientists visited the TNPRC site to conduct epidemiological study and to review lab practices to determine possible route of transmission. (This language in this paragraph is from GOHSEP update on 2/19/2015)

As a result of their joint investigation CDC and USDA concluded they needed assistance and technical advice from EPA. CDC reached out to EPA on January 27, 2015, requesting EPA's assistance and advice in developing soil sampling plans and remediation plans. As indicated in the Incident Action Plan (see Attachment 1) produced by the Governor's Office of Homeland Security and Emergency Preparedness (GOHSEP), EPA's response role for this incident is to provide assistance to the Unified Command comprised of local and state response agencies and the CDC. EPA is considered an Assisting Agency, an agency directly contributing tactical and other resources to the incident but not part of the Unified Command. (UC). In response this incident, CDC has been the lead federal agency and has been an active participant in the UC.

At CDC's request, EPA developed environmental sampling plans to aid in determining the presence or absence of Bp in the environment. EPA developed submitted sampling plans for air, water and soil on February 6, 2015. The sampling plans were implemented by TNPRC scientists. For the environmental sampling that occurred from February 8 to February 12, EPA arranged for portable sampling units to be provided to collect air samples. The air, soil and water sampling locations were targeted locations that had the highest likelihood of finding the bacteria. TNRPC staff collected the soil and water samples. EPA provided advice to TNPRC, the Potential Responsible Party, to ensure compliance with the plans. TNPRC shipped the samples to the CDC for laboratory analysis and interpretation. EPA completed these tasks and demobilized its staff on February 13, 2015. On February 20, 2015, CDC informed Unified Command that none of the screening environmental samples contained live or dead traces of the bacteria.

Unified Command initially indicated that the two field cages would be decontaminated and requested that EPA assisted TRNPC with the development of a decontamination strategy plan for two field cages that housed the first two infected monkeys. As the extent of exposure and the nature of the problem continued to evolve, additional cages which might require decontamination were identified. On March 13, 2015 CDC announced that it closed its investigation and had determined that the cause of contamination was due to poor internal

controls in the research center. CDC also concluded that there was no evidence to suggest that the organism was released into the surrounding environment based on their analysis of field samples collected by Tulane under EPA's sampling plan. Seeing that CDC had concluded that it is unlikely that Bp is a threat to the general population, EPA discontinued its assistance to CDC with respect to the response at TNPRC.

RESPONSE TO SPECIFIC REQUEST

1. ***An explanation of the EPA's scientific justification for the soil sampling plan used in the federal investigation at the Tulane National Primate Research Center, particularly as it pertains to the number of soil samples taken at the site, and whether the agency has sought outside input or consultation about that plan (if so, please provide us with a list of those partners).***

   - **Explain the justification for the number of soil samples taken:** EPA was requested to design a sampling plan which TNRPC would implement to evaluate if Bp may be present in the environment. The UC required a rapid evaluation of the environmental conditions. Thus, TNRPC conducted targeted sampling at locations having the greatest probability of identifying Bp based on the available epidemiological information and environmental conditions.

   - **Did EPA seek outside consultation on the sampling plan?** EPA worked within the Incident Command System and sought input, and approval of the plan prior to implementation, from the members of the Incident Management Team. Those included: GOHSEP, St Tammy Parish, Louisiana Department of Environmental Quality, Louisiana Department of Agriculture and Forestry, USDA, and CDC, EPA also coordinated internally with our Office of Research and Development's National Homeland Security Research Center for input on the sampling strategy, sampling procedures, and decontamination options.

     Additional details are included in the Quality Assurance Sampling Plan for Tulane University National Primate Research Center date February 2015 Section 3 Response Activities. (See Attachment 2)

2. ***A description of the procedure and specific equipment used by the EPA for air sampling pursuant to this investigation.***

   Air samples were collected utilizing Portable Sampling Units (PSUs). The PSUs utilized at the Tulane National Primate Research Center (TNPRC) were units used for the BioWatch program. The PSU is an aerosol monitor which draws in air and passes it through a filter. The filters are then manually collected, typically every 24 hours and shipped to a laboratory for analysis. CDC was responsible for coordinating the laboratory analysis and result interpretation of the filters at the Georgia Public Health Laboratory collected during the TNPRC sampling event. The filters were analyzed using standardized Bio Watch program polymerase chain reaction (PCR) techniques specific for *Burkholderia pseudomallei* (Bp). If a biological agent is detected, lab analysts will then perform a secondary test. A positive secondary test result is considered a PCR-verified positive and indicates the presence of a biological material in the air.

Three PSUs were used in the air sampling conducted at TNPRC. They were initially deployed throughout the South Campus in the following areas around the non-human primate enclosures; 1) The fence line nearest the Northlake Christian School, 2) Near the sewage aeration pond and 3) Near the gravel filter. The flow rate of the PSU's was set at 100 liters per minute (L/m). The PSU's were activated on Sunday February 8th and collected data on a 24 hour basis until Thursday February 12th. All twelve of the samples collected from the 4 days of sampling were negative for the presence of Bp or any other biological agents.

Additional details are included in the Quality Assurance Sampling Plan for Tulane University National Primate Research Center date February 2015 Section 3 Response Activities. (See Attachment 2)

3. A ***copy of the State of Louisiana's letter to the EPA requesting assistance in testing soil for B. pseudomallei.***

   See attached files
   - Copy of January 31, 2015, email request from GOHSEP requesting EPA staff to assist (Attachment 3)
   - 2/20 letter to EPA from GOHSEP (Attachment 4)
   - 3/13 letter to EPA from GOHSEP (Attachment 5)

4. ***A delineation of responsibilities among federal agencies for soil and air sampling in the wake of this and other events involving potential bioterrorism agents or infectious diseases.***

   CDC and USDA conducted a joint investigation of TNPRC on January 20-24, 2015. As a result of their joint investigation CDC and USDA concluded they needed assistance and technical advice from EPA. CDC reached out to EPA on January 27, 2015, requesting EPA's assistance and advice in developing soil sampling plans and remediation plans. EPA worked closely with our federal partners to provide air, soil, and water sampling advice to TNPRC. CDC is the federal lead for the epidemiological investigation and protection of public health

   However, EPA has various response authorities. Under EPA's CERCLA authority, biological agents are considered pollutants or contaminants and EPA has the authority to take action to contain or mitigate a threat. Under the National Response Framework, Emergency Support Function #10, EPA is the ESF coordinator for Oil and Hazardous Material Response which includes chemical, biological and radiological substances, whether accidentally or intentionally released. HSPD 10 directs EPA to develop "specific standards, protocols, capabilities to address the risks of contamination following a biological weapons attack and develop strategies, guidelines, and plans for decontamination of persons, equipment, and facilities."

   EPA also ensures "enforcement first," whereas (potentially) responsible parties are required to comply with CERCLA and other relevant authorities. The Tulane National Primate Research Center (TNPRC) is considered a potentially responsible party. Tulane was conducting their work for CDC, CDC is in charge of the Federal Select Agent Program. The

Unified Command noted that the investigation has identified lapses in personal protective equipment (PPE) and implementation of biosafety practices and security procedures in the Tulane building.

In past biological events, EPA has conducted the following activities:

- Capitol Hill Anthrax – this clearly was a terrorist event without an identified responsible party. EPA collected surface and air samples, developed a decontamination plan, and provided technical oversight of the contractor hired to conduct the decontamination. EPA provided technical assistance to the lead federal agency;
- Danbury, CT Anthrax Case – The home owner (responsible party) did not have the resources to respond the contamination. EPA was the lead federal agency for this response and collected environmental samples and conducted the decontamination;
- University of New Hampshire Anthrax Case – EPA served in a technical advisory role to the State of New Hampshire who was working with the responsible party (a nonprofit religious ministry), and to the State and federal public health officials; EPA collected one round of characterization samples to determine the extent of contamination in support the epidemiological and environmental evaluations. EPA advised the public health officials on decontamination options.
- Ricin – there have been several ricin cases over the last three years; EPA has provided technical advice on the sampling, analysis, and decontamination to the state public health officials. In some cases, EPA has collected samples and conducted decontamination whereas in other cases EPA has reviewed plans and provided technical consultation (dependent upon the local and state capabilities).
- Ebola – Since Ebola has been a primary concern in a healthcare setting, CDC has been the lead federal agency. However, EPA did prepare plans for clean-up outside of a health care setting should it be necessary. Thus far, Ebola cases in the US have not required EPA to consult or assist with clean up outside of a health care setting.

As indicated in the responses above, EPA has various authorities, and can provide various levels of assistance during a biological response ranging from advice to leading a response. Each incident is unique and EPA has the option to use its response authorities as appropriate.

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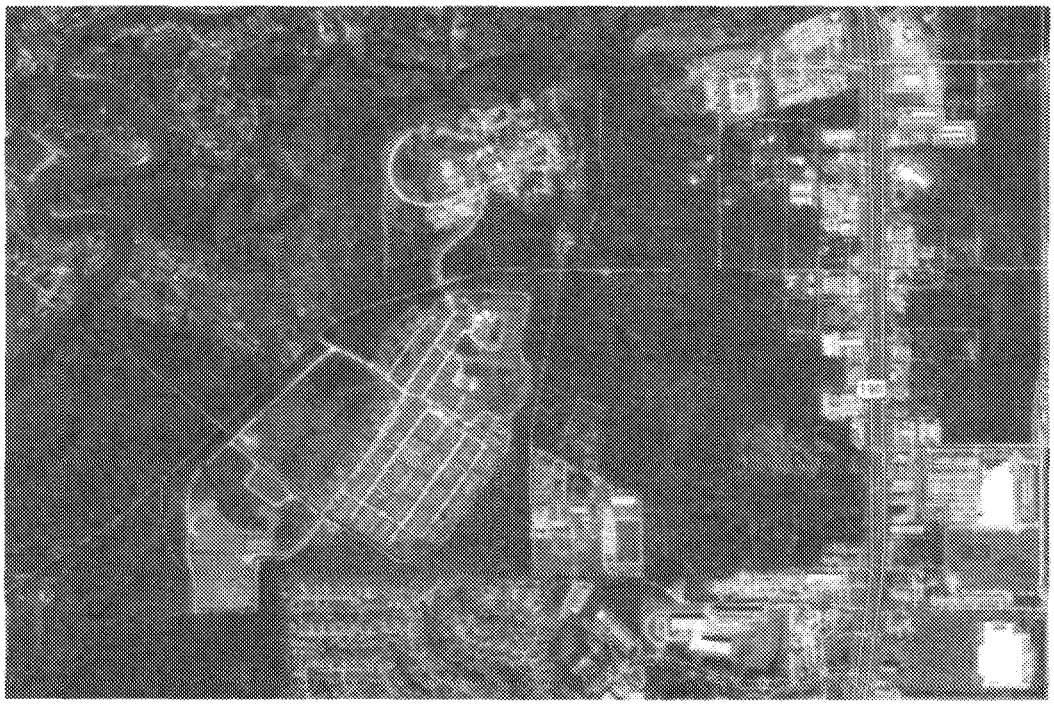
Governor's Office of Homeland Security & Emergency Preparedness

INCIDENT ACTION PLAN - 01



Incident Name: Tulane National Primate Research Center 15-005

Unified Command:

CDC - RADM Scott Deitchman

GOHSEP - Dir. Kevin Davis

LA DHH - Dr. Jimmy Guidry

St. Tammany - Dir. Dexter Accardo

Approved:

Operational Period:

Date: February 9, 2015

Time: 2/9/2015 - 0900hrs to 2/10/2015 - 0900hrs

St. Tammany Parish EOC
510 E. Boston Street
Covington, La. 70433
Office: 985-898-2359

St. Tammany Parish EOC - GPS Coordinates
30.476016, -90.095449

Prepared By	C.R.Simoneaux	Signature		Date	2/9/15	Time	1117hrs

Governor's Office of Homeland Security & Emergency Preparedness

INCIDENT OBJECTIVES		Incident Number	15-005	ICS 202
Incident Name	Tulane National Primate Research Center	Operational Period	2/9/2015 0900hrs to 2/10/2015 0900hrs	

	Objectives
1	**Investigation process - On Campus: To identify, isolate, remediate and prevent further tranmission of BP on campus grounds.**
	Sampling Objectives:
1.1	To conduct serological sampling to determine potential parameters of transmission exposure.
1.2	To conduct air sampling to determine potential of aerosolized transmission.
1.3	To conduct soil sampling within the cages to validate spread of BP in cage-soil.
1.4	To conduct soil sampling outside the cages to determine if BP has spread beyond enclosures
1.5	To conduct water sampling around the compound and at discharge points to determine if BP is growing in water discharges.
	Remediation Objectives:
1.6	To conduct remediation of enclosures where infected animals were - or are - located.
1.7	To conduct remediation outside the cages based on soil sampling results.
1.8	To identify potential mitigation activities should air and/or water samples come back positive.
2	**Surrounding Area - Off Campus: To conduct risk assessment(s) within a meaningful vicinity outside the compound to ascertain need for further sampling wildlife, livestock, and other potential at-risk animals.**
2.1	To conduct risk survey of animals in the area and determine whether these animals require further testing.
2.2	To utilize findings from the investigative process to determine need for further mitigation activities outside the compound.

Prepared by	C.R.Simoneaux	Signature		Date		Time	
Approved by		Signature		Date		Time	

Governor's Office of Homeland Security & Emergency Preparedness

INCIDENT OBJECTIVES		Incident Number	15-005	ICS 202 (page 2)
Incident Name	Tulane National Primate Research Center	Operational Period	2/9/2015 0900hrs to 2/10/2015 0900hrs	

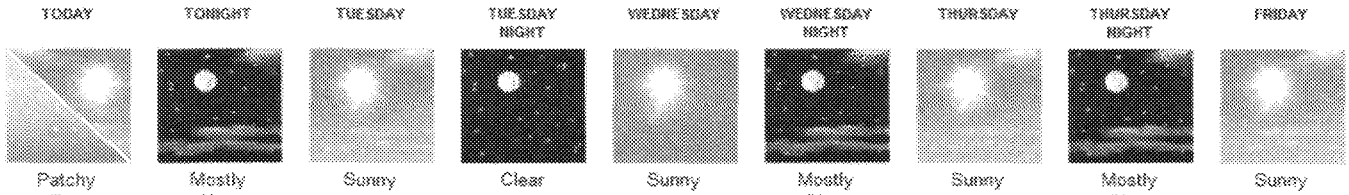
Objectives (continued)

3	**Public Communications**
3.1	To formalize JIC members under CDC lead.
3.2	To develop Frequently Asked Questions document in readiness for public dissemination.

Operational Period Command Emphasis
(Priorities, Key Decisions/Directions)

Expedient development and implementation of testing and response plans is the Unified Command emphasis, while at all times making decisions which are in the best interest of worker and public safety. Any issues which arise to impede this effort will be immediately communicated to the Unified Command for assistance and resolution. Full compliance with animal health and welfare regulations will be observed, and efforts will be made to minimze impacts to animal welfare.

NWS Weather Forecast for Covington, La. as of 2/9/2015 at 0600hrs CST



TODAY	TONIGHT	TUESDAY	TUESDAY NIGHT	WEDNESDAY	WEDNESDAY NIGHT	THURSDAY	THURSDAY NIGHT	FRIDAY
Patchy Fog	Mostly Clear	Sunny	Clear	Sunny	Mostly Clear	Sunny	Mostly Clear	Sunny
High: 74 °F	Low: 41 °F	High: 69 °F	Low: 37 °F	High: 64 °F	Low: 42 °F	High: 62 °F	Low: 31 °F	High: 59 °F

National Weather Service Office Slidell, La. 985-649-0429 http://www.srh.noaa.gov/lix/

Safety Message / Site Safety Plan

Safety of response personnel and the general public is paramount. Primary focus will be on strict adherence to safety rules and regulations and proper use of PPE. Any safety concerns, incidents or injuries must be immediately reported to a supervisor and the incident Safety Officer.

Is a Site Safety Plan Required?	Yes	No	Location of Site Safety Plan:

Incident Action Plan Components (check if attached)

x	Incident Action Plan Cover (ICS-200)		Medical Plan (ICS-206)
x	Incident Objectives (ICS-202)		Site Safety Plan (ICS-208)
x	Organization Assigment List (ICS-203)	x	Incident Map(s)
	Assignment List (ICS-204)	x	Joint Press Release 2-7-2015
x	Communications Plan (ICS-205T)	x	Melioidosis Fact Sheet

Prepared by	C.R.Simoneaux	Signature		Date		Time	
Approved by		Signature		Date		Time	

Governor's Office Of Homeland Security & Emergency Preparedness

ORGANIZATION ASSIGNMENT LIST		Incident Number	15-005	ICS 203
Incident Name	Tulane National Primate Research Center	Operational Period	2/9/2015 0900hrs to 2/10/2015 0900hrs	
Unified Command		**Operations Section**		
UC/IC	RADM Scott Deitchman, MD (CDC)	Operations Chief	Miguel Cruz, PhD (CDC)	
UC/IC	Dir. Kevin Davis (GOHSEP)	Dep. Ops Chief	Collins Simoneaux (GOHSEP)	
UC/IC	Jimmy Guidry, MD (LA DHH)	**Branch 1 - Investigation Branch**		
UC/IC	Dir. Dexter Accardo (St Tammany OHSEP)	Branch Director	Robbin Weyant, PhD (CDC)	
Command Staff				
Safety Officer	Robbin Weyant, PhD (CDC)			
PIO (JIC Primary Contacts)	* See PIO - JIC Information Below *			
Liaison Officer				
Agency Representative				
Tulane Primate Center	Dir. Mark Lackner, DVM	**Branch 2 - Remediation/Response Branch**		
Tulane Primate Center	Mark Alise	Branch Director	Bill Rhotenberry (EPA)	
USDA/APHIS	Kenneth Angel, DVM	Dep. Branch Dir.	Mike McAteer (EPA)	
USDA/APHIS	Katie Portacci, DVM	Tech Specialist - SSC	Mike Nalipinski (EPA)	
USDA/APHIS	Lily Rai, DVM			
USDA/APHIS	Vicki Guilfor, DVM			
US EPA	John Martin			
LDAF	Brent Robbins, DVM			
LA DHH	Gary Balsamo, DVM	**Joint Information Center**		
LDEQ	Mike Algero	Tulane PIO	Mike Strecker	
LDEQ	Jeff Dauzat	Tulane PIO	Debbie Grant	
Planning Section		CDC PIO (Lead)	Barbara Reynolds	
Planning Chief	David Schultz (GOHSEP)	CDC PIO	Jason McDonald	
Dep. Planning Chief	Paul Reeb (St. Tammany Parish)	CDC PIO	Christian Scheel	
Situation Unit		CDC PIO	Bernadette Burdin	
Resource Unit		US EPA PIO	Joseph Hubbard	
Documentation Unit	Vanessa Wall (St. Tammany Parish)	US EPA PIO	David Gray	
Demobilization Unit		GOHSEP	Mike Steele	
Technical Specialists (Specialty and Name)		LA DHH	Olivia Watkins	
GIS		LDAF	Veronica Mosgrove	
Logistics Section		St. Tammany Parish	Ronnie Simpson	
Logistics Chief	Clarence Powe (St. Tammany Parish)	**Air Operations**		
Dep. Logistics Chief		Air Ops Chief		
Service Branch		**ESF Coordination**		
Service Branch Dir.		ESF 1 - Transportation		
Communications Unit		ESF 2 - Communications		
IT Unit		ESF 3 - Public Works		
Medical Unit		ESF 4 - Fire Fighting		
Food Unit		ESF 5 - Emergency Mgt.		
Support Branch		ESF 6 - Mass Care & Assistance		
Support Branch Dir.		ESF 7 - Resources		
Supply Unit		ESF 8 - Public Health & Medical		
Facilities Unit		ESF 9 - Search and Rescue		
Ground Support Unit		ESF 10 - Oil, HazMat		
Finance Section		ESF 11 - Agriculture & Nat. Res.		
Finance Chief		ESF 12 - Energy		
Dep. Finance Chief		ESF 13 - Public Safety & Security		
Time Unit		ESF 14 - Recovery & Mitigation		
Procurement Unit		ESF 15 - External Affairs		
Cost Unit		ESF 16 - Military Affairs		

Prepared by	C.R.Simoneaux	Signature		Date		Time	
Approved by		Signature		Date		Time	

INCIDENT TELEPHONE/E-MAIL CONTACT LIST		Incident Number	15-005	ICS 205T
Incident Name	Tulane National Primate Research Center	Operational Period	2/9/2015 0900hrs to 2/10/2105 0900hrs	

Telephone/Email List			
Agency/Position	Name	Cell Phone	Email
** Note - See Last Page for PIO/JIC and Public Inquiry Phone Numbers **			
Tulane National Primate Research Center			
Tulane - Director	Andrew Lackner, DVM	985-966-6402	alackner@tulane.edu
Tulane - COO	Mark Alise	985-871-6200	malise@tulane.edu
Tulane - PIO	Mike Strecker	504-512-1347	mstreck@tulane.edu
Tulane - PIO	Debbie Grant	504-578-4071	dgrant@tulane.edu
St. Tammany Parish Contacts			
St Tammany Parish - President	Patricia Brister	985-898-2362	pbrister@stpgov.org
St Tammany Parish - OHSEP Dir.	Dexter Accardo	985-264-1087	daccardo@stpgov.org
St Tammany Parish - OHSEP	Clarence Powe	985-290-7654	cpowe@stpgov.org
St Tammany Parish - OSHEP	Paul Reeb	985-774-9710	pireeb@stpgov.org
St Tammany Parish - PIO	Ronnie Simpson	504-905-7841	rsimpson@stpgov.org
Louisiana State Agency Contacts			
Governor's Office	Sarah Turner		sarah.turner@la.gov
GOHSEP - Director	Kevin Davis	225-925-7345	kevin.davis@la.gov
GOHSEP - Chief of Staff	Christina Dayries	225-247-0797	christina.dayries@la.gov
GOHSEP - Deputy Director	Chris Guilbeaux	225-715-3191	christopher.guilbeaux@la.gov
GOHSEP - Asst. Deputy Dir.	Kevin Breaux	225-573-9345	kevin.breaux@la.gov
GOHSEP - Administrative Officer	James Smith	225-925-7500	james.b.simth@la.gov
GOHSEP - Executive Assistant	Laverna McNamee	225-925-7500	vernie.mcnamee@la.gov
GOHSEP - Operations Sect. Chief	Sean Wyatt	225-754-2225	sean.wyatt@la.gov
GOHSEP - Dep. Operations Chief	Jason Lachney	225-933-0173	jason.lachney@la.gov
GOHSEP - Operatons Officer	Emily Granier	225-925-7500	emily.granier@la.gov
GOHSEP - OpsO/WebEOC Admin	Melton Gaspard	985-634-2520	melton.gaspard@la.gov
GOHSEP - Planning Sect. Chief	David Schultz	225-252-2005	david.schultz@la.gov
GOHSEP - Logistics Chief	Michael Hamilton	225-335-1226	michael.hamilton@la.gov
GOHSEP - Region 1 Coordinator	Darry Delatte	225-485-7452	darryl.delatte@la.gov
GOHSEP - Region 9 Coordinator	Collins Simoneaux	225-329-4261	collins.simoneaux@la.gov
GOHSEP - PIO	Mike Steele	225-788-0095	mike.steele@la.gov
LA DHH - Secretary	Kathy Kliebert		kathy.kleibert@la.gov
LA DHH - Health Officer	Jimmy Guidry, MD	225-342-3417	jguidry@la.gov
LA DHH - Exec. Dir. Emerg. Prep.	Rosanne Prats, PhD	225-938-8059	rosanne.prats@la.gov
LA DHH - R9 Hosp. DRC	Keith Peek	985-290-2642	keith.peek@la.gov
LA DHH - Program Manager	Theresa Sokol	504-250-8672	theresa.sokol@la.gov
LA DHH - State PH Veterinarian	Gary Balsamo, DVM	504-568-8315	gary.balsamo@la.gov
LA DHH - PIO	Olivia Watkins	225-610-6660	olivia.watkins@la.gov

LDAF - Commissioner	Mike Strain, DVM	225-922-1233	mike.strain@ldaf.state.la.us
LDAF - State Veterinarian	Brent Robbins, DVM	985-264-4142	brobbins@la.gov
LDAF - Asst. State Veterinarian	Diane Stacy, DVM	225-935-2173	dstacy@ldaf.la.gov
LDAF - Asst. Commissioner	John Walther	985-438-6111	john_walther@ldaf.state.la.us
LDAF - PIO	Veronica Mosgrove	225-229-7147	vmosgrove@ldaf.la.gov
LDEQ - Secretary	Peggy Hatch		peggy.hatch@la.gov
LDEQ - Emergency Response Mgr	Bryan Riche	504-214-4138	bryan.riche@la.gov
LDEQ - ESS	Jeff Dauzat	504-736-7714	jeff.dauzat@la.gov
LDEQ - ES Manager	Mike Algero	225-329-9745	mike.algero@la.gov
LDEQ - ES2	Joshua Fowler	504-736-7737	joshua.fowler@la.gov
Federal Agency Contacts			
US CDC - Associate Director	RADM Scott Deitchman, MD	770-488-7145	sed2@cdc.gov
US CDC - Select Agent Prog. Dir.	Robbin Weyant, PhD	678-614-7284	rweyant@cdc.gov
US CDC - Emergency Ops Officer	Miguel Cruz, PhD	678-763-4703	mqc8@cdc.gov
US CDC - PIO (Lead)	Barbara Reynolds, PhD	404-918-1586	bsr0@cdc.gov
US CDC - PIO	Christian Scheel	404-488-0583	bin2@cdc.gov
US CDC - PIO	Jason McDonald	404-387-3660	gnf0@cdc.gov
US CDC - PIO	Bernadette Burden	404-213-6874	bbb8@cdc.gov
US EPA	Bill Rhotenberry	214-437-9804	rhotenberry.william@epa.gov
US EPA	Mike McAteer	214-354-9371	mcateer.mike@epa.gov
US EPA - OSC	John Martin	214-789-1994	martin.john@epa.gov
US EPA - Director, CMAD	Erica Canzler	202-564-2359	canzler.erica@epa.gov
US EPA - START	Samuel Check	972-977-1579	sam.check@westonsolutions.com
US EPA - START	José Ojeda	619-417-3298	jose.ojeda@westonsolutions.com
US EPA - START	Robert Sherman	225-573-9785	robert.sherman@westonsolutions.com
US EPA - PIO	Joseph Hubbard		hubbard.joseph@epa.gov
US EPA - PIO	David Gray	214-789-2619	gray.david@epa.gov
USDA - Asst Dist Director, Dist 4	Kenneth Angel, DVM	601-214-0722	kenneth.l.angel@aphis.usda.gov
USDA - Risk Analysis Proj. Mgr.	Katie Portacci, DVM	970-494-1741	katie.portacci@aphis.usda.gov
USDA -	Victoria Guilfoil, DVM	405-623-6505	victoria.v.guilfoil@aphis.usda.gov
USDA - PIO	Joelle Hayden	301-851-4040	joelle.r.hayden@aphis.usda.gov

INCIDENT PIOs - JIC Contacts			
Tulane - PIO (Public Inquiries)	Mike Strecker	504-512-1347	mstreck@tulane.edu
Tulane - PIO	Debbie Grant	504-578-4071	dgrant@tulane.edu
US CDC - PIO (CDC Lead)	Barbara Reynolds, PhD	404-918-1586	bsr0@cdc.gov
US CDC - PIO	Christian Scheel	404-488-0583	bjn2@cdc.gov
US CDC - PIO (Public Inquiries)	Jason McDonald	404-387-3660	anf0@cdc.gov
US CDC - PIO	Bernadette Burden	404-213-6874	btb8@cdc.gov
US EPA - PIO	Joseph Hubbard		hubbard.joseph@epa.gov
US EPA - PIO	David Gray	214-789-2619	gray.david@epa.gov
USDA - PIO	Joelle Hayden	301-851-4040	joelle.r.hayden@aphis.usda.gov
GOHSEP - PIO	Mike Steele	225-788-0095	mike.steele@la.gov
LA DHH - PIO	Olivia Watkins	225-610-6660	olivia.watkins@la.gov
LDAF - PIO	Veronica Mosgrove	225-229-7147	vmosgrove@ldaf.la.gov
St Tammany Parish - PIO	Ronnie Simpson	504-905-7841	rsimpson@stpgov.org
** Public Information Numbers - Only the Below Information is Releasable to the Public **			
Questions regarding the investigation or remediation activities are directed to CDC (Jason McDonald) at 404-387-3660			
Questions regarding the TNPRC facility are directed to Tulane (Mike Strecker) at 504-512-1347			
All other questions are directed to GOHSEP (Mike Steele) at Mike.Steele@La.gov			

Prepared by	C. R. Simoneaux	Signature		Date/Time	

Tulane National Primate Research Center
18703 3 Rivers Road, Covington, LA 70433

Ongoing Inquiry into Melioidosis Illness at Tulane National Research Center

Late November 2014, two non-human primates in the breeding colony at the Tulane National Primate Research Center (TNPRC), a private research facility, became ill and one was euthanized. In mid- December 2014, samples submitted to the CDC identified Burkholderia Pseudomallei as the causative agent. This strain of bacteria is not endemic in the US but was the subject of research at TNPRC. Because Burkholderia Pseudomallei is a tier 1 agent and the material was considered not in containment, the CDC and USDA initiated a joint investigation of TNPRC in January 2015. As part of the investigation conducted January 20-24, federal and state scientists visited the TNPRC site to conduct epidemiological study and to review lab practices to determine possible route of transmission.

A recent event is that one of the investigators fell ill with unspecific symptoms. A blood test was conducted and yesterday test results indicated a presence of antibodies in the blood indicating some exposure to BURKHOLDERIA PSEUDOMALLEI . It is too early to determine whether exposure was related to this recent visit to the center or whether the sick individual's travel history may have provided an opportunity for exposure.

The other members of the investigative team will be tested for possible exposure to the bacteria for baseline comparison and possible future diagnosis. This testing will provide some indication regarding route of transmission.

The Department of Health and Human Services' Centers for Disease Control and Prevention, along with the U. S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA), continues to work with Tulane University and state and local officials to identify, isolate, mitigate and prevent further transmission of BURKHOLDERIA PSEUDOMALLEI within the compound. Environmental testing – including Air, water, soil sampling - will guide remediation activities. Once samples are collected, it will take 1-2 weeks to obtain results.

Multiple steps are being taken to caution and advise workers, investigators, and neighboring stakeholders while the investigation continues. At present, there is no reason to believe that BURKHOLDERIA PSEUDOMALLEI has expanded beyond TPNRC. There are no reports of sick individuals at TPNRC. There are no reports of sick non-human primates at TPNRC. BP is not airborne and it is rarely transmitted from person to person or animal to person.

Governor Bobby Jindal said, "Earlier today, I spoke with President Brister and Superintendent Folse to pledge the state's support. State agencies are on the ground and embedded in St. Tammany's emergency operations center, and I have charged our agencies to lean forward and support their federal partners."

BURKHOLDERIA PSEUDOMALLEI is a causative agent for the disease Melioidosis. Melioidosis, also called Whitmore's disease, is an infectious disease that can infect humans or animals and is treatable with antibiotics. The disease is caused by the bacterium *Burkholderia pseudomallei*.

-MORE-

It is predominately a disease of tropical climates, especially in Southeast Asia and northern Australia where it is widespread. The bacteria causing melioidosis are found in contaminated water and soil. It is spread to humans and animals through direct contact with the contaminated source.

CDC's role is to protect the health and safety of researchers and the public. For more information about melioidosis, visit http://www.cdc.gov/melioidosis/index.html. Questions regarding the investigation and remediation activities should be directed to CDC (Jason McDonald) at 404-387-3660. Questions regarding the TPNRC facility should be directed to Tulane (Mike Strecker) at 504-512-1347. All other questions or concerns should be directed to Mike Steele at Mike.Steele@La.gov .

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-MORE-

Melioidosis Fact Sheet

What is melioidosis?
Melioidosis is a disease that affects humans and animals and is caused by the gram-negative bacterium *Burkholderia pseudomallei.* These bacteria are normally found in water and soil in certain parts of the world, including Southeast Asia and Northern Australia. Melioidosis can be severe and, in some cases, even fatal. Melioidosis has been found in a variety of animals, including mammals, reptiles, fish, and birds in or from areas where the disease is endemic.

How do people get melioidosis?
People can get melioidosis in several ways:

- When contaminated soil or water gets into their open wounds, abrasions, or their eyes, nose or mouth (mucous membranes).
- When they swallow food or water contaminated with the bacteria.
- When they improperly handle laboratory specimens contaminated with the bacteria.
- When they breathe in contaminated dust or water droplets.

In addition, it's theoretically possible that people might become infected when they have contact with body fluids from an infected animal.

What are the signs and symptoms of melioidosis?
Signs and symptoms of melioidosis vary depending on the type of infection and can easily be mistaken for other diseases such as pneumonia or tuberculosis. The incubation period ranges from one day to many years.

- For wound infections, signs and symptoms include localized pain or swelling.
- For pulmonary infections, signs and symptoms include cough, headache, fever, chest pain, anorexia (lack of appetite), and general muscle soreness.
- For bloodstream infections, signs and symptoms include high fever, headache, respiratory distress, disorientation, abdominal discomfort, and muscle tenderness.
- For infections that have spread throughout the body, signs and symptoms include fever, weight loss, stomach or chest pain, muscle or joint pain, headache, and encephalitis or seizures.

How is melioidosis diagnosed?
Melioidosis is diagnosed by isolating *Burkholderia pseudomallei* from the blood, urine, sputum, or skin lesions or from organ abscesses or by testing blood serum.

How is melioidosis treated?
Antibiotic treatment for melioidosis should start as soon as the disease is confirmed. Delaying treatment can result in poor outcomes. A physician will determine the most appropriate antibiotic treatment for a patient with a confirmed case of melioidosis.
Suggested reference: Wiersinga WJ, Currie BJ, Peacock SJ. Melioidosis. *N Engl J Med.* 2012;367(11):1035-44

ED_005457_00000075-00011

Am I at risk?
You are at risk for exposure to melioidosis if:

- You have had contact with soil or water in countries where the disease is endemic.
- You work with laboratory specimens contaminated with the bacteria.

There are only a few documented cases in which melioidosis has been spread from person to person in a healthcare facility (known as nosocomial transmissions). Transmission from an infected animal to a human has not been confirmed, but theoretically, it is possible.

The following conditions may increase your risk for getting melioidosis if you are exposed: **diabetes, chronic liver or kidney disease, alcohol abuse, blood cancers** such as leukemia (hematologic malignancy), **low white blood cell count** (neutropenia or neutrophil dysfunction), **chronic lung disease** (asthma, bronchitis, emphysema, or cystic fibrosis), **thalassemia** (a blood disorder), **long-term steroid use**, or other **conditions that suppress the body's ability to fight infections** (immunosuppression).

How can melioidosis be prevented?
Currently, there is no vaccine to prevent melioidosis infection, but there are steps you can take to protect yourself from exposure:

- People working in agricultural settings in endemic areas should wear boots to prevent infection through the feet and lower legs.
- People traveling to endemic countries should take precautions to avoid contact with contaminated soil, especially if they have any open wounds, cuts, or scrapes.
- Healthcare workers should use standard contact precautions (mask, gloves, and gown). Additionally, testing on *B. pseudomallei* organisms should be performed inside a biosafety cabinet. Safe laboratory practices/procedures should be followed when working with the organism.
- All laboratory exposures (high and low risk) should be reported to the CDC Division of Select Agents and Toxins (DSAT). The guidelines to assess laboratory exposure, including classification of low versus high risk, can be found at http://wwwnc.cdc.gov/eid/article/14/7/07-1501_article

How long does *Burkholderia pseudomallei* live on a surface?
3-7 days. In tests, the bacteria was applied at room temperature to surfaces such as paper, stainless steel, glass, and polyethylene. It was still there after 3 days but not after 7 days.

How do you kill *Burkholderia pseudomallei*?
Burkholderia pseudomallei can be killed by using any EPA-registered hospital disinfectant such as 1:10 bleach and quaternary ammonium compounds. In chlorinated water, the bacteria would not survive because they are susceptible to standard residual levels of chlorine. The bacteria are also susceptible to low levels of ultraviolet light.

Message

From: Nalipinski, Mike [Nalipinski.Mike@epa.gov]
Sent: 3/24/2015 12:18:50 PM
To: Martin, John [martin.john@epa.gov]
Subject: FW: Bp Remediation- Quick lime Ref #8 Tulane response
Attachments: effect of quicklime (calcium oxide) as an inhibitor of.pdf

John (not working on TNPRC) Martin:

See below for your reference. Looks like quick lime is only a temporary solution.....

Michael Nalipinski
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Ryan, Shawn
Sent: Tuesday, March 24, 2015 8:07 AM
To: Nalipinski, Mike
Cc: Calfee, Worth; Wood, Joe
Subject: RE: Bp Remediation- Quick lime Ref #8 Tulane response

Mike,

Here's the supporting study re: quicklime. It suggests quicklime as a temporary inhibitor at very high wt/wt % concentrations of CaO tilled into the soil (not sprayed on). It suggests that when soil conditions are again right for propagation, that propagation may occur – i.e., suggesting repeated treatment necessary to control Bp propagation in the soil.

Shawn

Shawn P. Ryan, Ph.D.
Division Director
Decontamination and Consequence Management Division
National Homeland Security Research Center
U.S. Environmental Protection Agency (MD-E343-06)
Office of Research and Development
109 T.W. Alexander Dr., Research Triangle Park, NC 27711
Phone 919-541-0699 Fax 919-541-0496

http://www.epa.gov/nhsrc

From: Nalipinski, Mike
Sent: Tuesday, March 17, 2015 10:07 AM
To: Ryan, Shawn
Subject: FW: Bp Remediation- Quick lime Ref #8 Tulane response

Michael Nalipinski
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Lackner, Andrew A [mailto:alackner@tulane.edu]
Sent: Tuesday, March 17, 2015 10:05 AM
To: Alise, Mark A; Nalipinski, Mike
Subject: Re: Bp Remediation- Quick lime Ref #8

OK. I see that in the reference.

In the paper I sent yesterday however they note that the soil was negative one year after treatment. Here is the text

The soil samples from the three sites at 5, 15, and 30-cm depth were investigated by culture again once after 12 mo of soil treatment, and these culture results were all negative.

I would also point out that is in the context of what must have been overwhelming contamination in that they did three soil samples at three depths and each soil sample was positive at least at one depth. In our case we have no evidence that the organism is even present.

best regards

Andrew

****
Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
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Professor of Microbiology, Immunology and Pathology
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****

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On Mar 17, 2015, at 6:41 AM, Alise, Mark A <malise@tulane.edu> wrote:

Not so good news on the quicklime. But they are trying to work with us and look into other agents.

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

Begin forwarded message:

From: "Nalipinski, Mike" <Nalipinski.Mike@epa.gov>
Date: March 17, 2015 at 6:38:27 AM CDT
To: "Alise, Mark A" <malise@tulane.edu>
Subject: FW: Bp Remediation- Quick lime Ref #8

Mark --

See below. The way I/we read the abstract it looks like lime may only be a temporary remedy. If we locate the whole paper I'll send that along. We are also looking at other materials that could be tilled into the soil like persulfate. More to come....

Michael Nalipinski
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U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Ryan, Shawn
Sent: Tuesday, March 17, 2015 7:34 AM
To: Nalipinski, Mike
Subject: RE: Bp Remediation- Quick lime Option

Trans R Soc Trop Med Hyg. 2004 Jun;98(6):337-41.

The effect of quicklime (calcium oxide) as an inhibitor of Burkholderia pseudomallei.

Na-ngam N[1], Angkititakul S, Noimay P, Thamlikitkul V.
Author information

- [1]Department of Veterinary Public Health, Faculty of Veterinary Medicine, Khon Kaen University, Khon Kaen 40002, Thailand.

Abstract

Measurement of in vitro activity of quicklime against Burkholderia pseudomallei revealed that quicklime at concentrations of 10% or more was bactericidal for up to 35 d. The effect of quicklime as an inhibitor of B. pseudomallei in soil from a rice field was studied in a laboratory setting. The soil, collected from a rice field in north-eastern Thailand, was mixed with B. pseudomallei. In experiment 1, quicklime was mixed with the soil in different amounts. In experiment 2, quicklime was spread over the soil surface. In experiment 3, quicklime solution was poured onto the soil. It was found that the pH of the soil in experiment 1 was much higher than that in experiments 2 and 3. Only quicklime mixed with soil at a concentration of 40% or more (weight/weight) was effective in inhibiting the growth of B. pseudomallei for up to six weeks.

Shawn

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http://www.epa.gov/nhsrc

From: Nalipinski, Mike
Sent: Tuesday, March 17, 2015 7:21 AM
To: Alise, Mark A
Cc: Martin, John; Ryan, Shawn
Subject: RE: Bp Remediation- Quick lime Option

Mark –
Thanks for the article regarding the application of quick lime to remediate Bp in soil at a zoo in northeastern Thailand. Do you have access to reference #8 that indicates bench scale tests were conducted evaluating the parameters that impact the effectiveness of the quick lime treatment? That would be informative to guide evaluation of the quick lime option for the Tulane case.

I am available anytime before noon (eastern) Wednesday March 18th to continue our conversation regarding technology options. Please advise what time is convenient for you.

Cheers,

V/R

Michael Nalipinski, Associate Director
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Monday, March 16, 2015 4:32 PM
To: Nalipinski, Mike
Cc: Lackner, Andrew A
Subject: Bp Remediation

Mike,

Here is the article Dr. Lackner referred to.

Please let me know a good time for Wednesday contact.

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

<image001.png>

Transactions of the Royal Society of Tropical Medicine and Hygiene (2004) **98**, 337–341

www.elsevierhealth.com/journals/trst

The effect of quicklime (calcium oxide) as an inhibitor of *Burkholderia pseudomallei*

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Received 23 April 2003; received in revised form 21 October 2003; accepted 28 October 2003

KEYWORDS
Melioidosis;
Burkholderia pseudomallei;
Quicklime;
Calcium oxide;
Thailand

Summary Measurement of in vitro activity of quicklime against *Burkholderia pseudomallei* revealed that quicklime at concentrations of 10% or more was bactericidal for up to 35 d. The effect of quicklime as an inhibitor of *B. pseudomallei* in soil from a rice field was studied in a laboratory setting. The soil, collected from a rice field in north-eastern Thailand, was mixed with *B. pseudomallei*. In experiment 1, quicklime was mixed with the soil in different amounts. In experiment 2, quicklime was spread over the soil surface. In experiment 3, quicklime solution was poured onto the soil. It was found that the pH of the soil in experiment 1 was much higher than that in experiments 2 and 3. Only quicklime mixed with soil at a concentration of 40% or more (weight/weight) was effective in inhibiting the growth of *B. pseudomallei* for up to six weeks.
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1. Introduction

Melioidosis is caused by *Burkholderia pseudomallei*, which is a saprophytic bacterium in the soil. The disease is prevalent in South-East Asia and northern Australia (Chaowagul et al., 1989; Dance, 1991; Suputtamongkol et al., 1994). Epidemiological studies of melioidosis and *B. pseudomallei* in Thailand have shown that the disease is more prevalent in north-eastern Thailand; arabinose-negative *B. pseudomallei* was also found in soil collected from north-eastern Thailand (Trakulsomboon et al., 2000; Vuddhakul et al., 1999). The organism can be readily isolated from environmental sources such as rice paddies, still or stagnant water and moist soils which predominate in the tropics, and it is believed that these habitats are the primary reservoirs (Ellison et al., 1969). Under laboratory conditions, it was found that *B. pseudomallei* survives best in an environment with a pH of 5.0–8.0, although it was also able to survive for a long period at pH 4.0 (Tong et al., 1996). Consequently, the survival of *B. pseudomallei* may be favoured by the relatively acidic environment of a rice paddy, which is usually pH 5.0–6.8 and is pH 4.4–7.7 in north-east Thailand (Kanai and Kondo, 1994). It was reported that *B. pseudomallei* was able to grow on glyphosphate, a non-selective herbicide,

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ED_005457_00000077-00001

as a sole phosphorous source (Peñaloza-Vazquez et al., 1995). *Burkholderia pseudomallei* can reduce nitrate in order to grow in an anaerobic environment, and the use of nitrate fertilizers might thus contribute to its proliferation in agricultural land (Kanai and Kondo, 1994).

Calcium oxide (quicklime) is a strong base and a disinfectant. The active ingredient that exerts killing activity against the pathogens is calcium hydroxide, which is produced when calcium oxide is mixed with water. A rapid reduction in total coliforms, *Salmonella* and *Shigella* counts was observed after the addition of quicklime and cement dust to sewage sludge (Amer, 1997; Plachy et al., 1996). One kilogram of quicklime spread over the sawdust bedding of dairy cows reduced bacterial counts (Hogan and Smith, 1997). Application of quicklime to pasture areas of a dairy herd which was paratuberculosis-positive was associated with a 72% reduction in the number of test-positive cattle (Johnson-Ifearulundu and Kaneene, 1999). In Thailand, quicklime has been used for a long time in farming systems. In addition, farmers usually apply quicklime to the soil in order to adjust soil conditions and eliminate some plant parasites. It was reported that quicklime could adjust the acid-base balance of the soil (Stevens and Laughlin, 1996). These applications reduced the need for chemical fertilizers, increased the quality of calcium in the soil and also increased grass production. An application of quicklime to soil was used for commercial carrot production to reduce the incidence of cavity spot disease in carrots (El-Tarabily et al., 1996).

The objectives of this study were to determine the in vitro activity of quicklime against arabinose-negative *B. pseudomallei* and the effect of quicklime on inhibiting arabinose-negative *B. pseudomallei* in soil under experimental conditions.

2. Materials and methods

2.1. Bacterial strain

The arabinose-negative *B. pseudomallei* used in the study was that isolated from the blood of a patient. The organism was grown on modified Ashdown's agar at 37 °C for 48 h. Five colonies of *B. pseudomallei* were suspended in Tryptic Soy Broth (TSB) and incubated overnight on an orbital shaker at room temperature. The concentration of pathogens was measured with a spectrophotometer at a wave length of 500 nm. The cultured broth was kept at 4 °C, and suspended in sterile distilled water in order to produce a concentration of 5.5×10^5 cfu/ml. This broth was used for all experiments.

2.2. Quicklime (CaO)

Quicklime was purchased from a factory in Saraburi Province, Thailand and dissolved in water at 30% (weight/volume) in order to produce a solution with a pH of at least 12.0.

2.3. In vitro study of quicklime against *Burkholderia pseudomallei*

Quicklime was dissolved in sterile distilled water to make 200 ml suspension of varying concentrations (weight in grams/volume in ml) of 2.5, 5, 10, 15, 20, 25, 30, 35, 40, 45 and 50%. A bottle of 200 ml sterile distilled water served as the control. Each sample was inoculated with 1 ml of *B. pseudomallei* suspension in TSB with 5.5×10^5 cfu/ml on days 1, 7, 14, 21, and 35. The mixtures were kept at room temperature and 3 ml of suspension was withdrawn at 0 h, after 6 h of incubation and just prior to the next inoculation of *B. pseudomallei*, added to 10 ml of threonine basal salt solution containing 20 mg/l colistin (TBSS-C20) and incubated at 42 °C for 48 h. The samples were then subcultured onto Ashdown's medium plates and incubated at 37 °C for 3 d. *Burkholderia pseudomallei* was identified using standard biochemical tests. The pH of the suspension was also measured along with the subculture.

2.4. Study of the inhibitory effect of quicklime against *Burkholderia pseudomallei* growth in soil

2.4.1. Soil sample

Soil was collected from a rice field in Khon Kaen province, Thailand. The soil was then left to dry under sunlight for two weeks and a culture of the soil sample revealed no *B. pseudomallei*. Forty kilograms of soil was put in each container to a depth of 40 cm. The soil was inoculated with 2.5 l of *B. pseudomallei* solution at a concentration of 5.5×10^5 cfu/ml.

2.4.2. Study procedures

Three experiments were performed using the above described samples. In experiment 1, quicklime was mixed with the soil at 2.5, 5, 10, 15, 20, 25, 30, 35, 40 and 50% (weight/weight) concentrations. In experiment 2, quicklime was spread over the soil at amounts of 0.25, 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5 and 5.0 kg/m^2. In experiment 3, quicklime solution in distilled water at concentrations of 2.5, 5, 10, 15, 20, 25, 30, 35, 40, 45 and 50% (weight/volume) was poured onto the soil once daily. A control soil without quicklime was set up

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for each experiment. All soil samples were soaked by spraying with water once daily and the containers of soil in all experiments were reinoculated with the same amount of *B. pseudomallei* every 7 to 10 d. Three grams of soil sample were collected at depths of 0, 5, 10, 20, and 30 cm on days 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 and every week for 6 weeks. The soil samples were taken to the laboratory for detection of *B. pseudomallei*. The pH of the soil sample was also recorded at the time of soil collection. A survival assay of *B. pseudomallei* was done by mixing the soil sample with distilled water for 2 min. Then 2 ml of the supernatant was transferred into 10 ml TBSS-C20. The mixture was incubated at 42 °C for 48 h, and subcultured onto modified Ashdown's agar. The plate was incubated at 37 °C for 48–72 h. *B. pseudomallei* was identified using standard biochemical procedures.

3. Results

3.1. In vitro activity of quicklime against *Burkholderia pseudomallei*

The pH values of the quicklime suspensions at different concentrations are shown in Table 1. All quicklime suspensions were alkaline. *Burkholderia pseudomallei* was consistently isolated from the control bottle without quicklime. The serial subcultures from the quicklime suspensions at all concentrations revealed no growth for up to 7 d. The quicklime suspension with a concentration of 5% was bactericidal for 21 d, whereas the quicklime suspension with a concentration of 10% or more exerted killing activity against *B. pseudomallei* for up to 35 d as shown in Table 1.

Table 1 The average pH and in vitro activity of quicklime suspensions against *Burkholderia pseudomallei*

Concentration of quicklime suspension (%) (weight/volume)	pH	Bactericidal activity at 6 h, 24 h, 7 d, 14 d, 21 d, and 35 d
0	7.8	No
2.5	8.81	Yes, up to day 7
5	9.77	Yes, up to day 21
10	12.14	Yes, up to day 35
15	12.41	Yes, up to day 35
20	12.45	Yes, up to day 35
25	12.59	Yes, up to day 35
30	12.61	Yes, up to day 35
35	12.66	Yes, up to day 35
40	12.72	Yes, up to day 35
45	12.72	Yes, up to day 35
50	12.73	Yes, up to day 35

Table 2 The average pH of the soil mixed with different amounts of quicklime (experiment 1)

Concentration of quicklime in soil mixture (%) (weight/weight)	pH
2.5	7.47
5	7.64
10	7.68
15	7.71
20	8.06
25	8.54
30	8.56
35	8.75
40	9.45
45	9.86
50	10.59

3.2. Inhibitory effect of quicklime against *Burkholderia pseudomallei* in soil

The pH of the soil without quicklime was 5 to 6 and *B. pseudomallei* was consistently detected. In contrast, the soil with quicklime had a pH higher than 6 as shown in Tables 2–4. The pH of the soil mixture with quicklime in experiment 1 was much higher than that in experiments 2 and 3, as also shown in Tables 2–4. In experiment 1, quicklime at 5% or more was effective in inhibiting the growth of *B. pseudomallei* for up to 7 d. However, only quicklime at 40% or more remained effective for up to 6 weeks. In experiments 2 and 3, *B. pseudomallei* could still be recovered from soil mixture at all concentrations of quicklime.

Table 3 The average pH of soil treated by surface-spreading of different amounts of quicklime (experiment 2)

Amount of quicklime in soil mixture (kg/m^2)	pH
0.25	6.63
0.5	6.79
1	6.97
1.5	6.84
2	7.17
2.5	7.14
3	7.26
3.5	7.18
4	7.29
4.5	7.25
5	7.32

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Table 4 The average pH of soil treated with quicklime solution (experiment 3)

Concentration of quicklime solution (%) (weight/volume)	pH
2.5	7.10
5	7.14
10	7.29
15	7.39
20	7.41
25	7.24
30	7.27
35	7.36
40	7.23
45	7.47
50	7.38

4. Discussion

Our study demonstrated that quicklime was also bactericidal against *B. pseudomallei* in addition to other pathogens such as coliforms, *Shigella* spp., *Salmonella typhimurium*, *Pythium coloratum* and *Mycobacterium paratuberculosis* as has been observed in previous studies (Hogan and Smith, 1997; Johnson-Ifearulundu and Kaneene, 1999; Plachy et al., 1996). It was also shown that a quicklime suspension with a pH of less than 10 was not effective, whereas that with pH of 12 or greater was always bactericidal. Since quicklime has been used for adjusting soil pH and preventing infectious diseases in plants (El-Tarabily et al., 1996; Peñaloza-Vazquez et al., 1995; Stevens and Laughlin, 1996), it could therefore be a potential substance for reducing the burden of *B. pseudomallei* in the soil of rice fields. Although several studies have demonstrated that quicklime is a strong disinfectant against various pathogens when it is either mixed with or spread over contaminated materials such as sewage sludge (Amer, 1997; Hogan and Smith, 1997; Johnson-Ifearulundu and Kaneene, 1999; Plachy et al., 1996), the findings from our study revealed that only soil mixed with a large amount of quicklime could inhibit the growth of *B. pseudomallei*, whereas quicklime spread over the soil or quicklime solution poured over the soil surface was not effective. This could be explained by differences in the textures of the contaminated materials. Sewage sludge or animal sawdust bedding is semisolid, whereas soil is solid. It is unlikely that quicklime spread over or poured over the soil surface can inhibit the growth of the pathogens residing far beneath the surface. Another explanation for our observation is that only the soil mixed with a large amount of quicklime will have a strongly alkaline pH of more than 8, since the killing activity of quicklime is dependent on an alkaline pH. Although rice stems in a rice field can grow at pH 4–10, studies on the effect of quicklime (or strong alkali) on the growth of rice and the ecological changes of the surrounding environment need to be explored prior to recommending quicklime as a measure for environmental control of *B. pseudomallei*, since quicklime has to be used in large amounts to decontaminate the soil from the presence of *B. pseudomallei*.

Acknowledgements

The authors would like to thank the Thailand Research Fund for supporting the study. The study was also partially supported by the Faculty of Veterinary Medicine, Khon Kaen University.

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Message

From: Nalipinski, Mike [Nalipinski.Mike@epa.gov]
Sent: 3/18/2015 5:39:08 PM
To: Martin, John [martin.john@epa.gov]
Subject: FW: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time

Importance: High

Michael Nalipinski
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Petersen, Chris
Sent: Wednesday, March 18, 2015 1:33 PM
To: Martin, John; Nalipinski, Mike; Ryan, Shawn; malise@tulane.edu
Cc: Smith, Monica; Crossland, Ronnie
Subject: FW: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time
Importance: High

John, Mike, Shawn and Mike – Due to circumstances beyond our control, the call scheduled for today will need to be postponed indefinitely. I apologize for this late notice and for any difficulties this may create. Thanks

J. Chris Petersen
Deputy Associate Director
Response and Prevention Branch
US EPA Region 6
1445 Ross Ave, Ste. 1200
Dallas, TX 75202
214-665-3167 office
214-665-7447 fax
214-789-2535 cell

From: Martin, John
Sent: Tuesday, March 17, 2015 4:25 PM
To: Smith, Monica; Petersen, Chris
Subject: FW: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time
Importance: High

They're close

John J. Martin
Federal On-Scene Coordinator (OSC)
1445 Ross Ave (6SF-PE)
Dallas, Texas 75202

214.665.6748 * *fax 214.665.2278*

From: Nalipinski, Mike
Sent: Tuesday, March 17, 2015 3:24 PM
To: Alise, Mark A
Cc: Ryan, Shawn; Martin, John
Subject: RE: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time
Importance: High

Mark –

Thanks for accommodating a call tomorrow at 1500 hrs Eastern Standard Time. We can use the following call in number:

877-299-3188 pass code 202 564 2359

Note that I've invited OSC John Martin Region 6 and Dr. Shawn Ryan NHSRC to the call. As you know John is the EPA lead out of Dallas and Shawn is the Director of EPA's Office of Research and Development National Homeland Security Research Center. Shawn's group has conducted extensive laboratory and field studies on different decontamination technologies.

The goal of tomorrow's meeting is to hopefully down select one or two technologies that the group could support and that would merit more detailed evaluation/consideration. In my previous e-mails EPA has offered several options and those, or if you have other alternatives, could be a framework for our conversation.

Have a good evening and looking forward to a productive discussion tomorrow.

Cheers,

V/R

Michael Nalipinski
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Tuesday, March 17, 2015 3:07 PM
To: Nalipinski, Mike
Cc: Lackner, Andrew A; Blanchard, James L
Subject: FW: Soil remediation options TNPRC

Mike,

Thanks for the information. I would like Dr. Lackner to join in our conversation tomorrow afternoon and I am copying him on this response.

We can talk at 2:00 pm CDT, 3:00 pm EDT if that works for you. If not we can work around other afternoon times.

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

From: <Nalipinski>, Mike <Nalipinski.Mike@epa.gov>
Date: Tuesday, March 17, 2015 at 1:34 PM
To: Mark Alise <malise@tulane.edu>
Cc: "Martin, John" <martin.john@epa.gov>, "Ryan, Shawn" <Ryan.Shawn@epa.gov>, "Petersen, Chris" <petersen.chris@epa.gov>, "Smith, Monica" <smith.monica@epa.gov>
Subject: FW: Soil remediation options TNPRC

Mark - Below and attached are some insights relative to technologies that could be considered for addressing the two field cages at the TNPRC. This input was received from the EPA's Office of Research and Development National Homeland Security Research Center (NHSRC). As background, NHSRC has conducted several studies to evaluate the efficacy of methyl bromide (MeBr) as a decontamination technology for bacillus anthraces (Ba). Using surrogates for Ba, namely BtK and Bg, MeBr has been proven effective. As you know MeBr has also been deployed in agricultural settings. MeBr could be broadcasted as a liquid during the tilling process and/or could also be applied as a liquid to the field cage that has a gravel base.

We have the most confidence in MeBr fumigation of the soilas it has proven effective in prior lab studies. Aside from the use of MeBr, we suggest looking at:

(1) Data supporting CaO; we are trying to get access to the reference with the lab study data. The abstract suggests inhibition up to 6 weeks when applied at 40% or more (wt/wt). Not sure if this "inhibition" means that additional or continued treatment is necessary for subsequent inhibition. We will look into it more when we get access to the paper. Any additional information that you are provided via Tulane may be helpful.

(2) Sodium persulfate (Klozur FMC) was shown in our laboratory studies to be an effective biological agent decontaminant in soil. We anticipate that it would be effective. It is typically injected in soil for treatment of organic contaminants. EPA has experience with it for Superfund Siteschlorinated solvents. Above are two attachments with some information. More info can be found at: http://www.peroxychem.com/chemistries/persulfates/products/klozur-persulfate/technical-documentation

(3) Metam sodium has also been shown to be an effective soil decontaminant for biological agents. There is considerable experience with it as it is one of the most widely used soil pesticides in the U.S. It would require longer aeration time (up to a month) and has the potential to produce toxic by-products in contact with water; so care would be necessary to reduce potential for exposure of people or animals. Also, there would need to be the discussion regarding suitable application for the soil type at the facility. There is a till-in application.

I hope the above information will be thought provoking and can guide our conversations as we continue to evaluate options to decontaminate the field cages. Please let me know if you would be available tomorrow March 18th to continue our discussion. I am available any time after noon eastern standard time.

Cheers,

V/R

Michael Nalipinski, Associate Director
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

Message

From: Nalipinski, Mike [Nalipinski.Mike@epa.gov]
Sent: 3/17/2015 8:23:57 PM
To: Alise, Mark A [malise@tulane.edu]
CC: Ryan, Shawn [Ryan.Shawn@epa.gov]; Martin, John [martin.john@epa.gov]
Subject: RE: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time

Importance: High

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Michael Nalipinski
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Boston, MA 02203

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From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Tuesday, March 17, 2015 3:07 PM
To: Nalipinski, Mike
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Thanks,

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Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

TULANE NATIONAL PRIMATE RESEARCH CENTER

From: <Nalipinski>, Mike <Nalipinski.Mike@epa.gov>
Date: Tuesday, March 17, 2015 at 1:34 PM
To: Mark Alise <malise@tulane.edu>
Cc: "Martin, John" <martin.john@epa.gov>, "Ryan, Shawn" <Ryan.Shawn@epa.gov>, "Petersen, Chris" <petersen.chris@epa.gov>, "Smith, Monica" <smith.monica@epa.gov>
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Cheers,

V/R

Michael Nalipinski, Associate Director
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

Message

From: Nalipinski, Mike [Nalipinski.Mike@epa.gov]
Sent: 3/17/2015 11:20:46 AM
To: Alise, Mark A [malise@tulane.edu]
CC: Martin, John [martin.john@epa.gov]; Ryan, Shawn [Ryan.Shawn@epa.gov]
Subject: RE: Bp Remediation- Quick lime Option

Mark –
Thanks for the article regarding the application of quick lime to remediate Bp in soil at a zoo in northeastern Thailand. Do you have access to reference #8 that indicates bench scale tests were conducted evaluating the parameters that impact the effectiveness of the quick lime treatment? That would be informative to guide evaluation of the quick lime option for the Tulane case.

I am available anytime before noon (eastern) Wednesday March 18th to continue our conversation regarding technology options. Please advise what time is convenient for you.

Cheers,

V/R

Michael Nalipinski, Associate Director
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Monday, March 16, 2015 4:32 PM
To: Nalipinski, Mike
Cc: Lackner, Andrew A
Subject: Bp Remediation

Mike,

Here is the article Dr. Lackner referred to.

Please let me know a good time for Wednesday contact.

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

TULANE NATIONAL PRIMATE
RESEARCH CENTER

Message

From: Alise, Mark A [malise@tulane.edu]
Sent: 3/16/2015 4:06:13 PM
To: Martin, John [martin.john@epa.gov]; Nalipinski, Mike [Nalipinski.Mike@epa.gov]
CC: Lackner, Andrew A [alackner@tulane.edu]; Bohm, Rudolf P [bohm@tulane.edu]; Blanchard, James L [jblanch1@tulane.edu]
Subject: FW: EPA Contact Information
Attachments: image001.png; 39980F81-6868-4F65-89A1-CEE04773E6E1[1].png

Importance: High

Mike and John,

If the times below don't work for you, please let us know when you are available and we will accommodate your schedule.

We are under a deadline from the Unified Incident Command to show progress on a remediation plan by this Friday.

Please contact us as soon as possible to begin the discussion.

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

From: <Alise>, Mark Alise <malise@tulane.edu>
Date: Friday, March 13, 2015 at 9:09 AM
To: "Martin.john@epa.gov" <Martin.john@epa.gov>, "nalipinski.mike@epa.gov" <nalipinski.mike@epa.gov>
Cc: Andrew Lackner <alackner@tulane.edu>, Rudolf Bohm <bohm@tulane.edu>
Subject: Re: EPA Contact Information

Mike and John,

We would like to set up a call with you next week to discuss remediation options for the two field cages on our south campus.

Some available times for us are (all CDT):

Monday, March 16
3:00 pm
4:00 pm

Wednesday, March 18
3:00 pm
4:00 pm

Thursday, March 19
10:00 am
11:00 am

Please let us know of your availability for a call.

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

From: <Deitchman>, "Scott (CDC/ONDIEH/NCEH)" <sed2@cdc.gov>
Date: Thursday, March 12, 2015 at 2:09 PM
To: Mark Alise <malise@tulane.edu>
Cc: Andrew Lackner <alackner@tulane.edu>, Rudolf Bohm <bohm@tulane.edu>, "Martin.john@epa.gov" <Martin.john@epa.gov>, "nalipinski.mike@epa.gov" <nalipinski.mike@epa.gov>
Subject: RE: EPA Contact Information

Mark,
The EPA representatives were John Martin from EPA Region 6, and Mike Nalipinski representing EPA headquarters. Both are on the CC line. Their phone numbers should be in the Unified Command IAP; don't have one at hand but can obtain if you don't have it.

Regards,
Scott

RADM Scott Deitchman, MD MPH, USPHS
Assistant Surgeon General
Associate Director for Environmental Health Emergencies
National Center for Environmental Health and
Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention
Atlanta GA USA

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Thursday, March 12, 2015 12:53 PM
To: Deitchman, Scott (CDC/ONDIEH/NCEH)
Cc: Lackner, Andrew A; Bohm, Rudolf P
Subject: EPA Contact Information

Scott,

Could you please provide us with the contact information for the EPA representatives on today's call?

Thanks,

Mark

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Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

TULANE NATIONAL PRIMATE RESEARCH CENTER

Message

From: Nalipinski, Mike [Nalipinski.Mike@epa.gov]
Sent: 3/13/2015 2:29:59 PM
To: Martin, John [martin.john@epa.gov]
Subject: FW: Tulane Field Pen Conf Call
Attachments: image001.png

John –

I'll accommodate any time that you want to have the conversation with Tulane. Prior to the meeting we should forward the chart that I sent you yesterday.

Hope that the UC meeting goes well. I'm NOT planning to call in unless directed by you.

Cheers,

Michael Nalipinski
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Friday, March 13, 2015 10:10 AM
To: Martin, John; Nalipinski, Mike
Cc: Lackner, Andrew A; Bohm, Rudolf P
Subject: Re: EPA Contact Information

Mike and John,

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Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

From: <Deitchman>, "Scott (CDC/ONDIEH/NCEH)" <sed2@cdc.gov>
Date: Thursday, March 12, 2015 at 2:09 PM
To: Mark Alise <malise@tulane.edu>
Cc: Andrew Lackner <alackner@tulane.edu>, Rudolf Bohm <bohm@tulane.edu>, "Martin.john@epa.gov" <Martin.john@epa.gov>, "nalipinski.mike@epa.gov" <nalipinski.mike@epa.gov>
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Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

Message

From: Alise, Mark A [malise@tulane.edu]
Sent: 3/13/2015 2:09:54 PM
To: Martin, John [martin.john@epa.gov]; Nalipinski, Mike [Nalipinski.Mike@epa.gov]
CC: Lackner, Andrew A [alackner@tulane.edu]; Bohm, Rudolf P [bohm@tulane.edu]
Subject: Re: EPA Contact Information
Attachments: image001.png

Flag: Follow up

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To: Mark Alise <malise@tulane.edu>

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To: Alise, Mark A [malise@tulane.edu]
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TULANE NATIONAL PRIMATE RESEARCH CENTER

Message

From: Alise, Mark A [malise@tulane.edu]
Sent: 3/12/2015 7:36:38 PM
To: Deitchman, Scott (CDC/ONDIEH/NCEH) [sed2@cdc.gov]
CC: Lackner, Andrew A [alackner@tulane.edu]; Bohm, Rudolf P [bohm@tulane.edu]; Martin, John [martin.john@epa.gov]; Nalipinski, Mike [Nalipinski.Mike@epa.gov]
Subject: Re: EPA Contact Information

I do have the contact list. Thanks for confirming.

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

On Mar 12, 2015, at 2:09 PM, Deitchman, Scott (CDC/ONDIEH/NCEH) <sed2@cdc.gov> wrote:

> Mark,
> The EPA representatives were John Martin from EPA Region 6, and Mike Nalipinski representing EPA headquarters. Both are on the CC line. Their phone numbers should be in the Unified Command IAP; don't have one at hand but can obtain if you don't have it.
>
> Regards,
> Scott
>
> RADM Scott Deitchman, MD MPH, USPHS
> Assistant Surgeon General
> Associate Director for Environmental Health Emergencies
> National Center for Environmental Health and
> Agency for Toxic Substances and Disease Registry
> Centers for Disease Control and Prevention
> Atlanta GA USA
>
> ---
>
> **From:** Alise, Mark A [mailto:malise@tulane.edu]
> **Sent:** Thursday, March 12, 2015 12:53 PM
> **To:** Deitchman, Scott (CDC/ONDIEH/NCEH)
> **Cc:** Lackner, Andrew A; Bohm, Rudolf P
> **Subject:** EPA Contact Information
>
> Scott,
>
> Could you please provide us with the contact information for the EPA representatives on today's call?
>
> Thanks,
>
> Mark
>
> Mark A. Alise, M.B.A., Ph.D.
> Chief Operations Officer
> Tulane National Primate Research Center
> 18703 Three Rivers Road
> Covington, LA 70433

985-871-6200

<image001.png>

50 YEARS OF RESEARCH EXCELLENCE

TULANE NATIONAL PRIMATE RESEARCH CENTER

Message

From: Canzler, Erica [Canzler.Erica@epa.gov]
Sent: 2/7/2015 1:04:58 AM
To: Tulis, Dana [Tulis.Dana@epa.gov]; Cheatham, Reggie [cheatham.reggie@epa.gov]; Crossland, Ronnie [Crossland.Ronnie@epa.gov]; Martin, John [martin.john@epa.gov]
Subject: Fwd: Burkholderia pseudomallei at the TNPRC (update 1)

Email with theory on contamination happening in hospital, it is possible that USDA inspected the hospital.

Sent from my iPhone

Begin forwarded message:

From: "Lackner, Andrew A" <alackner@tulane.edu>
Date: February 6, 2015 at 6:20:55 PM CST
To: "Kathy.kliebert@la.gov" <Kathy.kliebert@la.gov>, "Kevin.Davis@la.gov" <Kevin.Davis@la.gov>, "drstrain@ldaf.state.la.us" <drstrain@ldaf.state.la.us>, "Deitchman, Scott (CDC/ONDIEH/NCEH)" <sed2@cdc.gov>, "Victoria.Y.Guilfoil@aphis.usda.gov" <Victoria.Y.Guilfoil@aphis.usda.gov>, "canzler.erica@epa.gov" <canzler.erica@epa.gov>, "Weyant, Rob (CDC/OPHPR/DSAT)" <rsw2@cdc.gov>
Subject: Burkholderia pseudomallei at the TNPRC (update 1)

Dear colleagues,

I wanted to update you with additional information regarding the serology that was provided by the CDC. As noted at the Unified Command Meeting today, only one sample was seropositive, and this was the sample taken on 12/23/2014 from IB22, the animal that recovered from infection with *Burkholderia pseudomallei* . What may not have been noticed was that multiple samples taken from this same animal including one taken two days prior to admission to the hospital, were negative.

Also, both of the animals with confirmed cases were admitted to the hospital with nonspecific illness, but significant changes in clinical status did not appear until 7-9 days later (while the animals were still in the hospital). These two pieces of data together suggest that the exposure may have occurred in the hospital rather than in the breeding colony and raises the possibility that no infected animals were ever in the field cages.

While we remain committed to planning for decontamination of the relevant field cages, we think this additional information is worthy of consideration in the ongoing investigation to determine the origin of this incident.

We are arranging for additional blood sampling of the remaining animals in both field cages to occur early next week, in order to confirm that these animals remain negative.

We look forward to continuing our collaborative efforts on this complex issue and greatly appreciate the efforts of all involved.

Sincerely,

Andrew Lackner

****

Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu

****

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Message

From: Canzler, Erica [Canzler.Erica@epa.gov]
Sent: 2/7/2015 12:24:21 AM
To: Nalipinski, Mike [Nalipinski.Mike@epa.gov]; Martin, John [martin.john@epa.gov]
CC: jose.ojeda@westonsolutions.com
Subject: Fwd: Burkholderia pseudomallei at the TNPRC (update 1)

Fyi

Sent from my iPhone

Begin forwarded message:

From: "Lackner, Andrew A" <alackner@tulane.edu>
Date: February 6, 2015 at 6:20:55 PM CST
To: "Kathy.kliebert@la.gov" <Kathy.kliebert@la.gov>, "Kevin.Davis@la.gov" <Kevin.Davis@la.gov>, "drstrain@ldaf.state.la.us" <drstrain@ldaf.state.la.us>, "Deitchman, Scott (CDC/ONDIEH/NCEH)" <sed2@cdc.gov>, "Victoria.Y.Guilfoil@aphis.usda.gov" <Victoria.Y.Guilfoil@aphis.usda.gov>, "canzler.erica@epa.gov" <canzler.erica@epa.gov>, "Weyant, Rob (CDC/OPHPR/DSAT)" <rsw2@cdc.gov>
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Andrew Lackner

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18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu

****

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Message

From: Lackner, Andrew A [alackner@tulane.edu]
Sent: 1/28/2015 1:22:39 PM
To: Weyant, Rob (CDC/OPHPR/DSAT) [rsw2@cdc.gov]
CC: Thomas.J.Myers@aphis.usda.gov; Elizabeth.A.Lautner@aphis.usda.gov; Matthew.M.Erdman@aphis.usda.gov; Jonathan.T.Zack@aphis.usda.gov; Elizabeth.M.Brown@aphis.usda.gov; Mark.L.Davidson@aphis.usda.gov; Rick.E.Hill@aphis.usda.gov; Kevin.P.Varner@aphis.usda.gov; Donald.L.Varner@aphis.usda.gov; Michael.J.Logan@aphis.usda.gov; brobbins@ldaf.state.la.us; drstrain@ldaf.state.la.us; Hoffmaster, Alex (CDC/OID/NCEZID) [amh9@cdc.gov]; Ashley.Lewis@la.gov; Sarah.turner@la.gov; Sean.Wyatt@la.gov; Courtney, Sharon P [sharonc@tulane.edu]; Wright, Stephen P [swright7@tulane.edu]; Takeisha.Davis@la.gov; Theresa.Sokol@la.gov; vmosgrove@ldaf.state.la; brobbins@ldaf.state.la; Henkel, Richard (CDC/OPHPR/DSAT) [bzz3@cdc.gov]; Calder.Lynch@la.gov; Charlaynne.Prentiss@la.gov; Christina.Dayries@la.gov; Christopher.Guilbeaux@la.gov; daccardo@stpgov.org; Grant, Deborah L [dgrant@tulane.edu]; Sibley, Don A [dsibley@tulane.edu]; dstrain@ldaf.state.la; Gary.Balsamo@la.gov; Gina.Lagarde@la.gov; Jenna.IbergJohnson@la.gov; JGuidry@la.gov; John.Ford@la.gov; John_w@ldaf.state.la.us; Jtlane@la.gov; Kathy.kliebert@la.gov; Kevin.Davis@la.gov; Melton.Gaspard@la.gov; Strecker, Michael T [mstreck@tulane.edu]; Olivia.Watkins@la.gov; pbrister@stpgov.org; Raoult.Ratard@la.gov; Rosanne.Prats@la.gov; Holt, James D. (CDC/OCOO/OGC) [ape8@cdc.gov]; Gee, Jay (CDC/OID/NCEZID) [xzg4@cdc.gov]; Holmes, Harvey T. (CDC/OID/NCEZID) [hth1@cdc.gov]; Walke, Henry (CDC/OID/NCEZID) [hfw3@cdc.gov]; Delaney, Lisa (CDC/NIOSH/OD) [lkd2@cdc.gov]; Glass Elrod, Mindy (CDC/OID/NCEZID) [wzg0@cdc.gov]; Bower, William (CDC/OID/NCEZID) [wab4@cdc.gov]; Martin, John [martin.john@epa.gov]; Isaac, Freeda (CDC aphis.usda.gov) [freeda.e.isaac@aphis.usda.gov]; Divan, Charles (CDC aphis.usda.gov) [charles.l.divan@aphis.usda.gov]; scr1@cdc.gov; Bruner, Maria P. (CDC/OPHPR/DSAT) (CTR) [fvw3@cdc.gov]
Subject: Re: Burkholderia response update call
Attachments: removed.txt

Dear Dr. Weyant,

Thank you for setting up this call.

I would like to suggest that someone from CDC take summary minutes with any agreed upon action items for distribution after the call. This will help us all remain coordinated. In addition, since this is likely to be an ongoing issue it would probably be worth setting up a recurring call to get on peoples calendars. The calls could always be canceled if not needed. Lastly, I anticipate that a number of people may join the call late or leave early depending on their availability.

Best regards

Andrew Lackner

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Director and Chief Academic Officer, Tulane National Primate Research Center
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Covington, LA 70433
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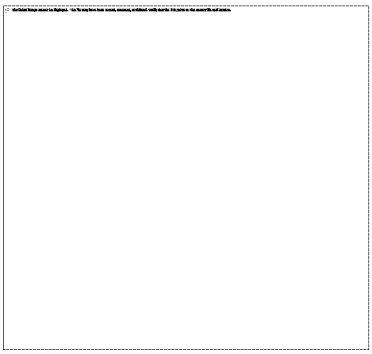
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu



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On Jan 27, 2015, at 4:54 PM, Weyant, Rob (CDC/OPHPR/DSAT) <rsw2@cdc.gov> wrote:

Good evening,

On behalf of the CDC/OPHPR Division of Select Agents and Toxins I would like to thank you all for the support and assistance that you provided to the CDC/USDA team during their site visit to the Tulane facility last week. Given the complexity of this incident, I believe that it would be good for us to touch base to make sure that the various response efforts are optimally coordinated.

I would like to invite you to join in a conference call tomorrow afternoon at 4:30pm Eastern Standard Time to discuss the various components of the response. Call in information is as follows:

Phone number: 866-692-3158
Pass code: 97188913

The agenda will cover:

- Serologic survey of animals in the colony
- Occupational health issues for workers
- Environmental sampling (yes/no and if yes, by what protocol)
- Environmental remediation
- Data organization and sharing
- Overall management of the response
- Other

Let me know if you have any other issues you'd like to discuss.

Many thanks,

Rob Weyant

Robbin S. Weyant, PhD, RBP(ABSA)
Captain, USPHS (Ret.)
Director, Division of Select Agents and Toxins
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
Office phone: 404-718-2001
Cell phone: 678-614-7284
SiprNet: Robbin.Weyant@dia.smil.mil
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Message

From: Weyant, Rob (CDC/OPHPR/DSAT) [rsw2@cdc.gov]
Sent: 1/28/2015 1:40:59 PM
To: Lackner, Andrew A [alackner@tulane.edu]
CC: Thomas.J.Myers@aphis.usda.gov; Elizabeth.A.Lautner@aphis.usda.gov; Matthew.M.Erdman@aphis.usda.gov; Jonathan.T.Zack@aphis.usda.gov; Elizabeth.M.Brown@aphis.usda.gov; Mark.L.Davidson@aphis.usda.gov; Rick.E.Hill@aphis.usda.gov; Kevin.P.Varner@aphis.usda.gov; Donald.L.Varner@aphis.usda.gov; Michael.J.Logan@aphis.usda.gov; brobbins@ldaf.state.la.us; drstrain@ldaf.state.la.us; Hoffmaster, Alex (CDC/OID/NCEZID) [amh9@cdc.gov]; Ashley.Lewis@la.gov; Sarah.turner@la.gov; Sean.Wyatt@la.gov; Courtney, Sharon P [sharonc@tulane.edu]; Wright, Stephen P [swright7@tulane.edu]; Takeisha.Davis@la.gov; Theresa.Sokol@la.gov; vmosgrove@ldaf.state.la; brobbins@ldaf.state.la; Henkel, Richard (CDC/OPHPR/DSAT) [bzz3@cdc.gov]; Calder.Lynch@la.gov; Charlaynne.Prentiss@la.gov; Christina.Dayries@la.gov; Christopher.Guilbeaux@la.gov; daccardo@stpgov.org; Grant, Deborah L [dgrant@tulane.edu]; Sibley, Don A [dsibley@tulane.edu]; dstrain@ldaf.state.la; Gary.Balsamo@la.gov; Gina.Lagarde@la.gov; Jenna.IbergJohnson@la.gov; JGuidry@la.gov; John.Ford@la.gov; John_w@ldaf.state.la.us; Jtlane@la.gov; Kathy.kliebert@la.gov; Kevin.Davis@la.gov; Melton.Gaspard@la.gov; Strecker, Michael T [mstreck@tulane.edu]; Olivia.Watkins@la.gov; pbrister@stpgov.org; Raoult.Ratard@la.gov; Rosanne.Prats@la.gov; Holt, James D. (CDC/OCOO/OGC) [ape8@cdc.gov]; Gee, Jay (CDC/OID/NCEZID) [xzg4@cdc.gov]; Holmes, Harvey T. (CDC/OID/NCEZID) [hth1@cdc.gov]; Walke, Henry (CDC/OID/NCEZID) [hfw3@cdc.gov]; Delaney, Lisa (CDC/NIOSH/OD) [lkd2@cdc.gov]; Glass Elrod, Mindy (CDC/OID/NCEZID) [wzg0@cdc.gov]; Bower, William (CDC/OID/NCEZID) [wab4@cdc.gov]; Martin, John [martin.john@epa.gov]; Isaac, Freeda (CDC aphis.usda.gov) [freeda.e.isaac@aphis.usda.gov]; Divan, Charles (CDC aphis.usda.gov) [charles.l.divan@aphis.usda.gov]; scr1@cdc.gov; Bruner, Maria P. (CDC/OPHPR/DSAT) (CTR) [fvw3@cdc.gov]
Subject: RE: Burkholderia response update call
Attachments: removed.txt

Good morning Dr. Lackner,

Thanks for the helpful suggestions. We will have someone taking notes and will send out a summary after the call. I agree that we probably need to set up a series of calls to track the project.

Thanks,

Rob Weyant

Robbin S. Weyant, PhD, RBP(ABSA)
Captain, USPHS (Ret.)
Director, Division of Select Agents and Toxins
Office of Public Health Preparedness and Response
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From: Lackner, Andrew A [mailto:alackner@tulane.edu]
Sent: Wednesday, January 28, 2015 8:23 AM
To: Weyant, Rob (CDC/OPHPR/DSAT)
Cc: Thomas.J.Myers@aphis.usda.gov; Elizabeth.A.Lautner@aphis.usda.gov; Matthew.M.Erdman@aphis.usda.gov; Jonathan.T.Zack@aphis.usda.gov; Elizabeth.M.Brown@aphis.usda.gov; Mark.L.Davidson@aphis.usda.gov;

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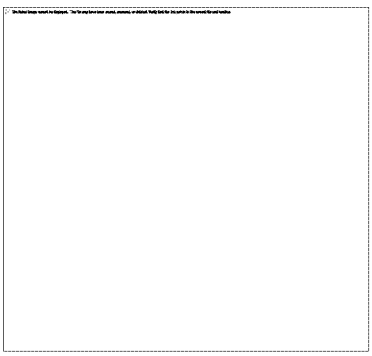

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	18	22	23	26
Site Name	Gerdau Ameristeel	Magnablend - Sodium Chlorite	OKC Ricin Home	Tulane NPRC - Bp
Region	6	6	6	6
SSID	A6G9	A6KX	A6KJ	A6KY
Address	300 Ward Road	100 West Sterrett Road	11217 North McKinley	18703 Three Rivers Road
City	Midlothian	Waxahachie	Oklahoma City	Covington
State	TX	TX	OK	LA
Federal Facility (Y/N)	N	N	N	N
NPL Status	Non-NPL	Non-NPL	Non-NPL	Non-NPL
Primary Site Type	Metal Fabrication (Ferrous and Nonferrous)	Manufacturing (Chemicals, Pharmaceuticals)	Other	Other
Primary Site Subtype	Metal Fabrication (Including Casting and Allied Industries)	Chemical and Allied Products	Other (Disposal/Recycl)	Research, Development, & Testing (R)
Action	PJ	PJ	RV	PJ
Lead (F / PRP)	PRP	PRP	Fund	PRP
Start Date	1/29/2015	1/26/2015	1/12/2015	2/2/2015
Completion Date	1/29/2015	1/26/2015	1/21/2015	6/21/2015
Critical Indicator	ER	ER	ER	ER
Media Type (MT) 1	Air	Air	Direct contact	Soil, water, air
Media Name (MN) 1	particulates	Vapor	Particulates	South Campus
Contaminant of Concern 1	VOCs	Sodium chlorite (31%)	Ricin toxin	Burkholderia psuedomallei
Volume 1	10	150	30	1.5
Unit 1	lbs	gallons	cu yds	cu yds
MT2	tire wire			
MN2	solid			
Contaminant of Concern 2	tire wire			
VOLUME 2	500			
UNIT 2	cu yds			
MT3	tire wire			
MN3	solid			

U.S. ENVIRONMENTAL PROTECTION AGENCY
POLLUTION/SITUATION REPORT
Gerdau Ameristeel - Removal Polrep
Initial Removal Polrep

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region VI

Subject: **POLREP #1**
INITIAL and FINAL
Gerdau Ameristeel

Midlothian, TX
Latitude: 32.4568680 Longitude: -97.0419460

To: Reggie Cheatham, EPA HQ OEM
Ronnie Crossland, EPA R6 Superfund
Anthony Buck, TCEQ

From: John Martin, EPA FOSC
Date: 1/29/2015
Reporting Period:

1. Introduction

1.1 Background

Site Number:	A6G9	**Contract Number:**	
D.O. Number:		**Action Memo Date:**	
Response Authority:		**Response Type:**	Emergency
Response Lead:		**Incident Category:**	
NPL Status:		**Operable Unit:**	
Mobilization Date:		**Start Date:**	1/29/2015
Demob Date:		**Completion Date:**	1/29/2015
CERCLIS ID:	TXN000606881	**RCRIS ID:**	
ERNS No.:		**State Notification:**	TCEQ
FPN#:		**Reimbursable Account #:**	

Incident Category: Fixed Facility

Location: 300 Ward Road, Midlothian, Ellis County, Texas. The geographic coordinate of the fire was Latitude: 32.456868 degrees North, Longitude: 97.041946 degrees West.

Description of Threat: A tire wire fire started due to an unknown cause at the Gerdau Ameristeel steel mill and steel recycling facility, emitting smoke downwind towards a business park located approximately 1 mile SW of the fire and a nearby residence approximately 0.75 miles S of the facility. The fire occurred approximately 0.15 miles SE of U.S. Highway 67. Throughout the incident, winds were predominately out of the NNW.

U.S. ENVIRONMENTAL PROTECTION AGENCY
POLLUTION/SITUATION REPORT
Magnablend - Sodium Chlorite - Removal Polrep
Initial and Final Removal Polrep

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region VI

Subject:	**POLREP #1** **INITIAL and FINAL** **Magnablend - Sodium Chlorite** **Waxahachie, TX**
To:	Ronnie Crossland, EPA R6 Superfund Reggie Cheatham, EPA HQ OEM Anthony Buck, TCEQ
From:	John Martin, OSC
Date:	1/26/2015
Reporting Period:	

1. Introduction

1.1 Background

Site Number:	A6KX	**Contract Number:**	
D.O. Number:		**Action Memo Date:**	
Response Authority:	CERCLA	**Response Type:**	Emergency
Response Lead:	EPA	**Incident Category:**	Removal Assessment
NPL Status:	Non NPL	**Operable Unit:**	
Mobilization Date:	1/26/2015	**Start Date:**	1/26/2015
Demob Date:	1/26/2015	**Completion Date:**	1/26/2015
CERCLIS ID:		**RCRIS ID:**	
ERNS No.:	NRC# 1106638	**State Notification:**	TCEQ
FPN#:		**Reimbursable Account #:**	

Incident Category: Active Production Facility

Location: 100 West Sterrett Road, Waxahachie, Ellis County, Texas. The geographic coordinate of the release was Latitude: 32.475007 degrees North, Longitude: 96.833628 degrees West.

Description of Threat: Univar, which owns and operates the Magnablend Texas Liquid facility, reported to the National Response Center (NRC# 1106638) a release of chlorine gas from a tote at 1515 hr on 26 January 2015 and that a 0.5 mile radius to the incident had been evacuated, including private citizens and employees.

On 26 January 2015 at approxiamtely 1400 hr local incident time, a gaseous release was observed from a 330 gallon poly tote containing approximately 150 gallons of 31% sodium chlorite solution at the Magnablend Texas Liquid Facility. The release occurred approximately 30 ft. west of the main structure

U.S. ENVIRONMENTAL PROTECTION AGENCY
POLLUTION/SITUATION REPORT
OKC Ricin Home - Removal Polrep
Final Removal Polrep

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region VI

Subject:	**POLREP #2** **OKC Ricin Home** **A6KJ** **Oklahoma City, OK** **Latitude: 35.5835448 Longitude: -97.5396926**
To:	Monty Elder, ODEQ Reggie Cheatham, EPA Ronnie Crossland, EPA
From:	John Martin, OSC
Date:	3/24/2015
Reporting Period:	

1. Introduction

1.1 Background

Site Number:	A6KJ	**Contract Number:**	EP-S6-07-01
D.O. Number:	0160	**Action Memo Date:**	
Response Authority:	CERCLA	**Response Type:**	Emergency
Response Lead:	EPA	**Incident Category:**	Removal Action
NPL Status:	Non NPL	**Operable Unit:**	
Mobilization Date:	1/11/2015	**Start Date:**	1/12/2015
Demob Date:	1/16/2015	**Completion Date:**	1/21/2015
CERCLIS ID:	OKN000604295	**RCRIS ID:**	
ERNS No.:		**State Notification:**	
FPN#:		**Reimbursable Account #:**	

1.1.1 Incident Category: Emergency Response

1.1.2 Site Description: The home was built in 1964 and is located in the northwestern portion of Oklahoma City. The single-story home is 1152 square feet with an attached garage. There are residential homes to the east, south, and west. To the immediate north is Morton Ave and then an undeveloped field that is surrounded by other residencial homes, a private high school, and multi-unit housing.

On April 17th, an individual was arrested in Oklahoma City for attempting to create ricin to murder his pregnant girlfriend. Acting on a tip, FBI searched the home and seized evidence and samples. The FBI's analytical results showed positive for ricin. On May 7th, EPA Region 6 staff were initially contacted by the Oklahoma Department of Environmental Quality, requesting biological response assistance related to ricin, for an incident in Oklahoma County. Oklahoma City County Health Department (OCCHD)

U.S. ENVIRONMENTAL PROTECTION AGENCY
POLLUTION/SITUATION REPORT
Tulane NPRC - Bp - Removal Polrep
Initial and Final Removal Polrep

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region VI

Subject:	**POLREP #1** **FINAL** **Tulane NPRC - Bp** **Covington, LA** **Latitude: 30.4417073 Longitude: -90.1100287**
To:	Ronnie Crossland, EPA R6 Superfund Reggie Cheatham, EPA HQ OEM Bryan Riche, LDEQ
From:	John Martin, OSC
Date:	5/13/2015
Reporting Period:	02/05/2015 - 02/13/2015

1. Introduction

1.1 Background

Site Number:	A6KY	**Contract Number:**	EP-W-06-042
D.O. Number:		**Action Memo Date:**	
Response Authority:	CERCLA	**Response Type:**	PRP Oversight
Response Lead:	PRP	**Incident Category:**	Removal Assessment
NPL Status:	Non NPL	**Operable Unit:**	
Mobilization Date:	2/2/2015	**Start Date:**	2/2/2015
Demob Date:	2/13/2015	**Completion Date:**	6/21/2015
CERCLIS ID:		**RCRIS ID:**	
ERNS No.:		**State Notification:**	
FPN#:		**Reimbursable Account #:**	

On 28 January 2015, the U.S. Centers for Disease Control and Prevention (CDC) requested assistance from EPA Region 6 during a biological response related to Burkholderia pseudomallei (B. pseudomallei) at the Tulane National Primate Research Center (TNPRC). The CDC sought guidance with environmental sampling and decontamination for potentially impacted areas from EPA Region 6.

OSC Martin mobilized to the St. Tammany Parish Emergency Operations Center on 2 February 2015 along with a member from the EPA Region 6 Superfund Technical Assessment and Response Team (START-3) contractor, Weston Solutions, Inc. In addition, Ms. Canzler, Director of the EPA CBRN Consequence Management Advisory Division (CMAD) mobilized to the site on 3 February 2015.

1.1.1 Incident Category: The Tulane National Primate Research Center (TNPRC) is one of eight centers that make up the National Primate Research Center Program funded by the National Institutes of

Message

From: Martin, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F9B5EF37318D4B0B9BBBCDAE012EA970-MARTIN, JOHN]
Sent: 5/12/2015 8:55:18 PM
To: Alise, Mark A [malise@tulane.edu]
Subject: RE: Response to the Committee on Homeland Security and Governmental Affairs
Attachments: LOG 653 - Letters to Sen Johnson and Carper-Tulane Primate Center.pdf

Here's a copy of the final response. Good discussions today on the conference call. I knew taking, preparing and tracking 600 samples would be a challenge. I look forward to the results.

I was wondering if written, could I get a copy of the Sampling Plan?

Thanks

John J. Martin
Federal On-Scene Coordinator (OSC)
1445 Ross Ave (6SF-PE)
Dallas, Texas 75202

214.665.6748 * *fax 214.665.2278*

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Tuesday, April 14, 2015 8:20 AM
To: Martin, John; Nalipinski, Mike
Cc: Lackner, Andrew A
Subject: Re: Response to the Committee on Homeland Security and Governmental Affairs

Thanks very much.

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

From: <Martin>, John <martin.john@epa.gov>
Date: Tuesday, April 14, 2015 at 8:18 AM
To: Mark Alise <malise@tulane.edu>, "Nalipinski, Mike" <Nalipinski.Mike@epa.gov>
Cc: Andrew Lackner <alackner@tulane.edu>
Subject: RE: Response to the Committee on Homeland Security and Governmental Affairs

Yes that's possible. When I get a copy of the signed final version, I'll be happy to forward it.

John J. Martin
Federal On-Scene Coordinator (OSC)
1445 Ross Ave (6SF-PE)
Dallas, Texas 75202

214.665.6748 * *fax 214.665.2278*

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Tuesday, April 14, 2015 8:15 AM
To: Nalipinski, Mike; Martin, John
Cc: Lackner, Andrew A
Subject: Response to the Committee on Homeland Security and Governmental Affairs

Mike and John,

On March 25 Senators Johnson and Carper of the US Senate Committee on Homeland Security and Governmental Affairs sent a letter to The Honorable Gina McCarthy, Administrator of the EPA regarding the incident at Tulane and requested a response. We would appreciate receiving a copy of the EPA response.

Please let me know if that is possible.

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

Appointment

From: Martin, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F9B5EF37318D4B0B9BBBCDAE012EA970-MARTIN, JOHN]
Sent: 4/21/2015 3:07:16 PM
To: Nalipinski, Mike [Nalipinski.Mike@epa.gov]; Canzler, Erica [Canzler.Erica@epa.gov]

Subject: FW: CALL - Tulane Panel - call in number 866-299-3188 code 202-566-0184
Location: CALL IN NUMBER - 866-299-3188 CODE 202-566-0184

Start: 4/13/2015 3:00:00 PM
End: 4/13/2015 3:30:00 PM
Show Time As: Tentative

One of the things that they requested me to brief today to Senior Management is "future work within EPA to address bio among the agencies." Could have meant the BIO Annex but I think they meant this Conf Call last week.

To briefly summarize the call last week, would you say " One of CDC's Lessons Learned from the Tulane Incident was since that the possibility of Select Agent Research Facilities to release Select Bio Agents accidentally, they requested that EPA provide additionally research on decontamination options for other bio agents not currently being researched. EPA's CMAT will take the lead and coordinate with ORD for developing decon options for a wider range of agents."

For the Bio Annex, I can say that there has been an ongoing federal workgroup to assess the current Bio Annex and proposed changes to the federal response as necessary for improve coordination.)?)

thanks

-----Original Appointment-----
From: Natarajan, Nitin
Sent: Monday, April 13, 2015 9:20 AM
To: Natarajan, Nitin; Martin, John; Rhotenberry, William; Crossland, Ronnie; Petersen, Chris; Smith, Monica; Cheatham, Reggie; Tulis, Dana; 'dms8@cdc.gov'
Cc: Edlund, Carl
Subject: FW: CALL - Tulane Panel - call in number 866-299-3188 code 202-566-0184
When: Monday, April 13, 2015 10:00 AM-10:30 AM (UTC-06:00) Central Time (US & Canada).
Where: CALL IN NUMBER - 866-299-3188 CODE 202-566-0184

John -- per Ronnie you should plan on listening in to the call. We will let Carl know you are on the call.

Bill - per Ronnie, please come up to Carl's conference room to sit in on the call with us. Monica

-----Original Appointment-----
From: Natarajan, Nitin
Sent: Thursday, April 09, 2015 2:05 PM
To: Natarajan, Nitin; Crossland, Ronnie; Petersen, Chris; Smith, Monica; Cheatham, Reggie; Tulis, Dana; 'dms8@cdc.gov'
Cc: Edlund, Carl
Subject: CALL - Tulane Panel - call in number 866-299-3188 code 202-566-0184
When: Monday, April 13, 2015 11:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: CALL IN NUMBER - 866-299-3188 CODE 202-566-0184

POC: Caroline Kenely – 202-566-2235 (scheduler)

From: Natarajan, Nitin
Sent: Wednesday, April 08, 2015 3:04 PM
To: Sosin, Dan (CDC/OPHPR/OD)
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH); Kenely, Caroline; Brooks, Becky
Subject: RE: information

I'm traveling tomorrow so was hoping for Friday. Maybe we can do Mon or Tuesday.

I've cc'd Caroline who can help with scheduling on our side.

Caroline - it'll be me, Reggie or Dana and Erica from HQ and Carl eglund and Ronnie crossland from R6.

Thanks all.

N

Nitin Natarajan
Deputy Assistant Administrator
Office of Solid Waste and Emergency Response
Environmental Protection Agency
202-566-0200 Office

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: 4/8/2015 14:55
To: Natarajan, Nitin
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: RE: information

I don't have anything on my calendar Nitin. Do you still have a desire for a call this week? I am out on Friday, so need to schedule tomorrow. Scott and I would try to both be on the call.

Thank you.

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Natarajan, Nitin [mailto:Natarajan.Nitin@epa.gov]
Sent: Tuesday, April 07, 2015 12:55 PM
To: Sosin, Dan (CDC/OPHPR/OD)
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: RE: information

I've chatted with our folks and we think we can get there from here. Can we setup a call this week with our folks to discuss?

N

Nitin Natarajan
Deputy Assistant Administrator
Office of Solid Waste and Emergency Response
Environmental Protection Agency
202-566-0200 Office

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: 4/7/2015 12:50
To: Natarajan, Nitin
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: FW: information

Nitin: in case you are not aware, it appears that Tulane is acting on its own to convene a panel of independent experts to weigh in on the environmental sampling needs. The deliberations of this group should be helpful for considering additional USG-sponsored deliberations on sampling for biological threats in the environment.

It will be good to have a suitable lab or two in mind to conduct the testing should Tulane and the local authorities decide to do more testing.

Best regards,

Dan

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: Tuesday, April 07, 2015 12:47 PM
To: Helfand, Rita (CDC/OID/NCEZID); Deitchman, Scott (CDC/ONDIEH/NCEH); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: RE: information

Thank you Rita ... based on where we are in this response and our position on environmental testing, it seems best to be responsive to this panel's information requests regarding how we tested samples (as you are), and be particularly careful not to offer a contrary position to the EPA sampling methods as provided initially on request of the state.

It may be helpful to the community members to have an independent panel offer advice on further sampling at this point as long as Tulane is prepared to act on the input. The results of this panel should be informative of the need to further USG planning work for future events as well.

Dan

Daniel M. Sosin, MD, MPH, FACP

Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Helfand, Rita (CDC/OID/NCEZID)
Sent: Tuesday, April 07, 2015 12:38 PM
To: Deitchman, Scott (CDC/ONDIEH/NCEH); Sosin, Dan (CDC/OPHPR/OD); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: FW: information

Fyi too

From: Hoffmaster, Alex (CDC/OID/NCEZID)
Sent: Tuesday, April 07, 2015 6:51 AM
To: Gee, Jay (CDC/OID/NCEZID); Glass Elrod, Mindy (CDC/OID/NCEZID); Blaney, David (CDC/OID/NCEZID); Nolen, Leisha (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID)
Cc: Belay, Ermias (CDC/OID/NCEZID); Helfand, Rita (CDC/OID/NCEZID); Damon, Inger K. (CDC/OID/NCEZID)
Subject: FW: information

See below regarding Tulane panel. Henry, Dave and I were just talking about this yesterday.

Mindy – well just send the consensus document along with any modifications done short description of how water was processed.
Alex

From: Lackner, Andrew A [mailto:alackner@tulane.edu]
Sent: Tuesday, April 07, 2015 6:17 AM
To: Hoffmaster, Alex (CDC/OID/NCEZID); Gee, Jay (CDC/OID/NCEZID)
Cc: Bohm, Rudolf P; Sibley, Don A
Subject: information

Alex,

As part of our response to the Burkholderia pseudomallei incident at Tulane an expert panel has been put together to help us work through the various issues that this has brought up. Among the members are David Wagner, Paul Keim and David Dance. Among the issues to consider is additional environmental testing. A question that came up in the discussion involved the methods used for environmental analyses to be sure that any future testing, if done, would be comparable with prior work. Thus, I would appreciate it if you could share details of how the analyses were performed.

best regards

Andrew
****
Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu

web: tnprc.tulane.edu
****

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Message

From: Martin, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F9B5EF37318D4B0B9BBBCDAE012EA970-MARTIN, JOHN]
Sent: 4/14/2015 1:18:37 PM
To: Alise, Mark A [malise@tulane.edu]; Nalipinski, Mike [Nalipinski.Mike@epa.gov]
CC: Lackner, Andrew A [alackner@tulane.edu]
Subject: RE: Response to the Committee on Homeland Security and Governmental Affairs

Yes that's possible. When I get a copy of the signed final version, I'll be happy to forward it.

John J. Martin
Federal On-Scene Coordinator (OSC)
1445 Ross Ave (6SF-PE)
Dallas, Texas 75202

214.665.6748 * *fax 214.665.2278*

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Tuesday, April 14, 2015 8:15 AM
To: Nalipinski, Mike; Martin, John
Cc: Lackner, Andrew A
Subject: Response to the Committee on Homeland Security and Governmental Affairs

Mike and John,

On March 25 Senators Johnson and Carper of the US Senate Committee on Homeland Security and Governmental Affairs sent a letter to The Honorable Gina McCarthy, Administrator of the EPA regarding the incident at Tulane and requested a response. We would appreciate receiving a copy of the EPA response.

Please let me know if that is possible.

Thanks,

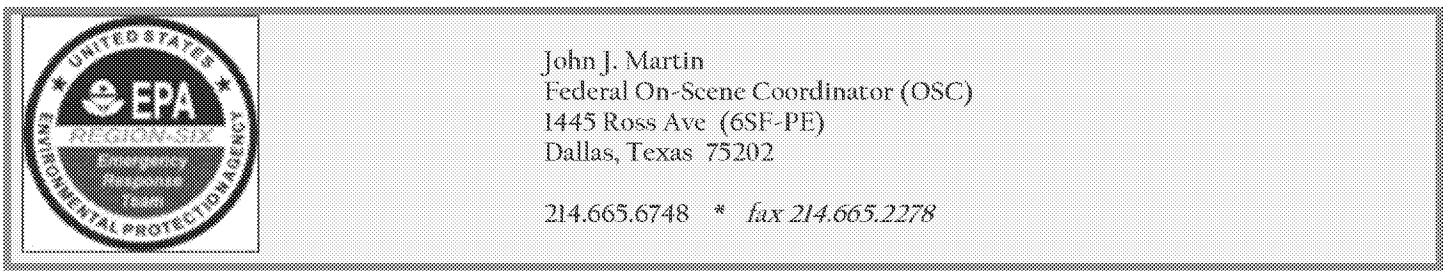
Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

Message

From: Martin, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F9B5EF37318D4B0B9BBBCDAE012EA970-MARTIN, JOHN]
Sent: 3/1/2015 6:23:30 PM
To: Nalipinski, Mike [Nalipinski.Mike@epa.gov]
Subject: FW: additional samples sent to CDC for confirmatory testing
Attachments: removed.txt

FYI in case you haven't seen this email sent before Scott's email.



John J. Martin
Federal On-Scene Coordinator (OSC)
1445 Ross Ave (6SF-PE)
Dallas, Texas 75202

214.665.6748 * *fax 214.665.2278*

From: Lackner, Andrew A [mailto:alackner@tulane.edu]
Sent: Saturday, February 28, 2015 11:34 AM
To: Kevin Davis (Kevin.Davis@LA.GOV); daccardo@stpgov.org; Sibley, Don A; Bohm, Rudolf P; Jimmy Guidry (DHH); jmlacour@wlf.la.gov; Brent Robbins (brobbins@ldaf.state.la.us) (brobbins@ldaf.state.la.us); Raoult Ratard <Raoult.Ratard@LA.GOV> (Raoult.Ratard@LA.GOV); Isaac, Freeda (CDC aphis.usda.gov); Katie.Portacci@aphis.usda.gov; Martin, John; Deitchman, Scott (CDC/ONDIEH/NCEH); Hoffmaster, Alex (CDC/OID/NCEZID); David Blaney; xdf8@cdc.gov; Grant, Deborah L; Alise, Mark A; Bohm, Rudolf P; Victoria.Y.Guilfoil@aphis.usda.gov; Kenneth.L.Angel@aphis.usda.gov
Subject: additional samples sent to CDC for confirmatory testing

Dear all,

We have sent a bacterial isolate from a nonhuman primate (IL88) that we are concerned could be Burkholderia to Alex Hoffmaster at CDC for confirmatory testing.

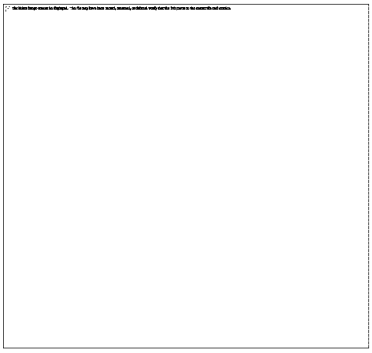
Here are relevant aspects of the case:

- Admitted to the animal hospital on 12/30/14 for trauma from R/12D. This was during the window of time when one of the infected cases (IB22) was in the hospital
- No clinical signs associated with a bacterial infection at admission
- The animal was treated in the same procedure room as the other 2 infected and 2 seropositive animals
- IL88 was treated twice in this procedure room prior to its initial decontamination
- Clinical signs of trauma resolved
- On a recheck on February 23 the animal had two small ulcerations on the abdomen. Bacterial cultures were taken, the animal was euthanized and a complete necropsy performed.

****

Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology

Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu



****

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Message

From: Martin, John [martin.john@epa.gov]
Sent: 2/20/2015 8:56:00 PM
To: Deitchman, Scott (CDC/ONDIEH/NCEH) [sed2@cdc.gov]
Subject: FW: USDA risk assessment team
Attachments: FIGURE 1 - SAMPLE LOCATION MAP.pdf; Sample Locations.xls.pdf; Tulane University ER QASP - v2.pdf

Fyi

Sent from my Windows Phone

From: Martin, John
Sent: 2/19/2015 11:54 AM
To: Katie.Portacci@aphis.usda.gov; mgc8@cdc.gov
Cc: Rhotenberry, William; McAteer, Mike; Nalipinski, Mike; Canzler, Erica; Jeff.dauzat@la.gov
Subject: RE: USDA risk assessment team

Here's the information you requested. Apologies it took so long. Not sure if you participated in this morning's UC Tulane Primate Center conf call but Dr Isaac (sp?) with USDA was asking about the status of these attachments and when be a good time to meet on site; the week of Feb 23 or Mar 2? Not sure if she got her answer but EPA won't be there next week. However, we should be in Covington the week of Mar 2.

The analytical results from our/Tulane's sampling activities should come from the CDC lab on Wed for the cultures. If any samples are positive, then the lab should conduct further analysis to determine the bacterium species. Not sure of the timing on that analysis.

Not sure if an environmental working group has been formally established but that is a good idea. If you like, please give me a call and we can discuss the next steps.

thanks

John J. Martin
Federal On-Scene Coordinator (OSC)
1445 Ross Ave (6SF-PE)
Dallas, Texas 75202

214.665.6748 * *fax 214.665.2278*

From: Rhotenberry, William
Sent: Tuesday, February 17, 2015 4:48 PM
To: Martin, John; McAteer, Mike
Subject: Fwd: USDA risk assessment team

Fyi
Sent from my iPhone

Begin forwarded message:

From: "Portacci, Katie - APHIS" <Katie.Portacci@aphis.usda.gov>
To: "Canzler, Erica" <Canzler.Erica@epa.gov>, "Cruz, Miguel (CDC/ONDIEH/NCEH) <mgc8@cdc.gov> (mgc8@cdc.gov)" <mgc8@cdc.gov>, "Rhotenberry, William" <Rhotenberry.William@epa.gov>, "Nalipinski, Mike" <Nalipinski.Mike@epa.gov>, "jmlacour@wlf.la.gov" <jmlacour@wlf.la.gov>, "" <Jeff.dauzat@la.gov>
Cc: "ROONEY, Alejandro - ARS" <Alejandro.Rooney@ARS.USDA.GOV>, "Clouse, Timothy L - APHIS" <Timothy.L.Clouse@aphis.usda.gov>
Subject: USDA risk assessment team

Hi everyone,
I do not think I am reaching the entire environmental working group, but I wanted to reach out to you and suggest meeting in Covington beginning 2/24 as a working group. Miguel, feel free to share and hopefully we can coordinate with everyone in the group. Sorry if I am jumping the gun, but we wanted to make plans in advance so we can get all our medical stuff out of the way. (If results from EPA will be longer than next Monday please let us know).

The USDA risk assessment team would like to come take a look at the environment outside of the facility. Coordinating our visit with the other agencies would give us all the opportunity to tour together and discuss the results as they come in. If all samples are negative, we need to discuss options for next steps and make sure we are all on the same page. It would be great if all agencies were able to give a collective recommendation to the state. Meeting with others concerned about these issues would help us discuss long-term monitoring options as well as potential mitigations.

Our proposed visit would include:

1. Walking the outer perimeter of the facility, particularly along water ways

2. Visiting sites downstream and upstream for current and future risks

3. Visiting livestock facilities (USDA would do alone unless others were interested)

4. Meeting with the group to discuss results interpretation and long term strategies/recommendations or next steps for analyses

5. Discussion additional sampling of soil or wildlife

We are concerned about the long-term establishment of B. pseudomallei outside of the facility. The environmental conditions in the area lend itself to this possibility (SEE MAP ATTACHED) On the left hand side of your screen, under the paper clip, you will see a layer symbol. You can use this to turn on/off layers.) If this occurs, the continued risk to humans and other animals would be present. We are going to look at the possible national extent that this organism could establish. The layers we are looking at are soil PH, Soil moisture, soil clay, and soil temperature. Please let us know if there are other layers you are looking at or would like us to look at. Water would be nice but we don't have great water layers and even if water gets too cold, it could hide in soil in the area.

Also data we are still missing and would love to fill in the gaps:

- Soil sampling plan/protocol

- Information on compost pile (what is in here, is it covered?)

Please let us know if others are on board! Miguel it'd be really great to have someone from your staff come with us.
(Also I'm not clear on how this group will interact with the science and technical working group so if someone from that group need to join us please do so!)

Thanks!

Katie Portacci, DVM, MPH, DACVPM | USDA APHIS Veterinary Services
Center for Epidemiology and Animal Health
Project Manager: Risk Analysis
2150 Centre Avenue, Bldg B | Ft Collins, CO 80526
970-494-7189 (office)/ 970-494-1741 (cell)
Katie.Portacci@aphis.usda.gov

The best doctor in the world is a veterinarian. He can't ask his patients what is the matter -- he's got to just know. – Will Rogers

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Message

From: Martin, John [martin.john@epa.gov]
Sent: 2/20/2015 9:00:45 PM
To: Petersen, Chris [petersen.chris@epa.gov]; Smith, Monica [smith.monica@epa.gov]; Rhotenberry, William [Rhotenberry.William@epa.gov]; McAteer, Mike [mcateer.mike@epa.gov]; Nalipinski, Mike [Nalipinski.Mike@epa.gov]; Canzler, Erica [Canzler.Erica@epa.gov]; Crossland, Ronnie [Crossland.Ronnie@epa.gov]
Subject: FW: Soil and water samples negative
Attachments: FIGURE 1 - SAMPLE LOCATION MAP.PDF; Sample Locations.xls.pdf; Tulane University ER QASP - v2.pdf

They still requesting our assistance. A letter is being /has been sent to Ron Curry. And they would CMAT to participate on the animal working group next Tuesay.

Sent from my Windows Phone

From: Deitchman, Scott (CDC/ONDIEH/NCEH)
Sent: 2/20/2015 2:56 PM
To: Kevin Davis (Kevin.Davis@LA.GOV); daccardo@stpgov.org; dsibley@tulane.edu; bohm@tulane.edu; Jimmy Guidry (DHH); jmlacour@wlf.la.gov; Jeff Dauzat (Jeff.Dauzat@LA.GOV); Brent Robbins (brobbins@ldaf.state.la.us) (brobbins@ldaf.state.la.us); Collins Simoneaux (Collins.Simoneaux@LA.GOV); Raoult Ratard <Raoult.Ratard@LA.GOV> (Raoult.Ratard@LA.GOV); dstacy@ldaf.la.gov; Isaac, Freeda (CDC aphis.usda.gov); Katie.Portacci@aphis.usda.gov; Martin, John; Canzler, Erica; Nalipinski, Mike
Subject: Soil and water samples negative

This afternoon the CDC laboratory informed us that they were able to complete the analysis of all soil and water samples. **All samples were negative for *Burkholderia pseudomallei*.**

The laboratory performed two tests: polymerized chain reaction (PCR) which looks for the organism, whether dead or alive, by detecting its genetic material (DNA); and culturing, which should grow any live organisms. All samples were negative by both tests.

The samples included: 42 soil samples; 15 water samples; and 12 swab samples. Attached are the sample location information and sampling plan that was provided by EPA.

Please share as appropriate within your organizations.

Regards,
Scott

RADM Scott Deitchman, MD MPH, USPHS
Assistant Surgeon General
Associate Director for Environmental Health Emergencies
National Center for Environmental Health and
Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention
Atlanta GA USA

Message

From: Martin, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F9B5EF37318D4B0B9BBBCDAE012EA970-MARTIN, JOHN]
Sent: 4/9/2015 4:12:12 PM
To: Nalipinski, Mike [Nalipinski.Mike@epa.gov]
Subject: FW: information

Looks like levels above our pay grade but I thought if I get invited, I'll try to invite you. Not sure what is meant by "be particularly careful not to offer a contrary position to the EPA sampling methods"? Shouldn't matter when the DQO is different or if the sampling methods are modified. Lab analysis may be different/tweaked but that's not EPA.

Ties into the message I'll keep pushing to USDA (today's call) and UC, that Tulane needs to develop the QASP and EPA could be part of the group that reviews/comments and acknowledges adequacy.

John J. Martin
Federal On-Scene Coordinator (OSC)
1445 Ross Ave (6SF-PE)
Dallas, Texas 75202

214.665.6748 * *fax 214.665.2278*

From: Crossland, Ronnie
Sent: Tuesday, April 07, 2015 12:16 PM
To: Smith, Monica
Cc: Petersen, Chris; Rhotenberry, William; Martin, John
Subject: FW: information

From: Coleman, Sam
Sent: Tuesday, April 07, 2015 12:08 PM
To: Natarajan, Nitin; Cheatham, Reggie; Tulis, Dana
Cc: Edlund, Carl; Crossland, Ronnie
Subject: RE: information

Carl Edlund, Ronnie Crossland

Samuel Coleman, P.E.,
Deputy Regional Administrator
coleman.sam@epa.gov
214.665.2100
214.665.3110 Direct
214.789.2016 Cell

From: Natarajan, Nitin
Sent: Tuesday, April 07, 2015 12:04 PM
To: Coleman, Sam; Cheatham, Reggie; Tulis, Dana
Subject: FW: information

I've suggested to CDC that we setup a call later this week to discuss. Who from your shops should we include?

N

Nitin Natarajan
Deputy Assistant Administrator
Office of Solid Waste and Emergency Response
Environmental Protection Agency
202-566-0200 Office

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: 4/7/2015 12:50
To: Natarajan, Nitin
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: FW: information

Nitin: in case you are not aware, it appears that Tulane is acting on its own to convene a panel of independent experts to weigh in on the environmental sampling needs. The deliberations of this group should be helpful for considering additional USG-sponsored deliberations on sampling for biological threats in the environment.

It will be good to have a suitable lab or two in mind to conduct the testing should Tulane and the local authorities decide to do more testing.

Best regards,

Dan

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: Tuesday, April 07, 2015 12:47 PM
To: Helfand, Rita (CDC/OID/NCEZID); Deitchman, Scott (CDC/ONDIEH/NCEH); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: RE: information

Thank you Rita ... based on where we are in this response and our position on environmental testing, it seems best to be responsive to this panel's information requests regarding how we tested samples (as you are), and be particularly careful not to offer a contrary position to the EPA sampling methods as provided initially on request of the state.

It may be helpful to the community members to have an independent panel offer advice on further sampling at this point as long as Tulane is prepared to act on the input. The results of this panel should be informative of the need to further USG planning work for future events as well.

Dan

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Helfand, Rita (CDC/OID/NCEZID)
Sent: Tuesday, April 07, 2015 12:38 PM
To: Deitchman, Scott (CDC/ONDIEH/NCEH); Sosin, Dan (CDC/OPHPR/OD); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: FW: information

Fyi too

From: Hoffmaster, Alex (CDC/OID/NCEZID)
Sent: Tuesday, April 07, 2015 6:51 AM
To: Gee, Jay (CDC/OID/NCEZID); Glass Elrod, Mindy (CDC/OID/NCEZID); Blaney, David (CDC/OID/NCEZID); Nolen, Leisha (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID)
Cc: Belay, Ermias (CDC/OID/NCEZID); Helfand, Rita (CDC/OID/NCEZID); Damon, Inger K. (CDC/OID/NCEZID)
Subject: FW: information

See below regarding Tulane panel. Henry, Dave and I were just talking about this yesterday.

Mindy – well just send the consensus document along with any modifications done short description of how water was processed.
Alex

From: Lackner, Andrew A [mailto:alackner@tulane.edu]
Sent: Tuesday, April 07, 2015 6:17 AM
To: Hoffmaster, Alex (CDC/OID/NCEZID); Gee, Jay (CDC/OID/NCEZID)
Cc: Bohm, Rudolf P; Sibley, Don A
Subject: information

Alex,

As part of our response to the Burkholderia pseudomallei incident at Tulane an expert panel has been put together to help us work through the various issues that this has brought up. Among the members are David Wagner, Paul Keim and David Dance. Among the issues to consider is additional environmental testing. A question that came up in the discussion involved the methods used for environmental analyses to be sure that any future testing, if done, would be comparable with prior work. Thus, I would appreciate it if you could share details of how the analyses were performed.

best regards

Andrew

****
Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu
****

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Message

From: Martin, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F9B5EF37318D4B0B9BBBCDAE012EA970-MARTIN, JOHN]
Sent: 2/19/2015 5:55:42 PM
To: Katie.Portacci@aphis.usda.gov; mgc8@cdc.gov
CC: Rhotenberry, William [Rhotenberry.William@epa.gov]; McAteer, Mike [mcateer.mike@epa.gov]; Nalipinski, Mike [Nalipinski.Mike@epa.gov]; Canzler, Erica [Canzler.Erica@epa.gov]; Jeff.dauzat@la.gov
Subject: RE: USDA risk assessment team
Attachments: FIGURE 1 - SAMPLE LOCATION MAP.pdf; Sample Locations.xls.pdf; Tulane University ER QASP - v2.pdf

Here's the information you requested. Apologies it took so long. Not sure if you participated in this morning's UC Tulane Primate Center conf call but Dr Isaac (sp?) with USDA was asking about the status of these attachments and when be a good time to meet on site; the week of Feb 23 or Mar 2? Not sure if she got her answer but EPA won't be there next week. However, we should be in Covington the week of Mar 2.

The analytical results from our/Tulane's sampling activities should come from the CDC lab on Wed for the cultures. If any samples are positive, then the lab should conduct further analysis to determine the bacterium species. Not sure of the timing on that analysis.

Not sure if an environmental working group has been formally established but that is a good idea. If you like, please give me a call and we can discuss the next steps.

thanks

John J. Martin
Federal On-Scene Coordinator (OSC)
1445 Ross Ave (6SF-PE)
Dallas, Texas 75202

214.665.6748 * *fax 214.665.2278*

From: Rhotenberry, William
Sent: Tuesday, February 17, 2015 4:48 PM
To: Martin, John; McAteer, Mike
Subject: Fwd: USDA risk assessment team

Fyi
Sent from my iPhone

Begin forwarded message:

> **From:** "Portacci, Katie - APHIS" <Katie.Portacci@aphis.usda.gov>
> **To:** "Canzler, Erica" <Canzler.Erica@epa.gov>, "Cruz, Miguel (CDC/ONDIEH/NCEH) <mgc8@cdc.gov> (mgc8@cdc.gov)" <mgc8@cdc.gov>, "Rhotenberry, William" <Rhotenberry.William@epa.gov>, "Nalipinski, Mike" <Nalipinski.Mike@epa.gov>, "jmlacour@wlf.la.gov" <jmlacour@wlf.la.gov>, "" <Jeff.dauzat@la.gov>

Cc: "ROONEY, Alejandro - ARS" <Alejandro.Rooney@ARS.USDA.GOV>, "Clouse, Timothy L - APHIS" <Timothy.L.Clouse@aphis.usda.gov>
Subject: USDA risk assessment team

Hi everyone,
I do not think I am reaching the entire environmental working group, but I wanted to reach out to you and suggest meeting in Covington beginning 2/24 as a working group. Miguel, feel free to share and hopefully we can coordinate with everyone in the group. Sorry if I am jumping the gun, but we wanted to make plans in advance so we can get all our medical stuff out of the way. (If results from EPA will be longer than next Monday please let us know).

The USDA risk assessment team would like to come take a look at the environment outside of the facility. Coordinating our visit with the other agencies would give us all the opportunity to tour together and discuss the results as they come in. If all samples are negative, we need to discuss options for next steps and make sure we are all on the same page. It would be great if all agencies were able to give a collective recommendation to the state. Meeting with others concerned about these issues would help us discuss long-term monitoring options as well as potential mitigations.

Our proposed visit would include:

1. Walking the outer perimeter of the facility, particularly along water ways

2. Visiting sites downstream and upstream for current and future risks

3. Visiting livestock facilities (USDA would do alone unless others were interested)

4. Meeting with the group to discuss results interpretation and long term strategies/recommendations or next steps for analyses

5. Discussion additional sampling of soil or wildlife

We are concerned about the long-term establishment of B. pseudomallei outside of the facility. The environmental conditions in the area lend itself to this possibility (SEE MAP ATTACHED) On the left hand side of your screen, under the paper clip, you will see a layer symbol. You can use this to turn on/off layers.) If this occurs, the continued risk to humans and other animals would be present. We are going to look at the possible national extent that this organism could establish. The layers we are looking at are soil PH, Soil moisture, soil clay, and soil temperature. Please let us know if there are other layers you are looking at or would like us to look at. Water would be nice but we don't have great water layers and even if water gets too cold, it could hide in soil in the area.

Also data we are still missing and would love to fill in the gaps:

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- Information on compost pile (what is in here, is it covered?)

Please let us know if others are on board! Miguel it'd be really great to have someone from your staff come with us.

(Also I'm not clear on how this group will interact with the science and technical working group so if someone from that group need to join us please do so!)

Thanks!

Katie Portacci, DVM, MPH, DACVPM | USDA APHIS Veterinary Services
Center for Epidemiology and Animal Health
Project Manager: Risk Analysis
2150 Centre Avenue, Bldg B | Ft Collins, CO 80526
970-494-7189 (office)/ 970-494-1741 (cell)
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Message

From: Martin, John [martin.john@epa.gov]
Sent: 2/4/2015 1:59:57 AM
To: Cheek, Sam [Sam.Cheek@WestonSolutions.com]
Subject: FW: Message Sent to our Community Neighbors

Sent from my Windows Phone

From: Alise, Mark A
Sent: 2/3/2015 5:07 PM
To: Martin, John
Subject: Message Sent to our Community Neighbors

John

Below is a copy of the message that we sent to our Community Advisory Board (a board of our neighbors in the business, education, local government, and residential community). We duplicated this message and also sent it to the homeowners associations of the two adjoining residential developments (Estates of Northpark and Versailles) as well as the headmaster at the adjoining school (Northlake Christian School):

Dear members of the TNPRC Community Advisory Board

I write to update you on a recent situation at the TNPRC.

As I indicated in my prior message, we identified two animals from our breeding colony infected with the bacteria *Burkholderia pseudomallei* (the cause of melioidosis) in November. I also mentioned that CDC was going to visit to help identify the source of infection in the macaques.

Personnel from both the CDC and USDA have completed their initial visit. The source of the infection has not been identified, but we continue to investigate this with the assistance of the CDC and USDA.

During the visit, the CDC indicated that the risk of human *Burkholderia pseudomallei* infection occurring as a result of these circumstances is "infinitesimal". However, we continue to actively monitor the situation, and, out of an abundance of caution, have implemented some enhancements to our procedures.

I would be happy to talk with you individually or as a group to discuss this further. Also, as more information becomes available, we will provide updates.

best regards

Andrew
****
Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433

We have not provided further updates beyond this message which was sent to the various recipients between Jan 17-20, 2015.

Let me know if you have any questions,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

TULANE NATIONAL PRIMATE
RESEARCH CENTER

Message

From: Martin, John [martin.john@epa.gov]
Sent: 2/4/2015 2:00:25 AM
To: Alise, Mark A [malise@tulane.edu]
Subject: RE: Message Sent to our Community Neighbors

Received. Thank you.

Sent from my Windows Phone

From: Alise, Mark A
Sent: 2/3/2015 5:07 PM
To: Martin, John
Subject: Message Sent to our Community Neighbors

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Tulane University Health Science Center
18703 Three Rivers Road
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Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

Message

From: Martin, John [martin.john@epa.gov]
Sent: 2/4/2015 3:51:25 AM
To: Petersen, Chris [petersen.chris@epa.gov]; Crossland, Ronnie [Crossland.Ronnie@epa.gov]
Subject: FW: Message Sent to our Community Neighbors

Sent from my Windows Phone

From: Martin, John
Sent: 2/3/2015 8:00 PM
To: Alise, Mark A
Subject: RE: Message Sent to our Community Neighbors

Received. Thank you.

Sent from my Windows Phone

From: Alise, Mark A
Sent: 2/3/2015 5:07 PM
To: Martin, John
Subject: Message Sent to our Community Neighbors

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Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

Message

From: Martin, John [martin.john@epa.gov]
Sent: 2/3/2015 5:06:39 AM
To: Cheek, Sam [Sam.Cheek@WestonSolutions.com]
Subject: FW: Burkholderia response update call
Attachments: removed.txt

Sent from my Windows Phone

From: Weyant, Rob (CDC/OPHPR/DSAT)
Sent: 1/28/2015 7:41 AM
To: Lackner, Andrew A
Cc: Thomas.J.Myers@aphis.usda.gov; Elizabeth.A.Lautner@aphis.usda.gov; Matthew.M.Erdman@aphis.usda.gov; Jonathan.T.Zack@aphis.usda.gov; Elizabeth.M.Brown@aphis.usda.gov; Mark.L.Davidson@aphis.usda.gov; Rick.E.Hill@aphis.usda.gov; Kevin.P.Varner@aphis.usda.gov; Donald.L.Varner@aphis.usda.gov; Michael.J.Logan@aphis.usda.gov; brobbins@ldaf.state.la.us; drstrain@ldaf.state.la.us; Hoffmaster, Alex (CDC/OID/NCEZID); Ashley.Lewis@la.gov; Sarah.turner@la.gov; Sean.Wyatt@la.gov; Courtney, Sharon P; Wright, Stephen P; Takeisha.Davis@la.gov; Theresa.Sokol@la.gov; vmosgrove@ldaf.state.la; brobbins@ldaf.state.la; Henkel, Richard (CDC/OPHPR/DSAT); Calder.Lynch@la.gov; Charlaynne.Prentiss@la.gov; Christina.Dayries@la.gov; Christopher.Guilbeaux@la.gov; daccardo@stpgov.org; Grant, Deborah L; Sibley, Don A; dstrain@ldaf.state.la; Gary.Balsamo@la.gov; Gina.Lagarde@la.gov; Jenna.IbergJohnson@la.gov; JGuidry@la.gov; John.Ford@la.gov; John_w@ldaf.state.la.us; Jtlane@la.gov; Kathy.kliebert@la.gov; Kevin.Davis@la.gov; Melton.Gaspard@la.gov; Strecker, Michael T; Olivia.Watkins@la.gov; pbrister@stpgov.org; Raoult.Ratard@la.gov; Rosanne.Prats@la.gov; Holt, James D. (CDC/OCOO/OGC); Gee, Jay (CDC/OID/NCEZID); Holmes, Harvey T. (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Delaney, Lisa (CDC/NIOSH/OD); Glass Elrod, Mindy (CDC/OID/NCEZID); Bower, William (CDC/OID/NCEZID); Martin, John; Isaac, Freeda (CDC aphis.usda.gov); Divan, Charles (CDC aphis.usda.gov); scr1@cdc.gov; Bruner, Maria P. (CDC/OPHPR/DSAT) (CTR)
Subject: RE: Burkholderia response update call

Good morning Dr. Lackner,

Thanks for the helpful suggestions. We will have someone taking notes and will send out a summary after the call. I agree that we probably need to set up a series of calls to track the project.

Thanks,

Rob Weyant
Robbin S. Weyant, PhD, RBP(ABSA)
Captain, USPHS (Ret.)
Director, Division of Select Agents and Toxins
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
Office phone: 404-718-2001
Cell phone: 678-614-7284
SiprNet: Robbin.Weyant@dia.smil.mil
DSAT Vision: To be the preeminent resource for the safety and security of biological agents and toxins.

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From: Lackner, Andrew A [mailto:alackner@tulane.edu]
Sent: Wednesday, January 28, 2015 8:23 AM
To: Weyant, Rob (CDC/OPHPR/DSAT)
Cc: Thomas.J.Myers@aphis.usda.gov; Elizabeth.A.Lautner@aphis.usda.gov; Matthew.M.Erdman@aphis.usda.gov; Jonathan.T.Zack@aphis.usda.gov; Elizabeth.M.Brown@aphis.usda.gov; Mark.L.Davidson@aphis.usda.gov; Rick.E.Hill@aphis.usda.gov; Kevin.P.Varner@aphis.usda.gov; Donald.L.Varner@aphis.usda.gov; Michael.J.Logan@aphis.usda.gov; brobbins@ldaf.state.la.us; drstrain@ldaf.state.la.us; Hoffmaster, Alex (CDC/OID/NCEZID); Ashley.Lewis@la.gov; Sarah.turner@la.gov; Sean.Wyatt@la.gov; Courtney, Sharon P; Wright, Stephen P; Takeisha.Davis@la.gov; Theresa.Sokol@la.gov; vmosgrove@ldaf.state.la; brobbins@ldaf.state.la; Henkel, Richard (CDC/OPHPR/DSAT); Calder.Lynch@la.gov; Charlaynne.Prentiss@la.gov; Christina.Dayries@la.gov; Christopher.Guilbeaux@la.gov; daccardo@stpgov.org; Grant, Deborah L; Sibley, Don A; dstrain@ldaf.state.la; Gary.Balsamo@la.gov; Gina.Lagarde@la.gov; Jenna.IbergJohnson@la.gov; JGuidry@la.gov; John.Ford@la.gov; John_w@ldaf.state.la.us; Jtlane@la.gov; Kathy.kliebert@la.gov; Kevin.Davis@la.gov; Melton.Gaspard@la.gov; Strecker, Michael T; Olivia.Watkins@la.gov; pbrister@stpgov.org; Raoult.Ratard@la.gov; Rosanne.Prats@la.gov; Holt, James D. (CDC/OCOO/OGC); Gee, Jay (CDC/OID/NCEZID); Holmes, Harvey T. (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Delaney, Lisa (CDC/NIOSH/OD); Glass Elrod, Mindy (CDC/OID/NCEZID); Bower, William (CDC/OID/NCEZID); Martin.John@epa.gov; Isaac, Freeda (CDC aphis.usda.gov); Divan, Charles (CDC aphis.usda.gov); Redd, Stephen (CDC/OPHPR/OD); Bruner, Maria P. (CDC/OPHPR/DSAT) (CTR)
Subject: Re: Burkholderia response update call

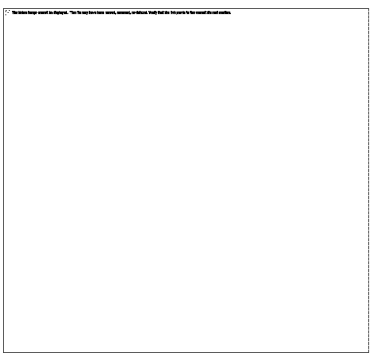
Dear Dr. Weyant,

Thank you for setting up this call.

I would like to suggest that someone from CDC take summary minutes with any agreed upon action items for distribution after the call. This will help us all remain coordinated. In addition, since this is likely to be an ongoing issue it would probably be worth setting up a recurring call to get on peoples calendars. The calls could always be canceled if not needed. Lastly, I anticipate that a number of people may join the call late or leave early depending on their availability.

Best regards

Andrew Lackner
****
Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu



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CONFIDENTIALITY NOTICE

This communication and any attachments may contain confidential and privileged information for the use of the designated recipient/s named above. Distribution, reproduction or any other use of this transmission by any party other than the intended recipient(s) is prohibited.

On Jan 27, 2015, at 4:54 PM, Weyant, Rob (CDC/OPHPR/DSAT) <rsw2@cdc.gov> wrote:

Good evening,

On behalf of the CDC/OPHPR Division of Select Agents and Toxins I would like to thank you all for the support and assistance that you provided to the CDC/USDA team during their site visit to the Tulane facility last week. Given the complexity of this incident, I believe that it would be good for us to touch base to make sure that the various response efforts are optimally coordinated.

I would like to invite you to join in a conference call tomorrow afternoon at 4:30pm Eastern Standard Time to discuss the various components of the response. Call in information is as follows:

Phone number: 866-692-3158
Pass code: 97188913

The agenda will cover:

- Serologic survey of animals in the colony
- Occupational health issues for workers
- Environmental sampling (yes/no and if yes, by what protocol)
- Environmental remediation
- Data organization and sharing
- Overall management of the response
- Other

Let me know if you have any other issues you'd like to discuss.

Many thanks,

Rob Weyant

Robbin S. Weyant, PhD, RBP(ABSA)
Captain, USPHS (Ret.)
Director, Division of Select Agents and Toxins
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
Office phone: 404-718-2001
Cell phone: 678-614-7284
SiprNet: Robbin.Weyant@dia.smil.mil
DSAT Vision: To be the preeminent resource for the safety and security of biological agents and toxins.

This document is intended for the exclusive use of the recipient(s) named above. It may contain sensitive information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient(s), any dissemination,

distribution, or copying is strictly prohibited. If you think you have received this document in error, please notify the sender immediately and destroy the original. Thank you.

Message

From: Martin, John [martin.john@epa.gov]
Sent: 2/4/2015 4:31:51 PM
To: Canzler, Erica [Canzler.Erica@epa.gov]; Nalipinski, Mike [Nalipinski.Mike@epa.gov]; Petersen, Chris [petersen.chris@epa.gov]; Crossland, Ronnie [Crossland.Ronnie@epa.gov]; Hubbard, Joseph [Hubbard.Joseph@epa.gov]
Subject: FW: Message Sent to our Community Neighbors

Fyi. This event seems. To be expanding. Uc needs to develop their message yesterday.
St Tammany is the pio at this but he was to form a JIC.
Sent from my Windows Phone

From: Alise, Mark A
Sent: 2/4/2015 9:53 AM
To: Martin, John
Subject: Re: Message Sent to our Community Neighbors

John,

There were actually two messages, the one I copied in my previous email and an earlier one. I have copied them both again here with the original dates sent in red.

On Jan 17, 2015 message

Dear members of the TNPRC Community Advisory Board

I write to make you aware of a recent situation at the TNPRC .

As you know we have a large number of animals at the TNPRC, most of which are outdoors in the breeding colony. Animals in this colony, as in the human population, get ill. Our animal health program identifies these animals, which are brought to our veterinary hospital for diagnosis and treatment.

In November two animals presented to the clinic with nonspecific clinical signs. After extensive clinical workups, including exploratory surgeries and bacterial cultures and assistance from the Centers of Disease Control (CDC), we determined that the animals were infected with the bacteria *Burkholderia pseudomallei* (the cause of melioidosis). One animal was euthanized on November 26 and the remaining animal has recovered. No additional cases have been recognized.

Risk of the bacteria becoming a threat to people or animals is negligible. Transmission of the bacteria generally occurs through contact with contaminated soil. Animal to human transmission of this bacteria is not known to occur and person-to-person transmission is extremely rare. No people have been infected and any TNPRC employee who was possibly exposed is being monitored.

TNPRC personnel contacted the CDC in accordance with federal research protocols. CDC officials are expected at the TNPRC next week and will join scientists at the TNPRC to continue ongoing collaborative efforts to identify the source of the infection in the macaques.

I would be happy to talk with you individually or as a group to discuss further. Regardless, as more information becomes available, we will provide updates.

best regards

January 26 message:

Dear members of the TNPRC Community Advisory Board

I write to update you on a recent situation at the TNPRC.

As I indicated in my prior message, we identified two animals from our breeding colony infected with the bacteria *Burkholderia pseudomallei* (the cause of melioidosis) in November. I also mentioned that CDC was going to visit to help identify the source of infection in the macaques.

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I would be happy to talk with you individually or as a group to discuss this further. Also, as more information becomes available, we will provide updates.

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

From: <Martin>, John <martin.john@epa.gov>
Date: Tuesday, February 3, 2015 at 8:00 PM
To: Mark Alise <malise@tulane.edu>
Subject: RE: Message Sent to our Community Neighbors

Received. Thank you.

Sent from my Windows Phone

From: Alise, Mark A
Sent: 2/3/2015 5:07 PM
To: Martin, John
Subject: Message Sent to our Community Neighbors

John

Below is a copy of the message that we sent to our Community Advisory Board (a board of our neighbors in the business, education, local government, and residential community). We duplicated this message and also sent it to the homeowners associations of the two adjoining residential developments (Estates of Northpark and Versailles) as well as the headmaster at the adjoining school (Northlake Christian School):

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best regards

Andrew
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Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433

We have not provided further updates beyond this message which was sent to the various recipients between Jan 17-20, 2015.

Let me know if you have any questions,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

TULANE NATIONAL PRIMATE
RESEARCH CENTER

Message

From: Martin, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F9B5EF37318D4B0B9BBBCDAE012EA970-MARTIN, JOHN]
Sent: 3/30/2015 8:01:28 PM
To: Ojeda, Jose [Jose.Ojeda@WestonSolutions.com]
Subject: FW: Soil and water samples negative
Attachments: FIGURE 1 - SAMPLE LOCATION MAP.PDF; Sample Locations.xls.pdf; Tulane University ER QASP - v2.pdf

---

From: Deitchman, Scott (CDC/ONDIEH/NCEH) [mailto:sed2@cdc.gov]
Sent: Friday, February 20, 2015 2:56 PM
To: Kevin Davis (Kevin.Davis@LA.GOV); daccardo@stpgov.org; dsibley@tulane.edu; bohm@tulane.edu; Jimmy Guidry (DHH); jmlacour@wlf.la.gov; Jeff Dauzat (Jeff.Dauzat@LA.GOV); Brent Robbins (brobbins@ldaf.state.la.us) (brobbins@ldaf.state.la.us); Collins Simoneaux (Collins.Simoneaux@LA.GOV); Raoult Ratard <Raoult.Ratard@LA.GOV> (Raoult.Ratard@LA.GOV); dstacy@ldaf.la.gov; Isaac, Freeda (CDC aphis.usda.gov); Katie.Portacci@aphis.usda.gov; Martin, John; Canzler, Erica; Nalipinski, Mike
Subject: Soil and water samples negative

This afternoon the CDC laboratory informed us that they were able to complete the analysis of all soil and water samples. **All samples were negative for *Burkholderia pseudomallei*.**

The laboratory performed two tests: polymerized chain reaction (PCR) which looks for the organism, whether dead or alive, by detecting its genetic material (DNA); and culturing, which should grow any live organisms. All samples were negative by both tests.

The samples included: 42 soil samples; 15 water samples; and 12 swab samples. Attached are the sample location information and sampling plan that was provided by EPA.

Please share as appropriate within your organizations.

Regards,
Scott

RADM Scott Deitchman, MD MPH, USPHS
Assistant Surgeon General
Associate Director for Environmental Health Emergencies
National Center for Environmental Health and
Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention
Atlanta GA USA

Message

From: Martin, John [martin.john@epa.gov]
Sent: 3/30/2015 7:16:47 PM
To: Smith, Monica [smith.monica@epa.gov]; Rhotenberry, William [Rhotenberry.William@epa.gov]
Subject: FW: Soil remediation options TNPRC Conf call Tues 3/31 0900 eastern

Importance: High

Sent from my Windows Phone

From: Nalipinski, Mike
Sent: 3/30/2015 12:39 PM
To: Alise, Mark A
Cc: Ryan, Shawn; Martin, John; Lackner, Andrew A; Bohm, Rudolf P; Blanchard, James L
Subject: RE: Soil remediation options TNPRC Conf call Tues 3/31 0900 eastern

Mark –

Please call in tomorrow at 866-299-3188 pass code 617 918 1228 at 0900 hrs eastern time to discuss decontamination options for the TNPRC field cages. The objective of the meeting will be to discuss various possible technologies and ideally agree on an acceptable technical approach. The next step would be for the TNPRC to prepare a proposal (based on our conversation) that would be submitted to the Unified Command for their review and approval.

Talk to you tomorrow.

Michael Nalipinski, Associate Director
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Monday, March 30, 2015 1:30 PM
To: Nalipinski, Mike
Cc: Ryan, Shawn; Martin, John; Lackner, Andrew A; Bohm, Rudolf P; Blanchard, James L
Subject: Re: Soil remediation options TNPRC Conf call
Importance: High

Mike,

Thanks for you call. Can we set up the conference call for 8:00 am CDT, 9:00 am EDT tomorrow March 31?

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433

985-871-6200

From: <Alise>, Mark Alise <malise@tulane.edu>
Date: Monday, March 30, 2015 at 10:27 AM
To: "Nalipinski, Mike" <Nalipinski.Mike@epa.gov>
Cc: "Ryan, Shawn" <Ryan.Shawn@epa.gov>, "Martin, John" <martin.john@epa.gov>, Andrew Lackner <alackner@tulane.edu>, Rudolf Bohm <bohm@tulane.edu>
Subject: Re: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time

Subsequent to the Unified Command meeting this morning, when can we re-schedule this call?

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

From: <Nalipinski>, Mike <Nalipinski.Mike@epa.gov>
Date: Tuesday, March 17, 2015 at 3:23 PM
To: Mark Alise <malise@tulane.edu>
Cc: "Ryan, Shawn" <Ryan.Shawn@epa.gov>, "Martin, John" <martin.john@epa.gov>
Subject: RE: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time

Mark --

Thanks for accommodating a call tomorrow at 1500 hrs Eastern Standard Time. We can use the following call in number:

877-299-3188 pass code 202 564 2359

Note that I've invited OSC John Martin Region 6 and Dr. Shawn Ryan NHSRC to the call. As you know John is the EPA lead out of Dallas and Shawn is the Director of EPA's Office of Research and Development National Homeland Security Research Center. Shawn's group has conducted extensive laboratory and field studies on different decontamination technologies.

The goal of tomorrow's meeting is to hopefully down select one or two technologies that the group could support and that would merit more detailed evaluation/consideration. In my previous e-mails EPA has offered several options and those, or if you have other alternatives, could be a framework for our conversation.

Have a good evening and looking forward to a productive discussion tomorrow.

Cheers,

V/R

Michael Nalipinski
CBRN Consequence Management and Advisory Division (CMAD)

U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Tuesday, March 17, 2015 3:07 PM
To: Nalipinski, Mike
Cc: Lackner, Andrew A; Blanchard, James L
Subject: FW: Soil remediation options TNPRC

Mike,

Thanks for the information. I would like Dr. Lackner to join in our conversation tomorrow afternoon and I am copying him on this response.

We can talk at 2:00 pm CDT, 3:00 pm EDT if that works for you. If not we can work around other afternoon times.

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

From: <Nalipinski>, Mike <Nalipinski.Mike@epa.gov>
Date: Tuesday, March 17, 2015 at 1:34 PM
To: Mark Alise <malise@tulane.edu>
Cc: "Martin, John" <martin.john@epa.gov>, "Ryan, Shawn" <Ryan.Shawn@epa.gov>, "Petersen, Chris" <petersen.chris@epa.gov>, "Smith, Monica" <smith.monica@epa.gov>
Subject: FW: Soil remediation options TNPRC

Mark - Below and attached are some insights relative to technologies that could be considered for addressing the two field cages at the TNPRC. This input was received from the EPA's Office of Research and Development National

Homeland Security Research Center (NHSRC). As background, NHSRC has conducted several studies to evaluate the efficacy of methyl bromide (MeBr) as a decontamination technology for bacillus anthraces (Ba). Using surrogates for Ba, namely BtK and Bg, MeBr has been proven effective. As you know MeBr has also been deployed in agricultural settings. MeBr could be broadcasted as a liquid during the tilling process and/or could also be applied as a liquid to the field cage that has a gravel base.

We have the most confidence in MeBr fumigation of the soilas it has proven effective in prior lab studies. Aside from the use of MeBr, we suggest looking at:

(1) Data supporting CaO; we are trying to get access to the reference with the lab study data. The abstract suggests inhibition up to 6 weeks when applied at 40% or more (wt/wt). Not sure if this "inhibition" means that additional or continued treatment is necessary for subsequent inhibition. We will look into it more when we get access to the paper. Any additional information that you are provided via Tulane may be helpful.
(2) Sodium persulfate (Klozur FMC) was shown in our laboratory studies to be an effective biological agent decontaminant in soil. We anticipate that it would be effective. It is typically injected in soil for treatment of organic contaminants. EPA has experience with it for Superfund Siteschlorinated solvents. Above are two attachments with some information. More info can be found at: http://www.peroxychem.com/chemistries/persulfates/products/klozur-persulfate/technical-documentation
(3) Metam sodium has also been shown to be an effective soil decontaminant for biological agents. There is considerable experience with it as it is one of the most widely used soil pesticides in the U.S. It would require longer aeration time (up to a month) and has the potential to produce toxic by-products in contact with water; so care would be necessary to reduce potential for exposure of people or animals. Also, there would need to be the discussion regarding suitable application for the soil type at the facility. There is a till-in application.

I hope the above information will be thought provoking and can guide our conversations as we continue to evaluate options to decontaminate the field cages. Please let me know if you would be available tomorrow March 18th to continue our discussion. I am available any time after noon eastern standard time.

Cheers,

V/R

Michael Nalipinski, Associate Director
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

Message

From: Martin, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F9B5EF37318D4B0B9BBBCDAE012EA970-MARTIN, JOHN]
Sent: 3/26/2015 8:56:55 PM
To: Smith, Monica [smith.monica@epa.gov]
Subject: FW: Message Sent to our Community Neighbors
Attachments: 39980F81-6868-4F65-89A1-CEE04773E6E1[18].png

John J. Martin
Federal On-Scene Coordinator (OSC)
1445 Ross Ave (6SF-PE)
Dallas, Texas 75202

214.665.6748 * *fax 214.665.2278*

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Wednesday, February 04, 2015 9:53 AM
To: Martin, John
Subject: Re: Message Sent to our Community Neighbors

John,

There were actually two messages, the one I copied in my previous email and an earlier one. I have copied them both again here with the original dates sent in red.

On Jan 17, 2015 message

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employee who was possibly exposed is being monitored.

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I would be happy to talk with you individually or as a group to discuss further. Regardless, as more information becomes available, we will provide updates.

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January 26 message:

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During the visit, the CDC indicated that the risk of human *Burkholderia pseudomallei* infection occurring as a result of these circumstances is "infinitesimal". However, we continue to actively monitor the situation, and, out of an abundance of caution, have implemented some enhancements to our procedures.

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Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

From: <Martin>, John <martin.john@epa.gov>
Date: Tuesday, February 3, 2015 at 8:00 PM
To: Mark Alise <malise@tulane.edu>
Subject: RE: Message Sent to our Community Neighbors

Received. Thank you.

Sent from my Windows Phone

From: Alise, Mark A
Sent: 2/3/2015 5:07 PM
To: Martin, John
Subject: Message Sent to our Community Neighbors

John

Below is a copy of the message that we sent to our Community Advisory Board (a board of our neighbors in the business, education, local government, and residential community). We duplicated this message and also sent it to the homeowners associations of the two adjoining residential developments (Estates of Northpark and Versailles) as well as the headmaster at the adjoining school (Northlake Christian School):

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Andrew
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Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433

We have not provided further updates beyond this message which was sent to the various recipients between Jan 17-20, 2015.

Let me know if you have any questions,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

TULANE NATIONAL PRIMATE
RESEARCH CENTER

Message

From: Martin, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F9B5EF37318D4B0B9BBBCDAE012EA970-MARTIN, JOHN]
Sent: 3/24/2015 12:46:12 PM
To: Nalipinski, Mike [Nalipinski.Mike@epa.gov]
Subject: RE: Bp Remediation- Quick lime Ref #8 Tulane response

That's interesting and important thing for someone to know, Mr "not working on Tulane" Mike.

John J. Martin
Federal On-Scene Coordinator (OSC)
1445 Ross Ave (6SF-PE)
Dallas, Texas 75202

214.665.6748 * *fax 214.665.2278*

From: Nalipinski, Mike
Sent: Tuesday, March 24, 2015 7:19 AM
To: Martin, John
Subject: FW: Bp Remediation- Quick lime Ref #8 Tulane response

John (not working on TNPRC) Martin:

See below for your reference. Looks like quick lime is only a temporary solution.....

Michael Nalipinski
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Ryan, Shawn
Sent: Tuesday, March 24, 2015 8:07 AM
To: Nalipinski, Mike
Cc: Calfee, Worth; Wood, Joe
Subject: RE: Bp Remediation- Quick lime Ref #8 Tulane response

Mike,

Here's the supporting study re: quicklime. It suggests quicklime as a temporary inhibitor at very high wt/wt % concentrations of CaO tilled into the soil (not sprayed on). It suggests that when soil conditions are again right for propagation, that propagation may occur – i.e., suggesting repeated treatment necessary to control Bp propagation in the soil.

Shawn

Shawn P. Ryan, Ph.D.
Division Director
Decontamination and Consequence Management Division
National Homeland Security Research Center
U.S. Environmental Protection Agency (MD-E343-06)
Office of Research and Development
109 T.W. Alexander Dr., Research Triangle Park, NC 27711
Phone 919-541-0699 Fax 919-541-0496

http://www.epa.gov/nhsrc

From: Nalipinski, Mike
Sent: Tuesday, March 17, 2015 10:07 AM
To: Ryan, Shawn
Subject: FW: Bp Remediation- Quick lime Ref #8 Tulane response

Michael Nalipinski
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Lackner, Andrew A [mailto:alackner@tulane.edu]
Sent: Tuesday, March 17, 2015 10:05 AM
To: Alise, Mark A; Nalipinski, Mike
Subject: Re: Bp Remediation- Quick lime Ref #8

OK. I see that in the reference.

In the paper I sent yesterday however they note that the soil was negative one year after treatment. Here is the text

The soil samples from the three sites at 5, 15, and 30-cm depth were investigated by culture again once after 12 mo of soil treatment, and these culture results were all negative.

I would also point out that is in the context of what must have been overwhelming contamination in that they did three soil samples at three depths and each soil sample was positive at least at one depth. In our case we have no evidence that the organism is even present.

best regards

Andrew
****

Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu
****

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On Mar 17, 2015, at 6:41 AM, Alise, Mark A <malise@tulane.edu> wrote:

Not so good news on the quicklime. But they are trying to work with us and look into other agents.

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

Begin forwarded message:

From: "Nalipinski, Mike" <Nalipinski.Mike@epa.gov>
Date: March 17, 2015 at 6:38:27 AM CDT
To: "Alise, Mark A" <malise@tulane.edu>
Subject: FW: Bp Remediation- Quick lime Ref #8

Mark –

See below. The way I/we read the abstract it looks like lime may only be a temporary remedy. If we locate the whole paper I'll send that along. We are also looking at other materials that could be tilled into the soil like persulfate. More to come....

Michael Nalipinski
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Ryan, Shawn
Sent: Tuesday, March 17, 2015 7:34 AM
To: Nalipinski, Mike
Subject: RE: Bp Remediation- Quick lime Option

Trans R Soc Trop Med Hyg. 2004 Jun;98(6):337-41.

The effect of quicklime (calcium oxide) as an inhibitor of Burkholderia pseudomallei.

Na-ngam N[1], Angkititakul S, Noimay P, Thamlikitkul V.
Author information

- [1]Department of Veterinary Public Health, Faculty of Veterinary Medicine, Khon Kaen University, Khon Kaen 40002, Thailand.

Abstract

Measurement of in vitro activity of quicklime against Burkholderia pseudomallei revealed that quicklime at concentrations of 10% or more was bactericidal for up to 35 d. The effect of quicklime as an inhibitor of B. pseudomallei in soil from a rice field was studied in a laboratory setting. The soil, collected from a rice field in north-eastern Thailand, was mixed with B. pseudomallei. In experiment 1, quicklime was mixed with the soil in different amounts. In experiment 2, quicklime was spread over the soil surface. In experiment 3, quicklime solution was poured onto the soil. It was found that the pH of the soil in experiment 1 was much higher than that in experiments 2 and 3. Only quicklime mixed with soil at a concentration of 40% or more (weight/weight) was effective in inhibiting the growth of B. pseudomallei for up to six weeks.

Shawn

Shawn P. Ryan, Ph.D.
Division Director
Decontamination and Consequence Management Division
National Homeland Security Research Center
U.S. Environmental Protection Agency (MD-E343-06)
Office of Research and Development
109 T.W. Alexander Dr., Research Triangle Park, NC 27711
Phone 919-541-0699 Fax 919-541-0496

http://www.epa.gov/nhsrc

From: Nalipinski, Mike
Sent: Tuesday, March 17, 2015 7:21 AM
To: Alise, Mark A
Cc: Martin, John; Ryan, Shawn
Subject: RE: Bp Remediation- Quick lime Option

Mark –
Thanks for the article regarding the application of quick lime to remediate Bp in soil at a zoo in northeastern Thailand. Do you have access to reference #8 that indicates bench scale tests were conducted evaluating the parameters that impact the effectiveness of the quick lime treatment? That would be informative to guide evaluation of the quick lime option for the Tulane case.

I am available anytime before noon (eastern) Wednesday March 18th to continue our conversation regarding technology options. Please advise what time is convenient for you.

Cheers,

V/R

Michael Nalipinski, Associate Director
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Monday, March 16, 2015 4:32 PM
To: Nalipinski, Mike
Cc: Lackner, Andrew A
Subject: Bp Remediation

Mike,

Here is the article Dr. Lackner referred to.

Please let me know a good time for Wednesday contact.

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

<image001.png>

Message

From: Martin, John [martin.john@epa.gov]
Sent: 3/18/2015 5:53:11 PM
To: Nalipinski, Mike [Nalipinski.Mike@epa.gov]
Subject: RE: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time

Odd I see my name in Chris' email but I did receive that email. Thanks for forwarding. Apologies. I thought we could respond with clarify our assistance / support role (no leadership) but higher decision makers are involved. Thanks again. CMAT did a great job.

PS may change again

Sent from my Windows Phone

From: Nalipinski, Mike
Sent: 3/18/2015 12:39 PM
To: Martin, John
Subject: FW: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time

Michael Nalipinski
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Petersen, Chris
Sent: Wednesday, March 18, 2015 1:33 PM
To: Martin, John; Nalipinski, Mike; Ryan, Shawn; malise@tulane.edu
Cc: Smith, Monica; Crossland, Ronnie
Subject: FW: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time
Importance: High

John, Mike, Shawn and Mike – Due to circumstances beyond our control, the call scheduled for today will need to be postponed indefinitely. I apologize for this late notice and for any difficulties this may create. Thanks

J. Chris Petersen
Deputy Associate Director
Response and Prevention Branch
US EPA Region 6
1445 Ross Ave, Ste. 1200
Dallas, TX 75202
214-665-3167 office
214-665-7447 fax
214-789-2535 cell

From: Martin, John
Sent: Tuesday, March 17, 2015 4:25 PM
To: Smith, Monica; Petersen, Chris
Subject: FW: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time
Importance: High

They're close

John J. Martin
Federal On-Scene Coordinator (OSC)
1445 Ross Ave (6SF-PE)
Dallas, Texas 75202

214.665.6748 * *fax 214.665.2278*

From: Nalipinski, Mike
Sent: Tuesday, March 17, 2015 3:24 PM
To: Alise, Mark A
Cc: Ryan, Shawn; Martin, John
Subject: RE: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time
Importance: High

Mark –

Thanks for accommodating a call tomorrow at 1500 hrs Eastern Standard Time. We can use the following call in number:

877-299-3188 pass code 202 564 2359

Note that I've invited OSC John Martin Region 6 and Dr. Shawn Ryan NHSRC to the call. As you know John is the EPA lead out of Dallas and Shawn is the Director of EPA's Office of Research and Development National Homeland Security Research Center. Shawn's group has conducted extensive laboratory and field studies on different decontamination technologies.

The goal of tomorrow's meeting is to hopefully down select one or two technologies that the group could support and that would merit more detailed evaluation/consideration. In my previous e-mails EPA has offered several options and those, or if you have other alternatives, could be a framework for our conversation.

Have a good evening and looking forward to a productive discussion tomorrow.

Cheers,

V/R

Michael Nalipinski
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Tuesday, March 17, 2015 3:07 PM
To: Nalipinski, Mike
Cc: Lackner, Andrew A; Blanchard, James L
Subject: FW: Soil remediation options TNPRC

Mike,

Thanks for the information. I would like Dr. Lackner to join in our conversation tomorrow afternoon and I am copying him on this response.

We can talk at 2:00 pm CDT, 3:00 pm EDT if that works for you. If not we can work around other afternoon times.

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

From: <Nalipinski>, Mike <Nalipinski.Mike@epa.gov>
Date: Tuesday, March 17, 2015 at 1:34 PM
To: Mark Alise <malise@tulane.edu>
Cc: "Martin, John" <martin.john@epa.gov>, "Ryan, Shawn" <Ryan.Shawn@epa.gov>, "Petersen, Chris" <petersen.chris@epa.gov>, "Smith, Monica" <smith.monica@epa.gov>
Subject: FW: Soil remediation options TNPRC

Mark - Below and attached are some insights relative to technologies that could be considered for addressing the two field cages at the TNPRC. This input was received from the EPA's Office of Research and Development National

Homeland Security Research Center (NHSRC). As background, NHSRC has conducted several studies to evaluate the efficacy of methyl bromide (MeBr) as a decontamination technology for bacillus anthraces (Ba). Using surrogates for Ba, namely BtK and Bg, MeBr has been proven effective. As you know MeBr has also been deployed in agricultural settings. MeBr could be broadcasted as a liquid during the tilling process and/or could also be applied as a liquid to the field cage that has a gravel base.

We have the most confidence in MeBr fumigation of the soilas it has proven effective in prior lab studies. Aside from the use of MeBr, we suggest looking at:

(1) Data supporting CaO; we are trying to get access to the reference with the lab study data. The abstract suggests inhibition up to 6 weeks when applied at 40% or more (wt/wt). Not sure if this "inhibition" means that additional or continued treatment is necessary for subsequent inhibition. We will look into it more when we get access to the paper. Any additional information that you are provided via Tulane may be helpful.
(2) Sodium persulfate (Klozur FMC) was shown in our laboratory studies to be an effective biological agent decontaminant in soil. We anticipate that it would be effective. It is typically injected in soil for treatment of organic contaminants. EPA has experience with it for Superfund Siteschlorinated solvents. Above are two attachments with some information. More info can be found at: http://www.peroxychem.com/chemistries/persulfates/products/klozur-persulfate/technical-documentation
(3) Metam sodium has also been shown to be an effective soil decontaminant for biological agents. There is considerable experience with it as it is one of the most widely used soil pesticides in the U.S. It would require longer aeration time (up to a month) and has the potential to produce toxic by-products in contact with water; so care would be necessary to reduce potential for exposure of people or animals. Also, there would need to be the discussion regarding suitable application for the soil type at the facility. There is a till-in application.

I hope the above information will be thought provoking and can guide our conversations as we continue to evaluate options to decontaminate the field cages. Please let me know if you would be available tomorrow March 18th to continue our discussion. I am available any time after noon eastern standard time.

Cheers,

V/R

Michael Nalipinski, Associate Director
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

Message

From: Martin, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F9B5EF37318D4B0B9BBBCDAE012EA970-MARTIN, JOHN]
Sent: 3/17/2015 9:24:32 PM
To: Smith, Monica [smith.monica@epa.gov]; Petersen, Chris [petersen.chris@epa.gov]
Subject: FW: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time

Importance: High

They're close

John J. Martin
Federal On-Scene Coordinator (OSC)
1445 Ross Ave (6SF-PE)
Dallas, Texas 75202

214.665.6748 * *fax 214.665.2278*

From: Nalipinski, Mike
Sent: Tuesday, March 17, 2015 3:24 PM
To: Alise, Mark A
Cc: Ryan, Shawn; Martin, John
Subject: RE: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time
Importance: High

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Have a good evening and looking forward to a productive discussion tomorrow.

Cheers,

V/R

Michael Nalipinski
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Tuesday, March 17, 2015 3:07 PM
To: Nalipinski, Mike
Cc: Lackner, Andrew A; Blanchard, James L
Subject: FW: Soil remediation options TNPRC

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Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

From: <Nalipinski>, Mike <Nalipinski.Mike@epa.gov>
Date: Tuesday, March 17, 2015 at 1:34 PM
To: Mark Alise <malise@tulane.edu>
Cc: "Martin, John" <martin.john@epa.gov>, "Ryan, Shawn" <Ryan.Shawn@epa.gov>, "Petersen, Chris" <petersen.chris@epa.gov>, "Smith, Monica" <smith.monica@epa.gov>
Subject: FW: Soil remediation options TNPRC

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Cheers,

V/R

Michael Nalipinski, Associate Director
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

Message

From: Lackner, Andrew A [alackner@tulane.edu]
Sent: 10/15/2015 5:58:12 PM
To: Collins Simoneaux [Collins.Simoneaux@LA.GOV]
CC: Scott Deitchman [sed2@cdc.gov]; Rosanne Prats [Rosanne.Prats@la.gov]; freeda.e.isaac@aphis.usda.gov; katie.portacci@aphis.usda.gov; kenneth.l.angel@aphis.usda.gov; brobbins@ldaf.la.gov; Martin, John [martin.john@epa.gov]; Mike Algero [Mike.Algero@LA.GOV]; Jim LaCour [JLaCour@wlf.la.gov]; Logan, Michael J - APHIS [Michael.J.Logan@aphis.usda.gov]; DSosin@cdc.gov; tpracheil@tulane.edu; pjreeb@stpgov.org; Clarence Powe [cpowe@stpgov.org]; Kevin Davis [Kevin.Davis@LA.GOV]; Dexter Accardo [daccardo@stpgov.org]; Jimmy Guidry (DHH) [Jimmy.Guidry2@LA.GOV]; Christopher Guilbeaux [Christopher.Guilbeaux@LA.GOV]; Mike Steele [Mike.Steele@LA.GOV]; Jason Lachney [Jason.Lachney@LA.GOV]; Melton Gaspard [Melton.Gaspard@LA.GOV]
Subject: Re: TNPRC Updates

Update from the TNPRC:

Since the last report 271 animals were screened by MRLAT assay and 10 that were non-negative have been sent to CDC for confirmatory testing by IHA. The results will be reported by CDC. A total of 2,895 unique animals have had their serum screened by IHA and/or MRLAT. This represents approximately 79.51% of the non-experimental colony.
****

Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu
****

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On Oct 15, 2015, at 9:23 AM, Collins Simoneaux <Collins.Simoneaux@LA.GOV> wrote:

Please send any updates for tomorrow's bi-weekly TNPRC Sitrep to the following list serve email address by 4:30pm CDT today: GOHSEP-EING3@LISTSERV.DOA.LA.GOV

Going forward, all sitrep updates should be sent to this email address.

Thanks,
Collins

Collins R. Simoneaux
Region 9 Coordinator
Governor's Office of Homeland Security
and Emergency Preparedness

225-925-7500 GOHSEP Office
225-329-4261 Cell Phone
collins.simoneaux@la.gov
www.getagameplan.org
www.gohsep.la.gov

Appointment

From: Natarajan, Nitin [Natarajan.Nitin@epa.gov]
Sent: 4/13/2015 2:20:06 PM
To: Natarajan, Nitin [Natarajan.Nitin@epa.gov]; Martin, John [martin.john@epa.gov]; Rhotenberry, William [Rhotenberry.William@epa.gov]; Crossland, Ronnie [Crossland.Ronnie@epa.gov]; Petersen, Chris [petersen.chris@epa.gov]; Smith, Monica [smith.monica@epa.gov]; Cheatham, Reggie [cheatham.reggie@epa.gov]; Tulis, Dana [Tulis.Dana@epa.gov]; 'dms8@cdc.gov' [dms8@cdc.gov]
CC: Edlund, Carl [edlund.carl@epa.gov]

Subject: FW: CALL - Tulane Panel - call in number 866-299-3188 code 202-566-0184
Location: CALL IN NUMBER - 866-299-3188 CODE 202-566-0184

Start: 4/13/2015 3:00:00 PM
End: 4/13/2015 3:30:00 PM
Show Time As: Busy

John – per Ronnie you should plan on listening in to the call. We will let Carl know you are on the call.

Bill - per Ronnie, please come up to Carl's conference room to sit in on the call with us. Monica

-----Original Appointment-----
From: Natarajan, Nitin
Sent: Thursday, April 09, 2015 2:05 PM
To: Natarajan, Nitin; Crossland, Ronnie; Petersen, Chris; Smith, Monica; Cheatham, Reggie; Tulis, Dana; 'dms8@cdc.gov'
Cc: Edlund, Carl
Subject: CALL - Tulane Panel - call in number 866-299-3188 code 202-566-0184
When: Monday, April 13, 2015 11:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: CALL IN NUMBER - 866-299-3188 CODE 202-566-0184

POC: Caroline Kenely – 202-566-2235 (scheduler)

From: Natarajan, Nitin
Sent: Wednesday, April 08, 2015 3:04 PM
To: Sosin, Dan (CDC/OPHPR/OD)
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH); Kenely, Caroline; Brooks, Becky
Subject: RE: information

I'm traveling tomorrow so was hoping for Friday. Maybe we can do Mon or Tuesday.

I've cc'd Caroline who can help with scheduling on our side.

Caroline - it'll be me, Reggie or Dana and Erica from HQ and Carl eglund and Ronnie crossland from R6.

Thanks all.

N

Nitin Natarajan
Deputy Assistant Administrator
Office of Solid Waste and Emergency Response
Environmental Protection Agency
202-566-0200 Office

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: 4/8/2015 14:55
To: Natarajan, Nitin
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: RE: information

I don't have anything on my calendar Nitin. Do you still have a desire for a call this week? I am out on Friday, so need to schedule tomorrow. Scott and I would try to both be on the call.

Thank you.

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Natarajan, Nitin [mailto:Natarajan.Nitin@epa.gov]
Sent: Tuesday, April 07, 2015 12:55 PM
To: Sosin, Dan (CDC/OPHPR/OD)
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: RE: information

I've chatted with our folks and we think we can get there from here. Can we setup a call this week with our folks to discuss?

N

Nitin Natarajan
Deputy Assistant Administrator
Office of Solid Waste and Emergency Response
Environmental Protection Agency
202-566-0200 Office

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: 4/7/2015 12:50
To: Natarajan, Nitin
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: FW: information

Nitin: in case you are not aware, it appears that Tulane is acting on its own to convene a panel of independent experts to weigh in on the environmental sampling needs. The deliberations of this group should be helpful for considering additional USG-sponsored deliberations on sampling for biological threats in the environment.

It will be good to have a suitable lab or two in mind to conduct the testing should Tulane and the local authorities decide to do more testing.

Best regards,

Dan

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: Tuesday, April 07, 2015 12:47 PM
To: Helfand, Rita (CDC/OID/NCEZID); Deitchman, Scott (CDC/ONDIEH/NCEH); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: RE: information

Thank you Rita ... based on where we are in this response and our position on environmental testing, it seems best to be responsive to this panel's information requests regarding how we tested samples (as you are), and be particularly careful not to offer a contrary position to the EPA sampling methods as provided initially on request of the state.

It may be helpful to the community members to have an independent panel offer advice on further sampling at this point as long as Tulane is prepared to act on the input. The results of this panel should be informative of the need to further USG planning work for future events as well.

Dan

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Helfand, Rita (CDC/OID/NCEZID)
Sent: Tuesday, April 07, 2015 12:38 PM
To: Deitchman, Scott (CDC/ONDIEH/NCEH); Sosin, Dan (CDC/OPHPR/OD); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: FW: information

Fyi too

From: Hoffmaster, Alex (CDC/OID/NCEZID)
Sent: Tuesday, April 07, 2015 6:51 AM
To: Gee, Jay (CDC/OID/NCEZID); Glass Elrod, Mindy (CDC/OID/NCEZID); Blaney, David (CDC/OID/NCEZID); Nolen, Leisha (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID)
Cc: Belay, Ermias (CDC/OID/NCEZID); Helfand, Rita (CDC/OID/NCEZID); Damon, Inger K. (CDC/OID/NCEZID)
Subject: FW: information

See below regarding Tulane panel. Henry, Dave and I were just talking about this yesterday.

Mindy – well just send the consensus document along with any modifications done short description of how water was processed.
Alex

From: Lackner, Andrew A [mailto:alackner@tulane.edu]
Sent: Tuesday, April 07, 2015 6:17 AM
To: Hoffmaster, Alex (CDC/OID/NCEZID); Gee, Jay (CDC/OID/NCEZID)
Cc: Bohm, Rudolf P; Sibley, Don A
Subject: information

Alex,

As part of our response to the Burkholderia pseudomallei incident at Tulane an expert panel has been put together to help us work through the various issues that this has brought up. Among the members are David Wagner, Paul Keim and David Dance. Among the issues to consider is additional environmental testing. A question that came up in the discussion involved the methods used for environmental analyses to be sure that any future testing, if done, would be comparable with prior work. Thus, I would appreciate it if you could share details of how the analyses were performed.

best regards

Andrew
****
Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu
****

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Message

From: Gray, David [gray.david@epa.gov]
Sent: 2/26/2015 2:00:47 PM
To: Mike Steele [Mike.Steele@LA.GOV]
CC: Petersen, Chris [petersen.chris@epa.gov]; Deitchman, Scott (CDC/ONDIEH/NCEH) [sed2@cdc.gov]; Gray, David [gray.david@epa.gov]
Subject: Unified Command REVIEW & APPROVAL
Attachments: Tulane University ER QASP - v2.pdf; FIGURE 1 - SAMPLE LOCATION MAP.PDF; Sample Locations.xls.pdf

Mike,

Scott has requested that Jimmy Guidry, Kevin Davis, Dexter Accardo weigh in on the release of this information. Scott has concurred. It will go to the USA Today reporter. Would you please forward it to them for their concurrence.

David

From: Deitchman, Scott (CDC/ONDIEH/NCEH) [mailto:sed2@cdc.gov]
Sent: Wednesday, February 25, 2015 6:01 PM
To: Gray, David; McDonald, Jason (CDC/OPHPR/OD); Reynolds, Barbara S. (CDC/OD/OADC); Burden, Bernadette (CDC/OD/OADC); Kenneth Angel; joelle.r.hayden@aphis.usda.gov; dgrant@tulane.edu; mstreck@tulane.edu; Ronnie Simpson; Olivia Watkins; Collins Simoneaux; Scheel, Christian (CDC/ONDIEH/NCEH); Mike Steele; Veronica Mosgrove; John Ford (DHH); Hubbard, Joseph; Mike Steele
Cc: Petersen, Chris
Subject: RE: USA Today Tulane request

This apparently has been moving on parallel tracks, since Chris Peterson of EPA Region 6 office also contacted me directly a short time ago. If the approval should come from Unified Command, then protocol would suggest the four representatives (Jimmy Guidry, Kevin Davis, Dexter Accardo, and I) should weigh in on the decision. In addition, Tulane should have the opportunity to review the document to see if there is any information they would regard as sensitive. My understanding is that, for security purposes, they typically do not disclose the locations of specific NHP facilities, some of which are described in the plan or identified on the aerial photograph (which otherwise, I believe, was just a Google maps satellite view).

For my part, aside from location data that Tulane might consider sensitive, I don't have concerns about releasing the information. We might also consider whether the documents in their entirety might be subject to FOIA.

Thanks,
Scott

RADM Scott Deitchman, MD MPH, USPHS
Assistant Surgeon General
Associate Director for Environmental Health Emergencies
National Center for Environmental Health and

Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention
Atlanta GA USA

From: Gray, David [mailto:gray.david@epa.gov]
Sent: Wednesday, February 25, 2015 6:50 PM
To: McDonald, Jason (CDC/OPHPR/OD); Reynolds, Barbara S. (CDC/OD/OADC); Burden, Bernadette (CDC/OD/OADC); Kenneth Angel; joelle.r.hayden@aphis.usda.gov; dgrant@tulane.edu; mstreck@tulane.edu; Ronnie Simpson; Olivia Watkins; Collins Simoneaux; Scheel, Christian (CDC/ONDIEH/NCEH); Mike Steele; Veronica Mosgrove; John Ford (DHH); Hubbard, Joseph; Mike Steele
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH); Petersen, Chris
Subject: RE: USA Today Tulane request

Thanks Jason. The best I can do is provide her with a copy of the sampling plan for the project. It needs to come from unified command – so Mike, I think that is you. But others need to be comfortable with the release of these documents.
David

From: McDonald, Jason (CDC/OPHPR/OD) [mailto:gnf0@cdc.gov]
Sent: Wednesday, February 25, 2015 3:55 PM
To: Gray, David; Reynolds, Barbara S. (CDC/OD/OADC); Burden, Bernadette (CDC/OD/OADC); Kenneth Angel; joelle.r.hayden@aphis.usda.gov; dgrant@tulane.edu; mstreck@tulane.edu; Ronnie Simpson; Olivia Watkins; Collins Simoneaux; Scheel, Christian (CDC/ONDIEH/NCEH); Mike Steele; Veronica Mosgrove; John Ford (DHH); Hubbard, Joseph; Mike Steele
Subject: RE: USA Today Tulane request

When Alison approached CDC, she requested details about the sampling; mainly, rationale for taking air samples, and where the ground and water samples were taken from. We thought EPA would be best to discuss that aspect.

CDC can let her know the results if she does not know already.

Mike or Ronnie: Will the fact that all air, water and soil samples were negative for the bacterium appear in today's release or has it been reported already?

From: Gray, David [mailto:gray.david@epa.gov]
Sent: Wednesday, February 25, 2015 4:35 PM
To: Reynolds, Barbara S. (CDC/OD/OADC); Burden, Bernadette (CDC/OD/OADC); Kenneth Angel; Gray, David; joelle.r.hayden@aphis.usda.gov; dgrant@tulane.edu; mstreck@tulane.edu; Ronnie Simpson; Olivia Watkins; Collins Simoneaux; Scheel, Christian (CDC/ONDIEH/NCEH); Mike Steele; McDonald, Jason (CDC/OPHPR/OD); Veronica Mosgrove; John Ford (DHH); Hubbard, Joseph; Mike Steele
Subject: FW: USA Today Tulane request

I don't believe that EPA should provide results to USA Today.

From: Durant, Jennah
Sent: Wednesday, February 25, 2015 3:32 PM
To: Gray, David
Cc: Hubbard, Joseph
Subject: USA Today Tulane request

Alison Young of USA Today is requesting detailed info on air, soil, and water samples from the Tulane research facility. She has been directed to EPA by CDC and USDA.

Email: ayoung@usatoday.com
Phone: 703-854-6466
Deadline: Noon Thursday

Message

From: Crossland, Ronnie [Crossland.Ronnie@epa.gov]
Sent: 2/23/2015 3:08:14 AM
To: Edlund, Carl [Edlund.Carl@epa.gov]
CC: Phillips, Pam [phillips.pam@epa.gov]; Petersen, Chris [petersen.chris@epa.gov]; Smith, Monica [smith.monica@epa.gov]
Subject: Fwd: Soil and water samples negative
Attachments: FIGURE 1 - SAMPLE LOCATION MAP.PDF; ATT00001.htm; Sample Locations.xls.pdf; ATT00002.htm; Tulane University ER QASP - v2.pdf; ATT00003.htm

Sent from my iPhone

Begin forwarded message:

> **From:** "Martin, John" <martin.john@epa.gov>
> **To:** "Petersen, Chris" <petersen.chris@epa.gov>, "Smith, Monica" <smith.monica@epa.gov>, "Rhotenberry, William" <Rhotenberry.William@epa.gov>, "McAteer, Mike" <mcateer.mike@epa.gov>, "Nalipinski, Mike" <Nalipinski.Mike@epa.gov>, "Canzler, Erica" <Canzler.Erica@epa.gov>, "Crossland, Ronnie" <Crossland.Ronnie@epa.gov>
> **Subject: FW: Soil and water samples negative**
>
> They still requesting our assistance. A letter is being /has been sent to Ron Curry. And they would CMAT to participate on the animal working group next Tuesay.
>
> Sent from my Windows Phone
>
> _____
> From: Deitchman, Scott (CDC/ONDIEH/NCEH)<mailto:sed2@cdc.gov>
> Sent: 2/20/2015 2:56 PM
> To: Kevin Davis (Kevin.Davis@LA.GOV)<mailto:Kevin.Davis@LA.GOV>; daccardo@stpgov.org<mailto:daccardo@stpgov.org>; dsibley@tulane.edu<mailto:dsibley@tulane.edu>; bohm@tulane.edu<mailto:bohm@tulane.edu>; Jimmy Guidry (DHH)<mailto:Jimmy.Guidry2@LA.GOV>; jmlacour@wlf.la.gov<mailto:jmlacour@wlf.la.gov>; Jeff Dauzat (Jeff.Dauzat@LA.GOV)<mailto:Jeff.Dauzat@LA.GOV>; Brent Robbins (brobbins@ldaf.state.la.us) (brobbins@ldaf.state.la.us)<mailto:brobbins@ldaf.state.la.us>; Collins Simoneaux (Collins.Simoneaux@LA.GOV)<mailto:Collins.Simoneaux@LA.GOV>; Raoult Ratard <Raoult.Ratard@LA.GOV> (Raoult.Ratard@LA.GOV)<mailto:Raoult.Ratard@LA.GOV>; dstacy@ldaf.la.gov<mailto:dstacy@ldaf.la.gov>; Isaac, Freeda (CDC aphis.usda.gov)<mailto:freeda.e.isaac@aphis.usda.gov>; Katie.Portacci@aphis.usda.gov<mailto:Katie.Portacci@aphis.usda.gov>; Martin, John<mailto:martin.john@epa.gov>; Canzler, Erica<mailto:Canzler.Erica@epa.gov>; Nalipinski, Mike<mailto:Nalipinski.Mike@epa.gov>
> Subject: Soil and water samples negative
>
> This afternoon the CDC laboratory informed us that they were able to complete the analysis of all soil and water samples. All samples were negative for Burkholderia pseudomallei.

The laboratory performed two tests: polymerized chain reaction (PCR) which looks for the organism, whether dead or alive, by detecting its genetic material (DNA); and culturing, which should grow any live organisms. All samples were negative by both tests.

The samples included: 42 soil samples; 15 water samples; and 12 swab samples. Attached are the sample location information and sampling plan that was provided by EPA.

Please share as appropriate within your organizations.

Regards,
Scott

RADM Scott Deitchman, MD MPH, USPHS
Assistant Surgeon General
Associate Director for Environmental Health Emergencies
National Center for Environmental Health and
Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention
Atlanta GA USA

Appointment

From: Kenely, Caroline [Kenely.Caroline@epa.gov]
Sent: 4/9/2015 7:25:18 PM
To: Crossland, Ronnie [Crossland.Ronnie@epa.gov]; Petersen, Chris [petersen.chris@epa.gov]; Smith, Monica [smith.monica@epa.gov]; Cheatham, Reggie [cheatham.reggie@epa.gov]; Tulis, Dana [Tulis.Dana@epa.gov]; 'dms8@cdc.gov' [dms8@cdc.gov]
CC: Edlund, Carl [Edlund.Carl@epa.gov]

Subject: CALL - Tulane Panel - call in number 866-299-3188 code 202-566-0184
Location: CALL IN NUMBER - 866-299-3188 CODE 202-566-0184

Start: 4/13/2015 3:00:00 PM
End: 4/13/2015 3:30:00 PM
Show Time As: Tentative

Required Attendees: Crossland, Ronnie; Petersen, Chris; Smith, Monica; Cheatham, Reggie; Tulis, Dana; dms8@cdc.gov
Optional Attendees: Edlund, Carl

POC: Caroline Kenely – 202-566-2235 (scheduler)

From: Natarajan, Nitin
Sent: Wednesday, April 08, 2015 3:04 PM
To: Sosin, Dan (CDC/OPHPR/OD)
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH); Kenely, Caroline; Brooks, Becky
Subject: RE: information

I'm traveling tomorrow so was hoping for Friday. Maybe we can do Mon or Tuesday.

I've cc'd Caroline who can help with scheduling on our side.

Caroline - it'll be me, Reggie or Dana and Erica from HQ and Carl eglund and Ronnie crossland from R6.

Thanks all.

N

Nitin Natarajan
Deputy Assistant Administrator
Office of Solid Waste and Emergency Response
Environmental Protection Agency
202-566-0200 Office

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: 4/8/2015 14:55
To: Natarajan, Nitin
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: RE: information

I don't have anything on my calendar Nitin. Do you still have a desire for a call this week? I am out on Friday, so need to schedule tomorrow. Scott and I would try to both be on the call.

Thank you.

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Natarajan, Nitin [mailto:Natarajan.Nitin@epa.gov]
Sent: Tuesday, April 07, 2015 12:55 PM
To: Sosin, Dan (CDC/OPHPR/OD)
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: RE: information

I've chatted with our folks and we think we can get there from here. Can we setup a call this week with our folks to discuss?

N

Nitin Natarajan
Deputy Assistant Administrator
Office of Solid Waste and Emergency Response
Environmental Protection Agency
202-566-0200 Office

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: 4/7/2015 12:50
To: Natarajan, Nitin
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: FW: information

Nitin: in case you are not aware, it appears that Tulane is acting on its own to convene a panel of independent experts to weigh in on the environmental sampling needs. The deliberations of this group should be helpful for considering additional USG-sponsored deliberations on sampling for biological threats in the environment.

It will be good to have a suitable lab or two in mind to conduct the testing should Tulane and the local authorities decide to do more testing.

Best regards,

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Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

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Sent: Tuesday, April 07, 2015 12:47 PM
To: Helfand, Rita (CDC/OID/NCEZID); Deitchman, Scott (CDC/ONDIEH/NCEH); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: RE: information

Thank you Rita ... based on where we are in this response and our position on environmental testing, it seems best to be responsive to this panel's information requests regarding how we tested samples (as you are), and be particularly careful not to offer a contrary position to the EPA sampling methods as provided initially on request of the state.

It may be helpful to the community members to have an independent panel offer advice on further sampling at this point as long as Tulane is prepared to act on the input. The results of this panel should be informative of the need to further USG planning work for future events as well.

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Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Helfand, Rita (CDC/OID/NCEZID)
Sent: Tuesday, April 07, 2015 12:38 PM
To: Deitchman, Scott (CDC/ONDIEH/NCEH); Sosin, Dan (CDC/OPHPR/OD); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: FW: information

Fyi too

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Sent: Tuesday, April 07, 2015 6:51 AM
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Cc: Belay, Ermias (CDC/OID/NCEZID); Helfand, Rita (CDC/OID/NCEZID); Damon, Inger K. (CDC/OID/NCEZID)
Subject: FW: information

See below regarding Tulane panel. Henry, Dave and I were just talking about this yesterday.

Mindy – well just send the consensus document along with any modifications done short description of how water was processed.
Alex

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Cc: Bohm, Rudolf P; Sibley, Don A
Subject: information

Alex,

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best regards

Andrew

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Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
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Tulane University Health Science Center
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****

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Message

From: Kenely, Caroline [Kenely.Caroline@epa.gov]
Sent: 4/9/2015 6:25:03 PM
To: Horner, Jo [Horner.Jo@epa.gov]
CC: Crossland, Ronnie [Crossland.Ronnie@epa.gov]; Petersen, Chris [petersen.chris@epa.gov]; Smith, Monica [smith.monica@epa.gov]; Carter, Timber [Carter.Timber@epa.gov]; Phillips, Pam [phillips.pam@epa.gov]
Subject: RE: information

Will do. Thanks.

From: Horner, Jo
Sent: Thursday, April 09, 2015 2:05 PM
To: Kenely, Caroline
Cc: Crossland, Ronnie; Petersen, Chris; Smith, Monica; Carter, Timber; Phillips, Pam
Subject: RE: information

I've rescheduled Carl's appointments to accommodate a 10 AM call CST on Monday, 4/13. Please include Ronnie Crossland, Chris Petersen, and Monica Smith on your meeting invitation.

Jo Horner
EPA Superfund , 6SF/SEE
214-665-7366

From: Kenely, Caroline
Sent: Thursday, April 09, 2015 11:39 AM
To: Horner, Jo
Subject: FW: information

Hi Jo,

I left you a vm. Please contact me concerning this call below. I'm looking at Monday, 4/13 at 11am my time. 10am your time.

From: Natarajan, Nitin
Sent: Wednesday, April 08, 2015 3:04 PM
To: Sosin, Dan (CDC/OPHPR/OD)
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH); Kenely, Caroline; Brooks, Becky
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Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu
****

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EPA Superfund , 6SF/SEE
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Caroline - it'll be me, Reggie or Dana and Erica from HQ and Carl eglund and Ronnie crossland from R6.

Thanks all.

N

Nitin Natarajan
Deputy Assistant Administrator
Office of Solid Waste and Emergency Response
Environmental Protection Agency
202-566-0200 Office

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: 4/8/2015 14:55
To: Natarajan, Nitin
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: RE: information

I don't have anything on my calendar Nitin. Do you still have a desire for a call this week? I am out on Friday, so need to schedule tomorrow. Scott and I would try to both be on the call.

Thank you.

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Natarajan, Nitin [mailto:Natarajan.Nitin@epa.gov]
Sent: Tuesday, April 07, 2015 12:55 PM
To: Sosin, Dan (CDC/OPHPR/OD)
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: RE: information

I've chatted with our folks and we think we can get there from here. Can we setup a call this week with our folks to discuss?

N

Nitin Natarajan
Deputy Assistant Administrator
Office of Solid Waste and Emergency Response
Environmental Protection Agency
202-566-0200 Office

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: 4/7/2015 12:50
To: Natarajan, Nitin
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: FW: information

Nitin: in case you are not aware, it appears that Tulane is acting on its own to convene a panel of independent experts to weigh in on the environmental sampling needs. The deliberations of this group should be helpful for considering additional USG-sponsored deliberations on sampling for biological threats in the environment.

It will be good to have a suitable lab or two in mind to conduct the testing should Tulane and the local authorities decide to do more testing.

Best regards,

Dan

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: Tuesday, April 07, 2015 12:47 PM
To: Helfand, Rita (CDC/OID/NCEZID); Deitchman, Scott (CDC/ONDIEH/NCEH); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: RE: information

Thank you Rita ... based on where we are in this response and our position on environmental testing, it seems best to be responsive to this panel's information requests regarding how we tested samples (as you are), and be particularly careful not to offer a contrary position to the EPA sampling methods as provided initially on request of the state.

It may be helpful to the community members to have an independent panel offer advice on further sampling at this point as long as Tulane is prepared to act on the input. The results of this panel should be informative of the need to further USG planning work for future events as well.

Dan

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Helfand, Rita (CDC/OID/NCEZID)
Sent: Tuesday, April 07, 2015 12:38 PM
To: Deitchman, Scott (CDC/ONDIEH/NCEH); Sosin, Dan (CDC/OPHPR/OD); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: FW: information

Fyi too

From: Hoffmaster, Alex (CDC/OID/NCEZID)
Sent: Tuesday, April 07, 2015 6:51 AM
To: Gee, Jay (CDC/OID/NCEZID); Glass Elrod, Mindy (CDC/OID/NCEZID); Blaney, David (CDC/OID/NCEZID); Nolen, Leisha (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID)
Cc: Belay, Ermias (CDC/OID/NCEZID); Helfand, Rita (CDC/OID/NCEZID); Damon, Inger K. (CDC/OID/NCEZID)
Subject: FW: information

See below regarding Tulane panel. Henry, Dave and I were just talking about this yesterday.

Mindy – well just send the consensus document along with any modifications done short description of how water was processed.
Alex

From: Lackner, Andrew A [mailto:alackner@tulane.edu]
Sent: Tuesday, April 07, 2015 6:17 AM
To: Hoffmaster, Alex (CDC/OID/NCEZID); Gee, Jay (CDC/OID/NCEZID)
Cc: Bohm, Rudolf P; Sibley, Don A
Subject: information

Alex,

As part of our response to the Burkholderia pseudomallei incident at Tulane an expert panel has been put together to help us work through the various issues that this has brought up. Among the members are David Wagner, Paul Keim and David Dance. Among the issues to consider is additional environmental testing. A question that came up in the discussion involved the methods used for environmental analyses to be sure that any future testing, if done, would be comparable with prior work. Thus, I would appreciate it if you could share details of how the analyses were performed.

best regards

Andrew

****
Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu
****

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Attachment 1
RESPONSE TO SPECIFIC REQUEST

1. ***An explanation of the EPA's scientific justification for the soil sampling plan used in the federal investigation at the Tulane National Primate Research Center, particularly as it pertains to the number of soil samples taken at the site, and whether the agency has sought outside input or consultation about that plan (if so, please provide us with a list of those partners).***

   - **Explain the justification for the number of soil samples taken:** EPA was requested to design a sampling plan for the Unified Command's consideration, for Tulane National Primate Research Center (TNPRC) to implement and for CDC to analyze and interpret. The purpose of this plan was to develop an approach to determine if *Burkholderia pseudomallei* (Bp) had been released from primate cages. Following the DHS and EPA's Planning Guidance for Recovery Following Biological Incidents and the joint CDC, DHS and EPA's interim final Reference Guide for Developing and Executing *Bacillus anthracis* Sampling Plans in Indoor Settings, EPA used known site factors like the source location and potential release direction to determine the sample locations and optimize the possibility of detecting Bp during the February sampling effort. EPA also included sampling protocols for TNPRC to follow during the implementation of the sampling plan. Attachment 2 is a copy of the sampling plan. During implementation, at the request of CDC, the plan was adjusted in the field to add sampling locations on the north campus.

   - **Did EPA seek outside consultation on the sampling plan?** EPA briefed the Unified Command and included all input received in the sampling plan. Unified Command included: St Tammy Parish, GOHSEP, Louisiana Department of Health and Hospitals and CDC. In addition, EPA also consulted with the Louisiana Department of Environmental Quality, Louisiana Department of Agriculture and Forestry, USDA, and EPA Office of Research and Development's National Homeland Security Research Center for input on the sampling strategy, sampling procedures, and decontamination options.

2. ***A description of the procedure and specific equipment used by the EPA for air sampling pursuant to this investigation.***

   The Portable Sampling Units (PSUs) utilized at the Tulane National Primate Research Center (TNPRC) were units designed and used for the Department of Homeland Security BioWatch program. All air samples were collected utilizing PSUs. Three PSUs were used in the air sampling conducted at TNPRC. They were initially deployed throughout the South Campus in the following areas around the non-human primate enclosures; 1) The fence line nearest the Northlake Christian School, 2) Near the sewage aeration pond and 3) Near the gravel filter. The PSU's were activated on Sunday February 8th and collected data on a 24 hour basis until Thursday February 12th. The samples were sent to CDC for analysis and interpretation. CDC found that all twelve of the samples collected from the 4 days of sampling were negative for the presence of Bp or any other biological agents.

Additional details are included in the Quality Assurance Sampling Plan for Tulane University National Primate Research Center date February 2015 Section 3 Response Activities. (See Attachment 2)

3. A ***copy of the State of Louisiana's letter to the EPA requesting assistance in testing soil for B. pseudomallei.***

   See attached files
   - Copy of January 31, 2015, email request from GOHSEP requesting EPA staff to assist (Attachment 3)
   - 2/20 letter to EPA from GOHSEP (Attachment 4)
   - 3/13 letter to EPA from GOHSEP (Attachment 5)

4. ***A delineation of responsibilities among federal agencies for soil and air sampling in the wake of this and other events involving potential bioterrorism agents or infectious diseases.***

   Under the Biological Incident Annex to the National Response Framework, the coordinating agency is the Department of Health and Human Services which includes CDC. Under this annex, EPA is considered a cooperating agency. In the TNPRC event, EPA fulfilled this role when on January 27, 2015, CDC asked EPA to provide technical assistance on how to sample air, soil and water and methods to decontaminate soil in the non-human primate enclosures that could be implemented on an emergency basis. EPA then drafted and presented a plan to the Unified Command which included the St Tammany Parish, Louisiana Governor's Office of Homeland Security and Emergency Preparedness (GOHSEP), Louisiana Department of Health and Hospitals (LDHH) and CDC on February 6, 2015. The Unified Command approved the sampling plan and EPA initiated air sampling on February 8, 2015, and TNPRC initiated soil and water sampling on February 9, 2015. TNPRC shipped all of the samples (air, soil, and water) to CDC for analysis and interpretation. On March 13, 2015, CDC announced that there was no evidence at that time to suggest the organism was released into the surrounding environment and it was unlikely there was any threat to the general population.

   EPA has authority under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), Pursuant to CERCLA, disease causing agents are considered pollutants or contaminants and EPA may take action to contain or mitigate a threatened or actual release. In addition, under the National Response Framework, Emergency Support Function (ESF) #10, EPA is the ESF coordinator for Oil and Hazardous Material Response which includes chemical, biological and radiological substances, whether accidentally or intentionally released. The Homeland Security Presidential Directive #10 directs EPA to, among other items, develop "specific standards, protocols, capabilities to address the risks of contamination following a biological weapons attack and develop strategies, guidelines, and plans for decontamination of persons, equipment, and facilities."

Message

From: Phillips, Pam [phillips.pam@epa.gov]
Sent: 4/9/2015 5:56:16 PM
To: Horner, Jo [Horner.Jo@epa.gov]
CC: Crossland, Ronnie [Crossland.Ronnie@epa.gov]; Petersen, Chris [petersen.chris@epa.gov]; Smith, Monica [smith.monica@epa.gov]
Subject: RE: information

Yes, move any meetings that interfere with this call. Delay the 10:30 staff meeting until 11 or push it to the afternoon. Ronnie, Chris P and Monica need to be on this call also as it concerns the Tulane issue.

From: Horner, Jo
Sent: Thursday, April 09, 2015 12:33 PM
To: Phillips, Pam
Subject: RE: information

Sorry, I meant the 10:30 meeting could be moved.

Jo Horner
EPA Superfund , 6SF/SEE
214-665-7366

From: Horner, Jo
Sent: Thursday, April 09, 2015 12:32 PM
To: 'Pam Phillips'
Subject: FW: information

Pam,

I don't want to respond to this without your input. The 9:15 meeting could be moved to 9 or another time to accommodate this meeting, if you think that is wise.

Jo Horner
EPA Superfund , 6SF/SEE
214-665-7366

From: Kenely, Caroline
Sent: Thursday, April 09, 2015 11:39 AM
To: Horner, Jo
Subject: FW: information

Hi Jo,

I left you a vm. Please contact me concerning this call below. I'm looking at Monday, 4/13 at 11am my time. 10am your time.

From: Natarajan, Nitin
Sent: Wednesday, April 08, 2015 3:04 PM
To: Sosin, Dan (CDC/OPHPR/OD)

Cc: Deitchman, Scott (CDC/ONDIEH/NCEH); Kenely, Caroline; Brooks, Becky
Subject: RE: information

I'm traveling tomorrow so was hoping for Friday. Maybe we can do Mon or Tuesday.

I've cc'd Caroline who can help with scheduling on our side.

Caroline - it'll be me, Reggie or Dana and Erica from HQ and Carl eglund and Ronnie crossland from R6.

Thanks all.

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Deputy Assistant Administrator
Office of Solid Waste and Emergency Response
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202-566-0200 Office

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Daniel M. Sosin, MD, MPH, FACP
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Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Natarajan, Nitin [mailto:Natarajan.Nitin@epa.gov]
Sent: Tuesday, April 07, 2015 12:55 PM
To: Sosin, Dan (CDC/OPHPR/OD)
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: RE: information

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Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
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To: Deitchman, Scott (CDC/ONDIEH/NCEH); Sosin, Dan (CDC/OPHPR/OD); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)

Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
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Subject: FW: information

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Alex

From: Lackner, Andrew A [mailto:alackner@tulane.edu]
Sent: Tuesday, April 07, 2015 6:17 AM
To: Hoffmaster, Alex (CDC/OID/NCEZID); Gee, Jay (CDC/OID/NCEZID)
Cc: Bohm, Rudolf P; Sibley, Don A
Subject: information

Alex,

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Andrew
****
Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu
****

CONFIDENTIALITY NOTICE

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Message

From: Smith, Monica [smith.monica@epa.gov]
Sent: 4/1/2015 7:25:02 PM
To: Crossland, Ronnie [Crossland.Ronnie@epa.gov]; Petersen, Chris [petersen.chris@epa.gov]
Subject: ATTACHMENTS FOR THE TULANE RESPONSE TO US SENATE
Attachments: Tulane University ER QASP - v2.pdf; january 31 2015 gohsep email requesting EPA assistance.pdf; Ron Curry - EPA Letter - March 13 2015.pdf; EPA Letter - February 20 2015.pdf

ATTACHMENT 1 – IS THE RESPONSE
ATTACHMENT 2 – IS THE QASP
ATTACHMENT 3 -THE EMAIL
ATTACHMENT 4- THE FEB 20 GOHSEP LETTER
ATTACHMENT 5 - THE MARCH 13 GOHSEP LETTER

Monica Smith
US EPA Region 6
Superfund Division
1445 Ross Avenue
Dallas, TX 75202-2733
214-665-6780 office
469-766-3398 cell
214-665-6660 fax

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Message

From: Nalipinski, Mike [Nalipinski.Mike@epa.gov]
Sent: 3/16/2015 4:28:37 PM
To: Petersen, Chris [petersen.chris@epa.gov]; Smith, Monica [smith.monica@epa.gov]
Subject: FW: EPA Pen Remediation Plan Request for conf call
Attachments: image001.png

Importance: High

FYI.....
Michael Nalipinski
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Monday, March 16, 2015 12:06 PM
To: Martin, John; Nalipinski, Mike
Cc: Lackner, Andrew A; Bohm, Rudolf P; Blanchard, James L
Subject: FW: EPA Contact Information
Importance: High

Mike and John,

If the times below don't work for you, please let us know when you are available and we will accommodate your schedule.

We are under a deadline from the Unified Incident Command to show progress on a remediation plan by this Friday.

Please contact us as soon as possible to begin the discussion.

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

TULANE NATIONAL PRIMATE RESEARCH CENTER

From: <Alise>, Mark Alise <malise@tulane.edu>
Date: Friday, March 13, 2015 at 9:09 AM
To: "Martin.john@epa.gov" <Martin.john@epa.gov>, "nalipinski.mike@epa.gov" <nalipinski.mike@epa.gov>
Cc: Andrew Lackner <alackner@tulane.edu>, Rudolf Bohm <bohm@tulane.edu>
Subject: Re: EPA Contact Information

Mike and John,

We would like to set up a call with you next week to discuss remediation options for the two field cages on our south campus.

Some available times for us are (all CDT):

Monday, March 16
3:00 pm
4:00 pm

Wednesday, March 18
3:00 pm
4:00 pm

Thursday, March 19
10:00 am
11:00 am

Please let us know of your availability for a call.

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

TULANE NATIONAL PRIMATE RESEARCH CENTER

From: <Deitchman>, "Scott (CDC/ONDIEH/NCEH)" <sed2@cdc.gov>
Date: Thursday, March 12, 2015 at 2:09 PM
To: Mark Alise <malise@tulane.edu>
Cc: Andrew Lackner <alackner@tulane.edu>, Rudolf Bohm <bohm@tulane.edu>, "Martin.john@epa.gov" <Martin.john@epa.gov>, "nalipinski.mike@epa.gov" <nalipinski.mike@epa.gov>
Subject: RE: EPA Contact Information

Mark,

The EPA representatives were John Martin from EPA Region 6, and Mike Nalipinski representing EPA headquarters. Both are on the CC line. Their phone numbers should be in the Unified Command IAP; don't have one at hand but can obtain if you don't have it.

Regards,
Scott

RADM Scott Deitchman, MD MPH, USPHS
Assistant Surgeon General
Associate Director for Environmental Health Emergencies
National Center for Environmental Health and
Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention
Atlanta GA USA

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Thursday, March 12, 2015 12:53 PM
To: Deitchman, Scott (CDC/ONDIEH/NCEH)
Cc: Lackner, Andrew A; Bohm, Rudolf P
Subject: EPA Contact Information

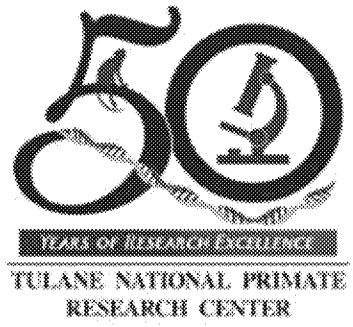
Scott,

Could you please provide us with the contact information for the EPA representatives on today's call?

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer
Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200



Message

From: Gray, David [gray.david@epa.gov]
Sent: 2/25/2015 11:49:31 PM
To: McDonald, Jason (CDC/OPHPR/OD) [gnf0@cdc.gov]; Reynolds, Barbara S. (CDC/OD/OADC) [bsr0@cdc.gov]; Burden, Bernadette (CDC/OD/OADC) [btb8@cdc.gov]; Kenneth Angel [kenneth.l.angel@aphis.usda.gov]; joelle.r.hayden@aphis.usda.gov; dgrant@tulane.edu; mstreck@tulane.edu; Ronnie Simpson [rsimpson@stpgov.org]; Olivia Watkins [Olivia.Watkins@LA.GOV]; Collins Simoneaux [Collins.Simoneaux@LA.GOV]; Scheel, Christian (CDC/ONDIEH/NCEH) [bjn2@cdc.gov]; Mike Steele [Mike.Steele@LA.GOV]; Veronica Mosgrove [vmosgrove@ldaf.la.gov]; John Ford (DHH) [JPFord@la.gov]; Hubbard, Joseph [Hubbard.Joseph@epa.gov]; Mike Steele [Mike.Steele@LA.GOV]
CC: sed2@cdc.gov; Petersen, Chris [petersen.chris@epa.gov]
Subject: RE: USA Today Tulane request
Attachments: Tulane University ER QASP - v2.pdf; FIGURE 1 - SAMPLE LOCATION MAP.PDF; Sample Locations.xls.pdf

Thanks Jason. The best I can do is provide her with a copy of the sampling plan for the project. It needs to come from unified command – so Mike, I think that is you. But others need to be comfortable with the release of these documents. David

---

From: McDonald, Jason (CDC/OPHPR/OD) [mailto:gnf0@cdc.gov]
Sent: Wednesday, February 25, 2015 3:55 PM
To: Gray, David; Reynolds, Barbara S. (CDC/OD/OADC); Burden, Bernadette (CDC/OD/OADC); Kenneth Angel; joelle.r.hayden@aphis.usda.gov; dgrant@tulane.edu; mstreck@tulane.edu; Ronnie Simpson; Olivia Watkins; Collins Simoneaux; Scheel, Christian (CDC/ONDIEH/NCEH); Mike Steele; Veronica Mosgrove; John Ford (DHH); Hubbard, Joseph; Mike Steele
Subject: RE: USA Today Tulane request

When Alison approached CDC, she requested details about the sampling; mainly, rationale for taking air samples, and where the ground and water samples were taken from. We thought EPA would be best to discuss that aspect.

CDC can let her know the results if she does not know already.

Mike or Ronnie: Will the fact that all air, water and soil samples were negative for the bacterium appear in today's release or has it been reported already?

From: Gray, David [mailto:gray.david@epa.gov]
Sent: Wednesday, February 25, 2015 4:35 PM
To: Reynolds, Barbara S. (CDC/OD/OADC); Burden, Bernadette (CDC/OD/OADC); Kenneth Angel; Gray, David; joelle.r.hayden@aphis.usda.gov; dgrant@tulane.edu; mstreck@tulane.edu; Ronnie Simpson; Olivia Watkins; Collins Simoneaux; Scheel, Christian (CDC/ONDIEH/NCEH); Mike Steele; McDonald, Jason (CDC/OPHPR/OD); Veronica Mosgrove; John Ford (DHH); Hubbard, Joseph; Mike Steele
Subject: FW: USA Today Tulane request

I don't believe that EPA should provide results to USA Today.

From: Durant, Jennah
Sent: Wednesday, February 25, 2015 3:32 PM
To: Gray, David

Cc: Hubbard, Joseph
Subject: USA Today Tulane request

Alison Young of USA Today is requesting detailed info on air, soil, and water samples from the Tulane research facility. She has been directed to EPA by CDC and USDA.

Email: ayoung@usatoday.com
Phone: 703-854-6466
Deadline: Noon Thursday

Message

From: Deitchman, Scott (CDC/ONDIEH/NCEH) [sed2@cdc.gov]
Sent: 2/26/2015 4:49:45 PM
To: Petersen, Chris [petersen.chris@epa.gov]
Subject: FW: Soil and water samples negative
Attachments: FIGURE 1 - SAMPLE LOCATION MAP.PDF; Sample Locations.xls.pdf; Tulane University ER QASP - v2.pdf

Importance: High

As discussed.

Thanks,
Scott

RADM Scott Deitchman, MD MPH, USPHS
Assistant Surgeon General
Associate Director for Environmental Health Emergencies
National Center for Environmental Health and
Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention
Atlanta GA USA

From: Deitchman, Scott (CDC/ONDIEH/NCEH)
Sent: Friday, February 20, 2015 3:56 PM
To: Kevin Davis (Kevin.Davis@LA.GOV); daccardo@stpgov.org; dsibley@tulane.edu; bohm@tulane.edu; Jimmy Guidry (DHH); jmlacour@wlf.la.gov; Jeff Dauzat (Jeff.Dauzat@LA.GOV); Brent Robbins (brobbins@ldaf.state.la.us) (brobbins@ldaf.state.la.us); Collins Simoneaux (Collins.Simoneaux@LA.GOV); Raoult Ratard <Raoult.Ratard@LA.GOV> (Raoult.Ratard@LA.GOV); dstacy@ldaf.la.gov; Isaac, Freeda (CDC aphis.usda.gov) (freeda.e.isaac@aphis.usda.gov); Katie.Portacci@aphis.usda.gov; Martin.john@epa.gov; Erica Canzler (canzler.erica@epa.gov); nalipinski.mike@epa.gov
Subject: Soil and water samples negative

This afternoon the CDC laboratory informed us that they were able to complete the analysis of all soil and water samples. **All samples were negative for *Burkholderia pseudomallei*.**

The laboratory performed two tests: polymerized chain reaction (PCR) which looks for the organism, whether dead or alive, by detecting its genetic material (DNA); and culturing, which should grow any live organisms. All samples were negative by both tests.

The samples included: 42 soil samples; 15 water samples; and 12 swab samples. Attached are the sample location information and sampling plan that was provided by EPA.

Please share as appropriate within your organizations.

Regards,
Scott

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Message

From: Petersen, Chris [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD3A9D0A7FF44172A8A34A8BEDCF349F-PETERSEN, CHRIS]
Sent: 2/26/2015 4:58:00 PM
To: John Martin [Martin.John@epa.gov]
Subject: FW: Soil and water samples negative
Attachments: FIGURE 1 - SAMPLE LOCATION MAP.PDF; Sample Locations.xls.pdf; Tulane University ER QASP - v2.pdf

Importance: High

J. Chris Petersen
Deputy Associate Director
Response and Prevention Branch
US EPA Region 6
1445 Ross Ave, Ste. 1200
Dallas, TX 75202
214-665-3167 office
214-665-7447 fax
214-789-2535 cell

From: Deitchman, Scott (CDC/ONDIEH/NCEH) [mailto:sed2@cdc.gov]
Sent: Thursday, February 26, 2015 10:50 AM
To: Petersen, Chris
Subject: FW: Soil and water samples negative
Importance: High

As discussed.

Thanks,
Scott

RADM Scott Deitchman, MD MPH, USPHS
Assistant Surgeon General
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Sent: 2/25/2015 11:47:20 PM
To: David Gray [Gray.David@epa.gov]
CC: sed2@cdc.gov
Subject: FW: USDA risk assessment team
Attachments: FIGURE 1 - SAMPLE LOCATION MAP.pdf; Sample Locations.xls.pdf; Tulane University ER QASP - v2.pdf

David – here is the sampling plan provided to Unified Command.

Scott – A USA Today reporter is the one asking for this information.

J. Chris Petersen
Deputy Associate Director
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Dallas, TX 75202
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Sent: 3/18/2015 5:32:46 PM
To: Martin, John [Martin.JohnJ@epa.gov]; Nalipinski, Mike [Nalipinski.Mike@epa.gov]; Ryan, Shawn [Ryan.Shawn@epa.gov]; malise@tulane.edu
CC: Monica Smith [Smith.Monica@epa.gov]; Ronnie Crossland [Crossland.Ronnie@epa.gov]
Subject: FW: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time

Importance: High

John, Mike, Shawn and Mike -- Due to circumstances beyond our control, the call scheduled for today will need to be postponed indefinitely. I apologize for this late notice and for any difficulties this may create. Thanks

J. Chris Petersen
Deputy Associate Director
Response and Prevention Branch
US EPA Region 6
1445 Ross Ave, Ste. 1200
Dallas, TX 75202
214-665-3167 office
214-665-7447 fax
214-789-2535 cell

From: Martin, John
Sent: Tuesday, March 17, 2015 4:25 PM
To: Smith, Monica; Petersen, Chris
Subject: FW: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time
Importance: High

They're close

John J. Martin
Federal On-Scene Coordinator (OSC)
1445 Ross Ave (6SF-PE)
Dallas, Texas 75202

214.665.6748 * *fax 214.665.2278*

From: Nalipinski, Mike
Sent: Tuesday, March 17, 2015 3:24 PM
To: Alise, Mark A
Cc: Ryan, Shawn; Martin, John

Subject: RE: Soil remediation options TNPRC Conf call Wed 18 March 1500 Eastern Std Time
Importance: High

Mark –

Thanks for accommodating a call tomorrow at 1500 hrs Eastern Standard Time. We can use the following call in number:

877-299-3188 pass code 202 564 2359

Note that I've invited OSC John Martin Region 6 and Dr. Shawn Ryan NHSRC to the call. As you know John is the EPA lead out of Dallas and Shawn is the Director of EPA's Office of Research and Development National Homeland Security Research Center. Shawn's group has conducted extensive laboratory and field studies on different decontamination technologies.

The goal of tomorrow's meeting is to hopefully down select one or two technologies that the group could support and that would merit more detailed evaluation/consideration. In my previous e-mails EPA has offered several options and those, or if you have other alternatives, could be a framework for our conversation.

Have a good evening and looking forward to a productive discussion tomorrow.

Cheers,

V/R

Michael Nalipinski
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

From: Alise, Mark A [mailto:malise@tulane.edu]
Sent: Tuesday, March 17, 2015 3:07 PM
To: Nalipinski, Mike
Cc: Lackner, Andrew A; Blanchard, James L
Subject: FW: Soil remediation options TNPRC

Mike,

Thanks for the information. I would like Dr. Lackner to join in our conversation tomorrow afternoon and I am copying him on this response.

We can talk at 2:00 pm CDT, 3:00 pm EDT if that works for you. If not we can work around other afternoon times.

Thanks,

Mark

Mark A. Alise, M.B.A., Ph.D.
Chief Operations Officer

Tulane National Primate Research Center
18703 Three Rivers Road
Covington, LA 70433
985-871-6200

TULANE NATIONAL PRIMATE RESEARCH CENTER

From: <Nalipinski>, Mike <Nalipinski.Mike@epa.gov>
Date: Tuesday, March 17, 2015 at 1:34 PM
To: Mark Alise <malise@tulane.edu>
Cc: "Martin, John" <martin.john@epa.gov>, "Ryan, Shawn" <Ryan.Shawn@epa.gov>, "Petersen, Chris" <petersen.chris@epa.gov>, "Smith, Monica" <smith.monica@epa.gov>
Subject: FW: Soil remediation options TNPRC

Mark - Below and attached are some insights relative to technologies that could be considered for addressing the two field cages at the TNPRC. This input was received from the EPA's Office of Research and Development National Homeland Security Research Center (NHSRC). As background, NHSRC has conducted several studies to evaluate the efficacy of methyl bromide (MeBr) as a decontamination technology for bacillus anthraces (Ba). Using surrogates for Ba, namely BtK and Bg, MeBr has been proven effective. As you know MeBr has also been deployed in agricultural settings. MeBr could be broadcasted as a liquid during the tilling process and/or could also be applied as a liquid to the field cage that has a gravel base.

We have the most confidence in MeBr fumigation of the soilas it has proven effective in prior lab studies. Aside from the use of MeBr, we suggest looking at:

(1) Data supporting CaO; we are trying to get access to the reference with the lab study data. The abstract suggests inhibition up to 6 weeks when applied at 40% or more (wt/wt). Not sure if this "inhibition" means that additional or continued treatment is necessary for subsequent inhibition. We will look into it more when we get access to the paper. Any additional information that you are provided via Tulane may be helpful.
(2) Sodium persulfate (Klozur FMC) was shown in our laboratory studies to be an effective biological agent decontaminant in soil. We anticipate that it would be effective. It is typically injected in soil for treatment of organic contaminants. EPA has experience with it for Superfund Siteschlorinated solvents. Above are two attachments with some information. More info can be found at: http://www.peroxychem.com/chemistries/persulfates/products/klozur-persulfate/technical-documentation
(3) Metam sodium has also been shown to be an effective soil decontaminant for biological agents. There is considerable experience with it as it is one of the most widely used soil pesticides in the U.S. It would require longer aeration time (up to a month) and has the potential to produce toxic by-products in contact with water; so care would be necessary to reduce potential for exposure of people or animals. Also, there would need to be the discussion regarding suitable application for the soil type at the facility. There is a till-in application.

I hope the above information will be thought provoking and can guide our conversations as we continue to evaluate options to decontaminate the field cages. Please let me know if you would be available tomorrow March 18th to continue our discussion. I am available any time after noon eastern standard time.

Cheers,

V/R

Michael Nalipinski, Associate Director
CBRN Consequence Management and Advisory Division (CMAD)
U.S. EPA Office of Emergency Management
Boston, MA 02203

Mobile - 617-680-5469
Office - 617-918-1268

Appointment

From: Natarajan, Nitin [Natarajan.Nitin@epa.gov]
Sent: 4/9/2015 7:05:00 PM
To: Natarajan, Nitin [Natarajan.Nitin@epa.gov]; Crossland, Ronnie [Crossland.Ronnie@epa.gov]; Petersen, Chris [petersen.chris@epa.gov]; Smith, Monica [smith.monica@epa.gov]; Cheatham, Reggie [cheatham.reggie@epa.gov]; Tulis, Dana [Tulis.Dana@epa.gov]; 'dms8@cdc.gov' [dms8@cdc.gov]
CC: Edlund, Carl [Edlund.Carl@epa.gov]

Subject: CALL - Tulane Panel - call in number 866-299-3188 code 202-566-0184
Location: CALL IN NUMBER - 866-299-3188 CODE 202-566-0184

Start: 4/13/2015 3:00:00 PM
End: 4/13/2015 3:30:00 PM
Show Time As: Tentative

Required Attendees: Crossland, Ronnie; Petersen, Chris; Smith, Monica; Cheatham, Reggie; Tulis, Dana; dms8@cdc.gov
Optional Attendees: Edlund, Carl

POC: Caroline Kenely – 202-566-2235 (scheduler)

From: Natarajan, Nitin
Sent: Wednesday, April 08, 2015 3:04 PM
To: Sosin, Dan (CDC/OPHPR/OD)
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH); Kenely, Caroline; Brooks, Becky
Subject: RE: information

I'm traveling tomorrow so was hoping for Friday. Maybe we can do Mon or Tuesday.

I've cc'd Caroline who can help with scheduling on our side.

Caroline - it'll be me, Reggie or Dana and Erica from HQ and Carl eglund and Ronnie crossland from R6.

Thanks all.

N

Nitin Natarajan
Deputy Assistant Administrator
Office of Solid Waste and Emergency Response
Environmental Protection Agency
202-566-0200 Office

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: 4/8/2015 14:55
To: Natarajan, Nitin
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: RE: information

I don't have anything on my calendar Nitin. Do you still have a desire for a call this week? I am out on Friday, so need to schedule tomorrow. Scott and I would try to both be on the call.

Thank you.

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Natarajan, Nitin [mailto:Natarajan.Nitin@epa.gov]
Sent: Tuesday, April 07, 2015 12:55 PM
To: Sosin, Dan (CDC/OPHPR/OD)
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: RE: information

I've chatted with our folks and we think we can get there from here. Can we setup a call this week with our folks to discuss?

N

Nitin Natarajan
Deputy Assistant Administrator
Office of Solid Waste and Emergency Response
Environmental Protection Agency
202-566-0200 Office

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: 4/7/2015 12:50
To: Natarajan, Nitin
Cc: Deitchman, Scott (CDC/ONDIEH/NCEH)
Subject: FW: information

Nitin: in case you are not aware, it appears that Tulane is acting on its own to convene a panel of independent experts to weigh in on the environmental sampling needs. The deliberations of this group should be helpful for considering additional USG-sponsored deliberations on sampling for biological threats in the environment.

It will be good to have a suitable lab or two in mind to conduct the testing should Tulane and the local authorities decide to do more testing.

Best regards,

Dan

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Office of Public Health Preparedness and Response
1600 Clifton Road, NE Mailstop D-44
404-639-7405

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: Tuesday, April 07, 2015 12:47 PM
To: Helfand, Rita (CDC/OID/NCEZID); Deitchman, Scott (CDC/ONDIEH/NCEH); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: RE: information

Thank you Rita ... based on where we are in this response and our position on environmental testing, it seems best to be responsive to this panel's information requests regarding how we tested samples (as you are), and be particularly careful not to offer a contrary position to the EPA sampling methods as provided initially on request of the state.

It may be helpful to the community members to have an independent panel offer advice on further sampling at this point as long as Tulane is prepared to act on the input. The results of this panel should be informative of the need to further USG planning work for future events as well.

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1600 Clifton Road, NE Mailstop D-44
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From: Helfand, Rita (CDC/OID/NCEZID)
Sent: Tuesday, April 07, 2015 12:38 PM
To: Deitchman, Scott (CDC/ONDIEH/NCEH); Sosin, Dan (CDC/OPHPR/OD); Weyant, Rob (CDC/OPHPR/DSAT); Redd, Stephen (CDC/OPHPR/OD)
Cc: Belay, Ermias (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID); Hoffmaster, Alex (CDC/OID/NCEZID)
Subject: FW: information

Fyi too

From: Hoffmaster, Alex (CDC/OID/NCEZID)
Sent: Tuesday, April 07, 2015 6:51 AM
To: Gee, Jay (CDC/OID/NCEZID); Glass Elrod, Mindy (CDC/OID/NCEZID); Blaney, David (CDC/OID/NCEZID); Nolen, Leisha (CDC/OID/NCEZID); Walke, Henry (CDC/OID/NCEZID)
Cc: Belay, Ermias (CDC/OID/NCEZID); Helfand, Rita (CDC/OID/NCEZID); Damon, Inger K. (CDC/OID/NCEZID)
Subject: FW: information

See below regarding Tulane panel. Henry, Dave and I were just talking about this yesterday.

Mindy – well just send the consensus document along with any modifications done short description of how water was processed.
Alex

From: Lackner, Andrew A [mailto:alackner@tulane.edu]
Sent: Tuesday, April 07, 2015 6:17 AM
To: Hoffmaster, Alex (CDC/OID/NCEZID); Gee, Jay (CDC/OID/NCEZID)
Cc: Bohm, Rudolf P; Sibley, Don A
Subject: information

Alex,

As part of our response to the Burkholderia pseudomallei incident at Tulane an expert panel has been put together to help us work through the various issues that this has brought up. Among the members are David Wagner, Paul Keim and David Dance. Among the issues to consider is additional environmental testing. A question that came up in the discussion involved the methods used for environmental analyses to be sure that any future testing, if done, would be comparable with prior work. Thus, I would appreciate it if you could share details of how the analyses were performed.

best regards

Andrew

****
Andrew A. Lackner, D.V.M., Ph.D., Dipl. A.C.V.P.
Director and Chief Academic Officer, Tulane National Primate Research Center
Professor of Microbiology, Immunology and Pathology
Tulane University Health Science Center
18703 Three Rivers Road
Covington, LA 70433
Tel 985-871-6201
Fax 985-871-6569
email: alackner@tulane.edu
web: tnprc.tulane.edu
****

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This communication and any attachments may contain confidential and privileged information for the use of the designated recipient/s named above. Distribution, reproduction or any other use of this transmission by any party other than the intended recipient(s) is prohibited.

Message

From: Rhotenberry, William [Rhotenberry.William@epa.gov]
Sent: 3/26/2015 10:49:27 PM
To: Smith, Monica [smith.monica@epa.gov]
Subject: Fwd: Tulane - QASP
Attachments: ATT00001.htm; Tulane University ER QASP - v2.pdf; ATT00002.htm

Let's try this

Sent from my iPhone

Begin forwarded message:

> **From:** "Ojeda, Jose" <Jose.Ojeda@WestonSolutions.com>
> **Date:** February 19, 2015 at 11:22:17 AM CST
> **To:** "Martin, John" <martin.john@epa.gov>
> **Cc:** "Rhotenberry, William" <Rhotenberry.William@epa.gov>, "McAteer, Mike" <mcateer.mike@epa.gov>
> **Subject: Tulane - QASP**
>
> See attached

Appointment

From: Natarajan, Nitin [Natarajan.Nitin@epa.gov]
Sent: 4/13/2015 2:20:05 PM
To: Natarajan, Nitin [Natarajan.Nitin@epa.gov]; Martin, John [martin.john@epa.gov]; Rhotenberry, William [Rhotenberry.William@epa.gov]; Crossland, Ronnie [Crossland.Ronnie@epa.gov]; Petersen, Chris [petersen.chris@epa.gov]; Smith, Monica [smith.monica@epa.gov]; Cheatham, Reggie [cheatham.reggie@epa.gov]; Tulis, Dana [Tulis.Dana@epa.gov]; 'dms8@cdc.gov' [dms8@cdc.gov]
CC: Edlund, Carl [Edlund.Carl@epa.gov]

Subject: FW: CALL - Tulane Panel - call in number 866-299-3188 code 202-566-0184
Location: CALL IN NUMBER - 866-299-3188 CODE 202-566-0184

Start: 4/13/2015 3:00:00 PM
End: 4/13/2015 3:30:00 PM
Show Time As: Tentative

John – per Ronnie you should plan on listening in to the call. We will let Carl know you are on the call.

Bill - per Ronnie, please come up to Carl's conference room to sit in on the call with us. Monica

-----Original Appointment-----
From: Natarajan, Nitin
Sent: Thursday, April 09, 2015 2:05 PM
To: Natarajan, Nitin; Crossland, Ronnie; Petersen, Chris; Smith, Monica; Cheatham, Reggie; Tulis, Dana; 'dms8@cdc.gov'
Cc: Edlund, Carl
Subject: CALL - Tulane Panel - call in number 866-299-3188 code 202-566-0184
When: Monday, April 13, 2015 11:00 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: CALL IN NUMBER - 866-299-3188 CODE 202-566-0184

POC: Caroline Kenely – 202-566-2235 (scheduler)

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To: Hoffmaster, Alex (CDC/OID/NCEZID); Gee, Jay (CDC/OID/NCEZID)
Cc: Bohm, Rudolf P; Sibley, Don A
Subject: information

Alex,

As part of our response to the Burkholderia pseudomallei incident at Tulane an expert panel has been put together to help us work through the various issues that this has brought up. Among the members are David Wagner, Paul Keim and David Dance. Among the issues to consider is additional environmental testing. A question that came up in the discussion involved the methods used for environmental analyses to be sure that any future testing, if done, would be comparable with prior work. Thus, I would appreciate it if you could share details of how the analyses were performed.

best regards

Andrew
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