EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 1-16

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-10-060	11/30/2010 To 07/31/2012 Base Option Period Number 1	NHSRC SAM Support

Contractor: COMPUTER SCIENCES CORPORATION

Specify Section and paragraph of Contract SOW: 2.7, 2.8.1, 2.8.2, 2.8.3, 2.8.4, 2.9, 3.1.4

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 08/01/2011 To 07/31/2012

Comments:
This action establishes WA 1-16 in Option Period 1 and requests a work plan and cost estimate for the attached PWS. Estimated LOE is 6414 direct labor hours. No costs shall be incurred against this WA until the effective date of 8/1/11.

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/30/2010 To 07/31/2012		0
This Action:		6,414
Total:		6,414

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name Kathy Hall	(Signature)	(Date)	Branch/Mail Code: Phone Number 513-379-5260 FAX Number:
Project Officer Name Nancy Muzzy	(Signature)	(Date)	Branch/Mail Code: Phone Number: 513-569-7864 FAX Number:
Other Agency Official Name	(Signature)	(Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name Cathy Basu	(Signature)	(Date)	Branch/Mail Code: Phone Number: 513-487-2042 FAX Number:

WSD Contract No: EP-C-10-060
EPA Office/Division: Water Security Division/Office of Water

Work Assignment WA-016 Option Period 1
Performance Work Statement (PWS)
EPA Lead/WAM: Kathy Hall
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National Homeland Security Research Center
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Period of performance: August 1, 2011 to July 31 2012

Title: *Homeland Security Analytical and Sample Collection Method Identification, Development, and Related Verification Supporting EPA NHSRC's Standardized Analytical Methods for Environmental Restoration Following Homeland Security Events (SAM)*

WSD Contract SOW Areas: 2.7, 2.8.1, 2.8.2, 2.8.3, 2.8.4, 2.9, 3.1.4, 3.1.10, 3.1.16, 3.1.17

LOE: 6414 **hours**

I. PURPOSE

The purpose of this work is to provide continued support for EPA National Homeland Security Research Center (NHSRC) initiatives in updating the Selected Analytical Methods for Environmental Remediation and Recovery (SAM) ; identifying, developing, and verifying analytical methods that can be used by multiple laboratories analyzing environmental samples during environmental remediation following a homeland security event; developing selected analytical and sample collection procedures; coordinating document reviews and revisions including compiling and responding to comments; facilitating procedure verifications; and supporting an interactive web page including development and maintenance. These analytical methods and supporting documents and web page address the chemical, radiological, and biological analytes (CBR) listed in NHSRC's SAM document, and support EPA laboratory networks, including the Environmental Response Laboratory Network (ERLN) and Water Laboratory Alliance. Importantly, analytical methods verified under this Work Assignment (WA) shall be demonstrated to assure that their performance characteristics (e.g. accuracy, limit of detection and robustness) meet site remediation goals, i.e. site clearance, for re-occupation as existed prior to the contamination event.

To achieve this purpose, the contractor shall provide technical, analytical, study coordination, and computer support. NHSRC will continue to coordinate with workgroups involved in developing SAM, including representatives from EPA Offices, EPA and State laboratories and representatives from the U.S. Centers for Disease Control and Prevention (CDC), Department of Agriculture (USDA), Food and Drug Administration (FDA), and U.S. Department of Homeland Security (DHS). NHSRC also will continue working with representatives from the Office of Solid Waste and Emergency Response (OSWER) and Office of Water, where appropriate, to leverage and avoid duplication of existing efforts.

Under this work assignment, the contractor shall provide technical support to EPA's development of SAM, development and verification of selected analytical and sample collection procedures, development and maintenance of a interactive web site, and development and verification of laboratory methods to identify and measure chemical, radiological and biological analytes included in SAM. Contractor support will be

required in the following areas:

- Data exchange, management, and review
- Single lab verification leading to multi-laboratory method validation studies
- Document revisions. The contractor shall verify each document as drafted and conduct minor revisions as needed. If necessary, major revisions need to be promptly identified such that EPA can determine appropriate follow-on actions.
- Web page development and support

II. BACKGROUND:

After 9/11, EPA initiated an Environmental Response Laboratory Network (ERLN). The need to establish a network of laboratories to effectively respond to possible contamination scenarios resulting from terrorist attacks was identified as a national vulnerability. The EPA would be responsible for the analysis of a large number of environmental samples in a short period of time putting a large demand on the nation's laboratory systems with respect to capacity and capability. NHSRC has the responsibility to research analytical methods to support the laboratories in measuring the many possible CBR agents that could be used in such attacks. Along with its partners, EPA has developed a document, *Selected Analytical Methods for Environmental Remediation and Recovery* (SAM), that compiles analytical methods which can be used during the remediation phase of cleanup. EPA is also working on additional documents such as collection procedures, companion documents, analytical protocols which support the SAM. This work is designed to help assure analytical methods exist to quickly and accurately identify selected agents and quantify residual contamination levels following decontamination.

III. QA REQUIREMENTS

The contractor must prepare a Quality Assurance Project Plan for approval by NHSRC. Work on NHSRC tasks cannot proceed until the contractor receives notification from the PO via e-mail that utilization of the QAPP is approved for use.

IV. DETAILED TASK DESCRIPTION:

The contractor shall perform the following tasks in support of SAM, SAM compendiums, development and verification of selected analytical and sample collection procedures, development and maintenance of a interactive web site and method development/verification addressing SAM analytes that may include 1) chemical 2) biological 3) radiological and 4) bio-toxins.

Task 0: Administration

The contractor shall develop a work plan that describes how each task will be carried out. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. The work plan shall also provide an analysis of the existing and projected constraints, and the feasibility of accomplishing the project's purpose. The work plan shall identify a schedule of activities/milestones leading to each of the final deliverables. The cost shall be based on individual sub-tasks and monthly report shall document cost/activities per subtasks. This task also includes monthly progress and financial reports. Monthly financial reports must include a table with the invoice LOE and costs` broken out by the tasks in this WA.

In addition, in each monthly progress report, the contractor shall, at the introduction to the discussion of this work assignment, discuss actual progress toward achieving the purpose of this work assignment, including problems encountered, issues that may need to be resolved, and anticipated timing for

completing the goals of the work assignment. The contractor shall provide an overview of contract projects, striving to implement efficiencies in performance when complimentary requirements are issued. The contractor shall assure that duplication of effort relative to other ongoing work assignments under this contract is not occurring.

Deliverables: Work plans, monthly progress and financial reports.

Task 1: Quality Assurance Project Plan (QAPP)

The contractor shall prepare a quality assurance project plan (QAPP) which ensures the quality of secondary data used to complete these tasks. Workplans shall explain that collection, use and analysis of data in this work assignment will be identical to the procedures described in the QAPP. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved.

Deliverables: Quality Assurance Project Plan (QAPP).

Task 2: Selected Analytical Methods for Environmental Remediation and Recovery (SAM) website

The contractor shall continue to develop and maintain the SAM interactive web page. The Contractor will upload and make searchable the most current revision of the SAM after each revision. The web page shall provide links as needed to SAM companion documents, past SAM revisions, analytical protocols, and sample collection plans. The web page shall also provide capability to receive and respond to comments. The contractor shall provide web page maintenance and monitoring, including log in of comments and response to comments. The Contractor is requested to propose specific steps/activities necessary to achieve desired goals.

Deliverables: Functional interactive web page updated as directed by WAM or Alternate WAM

Task 3: Selected Analytical Methods for Environmental Remediation and Recovery (SAM)

The Contractor shall support NHSRC in the updating and publishing of SAM revisions as requested. The Contractor shall support the planning and execution of each revision including (but not limited to): participate on SAM Core Team and/or workgroup meetings when requested, prepare meeting minutes, coordinate reviews (up to 4 per revision cycle), collect review comments, develop response to comment documentation for each review, resolution of comments with EPA WAM/Alternate WAM, prepare draft documents, prepare final document.

Deliverables: 508 Compliant SAM document

Task 4: SAM Companion Documents

The Contractor shall plan and execute, as requested, preparation of and /or updates to existing SAM related/companion documents. This will include, as applicable, up to 4 cycles of document review requiring coordination, collection of comments, preparation of response to comment documents, resolution of comments with EPA WAM/Alternate WAM, and updating draft document based on received and accepted comments.

Deliverables: 508 compliant documents - anticipate three documents during the option period.

Task 5: Laboratory Verification Studies for Chemical, Radiological and Biological Sampling and Analytical Protocols (SAPs)

The Contractor shall identify, coordinate, provide services of, and oversee laboratories conducting one chemical method verification for an existing draft Sampling and Analytical Protocols (SAPs) and/or existing documentation. Method verification/development will work toward identifying and confirming lowest detectable concentrations (or if available, EPA identified analytical target levels) in specified environmental matrix, such as, soil, water, air and surfaces. The goal of this work is to verify the method is sensitive and robust enough to detect contaminates at analytical target levels. For analytes without EPA analytical target levels (provided by the WAM/Alternate WAM), the Contractor shall coordinate with the WAM/Alternate WAM to provide a substitute number as a target level.
Contractor activities supporting each laboratory study under this task will require written technical direction from the EPA WAM/Alternate WAM. Information and data generated by the laboratories will be used to revise and improve the SAPs, and to establish performance criteria.

The following assumptions apply to work under this task:

- Labs participating in the verification effort are commercial labs under contract to perform lab work. (Electronic copies of draft SAPs will be provided by the EPA WAM/Alternate WAM as needed).
- Draft SAPs/methods shall include appropriate analytes currently identified in the most current revision of SAM. Appendix A provides general guidance/criteria for method verification/validation.
- Each draft SAP/method shall be laboratory verified, revised and/or developed as necessary and prepared for multi-lab validation.
- Each verification product will be suitable to initiate multi-lab validation. Each SAP verification project will be initiated by a Technical Directive (TD) issued by the WAM/Alternate WAM.

Following completion of each laboratory verification effort, the contractor shall recommend the revisions of applicable SAP based on study results. Such revision shall include items such as appropriate QC criteria, equipment and materials, instrument conditions, standard concentrations, spiking instructions, sample preparation procedures, procedures for handling interferences or analytical problems, and quality control performance criteria based on study results. In addition, any modifications and acknowledgments (e.g., participant laboratories) will be incorporated into each method.

The contractor shall also provide draft SAP documents to external and internal reviewers, including participant laboratories. This will include, as applicable, up to 4 cycles of document review requiring coordination, collection of comments, preparation of response to comment documents, resolution of comments with EPA WAM/Alternate WAM and study participants, and updating draft documents based on received and accepted comments.

Sub-task 5.1 Development of Laboratory Statements of Work

The contractor shall develop study designs and discuss the design of each study with the EPA WAM/Alternate WAM. Once a study design is approved by the EPA WAM/Alternate WAM and finalized, the contractor will develop a Study Plan to describe study organization and requirements. Study Plan components will include, at a minimum:

- Laboratory roles and responsibilities
- Study schedule
- Distribution of equipment, materials and samples
- Study sample types and number (e.g., reference and environmental matrices at various concentrations of analytes)
- Study sample preparation
- Spike compounds and concentration levels
- Samples for characterizing performance characteristics, including, but not limited to, those defined in Appendix B. Contractor shall recommend additional performance criteria necessary for this

study.

- Samples relating to quality control requirements for the SAP/method including, but not limited to, those discussed in Appendix C. Contractor shall recommend additional quality control criteria necessary for this study.
- Data and information requirements

The contractor shall also prepare laboratory Statements of Work to describe laboratory activities, schedules and reporting requirements. Statements of Work will specify the SAP(s) under evaluation, laboratory equipment requirements, and target analytes. The Statements of Work will be used to identify and procure qualified and interested laboratories under Sub-task 5.4.

Sub-task 5.2 SAP testing and verification support

The contractor shall provide testing, including limited method development, and verification support including identifying qualified laboratories for analytical methods development and verification for the analysis of SAM contaminants in a variety of environmental matrices. When possible, the contractor shall solicit voluntary participation from qualified laboratories. If needed, and upon concurrence by from the EPA WAM/Alternate WAM, the contractor will contract participant or sample preparation laboratories. The contractor shall ensure laboratories meet study schedules and provide sufficient data and information to prepare SAPs either for use in a follow-on study, or for use by multiple laboratories in the event of a homeland security event.

The contractor shall coordinate documents, prepare and ship study materials, standards and samples to participant labs, and shall serve as a resource for technical assistance throughout the period of each study. Specific activities under this sub-task may include:

- Recruitment of volunteer and/or contract laboratories and assessment of laboratory qualifications (e.g., experience with method instrumentation, similar compounds or organisms, and sample types)
- Development of detailed study instructions
- Procurement of consumable laboratory supplies
- Development of method-specific and study-specific data reporting forms
- Coordination with study participants, including EPA and other Federal or State laboratories
- Provide ongoing technical support to sample preparation and participant laboratories
- Provide logistical support to participating laboratories
- Provide technical support to participating laboratories to trouble shoot problems that arise directly from their participation in these studies (e.g., analytes not detected, positive control did not exhibit the appropriate response)

Sub-task 5.3 Data and Information Review

The contractor shall review, compile and analyze laboratory data and information relative to requirements in laboratory Statements of Work and Study Plan, and will consult with laboratories as needed to resolve data discrepancies. The contractor will evaluate study data, and use the data to (1) characterize method performance characteristics, such as those described in Appendix B, (for evaluation against the data quality objectives included in the draft methods), and (2) generate revised method quality control criteria (see Appendix C), if necessary, to ensure realistic data quality expectations are in place when the methods are used during site characterization and remediation activities. Activities performed during review of study data include:

- Track data submissions
- Review data packages for completeness

- Review preliminary data to identify discrepancies
- Address or resolve any data issues
- Develop study updates based on preliminary results
- Follow-up with laboratories to request additional information or clarify any notes or study results
- Compare data against method- and study-specific requirements
- Assess individual laboratory results to verify method ruggedness across multiple laboratories and sample types.
- Develop quality control (QC) criteria using appropriate control samples (e.g., spiked reference and environmental samples, see Appendix C).
- Prepare study data packages and summary reports to document data supporting each SAP

Deliverables: See Section V

Task 6: Technical Support for SAM Methods, Procedures, and Related Evaluation Studies

The Contractor shall provide technical support for work related to SAM products and SAM methods verification. This will include (but not limited to) the development of method reports, guidance documents, sample collection documents; statistical data analysis; study collaboration efforts; data review and analysis; preparation of comment/response documentation; participation in meetings and related meeting documentation; preparation of presentation and meeting materials. The contractor should plan on one trip to support this work.

Deliverables: See Section V

V. DELIVERABLES

Task	Deliverable	Due date
0	Monthly Report	Per contract requirements
1	QAPP	Draft 30 days after contract award, updated as necessary thereafter
2	SAM web page	Updated upon EPA request*, updated for a new revision of SAM with 30 days of SAM being published
3	SAM Document	508 compliant document by July 15, 2012.
4	SAM Companion Documents	Determined when requested by EPA*
5	Laboratory Studies: For each draft SAP/method:	
	Study Plan for EPA approval	10 Working Days following EPA request
	Lab SOW for EPA approval	5 Working days following approval of study plan
	Study report/method	30 working days following receipt of study task data (assumes 60 day for laboratory completion of each study task)
	Revised SAP/method based on method development/verification study*** (include analytical results/data package report**with basis for SAP/method changes)	30 working days following completion of final study report**
	Revise final SAP/method (ready for validation)	20 working days following receipt of final reviewer comments
	Publish SAP/method**	10 working days following EPA approval of

		response to reviewer comments
6	SAM products and SAM methods	Determined when requested by EPA*

* EPA will determine a schedule for delivery of a document/web update at the time of request

** It is expected that each SAP/method will be completed within a 1 year period. In response to the authorizing TD, the contractor shall provide a schedule to complete each SAP/method per the above schedule.

*** A template for format is suggested in Appendix A. Contractor shall recommend a uniform/standardized format for approval.

VI. REPORTING REQUIREMENTS

- Monthly Progress Reports (including a progress evaluation discussion)
- Financial Reports
- QA Supplemental report (if applicable)

VII. GREEN MEETINGS AND CONFERENCES

The contractor shall follow the provision of EPA prescription 1523.703-1, *Acquisition of environmentally preferable meeting and conference services (May 2007),* for the use of off-site commercial facilities for an EPA event, whether the event is a meeting, conference, training session, or other purpose. Environmental preferability is defined at FAR 2.101, and shall be used when soliciting quotes or offers for meeting/conference services on behalf of the Agency.

VII. TECHNICAL DIRECTION

All direction under this work assignment will be provided as written technical direction from the Work Assignment Manager (WAM) or Alternate WAM, as appropriate. The WAM or Alternate WAM is authorized to provide technical direction which clarifies the performance work statement as set forth in this work assignment. Before initializing any action under technical direction, the contractor shall ensure that the technical direction falls within the scope of the work and/or contract. Technical direction will be issued in writing or confirmed in writing by the WAM within (5) calendar days after verbal issuance. The COR will forward a copy of the technical direction memorandum to the Contracting Officer and Project Officer. Technical direction includes (1) direction to the contractor which assists the contractor in accomplishing this Performance Work Statement and (2) comments on and approval of reports and other deliverables. The Contracting Officer is the only person authorized to make changes to this work assignment or contract. Any changes must be approved by the Contracting Officer in writing, as an amendment to this work assignment and/or a modification to the contract.

QUALITY ASSURANCE SURVEILLANCE PLAN
for the Water Security Division's
Technical, Analytical, and Regulatory Mission Support
Performance Work Statement

Quality Assurance Surveillance Plan

The requirements contained in this work assignment are considered performance-based, focusing on the Agency's desired results and outcomes. The contractor shall be responsible for determining the most effective means by which these requirements will be fulfilled. In order to fulfill the requirements, the contractor shall design innovative processes and systems that can deliver the required services in a manner that will best meet the Agency's performance objectives. This performance-based requirement represents a challenge to the contractor to develop and apply innovative and efficient approaches for achieving results and meeting or exceeding the performance objectives, measures, and standards described below. The Contractor's performance will be reflected in the positive or negative evaluation offered by the Agency in the Past Performance Evaluation (PPE) which is evaluated annually (per the "Past Performance Evaluation" clause in the contract). The Work Assignment Manager shall submit a complete annual review of the areas outlined in the Quality Assurance Surveillance Plan (QASP), included in the contract, which will then be utilized by the Project Officer in preparing the overall evaluations submitted annually in response to the Past Performance Evaluation requirements in the contract.

General Management and Administration			
Performance Requirement	**Measurable Performance Standards**	**Surveillance Methods**	**Incentives/ Disincentives**
Management and Communications: The Contractor shall maintain contact with the EPA CO, PO and WAM throughout the performance of the contract and shall immediately bring potential problems to the attention of the appropriate EPA WAM. In cases where issues have a direct impact on project schedules and cost, the contractor shall provide options for EPA's consideration on resolving or mitigate the impacts	Any issues that impact project schedules and cost shall be brought to the attention of the appropriate EPA WAM within 3 business days of occurrence.	100% of active work assignments under the contract will be reviewed by the EPA WAM monthly (via monthly progress report) to identify unreported issues. The EPA WAM will report any issues to the EPA PO who will bring the issue(s) to the Contractor's attention through the CO.	**Unsatisfactory** rating under the category of Business Relations in the NIH Performance Evaluation System if two or more incidents occur when the contractor does not meet the measurable performance standards for a given contract period.
Timeliness: Services and deliverables shall be in accordance with schedules stated in each work assignment or tasking document, unless amended or modified by an approved EPA action.	Annually, 90% of all submitted deliverables shall be submitted no later than 6 business days past the due date	100% of active work assignments under the contract will be reviewed by the EPA WAM monthly (via monthly progress report & milestones established for each deliverable) to compare actual delivery dates against those approved. The EPA WAM will report any issues to the EPA PO who will bring the issue(s) to the Contractor's attention through the CO.	**Unsatisfactory** rating under the category of Timeliness in the NIH Performance Evaluation System when the contractor does not meet the measurable performance standards.

Cost Management and Control: The Contractor shall monitor, track and accurately report level of effort, labor cost, other direct cost and fee expenditures to EPA through progress reports and approved special reporting requirements. The Contractor shall assign appropriately leveled and skilled personnel to all tasks, practice and encourage time management, and ensure accurate and appropriate time keeping.	The contractor shall manage costs to the level of approved ceiling on the work assignment. The contractor shall notify the WAM/PO when 75% of the approved funding ceiling for the work assignment is reached.	The EPA PO will routinely meet with the Contractor's Project Manager to discuss the work progress and contract and individual work assignment expenditures. The EPA PO shall review the Contractor's monthly progress reports and request the WAMs verification of expenditures and technical progress before authorizing invoice payments.	**Unsatisfactory** rating under the category of Cost Control in the NIH Performance Evaluation System when the contractor does not meet the measurable performance standards.
Technical Effort: The analyses or products developed by the contractor shall be factual and defensible and based on sound science and engineering. All data shall be collected from reputable sources and quality assurance measures shall be conducted in accordance with agency requirements and any additional requirements outlined in individual work assignments or technical directives. Any work requiring the contractor to provide options or recommendations shall include the rationale used in selecting the option/recommendation and all other options and considered.	All analyses conducted for EPA by the Contractor must be factual and based on sound science and engineering. All analyses and products (initial and final drafts) shall conform in format and content to requirements specified by the WAM in written technical direction, and should meet the objectives stated in the work assignment. All initial draft documents shall be clearly written at a level appropriate to the targeted audience. All information shall be factual, technically sound, and accurate, with data sources identified. Draft versions of a document shall require no more than two editorial revisions.	EPA will review all analyses conducted by the Contractor and will independently consider the merit. EPA may opt to peer review analyses to further validate merit. The EPA WAM/TM will review initial drafts to assess technical accuracy and editorial quality. The WAM/TM will identify all inaccuracies and needed edits and corrections to the contractor in the initial review of draft documents	**Unsatisfactory** rating under the category of **QUALITY OF PRODUCT OR SERVICE** in the NIH Performance Evaluation System when the contractor does not meet the measurable performance standards. In addition, the Government may withhold fee payments associated with that segment of the work.

Socio-Economic Utilization: The Contractor shall assess all agency requirements outlined in work assignments for opportunities to fully utilize the knowledge and experience of its socio-economic team members. Work shall be allocated in a manner that ensures the Contractor's annual subcontracting goals are met.	The Contractor shall meet a standard of at least 80% of the dollar goals outlined in their subcontracting plan annually.	EPA will monitor the contractor's utilization of socio-economic firms by reviewing the contractor's submittal of Standard Forms (SF) 294 and (SF) 295.	If less than 80% is reached, the contractor shall outline the steps that will be taken to meet the annual goals outlined in their plan. Performance that does not meet the stated goals without sufficient justification will be reported as an **Unsatisfactory** rating under the category of **BUSINESS RELATIONS**, and **MEETING SDB SUBCONTRACTING REQUIREMENTS** in the NIH Performance Evaluation System.

Appendix A

The following terms and definitions are for use in method verification studies conducted under this PWS as adapted from "Method Validation Guidelines for Laboratories Performing Forensic Analysis of Chemical Terrorism", *Forensic Science Communications*, April 2005) prepared by FBI's Scientific Working Group on Forensic Analysis of Chemical Terrorism (SWGFACT).

Table 1: Summary Guidelines for Validating an Analytical Procedure

Procedure Purpose	Describe the purpose, which may include identifying unknown component(s); establishing presence and/or absence of specified analyte(s) and/or classes; quantifying specified analyte(s); and/or determining a physical property (e.g., mass, color, viscosity, flash point, particle morphology, crystalline structure).
Procedure Scope	Develop a clear and unambiguous statement defining the scope, which includes the matrix, target analyte(s), analytical technique, and intended purpose of the analytical procedure.
Selectivity	Describe the requirements of the analytical procedure with regard to selectivity. Describe experiments that should be performed to achieve the required selectivity. Consider the availability of reference materials, standards, matrix blanks.
Bias	Describe approaches used to assess bias, such as reference materials, alternate analytical procedures, or spike recovery.
Precision	Describe precision estimates, and state the range of conditions (e.g., analyte concentrations, matrices, instrumental parameters) over which the analytical procedure was validated.
Limit of Detection	Define the approach for estimating the limit of detection or provide a statement when this performance characteristic is not relevant to a validation.
Limit of Quantitation	Define the approach for determining the limit of quantitation.
Working Range	Describe the working range over which the analytical procedure was validated.
Calibration Model	Describe the type of calibration model acceptable to validate the analytical procedure. Assess linearity if applicable.
Critical Step	Provide any information about any steps that may be critical to the successful application of the analytical procedure.
Limitations	Identify all known limitations of the analytical procedure and its use. References list any previously documented analytical procedures referred to during the validation process. Include in validation documentation copies of analytical procedures that are not readily available.

Appendix B: Analytical Performance Characteristics

The following terms and definitions are for use in method verification studies conducted under this PWS as adapted from "Method Validation Guidelines for Laboratories Performing Forensic Analysis of Chemical Terrorism", *Forensic Science Communications*, April 2005, prepared by FBI's Scientific Working Group on Forensic Analysis of Chemical Terrorism (SWGFACT).

Accuracy

Accuracy is the extent to which an analytical result approaches the true value. The accuracy of an analytical measurement is related to the random error (precision) and the systematic error (bias).

Precision determination is made by repeating a measurement over a specified time frame appropriate for the intended analytical procedure use. The measure of precision will depend on the range of conditions (e.g., analyte concentrations, matrices, instrumental parameters) over which the analytical procedure is applied. The measurements should be made using the entire analytical procedure including all preparation and analysis steps.

Because the true value need not be known, a wide variety of materials may be used to assess precision, including reference materials, in-house quality control materials, and the actual samples of interest. Precision is typically expressed as the percent relative standard deviation (% RSD):

% RSD = standard deviation of measurements * 100% mean of measurements

Bias in an analytical procedure is determined by comparing the measurement result with the true value. Bias can be estimated by measuring materials of known composition, such as reference materials. Matrix matched reference materials are considered the preferred materials for estimating bias. When a suitable reference material is not available, bias may be estimated by the analysis of spiked samples. The behavior of the added analyte may differ from that of the native analyte, but spiking attempts to achieve the goal of matrix matching. Spike recovery is calculated as follows:

% spike recovery = (measured concentration spiked sample - measured concentration unspiked sample) * 100% concentration of spike contribution

Bias can also be estimated by comparing results obtained for the same samples using another analytical procedure with a known bias (i.e., a reference method).

Limit of Detection

The *limit of detection* is the lowest concentration or smallest amount of analyte that can be statistically differentiated from the analyte-free sample matrix. The limit of detection depends not only on the sensitivity but also on the instrumental noise and/or blank variability.

The *instrumental limit of detection* is a measure of instrument performance and is not sample matrix specific. It is a measure of either the instrumental signal-to-noise level or the variability of a standard blank. Of greater importance is the analytical procedure limit of detection. It incorporates not only the instrumental sensitivity and noise but also the variability induced by components of the sample matrix.

There are many approaches used to calculate the limit of detection; therefore, the laboratory should define its approach for determining a limit of detection.

The limit of detection may or may not be relevant in a validation study, depending on the concentration range and the intended purpose of the analytical procedure. For example, for analytical procedures when the analyte measured is always in the calibration range of the assay and well above the true limit of detection, it may be sufficient to indicate that the detection limit is "less than" the value of the lowest nonzero calibration standard.

Limit of Quantitation

The *limit of quantitation* is the lowest concentration or smallest amount of analyte that can be measured at a specified accuracy. There are many approaches used to calculate the limit of quantitation; therefore, the

laboratory should define its approach for determining a limit of quantitation.

The limit of quantitation may or may not be relevant in a validation study, depending on the concentration range and the intended purpose of the analytical procedure.

Linearity (or other calibration model)

Linearity is the extent to which an analytical procedure produces a signal directly proportional to the concentration or mass of the analyte of interest. Linearity (or other calibration model) is assessed by constructing a calibration curve (response versus analyte concentration) from known standards. Linear calibration models are frequently used, although various analytical procedures may yield acceptable nonlinear calibrations. The analyst can evaluate the linearity of the calibration curve by visual inspection or by using appropriate statistical methodology. The magnitude of the linear correlation coefficient, whereas sometimes used as a linearity measure, can be misleading. Depending on the number and spacing of calibration points, a visually nonlinear plot can lead to a correlation coefficient very close to one.

Working Range

Working range is the concentration or measurement range over which the analytical procedure has been validated. The concentration of the analyte of interest will have an effect on most analytical performance characteristics. Therefore, the analytical procedure should be validated for a working range consistent with its intended purpose.

The low end of the working range depends on the purpose of the analytical procedure. For example, if the purpose of the analysis at low concentrations is to simply indicate presence or absence of analyte, then the limit of detection may mark the low end of the working range. When accurate concentration values are needed, then the limit of quantitation may become the low end of the analytical procedure's working range.

If the analyte response exceeds the working range, the working range should be reestablished. A more common approach is to dilute the sample into the working range.

Selectivity

Selectivity is the extent to which an analytical procedure is free from interferences arising from nonanalytes, including matrix components.

Although it is possible to establish that an interference exists, it is more difficult to state that no interferences exist. Matrix interferences are usually sample specific and should be addressed on a matrix-by-matrix basis. Many instrumental analytical procedures have specific approaches that can be used to detect (and possibly circumvent) lack of selectivity. Some examples are the use of an alternate column in a chromatography method or the use of alternate emission lines in emission spectroscopy.

Another approach to assessing selectivity is using an alternate analytical procedure for reanalysis of the samples. This assessment is the most convincing when an independent or orthogonal analytical technique is employed. Orthogonal techniques respond to distinct characteristics of a particular analyte. Infrared spectroscopy and mass spectrometry are orthogonal to each other, whereas infrared and Raman spectroscopies are not orthogonal to each other.

Appendix C: False Positives and False Negatives

The following terms and definitions are for use in method verification studies conducted under this PWS as adapted from "Method Validation Guidelines for Laboratories Performing Forensic Analysis of Chemical Terrorism", *Forensic Science Communications*, April 2005, prepared by FBI's Scientific Working Group on Forensic Analysis of Chemical Terrorism (SWGFACT).

Several quality control considerations are especially important when applying an existing method to a matrix or analyte for which the analytical approach has not been validated. They should also be incorporated in a regular quality control program.

The *negative control (matrix blank)* is a sample that closely matches the samples being analyzed with regard to matrix components and is collected to establish the background level (presence and/or absence), of the analyte(s) of interest. It incorporates all the reagents employed in treating the samples of interest and is subjected to all sample-processing operations. Its role is to verify that the normal sample matrix does not interfere with or affect the analytical signal. The negative control may be difficult to obtain because many matrices cannot be closely matched or guaranteed to be free from analytes.

The *method blank* is a quality control sample that incorporates all the reagents employed in treating the samples of interest and is subjected to all sample processing operations. A method blank serves to verify that an identified component does not originate in the reagents, by cross contamination, or from the analytical process.

A *positive control* is a quality control sample containing the target analyte(s) and is subjected to all sample-processing operations. The positive control may be a spiked matrix similar to the one being analyzed, or it may be a reference material. The positive control serves to demonstrate that the analyte of interest would have been detected, if present, at or above a particular concentration.

Carryover is the addition of analyte from a sample or standard to subsequent samples in a series of analyses. Carryover should be evaluated as a part of the validation effort. Carryover can often occur during instrumental analysis. The incorporation of appropriate blanks at key points in the analytical workflow (i.e., after analyzing the standards) could demonstrate the absence of analyte carryover.