Re: Plan for urine collection

Elizabeth Allen to: Richard Kauffman 08/23/2011 05:35 PM

Cc: "David Farrer", "Jae Douglas", "Julie Early", "Kenneth G. (ATSDR/DHAC/EISAB) Orloff", Scott Downey, Sheila Fleming, "Sujata Joshi"

(b) (5)

[redacted]

Elizabeth

Richard Kauffman There is no merit to his concerns, and I think we... 08/23/2011 03:59:22 PM

From:	Richard Kauffman/R10/USEPA/US
To:	"Jae Douglas" <jae.p.douglas@state.or.us>, Elizabeth Allen/R10/USEPA/US@EPA, Scott Downey/R10/USEPA/US@EPA, Sheila Fleming/R10/USEPA/US@EPA, "Sujata Joshi" <sujata.joshi@state.or.us>
Cc:	"David Farrer" <David.G.Farrer@state.or.us>, "Julie Early" <Julie.Early-ALBERTS@state.or.us>, "Kenneth G. (ATSDR/DHAC/EISAB) Orloff" <keo1@cdc.gov>
Date:	08/23/2011 03:59 PM
Subject:	Re: Plan for urine collection

There is no merit to his concerns, and I think we should tell him so.
CAPT Richard R. Kauffman
Senior Regional Representative
ATSDR Region 10
RKauffman@cdc.gov
Cell (b) (6) [redacted]

From: "Jae P DOUGLAS" [jae.p.douglas@state.or.us]
Sent: 08/23/2011 03:43 PM MST
To: Elizabeth Allen; Scott Downey; Sheila Fleming; "Sujata JOSHI" <sujata.joshi@state.or.us>
Cc: "David G FARRER" <david.g.farrer@state.or.us>; "Julie EARLY-ALBERTS" <julie.early-alberts@state.or.us>; Richard Kauffman; "Kenneth G. (ATSDR/DHAC/EISAB) Orloff" <keo1@cdc.gov>
Subject: Re: Plan for urine collection

You were certainly right about OFS' concerns. Karen received this message from Terry Witt about his concerns...

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>>> "Terry Witt" <terry@ofsonline.org> Wednesday, August 17, 2011 5:43 PM >>>

KAREN: I have a difficult time accepting the new procedure you outlined in your memo below for collecting urine samples as it does NOT provide adequate QA/QC assurances.

It states in part: **"We are scheduling appointments directly with participants, and going door-to-door. We will provide a collection cup, and collect a urine sample on the spot. This approach maintains participant's confidentiality, allows a certain amount of schedule flexibility, and alleviates concerns related to collection methods."**

Allowing a participant to draw their own sample in an unsecured location (i.e. privately somewhere in their own home) does not insure the integrity or validity of the sample. You state it will maintain "confidentiality" but that will also include confidentiality as to what the person may or may not be doing to or with the sample. Under the current emotionally charged and adversarial circumstances, you must protect against falsification and doctoring of samples. Allowing sample collection to be done in a totally uncontrolled, unsecure environment provides no such safeguards.

Unfortunately I strongly disagree -- your new procedure does NOT alleviate OFS's concern about the collection method protocol and inadequate QA/QC.

Do we have any ideas about what can reasonably be done to increase confidence (i.e. temperature testing? anything else?)

Jae

>>> On 8/18/2011 at 11:58 AM, in message <4E4CFE7E.53B9.0007.0@DHS.STATE.OR.US>, Sujata JOSHI <SJOSHI@DHS.STATE.OR.US> wrote:

I meant to send this earlier in the week - I apologize for not getting it out until now.

Here is the plan for urine collection: ATSDR and OHA staff (3 teams of 2) will schedule

appointments (approximately 15 minutes) with participants at their homes. We will hand them a cup, and ask them to provide us with a sample. We will wait while they do their thing. They will hand us a warm cup. We will thank them for their time and leave.

Undoubtedly, this will still be of concern for folks at OFS. However, this is the last, final, unchangeable plan for the sample collection in August.

:)
-sujata

>>> <Kauffman.Richard@epamail.epa.gov> 8/15/2011 8:52 AM >>>
While waiting for the residents to collect a urine sample and provide it to us in the same visit will not eliminate all possible means of tainting the sample, it will clarify the chain of custody issues and eliminate many of the concerns being expressed. I had a voice mail from Terry Witt on this issue. If the cup of urine is warm when given back to us, we can be pretty sure it has been recently captured from their body.

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From:"Orloff, Kenneth G. (ATSDR/DHAC/EISAB)" <keo1@cdc.gov>
To:Elizabeth Allen/R10/USEPA/US@EPA, Sujata JOSHI <sujata.joshi@state.or.us>
Cc:David G FARRER <david.g.farrer@state.or.us>, Julie EARLY-ALBERTS <julie.early-alberts@state.or.us>, Karen BISHOP <karen.bishop@state.or.us>, Richard Kauffman/R10/USEPA/US@EPA, Sheila Fleming/R10/USEPA/US@EPA,

"Metcalf, Susan (ATSDR/DHAC/EISAB)" <swm1@cdc.gov>, "Moore, Susan (ATSDR/DHAC/EISAB)" <sym8@cdc.gov>, "Metcalf, Susan (ATSDR/DHAC/EISAB)" <swm1@cdc.gov>
Date:08/10/2011 04:17 AM
Subject:RE: issues re: urine sample collection

To play the devil's advocate, how would we know they didn't have someone else's urine hidden in the bathroom? What are we going to do- watch them pee in a cup to make sure it came from them?

We will proceed as planned.

Ken Orloff

-----Original Message-----
From: Allen.Elizabeth@epamail.epa.gov [mailto:Allen.Elizabeth@epamail.epa.gov]
Sent: Tuesday, August 09, 2011 9:19 PM
To: Sujata JOSHI
Cc: David G FARRER; Julie EARLY-ALBERTS; Karen BISHOP; Orloff, Kenneth G. (ATSDR/DHAC/EISAB); Kauffman.Richard@epamail.epa.gov; Fleming.Sheila@epamail.epa.gov; Metcalf, Susan (ATSDR/DHAC/EISAB)
Subject: Re: issues re: urine sample collection

A bit of clarification. Short of unannounced surprise urine tests, there is very little we can do in the unlikely event that someone chooses to intentionally expose themselves to Atrazine or 2,4-D as a means to ensure it is detected in their urine. Most simply, what is in question here is chain of custody procedures to provide us with defensible assurance that we know where the urine came from. Leaving sample containers at residences to be collected the following day leaves open to challenge that the urine sample was not actually obtained from the person to whom it is attributed. For these data to be usable in any way in this investigation, there must be a legally defensible chain of custody from the moment of sample collection to the lab.

Elizabeth

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From: "Sujata JOSHI" <sujata.joshi@state.or.us>
To: "Kenneth G. (ATSDR/DHAC/EISAB) Orloff" <keo1@cdc.gov>,
"Susan (ATSDR/DHAC/EISAB) Metcalf" <swm1@cdc.gov>
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<karen.bishop@state.or.us>, Richard
Kauffman/R10/USEPA/US@EPA
Date: 08/09/2011 04:44 PM
Subject: issues re: urine sample collection

Hi Ken,

Earlier today, we had a call with EPA to discuss some logistics for the environmental sampling. During the call, we talked a bit about the plan to collect urine samples (i.e., leave a collection cup with participants, and return the next day to collect the sample).

Elizabeth Allen, EPA's risk assessor on this investigation, brought this issue to our attention: There are some people (community members, industry groups) who believe that participants with strong opposition to the use of herbicides would go as far as "spiking" their urine by intentionally consuming or exposing themselves to atrazine and/or 2,4-D before providing a urine sample. Therefore, if we collect the urine samples in two appointments, any data from these samples will be viewed as unreliable or potentially tainted. The only way to collect defensible biosampling data would be to hand each participant a cup, and wait for them to collect a sample and hand it back to us.

This might sound far-fetched, but I do think it's something that would come back to haunt us (well, haunt the state agencies anyway). It's something that we heard during/after the community meeting, but I didn't