

1-2 – Q&A for "DOECAP-Accreditation Program and DoD ELAP Updates"

Presenters:

- Alyssa Wingard, DOE, EHSS-21
- William (Ed) Corl, PhD, Navy Laboratory Quality and Accreditation Office

	Asked by:	Question:
1	Meg Michell	<p>533 and 537 provide different holding times for PFAS. Holding times are not usually method specific for the same compound/matrix. Can any guidance be provided to establish holding times outside of methods for PFAS. EPA has not addressed this issue.</p> <p>This question was answered during the open forum.</p>
2	Debra D. Elliott	<p>Regarding not needing a rad license for non-rad samples, how are non-rad samples identified and handled? Are there separate lists/certs for those that have rad licenses versus those that don't?</p> <p>DOE sites do not traditionally possess "unknowns" for radiological samples posing radiological components above background. The DOE site will identify suspect areas and samples and coordinate with the laboratory on their needs for analysis prior to shipment or contracting. If there is the potential for suspect radiological components, then the site will make that determination and contract with the appropriate laboratories. If the area being sampled is suspect, meaning the sample is coming from an area that has not been historically free from any radiological component exposures or contamination, the laboratory will require a radiological license. If not suspect, then no license would be necessary.</p> <p>Answered by: Alyssa Wingard and Steve Clark</p>
3	Virgene Mulligan	<p>DOE is saying that labs do not have to have a material license if they are receiving nonradioactive samples. How is DOE defining a nonradioactive sample?</p> <p>DOE sites do not traditionally possess "unknowns" for radiological samples posing radiological components above background. The DOE site will identify suspect areas and samples and coordinate with the laboratory on their needs for analysis prior to shipment or contracting. If there is the potential for suspect radiological components, then the site will make that determination and contract with the appropriate laboratories. If the area being sampled is suspect, meaning the sample is coming from an area that</p>

		<p>has not been historically free from any radiological component exposures or contamination, the laboratory will require a radiological license. If not suspect, then no license would be necessary.</p> <p>Answered by: Alyssa Wingard and Steve Clark</p>
4	Phil Clark	<p>How do DOE sites send out samples as non-rad? In particular, for PFAS analysis?</p> <p>If the sites know the area was never contaminated, or is free of radiological contamination then the sample could be treated as non-radioactive samples. These determinations are to be made by the site of sample origination and coordinated with a laboratory able to process such samples. In these cases, a radiological license would be required.</p> <p>Answered by: Alyssa Wingard and Steve Clark</p>
5	Linda Harper	<p>What does your company do to qualify TSDF's to remain on your Qualified Suppliers List when the DOECAP report exceeds 3 years? We have been using the EPA ECHO report with the most recent state inspection report.</p> <p>If you talking about a clean harbors for haz waste not rad or mixed waste. It is on you to conduct the review for their suppliers lists once every 3 years.</p> <p>Answered by: Alyssa Wingard</p>
6	Marty Brewer	<p>What geotechnical parameters are labs accredited for? There seem to be very few labs accredited for geotechnical.</p> <p>The project should decide what testing requires accreditation. Laboratories can choose which methods for which they seek accreditation. For Air Force PFAS projects, usually only the PFAS testing requires accreditation, and the physicochemical testing can be accomplished by a non-accredited lab. Analysis of geotechnical or physicochemical parameters is generally not considered "definitive" testing and accreditation is not required.</p> <p>Answered by: QAOS</p>

Presenter:

- Adrian Hanley

	Asked by:	Question:
1	Meg Michell	<p>For the FTSs labeled standards, the issue may be a poor match for the injection internal standard. Is there any effort to find better matches?</p> <p>That seems unlikely. 18O2-PFHxS is the NIS for the 3 FTS EIS compounds as well as for 13C3-PFBS and 13C3-PFHxS. If the problem were with the NIS, you also would expect to see very high recoveries for both 13C3-PFBS and 13C3-PFHxS. Moreover, because the NIS is only injected, not extracted, its chemical similarity with the EIS compounds is less of an issue than the match of the EIS and the target analyte.</p> <p>Answered by: Adrian Hanley</p>
2	Tom Gilroy	<p>With discussions of including PFAS in NPDES permits, will it be added to the DMRQA study as well?</p> <p>The Clean Water Act Methods Program does not run the DMRQA study. However, assuming that we approve Method 1633 at 40 CFR Part 136, issue effluent guidelines that includes some of the PFAS covered by the method, and those regulated PFAS make it into individual discharge permits, I believe that some of those regulated PFAS will eventually be included in DMRQA studies.</p> <p>Answered by: Adrian Hanley</p>
3	Mohammad Ahmed	<p>1663 method , or any other method for PFAS using solid phase extraction , method should have some guideline when aqueous field sample come with even little sediment , it's takes way longer to filter and sometime it's just not filtering , method should have clear guideline what to do.</p> <p>Agreed, and we are planning to add more guidance on this in the final method, but as you note, it is an issue common to all SPE methods. Even with additional guidance, some of the problems will have to be addressed at the laboratory level with training and internal guidance as well.</p> <p>Answered by: Adrian Hanley</p>

1-4 – Q&A for "Method 1633 QSM Table B-24 Update"

Presenter:

- Janice Willey

	Asked by:	Question:
1	Mohammad Ahmed	<p>Once the final 1633 method comes out will that supersede all other current method and you only need this method to do all matrices and what about drinking water permit? Will they change to new method 1633?</p> <p>The scope of EPA Method 1633 does not include finished drinking water; EPA Methods 537.1 and 533 do. EPA Methods 537.1 and/or EPA Method 533 should be used for the analysis of drinking water samples.</p> <p>Answered by: Janice Willey & Adrian Hanley</p>
2	Meg Michell	<p>When the confirmation ion is not detected, the labs currently do not calculate a ratio and do not flag the data. What should they be doing?</p> <p>Per Section 15.1.1 of EPA Method 1633, for a target analyte to be identified in a sample, the quantitation AND confirmation ions peak responses must meet the specified S/N, retention time, and IAR requirements. If the required confirmation ion is not detected, the analyte is not detected in the sample and should be reported as a non-detect.</p> <p>Answered by: Janice Willey & Adrian Hanley</p>
3	Jennifer Keys	<p>For 1633, will temperature recommendations be revised?</p> <p>Temperature recommendations will not be revised in the next version of the method.</p> <p>Answered by: Janice Willey & Adrian Hanley</p>
4	Jeanne Mensingh	<p>What is too long a time period for a laboratory to determine their own derived limits?</p> <p>A minimum of 30 data points are required to generate laboratory-derived limits. Laboratories should follow their standard protocols for the generation of limits; the process to generate limits for PFAS should be no different than the process used for other methods.</p> <p>Answered by: Janice Willey & Adrian Hanley</p>

5	Meg Michell	<p>Method 1633 has confirmation ions for some EIS. If an ion ratio is out for an EIS, what should be done?</p> <p>This was answered during the presentation. Answered by: Adam Teufel</p>
6	Lisa Stafford	<p>Would you please provide a link for the paper on interferences for PFBA and PFPeA?</p> <p>Bangma, J., McCord, J., Giffard, N., Buckman, K., Petali, J., Chen, C., Amparo, D., Turpin, B., Morrison, G., & Strynar, M. (2023). Analytical method interferences for perfluoropentanoic acid (PFPeA) and perfluorobutanoic acid (PFBA) in biological and environmental samples. Chemosphere, 315, 137722. https://doi.org/https://doi.org/10.1016/j.chemosphere.2022.137722 Answered by: Janice Willey & Adrian Hanley</p>
7	Elizabeth Wessling	<p>Can you please restate the Level 4 validation criteria/frequency?</p> <p>Please see Section 4.4 of the DoD General Data Validation Guidelines. Answered by: Janice Willey & Adrian Hanley</p>
8	Marty Brewer	<p>Please clarify finished drinking water. What about treated systems that are not regulated? Private wells using groundwater?</p> <p>Finished drinking water is water that has been treated (coagulation, flocculation, sedimentation, filtration, and disinfection) prior to use. Private wells using groundwater have not gone through these processes, therefore are not finished drinking water. Answered by: Janice Willey & Adrian Hanley</p>

1-5 – Q&A for "EPA PFAS Methods Update, Part 2"

Presenter:

- Erin Shields

	Asked by:	Question:
1	Meg Michell	When will a draft version of OTM-50 be made available?

		By the end of the year (2023). Answered by: Erin Shields
2	Sarah Fischer	<p>Any theories why incinerated sulfonates were destructed more efficiently than carboxylated PFAS?</p> <p>The main theory (with some support from experiments and modeling) is that carboxylic acids are products of incomplete combustion. Carboxylic acids can form from FTOHs, and 1H-fluorocarbons in the atmosphere from hydrolysis and oxidation reactions (work by Mabury). So it would be expected that the PFCAs can be formed faster at high temperatures with water, oxygen, and carbon dioxide around. There are several instances where carboxylic acids (especially PFBA) appear to be formed or are harder to destroy in other destruction technologies. Some field tests have shown more PFCAs in the emissions too (occasionally because of scrubber water contamination). We are working on some experiments to determine if they are formed during PFAS destruction or not.</p> <p>Answered by: Erin Shields</p>

1-3 – Q&A for "EPA PFAS Methods Update, Part 1"

Presenter:

- Adrian Hanley

	Asked by:	Question:
1	Meg Michell	<p>For the FTSs labeled standards, the issue may be a poor match for the injection internal standard. Is there any effort to find better matches?</p> <p>That seems unlikely. 18O2-PFHxS is the NIS for the 3 FTS EIS compounds as well as for 13C3-PFBS and 13C3-PFHxS. If the problem were with the NIS, you also would expect to see very high recoveries for both 13C3-PFBS and 13C3-PFHxS. Moreover, because the NIS is only injected, not extracted, its chemical similarity with the EIS compounds is less of an issue than the match of the EIS and the target analyte.</p> <p>Answered by: Adrian Hanley</p>
2	Tom Gilroy	With discussions of including PFAS in NPDES permits, will it be added to the DMRQA study as well?

		<p>The Clean Water Act Methods Program does not run the DMRQA study. However, assuming that we approve Method 1633 at 40 CFR Part 136, issue effluent guidelines that includes some of the PFAS covered by the method, and those regulated PFAS make it into individual discharge permits, I believe that some of those regulated PFAS will eventually be included in DMRQA studies.</p> <p>Answered by: Adrian Hanley</p>
3	Mohammad Ahmed	<p>1663 method , or any other method for PFAS using solid phase extraction , method should have some guideline when aqueous field sample come with even little sediment , it's takes way longer to filter and sometime it's just not filtering , method should have clear guideline what to do.</p> <p>Agreed, and we are planning to add more guidance on this in the final method, but as you note, it is an issue common to all SPE methods. Even with additional guidance, some of the problems will have to be addressed at the laboratory level with training and internal guidance as well.</p> <p>Answered by: Adrian Hanley</p>

1-6 – Q&A for "SERDP/ESTCP PFAS Methods Update"

Presenter:

- Janice Willey

	Asked by:	Question:
1	Jennifer Keys	<p>Should we expect a revision to the prohibited sampling equipment list in the near future? Will sunscreen and Sharpies still be prohibited based on Jennifer Field's study?</p> <p>Yes, the EDQW white paper on sampling and analysis will be updated to reflect recent studies and the requirements of published EPA methods.</p> <p>Answered by: Janice Willey & Adrian Hanley</p>

1-7 – Q&A for "QSM v6.0: Overview of Quality Systems Manual"

Presenter:

- John Gumper

	Asked by:	Question:
1	Carol Gebhart	<p>6.2.7 what is meant by “certification” as certification implies there was an evaluation, and the result was a pass so certificate issued. Is an exam expected or is a signed declaration indicating training occurred accepted?</p> <p>Part of 6.2.7 requires that the employee “understands” the document so there is an expectation that understanding is evaluated. An exam for every document is not required but the certification should include some record of understanding (employee acknowledgement is sufficient). Answered by: QAOS Subgroup</p>
2	Carol Gebhart	<p>6.4.13i. Regarding records for instrument settings and configurations. Is it acceptable to have this defined in the SOP or are screenshots of what was used during actual analysis required?</p> <p>The laboratory shall provide a record of set of records that indicate what instrument settings were for a specific result. Different approaches to meeting this requirement are acceptable. The SOP itself is not a record of what instrument settings were used. Answered by: QAOS Subgroup</p>
3	Carol Gebhart	<p>6.4.14a. What is meant by “catastrophic failure” as this will mean something different for clients, labs, etc. does this mean anything outside of acceptance or is it continued outside tolerance (and what is the time to determine)?</p> <p>“Catastrophic” will be removed from the standard and the clause will be clarified to indicate that any deviation outside of the acceptance criteria will require implementation of the nonconforming work process. Answered by: QAOS Subgroup</p>
4	Mohammad Ahmed	<p>It was mention of client does not want to follow the DOD QSM requirement than lab has to apply for waiver Why lab has to go through the waiver process, why this is not client responsibility who is not following DOD QSM</p> <p>If the request for deviation originates with the customer, then a waiver is not required. Records of customer communication shall be maintained.</p>

		Answered by: QAOS Subgroup
5	James Elliot	<p>If a Prime requests a specific exception for a specific project, does the lab have to get a formal waiver to implement it? If so, what's the consequence if they implement it without a waiver? (Again, for a specific project)</p> <p>If the request for deviation originates with the customer, then a waiver is not required. Records of customer communication shall be maintained.</p> <p>Answered by: QAOS Subgroup</p>

1-8 – Q&A for "QSM v6.0: M1 – Proficiency Testing Module Updates"

Presenter:

- John Gumper

	Asked by:	Question:
1	Carol Gebhart	<p>Average and standard deviation are easily influenced by data that results in non-normal distribution and can be misleading, In such cases can labs use median and Zmad for alternate evaluations of performance</p> <p>At this time, we are only evaluating precision and bias based on standard deviation and recovery.</p> <p>Answered by: QAOS Subgroup</p>
2	Ryan Scheanwald	<p>If you have varying LCS spikes for one matrix/method/analyte combination and there is no PTP or 17043 provider, would a PT concentration between and the lowest LCS spike use be considered valid for the FoA or would a PT in each range be required?</p> <p>The concentration of the spikes used for PT shall be between the LOD and the highest concentration LCS. LCS shall be at or below the midrange of the calibration.</p> <p>Answered by: QAOS Subgroup</p>
3	Vicky Collom	<p>If pt provider 1 does not offer all foa analytes in a pt standard but pt provider 2 offers them - do you need to use provider 2? The extra analytes are not TNI fopts and by the way are never spiked in the pt studies of provider 2.</p>

		<p>If both PT samples are provided as a part of a FoPT, then either provider is acceptable. This also applies to aroclors.</p> <p>Answered by: QAOS Subgroup</p>
4	Carol Gebhart	<p>Pass and fail criteria for 2/3 rounds doesn't eliminate bias. Will the DOD/DOE be using Z-score or other performance trending to assess long term measuring system issues?</p> <p>The DoD/DOE has no plans to include additional trend assessments.</p> <p>Answered by: QAOS Subgroup</p>
5	Carol Gebhart	<p>ABs are changing to not requiring PT reports to be submitted and these are instead reviewed during annual assessment activity. Does this mean the ABs will need to revert?</p> <p>The QAOS will have a discussion with ABs and evaluate the proposed reporting requirements.</p> <p>Answered by: QAOS Subgroup</p>
6	Michele Sanders	<p>What does lists of FoPTs mean- is it a table of PTs or PT sources. What if you aren't TNI approved laboratory and you don't have access to TNI website?</p> <p>A FoPT is a set of matrix, technology/method, analyte combinations for which the composition, spike concentration ranges, and acceptance criteria have been established by TNI's Proficiency Testing Program Executive Committee. FoPT samples are publicly available. The FoPT Lists are at the TNI website and are also publicly available. https://nelac-institute.org/content/NEPTP/fopt.php</p> <p>Answered by: QAOS</p>

2-1 – Q&A for "QSM v6.0: M2 – Quality System General Requirements: Implementation and Updates"

Presenter:

- Kathi Gumper

	Asked by:	Question:
1	Mohammad Ahmed	Determining frequency and content quality record , what if lab has things automized and data is proceed automatically with out any

		<p>manual entries , what sort of documentation is required , similar when there are no manual log books for analyst to wire and it's all electronic. Determining frequency and content quality record , what if lab has things automized and data is proceed automatically with out any manual entries , what sort of documentation is required , similar when there are no manual log books for analyst to wire and it's all electronic</p> <p>If there are no manual changes to data, then there is no record required for manual changes to data. Records of changes to electronic data shall be maintained.</p> <p>Answered by: QAOS Subgroup</p>
2	Mohammad Ahmed	<p>Data loggers : if we are taking every 2 hours , let's say data loggers was scheduled to take a temperature every 2 hour and than here comes 2 pm and analyst opened the door at same time to put the samples or take the samples out , that particular point reading will be recorded higher so these instances are there when data loggers will be used</p> <p>The potential impacts of the frequency of data logger measurements should be evaluated by the laboratory. In the case outlined, the laboratory would need to follow their nonconforming work process.</p> <p>Answered by: QAOS Subgroup</p>
3	Ryan Scheanwald	<p>Refrigerator/freezer verification: The slide stated that non-conforming procedures must be enacted if data loggers show that the equipment is out of ± 2 C or out of control for >2 hours. The right column stated the refrigerator requirement is 0-6 C. If a storage refrigerator is set at 3 C and the data logger shows 5.1 C, is that non confirming or within 0-6C?</p> <p>No, the requirement for instituting nonconforming work is being outside of the acceptance criteria, which is 0-6 degrees C. 5.1 degrees, C is not an exceedance of the acceptance criteria.</p> <p>Answered by: QAOS Subgroup</p>
4	Jeanette Ardiente	<p>If a standard is not a CRM, do you have to run an independent verification with every calibration? Or is it possible to verify only once when opened?</p> <p>If not using a CRM, a second source verification must be run with every initial calibration.</p> <p>Answered by: QAOS Subgroup</p>

5	Carol Gebhart	<p>As ICV no longer required for 17034 standards, what about “buyer beware”? As even 17034 accredited vendors can have lot mistakes.</p> <p>The QAOS has determined that 17034 accreditation meets the minimum needs for the program. Evaluation of providers of products and services is required as a part of the laboratory’s evaluation of risk.</p> <p>Answered by: QAOS Subgroup</p>
6	Mohammad Ahmed	<p>Digestion and extraction is added what about distillation?</p> <p>Distillation will be added to the requirement.</p> <p>Answered by: QAOS Subgroup</p>
7	Elizabeth Wessling	<p>Section 7.5 records retention - whose use of the data? The end user may rely on underlying data for years after the laboratory does.</p> <p>This refers to the laboratory’s use. Note that the requirement defines use as supporting current laboratory activities.</p> <p>Answered by: QAOS Subgroup</p>
8	Vicky Collom	<p>The auxiliary equipment table 6-1 for thermometers indicates that correction factors are the acceptance criteria. If tolerances are being used and the thermometer is within tolerance there should be no corrective action - right?</p> <p>Right. Note that the laboratory is required to define this as a part of their risk evaluation.</p> <p>Answered by: QAOS Subgroup</p>
9	Salima Haniff	<p>table 6.1 list CF as acceptance criteria - does this mean that thermometer verifications no longer need acceptance criteria or range? is there an acceptable CF? When is the CF not acceptable?</p> <p>The QAOS will evaluate the organization of this table to ensure clarity.</p> <p>Answered by: QAOS Subgroup</p>
10	Mitzi Miller	<p>Section 6.5 In radchem many crms are not 17034. In addition running second source may be from the same and only vendor. In some cases count times preclude running ICV. Will ABs allow permanent waivers for these cases?</p>

		<p>Sent Alyssa and Steve an email. Do we need to make a revision?</p> <p>We are requiring CRMs to be used for calibration. We are requiring CRMs to be used for calibration. We use to require the ICV from a different source because there were not as many available certified reference materials in the past. However, if I understand your questioning, if there is no available ISO 17034 source, then yes, an exception will be necessary. However, the laboratory must still keep checking for any changes in availability of any 17034 sources. There will not be an assumed “permanent” waiver, just in case there is one that makes it to market.</p> <p>From Definitions: Authoritative Source (for CRMs): An authoritative source for reference materials is an organization such as a manufacturer, government organization, or designated repository that can provide reference materials with known or appropriate identity and purity for laboratory use. Use of such materials may be mandated by customer or regulator or may be the best materials available in lieu of availability of SRMs or CRMs from an ISO 17034-accredited provider.</p> <p>In addition running second source may be from the same and only vendor. There should already be language in the QSM to allow for this contingency.</p> <p>In some cases count times preclude running ICV. I cannot think of an example where count time would be a concern during initial calibration. Our intent is to have Initial Calibration Verification reasonably addressed in the pending revisions to the B-tables. Will ABs allow permanent waivers for these cases? Given the Authoritative Source language and the contingency language for sole source, there should be reasonable consideration by the ABs for the limited Rad standards on the market.</p> <p>Answered by: QAOS</p>
11	Carol Gebhart	<p>Comment not question When there is an 17025 requirement to be eliminated as stated with no additions, please use same format as module 2 sections 1 and 2 so it is clear something wasn't skipped (like 7.6 and 7.9).</p> <p>Those “skipped” sections will be added back into the document for clarity.</p> <p>Answered by: QAOS</p>

2-2 – Q&A for "QSM v6.0: M2 – Hazardous and Radioactive Materials Management and Health and Safety Practices"

Presenter:

– Steve Clark

	Asked by:	Question:
2	Stephanie Atkins	<p>It has been stated that DOE accredited laboratories are not required hold a RML. Does this also mean that those laboratories are exempt from the radioactive materials management plan requirements specified in 9.1; even though, samples may be coming from a DOE site?</p> <p>if there are suspect radioactive samples then yes, screening must be performed upon receipt. However, no license would be required. this would be addressed in your sample receipt management procedures.</p> <p>Answered by: Steve Clark</p>
1	Carol Gebhart	<p>Does the training need to be provided by external provider?</p> <p>RSO training is dictated by the license and state requirements.</p> <p>Answered by: QAOS Subgroup</p> <p>FOLLOW-UP QUESTION: The question regarding the other trainings as RSO is external, but HAZWOPER could be both and others (9.6.1b through e) could be created internally. The question was aimed at ensuring if there was ambiguity around whether it should be internal or external and the DOE has a preference it should be stated.</p> <p>Answer: The CFR can help more so since it identifies who can provide training and to whom, and at what frequency. Some states have additional requirements. HAZWOPER training requirements are based on the OSHA HAZWOPER Standard (29 CFR Part 1910.120) that applies to workers who are exposed to or handle hazardous materials. The main HAZWOPER training requirements are:</p> <ul style="list-style-type: none"> - 40 hours of off-site instruction and 3 days of field experience for general site workers and on-site management and supervisors - 24 hours of off-site instruction and 1 day of field experience for specific limited tasks or treatment, storage, and disposal facilities - 8 hours of annual refresher for all workers impacted.

		I would encourage each lab to check with their local and state HW regulators to work out specific requirements for their location. Answered by: QAOS
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2-4 – Q&A for " QSM v6.0: M4 – Update to the Chemical Testing Requirements"

Presenter:

– John Gumper

	Asked by:	Question:
1	Michele Sanders	If the laboratory does not report below the LOQ, the only quarterly requirement is to verify the LOQ on a quarterly basis. Is this correct? Correct. Answered by: QAOS Subgroup
2	Michele Sanders	7.1.1.k Why has the requirement for % relative error been added? EPA methods include criteria for coefficient of determination or coefficient of correlation and do not require % relative error. This evaluation is consistent with TNI module 4 and the QAOS believes it supports appropriate data quality for the program. Answered by: QAOS Subgroup
3	Marty Brewer	Does matrix specification only apply to method validation or also to reporting? Is it necessary for land to report soils separately thsn sediments, groundwater vs surface water? Please resubmit question with additional details. Answered by: QAOS Subgroup
4	Caprielle Larsen	When a lab modifies a reference method using the process described in the QSM, is the method listed as "mod" or "modified" on the lab's DoD-ELAP scope of accreditation, and the DENIX Accredited Lab Search? Modifications outside of those allowed by reference methods themselves should be listed as modifications on the laboratory's scope of accreditation and identified as such in DENIX. Answered by: QAOS Subgroup

5	Paul Junio	<p>While QSM 6 no longer requires an ICV when CRMs are used, don't the reference methods still require them (in general)?</p> <p>If the method requires an ICV, then it is still required to be performed. As methods are updated by the publishers, the ICVs are being removed.</p> <p>Answered by: QAOS Subgroup</p>
6	Paul Junio	<p>A point of clarification - TNI Module 4 already references non-zero calibration standards. This is not a change.</p> <p>Thank you.</p> <p>Answered by: QAOS Subgroup</p>
7	Mohammad Ahmed	<p>Results should not be reported above the highest response or concentration ?</p> <p>Results should not be reported above the concentration of the highest calibration point without qualification. If possible, samples should be diluted and rerun to be within the calibration range. Please further clarify the question if this does not address your concern.</p> <p>Answered by: QAOS Subgroup</p>
8	Ammie Martin	<p>With the change that a laboratory can report not detected data with high biased failing QC, will the DV SOPs be updated not to qualify this data?</p> <p>Data Validation Guidelines will be updated after the publication of QSM 6.0.</p> <p>Answered by: QAOS Subgroup</p>
9	Ryan Scheanwald	<p>With the removal of the CCV 2x rerun requirement, are laboratory allowed to rerun a CCV once after a failure and proceed with an acceptable second CCV result?</p> <p>Laboratories are required to view the failure as nonconforming work and take action, unless there is a clearly identifiable reason which only affected the CCV.</p> <p>Answered by: QAOS Subgroup</p>

10	Paul Junio	<p>MS/MSD are stated as required unless specifically exempt by the applicable method. Do you mean "exempt by" as opposed to "not required by" the applicable method?</p> <p>The QAOS group will evaluate this wording to ensure clarity. Answered by: QAOS Subgroup</p>
11	James Elliot	<p>Is site knowledge acceptable confirmation?</p> <p>No. Answered by: QAOS Subgroup</p>
12	Jeanette Ardiente	<p>Regarding confirming chromatography without a mass spectrometer, do the requirements also apply to ion chromatography?</p> <p>No, because those methods do not recommend or require second column confirmation. Answered by: QAOS Subgroup</p>
13	Ammie Martin	<p>Industry wide confirmation of direct aqueous injection VOAs and dissolved gases (e.g., RSK SOPs) is not common, even among QSM accredited laboratories. Will these now also require confirmation?</p> <p>No, because those methods do not recommend or require second column confirmation. Answered by: QAOS Subgroup</p>
14	Jannie Shaw-Busby	<p>Since Aroclors are the only allowance for not spiking all analytes in the LCS, does it mean that you now have to spike multi peak analytes such as toxaphene and chlorodane in pesticide methods?</p> <p>Yes. Answered by: QAOS Subgroup</p>
15	Mohammad Ahmed	<p>MS/MSD is not same as lcs , we deal with super fund sites and SVOC extracts concentrated down to 1ml they are black and viscous and expecting same recovery levels between LCS and MS/MSD is not logical and practical.</p> <p>The use of the LCS acceptance criteria is to allow the data user to know when the results are affected by the matrix. There is no requirement for the laboratory to reprepare or reanalyze samples due to MS or MSD failures.</p>

		Answered by: QAOS Subgroup
16	Elizabeth Wessling	<p>Does the lab need to acknowledge Arovlor peaks which do not confirm or just Arovlors that do not confirm?</p> <p>Yes, if the laboratory has Aroclor peaks that do not confirm, then need to acknowledge this in the report. Please provide further clarification if this does not address your concern.</p> <p>Answered by: QAOS Subgroup</p>
17	Kristin Lammers	<p>So the labs do not need to report or analyze all TAL of a method? It is up to the customer to indicate what they are looking for? What if you have a sample you do not know the exact compounds then state you want the entire TAL?</p> <p>The customer should specify which analytes they are requesting, which may be either the entire analyte list or a subset of analytes.</p> <p>Answered by: QAOS Subgroup</p>
18	Robert Hrabak	<p>In situations where the lcs is high and samples are non-detect or when ms/msd are out, is there a need to reshoot to confirm?</p> <p>The LCS would not need to be reanalyzed to confirm a failure. The LCS would not need to be reprepared and analyzed for field samples report as non-detects.</p> <p>The MS/MSD would not need to be reanalyzed to confirm a failure.</p> <p>A caveat is that one reason to reanalyze (reshoot) would be if the failure was a result of a bad injection.</p> <p>Answered by: QAOS</p>
19	Carol Gebhart	<p>The requirement as written for the %RE is to evaluate the lowest non- zero standard. Sometimes labs use a calibration standard below the LOQ. Would it make sense to evaluate the LOQ level standard for %RE instead of as the lowest non- zero standard ?</p> <p>Yes, it would be appropriate to evaluate the LOQ level standard for %RE. The requirement will be modified in Module 4 and the B-Tables to clarify the LOQ standard or lower concentration standard may be used when calculating the low-end %RE.</p> <p>Answered by: QAOS</p>

20	Michele Sanders	<p>7.3.2.e Will Appendix C not be required to use for LCS Acceptance Criteria?</p> <p>For batch control, LCS acceptance criteria should come from the customer, Appendix C limits, or the laboratory-developed limits, respectively.</p> <p>Answered by: QAOS</p>
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2-5 – Q&A for "QSM v6.0: M8 – Industrial Hygiene"

Presenter:

– John Gumpper

	Asked by:	Question:
1	Jessica Helland	<p>Will we get a response to our last comments on the new B tables?</p> <p>Yes, responses will be sent.</p> <p>Answered by: QAOS Subgroup</p>
2	Michele Sanders	<p>In Modules 8 and 3 it states that the modules cover requirements for laboratories seeking accreditation for Industrial Hygiene Testing. If a Laboratory is already certified by AIHA-LAP, an international accreditation organization, does the laboratory have to participate in these two modules?</p> <p>If the laboratory wishes to obtain accreditation to this standard, they must follow the requirements in the applicable modules.</p> <p>Answered by: QAOS Subgroup</p>
3	Michele Sanders	<p>Are the Accrediting Bodies certified to audit to Module 3 Asbestos and Module 8 Industrial Hygiene? We believe that a laboratory with DOECAP accreditation for Asbestos and Industrial Hygiene testing and without AIHA-LAP or NVLAP accreditation put themselves at risk of being sued if analysis results are challenged and found to be wrong.</p> <p>This will be addressed in the revised Conditions and Criteria with the ABs for both DoD and DOE. Projects are free to determine which accreditation is appropriate for their data needs. Laboratories are encouraged to evaluate which accreditations they wish to hold.</p> <p>Answered by: QAOS Subgroup</p>

4	Jessica Helland	<p>8.2.3 the requirement for commenting on lack of enough sample for MS and MSD or MD is overly burdensome to labs because the vast majority of IH samples are single shot, the whole sample is consumed during prep. Can it be removed or changed?</p> <p>The requirement for MS/MSD is not a part of the IH methods. Answered by: QAOS Subgroup</p>
5	Mohammad Ahmed	<p>Media blank e.g in digestion why it can't be DI water? you basically not introducing anything else when digesting the samples as per procedure. so why media has be sand, beads and not water?</p> <p>For IH testing the media blank will usually be some type of sorbent media that could introduce contamination. For testing of solids, the addition of sand or glass beads simulates the digestion process where some techniques may require a solid matrix to work properly (e.g., microwave digestion). Answered by: QAOS</p>

2-6 – Q&A for "QSM v6.0: Reporting Requirements"

Presenter:

- Nancy Cooper

	Asked by:	Question:
1	Marty Brewer	<p>Stage 4 lab report & same stage data validation required for waste characterization samples as project site samples? What stage report & data review required for waste samples?</p> <p>This would be a project decision. Answered by: QAOS</p>
2	Marty Brewer	<p>What is the criteria for documenting Q delete similar to manual integrations?</p> <p>The requirement is to retain records of the laboratory eliminating "false positives" (e.g., "Q delete") and the review of that decision. The QSM does not require those records be included in the report. Answered by: QAOS</p>

3	Meg Michell	<p>Will the sample result form require extract splits (where only part of the extract goes through the remaining procedure)? It impacts result calculations but is often not included at this summary level.</p> <p>The summary form does not require identifying volumes of extract splits.</p> <p>Answered by: QAOS</p>
4	Elizabeth Turner	<p>if client does not provide collect time does the lab state hold time could not be verified or do we not address the hold time issue at all?</p> <p>If the laboratory calculates a holding time violation and qualifies results based on the most conservative collection time, then the case narrative should indicate the qualification and lack of collection time provided by the customer. The collection time on the report should indicate only a date was provided.</p> <p>Answered by: QAOS</p>
5	Elizabeth Wessling	<p>To facilitate Stage 2B validation, can you add a requirement to document by method whether or not a CRM standard was used for calibration. That way the validation team will know that an ICV is not required.</p> <p>Good question! QAOS is drafting language to add this as a requirement in Section 7.8.</p> <p>Answered by: QAOS</p>

2-7 – Q&A for "QSM v6.0: Detection and Quantitation"

Presenter:

- Melinda McClellan

	Asked by:	Question:
1	Mohammad Ahmed	<p>LOD, MDL, why do we still have MDL number, any data reported below CRQL is flagged with estimated regardless so this statical number should not carry on , LOD makes more sense. emphasis should be achieving lower CRQL and report any positive hit under CRQL as an estimated and we do not need LOD AND MDL. Labs are spending way too many resources to have this done every quarter</p>

		<p>The MDL is a statistically derived number representing the instrument response that can be proven to be different than zero. In other words, a response above the MDL indicates that an analyte is certainly present.</p> <p>The LOD is an approximation of the concentration at which, if the analyte were present, there would be a 99% chance that it would be detected. In other words, if we do not detect the analyte (i.e., the instrument response was below that of the MDL), then we can be quite certain that the concentration is below the LOD.</p> <p>The LOQ, which is sometimes used as a reporting limit, is the concentration at which we begin to have known precision and bias, therefore a quantitative value can be reported.</p> <p>It is often the case that environmentally relevant concentrations fall near or below achievable laboratory LOQs. Therefore, it is important that we maintain the ability to accurately report presence and absence below the LOQ. While it is true that these values below the LOQ are qualitative in nature, they still provide important decision-making information to our projects.</p> <p>Consider the following example which illustrates the difference in reporting detections between the DL and LOD and non-detect results (i.e., results below the DL):</p> <p>DL (MDL) =1 LOD = 3 LOQ = 10</p> <p>Result = 15; Reported result 15 Result = 5; Reported result 5J (estimated) Result = 2; Reported result 2J (estimated) Result = 0.5; Reported result 3U (<3)</p> <p>Answered by: QAOS</p>
2	Carol Gebhart	<p>There are three values that are on the report (MDL, LOQ, and LOR) and all three are adjusted for factors. Is it possible that the MDL doesn't change? So this is the lab DL and it doesn't go smaller with changes in sample size. Of course the DL will be adjusted up as the factor requires but not down. Would the DOD/DOE accept this?</p>

		<p>The values for DL, LOD, and LOQ are always adjusted for sample-specific factors such as mass, volume, and dilution factors. These values will go up as samples are diluted or smaller sample masses or volumes are used for preparation. These values may go down if larger masses or volumes are used for preparation, as allowed by the reference methods.</p> <p>Answered by: QAOS</p>
3	Ammie Martin	<p>If the LOQ is < low calibration level, how are results not estimated between the LOQ and the low calibration level?</p> <p>The LOQ may not be set lower than the lowest calibration standard or the lowest check standard in the situation of a single-point calibration such as for certain metals methods.</p> <p>Answered by: QAOS</p>
4	Ammie Martin	<p>Will the databases be updated to now handle DL = LOD? They would not in the past due to data checkers run.</p> <p>Individual database managers will need to be contacted to determine how they intend to proceed with screening data. To the knowledge of this subgroup, DoD owned data systems will be modified to accept the appropriate data quality including the modification of data checkers to match with updated requirements.</p> <p>Answered by: QAOS</p>
5	Mohammad Ahmed	<p>Since reporting any concentration below the CRQL are estimated there is no point to have that LOD. same way you said price to me if LOD =DI , it's practically impossible , all mdl for each analyses are different even if someone try to run it to try to prove the point probably have to run 100 times .</p> <p>See response to question 1 above. Results below the LOQ are indeed estimated values; however, appropriate and accurate reporting of the presence or absence of an analyte can provide important information to DoD/DOE projects.</p> <p>Whether the DL and LOD for an individual analyte for a specific analysis may be equal will depend upon the concentration at which LOD spikes were initially run and passed acceptance criteria. It is not</p>

		<p>expected or required that these values will be equal for any particular analysis.</p> <p>Answered by: QAOS</p>
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2-8 – Q&A for "DOE/DoD Open Forum"

Presenter:

- All Presenters

	Asked by:	Question:
1	Ethan Turner	<p>General question about PFAS. I recognize that it is primarily an environmental concern. In terms of characterization of mixed and radioactive waste from DOE sites, is there potential for PFAS characterization to be included in the acceptance criteria of any of the treatment and disposal facilities at some point? Thanks.</p> <p>This question was answered during the open forum.</p>
2	Mohammad Ahmed	<p>For DOE sites, what's the ratio of work do you see between soil and drinking water /Waste water?</p> <p>This question was answered during the open forum.</p>
3	Nisreen Saikaly	<p>The laboratory commonly provides worksheets 19, 23, 24, 25, and 28 for QAPPs and SAPs. These worksheets sometimes contain errors and omit essential information. Is there a possibility to establish a mandate for laboratories to systematically review and incorporate these worksheets as appendices to their associated Standard Operating Procedures? This is for all analyses not just PFAS.</p> <p>This question was answered during the open forum.</p>
4	Marty Brewer	<p>Not in any sessions, but can we require labs to provide standardized UFP-QAPP worksheets based upon optimized WS guidance? Many labs reluctant to provide them or they are not complete or accurate.</p> <p>This question was answered during the open forum.</p>
5	Marty Brewer	<p>TSS screening/treatment for 1633 ironed out? 1633 versions & lab accreditation?</p> <p>This question was answered during the open forum.</p>

6	Salima Haniff	<p>Will typical TSS short hold time be in effect or will it be extended to 28 days?</p> <p>This question was answered during the open forum.</p>
7	Alexander Kegley	<p>What is the DoD stance on whether non-detect sample results may be reported without qualification when associated with QC fails above its acceptance criteria? (aka high-bias, non-detect)</p> <p>This question was answered during the open forum.</p>
8	Alexander Kegley	<p>Can you provide guidance on efficient ways of signing manual integrations? Is a per-sample signature acceptable in lieu of a per-analyte signature?</p> <p>This question was answered during the open forum.</p>
9	Alexander Kegley	<p>At what point does an addition to the laboratory become a new entity requiring its own accreditation? When the addition is across the street? Across town? Has a separate management structure?</p> <p>This question was answered during the open forum.</p>
10	Matthew Beaupre	<p>Modified methods reporting-if a method is modified, and data is reported via that modified method, for the sake of transparency, wouldn't it make sense to make it required to spell out the method is modified within the lab report/data package as a requirement? And wouldn't it be disingenuous if it wasn't reported as a modified method? I.e. 537.1 vs 537.1 Modified</p> <p>This question was answered during the open forum.</p>
11	Elizabeth Wessling	<p>How will recurring findings be tracked between the old and new QSM organization and numbering systems.</p> <p>Accreditation bodies shall determine how findings between accreditation visits performed under different versions of the QSM will be tracked. DoD/DOE does still expect findings are tracked between accreditation visits and that repeat findings are identified.</p> <p>Answered by: QAOS</p>

3-1 – Q&A for "Incremental Sampling Methodology"

Presenter:

- William (Ed) Corl, PhD, Navy Laboratory Quality and Accreditation Office
- Nicolette Andrzejczyk, PhD, NAVFAC Engineering & Expeditionary Warfare Center
- Anthony Danko, PhD, NAVFAC Engineering & Expeditionary Warfare Center

	Asked by:	Question:
1	Mohammad Ahmed	<p>I believe DOD AND DOE should have their own department to perform the in incremental sampling and sub sampling protocol, this will be more proactive for both labs and DOD/ DOE. Less cross continuation issue, less delay in data, one central location where all samples are sieved and dried and shipped.</p> <p>Mohammad, thanks for the suggestion. A centralized laboratory to handle ISM samples is an interesting idea. Unfortunately the logistics and costs involved would prevent that from being viable. Table B30 will be included in QSM version 6 that will specify ISM specific requirements for PAH's in soil.</p> <p>Answered by: Ed Corl</p>
2	Meg Michell	<p>Was moisture added to the blank soil used in the PAH ISM study? What can you tell us about the characteristics of the blank soil used (e.g., sieved to a certain size etc)</p> <p>No moisture added. The soils were dry as received. However, a little moisture is beneficial for microwave and labs were free to add if their procedures allow for it. Thanks Ed</p>
3	Ammie Martin	<p>Table B30 if the RSD fails on the replicate and the batch was ground would they only need to reprepare or qualify that sample? It is logical that if it didn't work for that sample it likely didn't work for the remainder and all samples should be reprepared.</p> <p>Agree! Thanks for this one. Yes, if they milled the sample and it failed the 30% criteria there might be something else going on. They could pull more sub samples from the original or just rerun. Ed</p>
4	Elizabeth Wessling	<p>Why not use the added deuterated compounds as EIS isotopes?</p> <p>This question was answered during the open forum.</p>

5	Jay Clausen	<p>More of a comment than a question. CRREL has developed and tested an ISM methodology for metals which is documented in a number of CRREL Technical Reports and journal publications. The intent was to provide this methodology as an Appendix to Method 3050 similar to what was done for Method 8330. Unfortunately, the planned update to 3050 has yet to be released by the USEPA.</p> <p>As we discussed Jay. Thanks. I will share with the EDQW. Hope we can have a beer sometime before you retire! Ed</p>
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3-3 – Q&A for "Data Review and Management Update"

Presenter:

– Melinda McClellan

	Asked by:	Question:
1	Ammie Martin	<p>Based on the importance of the field notes/data, especially the water quality parameters, has a validation guideline for validation of field data been considered?</p> <p>The Data Review and Management Subgroup will consider the development of guidelines for the validation of this data; however, we do not have a guideline in development at this time. Individual projects are encouraged to work with the project team to determine the appropriate type and extent of validation and to document those requirements in the project QAPP or SAP.</p> <p>Answered by: QAOS</p>