DoD Quality Systems Manual (DoD QSM)
Frequently Asked Questions (FAQs)
(Updated October 2011)

General

Question: (Appendix F) Do the Table F requirements apply to methods such as Methods 624, 625, etc.?

EDQW Response: No, Table F requirements only apply to methods based on the listed SW-846 methods.

Question: (Appendix F) Did the EDQW review EPA Method Updates IV prior to releasing DoD QSM Version 4?

EDQW Response: Yes. However, the Appendix F tables still contain QC requirements that may be different from the latest published EPA SW-846 methods but have been determined by the EDQW to be necessary.

Question: Do the requirements listed in Appendix F of the DoD QSM apply to CLP methods?

EDQW Response: If a laboratory is seeking DOD ELAP accreditation for a CLP method, then all requirements of that method (as opposed to the method specific requirements for SW-846 methods contained in Appendix F of the DoD QSM) would apply and be evaluated.

Quality Systems and Proficiency Testing (PT)

Question: (NELAC 4.1.1.1 and Gray Box 3) Do you intend for all Technical Directors to be held to the requirements with regards to the microbiology 4 hour course?

EDQW Response: The qualification requirements for Technical Director are NELAC requirements and should be applied in the same manner as required for NELAP accreditations.

Question: (Gray Box 10) Requirements on subcontracting in Gray Box 10 conflict with 4.5.1, which requires subcontracted work to be performed by a NELAP-accredited laboratory.

EDQW Response: When Gray Boxes conflict with NELAC text, the Gray Box will be followed.

Question: Can an approved laboratory outsource its data processing department?

EDQW Response: Yes. However, all data processing steps must be performed by organizations/personnel who comply with the subcontracting requirements of the DoD QSM. The subcontracted entity may be another DoD ELAP accredited laboratory or subcontractor personnel who provide this service in compliance with the laboratory's quality system.

Question: (Gray Box 23) For PTs for multi-component methods where the 80% rule applies, if a laboratory fails the analyte twice in a row but passes the 80% rule; are corrective actions required for that compound?

EDQW Response: Yes.

Question: Are PT results acceptable for all methods that use the same technology when the lab reports results from just one of the methods in cases where their results were produced using an SOP that combines similar methods?

EDQW Response: The laboratory must prepare, analyze, and report the results for their PTs using each method that is under the scope of their accreditation.

Question: Does the QSM requirement for acceptable PT performance cover only those PT samples recognized in the 2003 NELAC FOT tables or does the requirement cover all appropriate PT samples available from providers that are manufactured, sold, and scored according to NELAC approved procedures?

EDQW Response: Acceptable PT performance covers all appropriate PT samples available from providers that are manufactured, sold, and scored according to NELAC approved procedures. Any method on the scope of accreditation must have an acceptable PT regardless whether it is on the NELAC 2003 FOT, if available.

Question: Does the DoD ELAP allow for the evaluation of PT results using the requirements in the 2009 TNI standard?

EDQW Response: The EDQW allows PT providers to report using the 2009 TNI standards, and ABs evaluating results based on the 2009 TNI PT process.

Question: (Gray Box 24) Do the requirements for the Demonstration of capability (DOC) apply to all methods or just laboratory-developed methods?

EDQW Response: All methods.

Question: Do LCS studies for on-going DOCs have to be consecutive?

EDQW Response: If on-going DOCs are verified using LCS results, they must be based on consecutive LCS studies as required by NELAC. However, a laboratory is not required to generate an on-going DOC study by analyzing four new LCS. The laboratory can document DOCs based on historical data by evaluation of four LCS's from consecutive runs.

Question: Does a prep method DOC require that they be associated with a specific analytical method?

EDQW Response: Yes.

Question: (Gray Box 44) What is meant by technical completeness and accuracy?

EDQW Response: In the context of Gray Box 44, completeness and accuracy mean that all required elements of the client's data package are included and accurately reported.

Support Equipment

Question: (Gray Box 31) Can the NMI calibration checks be done by state agencies or others?

EDQW Response: Yes, if the state agency qualifies as an NMI.

Question: (Gray Box 31) Is a thermometer reading of 6°C acceptable when the requirements are 0°C to 6°C?

EDQW Response: Yes.

Question: (Gray Box 31) If you use weights "daily" as "support equipment" do they need more than a 5-year re-check?

EDQW Response: No.

Question: (Gray Box 31) What correction factor are you going to use when you get different correction factors at the two temperatures the thermometer is checked at?

EDQW Response: The laboratory must have a scientifically valid and documented procedure for determining correction factors. The laboratory procedure should address this issue or the thermometer should be replaced.

Question: (Gray Box 40) "If temperature blank is not available, other procedures may be used (e.g., IR Gun)". An assessor asked how the IR Gun is covered under the Gray Box 31 requirements.

EDQW Response: The performance checks for the IR Gun will be the same as the electronic thermometer requirements of Gray Box 31. (Please note that the beam size on and the thermal emissivity of the surface of sample containers affect the accuracy of temperature measurement by IR Gun.)

Quality Control (QC) and Calibration

Question: (Gray Box D-2) For PCBs other than 1016/1260, does a lab need to re-prep/reprocess and provide multi-point QC if another Aroclor is identified?

EDQW Response: If an Aroclor other than 1016/1260 is identified in the sample, the laboratory shall use a multi-point calibration of that Aroclor of concern to quantify the Aroclor.

Question: Can a laboratory default to the DoD LCS limits to control their batches, or do they have to use their in-house limits?

EDQW Response: Yes, a laboratory may use the DoD LCS limits for the purpose of batch control; however, it must also generate in-house limits for the purpose of detecting trends in its processes.

Question: (Appendix F Tables) Does the "not forced through the origin" apply to all types of calibration curves?

EDQW Response: No, see Appendix F tables for specific requirements.

Question: (Appendix F) Are methods 8260C and 8270D compliant with DOD QSM requirements? Table F-4 discusses SPCC and CCC response factor acceptance criteria. The most recent versions of these methods do not establish these criteria. However, the revised methods do establish minimum response factors for certain target analytes, which our calibrations must meet.

EDQW Response: The Table F appendix is based on all SW-846 method versions available at the time of publication, regardless of status (promulgated, draft, or proposed). The requirements in this appendix represent the minimum requirements for DoD regardless of method version. If there is a contradiction between the method and the following tables, the requirements specified in the tables shall be followed unless project- specific or regulatory approval is required.

Question: (Appendix F) Table F-12: Interference Check Sample (ICS), Tuning, and Interference Threshold study are not requirements of Methods 6850 and 6860. Are these requirements incorrectly listed in Table F-12?

EDQW Response: No, they are not incorrectly listed. The MCT, ICS, tuning, and interference threshold study requirements are not included in Methods 6850 and 6860; however, they were intentionally included in Table F-12. These requirements were intentionally "carried forward" from earlier methods and must be met for Methods 6850 and 6860. The MCT is applicable to Methods 6850 and 6860 because high levels of common anions and total dissolved solids could affect the integrity of these analyses in the same manner as Method 314.0 is affected. Laboratories should follow the guidelines presented in Method 314.0 for determining the MCT. This is a needed step due to the wide range of instrument setups (instruments, columns, and mobile phases) that are being used. Some columns have been proven to be greatly affected with time, by high levels of common anions and total dissolved solids. Columns that have been affected by these factors may no longer be capable of meeting the recovery and perchlorate ratio criteria. The tuning solution is essentially a perchlorate standard. Most laboratories dilute a high concentration perchlorate standard for this use. Tuning is required. The Interference Threshold Study is required, as this information and the MCT will help determine the suppressor levels in the ICS.

Question: (Appendix F) For Method 8310, if an analyte was detected using the UV detector; does a fluorescence detector satisfy the requirement of being a "second detector" for confirmation?

EDQW Response: Yes, the fluorescence detector is an acceptable confirmation for Method 8310, unless a project specifies another means (GC or GC/MS).

Question: For 8260/8270 internal standards verification QC check, the QSM states that the acceptance criteria is "Retention time ± 30 seconds from retention time of the midpoint standard in the ICAL; EICP area within -50% to +100% of ICAL midpoint standard." Can the verification be based on the CCVs rather than the midpoint ICAL?

EDQW Response: The internal standard retention time must be ± 30 seconds from retention time of the midpoint standard in the ICAL on days an ICAL is performed. On days when an ICAL is not performed, the daily initial CCV is used. The EICP area must be within -50% to +100% of the ICAL midpoint standard at all times. (Appendix F, Table F-4)
It should be noted that Methods 8260C and 8270D require the evaluation of area to be against the midpoint of the calibration as well, and do not allow updates by daily initial CCV area (Section 7.10 of Method 8260C and Section 7.5.2 of Method 8270D).

Question: For 8270, can the DDT breakdown check be eliminated if there are no pesticides as target analytes?

EDQW Response: No, DDT breakdown is a system check for injector inertness, and is applicable to all the analytes, not just pesticides (Appendix F, Table F-4).

Question: If ICP results are never reported above the high standard, does a linear dynamic range standard still need to be run?

EDQW Response: Yes, a linear dynamic range standard must be run every 6 months and evaluated as required by Appendix F Table F-7. However you may analyze your high calibration standard to satisfy this requirement.

Question: According to QSM, for Method 8330B triplicates are collected during the subsampling process from a sample expected to contain highest levels of explosives within the Quantitation range. What happens if there are data points that are non-detected or less than the RL within the triplicate results?

EDQW Response: For QSM compliance, only triplicate results greater than the RL (or LOQ) are to be used for calculating and evaluating RSD.

Question: For method 8330B, how is soil holding time determined? Is it after the samples are collected, after they are dried or after they are ground?

EDQW Response: Sample hold time starts when the sample is removed from nature (i.e. after the samples are collected). In the case of Method 8330B, soil samples should be treated just like the analysis of base neutral acids (semi-volatiles) in soil samples, which require that hold time start after samples are collected in the field.

Question: Is a soil grinding blank required between each sample for Method 8330B?

EDQW Response: A soil grinding blank is required between each 8330B sample, regardless of the type of grinding performed.

Limit of Detection (LOD) and Limit of Quantification (LOQ)

Question: (Gray Box D-13) What are the acceptable ways to determine the signal to noise ratio with regard to the LOD verification?

EDQW Response: The apparent signal to noise ratio at the LOD must be at least three and the results must meet all method requirements for analyte identification (e.g., ion abundance, second-column confirmation, or pattern recognition.) For data systems that do not provide a measure of noise, the signal produced by the verification sample must produce a result that is at least three standard deviations greater than the mean method blank concentrations. The signal to noise ratio must be performed using a scientifically valid and documented procedure.

Question: (Gray Box D-13) "Limit of Detection (LOD) must be verified quarterly on each instrument." An assessor asked for clarification in regards to if the laboratory does not currently have DoD projects – must they still meet the requirements?

EDQW Response: Yes, the requirement for quarterly LOD verification must be followed to maintain accreditation under the DoD ELAP.

Question: Are methods not covered by Table F (e.g., drinking water methods) required to meet the LOD and LOQ verification requirements in the QSM?

EDQW Response: Yes, LOD/LOQ verifications must be determined for any method listed on the laboratory DoD Scope of Accreditation, except in cases where it would not be appropriate to do so (e.g., pH methods).

Question: The Tables in Appendix F discuss an RL for method blank criteria. Is this supposed to be the LOQ?

EDQW Response: No, an RL is a customer defined project specific reporting limit. The Appendix B Glossary gives the definition of reporting limits – "Reporting Limit: A client-specified lowest concentration value that meets project requirements for quantitative data with known precision and bias for a specific analyte in a specific matrix." An LOQ is a laboratory determined quantitation limit and may or may not be equal to the project specified RL. However, in no case, may the laboratory's LOQ be greater than the project specific RL if they both have compatible precision and bias.

Question: The LOD and LOQ are performed initially followed by quarterly verification on each instrument. For several methods different combinations of preparation techniques are employed (e.g. clean-up steps). Does a laboratory have to perform an LOD and LOQ verification using all the possible combinations of preparation techniques or can the laboratory perform its most common combination to perform the LOD/LOQ? Does the laboratory have to report the LOD/LOQ preparations and analytical steps used and that this differs from the preparation techniques reported for the samples analyzed?

EDQW Response: As a minimum for DOD-ELAP accreditation, each preparation method listed on the scope of accreditation must have quarterly LOD/LOQ verifications. Not all possible combinations of preparation and cleanup techniques are required to have LOD/LOQ verifications. However, if LOD/LOQ verifications are not performed on all combinations, the laboratory must base the LOD/LOQ verifications on the worst case basis (preparation method with all applicable cleanup steps).

Question: The QSM does not state that the LOD can be greater than the spiking level. If we can establish that we can see the LOD and the level is acceptable for the project does it matter that the spiking level is below the LOD?

EDQW Response: The DoD QSM version 4.2 allows LOD checks of the detection limit (DL) at "greater than 1-4x" for multi-analyte standards. The spike concentration does establish the LOD. Although it is not explicitly stated in the QSM, it is valid to allow the reported LOD to be higher than the spiking level if the original spiking level meets the LOD check criteria.

Question: Could a laboratory set its LOD at the DL, if LOD verification at 1 times the DL passes?

EDQW Response: No. Version 4.2 of the QSM requires that the LOD be "greater than 1-4x" of the DL for multi-analyte standards and "2-3x" the DL for single analyte standards, with the spiked value establishing the LOD. Equating the LOD and DL either results in an artificially inflated DL or an unsustainable LOD. Either of these conditions may result in the laboratory providing data that is not suitable for the project's intended use.

Question: Section D.1.2.2. (b) of the DoD QSM states that a laboratory should verify LOQ annually. QSM Box D-14 states that for DoD Projects the LOQ must verify, at a minimum, quarterly. Please clarify whether the lab established LOQ should be verified annually or quarterly.

EDQW Response: Section D.1.2.2. (b) is NELAC language, which requires an annual LOQ verification. Box D-14 requires that the LOQ be set within the calibration range and then verified quarterly. Box D-14 supersedes the language in section D.1.2.2.b. A quarterly LOQ verification is required in lieu of an annual verification.

Question: Do precision and bias measurement need to be evaluated across the entire analytical calibration range for both standard and non-standard methods for IDOC?

EDQW Response: It is only necessary to determine precision and bias for the initial demonstration of capability (IDOC) across the analytical calibration range for non-standard methods. When performing IDOC for standard methods, the laboratory must perform four LCS runs at acceptable precision & bias, as determined by the laboratory. These LCS's do not have to be over the entire calibration range.

Reporting Requirements

Question: If project-specific requirements are less stringent than DoD ELAP requirements, can the AB logo and certification number still be displayed on the report?

EDQW Response: Yes, unless prohibited by the ABs.

Question: How are precision and bias at the LOQ to be reported?

EDQW Response: Precision and bias (recovery and %RSD at the LOQ) for each analyte and matrix must be reported in the laboratory report unless documented concurrence by the DoD client for not reporting this information is available.

Question: (Appendix E) On reports, are the laboratories required to list DL, LOD, and LOQ? What is the minimum?

EDQW Response: The laboratory must report the LOD and LOQ along with associated precision and bias for environmental restoration projects unless the DoD client provides documented instructions that this is not required.

Question: (Appendix E) Does the statement "The following information is optional but may be required site-specifically" apply to the last 9 bullets under number 4, or the rest of the list (numbers 5 thru 7)?

EDQW Response: This option applies to the last nine bullets of number 4 only.

Question: The QSM in Appendix E requires info that shall be on the cover sheet. What if this information is elsewhere, like page 2? Is that acceptable?

EDQW Response: Yes. However, Appendix E only applies in the absence of client specified reporting criteria.

Question: Do the date and time have to be included in the report?

EDQW Response: Yes, Appendix E states that results reported for each sample shall contain the date and time the sample is analyzed and extracted or prepared unless noted elsewhere in the data package. In any case, all results must be reported in accordance with project requirements.

Question: For manual integration audit trails – is it acceptable to narrate that "before" integrations can be provided to the client upon request?

EDQW Response: For DoD projects, if raw data (e.g., chromatograms, mass spectrum results) are to be reported to the client, the "before" and "after" manual integrations shall be reported.

Question: Is it acceptable to report the client specified control limits only and not the laboratory in-house control limits?

EDQW Response: The laboratory may report the client specified limits, since they take precedence (see bullet 1 in the text box, page G-1); however, according to the QSM citation in the question (bullet 1, page G-6) the lab must also report their in-house control limits if they are outside the DOD control limits.

Question: Are dioxins/furans treated differently with regard to reporting results? Do dioxins/furans have LODs? Would it be acceptable for a laboratory to report results with LOQ and EDL/EMPC (regardless of whether or not there are LODs)?

EDQW Response: Dioxins/furans are not treated differently with regard to reporting results and they do have LODs, as well as method required EDLs. Laboratories shall follow the requirements for DL/LOD/LOQ (plus the method-specified EDL) as shown in Table F-6 of QSM. It is acceptable to report non-detect values to the EDL in lieu of the LOD, but that would be a project specific requirement only, and will not alleviate the need to determine the LOD.

Question: The DOD QSM requires the flagging of associated compounds when surrogates do not meet the established criteria, what does “associated” means?

EDQW Response: In the DoD QSM "associated compounds" are considered to be compounds that are of the same class as the surrogate (i.e. volatiles, acid extractable and base neutrals). If the surrogate for one of these classes does not meet the established criteria, then the associated compounds are flagged.