

DoD Quality Systems Manual for Environmental Laboratories (DoD QSM)

1. **Question:** The QSM is not consistent with the new TNI standard.

EDOW Response: True. The TNI standard has not yet been implemented by the states. At such time as the TNI standard is implemented by the states, the DoD QSM will be revised to reflect the new standard.

2. **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?

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

3. **Question:** **Gray Box 10:** – Subcontracting. Requirements in Gray Box 10 conflict with 4.5.1 which requires subcontracted work to be performed by a NELAP-accredited laboratory.

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

4. **Question:** **Gray Box 14:** When is the start and stop time of sample preparation required to be recorded?

EDOW Response: Both date and time of preparation and analysis are considered essential information, and must always be reported, regardless of the length of the holding time. For the purpose of batch processing, the start and stop times of the batch preparation shall be recorded.

5. **Question:** **Gray Box 15:** – audit personnel must be “trained and qualified”, what does this mean?

EDOW Response: Laboratories shall determine the training and qualification requirements for audit personnel and shall establish procedures to ensure that audit personnel are trained and qualified (i.e. have the necessary education and/or experience required for their assigned positions). The requirements and procedures must be documented.

6. **Question:** **Gray Box 15:** What is acceptable training for a Quality Manager to conduct internal audits?

EDQW Response: The laboratory shall have procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the tasks of the individual within the laboratory. The Quality Manager must have documented training and/or experience in QA/QC procedures and be knowledgeable in the quality system as defined in the NELAC standards. The quality manager plans and organizes audits; such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

7. **Question:** **Gray Box 20:** Which SOPs are considered exempt from the yearly review cycle? What are considered Administrative SOPs?

EDQW Response: The quality manual and all technical SOPs (e.g., sample preparation, analytical procedures, sample storage, sample receipt, etc.) shall be reviewed for accuracy and adequacy annually and whenever method procedures change, and updated as appropriate. All such reviews shall be documented and made available for assessment.

Non-technical SOP's that are not required elements of the quality manual (e.g., personnel policies, timekeeping procedures, payroll, etc.) are considered Administrative SOP's and are not required to be reviewed annually.

8. **Question:** **DoD Gray Box 21:** What constitutes a method deviation? For example, are changes in stoichiometry, or change in eluent for HPLC (if all the components are resolved) considered deviations? It is understood that all calibration and quality control must meet criteria regardless of change.

EDQW Response: Method deviations are changes to requirements of a published method; however, methods must meet quality control requirements of the appropriate Appendix F table.

9. **Question:** **Gray Box 23:** – What is meant by “list of analytes in the method shall be used?” What list? The list at the beginning of the method, or the list at the end or the list at the beginning of the chapter? If you use the method list are we holding a lab to analyze ALL analytes, even the obscure ones?

EDQW Response: Laboratories will analyze for analytes that are within their scope of accreditation. If the project does not specify analytes, the laboratory must communicate the list of analytes within their scope to the DoD project. If the project requires analytes that are not within the laboratory's scope of accreditation, the laboratory must become accredited for the specific analytes or testing must be performed by another DoD ELAP accredited laboratory.

10. **Question:** **DoD 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.

11. **Question: Gray Box 24:** Do the requirements for the validation of methods apply to all methods or just laboratory-developed methods?

EDQW Response: All methods.

12. **Question: DoD Gray Box 29:** If the electronic system allows the capture of the name of the person performing manual integration, date and rationale for performing the manual integration, is a printout of this information acceptable or does the analyst have to sign and date each chromatogram?

EDQW Response: If the printed name meets the requirements of an electronic signature, this is acceptable. If the analyst is not required to login with a unique username and password or the user simply enters the analyst's name in a text field, this is not acceptable.

13. **Question: Gray Box 29:** "When manual integrations are performed, raw data records (chromatograms before and after manipulation) shall include a complete audit trail for those manipulations." Is it acceptable for the laboratory to maintain these electronically?

EDQW Response: Records for manual integrations may be maintained electronically as long as all requirements, including signature requirements, are met and the results can be historically reconstructed.

14. **Question: DoD Box 30:** Does the requirement to verify the operation of all data reduction processes apply to instrument software, e.g. ChemStation?

EDQW Response: Yes

15. **Question: Gray Box 31:** Is the analytical balance acceptance criteria of ± 0.05 mg correct?

EDQW Response: No, it should be ± 0.5 mg.

16. **Question: Gray Box 31:** Is a minimum/maximum thermometer allowed?

EDQW Response: Yes, if appropriate for the application.

17. **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.

18. **Question: Gray Box 31:** - Is a thermometer reading of 6°C acceptable when the requirements are 0°C TO 6°C?

EDQW Response: Yes.

19. **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.

20. **Question: Gray Box 31:** What correction factor are you 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’s procedure should address this issue or the thermometer should be replaced.

21. **Question: Gray Box 31:** For equipment that is required to be checked “By lot before use”, such as Class B glassware and non-volumetric labware, that the laboratory had checked by the old QSM requirements, do they have to check the lots currently used by the new procedure?

EDQW Response: No, equipment accepted under the requirements of Version 3.0 do not have to be rechecked to meet the requirements of Version 4.1 to meet this requirement. However, all equipment received or placed into service after the laboratory implements Version 4.1 of the DoD QSM must meet the requirements of Version 4.1 of the DoD QSM.

22. **Question: NELAC 5.5.10:** Is running two continuing calibration verifications and not evaluating the second if the first one passes allowed?

EDQW Response: If the laboratory runs two CCV’s, the laboratory has to evaluate both.

23. **Question: Gray Box 37:** With regard to analyzing two CCVs routinely, what is an acceptable practice for utilizing data where one passes and one fails?

EDQW Response: Both CCV’s must be evaluated. If either CCV fails, perform corrective actions as required by NELAC Section 5.5.10 and reanalyze all samples since last acceptable calibration verification as required by Gray Box 37.

24. **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.

25. **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.

26. **Question:** **NELAC Section 5.6.1** requires all equipment to be 'calibrated', which has specific meaning in ILAC MRAs. ABs must follow ILAC rules in interpretation of ISO 17025 in terms of calibration and use of traceable reference standards.

EDQW Response: This is a NELAC requirement. Questions concerning NELAC text should be forwarded to the NELAP Board of Directors for resolution.

27. **Question:** **Gray Box C-2:** What is a 'non-standard' method?

EDQW Response: Methods that are not published in Standard Methods for the Examination of Water and Wastewater or by recognized entities such as EPA, ASTM, NIOSH, etc. are considered non-standard methods.

28. **Question:** **Gray Box D-2:** What are 'target analytes'? If a project defines a long list of analytes by contract such as 'use Title nine list of analytes' are all of these 'target analytes'? If so, this means that ME limits are not allowed for DoD work.

EDQW Response: Target analytes are analytes identified by the client on a project-specific basis. Marginal Exceedances (ME) are not allowed for target analytes.

29. **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 to quantify the Aroclor.

30. **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.

31. **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 doesn’t 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.

32. **Question: Gray Box D-14:** - The LOQ must be set ‘within’ the calibration range. Can the LOQ be at the low calibration point?

EDQW Response: Yes.

33. **Question: Gray Box D-14:** How are precision and bias at the LOQ to be reported?

EDQW Response: Precision and bias 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.

34. **Question: Gray Box D-14:** Upon review of the DoD QSM ver.4, it has come to our attention that a quarterly verification of the MDL's is required by analyzing the LOQ to ensure the MDL's are still valid. Would like to know that if the MDL's were analyzed on 10/25/2009 and not confirmed on quarterly basis could we start the verification process now based on the Oct 09 MDL's rather than reanalyzing the MDL's again?

EDQW Response: The DoD QSM VERSION 4.1 only requires that a scientifically valid Detection Limit (such as a MDL) be established. The DL is verified with a quarterly LOD. If the Previous MDL study is still considered valid by the laboratory, then this establishes your DL. You would then only need to verify this with an LOD verification, and then quarterly thereafter.

35. **Question: Gray Box D-47:** “Example, sample 1, result <4 U ppb.” Is the less than intended to be in the example? We understood the U to mean less than. Are both the < and U required when analyte is not detected at all?

EDQW Response: No, the Gray Box example includes both, but this is not required. However, the laboratory must report the result consistently.

36. **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. The 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.

37. **Question:** Does a prep method DOC require that they be tied to a specific analytical method?

EDQW Response: Yes.

38. **Question:** **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.

39. **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 5-7)?

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

40. **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.

41. **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.

42. **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.

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

EDQW Response: Yes.

44. **Question:** **Appendix F:** Are methods 8260C and 8270D compliant with DOD QSM requirements? Table F-4 discusses SPCC's and CCCs 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: SW-846 Methods: This appendix is based on all 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."

The only method tables that identify a specific version of a method are Tables F-2 and F-3, which specify requirements for versions of Method 8330.

45. **Question:** Appendix F Did the EDQW review EPA Method updates (IV) prior to releasing DoD QSM V4.1?

EDQW Response: Yes. However, the appendix F tables still contain QC requirements that may have been dropped from the latest draft EPA methods but have been determined by the EDQW to be necessary

46. **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, 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. Even though not required, 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 to determine the suppressor levels in the ICS.

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

EDQW Response: Yes, Appendix E 4. 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.

48. **Question:** Are laboratories expected to maintain control charts for every single compound for all methods and matrices, or can labs choose several representative compounds to chart?

EDQW Response: Gray Box D-3 requires laboratories to establish and maintain in-house control limits for all methods, matrices and analytes. Gray Box D-3 also requires that "Control charts shall be maintained and used to detect trends and prevent out-of-control conditions." Laboratories are not required to maintain control charts for all analytes on their DoD ELAP Scope of Accreditation..

49. **Question:** Does the LOD need to be reported for all methods?

EDQW Response: Yes, unless not applicable to the test or specifically excluded by the project..

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

EDQW Response: No, RL's are customer defined project specific reporting limits. Page B-8 of Appendix B 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.

51. **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. (Appendix E 7).

52. **Question:** Is it acceptable to report the client specified control limits only and not the laboratory's 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".

53. **Question:** Can the LOD be equal to the LOQ?

EDQW Response: Yes. However, this is not the intent of the DoD QSM and will probably not be acceptable to most DoD projects. The LOQ is typically larger than the LOD but may be equal to the LOD, depending upon the acceptance limits for

precision and bias of the specific project. See the DoD EDQW Detection/Quantitation Fact sheet for more details.

54. **Question:** Appendix Table F-2. 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?

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

56. **Question:** For 8260/8270 internal standards verification QC check, the QSM states that the acceptance criteria is "Retention time \pm 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 \pm 30 seconds from retention time of the midpoint standard in the ICAL on days an ICAL is performed. On days when ICAL is not performed, the initial CCV is used. The EICP area must be within 50% to +100% of ICAL midpoint standard at all times. (Appendix F, Table F-4)

It should be noted that Methods 8270D and 8260C required the evaluation of area to be against the midpoint of the calibration as well, and does not allow updates by CCV area (Section 7.5.2 of Method 8270D, Section 7.10 of Method 8260C).

57. **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)

58. **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.

59. **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?

60.

EDQW Response: Yes, unless prohibited by the AB.

61. **Question:** Are LOD/LOQ determinations and quarterly verifications required for non-SW846 methods listed on the laboratory's DoD ELAP Scope of Accreditation.

EDQW Response: Yes, if it is appropriate to determine LOD/LOQ for the type of testing.

62. **Question:** DoD QSM gray box 31 states that the Performance Check for liquid in glass thermometers is to bracket the target temperature. But this is not a requirement for digital thermometers. Why does the check need to bracket when using glass thermometers? Why does a 4C thermometer need checked at anything but 4C?

EDQW Response: The requirement to check electronic thermometers at temperatures that bracket the target temperature was removed from DoD QSM Gray Box 31 because it is impractical to check thermometers that are "built in" to the coolers this way. However, it is important to note that, the Gray Box 31 allowance to check electronic thermometers at a single temperature only applies for thermometers used at a single temperature such as those built-in to coolers/freezers etc. This allowance does not apply to hand held units. The check of glass thermometers at temperatures that bracket the range is typically not an issue. However, if the laboratory's freezers/coolers have glass thermometers built into them and they cannot be removed and checked as prescribed by DoD Gray Box 31, the requirement to check them at temperatures that bracket the target temperature does not apply to them.