



**LABORATORY
ACCREDITATION
BUREAU** a division of **AS-B**

Welcome

2015 DoD Environmental Monitoring & Data Quality Workshop

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"Improving Laboratories through Accreditation"



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Transfer Policy

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Purpose and scope

- This procedure defines the process for a laboratory to transfer their accreditation to an L-A-B accreditation.
- Only laboratories currently accredited and in good standing by an ILAC signatory AB qualify for a transfer of accreditation per this procedure

Procedure

- The applicant laboratory shall complete the L-A-B application for accreditation process and express their intension for transfer of accreditation
- L-A-B shall
 - Confirm the applicant laboratory is currently accredited by the ILAC signatory AB
 - Make note of the laboratory expiration date to confirm qualification for transfer



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Procedure

The following documents may be requested for a transfer of accreditation

- The last assessment report from the accreditation body
- All non-compliances or other forms of deficiency reports covering the last two assessments



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Procedure

Documents requested to provide a transfer of accreditation

- Copies of all corrective actions and supporting evidence associated with the last two assessments
- Evidence that existing accreditation and status is valid in good standing and current with financial obligations

Procedure

Based on a review of the application and supporting documents L-A-B will determine

- Type II surveillance transfer assessment or
- An initial assessment visit



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Procedure

Type II surveillance transfer

- Will be performed and will focus on the technical areas of the lab including technical evaluation of the scope of accreditation

Procedure

Initial Assessment visit

- Required if one or more of the following reflect the status of the laboratory
 - Previous (present) accreditation has already expired
 - Present scope of accreditation shows questionable content



Procedure

Initial Assessment visit

- Corrective actions and supporting material are not suitable based on the description of the non-conformances
- The accreditation body's assessment report recommends Suspension or Termination for technical reasons

Procedure

- Next Assessment following a Type II transfer will be a Year 0 full assessment

Procedure

- L-A-B may request additional information from the laboratory during a review



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Procedure

- In no case shall the accreditation be granted without one or the other type of onsite visit having taken place



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DoD ELAP Scope Expansion

Typical Types of Scope Expansion Requests

1. Addition of a New Technology
2. Addition of a New Method (with analytes) to an Existing Technology
3. Addition of a New Analyte to an Existing Method

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DoD ELAP Scope Expansion

1. Addition of a New Technology

- This request typically requires
 - A complete document review,
 - On site verification of the requested documents, and
 - Demonstration and technical observation of the laboratory's SOP's.

DoD Scope Expansion

Documentation Required for Review for Scope Expansion

- Updated L-A-B Proposed Scope of Accreditation
- Laboratory Technical SOP's
- LOD/LOQ Verifications (For each Matrix to be included on the Scope)
- In house LCS Control Charts and Limits
- DOC and IDOC
- Complete Data Packages – covering the added methods/ analytes
- Proficiency Testing Results (last three rounds covering all matrixes / analytes from scope testing)(QSM V5 Volume 1 Module 1 PT Requirements for Accreditation)

DoD ELAP Scope Expansion

2. Addition of a New Method (with analytes) to an Existing Technology

- This request typically requires
 - A complete document review,
 - And not necessarily an onsite evaluation

DoD ELAP Scope Expansion

3. Addition of a New Analyte to an Existing Method

- This request typically requires
 - A complete document review,
 - And not necessarily an onsite evaluation

DoD ELAP Scope Expansion

L-A-B Documentation check list and the Documentation required for review for scope expansion are required to be send to L-A-B to process the scope expansion request.



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Most common assessment findings

L-A-B uses this information to:

- Help develop guidelines for our laboratories
- To train our assessors to show some consistency

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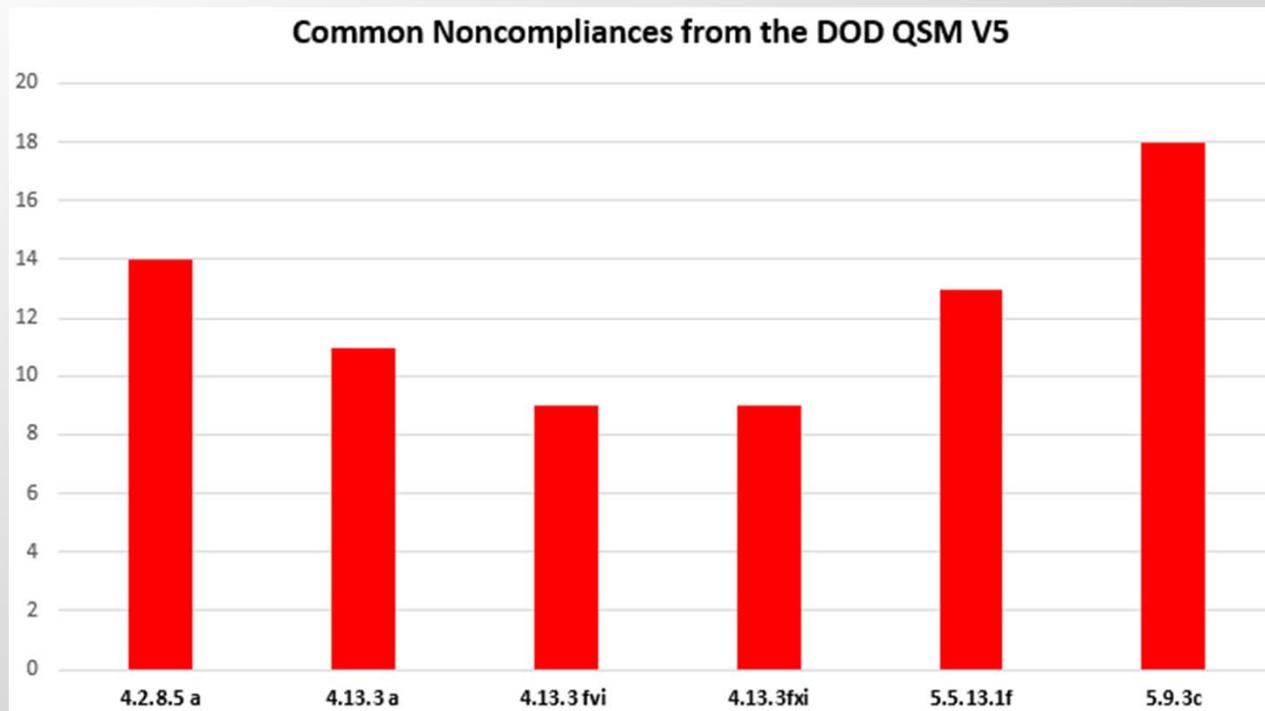


Most common assessment findings

Common Non- compliances from the QSM V5

1. Module 2 section 5.9.3 c)
2. Module 2 section 4.2.8.5 a)
3. Module 2 section 5.5.13.1 f)
4. Module 2 section 4.13.3 a)
5. Module 2 section 4.13.3 f) vi and xi

Most common assessment findings





Most common assessment findings

Common Non- compliances from the QSM V5

5. Module 2 section 4.13.3 f) vi and xi

All information necessary for the historical reconstruction of data shall be maintained by the laboratory.

vi) Instrumentation identification and instrument operating conditions/ parameters or reference to such data

xi) Standard and reagent origin, receipt, preparation and use

Most common assessment findings

Common Non- compliances from the QSM V5

4. Module 2 section 4.13.3 a)

The laboratory shall establish a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation. This system shall produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods and related laboratory activities, such as sample receipt, sample preparation, or data verification , and inter-laboratory transfers of samples and/ or extracts.



Most common assessment findings

Common Non-compliances from the QSM V5

3. Module 2 section 5.5.13.1 f)

The results of calibration and verification of support equipment must be within the specifications required of the application for which this equipment is used or the equipment must be removed from service until repaired. Calibration and verification records, including those of established correction factors must be maintained. In the absence of method specific requirements the minimum requirements are as follows (QSM V5 Module 2 table on page 26-27)

Most common assessment findings

Performance Check	Frequency	Acceptance Criteria
Balance calibration check [Using two standard weights that bracket the expected mass]	Daily prior to use	Top-loading balance: $\pm 2\%$ or $\pm 0.02\text{g}$, whichever is greater Analytical balance: $\pm 0.1\%$ or $\pm 0.5\text{mg}$, whichever is greater
Verification of standard mass [Using weights traceable to the International System of Units (SI) through a NMI]	Every 5 years	Certificate of Calibration from ISO/IEC 17025 accredited calibration laboratory
Monitoring of refrigerator/freezer temperatures	Daily (i.e. 7 days per week) [use MIN/MAX thermometers or data loggers equipped with notification of out of control event capabilities if personnel not available to record daily]	Refrigerators: 0°C to 6°C Freezers: $\leq -10^{\circ}\text{C}$
Thermometer verification check [Using a thermometer traceable to the SI through an NMI] [Performed at two temperatures that bracket the target temperature(s). Assume linearity between the two bracketing temperatures.] [If only a single temperature is used, at the temperature of use]	Liquid in glass: Before first use and annually Electronic: Before first use and quarterly	Apply correction factors or replace thermometer
Volumetric labware	Class B: By lot before first use Class A and B: Upon evidence of deterioration	Bias: Mean within $\pm 2\%$ of nominal volume Precision: RSD $\leq 1\%$ of nominal volume (based on 10 replicate measurements)
Non-volumetric labware [Applicable only when used for measuring initial sample volume and final extract/ digestates volume]	By lot before first use or upon evidence of deterioration	Bias: Mean within $\pm 3\%$ of nominal volume Precision: RSD $\leq 3\%$ of nominal volume (based on 10 replicate measurements)



Most common assessment findings

Performance Check	Frequency	Acceptance Criteria
Mechanical volumetric pipette	Daily before use	Bias: Mean within $\pm 2\%$ of nominal volume Precision: RSD $\leq 1\%$ of nominal volume (based on minimum of 3 replicate measurements) [Note: for variable volume pipettes, the nominal volume is the volume of use]
Glass microliter syringe	Upon receipt and upon evidence of deterioration	General Certificate of Bias & Precision upon receipt Replace if deterioration is evident
Drying oven temperature check	Daily prior to and after use	Within $\pm 5\%$ of set temperature
Water purification system	Daily prior to use	Per Laboratory SOP
Radiological Survey Equipment	Daily prior to use [The battery is checked; a background reading is taken; and verified with a radiological source]	Per Laboratory SOP

Most common assessment findings

Common Non- compliances from the QSM V5

2. Module 2 section 4.2.8.5 a)

Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions handling customer complains, and all methods

a) These documents for example, may be equipment manuals provided by the manufacturer, or internally written documents with adequate detail to allow someone similarly qualified, other than analyst , to reproduce the procedures used to generate the test result

Most common assessment findings

Common Non-compliances from the QSM V5

1. Module 2 section 5.9.3 c)

The laboratory shall have procedures for the development of acceptance/ rejection criteria where no method or regulatory criteria exist.

The quality control protocols specified by the laboratory's SOP shall be followed (see Section 4.2.8.5 in this Standard). The laboratory shall ensure that the essential standards outlined in Technical Modules or mandated methods or regulations (whichever are more stringent) are incorporated into their method manuals. When it is not apparent which is more stringent, the QC in the mandated method or regulations is to be followed.

Most common assessment findings

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THANK YOU!

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