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Implementation and Assessment of LCS Control Limits in the Laboratory

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Topics

- What does the QSM require?
- How should a laboratory's in-house LCS control limits be used?
- How should the project-specific LCS control limits be used?
- How should the QSM LCS control limits be used?
- How is the LCS study used in assessments?

What is an LCS?

- Laboratory Control Sample.
- Analyte-free matrix spiked with target analytes used to document laboratory performance.
- Prepared with each batch of 20 or fewer samples.
- Processed through the entire samples preparation and analysis sequence.

What does the QSM Require?

- Laboratories must determine their **in-house** LCS control limits.
- Compile LCS recovery data for specific analyte-method-matrix combinations over time (at least 30 samples)
- Must have statistically established LCS control limits for all combinations on scope.
- Must have procedures documented for establishing LCS control limits.

What does the QSM Require?

- In-house LCS limits must meet requirements listed in 1.7.3.2.3(c) of V1M4 of the QSM Version 5.0.
- LCS limits must be used to monitor performance and estimate contribution to analytical uncertainty.
- Must have procedures documented for establishing LCS control limits.

Batch-Specific LCS Requirement

- An LCS or LCS duplicate pair must be processed with each batch of 20 or fewer field samples (of the same matrix).
- Comparison of LCS results to in-house LCS control limits verifies whether analytical system is in control.
- Comparison of LCS results to MS/MSD results helps identify matrix interferences and other analytical problems.

How to use the Lab's Limits

- Project chemist should compare a lab's in-house limits with project specific limits for precision and bias.
- To meet the project's DQOs, the lab's in-house limits must meet the project specific Measurement Performance Criteria (or QSM limits) for precision and bias.
- Keep in mind that the LCS is the best case scenario.

How to use the Project Specific LCS Limits.

- Project teams shall establish project-specific LCS limits.
- DoD QSM limits may be adopted if they meet the projects DQOs.
- Any lab with in-house limits outside the project-specific limits shall not be used.

Method-Specified LCS Control Data.

- LCS results (% recovery and standard deviation) published in the method.
- Provide method-performance data under controlled conditions (e.g., single-laboratory trials, specified spike concentrations, skilled analysts, method performed *as written)* defined in the method.
- Data may represent various matrices, preparation methods, and concentration levels.
- Results should NOT be used as absolute QC acceptance criteria for method performance.

How to use the QSM LCS Control Limits

- For DoD projects the lab must use the QSM LCS control limits for batch quality control and data reporting unless project-specific limits are specified.
- When project-specific analytes are not included in Appendix C, lab's must use their in-house limits.

What to Consider When Using the QSM LCS Control Limits

- The QSM limits are likely to have a wider range than individual labs as data was pooled from multiple labs using their own SOPs.
- In most cases the LCS samples were prepared by spiking a matrix at the mid-point of the calibration curve which is likely higher than a project's decision level.

What to Consider When Using the QSM LCS Control Limits

- Only three classes of analytes (metals, explosives, and PAHs) were evaluated using more than one method meaning only these can be used for method performance comparison.
- Modifications to methods can improve performance but may require method validation and regulatory agency approval.

How do ABs use the LCS Study in Assessments?

- Ensure that spiking levels are at or below the mid-level and that all target analytes are tracked.
- Spot check for CCV failures when a target analyte fails in the LCS/LCSD.
- Examine LCS trending charts to ensure that the labs in house limits would be able to support the QSM limits for DoD projects.

How do ABs use the LCS Study is Assessments?

- Look for outliers in LCS trending data and examine corrective actions.
- Ensure that when failures occur, that samples are re-extracted or re-processed.
- Ensure that surrogates and target analytes are treated the same for calibration checks.

Accreditation?

- Can a lab be accredited with in-house limits that do not match the QSM limits?
  - Yes—We will evaluate the laboratory in-house limits to ensure that the data supports migration to the QSM/ project limits if necessary.

Questions / Comments

For Further Information

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