Utilizing Technical Components of V1M4 Quality Systems for Chemical Testing to Aid in Producing Reliable Data in Your Laboratory

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Presentation Overview

- Purpose: Practical overview of TNI V1M4 Quality Systems for Chemical Testing

- Focus: Implementation & legal defensibility

- What we'll cover:
  - Why V1M4 is important
  - Breakdown of technical components
  - How to ensure reliability in your lab

Why V1M4 Is Necessary

- ISO/IEC 17025 lacks detail for chemical testing
- Module 2 doesn't address many chemical testing challenges
- EPA/ASTM methods often lack quality controls
- V1M4 fills critical gaps for chemical testing reliability

Legal Standing – Daubert v. Merrell Dow (1993)

□ Supreme Court case on admissibility of scientific data

Daubert Foundation Principles

□ Sets requirements for whether a scientific technique:

  ➢ Has been tested
  ➢ Has been accepted within the scientific community
  ➢ Has a high known or potential rate of error
  ➢ Has professional standards controlling the technique's operation.
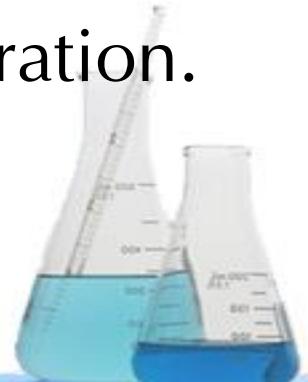
Overview of V1M4 Sections

- Introduction and Scope
- Method Selection and Validation
- Demonstration of Capability (DOC)
- Instrument Calibration
- Method Blank & LCS
- Sample Handling

Introduction and Scope

- Minimum QC for all chemical testing
- Allows for more rigorous controls where needed
- Aligns with Daubert's "professional standards"

Method Selection

- Reference methods preferred
- All methods must be validated
- Additional analytes may be added to validated methods
- Supports method reliability and defensibility

Method Validation

- Determine and verify LOD/LOQ
- Evaluate precision, bias, and selectivity
- Required for all methods; non-reference methods need full validation

Limit of Detection (LOD)

- Based on 2016 standard; draft update aligns with EPA 40 CFR 136 App. B
- Required unless inappropriate
- Initial determination and periodic verification

Limit of Quantitation (LOQ)

- Required unless inappropriate
- Must match or exceed lowest calibration point
- Requires verification over time

Precision and Bias

- DOC is sufficient for reference methods
- Full evaluation for non-reference methods
- Must test in applicable matrices

Selectivity

- Best practices include:
  - Second column confirmation
  - Mass calibration
  - Interference checks

Demonstration of Capability (DOC)

- Analyst-specific requirement
- 4 spike replicates recommended
- Flexible approaches allowed

Instrument Calibration – General

- Framework provided; flexibility allowed
- Must meet stricter method or regulatory standards if applicable

Initial Calibration

- Requires:
  - Traceability
  - Minimum number of standards
  - Relative error check
  - Calibration verification

Calibration Verification

- Procedure not mandated
- Must include corrective actions
- Allows for special cases

Method Blank

- 1 per batch required (if applicable)
- Outlines failure protocols
- Exceptions allowed

Laboratory Control Sample (LCS)

- 1 per batch (if applicable)
- Marginal exceedances may be acceptable
- Failure action steps required

Sample Handling

- Defines and verifies preservation
- Supports traceability and known error control

Summary & Takeaways

- V1M4 provides technical and legal strength
- Centralized quality guidance for chemical testing
- Aligns with Daubert and supports data defensibility

Questions & Contact Info

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