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Hot Topics for the Newly Accredited TNI Laboratory

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Overview

- Organizational structure and staffing requirements
- Documentation of purchasing and contracts
- Method Validation and SOPs
- Error and Uncertainty evaluation
- Accurate and Complete Records
- Documents versus records
- Understanding traceability with respect to ISO 17025 and 17034
- MDL/LOQ verifications

Disclaimer: This is not an exhaustive list of TNI Requirements.

Organization Structure and Staffing Requirements

- Staff may have multiple roles withing the operation, but clearly defined in the Quality Manual
- Specific Educational and Experience criteria requirements for the Technical Director (Some states may have additional requirements)
- Clearly defined roles and responsibility for all staff
- Must have a back-up plan for certain positions

Contracts and Purchasing Requirements

- Laboratory must have a process for qualifying suppliers/supplies
- Maintain a registry of approved vendors
- Maintain records of supplies received and reviewed against method specifications prior to use.
- Clearly define the scope of service in client contracts including review and acceptance, including methods and analytes to be conducted
- Maintain communication logs with clients
- Document client approval of changes in the scope of service

Verification of Method Implementation

Published Test Methods

Validation of the method is not required for published methods, except for method defined initial demonstrations (LOQ, LOD, DOC, accuracy, and precision etc.). Pay attention to the method requirements, specifically if the method is in support of SDWA.

Non-standard Methods

- Develop a SOP for the method, including types of samples and sampling, and analytes to be measured
- Calibration using reference standards or reference materials
- Comparison of results achieved with other methods
- Evaluate accuracy and precision by matrix, run actual samples
- Interlaboratory comparisons, if available
- Systematic assessment of the factors influencing the result
- Assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

SOPs

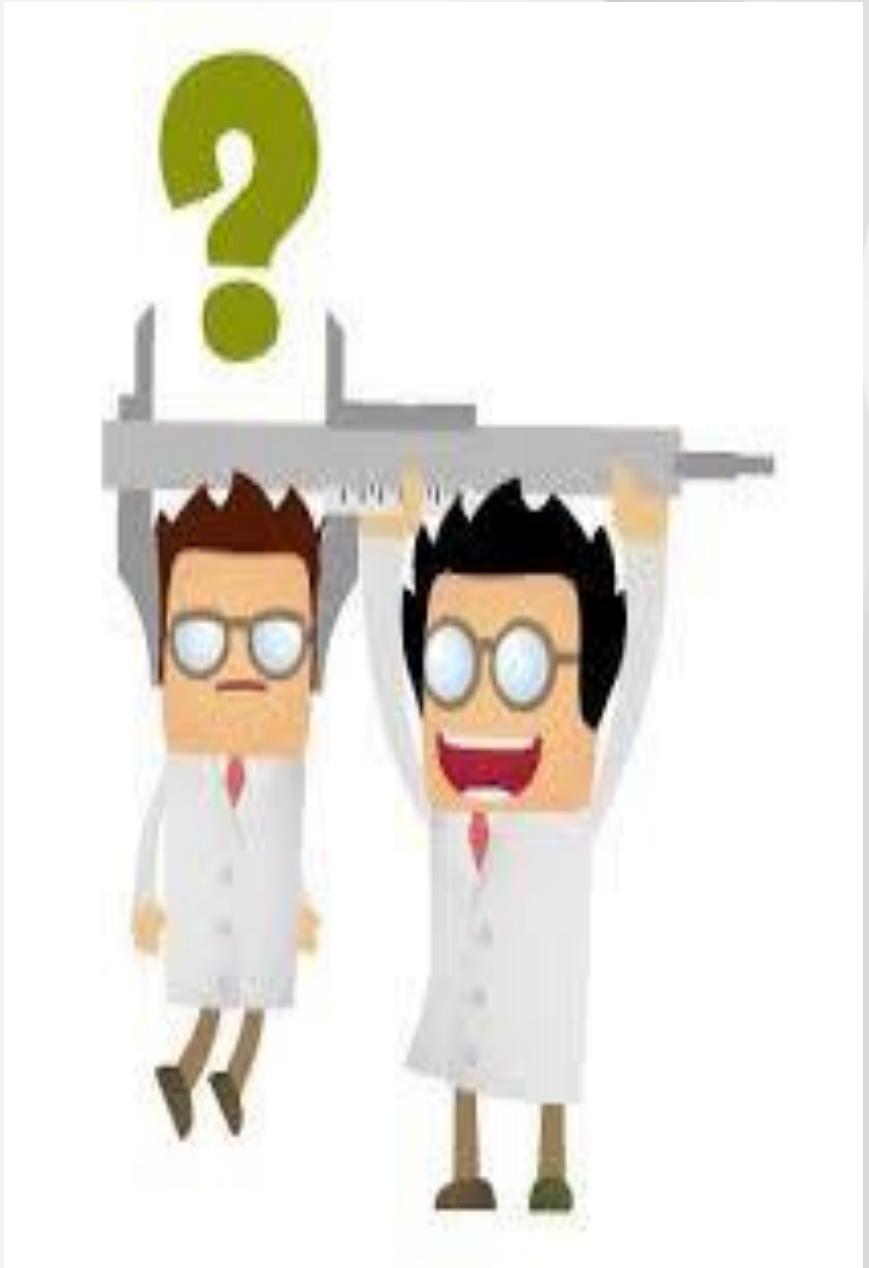
- Document controlled regardless of media
- Readily available to all staff at the point of use
- Approved for use by management
- Staff acknowledgement to comply with the procedure
- Subject to periodic review

V1M2: 4.2.8.5.f

i. identification of the method;
ii. applicable matrix or matrices;
iii. limits of detection and quantitation;
iv. scope and application, including analytes to be analyzed;
v. summary of the method;
vi. definitions;
vii. interferences;
viii. safety;
ix. equipment and supplies;
x. reagents and standards;
xi. sample collection, preservation, shipment and storage;
xii. quality control;
xiii. calibration and standardization;
xiv. procedure;
xv. data analysis and calculations;
xvi. method performance;
xvii. pollution prevention;
xviii. data assessment and acceptance criteria for QC measures;
xix. corrective actions for out-of-control data;
xx. contingencies for handling out-of-control or unacceptable data;
xxi. waste management;
xxii. references; and
xxiii. any tables, diagrams, flowcharts and validation data.

Error and Uncertainty

- Have a procedure for determining uncertainty (Accuracy, Precision, Calibrations)
- Make Uncertainty Data available upon client request
- Apply to measurements where method defined
- Calculate the easy way – LCS control chart or the hard way – The GUM (JCGM - Joint Committee for Guides in Metrology (iso.org))



Reporting Requirements

- Commercial lab verses Captive Lab.
- Meet the contractual requirements of the customer.
- Clearly document the quality of the data reported, including deviations and nonconformances.
- Issued by an approved lab signatory.
- Document any revisions or changes after reporting.
- Clearly identify subcontracted data down to analyte.

Document vs Records

Documents: The How!

Laboratory specific information such as SOPs, Forms, Templates that describe the activities of the lab. Documents are ALL controlled via the lab's document control procedures.

Records: The What!

- Creates a history of the event
- Specific to the analysis, project, activity
- Examples includes: Analytical results, contracts, training files, validation data, internal laboratory verifications, test reports, images…..the list goes on and on!
- Anything the lab retains to support the reconstruction of the project.
- All entries to records are captured at the time the observation or action was taken.
- Defined retention plan (minimum of 5yrs, but may vary)

Documents Versus Records

Do not apply document requirements to records and vice versa!

Traceability and ISO 17034

- All measurements must be documented to capture traceability to the equipment, chemicals, staff and supplies.
- Standards shall be purchased from an accredited vendor (if available). An accredited vendor is on that has been verified to be compliant with ISO 17034.
- Either the primary or secondary standard may carry the traceability to ISO 17034.
- Accredited vendors proudly display the accreditation logo on the COA.
- Read the COA thoroughly. Often the wording may be misleading.

Traceability and ISO 17034 (cont.)

- Metrology Traceability requires Vendor to be a certified ISO17025 Calibration Laboratory.
- Standards and Reference materials must be traceable to ISO 17034 providers (where available).
- Retain all certificates in support of data generated in accordance with the retention schedule.
- Know the difference between the two certificates and when to use them!

MDL and LOQ Verification

- MDLS: 40CFR Part 135 Appendix B
- DW Methods may require a different frequency
- MDL/ LOQ must include all steps in the analytical process
- Specific spike concentration and replicates required
- Verified quarterly
- Lab defines acceptance criteria, unless specified by the test method
- If verification fails, a repeat study must be conducted within 30 days.
- For on going determinations, use all or last 50 method blanks

Q&A

THANK YOU.

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