QSM 6.0 Update

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ChemVal Consulting, Inc

Please Note – Chemval, as a Consultant – Does not have a Vote.

- ChemVal Consulting personnel do not have a vote in decisions made by the QAOS subgroup on QSM language.

Why a new QSM?

- QSM V1M2 4.x and 5.x were based on the "backbone" of ISO/IEC 17025-2005
- ISO/IEC 17025-2005 received a major update in 2017
- QSM 5.3 was a "gap" document that included the ISO 17025-2017 language without removing the ISO 17025-2005 language.
- QSM 5.4 was issued to add Table B-24 additional PFAS requirements for Draft EPA Method 1633.

QSM 6.0 Status

- QSM 6.0 V1M2 is structured in line with ISO/IEC 17025-2017
  - Allows for more efficient assessments and accreditation
- Current document is NOT complete
  - Some portions are still being drafted
  - Some portions are out for comment
    - Comments may indicate needed changes
- Covid impacted the timeline, delaying development

DISCLAIMER!!

This presentation is based on current drafts and direction of the QAOS Subgroup

Structure

- TNI Standard Structure will be maintained
  - Module format
  - V1M2 will be reconfigured to match ISO/IEC 17025-2017
  - Addition of Module 8 – Industrial Hygiene
- TNI references have been updated to TNI 2016

V1M2 – Additions and Deletions

- All of ISO/IEC 17025-2017 must be included
- Some TNI requirements have been dropped - Redundant with ISO/IEC 17025-2017

Philosophy Changes

- Moving from ISO/IEC 17025-2005 to 17025-2017 included some philosophy changes
- The standard changed from more prescriptive to more risk-based
  - QSM 4.x, 5.x: “Here are your risks and here are your mitigations”
  - QSM 6.0 is moving to implement more of a risk-based approach.

Philosophy Changes, continued

- Most policy requirements were eliminated from the ISO 17025-2017 Standard; therefore QSM 6.0 is also removing them.
- Many procedure requirements were eliminated from the ISO 17025-2017 Standard and some are being removed from QSM 6.0.

Appendices

- Appendix A, Reporting Requirements, will be eliminated. Requirements deemed necessary will be placed in V1M2 7.8
- Appendix E, HASQARD Checklist, will be eliminated. Requirements deemed necessary will be placed in the appropriate module/section.

Other Trends

- The terms “document” and “record” will remain and be aligned with ISO 17025-2017 language.
  - E.g., “The laboratory shall document a procedure and maintain records”
- Significant effort is being made to remove unenforceable requirements
  - “The laboratory shall consider…”
- Text devoted to philosophy, guidance, and examples will be limited.

Changes in V1M2

Highlighting significant changes or significant rewrites

Section 4 - Impartiality

- The Data Integrity requirements have been rewritten
- Program Requirements are in Section 4
  - Some new requirements are included
- Training Requirements are included in the Personnel section of the Standard (6.2)

Data Integrity Program Requirements

- [QSM 4.1.6] **DoD/DOE Requirement**
- In addition to 4.1, the following DoD/DOE requirement applies:
- The laboratory shall establish and maintain a documented program to detect and deter improper, inappropriate or prohibited actions.
- 4.1.6.a This program shall be reviewed annually by management. Records of this review shall be maintained. Management shall indicate their commitment to the program by signature.

Data Integrity Program Requirements

- 4.1.6.b The program shall include requirements for the following: 1) annual training of all laboratory personnel on their obligations under the program; 2) signed commitment of all laboratory personnel to their obligations under the program, including to behave impartially and to refrain from inappropriate practices, 3) periodic, in-depth monitoring for improper or inappropriate actions; and, 4) investigations into potential or suspected improper or inappropriate actions.
- 4.1.6.c The requirements for periodic, in-depth monitoring for improper, inappropriate, or prohibited actions shall include a schedule of items to be reviewed. Records shall be maintained to demonstrate compliance with the schedule.

Data Integrity Program Requirements

- 4.1.6.d The requirements for investigation shall include a procedure for reporting of potential or suspected inappropriate or improper practices in the laboratory and a process whereby laboratory management is informed of the issues.
- 4.1.6.e Management shall ensure a receptive environment in which all employees may privately discuss potential issues or report items of concern. Management shall ensure no retaliation, interference, coercion, or intimidation of employees reporting concerns or potential issues.

Data Integrity Program Requirements

- 4.1.6.f Laboratory management shall evaluate any reports of potential or suspected inappropriate or improper practices. Where management determines the need for further investigation, it shall assign appropriate personnel with technical and quality assurance capability to perform the investigation. Findings of inappropriate, improper, or prohibited practices are considered non-conforming work. Records of investigations shall be maintained, including any notifications made to customers receiving any affected data.
- 4.1.6.g Laboratories must report any instances of inappropriate and prohibited laboratory practices to their AB within 15 business days of discovery. Discovery includes findings of such inappropriate practices by laboratory staff or customer stakeholders. Laboratories must submit records of associated corrections taken or proposed corrective actions to their AB within 30 business days of discovery.

Section 5 - Structural Requirements

- Very few changes are being made to this section.
- The text of ISO/IEC 17025-2017 addresses most of the requirements that were formerly contained in section 5.2 of V1M2
- One major exception: Requirements for
  - Technical Manager
  - Quality Manager

Technical and Quality Managers

- ISO/IEC 17025-2017, 5.2: The laboratory shall identify management that has overall responsibility for the laboratory, and;
- ISO/IEC 17025-2017, 5.5: The laboratory shall
  - a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;
  - b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;
- Section 5.6 has a few more specifics

Technical and Quality Managers

- DoD will follow the language of the ISO/IEC 17025-2017 Standard
- DOE will differ from DoD and have prescriptive language for Technical and Quality Managers

DOE Technical Manager

- [QSM 5.2.a] DOE only requirement
- In addition to the requirement in 5.2, the following specific management responsibilities shall be defined
- The laboratory's technical manager(s), however named shall be laboratory personnel who meet the educational and experience requirements in section 6.2 and are actively available for technical consultation for laboratory operations for the fields of accreditation which they manage. The technical manager(s) duties and responsibilities shall include:

DOE Technical Manager, continued

- Ensuring the quality of data generated by the laboratory through participation in laboratory management review, review of quality assurance records and quality control data, review of data packages, and authorizing reports;
- Defining the minimum qualifications, experience, and skills necessary for all positions in the laboratory;
- Ensuring that all laboratory technical staff have demonstrated capability…

DOE Technical Manager, Continued

- Providing for on-going training opportunities for all technical staff and ensuring on-going competence demonstrations;
- Ensuring adequate supervision of all personnel employed by the laboratory;
- Appointing a qualified member of staff to temporarily perform these functions in the event of an extended absence greater than 15 days.

DOE Quality Manager

- [QSM 5.2.b] DOE only requirement
- In addition to the requirement in 5.2, the following specific management responsibilities shall be defined:
- The Quality Manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times. Where staffing is limited, the quality manager may also be the technical manager. The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual. Furthermore, the laboratory's Quality Manager and/or his/her designee(s) shall:

DOE Quality Manager, Continued

- Have direct access to the highest level of management at which decisions are made on laboratory policy or resources;
- Serve as the focal point for QA and QC and be responsible for the oversight and/or review of quality control data
- Function independently from laboratory operations for which they have quality assurance oversight;
- Evaluate data objectively and perform assessments without outside (e.g., managerial) influence;

DOE Quality Manager, Continued

- Arrange for or conduct internal audits annually;
- Notify laboratory management of deficiencies in the quality system; and monitor corrective actions.
- Plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.
- Maintain the currency of the quality manual.

DOE Quality Manager, Continued

- Review (or oversee the review of) the quality manual at least annually and update it if needed.
- Perform periodic inspections (at least annually) of the LIMS by the Quality Manager or designee to ensure the integrity of electronic data. The Quality Manager or designee shall maintain records of inspections and submit reports to laboratory management noting any problems identified with electronic data processing and stating the corrective actions taken;

Section 6 - Resource Requirements

- Personnel Section
  - Qualifications for DOE Technical and Quality Managers
  - Training Requirements for Data Integrity Program
    - Clarifications
    - Expansion of examples

DOE Technical Manager Qualifications

- [QSM 6.2.8] DOE only requirement
- The following shall be implemented in addition to 6.2
- Technical Manager educational and experience qualifications will be developed, required, and documented by the laboratory management.

DOE Quality Manager Qualifications

- [QSM 6.2.9] DOE only requirement
- The Quality Manager (however named) shall have, at a minimum, the following qualifications:
- QSM 6.2.9.a) have documented training and/or experience in Quality Assurance and Quality Control procedures and the laboratory's quality system;
- QSM 6.2.9.b) have a general knowledge of the analytical methods for which data review is performed;

Data Integrity Training

- A few changes to the introductory paragraph
- Expansion of required examples
- One significant addition

Data Integrity Training, continued

- [QSM 6.2.11] In addition to the requirements in 6.2 the following applies:
- Data integrity training shall encompass requirements for complete records supporting all reported data, including data with quality control outliers , and requirements to refrain from improper, inappropriate, and prohibited actions. Employees shall be informed that evidence of participation in improper, inappropriate, or prohibited actions shall result in an investigation. The outcome of such an investigation could have serious consequences for involved personnel including immediate termination, debarment, or civil/criminal prosecution.

Data Integrity Training, continued

- [QSM 6.2.12.i] reporting data from a modified method without client approval, including, but not limited to, changing the stoichiometry or detection system of a method, reducing the number of extractions, and reducing acid concentrations for digestions.

6.3 - Facilities and Environmental Conditions

- No significant changes
- Requirements for storage blanks for VOA storage areas are being maintained.
  - Records are required

6.4 - Equipment

- Some clarifications
- Significant changes to a few items in Equipment Table (Table 5-1 in current QSM)

Equipment Table Changes

- Verification of Working Standard Masses, i.e., masses used for daily balance verification.
- Option 1: by comparison to calibrated reference weights not in daily use. or
- Option 2: by check on balance immediately (same day) after required balance calibration from accredited calibration provider

- Frequency-Annually
- Acceptance Criteria-

  ± 0.1% or ± 0.2 mg, whichever is greater

Equipment Table Changes

- Monitoring of refrigerator/freezer temperatures
- Metrological Traceability not required for sample and standard storage
- Frequency-
  Daily (i.e., 7 days per week)
- When personnel or an automated system are not available to record daily, use MIN/MAX thermometers or data loggers to monitor.
- Evaluate the data from devices upon return to the lab. The laboratory shall enact their non-conforming work procedures within 24 hours of detecting any excursion of ≥ 2 °C or any excursion greater than 2 hours.
- Acceptance criteria-

  Refrigerators: 0°C to 6°C

  Freezers: ≤ -10°C

Equipment Table Changes

- 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 the range of use is ≤ 10 °C (e.g. 10 to 20 °C), only a single temperature is used, verify within the range at the temperature of use
- Metrological Traceability not required for sample and standard storage.

- Frequency - Liquid in glass, electronic: Before first use and annually

  Hand-held Infrared: Before first use and quarterly

  Traceable thermometers shall be verified as required and correction factors used when appropriate
- Acceptance criteria-

  Apply correction factors or replace thermometer

Equipment Table Changes

- Timer

- Frequency –

  Timer traceable to NIST where the uncertainty of the time measurement is critical to the reported value.

- Acceptance Criteria –

  Per Laboratory SOP

6.5 - Metrological Traceability
6.6 - Externally Provided Products and Services

- No significant changes-some clarification of requirements

Section 7 - Process Requirements

- Important changes in a few sections
  - Use of Modified Methods
- 7.1 - Review of Requests, Tenders and Contracts
- 7.2 - Selection, Verification and Validation of Methods

7.1 - Review of Requests, Tenders and Contracts

- ISO/IEC 17025-2017 added the requirement to obtain customers' approval for use of external laboratory services.
- QSM 6.0 will add a requirement for maintaining records of that approval
  - Subcontract laboratories
  - Other outside services involved in generating reportable data
- Requirements for obtaining waivers from QSM requirements
  - Subject of presentation later today

Method Validation Changes

- Standard must be followed
- Validation of changes to preparation techniques must include challenges from actual sample matrices
- PT samples are NOT enough

- The following language is still in draft

Method Validation Additions

- 7.2.2.1 DoD/DOE Requirement: When a modification of a method includes changes to sample preparation steps, the validation process shall include analysis of field samples in the matrices of concern. Such demonstration will preferentially include parallel studies using the published method versus the modified method.

- a. Where available, this study shall use field samples containing target analytes, which are then spiked with additional analytes not found natively in the samples. At a minimum, the demonstration shall include analysis of spiked field samples spiked at multiple levels as described in V1M4, Section 1.5.3.b. In this context, "matrices of concern" means samples that are similar to or from specific sampling sites in which the method will be used.

Method Validation Additions, continued

- b. It is not appropriate to use, for example, clean sand, diatomaceous earth, or glass beads as the sole analysis matrix for demonstrating preparation modifications for soil methods. Similarly, while the analysis of Proficiency Testing samples (PTs) and laboratory control samples (LCS) is required as part of the validation, it is not appropriate to use only analysis of Proficiency Testing samples or Laboratory Control samples to demonstrate modifications of preparation methods.

- c. Where modifications to the analytical portion of the method are planned, the laboratory shall take into consideration any effects the matrix may have on the analysis.

Method Validation Additions, continued

- 7.2.2.4 DoD/DOE Requirement: The laboratory shall collate and maintain all of the records required under this section, retain them for five years after the last use of the method they support, and make them available upon request to customers, and Accreditation Bodies., and DoD/DOE personnel.

7.3 - Sampling
7.4 - Handling of Test Items
7.5 – Technical Records

- There are not significant changes proposed for these sections
- Requirements added to the ISO 17025-2017 Standard in previous QSM versions will be maintained

7.6 - Evaluation of Measurement Uncertainty
7.7 - Assuring the Validity of Results

- No significant changes are proposed for these sections
- NOTE: V1M1 has a significant change regarding in-house PT studies – stay tuned

7.8 - Reporting of Results

- Expect major changes to this section
- Appendix A will be dropped
- Requirements maintained from Appendix A will be moved to Section 7.8
- Currently in process; draft language is not yet available

7.9 - Complaints
7.10 - Control of Non-Conforming Work

- No significant changes from ISO/IEC 17025-2017
  - NOTE: 2017 ISO standard significantly changed complaint requirements.
- Requirements in current QSM for customer notifications will be maintained

7.11 - Control of Data and Information Management

- No significant changes to ISO/IEC 17025-2017 text
  - New standard significantly upgraded requirements
- Requirements in current QSM will be maintained
  - Some are removed as redundant with ISO/IEC 17025-2017 language

Section 8 - Management System Requirements

- Section 8.1 - “Option A” is required
- A few significant changes
- Additional requirements in current QSM will be maintained in most cases
- Note: None of the language in Section 8 is in final draft

8.2 - Management System Documentation

- Requirements for Quality Manuals will be included here
  - QSM 6.0 is keeping the requirement for a Quality Manual
  - Road map to the management system
- The list of requirements from previous versions will be consolidated
  - No more cover page requirements
  - No more list of accreditations

Quality Manual Requirements

- [QSM 8.2.1.a] DOD/DOE Requirement
- In addition to the requirement in 8.2.1, the following is required:
- The laboratory shall have a quality manual and the quality manual shall address or make reference to:

  i. the procedures and policies that support the management system;

  ii. test methods, however named, under which the laboratory performs testing;

  iii. the impartiality requirements;

  iv. the confidentiality requirements;

Quality Manual Requirements, continued

v. the organizational structural requirements, including its place in any parent organization, and relevant organizational charts ;

vi. the personnel requirements;

vii. the facility and environmental condition requirements;

viii. the equipment requirements;

ix. the metrological traceability requirements;

x. the requirements for externally provided products and services;

xi. the requirements for review of requests, tenders and contracts;

Quality Manual Requirements, continued

xii. the requirements for the selection and verification of methods;

xiii. the requirements for the validation of methods;

xiv. the sampling requirements;

xv. the requirements for the handling of test or calibration items;

xvi. the requirements for technical records;

xvii. the evaluation of measurement uncertainty requirements;

xviii. the requirements ensuring the validity of results;

Quality Manual Requirements, continued

xix. the reporting requirements;

xx. the requirements for complaints;

xxi. the nonconforming work requirements;

xxii. the control of data and information management requirements;

xxiii. the management system documentation requirements;

xxiv. the requirements for the control of management system documents;

Quality Manual Requirements, continued

xxv. the requirements for the control of records;

xxvi. the requirements for actions to address risks and opportunities;

xxvii. the requirements for improvement;

xxviii. the requirements for corrective actions;

xxix. the requirements for internal audits;

xxx. the requirements for management reviews.

xxxi. procedures for permitting deviations from management system requirements or standard specifications, including which personnel may approve the deviation.

8.3 - Control of Management System Documents
8.4 - Control of Records

- No significant changes
- Additional requirements in current QSM will be carried forward

8.5 - Actions to Address Risks and Opportunities

- QSM 6.0 will include a list of specific items laboratories shall address [currently in draft]
- Records of evaluation and mitigation shall be maintained

Required Risk Evaluation

- Risks to data validity associated with any new method modifications or in-house developed methods;
- Risks associated with metrological traceability procedures to ensure no negative impact to data validity and uncertainty;
- Risks associated with externally provided products and services
- Identifying likely contaminants which may be encountered in the laboratory facilities or it's supplies, and mitigating risks that these could negatively impact confidence in analytical results

Required Risk Evaluation, continued

- Determining minimum qualifications for technical personnel, supervisory personnel, and other technical and quality management personnel
- Ensuring alternate personnel are designated, trained and authorized for key roles and responsibilities;
- Determining for which methods LOD and LOQ verifications will be performed quarterly and which will be performed with each batch analyzed;
- Use of electronic signatures;
- Determining which version(s) of methods best fits the needs of the laboratory's customers;

8.6 - Improvement

- No proposed changes to ISO/IEC 17025-2017 Text

8.7 - Corrective Action

- QSM will require a procedure for performing corrective action
- The procedure shall include assigned responsibilities
- The procedure shall require tracking of corrective actions through all steps
- Records shall be maintained

8.8 - Internal Audits

- Most of the current QSM requirements will be maintained
  - Auditor independence will be required
- Annual audit frequency requirement will be maintained
- "Any activity that has the potential to affect the validity of results shall be audited. The audit schedule shall ensure that all areas of the laboratory are reviewed over the course of one year, with no area exceeding a period of 18 months between audit events. The review shall include both technical and quality management systems."

Internal Audit QSM Requirements

- Laboratories shall notify DoD/DOE clients within 15 business days of discovery when the investigation casts doubt on the validity of results.
- DOE Only: The laboratory QA program shall identify the required distribution of internal audit reports and all related documentation. [from HASQARD]

8.9 - Management Review

- QSM will require a procedure for performing Management Review
- Current QSM requirements for tracking resulting actions will be maintained
- DOE Only Requirement: Management reviews shall also include laboratory radiation health and safety, radioactive hazardous waste, and radioactive materials management functions, where applicable (i.e., when radioactive samples are analyzed).
- DOE Only Requirement The laboratory QA program shall identify the required distribution of management review reports and all related documentation. [from HASQARD]

Other Changes - V1M1 Proficiency Testing Module

- Module 1 was distributed for comment several weeks ago
- Module includes specific requirements for laboratories to follow when no commercial PT is available

In-House PT Activities

- The laboratory shall submit in writing to their DoD ELAP AB and/or their DOECAP-AP AB, and their impacted customer(s), a list of items on their scope of accreditation for which no suitable commercial PT is available.
- For these methods, Precision and Bias studies shall be performed twice per year, meeting the same time requirements as those for commercial proficiency testing.
- Minimum of 8 samples per year for each parameter

In-House PT Activities, continued.

- Evaluate recovery and precision
- Compare to limits
  - Customer, if provided
  - Laboratory, if not provided by customer
- Take corrective action as require for commercial PT analyses
- Report results to the laboratory's AB

B-Table Template Changes

- Paradigm change from "tightest criterion" for some checks to following the quoted method
  - Mass spectrometer tuning
  - ICP interference checks
- Changes to the format of the B-Table
  - "Comments" column has been eliminated
  - Former Comments have been made requirements or eliminated
- Four B-Tables have been sent out for comment
  - Final "Global Template" is not quite finalized

LOD-LOQ

- Currently in draft and vigorous discussion stage
- Requirements will be added to the presentation if available in time

Thank you!!!

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