

Quality Systems Manual (QSM)

Version 5: Update



***Presented to:
EMDQ Workshop 2012
La Jolla, Ca.***

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Agenda



- New Format For QSM version 5
- QSM Changes, Additions & Deletions
- New LCS study
- Who we are: Our Quality Assurance Oversight Subgroup (QAOS)
- Questions

For in much wisdom is much grief; and he that increases knowledge increases sorrow.

Eccles. 1:18 (NIV)

New Format for the QSM

- Will be based on ISO 17025:2005 *General requirements for the competence of testing and calibration laboratories* and Volume 1 of The NELAC Institute (TNI) Standards (September 2009)
- The new QSM is designed for use in conjunction with the ISO and TNI standards. It will be released as a stand alone document.
 - ❖ Copyright issues prevent inclusion of ISO/TNI text
 - ❖ Can freely distribute and post

New Format (cont.)



DoD-ELAP and DOE CAP programs are expected to remain as currently implemented

- DoD/DOE specific language is presented as text to accompany the associated ISO/TNI clauses and is presented as:
 - ❖ Additional requirements
 - ❖ Clarifications of existing text
 - ❖ Guidance
- DoD/DOE requirements have been consolidated to the maximum extent possible, exceptions include:
 - ❖ DoD accreditation program
 - ❖ RAD health/safety programs

New Format (cont.)

Some example language:

4.2.8.4 p) DoD/DOE (Clarification)

The following shall be implemented as a clarification to TNI 4.2.8.4 p):

The procedures for audits and data review shall specify which records must be included in the review.

4.14 DoD/DOE (Requirement)

In addition to clauses 4.14.1 through 4.14.5, the following is required:

4.14.6 The audit schedule shall ensure that all areas of the laboratory are reviewed over the course of one year.

New Format (cont.)

Some example language:

4.13.3 DoD/DOE (Guidance)

The following is guidance to TNI 4.13.3:

Dual storage of records at separate locations is considered an acceptable option for the purpose of protecting records against fire, theft, or loss.

1.5.2.1 DoD/DOE (Requirement)

The following shall be implemented in lieu of TNI 1.5.2.1.f):

f) For DoD/DOE, the LOD shall be verified quarterly.

What's in a name?

- Expect the combined DoD/DOE document to contain a title that blends both organizations into one due to previous contract awards, procurement policies, and other guidance manuals that reference either QSM or QSAS:

DoD Quality Systems Manual for Environmental Laboratories Version 5.0 & DOE Quality Systems for Analytical Services Version 3.0

Module Overview

- Module 2: General Quality Systems – completed draft version; DoD/DOE Glossary inserted in front; RAD specific definitions to be added.
- Module 3: Asbestos – completed draft version; minor changes to TNI Module.
- Module 4: Chemistry – completed draft version.

Module Overview (cont.)

- Module 5: Microbiology – review in progress; no changes expected at this time.
- Module 6: Radiochemistry – completed draft version.
- Module 7: Toxicology - review completed. No changes expected.

Changes, Deletions, & Additions

- **Module 2 Quality Systems**

Section 4:

- a. Deleted section on Qualifications and Experience Tables for lab personnel
- b. Added Quality Manager has ability to stop unsatisfactory work
- c. Added documents that provide instructions are considered a part of the QS and subject to document control (i.e. cheat sheets)
- d. Added labs shall only report analytes from their scope of accreditation (DoD only)

Changes, Deletions, & Additions (cont.)

- e. Added client feedback requirements that shall be sought (i.e., obsolete methods; method modification required; mismatched detection/action levels; problems with received samples)
- f. Clarified subcontracting:
 - Must meet the requirements of the Standard
 - DoD labs must be DoD-ELAP accredited
 - DOE labs must be approved by appropriate DOE representative
 - Outsourced QS elements (such as data review) must comply with the standard and are subject to review/approval by DoD/DOE

Changes, Deletions, & Additions (cont.)

- g. Added willful avoidance of approved corrective actions may result in loss of DoD accreditation or DOECAP priority I findings

Section 5:

- a. Storage blanks for volatile analysis analyzed at a minimum every 14 days
- b. Added section on data security: LIMS (requires passwords); spreadsheet calculations (requires verification); software development (requires validation)
- c. Glass syringes for Precision & Bias requires general certificate of uncertainty upon receipt
- d. Added legal Chain of Custody protocols when required and not provided by a State or Federal program

Changes, Deletions, & Additions (cont.)

- **Module 4 Chemistry:**

- a. LOD established at greater than or equal to two times the DL
- b. LOD/LOQ determinations based on scope of accreditation (including prep methods) and can be based on “worst case” basis when multiple cleanup/extractions are used
- c. LOD/LOQ can be verified on a per batch basis (mobile labs/infrequent tests)
- d. Second manufacturer (second source) can be same manufacturer if independently prepared from different source material
- e. Metals analysis with a single point calibration: samples above the quant range (but within the LDR) can be reported if a successful CCV above the sample results is run

Changes, Deletions, & Additions (cont.)

- f. Method Blanks fail if they exceed $\frac{1}{2}$ the LOQ AND are greater than $1/20^{\text{th}}$ the amount measured in any associated sample (or $1/20^{\text{th}}$ the regulatory limit)

- g. For CCVs: the following shall be implemented in lieu of TNI 1.7.2.e):
 - If a CCV fails, the laboratory can immediately analyze two consecutive CCVs
 - Both of these CCVs must meet acceptance criteria in order for the samples to be reported without reanalysis
 - If either of these two CCVs fail or the if the laboratory cannot immediately analyze two CCVs, the associated samples cannot be reported and must be reanalyzed
 - Take corrective action(s) if the above scenario fails until an acceptable CCV is obtained. All affected samples since the last acceptable CCV must be reanalyzed

Proficiency Testing (PT) Samples

- Section 5.9 (PT Requirements) in the Quality Systems Manual has been removed
- Expect to create a new section in Module 2: Quality Systems for proficiency requirements:
 - ✦ Based on accreditation for PT providers as ISO Guide 43 (soon to be ISO 17043)
 - ✦ Will require PT samples for all analytes that are on a scope of accreditation
 - ✦ Will require PT samples twice a year
 - ✦ Acceptance/Failure based on program(s) participated in by the PT provider

Will allow for participation of other providers such as the DOE-MAPEP Mixed Analyte Performance Evaluation Program

Other Items of Interest

- Appendix A: References - Removed from the standard
- Appendix E: Reporting Requirements – Update is in progress
- Appendix F: Method Tables – Update in progress
 - ✧ Includes latest EPA update V information, where available
 - ✧ Redundant information eliminated
 - ✧ Previous Method Tables are completed
 - ✧ RADCHEM Method Tables to be added:
 - Alpha Spectroscopy
 - Liquid Scintillation
 - Beta/Gamma Spectroscopy
 - ✧ New Tables (Chemistry):
 - Chemical Warfare Agents (CWA)
 - PFOA/PFOS

LCS Study

❖ **Appendix G LCS Study will be removed from the document:**

- Based on data now over a decade old
- Based on a limited data set
- Does not include all analytes of interest

❖ **New LCS Study is underway:**

- Expect all accredited/approved laboratories in the DoD/DOE universe to participate
- Will require uncensored data sets
- Contract support will be used to collect/analyze data to ensure confidentiality
- Results will be published as a stand alone document

Timeline

- Draft version of completed Modules and Tables will be available on DENIX website after our EMDQ Workshop
- Attendees will be emailed a link to the documents
- DoD/DOE work group will continue with unfinished Modules & Tables throughout Spring 2012
- Comments received/variance requests will be evaluated over the summer 2012
- Draft Final document expected by Fall 2012
- Signed DoD/DOE Standard expected in Winter 2013

Environmental Data Quality Workgroup (EDQW)

- The EDQW subgroup that created the new DoD/DOE Standard is composed of the following participants:
 - Navy: Fred McLean (Chair); Janice Willey; William (Ed) Corl
 - Army: Chung-Rei Mao; Charles Stoner
 - Air Force: John (Seb) Gillette
 - DOE: Joe Pardue; Todd Hardt
 - Contractor: Alyssa Wingard

Questions ???



We have answers*

Do not say, “Why were the old days (*of QSM 4.2*) better than these?” For it is not wise to ask such questions.

Eccles. 7:10 (NIV)

Workshop participants are invited to ask questions of the EDQW in the open forum session: Wednesday, March 28th