DoD *Quality Systems Manual:* *Implementation and Future Directions*

Jackie Sample, Chair EDQW, NAVSEA
William Batschelet, PhD, AFCEE
George Lee, PhD, AFIOH
Fred McLean, NAVSEA

Purpose of Briefing

- Review the *Quality Systems Manual for Environmental Laboratories* (QSM)
- Discuss implementation efforts and procurement policy
- Highlight changes in the proposed Draft Version 3 update
- Present overview of joint-DoD Laboratory Assessment Protocol

Quality Systems Manual

- **Provides requirements for a laboratory quality system**
- **Describes content of the lab's quality manual**
- **Based on National Environmental Laboratory Accreditation Conference (NELAC) Chapter 5 (Quality Systems) language**

Quality Systems Manual (cont'd)

- **Clarifies DoD implementation of NELAC quality system**
  - **Gray boxes throughout document**
- **Four DoD appendices added in Version 2**
- **QSM Version 2 in place since June 2002**

Implementation of QSM

Current QSM Implementation

- QSM designed to replace parts of each DoD components' documents:
  - Navy Installation Restoration Chemical Data Quality Manual (IR CDQM)
  - AFCEE Quality Assurance Project Plan
  - U.S. Army Corps of Engineers Appendix I of Engineer Manual (EM) 200-1-3
- Full implementation of each version of QSM expected within 2 years of its release

Laboratory Assessment Protocol

- **Draft final protocol to be DoD-wide standard for assessing environmental laboratories**
- **All laboratories doing work for DoD will be assessed against the QSM**
- **Pilot of assessment protocol underway**

Draft DoD Procurement Policy

- **DoD Procurement Policy for Implementing 'Higher-Level' Contract Quality Requirements**
- **Applies to all solicitations, contracts, and purchases involving environmental measurements**
- **Includes to Federal Acquisitions Regulations (FAR)**
  - **May be performance-based**
  - **Shall include QA/QC criteria**

Draft DoD Procurement Policy (cont'd)

- **Key provisions:**
  - **Government roles and responsibilities**
  - **Contractor roles and responsibilities**
  - **Quality systems documentation requirements (labs conform to DoD QSM)**
  - **Minimum laboratory qualifications (national or State recognition, approval from one or more DoD component, PT results)**
  - **Minimum qualifications for quality assurance managers and project chemists**
  - **Sample contract clauses**

DoD
Quality Systems Manual for Environmental Laboratories
Version 2

Benefits of QSM

- Standardization of processes throughout DoD
- Alignment with NELAP
- Deterrence of improper, unethical, or illegal actions
- Policy guidance for labs involved in all types of testing
- Foundation for standardization of future processes

Important Theme Throughout QSM

Any specific requirements contained in this manual are superseded by project-specific requirements or regulations.

NELAC Chapter 5 Quality Systems

- Laboratory organization and management
- Documentation requirements (quality manual, SOPs, records)
- Essential QC procedures
- Analyst training and demonstration of capability
- Equipment/instrument and reference materials requirements

Key DoD Clarifications (QSM Version 2)

- Minimum data qualifiers
- Method Detection Limit (MDL) studies and verification checks
- Definition of work cells
- Detection and prevention of improper actions
- Clarification of calibration issues (concentrations of standards, # of points, flagging)
- Modification or addition of definitions

Appendix DoD A: Reporting Requirements

- **Describes mandatory and optional requirements**
- **Focuses on key elements important to understanding analytical data quality**

Appendix DoD B: Quality Control Requirements

- **Defines and describes evaluation of key QC checks**
- **Consolidates DoD data quality requirements on instrument-based tables**
- **Identifies appropriate corrective actions and flagging**

Appendix DoD C: Target Analyte Lists

- **Used as default when no project- specific analytes identified**
- **Encourages use of shorter, project-specific list**

Appendix DoD D: LCS Control Limits

- **Mandatory DoD-wide QC limits**
- **Provides batch acceptance criteria**
- **Random marginal exceedances allowed, if not project-specific analytes**
- **Benchmarks for evaluating alternative methods**
- **Basis is study using over 40,000 data points**

Draft QSM Version 3 – Future Directions

NELAC 2003 Update

- QSM V3 will incorporate most recent NELAC revision (June 2003)
- Follows ISO 17025 (in lieu of ISO Guide 25)
  - Completely reorganized
  - New section on Organization
  - Addresses measurement uncertainty
  - Use of ISO terms: *limit of quantitation* (LOQ) and *limit of detection* (LOD)

NELAC 2003 Update (cont'd)

- Additional language on data integrity
- Evaluation requirements for non-standard methods (instead of PBMS)
- Incorporates LCS marginal exceedance allowance concept from QSM V2

What's New In QSM Version 3?

- **International scope (box 1, 1.2)**
  - Expanded beyond U.S. and possessions
- **Informal documents (box 14, 4.3.1)**
  - Worksheets, posters must be consistent with current version of manual or SOP
- **Subcontractor laboratories (box 15, 4.5.1)**
  - Primary lab must consult with client and allow to overrule prior to use of any subcontractor
- **Client notification (box 17, 4.7)**
  - Encourages proactive engagement
  - Examples of situations for notification

What's New In QSM Version 3?

- **Worksheets (box 21, 4.12.2.5.2.a)**
  - **Must be bound and pre-numbered**
- **Targeting weights (box 64, 5.7.1)**
  - **Not allowed for small soil samples with coarse, heterogeneous particles**
- **Reporting estimate of measurement uncertainty (box 43, 5.4.6.2)**
  - **Clarify only for lab's portion of process**
  - **Labs may estimate uncertainty using LCS results**
  - **Only required when specified by client**

What's New In Draft QSM Version 3?

- **Incorporated PT sample requirements from NELAC Chapter 2 (box 73, 5.9.1.b)**
  - **Labs working for DoD *must* participate in PT program**
  - **PTs required every 6 months**
  - **Must pass 2 of last 3**
  - **80% of analytes must produce acceptable results for the group to pass**

What's New In Draft QSM Version 3?

- **NELAC changed from detection and quantitation limit to LOD and LOQ**
  - **Revised DoD boxes to match NELAC terminology**
- **LOQ defined as lower limit by NELAC**
  - **Established by lowest standard of calibration**
  - **Must be ≥ 3 x LOD**
- **Introduced *Quantitation Range* concept (box D19, D.1.2.2)**
  - **Stress quantitation bound by both upper and lower ends of calibration curve**

What's New In QSM Version 3?

- **Updated MDL study requirements (box D-18, D.1.2.1)**
  - **Establish LOD by determining MDL or alternative approach (must be 99% confidence)**
  - **MDLs based on analyte concentration of 7 replicates – Evaluation of concentrations based on ratio of mean recovered concentration and calculated MDL**
    - **1-5 for reagent water**
    - **1-10 for other matrices**
  - **MDL verification checks acceptable if reliably detected and identified by method-specified criteria**
    - **If no confirmation, check sample must produce a signal at least 3 x instrument's noise level**

What's New In Draft QSM Version 3?

- **Continued proficiency (box 29, 5.2.6.c.3.iv)**
  - **Use ongoing review of QC samples as demonstration of continued proficiency**
- **Work Cell demonstration of capability (box C-2, C.1)**
  - **Clarified only on individual basis**
  - **Not dependent on combinations of work cell members**

What's New In Draft QSM Version 3?

- **Initial Test Method Evaluation (new NELAC Section C.3)**
  - **QC Requirements for Lab Developed or Non-Standard Methods (box C-5)**
    - **Calibration, precision/accuracy, analyte ID**
  - **Verification of LOD (box C-6)**
    - **Ion abundance, second column confirmation, pattern recognition**
  - **Validation of LOQ (box C-7)**
    - **No lower than lowest calibration standard**

What's New In Draft QSM Version 3?

- **Initial Test Method Evaluation**
  - **Precision and Accuracy/Bias (box C-8)**
    - **Compare to LCS mean and standard deviation**
  - **New Matrix (box C-9)**
    - **Must analyze 3 MS/MSD**
  - **Selectivity for Non-Standard Methods (box C-10)**
    - **Use common selectivity checks for similar technology or method**

What's New In Draft QSM Version 3?

- **Marginal exceedance allowance for LCS (D.1.1.2.1.e)**
  - **NELAC now follows QSM V2 (from Appendix DoD-D)**
  - **Added minor clarifications (defined random, marginal exceedance limits, etc.) (boxes D-8 to 10)**
  - **Appendix DoD-D reiterates policy and lists DoD LCS control limits**

What's New In Draft QSM Version 3?

- **Guidance for labs to generate in-house LCS control limits (box D-7)**
  - **Statistically derived, based on 30+ data points**
  - **Updated annually or after major change**
  - **Cannot exclude failed data points**
  - **Use of control charts for trend analysis recommended**
- **In house limits to be used if DoD limits or project-specific limits not available**

What's New In Draft QSM Version 3?

- **Matrix spike/matrix spike duplicate frequency (box D-11, D.1.1.3.1)**
  - **One per preparatory batch (formerly 1 in 20 samples)**
  - **Must be same environmental matrix as samples**
- **Matrix duplicate frequency (box D-15, D.1.1.3.2)**
  - **If concentration > 5 x LOQ, may analyze matrix duplicate in place of MSD**
  - **One per preparatory batch**

What's New In Draft QSM Version 3?

- **Updated Appendix DoD-B tables**
  - **Made consistent with Method 8000C (Removed Grand Mean option for initial calibration)**
  - **No longer references specific SW-846 updates by letter**
  - **Allows use of "best" requirements from all published versions**

DoD Laboratory Assessment Protocol

Assessment Protocol

- **Purpose is to standardize lab assessments performed by DoD**
  - **Increase trust between components**
  - **Allow info to be shared between components**
  - **Ultimately reduce redundancy and costs**
- **Based on QSM, Final Version 2**
  - **Will be updated when version 3 is in place**
- **Assessments can be for:**
  - **Pre-qualification**
  - **Assessment against project-specific needs**
  - **Continuing check of compliance**

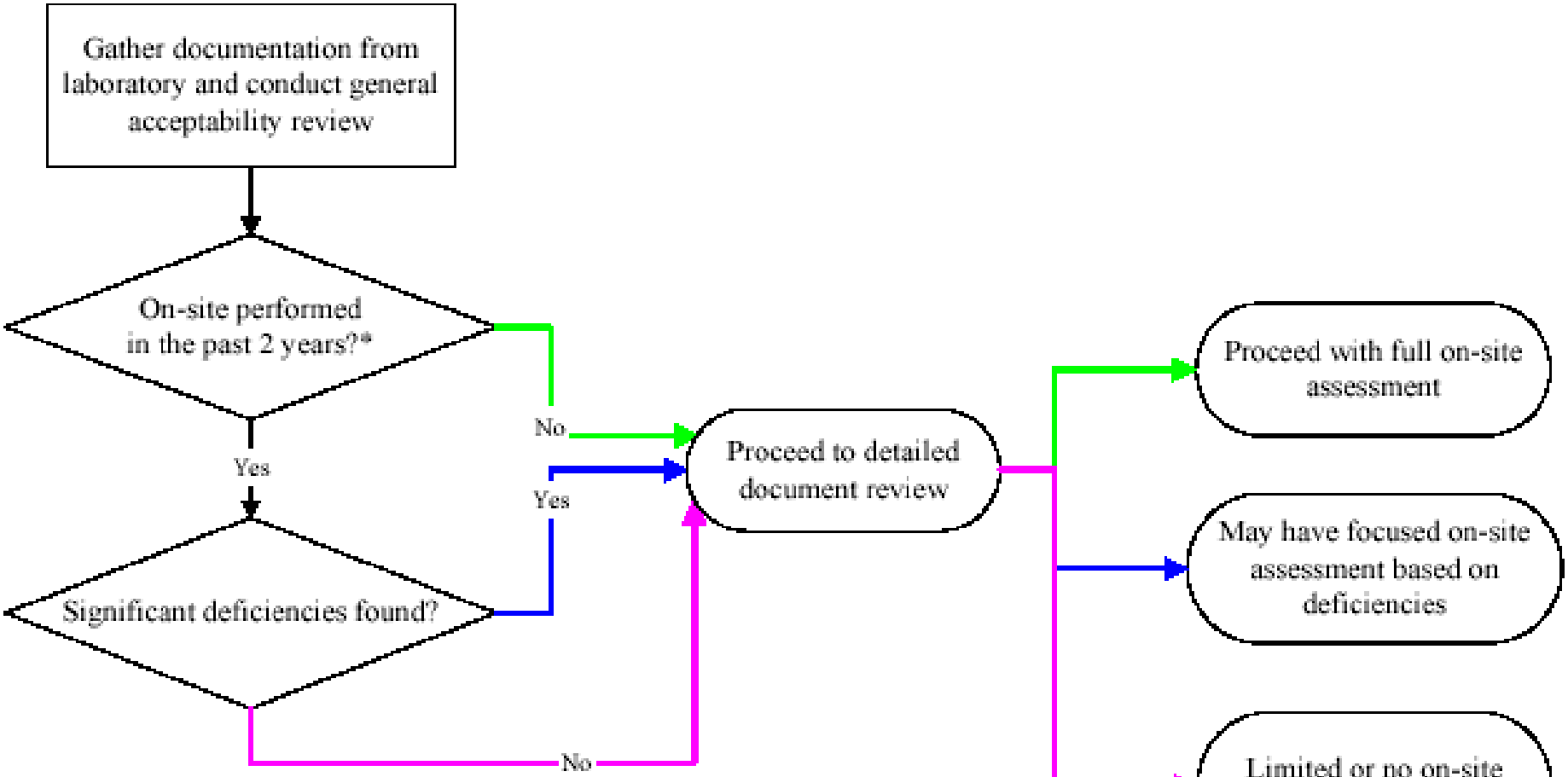
Documentation

- Overall protocol describing procedure
- Three appendices (SOPs) with additional detail:
  - A: SOP for Performing Lab Document Reviews
  - B: SOP for Performing Lab Procedures Reviews
  - C: SOP for Performing On-site Lab Assessments
- Each SOP has series of checklists as attachments

DoD Laboratory Assessment Protocol

- **Protocol stresses review of documentation and previous assessments**
  - **Recent NELAP, DoD, or other accreditations**
  - **PT samples results**
  - **SOPs and quality manual**
- **Takes into consideration**
  - **Lab's experience working with DoD**
  - **Scope of work**
  - **Quality of lab's documentation**
- **Extensive on-site assessment is not always necessary**

Assessment Protocol



*By NELAP or any DoD component.

Document Review

- **Covers all types of lab documentation**
  - **Quality Manual, Method Manuals, PT sample results, previous audit or assessment reports**

1) General acceptability review

- **Completeness check**
- **Do docs appear to meet QSM requirements?**
- **Any significant deficiencies?**

2) Detailed document review

- **Should DoD accept or reject lab?**
- **Is on-site assessment necessary?**

Document Review Checklists

- Overarching questions for nine major sections
- Specific supporting questions help to answer overarching questions
- Supporting questions closely follow QSM (includes references to sections)
  - From DoD clarification boxes and NELAC text (if necessary)

Laboratory Procedures Reviews

- **Review of specific type of documentation**
  - **SOPs, operating instructions, method manuals**
- **Conducted as part of off-site doc review or on-site assessment, or both**

On-site Laboratory Assessments

- **Purpose is to confirm that lab implements documented procedures properly; follow-up on questions from doc review**
- **Detailed Document Review Checklist may be used to evaluate quality system**
  - **Fill in holes from document review**

On-site Laboratory Assessments Checklists

- **Checklists available to evaluate ability to perform specific methods**
  - **Grouped by technology**
  - **Based on Appendix DoD-B tables from QSM V2**

GC and HPLC
ICP, GFAA, CVAA
Colorimetric CrVI
Cyanide
Common Anions

GC/MS
ICP/MS
High Res GC/Low Res MS
High Res GC/High Res MS

Also Generic Checklist for any other technology or method.

DoD Laboratory Assessment Protocol Pilot Test

- Currently pilot testing protocol on DoD and commercial labs
- DoD facility to be audited first (late Summer 2004)
- Commercial Lab audited after DoD (late Fall 2004)
- Protocol may be modified based on lessons learned from pilots

Conclusion

Next Steps

- QSM V3 distributed for stakeholder comment (late summer 2004)
- QAA/TAT address comments (late fall)
- DoD concurrence on QSM V3 (January 2005)
- Pilot test DoD-wide laboratory assessment protocol (late summer to fall)

Questions?

William Batschelet, PhD
AFCEE
(210) 536-5658
william.batschelet@brooks.af.mil

George Lee, PhD
AFIOH
(210) 536-6166
george.lee@brooks.af.mil

Fred McLean
NAVSEA
(843) 764-7337 ext. 22
mcleanfs@navsea.navy.mil

Clem Rastatter
Versar, Inc.
(703) 642-6776
rastacle@versar.com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