Comparison of USACE Shell and DOD Quality Systems Manual (QSM) Requirements

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HTRW-CX

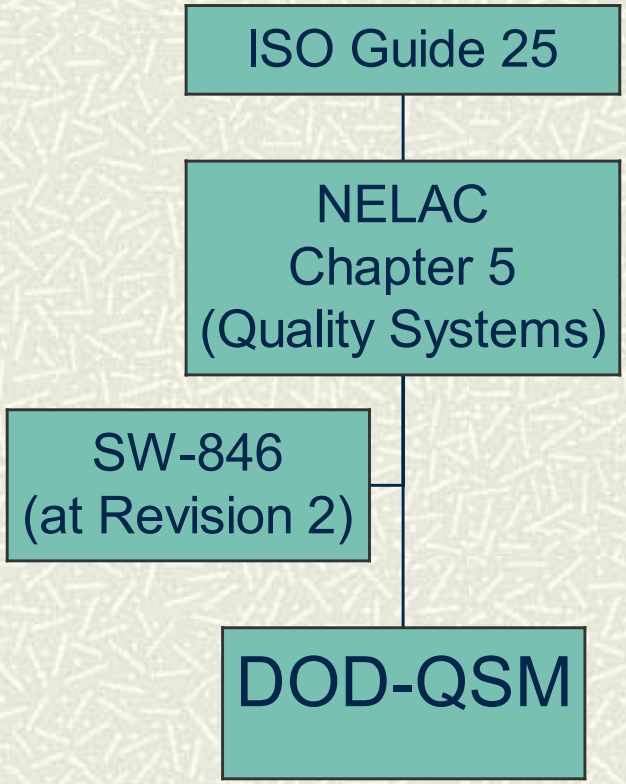
What is the USACE Shell?

- USACE Policy on District Specifications for Environmental Chemical Analyses
- Released in 8 Dec 1998 HQ memorandum, Interim Chemical Data Quality Management (CDQM) Policy for USACE Hazardous, Toxic, and Radioactive Waste (HTRW) Sites
- Incorporated as Appendix I of EM 200-1-3, Requirements for the Preparation of Sampling and Analyses Plans (Feb. 2001)

What is the DOD-QSM?

- Consensus Standard for Environmental Laboratories working on behalf of the DOD Branch Services (Army, Navy, AF)
- Authored by EDQW QA-TAT (Quality Assurance Task Action Team)
- Released from DUSDES (Department Undersecretary of Defense for Environmental Security) in June 2001
- July 11, 2001 memorandum responded to DUSDES - Army Implementation of DOD-QSM for Environmental Laboratories
- Revision 1 is available at http://denix.osd.mil
- Updating to Revision 2 is pending (*ETA Fall 2002*)

Background Documents



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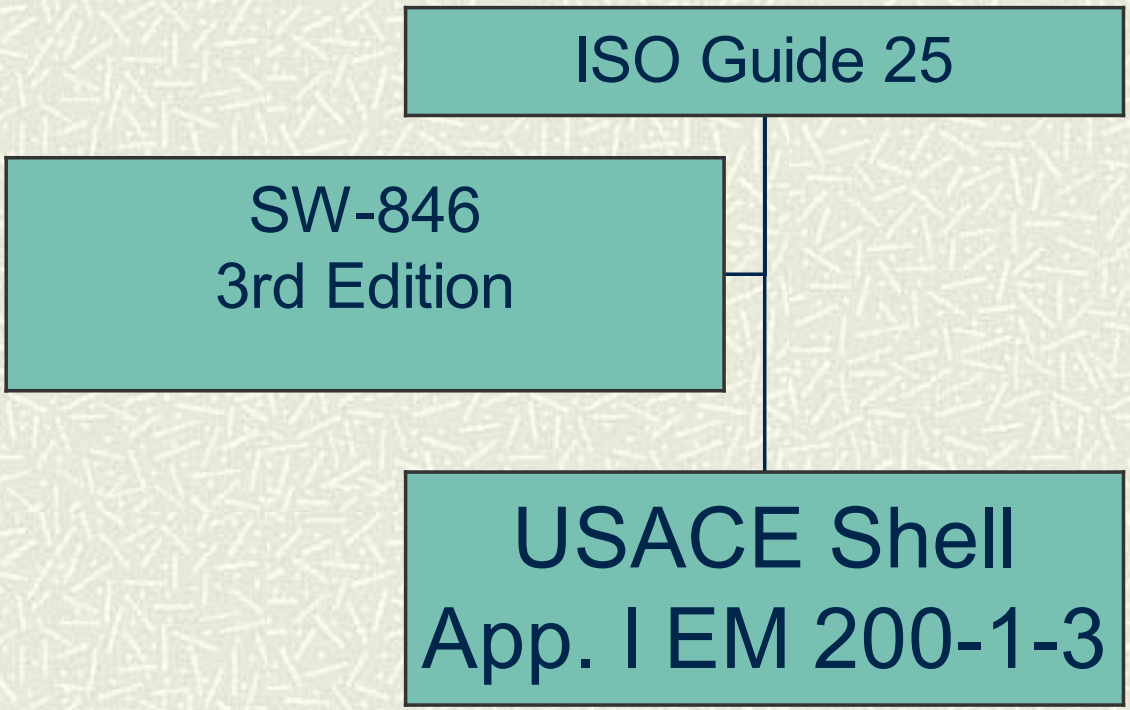

Common Ground between NELAC, DOD-QSM, and Shell

- Identical Requirements (ISO Guide 25)
  - Quality System Establishment
  - Quality Manual
  - Essential Quality Control *(general requirements)*
  - Laboratory Management Responsibilities
- Similar Requirements
  - Records *(general requirements)*
  - Sample Receipt Protocols

Quality Systems Establishment Commandment (ISO Guide 25)

‘The laboratory shall establish and maintain a quality system based on the required elements contained in this chapter and appropriate to the type, range and volume of environmental testing activities it undertakes.’

NELAC Value Added

- Applicable for the generation of Definitive Data
  - Excepts sole–support labs from NELAC standards
- Report test result with estimated uncertainty, when necessary.
- Audit Requirements
  - Internal Audits and Review, Managerial Review, and Performance Audits
- Unencumbered Work Areas
  - Sample receipt, data handling and storage, supply and waste storage
- Equipment or Instruments subjected to (evidence) overloading must be taken **out of service**, repaired, and verified as acceptable performance.
- Sample Acceptance and Tracking requirements
- Outside Support Services and Supplies
- Administrative and Raw Calibration Data Records to Retain

NELAC Omissions / Detrimental Brevity

- **SOPs** – Allows use of reference method alone without further elaboration
- No guidance on the elements for a '***Fraud***' **Prevention Program**
- **Personnel Qualifications** established for only the Technical Director and the QAO
- **Demonstration of Capability** (DOC) Not Analyst Specific (work cell concept)
- **Manual integration** support documentation lacking
- **Detection and Quantitation Limit** requirements ambiguous
- **Calibration and Calibration Verification** guidance lacking specifics
- **Batch QC (MB, LCS, MS, MSD, surrogates)** guidance lacking specifics
- **Data may be reported without any corrective actions** performed.
- No specifics on **Procedures for Data Verification** by lab personnel or **Level of Review**
- No guidance on **Data Qualification protocols**
- Few Technical Aspects of the **Data Report Packages** identified

USACE Shell Value Added

- Fraud Prevention Program Elements adopted
- Method Sensitivity Assessment adopted
  - MDLs per 40 CFR 136 part B
  - MDL check sample detected to **3X noise level**
  - QL ≥ 3X MDL
  - RL no lower than low calibration standard or LL-CCV
- Calibration Procedures adopted
  - Support Equipment – application of ASTM standard criteria
  - Initial Calibration – Ceiling limit for individual compounds when '*Grand Mean*' (AVG of all % RSD) used **(more stringent criteria established in draft revision 2)**
  - LL-CCV for ICP analysis (**±30% of expected value**)

USACE Shell Value Added

- Batch QC Procedures adopted
  - Method Blank (MB) criteria < $\frac{1}{2}$ Reporting Limit
  - Lab Control Sample (LCS)
    - Includes all Target Analytes, unless project's specify COC
    - Sporadic Marginal Failure concept in evaluating LCS acceptance
  - Corrective Actions mandate ONE reanalysis, then qualification of data allowed
- Data Review (3-tier) Procedures adopted
- Minimum Technical Elements identified for Data Report Packages

DOD-QSM Value Added

- Management Responsibilities for Corrective Actions
- Requires all Failed DOC Attempts be retained with successful DOC Certification documentation
- Manual Integration Documentation Requirements
- Calibration Clarifications
  - GC/MS CCV criteria evaluates all Target Analytes
  - Corrective Actions for failed CCV requires reevaluation at low and mid-concentration levels
- DOD LCS Control Limits established based on REAL DATA!
  - Calls out Poor Performers, and omits from evaluation of batch acceptance
  - Provides a basis to evaluate contract lab's in-house limits
  - Establishes technically sound QC criteria for batch acceptance

The Lost Criteria

- Items currently required within the Shell that were not adopted within DOD-QSM
  - Personnel qualifications for lab personnel (source CLP SOW)
  - Standards < 96% pure must be corrected for
  - Initial calibration mandatory after CCV
  - Quantitation of ICP results bound by the one standard's concentration (no allowance for linear range)
  - RSD of duplicate injections / multiple exposures of metals analyses (ICP and GFAA)
  - Quantitative assessment of PCP and Benzidine tailing factors for Semivolatile analysis (source Method 525)

Bottom Line –

- All documents lack guidance on Electronic Data Deliverable requirements….up to the district to address this and any other issues into contracts…
- **NELAC is Not Sufficient to Stand-Alone**
- DOD-QSM improves upon NELAC with influence from all DOD agencies, including Shell
- DOD-QSM revision 2 will include sufficient detail to supercede the Shell
- DOD-QSM guidance can be superceded by project DQOs