

DoD Quality Systems Manual

Promoting Best Practices

WTQA Symposium
August 13, 2002



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Purpose of Briefing



- ◆ Review background of Quality Systems Manual (QSM)
- ◆ Summarize changes to the QSM in Version 2
 - ❖ Updated NELAC language
 - ◆ NELAC Plus
 - ❖ Four new DoD appendices



Data Quality Objectives



- ◆ Defensible data of known quality and documented performance
- ◆ Ethical criteria
- ◆ Performance criteria
 - ❖ Quality Systems Manual



Environmental Data Quality Workgroup



- ◆ EDQW tasks:
 - ❖ Develop and recommend policy
 - ❖ Provide exchange of knowledge
 - ❖ Coordinate response to regulatory issues
 - ❖ Respond to DoD IG data quality issues
 - ❖ Represent DoD on the IDQTF
- ◆ QAA/TAT subgroup tasked to create the QSM



Quality Systems Manual



- ◆ Based on NELAC Chapter 5 (Quality Systems)
- ◆ Adds clarifications in the form of gray boxes throughout the document
- ◆ Enables labs to create a standardized quality system that meets requirements of multiple clients
- ◆ Version 1 (Oct 00) adopted in a memo from DUSD(ES) dated December 5, 2000
- ◆ To be updated regularly



QSM - Version 2



- ◆ Incorporates changes to NELAC Chapter 5 language based on Voted Revision 14 (June 29, 2000)
- ◆ Addresses changes to NELAC through modification or addition of DoD clarification boxes, as appropriate
- ◆ Adds four DoD Appendices (A, B, C, D)



Appendix DoD-A: *Reporting Requirements*



- ◆ Purpose - To create consistent report content across all DoD projects
- ◆ Outlines DoD's reporting requirements for hard copy reports from the laboratory
- ◆ Includes mandatory and optional requirements



Appendices DoD-B, C and D



These appendices

- ❖ focus on SW-846 methods, but
- ❖ make clear that use of non-SW-846 methods is acceptable.



Appendix DoD-B: *Quality Control Requirements*



- ◆ Purposes -
 - ❖ To provide clarification when there are vagaries between existing guidance documents
 - ❖ To state a DoD preference when multiple options are acceptable
- ◆ Contains tables that consolidate DoD data quality requirements for common SW-846 methods into a technology-based, easy-to-use reference format



Appendix DoD-B: *Quality Control Requirements*



Introductory text includes

- ❖ Definition of QC checks
- ❖ Purpose of QC checks
- ❖ Explanation of how results should be evaluated and compared to results from other QC checks



Appendix DoD-B: *Quality Control Requirements*



- ◆ Includes extremely detailed tables organized by QC check (ICAL, MS, etc.)
- ◆ Identifies frequency, acceptance criteria, corrective action, flagging criteria, and additional comments for each QC check

Note: These are DoD requirements based on EPA guidance.



Laboratory Data Qualifiers



- ◆ U, J, B, N, Q
 - ❖ R-Flag: Eliminated
 - ❖ U-Flag: Undetected at MDL
 - ❖ N-Flag: Nontarget analyte
- ◆ Q-Flag: One or more QC criteria failed
 - ❖ Data usability assessed in data review/validation
 - ❖ Relieve laboratory from burden of usability assessment



Appendix DoD-C: Target Analyte Lists



- ◆ Purpose - To be used when the laboratory has not been given guidance by the client on what to analyze for within a given analyte group
- ◆ Lists of analytes derived from:
 - ❖ SW-846 methods
 - ❖ Common analytes of concern at DoD sites
 - ❖ Superfund list of 110 frequently occurring chemicals
- ◆ Project-specific analytes supercede Target Analyte List



Appendix DoD-D: LCS Control Limits



- ◆ Purpose - To provide a means for assessing batch acceptance when project-specific criteria are not available
- ◆ Addresses issues with nine SW-846 methods
- ◆ Establishes benchmarks for evaluating alternative methods using PBMS
- ◆ Allows for sporadic marginal exceedances
- ◆ Recognizes poor-performing analytes



Marginal Exceedances



- ◆ Limits generated at $\text{mean} \pm 3 * \text{SD}$ for most methods
- ◆ Marginal exceedances of control limits up to $\text{mean} \pm 4 * \text{SD}$ (called ME limits) allowed for methods with long list of analytes
 - ❖ Not to exceed 5% of the total number of analytes
 - ❖ Must be random
- ◆ Project-specific data quality criteria supercede all limits



Poor-Performing Analytes



- ◆ Statistical lower control limit of 10% or less
- ◆ Not appropriate to control batch acceptance on poor performers
- ◆ If poor performer is a project-specific analyte of concern or is detected in project samples, lab should contact client



ANOVA Results



- ◆ Looked at impact from various parameters
- ◆ Results not significant for most methods
 - ❖ No trends in significant differences
 - ❖ No relevance to the environment
 - ❖ No practical differences (small absolute numbers)
- ◆ Significant difference in extraction method for explosives in water matrix



Additional Policy Issues



- ◆ LCS Failure
 - ❖ Exceedance of a LCS-CL by a project-specific analyte of concern
 - ❖ Exceedance of the LCS-CLs by more than the permissible number of analytes
 - ❖ Exceedance of the ME limits by one or more analytes
- ◆ Corrective Action
 - ❖ Applies to all analytes that exceeded LCS-CLs



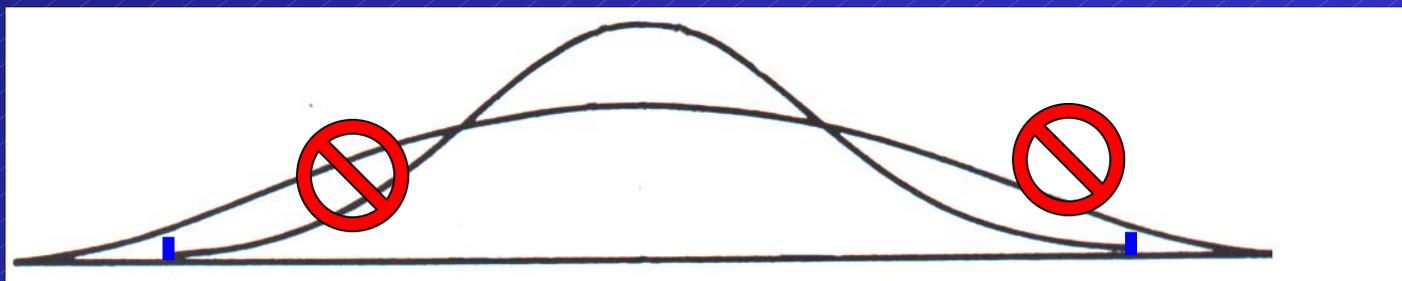
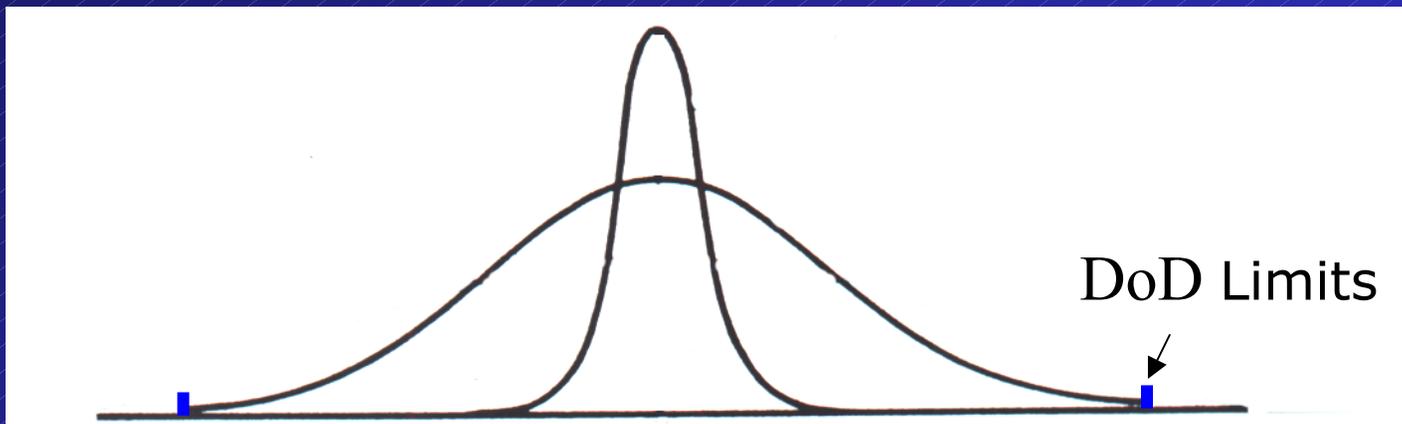
Additional Policy Issues



- ◆ Surrogates
 - ❖ Limits in separate table from other compounds
 - ❖ Marginal exceedance not acceptable for surrogates
- ◆ In-house LCS Limits
 - ❖ Labs should still generate
 - ❖ Use as quality control measure
 - ❖ Track lab performance and trends
- ◆ Limits must not exceed DoD limits



Laboratory Limits Within DoD Limits



No Shotgunning!



Next Steps



- ◆ Version 1 of QSM currently being implemented by DoD components
 - ❖ www.denix.osd.mil
- ◆ Version 2 of QSM
 - ❖ Revisions have been finalized
 - ❖ Awaiting approval by EDQW and subsequent implementation by DoD
 - ❖ www.denix.osd.mil/denix/Public/Library/Compliance/EDQW/DODV2_Mar02_final.pdf