

DoD ELAP Program Overview:

***Presented to:
EMDQ Workshop
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Agenda

- DoD ELAP Status Update
- Latest QSM Updates

The background of the slide features a large, faint, light blue chemical structure, likely a complex organic molecule with multiple rings and functional groups, including what appears to be a nucleobase or a similar heterocyclic system. The structure is semi-transparent and serves as a decorative backdrop for the text.

DoD ELAP

DoD ELAP Status Update

- Current Status of Laboratories and QSM Version 5 implementation
- DoD ELAP Distribution
- Accreditation Bodies – Trends
- DoD ELAP Scopes
- Oversight and Implementation Issues
- DENIX Database
- Frequent Findings
- Resources

DoD ELAP

Accreditation Bodies

All are International Laboratory Accreditation
Cooperation (ILAC) Signatories

- American Association for Laboratory Accreditation (A2LA)
- ANSI-ASQ National Accreditation Board (ANAB)
- Laboratory Accreditation Bureau (L-A-B)
- Perry Johnson Laboratory Accreditation, Inc. (PJLA)

Current Status of Labs and QSM Version 5 Implementation

- 97 Labs currently accredited. Prior to DoD ELAP 44 Laboratories.
- All 4 ABs performing assessments to QSM Version 5.
- All Labs must be accredited to QSM Version 5 by 1/1/2016.

Current Status of Labs and QSM Version 5 Implementation

- 36 Laboratories are still accredited to QSM Version 4.2
 - A2LA – 11 laboratories
 - PJLA – 17 laboratories
 - LAB – 6 laboratories
 - ANAB – 2 laboratories

DoD ELAP Distribution

Accredited Laboratories

State	Labs	State	Labs	State/Province	Labs
Alaska	1	Maryland	1	Oregon	1
Arkansas	1	Massachusetts	3	Pennsylvania	3
California	15	Michigan	6	Rhode Island	2
Colorado	2	Minnesota	1	South Carolina	2
Delaware	1	Missouri	3	Tennessee	5
Florida	8	Nevada	1	Texas	6
Georgia	2	New Hampshire	2	Utah	2
Illinois	1	New Jersey	2	Vermont	1
Indiana	1	New York	1	Washington	7
Kansas	1	North Carolina	4	Wisconsin	3
Louisiana	2	Ohio	3	Italy	2
Maine	1	Oklahoma	1	Canada	1

DoD ELAP – AB Distribution

AB	# of Labs - Current	# of Labs – end 2014	# of Labs end of 2013	# of Labs end 2012
A2LA	26	27	29	29
ANAB	12	12	11	14
LAB	31	28	28	31
PJLA	28	35	31	28

- Continuing to see a shift in market
- Transfers amongst ABs
- Scope Shift

DoD ELAP Scope

- Applies to all laboratories regardless of
 - Size
 - Volume of business
 - Field(s) of accreditation
 - Public/private
 - Mobile/fixed
 - CONUS/OCONUS

DoD ELAP Scopes

Changes from 2009 to 2015

- Scopes are being streamlined
- “Specialty Analyses”
 - PFOA/PFOS
 - Chemical Warfare agents
 - 8330B
 - TO-15
- Elimination of ASTM Methods
- Elimination of Standard Methods
- Labs working with projects to have accreditation to meet projects needs

DoD ELAP Oversight

- Witness New Assessors
- Review assessment reports
- Witness each AB on-site
- Participate in ILAC Peer Reviews
- Database with accreditation expiration dates
- Bi-Monthly AB Calls
- Annual Individual AB Calls
- Annual Face to Face Meeting with ABs

DENIX Database

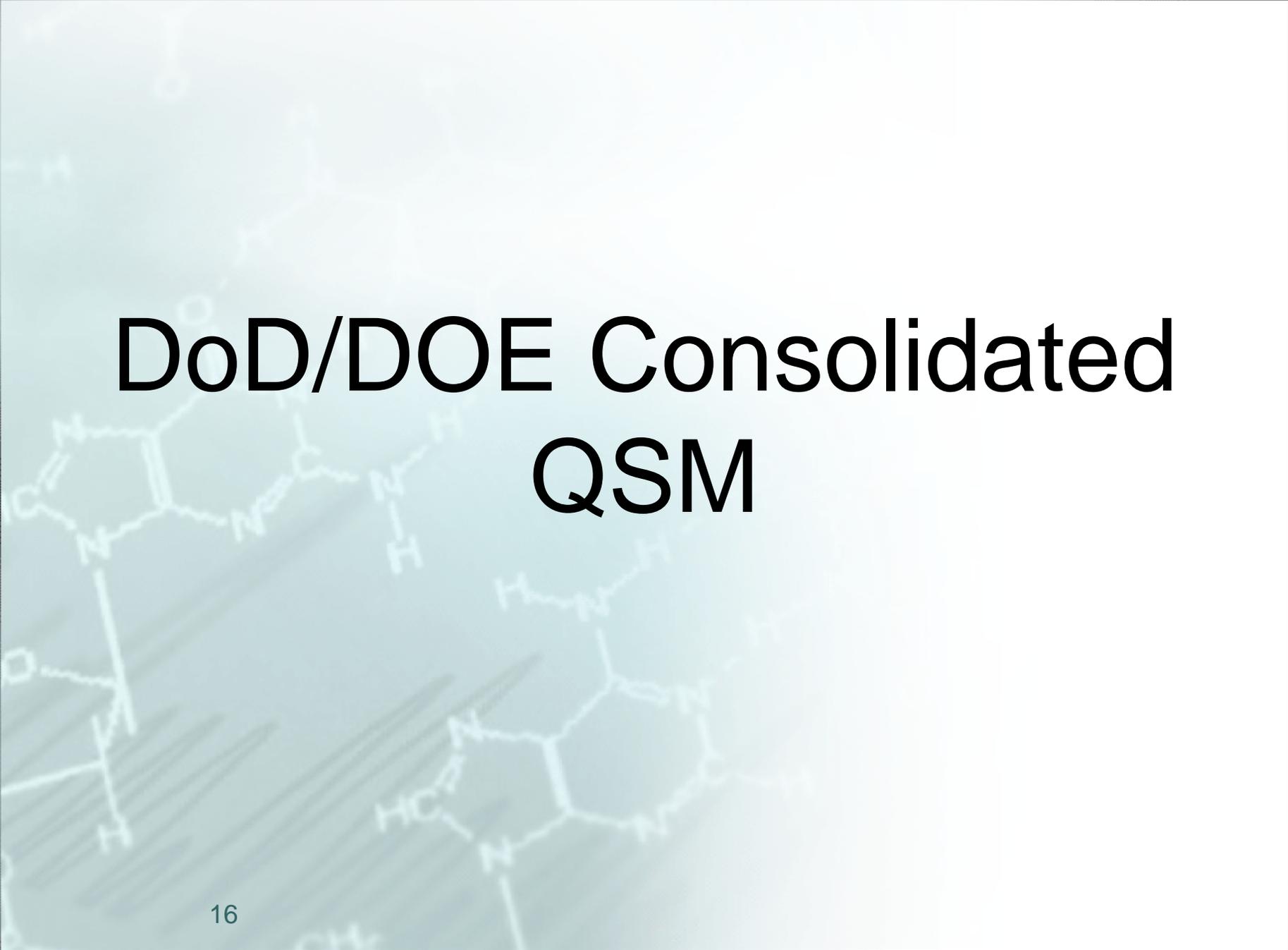
- Real time – all labs accredited
- Database developed by DENIX
- Information supplied by AB
- List includes method but not analyte
- List updated by AB
- Lab status must be verified on AB website

Common Findings

- Laboratory Practice or SOP does not match published method or lab is not following own SOP
- Deviations from test methods are not documented and technically justified
- Laboratories are not determining LOD/LOQ quarterly
- Internal Audits
- Management Review
- Not running QC samples at required frequency
- Records not maintained for equipment and supplies

DoD ELAP Resources

- DoD ELAP Fact Sheet
- QSM Version 5
- Detection and Quantitation Fact Sheet
- DoD ELAP & QSM FAQ's
- DoD EMDQ Workshop
- Policy Memos
- Webinars – 8330B
- Published on websites:
 - <https://www.denix.osd.mil/portal/page/portal/EDQW>
 - www.navylabs.navy.mil

The background of the slide features several faint, overlapping chemical structures. These include a complex heterocyclic ring system with nitrogen and oxygen atoms, a linear chain of atoms with various functional groups, and a five-membered ring containing a nitrogen atom. The structures are rendered in a light, semi-transparent style, creating a scientific and technical atmosphere.

DoD/DOE Consolidated QSM

QSM Update

- QSM Overview
- A few New Frequently Asked Questions (FAQs)
- QSM Version 5.1 Update

QSM

- Standard has multiple cover pages; a consolidated DoD/DOE cover page; a DoD cover page for QSM Version 5.0; a DOE cover page for QSAS Version 3.0.
- DoD and DOE signed out Fourth Quarter 2013.
- For DoD, accreditation to QSM Version 5.0 started in January 2014. All Laboratories must be accredited to QSM Version 5.0 by 1/1/2016.

Some FAQs

Hello, I'm seeking clarification regarding the LOD/LOQ quarterly determination requirement ("DoD QSM v5, Sect.1.5.2.1.g: "The LOD shall be verified quarterly.") Specifically, the interpretation of "quarterly" is the question. Does it mean analyzed during the each quarter of the calendar year or every 90 days?

ANS: We have interpreted this as "each quarter of the calendar year" and not as 90 days.

Some FAQs

In DoD QSM vs. 5.0 we could not find "Any established LOQ must be above the LOD." Is this no longer required?

ANS: Yes, it is still required. It is not specifically mentioned in the QSM since it is already a TNI requirement in Module 4, section 1.5.2.2.d:

d) When an LOD is determined or verified by the laboratory, the LOQ shall be above the LOD.

Some FAQs

I would like your input on this. The way that I read the QSM 5.0 is that project-specific MS/MSDs are required (by section 1.7.3.3.1 of Module 4: Quality Systems for Chemical Testing) if the project requires compliance with the DoD QSM 5.0?

ANS: The short answer to your question is: Yes, per section 1.7.3.3.1 a laboratory must analyze MS/MSDs specific to a DoD project in their batch (this is in case there are multiple sources for the samples in the batch). It is important for the projects to understand though, that QSM 5.0 applies to the lab's ACCREDITATION, not necessarily to any lab's analytical work on a specific DoD project.

Section 1.7.3.3.1 also goes on to explain that MS/MSDs are not appropriate for all projects in all cases, and that each PROJECT must decide if MS/MSDs are going to be required; what frequency they will be collected; and how the results will be evaluated.

Version 5.1

- Clarify on when it is appropriate/not appropriate to use “force through zero” calibrations.
- Work on negative intercepts in metals analysis. How to address negative Continuing Calibration Blanks (CCB) in metals. Treat CCB failures similar to how CCV failures are resolved.
- Create a general formula for calculating the Detection Limit (DL) using the Combined Standard Uncertainty (CSU).
- Incorporate the use of a background quench curve to assess the proper background to be subtracted for scintillation counting.

Version 5.1

- Add new section(s) or Tables to Address the following areas:
 - Air methods such as TO-14 and TO-15, to avoid confusion with the general GC/MS Table
 - ISM requirements (Sieving, Drying, Grinding) Table for 8330B elucidated during our conference call last Winter
 - SIM requirements for Method 8270 analytes
 - Requirements for Explosives by LC/MS or LC/MS/MS (such as Method 8321)

QUESTIONS????

For more information:

<https://www.denix.osd.mil/portal/page/portal/EDQW>

www.navylabs.navy.mil

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