

DoD ELAP Program Overview

EMDQ Workshop

April 2016

St. Louis, MO

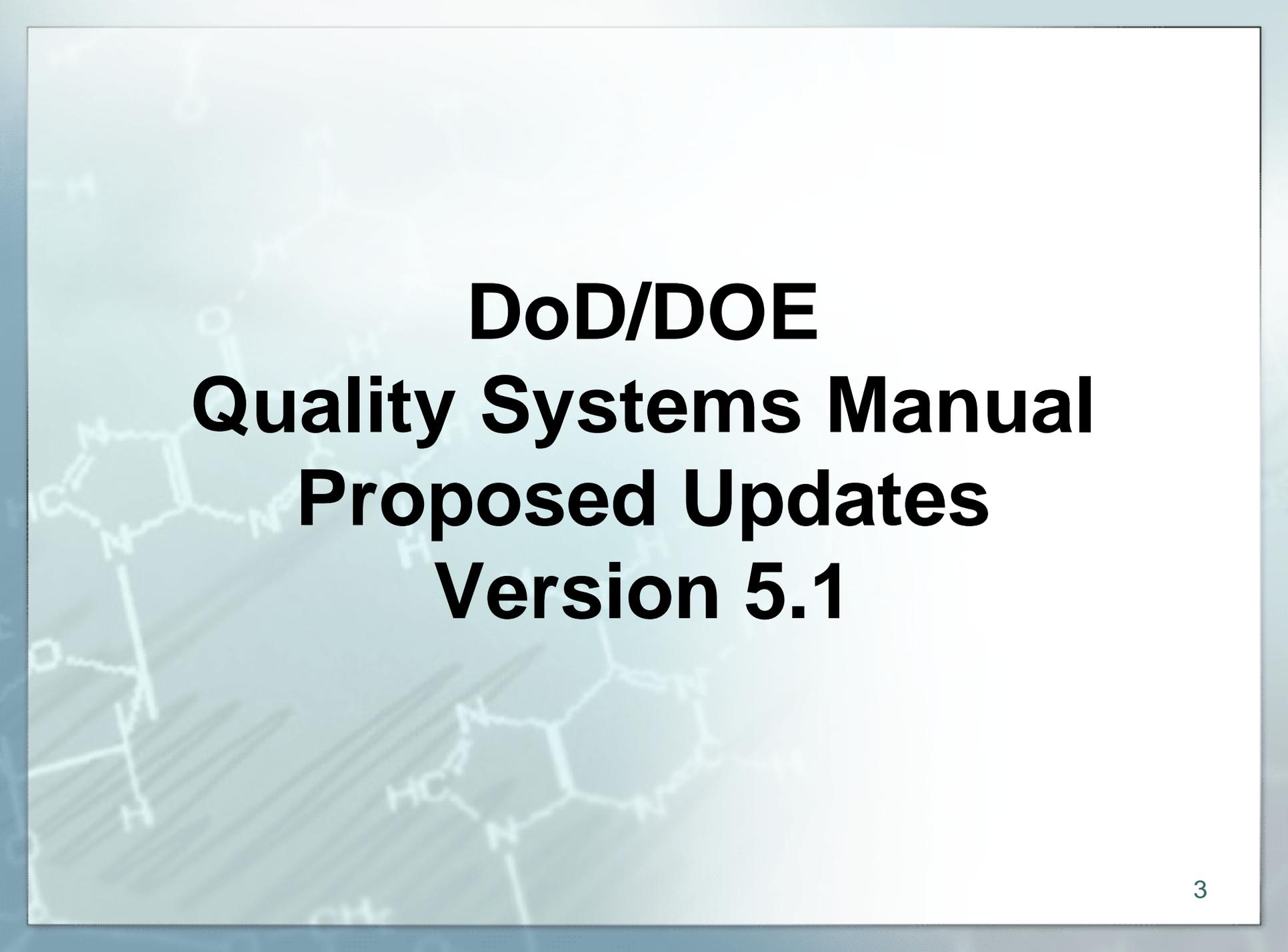
Presented by:

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*Navy Laboratory Quality & Accreditation Office
Chair, DoD Quality Assurance Oversight Subgroup*

Agenda

- **Status of QSM Version 5.1**
- **DoD ELAP Status Update**

The background of the slide features several faint, light-colored chemical structures, including what appears to be a nucleotide base and a peptide chain, overlaid on a light blue gradient.

DoD/DOE Quality Systems Manual Proposed Updates Version 5.1

DoD/DOE Quality Assurance Oversight Subgroup

➤ **Consensus working group for the EDQW:**

- **Composed of members of the Air Force, Army, Public Health Command, Navy, and DOE;**
- **Weekly meetings to discuss QSM changes and updates;**
- **Generate responses to questions received from DENIX, ABs, and laboratories;**

DoD/DOE QSM Proposed Updates

Version 5.1

- **Add new tables to address the following areas:**
 - **Air Methods such as TO-14 and TO-15, to avoid confusion with the general GC/MS Table;**
 - **SIM Requirements for Method 8270 analytes;**
 - **ISM table added for soil preparation for large volume (1Kg or greater) samples;**
 - **Requirements for Explosives by LC/MS or LC/MS/MS (such as Method 8321);**
 - **PFOA/PFOS table changes based on recent outreach efforts.**

DoD/DOE QSM Proposed Updates

Version 5.1

➤ Added New Requirements:

- **Inappropriate Practices Memo issued June 2015 - Requirements added to QSM Version 5.1.**
 - **Requires any Instances of inappropriate and prohibited practices as detailed in Section 5.2.7 to be reported to the laboratory's AB within 30 days of discovery.**
 - **Requires client notification of all affected data.**

DoD/DOE QSM Proposed Updates

Version 5.1

➤ Added New Requirements:

▪ Project Deviations

- **Waivers from QSM requirements must be requested in writing from the appropriate DoD Chemist or Contractor Project Chemist on a project-specific basis and shall include technical justification for the waiver. Documentation of approval for the waiver must be maintained by the laboratory and readily available for review.**
- **A laboratory must have the documented ability to meet all QSM requirements in order to be accredited. Laboratories cannot submit variances to AB's to allow deviation from QSM requirements as part of their accreditation. Variances must be project specific.**

DoD/DOE QSM Proposed Updates

Version 5.1

- **Changed requirement for corrective action for failing CCV.**
 - **Recalibration is no longer first corrective action to take.**
- **Initial and Continuing Calibration (ICB) and Continuing Calibration Blanks (CCB) in metals**
 - **The Absolute values of all analytes must be $< 1/2$ LOQ or $< 1/10$ the amount measured in any sample.**
- **CCBs may not be re-analyzed without re-analysis of the associated samples and CCVs.**
- **Added Low-Level Calibration Check Standard requirement to Table 7 – Metals by AA.**

DoD/DOE QSM Proposed Updates

Version 5.1

- For metals with a single point calibration, may report a result greater than the quantitation range if a high level CCV is analyzed
- 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.
- An Appendix will be added for EDD Accreditation

DoD/DOE QSM Proposed Updates

Version 5.1

➤ Corrections/Changes to Tables:

- Tables 7,8,9,10 (Metals) Post Digestion Spike criteria when MS/MSD fails and samples with concentrations <50x LOQ.
- Reporting of Total TEQ for Dioxins/Furans based on EDL, EQL, EMPC whereas Tables are based on DL, LOD, LOQ.
- Radchem Methods that do not use prep steps
 - Gamma Spec, Alpha Beta wipes – will allow use of CCV as an LCS
- LOD exception for surrogates in volatile analysis with single point calibration.

DoD/DOE QSM Proposed Updates

Version 5.1

April 2016

- **Distribute proposed requirements to laboratories, experts, and assessors for comment.**

June 2016

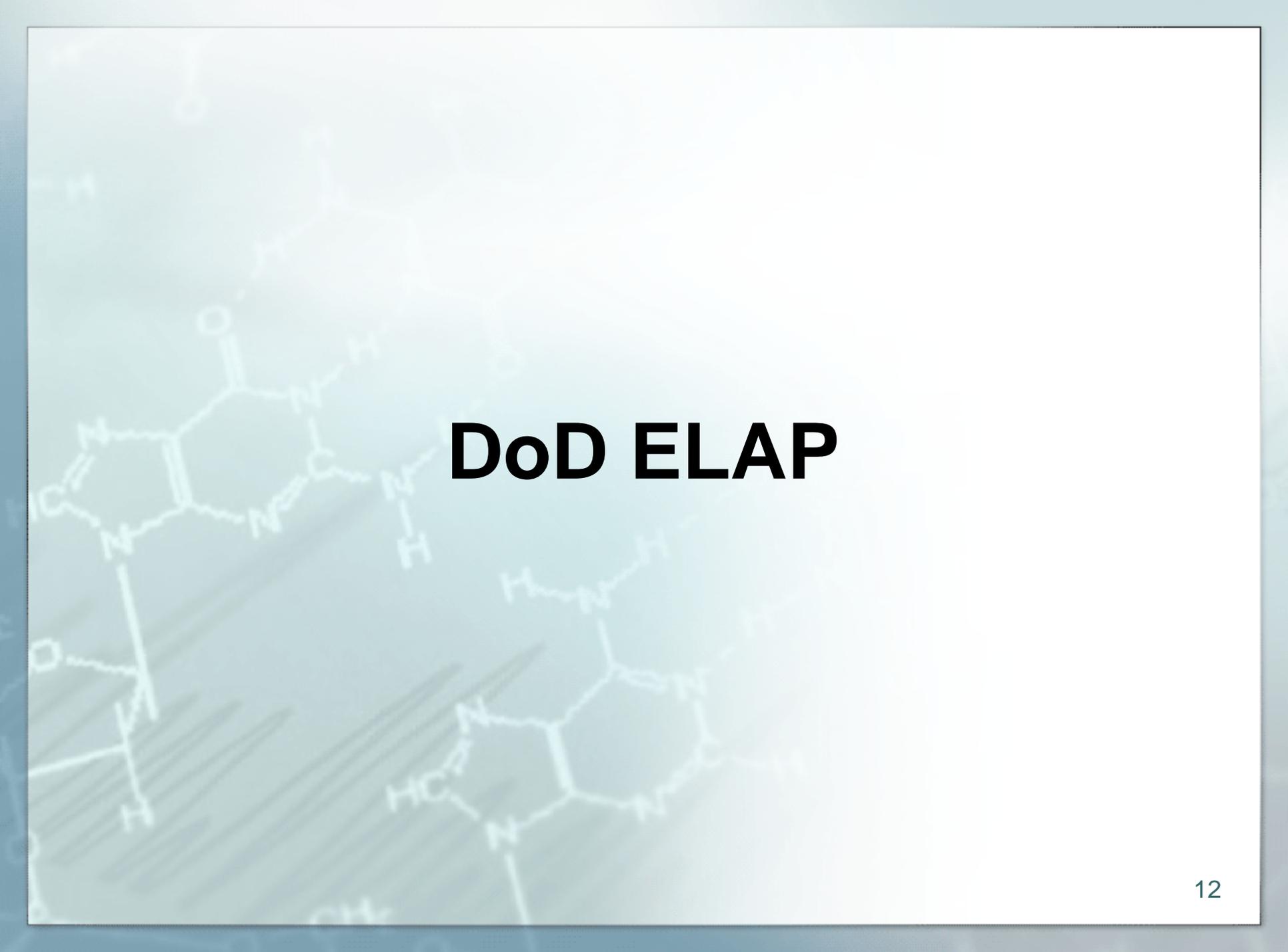
- **Submit comments and recommended changes to EDQW Principals and DOE for approval.**

September 2016

- **Present Changes at DOECAP workshop.**

January 2017

- **Publish QSM 5.1.**

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

- **DoD ELAP Distribution**
- **Accreditation Bodies – Trends**
- **DoD ELAP Scopes**
- **Oversight and Implementation Issues**
- **DENIX Database**
- **Frequent Findings**

DoD ELAP Status

➤ Status of Laboratories:

- Year 2009 (before DoD ELAP) - 44 laboratories
- March 2016
 - 93 laboratories accredited (decrease of 7 from September 2015)
- All laboratories performing work for the DoD must be accredited to QSM Version 5.0.

DoD ELAP Accreditation Bodies

- **American Association for Laboratory Accreditation (A2LA)**
- **Perry Johnson Laboratory Accreditation, Inc. (PJLA)**
- **ANSI-ASQ National Accreditation Board (ANAB) d/b/a L-A-B**

DoD ELAP Status

(as of 3/30/16)

AB	2016	2015	2014	2013	2012	2011	2010
A2LA	24	22	27	29	30	24	15
ANAB*	12	11	11	11	14	24	21
LAB*	29	31	32	28	31	28	19
PJLA	28	29	28	31	27	23	12
Total Labs	93	93	98	99	102	99	67

*ANAB acquired LAB December 2015.

- **Continuing to see a shift in market – biggest shift based on combined assessments, service issues.**
- **Scopes continuing to be modified based on market.**

DoD ELAP Scope

- **Applies to all laboratories regardless of:**
 - **Size**
 - **Volume of business**
 - **Field(s) of accreditation**
 - **Public/private**
 - **Mobile/fixed**
 - **CONUS/OCONUS – 5 International laboratories**

DoD ELAP Scope

➤ Changes from 2009 to 2015:

- **Scopes of Accreditation are being streamlined**
- **“Specialty Analyses”**
 - PFOA/PFOS
 - Method 8330B
 - Air Methods
- **Elimination of ASTM Methods**
- **Elimination of Standard Methods**
- **Labs working with projects to have accreditation to meet projects needs**
- **Nomenclature – no more “SOP Names”**

DoD ELAP Oversight

- **EDQW continues to monitor DoD ELAP:**
 - **Monitoring scopes and load sheets for consistency.**
 - **Labs are being removed from DENIX once they expire, withdraw, or are suspended from DoD ELAP. EDQW Principals notified immediately of all removals.**
 - **DENIX received a 100% review and reconciliation in 2015.**

DoD ELAP Oversight

➤ Oversight Visits:

- **New Assessors**
- **Each AB**
- **New Lead Assessors**
- **Complaint Situations**
- **Verify Assessor knowledge of QSM requirements during multi-agency assessments**

DoD ELAP Oversight

➤ Oversight Visits:

- **2015 eight on-site observations by the EDQW.**
- **Focus was transition from QSM Version 4.2 to QSM Version 5.0.**
- **Two of the three ABs have been authorized to perform State assessments along with ISO-17025/DoD-ELAP – focus on assessment of QSM requirements.**

DoD ELAP Oversight

- **EDQW continues to monitor DoD ELAP:**
 - **Teleconferences every quarter**
 - **Review every assessment report**
 - **Participate in ILAC Peer Reviews**
 - **Participate in AB annual meeting and training**
 - **Database with accreditation expiration dates**
 - **Annual Individual AB Calls**
 - **Annual Face to Face Meeting with ABs**

DoD ELAP Oversight

Inappropriate Practices Memo

“The EDQW is now requiring all DoD ELAP laboratories to report and submit the associated corrective action on any instances of inappropriate and prohibited laboratory practices, as detailed in Section 5.2.7 of the DoD QSM Version 5.0, discovered during any internal or external assessment or investigation to your AB as soon as practicable. As your AB, we will then have the responsibility of informing the EDQW of the laboratory’s deviation from the requirements of the QSM. Your AB and the EDQW deem these infractions as quite serious and appreciates the cooperation from all involved parties on this matter.”

DoD ELAP Oversight

- **EDQW continues to monitor DoD ELAP:**
 - **Inappropriate Practices Memo**
 - **6 Instances Communicated**
 - **4 Actual instances of inappropriate practice**
 - **Laboratories were required to notify all affected clients**
 - **Thorough investigation of data sets**

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**
- **Historical Reconstruction**

QUESTIONS???

For more information:

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

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