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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 188

[Docket ID: DOD-2013-OS-0230]

RIN 0790-AJ16

DoD Environmental Laboratory Accreditation Program (ELAP)

AGENCY: Under Secretary of Defense for Acquisition, Technology, and Logistics, DoD.

ACTION: Final rule.

SUMMARY: This final rule establishes policy, assigns responsibilities, and provides procedures to be used by DoD personnel for the operation and management of the DoD ELAP.

The DoD ELAP provides a unified DoD program through which commercial environmental laboratories can voluntarily demonstrate competency and document conformance to the international quality systems standards as they are implemented by DoD.

DATES: This rule is effective on [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Edmund Miller, 571-372-6904.

SUPPLEMENTARY INFORMATION:

On October 15, 2015 (80 FR 61997-62003), the Department of Defense published a proposed rule in the Federal Register titled “DoD Environmental Laboratory Accreditation Program (ELAP)” for a 60-day public comment period. After the 60-day public comment period had completed, no public comments were received. As a result, no changes were made to the rule text.

EXECUTIVE SUMMARY

The purpose of this regulatory action is to document the procedures for the operation and management of the DoD Environmental Laboratory Accreditation Program (ELAP). The legal authority for the regulatory action is Section 515, Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554), which directed the Office of Management and Budget (OMB) to issue government-wide guidelines that “provide policy and procedural guidance to Federal Agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal Agencies.” OMB guidelines, provided by FR Volume 67, Number 36, page 8452 (February 22, 2002) required federal agencies to maintain a basic standard of quality and take appropriate steps to incorporate information quality criteria into DoD public information dissemination practices. The guidance further provided that DoD Components shall adopt standards of quality that are appropriate to the nature and timeliness of the information they disseminate. The DoD ELAP provides the standards for ensuring the quality, objectivity, utility, and integrity of definitive environmental testing data disseminated by DoD for the Defense Environmental Restoration Program (DERP).

This rule includes a general overview of DoD ELAP and establishment of standard operating procedures. It utilizes the baseline quality systems requirements of The NELAC Institute (TNI) and ISO/IEC 17025 standards, but alone neither of these standards meet the testing and analysis needs for DERP. Therefore the DoD Quality Systems Manual (QSM) for environmental laboratories serves as the standard for DoD ELAP accreditation. The QSM contains the minimum requirements DoD considers essential to ensure the generation of definitive environmental data of known quality, appropriate for their intended uses. These minimal needs

are not met by TNI or ISO 17025 standards alone. The DoD ELAP includes procedures on how to evaluate and recognize 3rd party accreditation bodies; perform and document government oversight of the DoD ELAP to ensure ongoing compliance with program requirements and to identify opportunities for continual improvement; conduct project-specific laboratory approvals for specific tests not addressed in the DoD ELAP; and handle specific complaints concerning the processes established by the DoD ELAP or the QSM.

Past DoD laboratory assessment programs were specific to each DoD Component and limited to available resources. This created an overlap in assessments and fewer opportunities for laboratories to participate on DoD contracts. This rule proposes to establish a program to allow qualified laboratories to receive third-party accreditation and become eligible to provide environmental sampling and testing services for DoD. It will be a voluntary program open to any qualified laboratories wishing to participate, thereby promoting fair and open competition among commercial laboratories.

Since laboratories fund their own participation in the accreditation process, it will allow DoD to focus its resources on providing oversight of laboratory contracts. By proposing to replace separate DoD Component-specific laboratory approval programs, The DoD ELAP will eliminate redundant assessments, promote interoperability across the Department, streamline the process for DoD to identify and procure competent providers of environmental laboratory services, and provide more opportunities for commercial laboratories to participate in DoD environmental sampling and testing contracts.

The scope of accreditation under ELAP includes specific laboratory services such as the test methods used, type of material tested (soil, water, etc.), and type of contaminants measured. The

evaluation of a test method also includes the use of internal laboratory standard operating procedures.

Statement of Legal Authority: 15 U.S.C. 3701 promotes transfer and utilization of science and technology resources of the Federal government. Public Law 106-554 requires the Federal government to ensure the quality and integrity of information disseminated by Federal agencies. In response, the DoD ELAP sets forth requirements on environmental laboratories conducting analytical testing for DoD to generate documented quality data capable of being reproduced in accordance with commonly accepted scientific standards and practices.

REGULATORY PROCEDURES

Executive Order 12866, “Regulatory Planning and Review” and Executive Order 13563, “Improving Regulation and Regulatory Review”

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a “significant regulatory action,” because it does not: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy

issues arising out of legal mandates, the President's priorities, or the principles set forth in these Executive Orders.

Sec. 202, Pub. L. 104-4, “Unfunded Mandates Reform Act”

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4) requires agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately \$141 million. This rule will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

Public Law 96-354, “Regulatory Flexibility Act” (5 U.S.C. 601)

The Department of Defense does not expect this final rule would have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601, et. seq.). The rule establishes a policy to provide a unified DoD program for commercial environmental laboratories to voluntarily demonstrate competency and document conformance to the international quality system standards already implemented by DoD. The Department’s experience with these laboratories indicates that the professional skill and technical requirements of the accreditation program limits the numbers of entities that are likely to be impacted by this rule to approximately 100 entities. Therefore, the Regulatory Flexibility Act, as amended, does not require that DoD prepare a regulatory flexibility analysis.

Public Law 96-511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35)

It has been certified that 32 CFR part 188 does not impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995. The requirements in this rule do not require OMB approval under the Paperwork Reduction Act as the information is collected by the

four accreditation bodies and not the Department. These accreditation bodies accredit the laboratories to meet DoD standards for environmental sampling and testing.

Executive Order 13132, “Federalism”

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have a substantial effect on State and local governments.

List of Subjects in 32 CFR Part 188

Laboratories, Oversight.

Accordingly, 32 CFR part 188 is added to read as follows:

PART 188—DOD ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (ELAP)

Sec.

188.1 Purpose.

188.2 Applicability.

188.3 Definitions.

188.4 Policy.

188.5 Responsibilities.

188.6 Procedures.

Authority: 15 U.S.C. 3701; Pub. L. 106-554, 114 Stat. 2763.

§188.1 Purpose.

This part implements policy, assigns responsibilities, and provides procedures to be used by DoD personnel for the operation and management of the DoD ELAP.

§188.2 Applicability.

This part applies to Office of the Secretary of Defense, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this part as the “DoD Components”).

§188.3 Definitions.

Unless otherwise noted, these terms and their definitions are for the purposes of this part.

Accreditation. Third-party attestation conveying formal demonstration of a laboratory’s competence to carry out specific tasks.

Accreditation body (AB). Authoritative organization that performs accreditation.

Assessment. Process undertaken by an AB to evaluate the competence of a laboratory, based on requirements contained in the DoD Quality Systems Manual for Environmental Laboratories (QSM), for a defined scope of accreditation.

Change. A reissuance of the DoD QSM containing minor changes to requirements or clarifications of existing requirements necessary to ensure consistent implementation.

Complaint. Defined in International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2005, “General Requirements for the Competence of Testing and Calibration Laboratories” (available for purchase at <http://www.iso.org/iso/store.htm>).

Contractor project chemist. Defined in Under Secretary of Defense for Acquisition, Technology, and Logistics Memorandum, “Acquisitions Involving Environmental Sampling or Testing

Services” (available at <http://www.acq.osd.mil/dpap/dars/dfars/changenotice/2008/20080303/223.7.pdf>).

Corrective action response. Description, prepared by the laboratory, of specific actions to be taken to correct a deficiency and prevent its reoccurrence.

Deficiency. An unauthorized deviation from requirements.

Definitive data. Defined in DoD Instruction 4715.15, “Environmental Quality Systems” (available at <http://www.dtic.mil/whs/directives/corres/pdf/471515p.pdf>).

Environmental Data Quality Workgroup (EDQW) component principal. A voting member of the DoD EDQW.

Errata sheet. A document prepared by the EDQW and issued by the EDQW chair, defining minor “pen and ink” changes that apply to the most recently issued version of the DoD QSM. Errata will be corrected in the next change or revision of the DoD QSM.

Government chemist. Defined in USD(AT&L) Memorandum, “Acquisitions Involving Environmental Sampling or Testing Services.”

Government oversight. The set of activities performed by or on behalf of the DoD EDQW to provide assurance that ABs and assessors are providing thorough, consistent, objective, and impartial assessments within the specified scopes of accreditation and to identify opportunities for continual improvement of the DoD QSM and DoD ELAP.

International Laboratory Accreditation Cooperation (ILAC) mutual recognition arrangement (MRA). An arrangement through which ABs are evaluated and accepted by their peers for conformance to ILAC rules and procedures. To be accepted into the ILAC MRA, the AB must become a signatory to its requirements; specifically, it must commit to maintain conformance with the current version of Deputy Secretary of Defense Memorandum, “Ensuring Quality of

Information Disseminated to the Public by the Department of Defense") and ensure that the laboratories it accredits comply with ISO/IEC 17025:2005.

ILAC MRA peer evaluation. The process through which ABs are assessed by other ABs and receive or maintain acceptance into the ILAC MRA.

Project-specific laboratory approval. The set of activities undertaken by the DoD EDQW to assess whether a laboratory is competent to perform specific tests, in the case where no DoD-ELAP accredited laboratory is able to perform the required tests.

Quality system. Defined in ISO/IEC 17025:2005.

Recognition. The acceptance of an AB by the EDQW based on its demonstrated commitment to maintain signatory status in the ILAC MRA and accept the DoD ELAP conditions and criteria for recognition.

Revision. A reissuance of the DoD QSM containing significant changes in requirements or scope. A significant change is one that could reasonably be expected to affect a laboratory's ability to comply with the requirement (i.e., the laboratory is likely to have to make a change in its quality system or technical procedures in order to maintain compliance).

Scope of accreditation. Specific laboratory services, stated in terms of test method, matrix, and analyte, for which accreditation is sought or has been granted.

§188.4 Policy.

It is DoD policy, in accordance with DoD Instruction 4715.15, to implement the DoD ELAP for the collection of definitive data in support of the Defense Environmental Restoration Program (DERP) at all DoD operations, activities, and installations, including government-owned, contractor-operated facilities and formerly used defense sites.

§188.5 Responsibilities.

(a) Secretaries of the Military Departments and Director, Defense Logistics Agency (DLA).

The Director, DLA, is under the authority, direction, and control of the USD(AT&L), through the Assistant Secretary of Defense for Logistics and Materiel Readiness. The Secretaries of the Military Departments and Director, DLA:

(1) Provide resources to support project-specific government oversight for the collection of definitive data in support of the DERP.

(2) Provide resources to support project-specific laboratory approvals, if required.

(b) Secretary of the Navy. In addition to the responsibilities in paragraph (a) of this section, the Secretary of the Navy plans, programs, and budgets for DoD EDQW activities necessary to support government oversight of the DoD ELAP.

§188.6 Procedures.

(a) DoD ELAP Overview--(1) Introduction. (i) DoD ELAP provides a unified DoD program through which commercial environmental laboratories can voluntarily demonstrate competency and document conformance to the international standard established in ISO/IEC 17025:2005 as implemented by the Deputy Under Secretary of Defense for Environmental Security Memorandum, “DoD Quality Systems Manual for Environmental Laboratories” (available at <http://www.denix.osd.mil/edqw/upload/QSM-V4-2-Final-102510.pdf>) (referred to in this part as the “DoD Quality Systems Manual for Environmental Laboratories (QSM)”). The DoD QSM provides minimum quality systems requirements, based on ISO/IEC 17025:2005, for environmental laboratories performing testing for DoD.

(ii) DoD ELAP was developed in compliance with 15 U.S.C. 3701 (also known as the “National Technology Transfer and Advancement Act”). Support and guidance was provided by the National Institute of Standards and Technology, following procedures used to establish similar

programs for other areas of testing. The DoD ELAP supports implementation of section 515 of Public Law 106-554, “Treasury and General Government Appropriations Act, 2001” and Office of Management and Budget Guidance, “Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies” (67 FR 8452) as implemented by Deputy Secretary of Defense Memorandum, “Ensuring Quality of Information Disseminated to the Public by the Department of Defense.”

(iii) Using third party ABs operating in accordance with the international standard ISO/IEC 17011:2004(E), “Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies” (available for purchase at <http://www.iso.org/iso/store.htm>), the DoD ELAP:

- (A) Promotes interoperability among the DoD Components.
- (B) Promotes fair and open competition among commercial laboratories.
- (C) Streamlines the process for identifying and procuring competent providers of environmental laboratory services.
- (D) Promotes the collection of data of known and documented quality.

(2) Authority. Operation of the DoD ELAP is authorized by DoD Instruction 4715.15.

(3) Program requirements. (i) Pursuant to DoD Instruction 4715.15, laboratories seeking to perform testing in support of the DERP must be accredited in accordance with DoD ELAP.

(ii) The DoD ELAP applies to:

- (A) Environmental programs at DoD operations, activities, and installations, including government-owned, contractor-operated facilities and formerly used defense sites.
- (B) Permanent, temporary, and mobile laboratories regardless of their size, volume of business, or field of accreditation that generate definitive data.

- (iii) Participation in the program is voluntary and open to all laboratories that operate under a quality system conforming to ISO/IEC 17025:2005 and Deputy Under Secretary of Defense for Environmental Security Memorandum, “DoD Quality Systems Manual for Environmental Laboratories.” Laboratories may seek accreditation for any method they perform in accordance with documented procedures, including non-standard methods. Laboratories are free to select any participating AB for accreditation services.
- (iv) To participate in DoD ELAP, ABs must be U.S.-based signatories to the ILAC MRA and must operate in accordance with ISO/IEC 17011:2004(E).

- (4) Program oversight. In accordance with Assistant Deputy Under Secretary of Defense for Installations and Environment Memorandum, “DoD Environmental Data Quality Workgroup Charter” (available at <http://www.denix.osd.mil/edqw/upload/USA004743-10-Signed-Memo-to-DASs-DLA-DoD-Envir-Data-Quality-Workgroup-Charter-1Oct10-1.pdf>), the DoD EDQW:
 - (i) Provides coordinated responses to legislative and regulatory initiatives.
 - (ii) Responds to requests for DoD Component information.
 - (iii) Develops and recommends department-wide policy related to sampling, testing, and quality assurance for environmental programs.
 - (iv) Implements and provides oversight for the DoD ELAP.
 - (v) Includes technical experts from the Military Services and DLA as well as an EDQW component principal (voting) member from each of the Military Services.
 - (vi) Specifies the EDQW Navy principal, Director of Naval Sea Systems Command (NAVSEASYSCOM) 04XQ(LABS), serve as EDQW chair.
- (b) Maintaining the DoD QSM--(1) General. The DoD EDQW will maintain and improve the DoD QSM to ensure that:

- (i) The DoD QSM remains current in accordance with ISO/IEC 17025:2005.
 - (ii) Minimum essential requirements are met.
 - (iii) Requirements are clear, concise, and auditible.
 - (iv) The DoD QSM will efficiently and effectively support the DoD ELAP.
- (2) Procedures-- (i) Annual review. At a minimum, the DoD EDQW will perform an annual review of the DoD QSM, based on feedback received from participants in DoD ELAP (e.g., DoD Components, commercial laboratories, and ABs). The review will also address any revisions to ISO/IEC 17025:2005.
- (ii) Ongoing review. As received, the DoD EDQW will respond to questions submitted through the Defense Environmental Network Information Exchange (DENIX) concerning the interpretation of DoD QSM requirements. DoD EDQW participants will forward all questions through their EDQW component principal to the DoD EDQW chair.
- (iii) Issuances. The DoD EDQW chair will prepare DoD QSM updates:
- (A) Correspondence. The DoD EDQW chair, in consultation with the EDQW component principals, will prepare correspondence (e-mail or memorandum) providing responses to all written requests for clarification and interpretation of the DoD QSM. Depending on the significance of the issue, as determined by the EDQW chair, the response may also result in a posting to the frequently asked question (FAQ) section of the appropriate websites.
- (B) Errata sheets. Minor corrections to the DoD QSM, such as typographical errors, may be made by the issuance of an errata sheet defining “pen and ink” changes that apply to the current version of the DoD QSM. Following concurrence by all EDQW component principals, errata sheets will be issued as needed by the DoD EDQW chair. Errata will be corrected in the next change or revision to the DoD QSM.

(C) Changes. Changes to the DoD QSM will be issued as necessary to reflect minor changes to requirements or clarifications of existing requirements that are necessary to ensure consistent implementation. Following concurrence by the EDQW component principals, changes will be issued by the DoD EDQW chair in the form of a complete DoD QSM.

(1) The first change to DoD QSM Version 4 will be numbered Version 4.1, the second change will be Version 4.2, etc.

(2) Changes to the DoD QSM will be posted on DENIX in place of the previous version or change of the DoD QSM.

(D) Revisions. A revision will be issued if one or more of the proposed changes could reasonably be expected to affect a laboratory's ability to comply with the requirement (i.e., the laboratory is likely to have to make a change in its quality system or technical procedures).

(1) Once EDQW component principals have reached consensus on the proposed revision, the DoD EDQW chair will forward the proposed revision to all participating DoD ELAP-accredited laboratories and ABs for review.

(2) The DoD EDQW will review and respond to comments received from the DoD ELAP-accredited laboratories and ABs within the designated comment period.

(3) Following concurrence by the EDQW component principals, revisions will be issued by the DoD EDQW chair in the form of a complete DoD QSM.

(4) A revision of Version 4 will be issued as Version 5, a revision of Version 5 will be issued as Version 6, etc.

(5) The final revised version of the DoD QSM will be posted on DENIX in place of the previous version including any DoD QSM updates.

(3) Continual improvement. The DoD EDQW will meet with the ABs on an annual basis to review lessons learned and identify additional opportunities for continual improvement of the DoD ELAP and the DoD QSM.

(4) Data and records management. Through NAVSEASYSCOM, the DoD EDQW will maintain all DoD QSM updates in accordance with Secretary of the Navy Manual M-5210.1, “Department of the Navy Records Management Program: Records Management Manual” (available at <http://doni.daps.dla.mil/SECNAV%20Manuals1/5210.1.pdf>).

(c) Recognizing ABs.--(1) General. (i) The DoD EDQW will:

(A) Use the procedures in this paragraph to evaluate and recognize third-party ABs in support of the DoD ELAP.

(B) Develop and maintain the application for recognition, the conditions and criteria for recognition and related forms, and review submitted AB applications for completeness and compliance with DoD ELAP requirements.

(ii) The DoD EDQW chair, following consultation with and concurrence by the EDQW component principals, grants or revokes AB recognition in accordance with this paragraph.

(2) Limitations. Candidate ABs must be U.S.-based signatories in good standing to the ILAC MRA. ABs must maintain ILAC recognition to maintain DoD ELAP recognition. Because the EDQW continually monitors AB performance, no pre-defined limits are placed on the duration of recognition; however, the EDQW may revoke recognition at any time, for cause, in accordance with paragraph (c)(3)(vii) of this section.

(3) Procedures. (i) Upon receipt of an application for recognition, the DoD EDQW will review the application package for completeness. A complete application package must include:

(A) Application for recognition.

- (B) Signed acceptance of the conditions and criteria for DoD ELAP recognition.
 - (C) Electronic copy of the AB's quality systems documentation.
 - (D) Copy of the most recent ILAC MRA peer evaluation documentation.
- (ii) If necessary to complete the review, the DoD EDQW will request additional documentation from the applicant.
 - (iii) The EDQW component principals will review the application package for compliance with requirements. Prior to granting recognition, the EDQW component principals must unanimously concur that all application requirements have been met.
 - (iv) Once the EDQW component principals have completed review of the application package, the DoD EDQW chair will notify the AB, either granting recognition or citing specific reasons for not doing so (i.e., indicating which areas of the application package are deficient).
 - (v) Once recognition has been granted, the DoD EDQW chair will post the name and contact information of the AB on DENIX.
 - (vi) With unanimous concurrence, the EDQW component principals may revoke recognition if the AB:
 - (A) Violates any of the conditions or criteria for recognition.
 - (B) Fails to operate in accordance with its documented quality system.
- (vii) Should it become necessary to revoke an AB's recognition, the DoD EDQW chair will notify the AB stating specific reasons for the revocation and remove the AB's name from the list of DoD ELAP-recognized ABs.
 - (viii) If recognition is revoked, the AB must immediately cease to perform all DoD ELAP assessments.

(ix) ABs who have been denied recognition, or ABs whose recognition has been revoked, may appeal that decision.

(A) Within 15 calendar days of its receipt of a notice denying or revoking recognition, the AB must submit to the DoD EDQW chair a written statement with supporting documentation contesting the denial or revocation.

(B) The submission must demonstrate that:

- (1) Clear, factual errors were made by the DoD EDQW during the review of the AB's application for recognition; or
 - (2) The decision to revoke recognition was based on clear, factual errors, and that the AB would have been determined to meet all requirements for recognition if those errors had been corrected.
- (x) The DoD EDQW will have up to 30 calendar days to review the appeal and provide written notice to the AB either accepting the appeal and granting, or restoring, recognition, or explaining the basis for denying the appeal.

(4) Continual improvement. The DoD EDQW will meet with ABs on an annual basis to review lessons learned and identify additional opportunities for continual improvement of the DoD ELAP. On a 5-year cycle, at minimum, the DoD EDQW will evaluate whether the process for evaluating and recognizing ABs is continuing to meet DoD needs.

(5) Data and records management. Through NAVSEASYSCOM, the DoD EDQW, will maintain copies of all application packages and associated documentation in accordance with Secretary of the Navy Manual M-5210.1.

(d) Performing government oversight--(1) General. DoD personnel will use the procedures in this paragraph to perform and document government oversight of the DoD ELAP. Government oversight will include monitoring the performance of AB assessors during laboratory

assessments, reviewing laboratory assessment reports, observing ILAC MRA peer evaluations, and evaluating AB websites for content on accredited laboratories.

(2) Limitations. (i) DoD personnel performing oversight must observe, but must not participate in, laboratory assessments or ILAC MRA peer evaluations. Specifically, DoD personnel must not:

(A) Offer specific advice to the laboratory regarding the development or implementation of quality systems or technical procedures;

(B) Offer specific advice or direction to assessors or peer evaluators regarding accreditation processes, assessment procedures, or documentation of findings; or

(C) Impede assessors, peer reviewers, or laboratory personnel in any way during the performance of their work, including technical procedures, document reviews, observations, interviews, and meetings.

(ii) If, during the course of an assessment, questions by laboratory personnel or assessors are directed to DoD personnel, personnel must limit responses to specific text from the DoD QSM or published FAQs. DoD personnel must not render opinions regarding interpretation of the DoD QSM. If there are questions about the DoD QSM that require interpretation, DoD personnel must advise the assessor to contact the AB who may, if necessary, contact the DoD EDQW chair for a coordinated response.

(iii) If DoD personnel observe any evidence of inappropriate practices on the part of assessors or laboratory personnel during the course of the assessment, they must record the observations and notify the DoD EDQW chair immediately (inappropriate practices are identified in the DoD QSM). DoD personnel must not call either the laboratory's or the assessor's attention to the specific practice in question.

- (3) Personnel qualifications. DoD personnel or contractors performing oversight must:
- (i) Meet the government chemist or contractor project chemist requirements contained in the USD(AT&L) Memorandum, “Acquisitions Involving Environmental Sampling or Testing Services.”
 - (ii) Have a working knowledge of the DoD QSM requirements and be familiar with environmental test methods and instrumentation.
 - (iii) Obey all laboratory instructions regarding health and safety precautions while in the laboratory.
- (4) Procedures. (i) The DoD EDQW will maintain an up-to-date calendar of scheduled assessments and peer evaluations based on input from the ABs, peer evaluators, and assigned oversight personnel.
- (ii) Once an assessment or peer review has been scheduled, the EDQW component principals will determine if DoD oversight of the activity will be performed. The goal will be to observe a representative number of activities for each AB.
 - (iii) The EDQW component principals will provide the DoD EDQW chair the names of personnel from their respective DoD Components who will participate in the oversight.
 - (iv) The DoD EDQW chair will provide the AB with contact information for the oversight personnel.
 - (v) If two or more DoD personnel are scheduled to monitor the assessment, the DoD EDQW chair will designate a lead that will be responsible for compiling an oversight report.
 - (vi) The lead for the oversight activity will request a copy of the assessment plan from the AB’s lead assessor and distribute it to other oversight personnel.

- (vii) The lead will review the assessment plan to determine the scope of accreditation and ensure that oversight personnel are assigned to monitor a cross-section of the assessment.
- (viii) Persons performing oversight will review previous oversight reports, if available, for the particular AB and assessors performing the assessment.
- (ix) Observing all health and safety protective measures, oversight personnel must accompany the assessor(s) as they witness procedures and conduct interviews, taking care not to interfere with the assessment.

(5) Reporting. Within 15 calendar days of the onsite assessment, the lead for the oversight activity will complete an oversight report and forward the completed report through the appropriate EDQW component principal to the DoD EDQW chair.

- (i) The DoD EDQW chair will provide copies of the report to the EDQW component principals for review.
- (ii) After review by the EDQW component principals, the DoD EDQW chair will provide a summary of the oversight report to the AB performing the assessment.

(6) Handling disputes. Laboratories must follow the AB's dispute resolution process for all disputes concerning the assessment or accreditation of the laboratory, including disagreements involving an interpretation of the DoD QSM arising during the accreditation process.

- (i) In the event the laboratory and the AB are unable to resolve a disagreement concerning the interpretation of the DoD QSM, either the laboratory or the AB may request the DoD EDQW provide an interpretation of the DoD QSM. The DoD EDQW chair will provide a written response to the laboratory and the AB providing the DoD authoritative interpretation of the DoD QSM. No review of this interpretation will be available to the laboratory or the AB.

(ii) The DoD EDQW will not consider or take a position on requests by either a laboratory or an AB on a dispute concerning accreditation of the laboratory.

(7) Continual improvement. The DoD EDQW will:

(i) Review the ABs' assessment reports and the DoD oversight reports to evaluate the thoroughness, consistency, objectivity, and impartiality of the DoD ELAP assessments.

(ii) Compare assessment reports across laboratories, ABs, and assessors.

(iii) Compare DoD ELAP findings to findings from previous assessments.

(iv) Identify opportunities for continual improvement of the DoD ELAP.

(v) Meet with ABs on an annual basis to review lessons learned and identify additional opportunities for continual improvement of the DoD ELAP.

(8) Data and records management. Through NAVSEASYSCOM, the DoD EDQW will maintain copies of all oversight reports in accordance with Secretary of the Navy Manual M-5210.1.

(e) Conducting project-specific laboratory approvals--(1) General. The DoD EDQW will use the procedures in this paragraph to conduct project-specific laboratory approvals for specific tests in the rare instances when DoD is unable to identify a DoD ELAP-accredited laboratory capable of providing the required services. This will ensure that competent laboratories are used to support DoD environmental projects. Examples of these rare instances include:

(i) The required method, matrix, or analyte is not included in the scope of accreditation for any existing DoD ELAP-accredited laboratories.

(ii) The required method, matrix, and analyte combination is included in the scope of accreditation for an existing accredited laboratory; however, the laboratory is unable to meet one or more of the project-specific measurement performance criteria.

(2) Limitations. (i) Project-specific laboratory approvals are not to be used as substitutes for the required DoD ELAP-accreditation.

(ii) The DoD EDQW will not perform project-specific laboratory approvals in cases where one or more DoD ELAP-accredited laboratories capable of meeting project-specific requirements are available.

(iii) The project-specific laboratory approval is a one-time approval, the specific terms of which will be outlined in the approval notice issued by the DoD EDQW.

(3) Personnel qualifications. DoD personnel and contractors assessing laboratories for the purpose of performing project-specific laboratory approvals must meet the government chemist or contractor project chemist requirements contained in USD(AT&L) Memorandum, “Acquisitions Involving Environmental Sampling or Testing Services.” Personnel must have a working knowledge of the DoD QSM requirements and be familiar with required environmental test methods and instrumentation.

(4) Procedures. (i) If a project-specific laboratory approval is requested, the DoD EDQW will request and review a copy of the project’s quality assurance project plan (QAPP).

(ii) If, after review of the QAPP, the DoD EDQW determines that an existing DoD ELAP-accredited laboratory is available to provide the required services, the laboratory contact information will be provided to the project manager requesting assistance.

(iii) If, after review of the QAPP, the DoD EDQW determines that no existing DoD ELAP-accredited laboratory is available to provide the required services, the DoD EDQW will:

(A) Work with the project team to determine whether the use of alternative procedures by an existing DoD ELAP-accredited laboratory is feasible;

- (B) Determine if the required services can be added to the scope of accreditation of an existing DoD ELAP-accredited laboratory; or
- (C) Work with the project team to identify a candidate laboratory for project-specific laboratory approval.
 - (iv) If a project-specific approval is needed, the DoD EDQW will:
 - (A) Determine the type of assessment required (on-site, document review, etc.).
 - (B) Determine if additional funding is required to support the assessment. If additional funding is required, the DoD EDQW will provide a cost estimate and work with the project manager to establish funding.
 - (v) If the DoD EDQW determines that a project-specific laboratory approval is warranted and resources (including funding and technical expertise) are available to support the assessment, the DoD EDQW chair will coordinate with the EDQW component principals to appoint an assessment team with appropriate technical backgrounds.
 - (vi) The DoD EDQW chair will designate an assessment team leader. The assessment team leader will:
 - (A) Request the documentation needed to perform the assessment.
 - (B) Assign responsibilities for individual members of the assessment team, if appropriate.
 - (C) Coordinate the document reviews.
 - (D) Lead the assessment team in the performance of the on-site assessment, if required.
 - (E) Provide a report to the DoD EDQW chair. The report will identify whether:
 - (1) The laboratory is capable of meeting all project-specific requirements.
 - (2) Documentation procedures are in place to provide data that are scientifically valid, defensible, and reproducible.

(3) Any deficiencies must be corrected prior to granting the project-specific laboratory approval.

(vii) The DoD EDQW chair, with concurrence by the EDQW component principals, will issue a report to the project manager and laboratory detailing the results of the assessment and any deficiencies that must be corrected prior to granting a project-specific laboratory approval.

(viii) Upon receipt of the laboratory's corrective action response, if required, the assessment team will:

(A) Review the laboratory's corrective action response for resolving the deficiencies.

(B) Provide the EDQW component principals with a final report describing the resolution of findings and containing recommendations on whether to grant the project-specific laboratory approval.

(ix) The DoD EDQW chair, with concurrence by the EDQW component principals, will prepare a report for the DoD project manager describing the results of the assessment and the status and terms of the project-specific laboratory approval. Information about project-specific laboratory approvals will not be posted on websites listing DoD ELAP-accredited laboratories.

(5) Continual improvement. The EDQW component principals will review project-specific laboratory assessment reports to evaluate the thoroughness, consistency, objectivity, and impartiality of project-specific assessments and make recommendations for continual improvement of the DoD QSM and the DoD ELAP.

(6) Data and records management. Through NAVSEASYSCOM, the DoD EDQW will maintain copies of all laboratory records and project-specific assessment reports in accordance with Secretary of the Navy Manual M-5210.1.

(f) Handling complaints--(1) General. The DoD EDQW will use the procedures in this paragraph to handle complaints concerning the processes established in the DoD ELAP or the

DoD QSM. The DoD EDQW will document and resolve complaints promptly through the appropriate channels, consistently and objectively, and identify and implement any necessary corrective action arising from complaints. Complaints generally fall into one of four categories:

- (i) Complaints by any party against an accredited laboratory.
- (ii) Complaints by any party against an AB.
- (iii) Complaints by any party concerning any assessor acting on behalf of the AB.
- (iv) Complaints by any party against the DoD ELAP itself.

(2) Limitations. The procedures in this paragraph:

- (i) Do not address appeals by laboratories regarding accreditation decisions by ABs. Appeals to decisions made by ABs regarding the accreditation status of any laboratory must be filed directly with the AB in accordance with agreements in place between the laboratory and the AB.
- (ii) Are not designed to handle allegations of unethical or illegal actions as described in paragraph (d)(2)(iii) of this section.
- (iii) Do not address complaints involving contractual requirements between a laboratory and its client. All contracting issues must be resolved with the contracting officer.

(3) Procedures. (i) All complaints must be filed in writing to the EDQW chair. All complaints must provide the basis for the complaint (i.e., the specific process or requirement in the DoD ELAP or the DoD QSM that has not been satisfied or is believed to need changing) and supporting documentation, including descriptions of attempts to resolve the complaint by the laboratory or the AB.

(ii) Upon receipt of the complaint, the DoD EDQW chair will assign a unique identifier to the complaint, send a notice of acknowledgement to the complainant, and forward a copy of the complaint to the EDQW component principals.

(iii) In consultation with the EDQW component principals, the DoD EDQW chair will make a preliminary determination of the validity of the complaint. Following preliminary review, the actions available to the DoD EDQW chair include:

(A) If the DoD EDQW chair determines the complaint should be handled directly between the complainant and the subject of the complaint, the DoD EDQW will refer the complaint to the laboratory, or AB, as appropriate. The DoD EDQW will notify the complainant of the referral, but will take no further action with respect to investigation of the complaint. The subject of the complaint will be expected to respond to the complainant in accordance with their established procedures and timelines. A copy of the response will be provided to the DoD EDQW.

(B) If insufficient information has been provided to determine whether the complaint has merit, the DoD EDQW will return the complaint to the complainant with a request for additional supporting documentation.

(C) If the complaint appears to have merit and the parties to the complaint have been unable to resolve it, the DoD EDQW will investigate the complaint and recommend actions for its resolution.

(D) If available information does not support the complaint, the DoD EDQW may reject the complaint.

(E) If the complaint alleges inappropriate laboratory practices or other misconduct, the DoD EDQW chair will consult legal counsel to determine the recommended course of action.

(iv) In all cases, the DoD EDQW will notify the complainant and any other entity involved in the complaint and explain the response of the EDQW to the complaint.

(4) Continual improvement. The DoD EDQW will look into root causes and trends in complaints to help identify actions that should be taken by the DoD EDQW, or any parties involved with DoD ELAP, to prevent recurrence of problems that led to the complaints.

(5) Data and records management. Through NAVSEASYSCOM, the DoD EDQW will maintain copies of all complaint documentation in accordance with Secretary of the Navy Manual M-5210.1.

Dated: November 14, 2016.

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Alternate OSD Federal Register Liaison Officer, Department of Defense.

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