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DOE STANDARD

DEPARTMENT OF ENERGY LABORATORY ACCREDITATION PROGRAM ADMINISTRATION

U.S. Department of Energy
Washington, DC. 20585

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FOREWORD

The Department of Energy (DOE) implemented the DOE Laboratory Accreditation Program (DOELAP) for external dosimetry in 1986 and for radiobioassay in 1998. The objective of DOELAP is to assure the competency of dosimetry and radiobioassay measurements, provide calibration intercomparisons, perform site assessments, and encourage applied research in areas where there is a technology shortfall. DOE also expects the program to enhance cooperation and technical information exchange among its sites and facilities in order to provide a more standardized and uniform radiation dosimetry capability. DOE sites and facilities are expected to use standards and other technical guidance from DOE to ensure that the performance of external dosimetry and radiobioassay measurements are adequate to meet the standards of Title 10, Code of Federal Regulations, Part 835, *Occupational Radiation Protection* and related documents.

Throughout this standard, the word “shall” is used to denote a required action that is to be performed, and the word “should” is used to denote an action that is expected to be performed unless documentation is provided validating technical equivalence.

1 PURPOSE AND SCOPE

(a) This technical standard sets forth the program administration and accreditation process by which the U.S. Department of Energy Laboratory Accreditation Program (DOELAP) operates to accredit Department of Energy (DOE) dosimetry and radiobioassay programs used for worker monitoring and protection in accordance with Title 10, Code of Federal Regulations, Part 835, *Occupational Radiation Protection* (10 CFR 835).

(b) Specific performance testing and site assessment criteria for accreditation are contained in DOE-STD-1095, *Department of Energy Laboratory Accreditation Program for Personnel Dosimetry Systems* and DOE-STD-1112, *Department of Energy Laboratory Accreditation for Radiobioassay*.

2 APPLICABILITY

This technical standard applies to DOE Headquarters, field elements, and contractors working to the requirements of 10 CFR 835.

3 PROGRAM ADMINISTRATION AND RESPONSIBILITIES

DOELAP is administered by the Office of Worker Safety and Health Policy (AU-11). DOELAP accreditation is based on evaluation of a laboratory's management, technical qualifications, and competence for conducting specific test methods, measurements, and services in external dosimetry and radiobioassay. Accreditation is granted only after a thorough evaluation of an applicant demonstrates that all DOELAP requirements have been fulfilled, and is acknowledged by the issuance of a Certificate of Accreditation.

3.1 DOELAP Administrator

The DOELAP Administrator is responsible for the development of policies, procedures, and standards necessary for the implementation and continued improvement of DOELAP. The Administrator makes the final decision on accreditation, amendments, technical equivalency, and appeals. The Administrator appoints and removes Oversight Board members and assessors.

3.2 Senior Technical Manager

A Senior Technical Manager (STM) manages the performance testing program and coordinates the accreditation process for each of the two DOELAP programs – external dosimetry and radiobioassay. The STM is located at the Performance Testing Laboratory and is responsible

for the following:

- Maintaining schedules for receipt of applications, performance testing and on-site assessments;
- Ensuring continued training of assessors (e.g., classroom instruction, web based training, and routine webinars);
- Making recommendations on requests for amendments, technical equivalency, or accreditation changes to the DOELAP Administrator;
- Making recommendations to the Oversight Board and Administrator regarding accreditation applications, performance testing, on-site assessments, technical equivalencies, or other DOELAP issues; and
- Maintaining records that support accreditation of dosimetry and radiobioassay programs.

3.3 Oversight Board

Oversight Boards are established for the personnel external dosimetry and radiobioassay accreditation programs, and consist of five individuals who are appointed by the DOELAP Administrator and each serve a five-year term. Oversight Board members have extensive knowledge as well as experience in implementing a DOELAP-accredited external dosimetry or radiobioassay program. The DOELAP Administrator may allow a current member to serve one or more successive terms. The charter for the DOELAP Oversight Board is listed in Appendix B.

3.4 Assessor

An assessor is an individual recognized by DOELAP as a technical expert who has been trained and qualified by DOELAP to perform assessments. An assessor conducts on-site assessments in support of the DOELAP accreditation process. To maintain assessor status, an assessor shall complete DOELAP-sponsored assessor training and participate in at least one on-site assessment triennially.

3.5 DOE Field Element Managers

DOE Field Element Managers are responsible for ensuring that external dosimetry and radiobioassay programs under their management receive and maintain DOELAP accreditation, or receive exception from accreditation in accordance with 10 CFR Part 835.

3.6 Performance Testing Laboratory

The Performance Testing Laboratory is independent of the applicant’s operation and authorized by DOE to conduct performance testing for DOELAP. Performance testing for

external dosimetry is conducted in accordance with ANSI/HPS N13.11-2009, *American National Standard for Personnel Dosimetry Performance – Criteria for Testing* and ANSI/HPS N13.32, *Performance Testing for Extremity Dosimeters*. For Radiobioassay, performance testing is conducted in accordance with ANSI/HPS N13.30-2011, *Performance Criteria for Radiobioassay*.

4 ACCREDITATION PROCESS

4.1 Application for Accreditation

(a) A completed application shall be routed through the cognizant DOE field element for approval and submitted to the STM. The application shall contain the following:

- A description of each external dosimetry processing system or radiobioassay program employed including specific instrumentation, apparatus, and protocols used;
- The requested categories for which accreditation is sought;
- The submittal of required program documents;
- The identification of a program manager who authenticates the submitted information and is authorized to commit the organization's resources to secure and maintain accreditation;
- The identification of an individual to be the point of contact for routine DOELAP communications and activities; and
- The submittal of the Quality Assurance Manual and supporting documentation.

(b) The requested technical information should be as descriptive as possible without divulging proprietary information.

(c) Along with the application, programs seeking initial accreditation shall submit a detailed self-assessment of their program using the applicable DOELAP requirements. Performing a self-assessment helps the program identify areas of noncompliance and improves the overall quality as the program prepares for the initial on-site assessment.

4.2 Performance Evaluation Test

Performance evaluation testing compares the results from the applicant's measurements to known doses delivered to the applicant's dosimeters or the radiobioassay program's analysis of biological samples and phantoms spiked with known concentrations of various radionuclides. The known values are not revealed to the applicant until after the results from all participants are reported. Comparing the reported experimental results from the applicant's measurement process with the known spiked values or delivered doses provides a test of the program's proficiency in terms of both accuracy and precision. A variation beyond

established acceptance criteria provides the basis for denying accreditation or granting only partial accreditation by the DOELAP Administrator. More information specific to the proficiency testing of external dosimetry programs or radiobioassay programs is provided in the respective DOELAP standards.

4.3 On-Site Assessment

Prior to approval for accreditation, the program shall undergo an on-site assessment by DOELAP Assessors to demonstrate its ability to perform competently in accordance with DOELAP requirements. For initial accreditation, an on-site assessment is conducted after performance testing is completed. A monitoring visit may be conducted after implementation of the new system or if major deficiencies were identified during an on-site assessment. Following initial accreditation, a triennial assessment is required.

4.3.1 Assessor Selection

The STM assigns a minimum of two DOELAP qualified assessors to evaluate all information collected from an applicant's program to conduct an on-site assessment. The STM will notify the applicant program and the cognizant field element of the assessment. The applicant may request an alternate assessor if a conflict of interest exists.

4.3.2 Document Review

The STM shall provide the DOELAP assessors with the application, documented quality assurance program, and supporting documentation. The DOELAP assessors shall review all aspects of the laboratory's management system to ensure it meets DOELAP requirements. The DOELAP assessor may request additional documentation from the program to facilitate the review. In cases where the assessor in coordination with the STM determines that the management system documentation requires significant revision, DOELAP may require the laboratory to improve its documentation and submit it for further review prior to proceeding with the accreditation process.

4.3.3 Scheduling

On-site assessments are typically conducted over a two to three day period depending on the proposed scope of accreditation. The assessment team lead will coordinate with the applicant's authorized program representative to schedule the onsite assessment and make any other necessary arrangements. When possible, the assessment should be scheduled during a time that minimizes disruptions but still allows the assessors to view the normal operations of the laboratory.

4.4 On-Site Assessment

To ensure consistency between assessments, assessors use a checklist provided by DOELAP. Checklists are normative documents that include the requirements of DOE-STD-1095, DOE-STD-1112, as well as other referenced consensus standards.

4.4.1 Opening Meeting

The assessors begin the on-site assessment with an opening meeting with management and laboratory personnel to explain the assessment criteria and agenda.

4.4.2 Assessment

(a) The assessors review program documents and records, observe processes, inspect facilities, and interview personnel to evaluate the program and determine whether DOELAP requirements are met. The assessors also review any previous DOELAP assessment corrective actions to ensure they have been implemented. Findings, including non-conformances and noteworthy practices, are categorized and transmitted in a written report to the STM. Findings are categorized as follows:

- **Observation.** An Observation is either a suggested improvement that a program may incorporate at its own discretion or a noteworthy practice. The suggestion is offered to help "fine tune" a program. No written response is required.

- **Concern.** A Concern is an element of a program that is considered marginal with respect to compliance with DOELAP criteria, but does not have a significant, immediate, and continuing adverse impact on dosimetry program quality. When the assessment results in a finding of Concern, the program shall

    - Develop a corrective action plan and submit it to the STM through the appropriate field element within 45 days of the close-out meeting.
    - Complete all corrective actions within one year of the assessment close-out meeting. For any corrective action lasting longer than one year, the program shall notify the STM and the appropriate DOE field element. The program shall provide a written justification for why the corrective actions were not completed within one year. The STM may ask for additional documentation, such as a tentative schedule and estimated completion date.
    - Evaluate the effectiveness of the corrective action. Ensure documentation is available for review during the next on-site assessment.

One or more Concerns will not affect a program's accreditation; however, any recurrent Concern identified during the program's next accreditation cycle, irrespective of any corrective action implemented, will automatically be elevated to a deficiency.

- **Deficiency.** A deficiency finding has a significant, immediate, and continuing adverse impact on the quality of a dosimetry or radiobioassay program. A Deficiency results in the suspension of an application for accreditation. When the assessment results in a finding of Deficiency, the program shall

    - Develop a corrective action plan and submit it to the STM through the appropriate field element within 45 days of the assessment close-out meeting.
    - Complete all corrective actions within 60 days of the assessment close-out meeting. Evidence that a corrective action has been completed shall be received by the STM within 60 calendar days of the close-out meeting to reactivate the suspended application. Corrective actions may be confirmed by a monitoring visit.
    - Evaluate the effectiveness of the corrective action. Ensure documentation is available for review during the next on-site assessment.

(b) Assessment findings that result in substantial cited deficiencies, as determined by the DOELAP Administrator, may result in the suspension or revocation of a programs current accreditation until all corrective actions are completed. Substantial deficiencies may require a monitoring visit prior to resumption of DOELAP Accredited activities.

(c) Any recurrent Deficiency identified during the program's next accreditation cycle, irrespective of any corrective action implemented, will result in a suspension of the DOELAP application until an official review of the deficiency and corrective action has been conducted by DOELAP.

4.4.3 Close-Out Meeting

At the conclusion of the on-site assessment, the assessors will conduct a close-out meeting to review their visit and discuss any findings with the appropriate members of the program's management and DOE Field Element Representative. A copy of the written report, which provides a summary of each finding, shall be signed and left with the authorized program representative. The assessors will then forward the original assessment report to the STM for use in the technical evaluation of the program's accreditation application.

4.5 Corrective Action Plan

For findings at the concern or deficiency level, the program shall submit a corrective action plan through its cognizant field element to the STM for approval. The corrective action plan shall include the actions to be taken by the program to address the concerns and deficiencies, as well as the dates of completion of the actions. Any subsequent modification to the plan shall be approved by the STM and include evidence that the cognizant DOE field element has

been copied.

4.6 Monitoring Visits

Monitoring visits serves to verify reported changes to a facility or operation or to explore the reason(s) for poor performance during performance evaluation testing. Assessors may be assigned to make a monitoring visit at any time during an accreditation period, in addition to a regularly scheduled on-site assessment. A monitoring visit may be performed as a follow up to previous on-site assessment, a continued evaluation of a newly accredited program, a follow up of a poor performance testing session, to evaluate recent programmatic changes that could significantly impact the quality of a program, to follow up on a technical equivalence request, or at the request of the DOE Field Element. Monitoring visits are coordinated by the STM with notification to the DOE Field Element. The scope of a monitoring visit is commensurate on the type of monitoring visit being performed and should be communicated in advance by the STM to the DOE Field Element. The conduct of a monitoring visit will follow the process of an assessment as described in Section 4.4, though the scope may range from an evaluation of a single quality assurance element to a complete programmatic review.

5 ACCREDITATION

Following a program's technical evaluation, the STM shall prepare a recommendation package for the Oversight Board with the STM's recommendation to either grant or deny accreditation. The Oversight Board shall review the recommendation package and propose to the DOELAP Administrator that the accreditation be either granted or denied. If denial of an accreditation is recommended, the Oversight Board shall provide a basis for the recommendation.

The DOELAP Administrator shall review all accreditation documents and recommendations and make a final determination to either grant or deny accreditation. If granted, the Administrator issues a Certificate of Accreditation and associated Conditions of Accreditation.

5.1 Certificate of Accreditation

The Certificate of Accreditation is issued to recognize the accreditation of the external dosimetry and radiobioassay programs. It names the accredited program and the effective date of the accreditation.

5.2 Conditions of Accreditation

The Conditions of Accreditation is issued along with the DOELAP Certificate of Accreditation and details the performance categories and radionuclides, external dosimetry or radiobioassay systems, and the sample types or matrices that are being accredited for use in

routine monitoring to determine personnel dose of record. It includes the accreditation period, which is typically three years from the effective date of the accreditation noted on the Certificate of Accreditation, although shorter periods may be imposed for new or marginally performing programs.

5.3 Partial Accreditation

The Administrator may approve partial accreditation for satisfactory performance in one or more of the testing category subsets identified in the application. If a system did not meet the DOELAP performance testing criteria for a particular accreditation category subset, a retest for the failed measurement is scheduled for the next test session. The accreditation process may continue for other requested categories in which the performance testing criteria were met.

5.4 Modifications to Accredited Program

(a) The STM shall be notified whenever changes are made to key personnel, processes, procedures, equipment, facilities, software, or other systems that were listed in the Application for Accreditation.

(b) Routine maintenance, where the processes and quality control is formally documented in the program's quality assurance manual or supporting documentation, is not considered a program modification.

5.4.1 Notification to the STM

(a) Modifications, deletions, or additions to systems, processes, or equipment that were identified in the application; that were reviewed during the onsite assessment; that are outside the scope of the accredited configuration control system; or that may indirectly impact the program's ability to accurately perform, record, and report external dosimetry and radiobioassay results shall be reported in writing to the STM within 45 days prior to the change, if feasible. Examples of changes that require notification include

- Changes to the laboratory's management system
- Significant facility changes
- Changes in key senior staff or organization structure
- Significant change to primary policies
- Significant changes to resources

(b) Notification of modifications may be made via email or by official letter correspondence to the STM, with a copy to the cognizant field element. The STM may require the program to provide additional information in order to evaluate the status of the accreditation with

respect to the modification or a demonstration of technical equivalence to ensure that the modifications meet DOELAP requirements.

5.4.2 Technical Equivalence

(a) Modifications to processes, equipment or facilities that are significantly different from the DOELAP accredited configuration and that directly impacts the program's ability to accurately perform, record, or report dosimeter or radiobioassay results will require a demonstration of technical equivalence showing the modification meets or exceeds the program's capabilities and commitments as stated in the DOELAP application or Quality Assurance Program documentation. Demonstrations of technical equivalence shall be reported in writing to the STM 45 days prior to the proposed implementation date, if feasible. Examples of modifications that require technical equivalence include:

- Replacement of a major equipment component
- Change in critical software
- Change in a dosimeter algorithm outside of routine DOELAP performance testing
- Change in the analysis mode
- Major change in analytical procedures or methods
- Employing new procedures or methods

(b) It is recommended that the authorized program representative discuss the details of the modification and proposed technical verification plan with the STM prior to performing the testing needed to show technical equivalence. The STM may be able to provide additional guidance to ensure the technical equivalence documentation meets DOELAP requirements.

(c) The program shall submit evidence supporting a conclusion that the modified system will be technically equivalent or superior to the accredited system. Documentation to support technical equivalence shall be routed through the cognizant field element for approval prior to being sent to the STM. The STM will review the documentation and make a recommendation to the DOELAP Administrator. The DOELAP Administrator will make the final determination and notification. The STM or the DOELAP Administrator may require additional information or verifications to be performed before granting technical equivalence.

5.5 Amendment

The STM shall be notified if a change in the type or quality of a radiation field or radiological environment occurs or is anticipated. The notification shall describe how the current accredited system is adequate or request an amendment to the current accreditation. A

program may request an amendment to a current accreditation through additional performance testing for an existing system or performance testing of a new or supplemental system.

5.6 Appeals

(a) A program may petition the DOELAP Administrator to appeal an adverse determination regarding accreditation, including revoking all or part of the program's scope of accreditation, denial of technical equivalence, or denial of amendment requests.

(b) A petition to appeal shall be submitted to the DOELAP Administrator no later than 45 days following the receipt of an adverse determination letter. The petition should explain the reason(s) for the appeal, include appropriate supporting documentation, and shall be submitted to the cognizant field element before forwarding to the DOELAP Administrator.

(c) Once a petition to appeal has been received, it will be investigated by the DOELAP Administrator. The Administrator may select a group of qualified experts, who are independent of the program petitioning the appeal, to investigate the appeal and provide recommendations.

5.7 Accreditations in Good Standing

When a program submits the DOELAP application before the application deadline and participates during their regularly assigned test cycle and on-site assessment, the program's current accreditation will remain in good standing until an official decision is made by DOELAP. This includes accreditations that are past the effective end date of their current accreditation and are awaiting a formal decision from DOELAP on the accreditation renewal.

6 Correspondence

An initial submittal, e.g., an application, a request, a corrective action plan, to DOELAP by a DOE field element or contractor shall include evidence that the submittal has been formally reviewed and approved by the cognizant DOE field element. Subsequent submittals to DOELAP shall include evidence that the cognizant DOE field element has been copied.

7 Commercial Vendors

7.1 Vendor Qualification

Vendor qualification is the process by which a commercial vendor is evaluated to determine if it can provide external dosimetry or radiobioassay services that meet the requirements of

DOELAP. Similar to initial DOELAP Accreditations, vendors who go through the qualification process are required to submit an application including a self-assessment, undergo performance testing, and satisfactorily pass an on-site assessment. This optional vetting process is not an accreditation, but it ensures that vendors can demonstrate to DOELAP accredited programs, or programs seeking DOELAP accreditation that they can meet the DOELAP requirements.

7.2 Programs Using Commercial Vendors

When a DOELAP accredited program uses a commercial vendor, the DOELAP accredited program is responsible for ensuring the vendor maintains compliance with all DOELAP requirements. This includes conducting initial and recurring on-site assessments. The program is also responsible for ensuring appropriate corrective actions are implemented in response to any deficiencies found during an assessment, including on-site assessments conducted by DOELAP.

APPENDIX A - REFERENCES

The current versions of the following documents allow for complete implementation of this technical standard:

American National Standards Institute (ANSI). 2009. *Personnel Dosimetry Performance – Criteria for Testing*. ANSI/HPS N13.11-2009. New York, NY.

American National Standards Institute (ANSI). 2008. *Performance Testing of Extremity Dosimeters*. ANSI/HPS N13.32-2008. New York, NY.

American National Standards Institute (ANSI). 2011. *Performance Criteria for Radiobioassay.* ANSI/HPS N13.30-2011. New York, NY.

U.S. Department of Energy. 2008a. *Radiation Protection Programs Guide for use with Title 10, Code of Federal Regulations, Part 835, Occupational Radiation Protection,* DOE G 441.1-1C, Admin Chg 1. Washington, D. C.

U.S. Department of Energy. 2011. *Department of Energy Laboratory Accreditation Program for Personnel Dosimetry.* DOE-STD-1095-2011. Washington, DC.

U.S. Department of Energy. 2011. Title 10, Code of Federal Regulations, Part 830, *Nuclear Safety Management.* Washington, DC.

U.S. Department of Energy. 2011. Title 10, Code of Federal Regulations, Part 835, *Occupational Radiation Protection*. Washington, DC.

U.S. Department of Energy. 2016. *Department of Energy Laboratory Accreditation Program for Radiobioassay.* DOE-STD-1112-2016. Washington, DC.

APPENDIX B - DOELAP OVERSIGHT BOARD CHARTER

Purpose

THE DOE Laboratory Accreditation Program (DOELAP) Oversight Board is established to advise the DOELAP Administrator regarding dosimetry or radiobioassay issues, review recommendations by the DOELAP Senior Technical Manager (STM) regarding accreditation of DOE site personnel dosimetry or radiobioassay programs, conduct reviews of the Performance Testing Laboratory (PTL) and DOELAP technical standards and site assessment criteria. The primary purpose of the Board is to provide support to the DOELAP Administrator to ensure technical quality and consistency of DOELAP technical standards and on-site assessments.

Organization

Members of the Board shall be appointed by the DOELAP Administrator. Candidates are selected from nominations by the respective DOE field elements. The Oversight Board typically consists of five members who each serve a five year term. Members of the Oversight Board shall select one member to serve as chairman. Reappointment of members to subsequent terms may occur. Members of the committee shall have expert knowledge of external dosimetry or radiobioassay practice and regulatory requirements.

Meetings

Each Board meet once a year to review laboratory accreditation documentation. Additional meetings via internet or telephone conference may take place on an *ad hoc* basis. The voting criteria and quorum for the DOELAP Oversight Board functions shall be by simple majority of at least three voting members.

Responsibilities

The Oversight Board:

Reviews recommendations made by the STM and advises the DOELAP Administrator regarding approval or denial of DOE or DOE contractor external dosimetry or radiobioassay programs. An Oversight Board member shall be excused from evaluating and voting on any issue where there may be a conflict of interest.

Evaluates the performance testing laboratories triennially for traceability of equipment and standards to the National Institute of Standards and Technology (NIST) and conformance with operating procedures.

Reviews assessment findings and corrective action plans for mitigating concerns or deficiencies in

dosimetry or radiobioassay programs identified by DOELAP assessors.

Recommends to the DOELAP Administrator appropriate changes to the DOELAP program based on review of DOELAP documentation, on-site assessment criteria, and standards.

Records

Records of Board meetings and recommendations for accreditation or denial of DOE site dosimetry or radiobioassay programs are maintained by the STM.

Authority

The Board is established as an advisory body. Therefore, decisions and recommendations made by the Board will not be binding on the DOELAP Administrator, but will carry significant weight in the conduct of DOELAP.

APPENDIX C – DOELAP EXCEPTIONS

Request for exceptions to DOELAP in accordance with §835.402(b)(2) and §835.402(d)(2) shall be forwarded through the cognizant field element and the appropriate HQ program office, to the DOELAP Administrator. The DOELAP Administrator will then conduct a technical review and prepare a recommendation and formally approve or deny requests for exception to DOELAP requirements.

Requests for exception in accordance with §835.402(b)(2) or §835.402(d)(2) shall provide sufficient documentation to demonstrate that either (1) there is no resident personnel dosimetry program, the reported external radiation doses are not significant (typically less than 100 mrem), and either another DOELAP or a National Voluntary Accreditation Program (NVLAP) accredited service is employed; or (2) the site participates in a routine performance testing program that demonstrates that they maintain a level of performance substantially equivalent to that of a program accredited under DOELAP.

A request for exception under condition (1) above shall provide at least the following information:

- The name and address of the personnel dosimetry service provided. If the processor is NVLAP accredited, a copy of the certificate and accredited categories shall be provided.
- The number of personnel participating in the dosimetry program.
- For the last five years, the range of occupational doses received by personnel, the average annual external dose for all personnel monitored, and those who had a measurable exposure.
- A description of all applicable source terms.
- A justification of the dosimeter selected (if applicable).
- A description of the quality assurance program in effect.

Once final approval for an exception has been received, the Radiation Protection Program shall be updated to address the exception. The internal audit program shall also include a routine review of the dosimetry program to ensure that there has not been any programmatic modifications that could impact the exception.