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DOE STANDARD

DEPARTMENT OF ENERGY LABORATORY ACCREDITATION PROGRAM ADMINISTRATION



**U.S. Department of Energy
Washington, D.C. 20585**

AREA SAFT

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FOREWORD

The Department of Energy (DOE) implemented the DOE Laboratory Accreditation Program (DOELAP) for external dosimetry in 1987 and for radiobioassay in 1998. DOELAP strives to maintain and improve the competency of dose measurement laboratories through performance testing, program-specific calibrations traceable to national standards organizations, and onsite assessments. The DOE also expects DOELAP to enhance cooperation and technical information exchange among its sites and facilities in order to provide a more standardized and uniform radiation dosimetry capability.

This technical standard updates the administrative requirements for the accreditation process. It also differs from the previous version in that some authority is delegated to the Performance Testing Laboratory senior technical managers in an effort to improve DOELAP's efficiency. Other changes include the formalization of what is now termed secondary accreditation, the initiation of a vendor qualification program, and a revised method for determining technical equivalence. Finally, this technical standard continues the minimalist theme that was begun with technical standard DOE-STD-1095-2011, *Department of Energy Laboratory Accreditation for External Dosimetry*, in that the technical standard is limited to requirements and other, succinct regulatory information. Guidance in addressing the requirements and conditions provided in the DOELAP technical standards, as well as other supporting information, are being compiled into a guidance handbook that will follow the issuance of this technical standard.

Throughout this standard, the word "shall" is used to denote an action that is to be performed if the objectives of this standard are to be met, and the word "should" is used to denote an action that is expected to be performed unless documentation is provided showing technical equivalence.

Compliance with a DOE Technical Standard is not mandatory unless it is adopted as a requirement in a contract or subcontract with DOE or in an applicable regulation. Title 10 C.F.R. § 835.402(b) and (d) require that dose monitoring programs implemented to demonstrate compliance with § 835.402(a) and (c), respectively, ". . . shall be: (1) Accredited, or excepted from accreditation, in accordance with the DOE Laboratory Accreditation Program. . . ; or (2) Determined by the Secretarial Officer responsible for environment, safety and health matters to have performance substantially equivalent to that of programs accredited under the DOE Laboratory Accreditation Program. . . ." Consequently, because this technical standard prescribes the means by which persons or entities subject to 10 C.F.R. Part 835 satisfy the requirement to be accredited or excepted from accreditation ". . . in accordance with the DOE Laboratory Accreditation Program. . .," persons or entities required to comply with 10 C.F.R. § 835.402 must (1) comply with this technical standard in order to be accredited or excepted from accreditation under DOE's Laboratory Accreditation Program. . . ; or (2) be determined ". . . by the Secretarial Officer responsible for environment, safety and health matters to have performance substantially equivalent to that of programs accredited under the DOE Laboratory Accreditation Program. . . ."

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This DOE technical standard is approved for use by all DOE components and their contractors. Beneficial comments (recommendations, additions, and deletions) and any pertinent data that may be of use in improving this document should be addressed to the Office of Health, Safety and Security (HS-23), U.S. Department of Energy, Washington, DC, 20585, by letter or by following the instructions in the Technical Standards Program Procedures on the DOE Technical Standards Program web site (www.hss.energy.gov/nuclearsafety/ns/techstds/).

This technical standard's effective date is August 1, 2013.

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ACRONYMS/ABBREVIATIONS

ANSI	American National Standards Institute
CFR	Code of Federal Regulations
DOE	U.S. Department of Energy
DOELAP	Department of Energy Laboratory Accreditation Program
HPS	Health Physics Society
PTL	Performance Testing Laboratory
STM	Senior Technical Manager

1. SCOPE

This technical standard provides a brief description of and an administrative framework for DOELAP activities, and establishes parameters for accreditation and other actions. Detailed information on addressing the requirements in this technical standard is provided in the DOELAP technical standards listed below and is explained further in the supplemental handbook.

2. REFERENCES

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

U.S. Code of Federal Regulations, Title 10, Part 820, *Procedural Rules for DOE Nuclear Activities*.

U.S. Code of Federal Regulations, Title 10, Part 830, *Nuclear Safety Management*.

U.S. Code of Federal Regulations, Title 10, Part 835, *Occupational Radiation Protection*.

U.S. Department of Energy, *Department of Energy Laboratory Accreditation for External Dosimetry*, DOE-STD-1095-2011.

U.S. Department of Energy, *Department of Energy Laboratory Accreditation Program for Radiobioassay*, DOE-STD-1112-98.

U.S. Department of Energy, *Implementation Guide for Use with 10 C.F.R. 835*, DOE G 441.1-1C, Washington, DC.

3. DEFINITIONS

Accreditation. The certification, through DOELAP, that an external dosimetry or a radiobioassay program meets the requirements for specified measurements and quality assurance. The process of accreditation includes testing dosimetry and radiobioassay system performance and an onsite assessment of associated quality assurance, records, calibration programs, and any corrective actions. An accreditation is specifically defined through the *Conditions of Accreditation* document.

Applicant. A DOE site external dosimetry or radiobioassay program that has submitted an application for DOELAP accreditation and is participating in the accreditation process. While a DOE contractor is usually the “applicant,” the cognizant DOE field office is a partner

in the accreditation process. An applicant may also be a commercial vendor who has applied to DOELAP to be designated a Qualified Vendor.

Assessment. An onsite review undertaken by DOELAP to assess the competence of an external dosimetry or radiobioassay program, based on this technical standard as well as the appropriate technical standard for external dosimetry or radiobioassay, for a defined scope of accreditation or qualification.

NOTE: Assessing the competence of a program involves assessing the entire external dosimetry or radiobioassay operations of a contractor or vendor, including the competence of the personnel, the validity of the methodology used, and the accuracy and precision of the measurement results.

Commercial Vendor. A commercial enterprise in the public domain that offers external dosimetry or radiobioassay services.

Conditions of Accreditation. A regulatory document, issued by DOELAP, that specifies the performance categories, external dosimetry or radiobioassay systems, and quality assurance measures that are being accredited for use in determining personnel dose.

Conditions of Vendor Qualification. A regulatory document, issued by DOELAP, that specifies the performance categories, external dosimetry or radiobioassay systems, and quality assurance measures of a commercial vendor that are qualified for use by a DOE contractor as a component of an accredited program.

For Cause. An action, such as the termination of an application or accreditation, or the conduct of a monitoring assessment, that is based on a breach, misfeasance, or other inappropriate action by an applicant, or an accredited or qualified program.

Performance Testing Laboratory. A laboratory independent of the applicant's operation and authorized by DOE to conduct performance testing for DOELAP. The DOE Radiological and Environmental Sciences Laboratory, located at Idaho Falls, Idaho, is the DOELAP performance testing laboratory.

Secondary Accreditation. A type of accreditation where a DOE contractor, at site A, purchases external dosimetry or radiobioassay services, or both, from a DOELAP primary-accredited program at site B.

Vendor Qualification. The certification, through DOELAP, that a commercial vendor of external dosimetry or radiobioassay services offers those services in a manner that meets

DOELAP criteria. Vendor qualification includes testing dosimetry or radiobioassay system performance and an onsite assessment of associated quality assurance, records, calibration programs, and any corrective actions. A qualification is specifically defined through the *Conditions of Vendor Qualification* document.

4. ADMINISTRATION

4.1 DOELAP Administrator

The DOELAP Administrator is the Federal official who is directly responsible for and has authority over DOELAP.

4.1.1. The DOELAP Administrator shall:

- a. establish policies, procedures, standards, and guidance necessary to implement and improve DOELAP,
- b. coordinate DOELAP implementation and improvement with the Performance Testing Laboratory (PTL),
- c. solicit DOE field organizations for volunteers to assist DOELAP and from those volunteers establish a group who, by demonstration of sufficient knowledge, experience, and training in external dosimetry, radiobioassay, or internal dosimetry, are recognized as technical experts,
- d. appoint individuals to the Oversight and Appeal Boards from the available group of technical experts (an Oversight Board member will not serve on an Appeal Board),
- e. make the final determination on Oversight and Appeal Board recommendations, and
- f. grant accreditations, qualifications, modifications, exceptions, and issue other decisions.

4.1.2. The DOELAP Administrator may reject an application, request, or a petition, or revoke an accreditation, qualification, or modification for cause.

4.2. DOELAP Senior Technical Manager

The DOELAP Senior Technical Manager (STM) manages the performance testing program and the accreditation process for external dosimetry or radiobioassay programs. The STM is typically an employee of the PTL. This person is responsible for:

- a. maintaining and improving the performance testing program,
- b. training assessors from the available group of technical experts and evaluating their performance,
- c. reviewing, evaluating, and acting on applications for accreditation and qualification, performance evaluation testing results, and onsite assessment reports,
- d. maintaining schedules for performance testing and onsite assessments,
- e. making recommendations to an Oversight Board on accreditation and qualification applications based on application responses, performance testing and onsite assessment results, and any applicant response to those results, and
- f. reviewing, evaluating, and acting on requests for modification and making recommendations regarding such to the DOELAP Administrator.

4.3. Oversight Board

An Oversight Board consists of five members who each serve a five-year term. Oversight Board members typically have extensive technical 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. An Oversight Board shall:

- a. select one member to serve as the chairperson for a three year period,
- b. establish a quorum and voting criteria by a simple majority of the members,
- c. review STM recommendations and referred requests for modification and recommend further action to the DOELAP Administrator (a member will be recused when the member's site program has a petition before the Board),
- d. assess the PTL triennially for conformance with applicable procedures, standards, and accreditations,

- e. prepare a record of each meeting and submit that record to the STM for archiving, and
- f. advise the DOELAP Administrator on issues pertinent to the Laboratory Accreditation Program.

4.4. Appeal Board

An Appeal Board is formed on an *ad hoc* basis and consists of three members who are not affiliated with the organization making an appeal. The Board shall:

- a. select one member to serve as the chairperson,
- b. establish a quorum and voting criteria by a simple majority of the members,
- c. critique an appeal and recommend a final action to the DOELAP Administrator, and
- d. prepare a record of the meeting and submit that record to the STM for archiving.

4.5. Assessor

An assessor is an individual recognized by DOELAP as a technical expert and who has been trained by DOELAP to perform assessments. An assessor conducts onsite assessments in support of the DOELAP accreditation process. To maintain assessor status, an assessor shall, every three years:

- a. take DOELAP-sponsored assessor training, and
- b. participate in at least one onsite assessment.

5. GENERAL REQUIREMENT

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

6. ACCREDITATION

6.1. Exception

- a. A DOE site radiation protection program may apply for exception to accreditation where there is no resident external dosimetry or radiobioassay system, the annual

dose for the most exposed individual is less than the monitoring thresholds specified in 10 C.F.R. Part 835.402(a)(1-4) or (c), and either a DOELAP or a National Voluntary Laboratory Accreditation Program accredited or a qualified service is utilized to ensure a monitoring threshold is not exceeded.

b. An exception is valid for up to five years after the effective date.

6.2 Primary Accreditation

Primary, or direct, accreditation is for a DOE site radiation dose monitoring program for compliance with 10 C.F.R. Part 835.402. The dose monitoring program may have its own systems, facilities, and personnel, purchase support from a qualified vendor, or some combination thereof.

6.3. Secondary Accreditation

Secondary accreditation is an option for a DOE contractor to obtain personnel dose monitoring support from a primary-accredited DOE program located at another site, in lieu of utilizing a commercial vendor.

Secondary accreditation may not be an option where there is an existing, onsite, DOELAP-accredited program. Secondary accreditation in this circumstance will be considered on a case-by-case basis by the DOELAP Administrator after consultation with the cognizant DOE field office.

6.4. Accreditation Process

6.4.1. The accreditation process generally consists of the following order of events:

- a. The DOE contractor responsible for the dose monitoring program submits a completed, cognizant DOE field office-approved, application to the STM.
- b. Application review by a DOELAP STM.
- c. Performance testing as prescribed by the applicable DOELAP technical standard.
- d. Onsite assessment based on DOELAP requirements.
- e. Development of an accreditation recommendation to an Oversight Board by a DOELAP STM based on the application responses and performance testing and onsite assessment results.

f. Oversight Board review and recommendation to the DOELAP Administrator for further action.

6.4.2. DOELAP has established timeframes and deadlines for the external dosimetry and radiobioassay accreditation processes. A request to modify a timeframe or a deadline will be considered by the DOELAP Administrator on a case-by-case basis.

6.5. Onsite Assessment

6.5.1. An onsite assessment is conducted to validate the responses to an application, assess the completion and effectiveness of any corrective action, and to determine whether an applicant is able to perform in a credible manner. An assessment generally consists of the following order of events:

- a. Establishing the assessment team, scheduling the assessment, and the team's documentation review.
- b. An entrance meeting where the team explains the assessment process, its agenda, and schedules the exit briefing.
- c. The assessment based on DOELAP requirements.
- d. The team's compilation of its assessment data, and a factual accuracy review by program representatives. The factual accuracy review is only of the team's data that will be later used to develop the assessment results.
- e. An exit briefing where the assessment team presents and discusses the results, and provides the program representatives a copy of its assessment report.
- f. The team completes its assignment by providing its report to the STM.

6.5.2. There are three categories of assessment results:

- a. Observation: This could be a suggested improvement that a program may incorporate or the highlighting of a noteworthy practice. No written response to DOELAP is required.
- b. Concern: This is for any aspect that is considered marginal with respect to a site dose monitoring program's management, performance, or quality assurance.

- (1) A Concern shall be remediated through a corrective action plan and the plan shall be submitted to the STM no later than 45 calendar days after the date of the exit briefing. Any corrective action having a completion period greater than one year will not receive favorable consideration without a sufficient justification.
 - (2) Evidence that a corrective action plan has been completed and an assessment of the effectiveness of the corrective action(s) shall be available for the next accreditation assessment.
 - (3) A Concern identified by the previous onsite assessment that has been found to be unresolved irrespective of any corrective action(s) shall be recategorized as a Deficiency.
- c. Deficiency: This is any aspect of a program that the assessment team believes prevents the program from functioning competently. A Deficiency suspends an application.
- (1) A Deficiency shall be remediated through a corrective action plan and the plan shall be submitted to the STM no later than 45 calendar days after the date of the exit briefing.
 - (2) Evidence that a corrective action plan has been completed shall be received by the STM within 60 calendar days of the exit briefing's date to reactivate the application.
 - (3) An assessment of the effectiveness of the corrective action(s) shall be available for the next accreditation assessment.
 - (4) A Deficiency identified by the previous onsite assessment that has been found to be recurrent shall suspend an application and initiate a for cause review.
- 6.5.3. An accredited program may undergo a monitoring assessment at any time during the accreditation period. A monitoring assessment may occur for cause or on a random basis. The scope of a monitoring assessment may range from a spot check to a complete assessment.

6.6. Accreditation

- 6.6.1. An accreditation is valid for up to three years after the effective date.
- 6.6.2. A current accreditation may remain in effect beyond the expiration date if an application to renew it has been received by the STM by the appropriate deadline.
- 6.6.3. If an applicant failed a performance testing category, then the applicant may receive partial accreditation based on the performance tests that were passed. Successful retesting will restore a previously failed performance category.
- 6.6.4. A new program that has achieved accreditation shall undergo a monitoring assessment approximately one year after the effective date.

7. VENDOR QUALIFICATION

7.1. Overview

Vendor Qualification is a means to make a commercial vendor of external dosimetry and radiobioassay services conveniently available to DOE contractors by first vetting the interested vendor through a process similar to DOELAP accreditation. A commercial vendor already providing service to a DOE contractor may continue to do so during the qualification process.

7.2. Qualification Process

The qualification process parallels that for accreditation as described in sections 6.4 through 6.6 above except that Vendor Qualification does not involve a DOE field office.

7.3. Qualification

- 7.3.1 A qualification is valid for up to three years after the effective date.
- 7.3.2. A qualified vendor shall undergo annual performance testing to maintain the qualification.

8. MODIFICATION

8.1. Technical Equivalence

DOELAP accredits the program that is presented to it through the program's description in the application, the results of the program's performance testing, and any program adjustments stemming from an onsite assessment as well as based on an Oversight Board's recommendation. Any change to the accredited program's configuration, then, may require a determination of technical equivalence by DOELAP before it goes into effect. Some changes, e.g., an update of a software version, an analytical procedure or algorithm refinement, or a like-for-like replacement of a detector system component, such that the accredited program's precision or accuracy is not reduced, may not require a determination of technical equivalence. Therefore, it is strongly recommended that a representative of an accredited program first discuss any anticipated change to the program with the appropriate STM to determine if a technical equivalence request is necessary.

A request for technical equivalence should be received by the STM no less than 45 calendar days before the proposed date of the change for issuance of a timely response.

8.2 Amendment

8.2.1. A change in the scope of an accredited or qualified program, e.g., an expanded capability, shall be authorized by an amendment to the Conditions of Accreditation (or Vendor Qualification) prior to the change going into effect. A request for an amendment should be received by the STM no less than 45 calendar days before the proposed date of the change for issuance of a timely response.

8.2.2. An amendment request to add one or more performance categories shall require performance testing as appropriate. This type of amendment shall be coordinated with an STM.

8.3 Appeal

An applicant may petition the DOELAP Administrator, no later than 45 calendar days after the date of the decision, to have an adverse decision reviewed by an Appeal

Board. The petition shall explain the reason(s) for the appeal and provide any appropriate, supportive documentation.

CONCLUDING MATERIAL

Review Activity:

National Nuclear Security Administration
Office of Environmental Management
Office of Health, Safety and Security
Office of Nuclear Energy
Office of Science

Preparing Activity:

DOE-HS-23

Project Number:

SAFT-0122

Site Offices:

Ames Site Office
Argonne Site Office
Berkeley Site Office
Brookhaven Site Office
Carlsbad Field Office
Chicago Office
Fermi Site Office
Grand Junction Office
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