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DOE STANDARD

DEPARTMENT OF ENERGY LABORATORY ACCREDITATION PROGRAM FOR RADIOBIOASSAY



**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 radiobioassay in 1998 through DOE-STD-1112-98, *The Department of Energy Laboratory Accreditation Program for Radiobioassay*. DOELAP evaluates the quality of DOE radiobioassay programs through performance testing, program-specific quality assurance practice and procedure evaluations, and onsite assessments.

This technical standard revises the original standard for radiobioassay program accreditation. Guidance information contained in that document will be updated and made available in the DOELAP guidance handbook. This DOELAP technical standard defines performance testing and onsite assessment criteria to be met by DOE site radiobioassay programs seeking DOELAP accreditation. Further, DOELAP, in recognition of the use of commercial vendors for radiobioassay services, has implemented a qualification process that is similar to accreditation. Additional information regarding Qualified Vendor status is available in technical standard DOE-STD-1111-2013, *Department of Energy Laboratory Accreditation Program Administration*.

The program defined in this technical standard is the culmination of many years of effort by DOE to provide a structured means for assuring the quality of radiobioassay measurement performance in DOE site radiobioassay programs. Beginning in 1981, the DOE embarked on a program of evaluating and testing radiobioassay laboratories for both direct (*in vivo*) and indirect (*in vitro*) radiobioassay measurements to foster significant improvements in worker radiation safety. The pathway for program development has been to encourage the development of performance standards by national consensus standards organizations, evaluate the feasibility and technical appropriateness of the standards for application in DOE operations, and develop and implement a performance testing program. DOE's efforts in the development of performance standards, blind testing programs, improvements in calibration standards, and site evaluation criteria have assisted this effort. In addition, research efforts in radiobioassay analytical technique improvements and standards development have been supported by the DOE to enhance the quality of radiobioassay measurements.

This standard establishes the technical and quality assurance bases for the Performance Testing Program that administers the radiobioassay testing program and onsite assessments for DOE site radiobioassay programs seeking DOELAP accreditation. The performance testing categories for radiobioassay are based on ANSI/HPS N13.30-2011, *Performance Criteria for Radiobioassay*. Throughout this standard, the word "shall" is used to denote an action required to meet the objective of this standard, and the word "should" is used to denote an expected practice to be performed unless documentation is provided that demonstrates technical equivalence.

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 Worker Safety

and Health Policy (AU-11), U.S. Department of Energy, Washington, DC, 20585, by letter or by contacting the Technical Standards Program manager on the DOE Technical Standards Program Overview web site (<http://www.energy.gov/ehss/program-overview>).

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(d) requires that “Internal dose monitoring programs implemented to demonstrate compliance with § 835.402(c) . . . shall be: (1) Accredited, or excepted from accreditation, in accordance with the DOE Laboratory Accreditation Program for Radiobioassay; 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 for Radiobioassay.” 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 for Radiobioassay,” 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 for Radiobioassay; 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 for Radiobioassay.”

This technical standard’s effective date is August 1, 2016.

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TABLE OF CONTENTS

ACRONYMS/ABBREVIATIONSvi

1. SCOPE..... 1

2. GENERAL REQUIREMENTS AND INFORMATION..... 2

3. DIRECT RADIOBIOASSAY PERFORMANCE TESTING 3

4. INDIRECT RADIOBIOASSAY PERFORMANCE TESTING..... 3

5. ONSITE ASSESSMENT 4

6. REFERENCES..... 4

7. DEFINITIONS..... 4

APPENDIX A - QUALITY ASSURANCE PROGRAM6

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

- 1.1. This technical standard describes the U.S. Department of Energy Laboratory Accreditation Program (DOELAP) for radiobioassay, in support of worker health and safety. DOELAP accreditation involves performance testing and documentation of program elements important to the long-term quality assurance of a radiobioassay program, and assessment of the program's ability to accurately perform, record, and report the measurement of radioactive material within the human body and in biological samples from it. DOELAP also provides a qualification process for interested commercial vendors of radiobioassay services. The qualification process is nearly identical to that for accreditation, thus the criteria in this technical standard are applicable to a vendor applying for qualification.

DOELAP, though, does not evaluate the design and implementation of a radiobioassay program at a DOE site nor evaluate any process used to determine internal dose. Accreditation involves:

- a. Performance testing a radiobioassay program based on ANSI/HPS N13.30-2011, *Performance Criteria for Radiobioassay*.
- b. Onsite assessment of a radiobioassay program's quality assurance, staffing, facilities, equipment, documentation, records, etc., by DOELAP assessors using information contained in this and other DOELAP technical standards and the DOELAP handbook.

References herein to an ANSI standard pertain to the above version. However, as this consensus standard is subject to change, the reference may be revised as appropriate. Notice will be given in the *Federal Register* when a new ANSI standard is to be implemented, along with an appropriate timeframe for implementation.

- 1.2. Direct or indirect radiobioassay methods used for identifying and quantifying radionuclides are included in the scope of DOELAP for radiobioassay. Accreditation under this standard applies to methods employed in a contractor dose monitoring program conducted in compliance with 10 C.F.R. 835.402(d).
- 1.3. This standard is specific to the technical characteristics of, and the quality assurance program supporting, a radiobioassay program at a DOE site and that of a qualified vendor's program. Biokinetic models and internal dosimetry protocols used to determine radioactive material intake and internal dose are not included in the scope of the accreditation program. Further, no consideration is given to any administrative aspect such as report format or compliance with requirements outside of 10 C.F.R. Part 830, *Nuclear Safety Management*, and 10 C.F.R. Part 835, *Occupational Radiation Protection*.

2. GENERAL REQUIREMENTS AND INFORMATION

- 2.1. ANSI/HPS N13.30-2011 is incorporated into this standard. DOELAP may modify any specification as necessary to assure conservatism in the accreditation process. Any modification will be discussed in the DOELAP Handbook.
- 2.2. A radiobioassay system shall be tested if it is used to demonstrate compliance with 10 C.F.R. 835.402(d).
- 2.3. The applicant shall select the testing category or categories for each radiobioassay system.
- 2.4. An applicant applying for accreditation in an entire performance testing category shall:
 - a. be capable of measuring each radionuclide in that category, and
 - b. report results for each radionuclide requested by the PTL.
- 2.5. Specific information supporting accreditation shall be submitted to the PTL in the application. For example, the applicant would provide the following information:
 - a. The performance category or categories to be tested in.
 - b. A concise description of each radiobioassay system to be performance tested.
- 2.6. The applicant shall implement a quality assurance program (QAP). 10 CFR 830.122 prescribes basic components of and criteria for a QAP and HPS/ANSI N13.30-2011 establishes QAP criteria for a radiobioassay program. The applicant's QAP shall address the criteria applicable to its program. Appendix A provides a general summary of the criteria and a basis for onsite assessment guidance.
- 2.7. The Senior Technical Manager (STM), as defined in DOE-STD-1111-2013, coordinates performance testing and the onsite assessment with the authorized representative.
- 2.8. The applicant shall report the performance testing measurement results to the PTL by the requested date. Failure by an applicant to submit all measurement results by that date may result in failure of the affected test category; failure under this circumstance will not be remedied through a subsequent retest.
- 2.9. The PTL will report the evaluated performance testing results to the applicant after the evaluations have been compiled. An estimate of the uncertainty of the assigned values of activity will be included. The PTL will not accept any request to change or void any reported result after the test results have been distributed. Prior to distribution of the testing results, the STM may, at the STM's discretion, accept a

request to change a reported value if the applicant's reanalysis of a sample indicates an erroneous value was reported.

3. DIRECT RADIOBIOASSAY PERFORMANCE TESTING

- 3.1 The applicant shall use the counting procedure(s) and counting time(s) normally employed for analysis of that radionuclide in worker measurements. Any deviation from a measurement protocol shall be documented in the report to the PTL.
- 3.2. Five replicate results shall be reported for each radionuclide for which the applicant requested accreditation. These results are derived by counting the phantom once in the normal measurement configuration used for workers, removing the phantom from the measurement configuration, and then repositioning the phantom into the normal measurement configuration and repeating the process for a total of 5 times. For measurements of the lung phantoms, the applicant is expected to provide its own Lawrence Livermore National Laboratory (LLNL) torso phantom; the chest wall thickness that was used to determine minimum detectable activities should be utilized for the accreditation application. Repositioning should include the disassembly and reassembly of the phantom components prior to a recount.
- 3.3. An applicant may elect to retest if the performance testing results for any selected category do not meet specifications.
- 3.4. An applicant is allowed a maximum of 2 retests, irrespective of which direct radiobioassay performance testing category may have failed. Failure of the second retest will result in failure of the application for direct radiobioassay accreditation. The DOELAP Administrator will provide formal notification to a renewal applicant that the direct radiobioassay accreditation has expired.

4. INDIRECT RADIOBIOASSAY PERFORMANCE TESTING

- 4.1 The applicant shall use the analytical procedure(s) and counting time(s) normally employed for analysis of that radionuclide in worker measurements. Any deviation from a measurement protocol shall be documented in the report to the PTL.
- 4.2 The applicant shall analyze at least 5 of the PTL-provided samples for the particular radionuclide in which the applicant is seeking accreditation.
- 4.3 An applicant may elect to retest if the performance testing results for any selected category do not meet specifications.
- 4.4 An applicant is allowed a maximum of 2 retests, irrespective of which indirect radiobioassay performance testing category may have failed. Failure of the second retest will result in failure of the application for indirect radiobioassay accreditation. The

DOELAP Administrator will provide formal notification to a renewal applicant that the indirect radiobioassay accreditation has expired.

5. ONSITE ASSESSMENT

To become accredited or designated a qualified vendor, an applicant shall demonstrate its ability to conduct a competent radiobioassay program as specified by this technical standard. The onsite assessment will assess the organization, quality assurance, documentation, and technical aspects of the radiobioassay program; for accreditation, the assessment will address the program's ability to support dose determinations from occupational radiation exposure. For initial accreditation or vendor qualification, an onsite assessment will occur after performance testing has been satisfactorily completed. Any identified concern or deficiency shall be addressed as explained in DOE-STD-1111-2013. General onsite assessment information may also be found in the handbook.

6. 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 Program Administration*, DOE-STD-1111-2013, Washington, DC.

U.S. Department of Energy, *Department of Energy Laboratory Accreditation Program Handbook*, DOE-HDBK-1218-2016, Washington, DC.

ANSI/HPS N13.30-2011, *Performance Criteria for Radiobioassay*, Health Physics Society, McLean, VA.

7. DEFINITIONS

Accreditation. The determination through DOELAP that a radiobioassay program meets the criteria in this standard for selected performance testing categories and quality assurance. The process of accreditation includes testing radiobioassay system performance and an onsite assessment of associated quality assurance, records, measurement programs, and any previous corrective actions. An accreditation is specifically defined through the *Conditions of Accreditation* document.

Applicant. A DOE site radiobioassay program that has submitted an application for DOELAP accreditation and is participating in the accreditation process. An applicant may also be a commercial vendor that has applied to DOELAP to be a Qualified Vendor.

Assessment. An onsite review undertaken by DOELAP to assess the competence of a radiobioassay program, based on this standard, for a defined scope of accreditation.

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

Authorized Representative. A person identified by the applicant who provides a single point of contact for coordinating with the PTL the applicant's participation in the performance testing and the onsite assessment processes.

Conditions of Accreditation. A regulatory document, issued by DOELAP, that specifies the performance categories, radiobioassay systems, and quality assurance measures that are being accredited.

Direct Radiobioassay. The assessment of radionuclides and quantities in the human body by detection of the radiations emitted from the individual and typically measured by external detection systems (also known as *in vivo* radiobioassay).

Indirect Radiobioassay. The measurement or analysis of radionuclides in biological samples from a human body (also known as *in vitro* radiobioassay).

Performance Testing Laboratory. A laboratory authorized by DOE to conduct performance testing specified by this standard. The DOE Radiological and Environmental Sciences Laboratory, located at Idaho Falls, Idaho, is the DOELAP performance testing laboratory.

Radiobioassay Program. The personnel, management, quality assurance, operation, and radiobioassay system(s) used to ascertain an amount of radioactive material resulting from an occupational exposure.

Radiobioassay System. The software, analytical method(s), measurement method(s), and detection method(s) used to identify and quantify radioactive material in the human body or biological samples.

APPENDIX A. QUALITY ASSURANCE PROGRAM

The following is a general summary of QAP criteria applicable to a radiobioassay program. International Standard ISO/IEC 17025:2005(E), *General requirements for the competence of testing and calibration laboratories*, may be used for supplemental information. The listing utilizes the 10 CFR 830.122 format for convenience.

1. Program

- Established organizational structure, interfaces, and operational responsibilities.
- Established management processes.

2. Personnel Training and Qualification

- Training and qualification of laboratory personnel.
- Continued training.

3. Quality Improvement

- Established processes to identify and correct quality problems.
- Observation of operations and evaluation of quality control data.
- Identification and correction of processes that do not meet established requirements.
- Development and implementation of corrective actions that include measures to prevent recurrence.
- Surveillances to identify items, services, and processes needing improvement.

4. Documents and Records

- Development, approval, control, and maintenance of documents that prescribe work processes and specify requirements.
- Quality assurance records.

5. Work Processes

- Control and maintenance of calibration methods and materials.
- Work performed in accordance with administrative controls, and regulatory and technical documents.
- Software validation.
- Chain of custody.
- Documentation of quality control processes.
- Equipment maintenance.

6. Procurement

- Procured items and services meet established requirements.
- Procured items and services perform as specified.

7. Inspection and Acceptance Testing

- Inspection and testing of specified services, material, and equipment.
- Calibration and maintenance of equipment used for inspections and tests.

8. Management Assessment

- Scheduled review of procedures, specifications, and operating logs.
- Management assesses its management processes to identify and correct problems.

9. Independent Assessment

- Use of independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.

CONCLUDING MATERIAL

Review Activity:

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