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DOE-STD-1112-2019

DOE STANDARD

DEPARTMENT OF ENERGY LABORATORY ACCREDITATION PROGRAM FOR RADIOBIOASSAY

U.S. Department of Energy
Washington, DC 20585

AREA SAFT

FOREWORD

The Department of Energy (DOE) implemented the DOE Laboratory Accreditation Program (DOELAP) for external dosimetry in 1986 and then radiobioassay in 1998. DOELAP requirements for Administration are outlined in DOE-STD-1111, *Department of Energy Laboratory Accreditation Program Administration*, and the requirements for external dosimetry are outlined in DOE-STD-1095, *Department of Energy Laboratory Accreditation Program for Personnel Dosimetry*.

The objective of the DOELAP radiobioassay program is to assure the competency of radiobioassay measurements through performance testing, program-specific quality assurance practice and procedure evaluations, and onsite assessments. DOE also expects the program to enhance cooperation and technical information exchange among its sites and facilities to provide a more standardized and uniform radiobioassay capability. DOE sites and facilities are expected to use standards and other technical guidance from the Department to ensure that the performance of radiobioassay measurements are adequate to meet the requirements of Title 10, Code of Federal Regulations (CFR), Part 835, *Occupational Radiation Protection* and related documents.

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.

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1 PURPOSE AND SCOPE

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 human biological samples. The information in this technical standard is intended for use by accredited programs, programs seeking accreditation, the Performance Testing Laboratory (PTL), DOELAP Assessors, and subcontracted vendors for implementation of the DOELAP requirements, including the technical and quality assurance aspects of the accredited program.

2 APPLICABILITY

This technical standard applies to DOE Headquarters, field organizations, and contractors working to the individual monitoring requirements of 10 CFR Part 835. For the purposes of accreditation, radiobioassay includes direct (in vivo) and indirect (in vitro) methods.

3 ACCREDITATION PROCESS

To be granted accreditation, the following is required:

- Timely submittal of an application in accordance with the timeline set by the DOELAP Senior Technical Manager (STM);
- Compliance with DOELAP requirements contained in this standard;
- Demonstration of proficiency of radiobioassay measurements within acceptable limits of accuracy; and
- Successful resolution of all findings from an on-site assessment conducted by DOELAP Assessors.

3.1 Application

(a) Consideration for DOELAP accreditation requires the submission of an application, including the documented quality assurance program. Initial applicants shall also submit a program self-assessment.

(b) The program self-assessment is a documented internal review conducted by the applicant, which compares the program's compliance status to the requirements set forth in this standard. Lines of inquiry for the self-assessment can be obtained through the DOELAP STM.

3.2 Performance Testing

(a) Proficiency shall be demonstrated on radiobioassay systems that the program intends to

use to demonstrate compliance with 10 CFR Part 835.402. The testing categories selected in the application for which accreditation is desired shall be representative of the evaluations that are made as part of an internal dose monitoring program and the technical basis shall be documented.

(b) Performance testing for determining the accuracy of direct and indirect radiobioassay measurements is conducted in accordance with the American National Standards Institute/Health Physics Society (ANSI/HPS) standard N13.30, *Performance Criteria for Radiobioassay*.

(c) Performance testing shall be defined and consistent with routine measurement protocols. Procedures and counting times normally employed for analysis of radionuclides in worker measurements shall be used. The STM shall be notified of any deviation from a measurement protocol, in accordance with the notification requirements listed in DOE-STD-1111.

(d) The performance criteria used for DOELAP for Radiobioassay measurements results is the root-mean squared error statistic. A discussion of the use and acceptable limits are found in ANSI N13.30-2011.

(e) The applicant shall review the performance testing data for potential improvements in the radiobioassay measurement system.

(f) An applicant may elect to retest if the performance testing results for each selected category do not meet the acceptance criteria. An applicant is allowed a maximum of 2 retests, irrespective of which performance category may have failed. Failure of the second retest will result in failure of the application for accreditation.

3.2.1 Direct Radiobioassay Performance Testing

(a) An applicant shall designate from Table 2 of ANSI N13.30-2011, *Minimum testing level (MTL) for direct radiobioassay performance testing*, each radionuclide that will be performance tested. The specified test radionuclides of Table 2 represent a minimum program for testing the capabilities of a service laboratory to evaluate their measurement program and shall be representative of the evaluations that are made as part of an internal dose monitoring program. For each measurement category, a set of phantom organs or phantoms will be sent to the participating laboratory to be quantitatively measured.

(b) The performance testing laboratory will develop or procure calibration phantoms having activities within the MTL listed in Table 2. These phantoms will be shipped to the applicant service laboratories. Phantoms used for the measurement categories are a bottle manikin absorption (BOMAB) phantom for whole body counting, calibration lung sets for the Lawrence Livermore National Laboratory (LLNL) torso phantom for lung counting, and the ANSI N44.3 (1973) thyroid phantom for thyroid counting.

(c) The service laboratory may choose to analyze one or all of the radionuclides in the test phantom. For each radionuclide for which the applicant requests accreditation, five replicate results shall be reported. 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 in the normal measurement configuration, repeating the process for a total of five times. The chest wall thickness that was used to determine minimum detectable activities should be utilized for the accreditation application.

(d) The program shall ensure performance testing results are submitted via the electronic reporting link sent to them from the PTL. The individual measurement results, reported at the date and time that the measurement was made, shall include the estimation of the total propagated uncertainty, reported at one standard deviation, for each result.

3.2.2 Indirect Radiobioassay Performance Testing

(a) An applicant shall designate from Table 3 of ANSI N13.30-2011, *Minimum testing level (MTL) for indirect radiobioassay performance testing*, which radionuclides will be performance tested. The specified test radionuclides of Table 3 represent a minimum program for testing the capabilities of a service laboratory to evaluate their measurement program and shall be representative of the evaluations that are made as part of an internal dose monitoring program. If test radionuclides listed in Table 3 are not representative of typical radionuclides encountered, the program shall notify the STM to determine if the PTL can provide the additional radionuclide or an appropriate alternative.

(b) The PTL will provide six samples in the urine or fecal matrix in the range of 1 to 20 times the MTL. These samples, along with five blank samples will be shipped to the service laboratory for analysis.

(c) The laboratory shall analyze at least five out of the six samples for the particular analyte in which the laboratory is seeking accreditation. The service laboratory should report results to the PTL no later than 45 days after the sample receipt. Results reported after 45 days shall receive prior written approval by the STM.

(d) The service laboratory shall submit their performance testing results via the electronic reporting link sent to them from the PTL. The individual measurement results, reported at the date and time that the measurement was made, shall include the estimation of the total propagated uncertainty, reported at one standard deviation, for each result.

3.3 On-site Assessment

An on-site assessment of an applicant's program is conducted initially and triennially thereafter to ensure a program meets the quality assurance requirements prescribed in this standard. For accreditation, an on-site assessment is conducted after performance testing is completed. A monitoring assessment may also be conducted after implementation of a new program or if major deficiencies were identified during an on-site assessment of an established program.

4 QUALITY ASSURANCE

4.1 Quality Assurance Program

(a) The program shall have a documented quality assurance program describing the internal management structure, system of procedures, and practices to ensure radiobioassay measurements are accurate, repeatable, verifiable, and properly recorded.

(b) The program's quality assurance manual or supporting documentation shall include

- A statement of quality policy and quality objectives;
- Documented processes, procedures, and instructions;
- Documents needed to ensure effective planning, operation, and control of processes;
- Records required to demonstrate compliance with the quality assurance program;
- Technical Basis Documentation;
- Training objectives and processes for maintaining proficiency;
- Practices for handling and resolving contested results; and
- External interface agreements (if applicable).

4.2 Program Management

(a) Managerial and technical personnel shall have the resources needed to carry out their duties, including the implementation of the Quality Assurance Program.

(b) A technical lead (however named), who is experienced in applied radiobioassay and knowledgeable in the design and operation of the radiobioassay measurement system(s) currently used, shall be assigned. The technical lead is responsible for approving radiobioassay data and making decisions regarding questionable data.

(c) A quality assurance (QA) lead (however named), who has responsibility and authority for ensuring that the quality assurance program is implemented, shall be assigned. The QA lead shall have authority to communicate quality assurance issues directly with the technical lead and other organizational management. The program technical lead may function as the QA lead as long as the responsibilities are clearly defined.

(d) Responsibilities for the implementation of the quality assurance program shall be defined, including the organizational structure and functional responsibilities of key personnel.

(e) The individuals responsible for the implementation of the quality assurance program may delegate work to others but shall retain responsibility.

(f) Management and personnel shall be free from undue internal and external influences that

may adversely impact the quality of their work.

(g) Management shall conduct a formal review of the Radiobioassay Quality Assurance Program during the 3-year DOELAP accreditation cycle. The review shall be completed at least one year before the accreditation end period so that it is available for the DOELAP on-site assessment. Management shall consist of the QA lead, the technical lead, and a member of senior management that has authority for allocation of resources. The review shall include assessing opportunities for improvement and the need for changes to policies or processes. At minimum, the review shall include

- A comparison of quality objectives and standards against achievements;
- An assessment and test results;
- Non-conformances and corresponding corrective actions, preventative measures, and deficiency trends;
- Results from external and internal audits; and
- Other relevant factors, such as quality control activities, resources, and training.

(h) A program shall have a documented plan for continuity of operations. This includes service contracts, in-house maintenance, spare parts capabilities, and unexpected loss of key personnel.

(i) When more than one organization is involved in the implementation of the requirements for DOELAP accreditation (e.g., major equipment maintenance, calibration, document control and records); the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented.

(j) When a vendor or subcontractor is involved in the implementation of the requirements for DOELAP accreditation, the accredited program shall have a procedure describing how they will ensure that all of the DOELAP requirements are maintained.

(k) External audits of a vendor or subcontractor's quality assurance program shall be performed initially and at least once during the DOELAP accreditation period. Audits should be performed at least one year prior to the DOELAP on-site assessment to allow assessors to evaluate the program's progress in assigning issues to staff for tracking corrective actions through to completion. The audits shall be supplemented by an ongoing evaluation of the performance of the vendor or subcontractor.

4.3 Personnel Training and Qualifications

(a) All personnel performing accredited activities shall have the training, qualifications, and competence to perform their assigned tasks effectively.

(b) A training program commensurate with the complexity and scope of the assigned responsibilities shall be documented. Training shall be provided to achieve initial proficiency, maintain proficiency, and adapt to changes in job responsibilities, new

technologies, or policies and procedures.

(c) The technical lead shall initially and at least annually evaluate and document the proficiency of each staff member authorized to perform radiobioassay functions. This proficiency assessment shall include an observation of performance.

(d) In the event that proficiency is not achieved or maintained, any person's work duties that impact the quality of accredited activities shall be under the direction or supervision of a properly trained and qualified individual. Such personnel shall not be the primary signatory on radiobioassay records or Quality Assurance/Quality Control (QA/QC) reports until proficiency is demonstrated.

(e) Personnel shall be knowledgeable in methods to appropriately identify and control radioactive contamination (internal or external).

4.4 Documents and Records

(a) A system shall be in place which clearly describes which records are kept and practices followed through the entire radiobioassay cycle.

(b) All documents that form the quality assurance program shall be controlled to ensure that the correct documents are being employed. Documents shall be reviewed for accuracy and approved by authorized personnel in accordance with documented review frequencies.

(c) A comprehensive record of analyses and measurements shall be maintained. Records shall contain sufficient identification to allow correlation with calibration and quality control records.

(d) Procedures shall be established and maintained for identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records.

(e) All quality assurance and technical records shall be legible, easily retrievable, and stored in a suitable environment to prevent damage, deterioration, or loss. Records shall be available for review during the on-site assessment.

(f) Electronic records shall be protected and regularly backed-up on a pre-determined schedule to prevent unauthorized access, amendment, or loss.

4.5 Work Processes

(a) Work processes shall control the preservation of measurements, radiobioassay records, and other data on which the dose is based, and maintain their traceability to the individual concerned. All accredited activities that can influence the assignment of dose to an individual shall be conducted in accordance with established procedures, which shall include the following:

- Work methods and sequence;

- Equipment to be used;
- Work environment;
- Quality control;
- Acceptance criteria;
- Minimum Detectable Amounts;
- Inspection points; and
- Handling, storage, retrieval, and shipment of samples.

4.6 Quality Improvement

(a) Quality control procedures shall be implemented to ensure that the equipment performs at the levels of precision and accuracy defined for each measurement protocol. Quality control data shall be recorded in such a way that trends are detectable. For indirect radiobioassay, the number of quality control spiked samples shall be at least 5% of the total samples analyzed and, when applicable, a reagent blank shall be analyzed with each set of samples. For direct radiobioassay, quality control checks shall be conducted daily when equipment is in use.

(b) When quality control data is found to be outside pre-defined acceptance criteria, corrective actions shall be implemented and documented to prevent incorrect results from being reported. Reevaluation of all measurements since last acceptance shall be performed.

(c) The laboratory shall use appropriate techniques to ensure the proper identification and qualification of specific radionuclides, including separating interferences and resolving a mixture of radionuclides.

(d) Blind testing shall be conducted to validate the overall performance of the radiobioassay system and the frequency of monitoring shall be documented. Blind testing samples that are submitted for analyses, over time, shall include samples that demonstrate accuracy, false positive, false negative and sensitivity evaluations. Blind testing samples shall contain chemical, matrix and radionuclide interferences common to the program's routine samples. Procedures describing steps to be taken in the event that blind testing results are outside of pre-established criteria shall be documented.

(e) The technical basis for the following system characteristics shall be documented:

- Derivation of Decision Levels (L_c);
- Methods for calculating and verifying Minimum Detectable Amounts (MDAs); and
- Estimation of measurement uncertainties (e.g., calibration counting, measurement of volume or weight, losses of chemical separations, transfer, operations, impurities).

(f) Software verification and validation (V & V) shall be performed in accordance with an appropriate, documented software quality assurance program. V & V shall include process control software, data processing, and record keeping. In addition, software version control shall be included in the program's documented control procedures for all software.

(g) When a computer or laboratory information system is used to input, store, calculate, or retrieve data in relation to key Radiobioassay measurement steps, the program shall

- Establish and maintain procedures describing the processes;
- Validate the accuracy of data entry; and
- Verify the accuracy of any calculations performed.

(h) The variability of test results among staff, equipment, and locations shall be assessed to ensure consistency.

(i) Internal audits shall be conducted at least annually and structured in a way to ensure that all elements of this standard are reviewed over the three year accreditation period. All audits and actions taken for correcting identified problems and preventative actions implemented to prevent recurrence shall be documented.

4.7 Facilities and Equipment

(a) Facilities and equipment shall be adequate to perform the type(s) of service(s) for which accreditation is sought. A list and description of facilities and equipment which have the potential to impact the quality of radiobioassay measurement results shall be available for review.

(b) Adequate facilities and equipment shall have the following:

- Sufficient space to perform measurements;
- Proper shielding of areas from unwanted radiation;
- Environmental monitoring and controls, including background radiation; and
- Properly calibrated equipment.

4.8 Maintenance and Calibration

(a) A preventative maintenance program for radiobioassay measurement systems shall be implemented.

(b) Equipment used for radiobioassay measurements or quality control shall be periodically calibrated or whenever the accuracy of the equipment is suspect. Calibration procedures shall identify required accuracy and define the methods and frequency for checking accuracy. Calibration procedures shall not be less restrictive than the manufacturer's

prescribed requirements.

(c) Calibration or verification records shall include

- Equipment name or description;
- Model, style, and serial number;
- Manufacturer;
- Notation of all equipment variables requiring calibration or verification;
- The range of the calibration/verification;
- The resolution of the instrument and its allowable error;
- Calibration or verification date and schedule;
- Date and result of last calibration;
- Identity of the laboratory individual and external service responsible for calibration;
- Source of reference standard or phantom and traceability; and
- Environmental conditions.

(d) Equipment shall be properly identified to correlate with calibration records and maintenance logs.

(e) A calibration shall be performed for the specific radionuclide or energy range for each measurement system. Calibrations of *direct radiobioassay* measurement systems shall be performed with known sources of radionuclides incorporated into a suitable simulation of the body parts of interest, or with techniques that are technically equivalent.

(f) All calibrations and characterizations shall be performed using reference standards traceable to the National Institute of Standards and Technology (NIST) national standards or standards maintained by an equivalent national standards authority.

(g) When results are found to be out of tolerance, reviews of the equipment used to generate the results shall be conducted to determine the validity of the data and the corrective actions to be taken.

4.9 Reporting

(a) The direct radiobioassay measurement report developed for the permanent record shall include, or reference the location of, the following:

- Subject identification;

- Date, time, and nature of examination;
- Identification of radionuclide(s) for which the subject was analyzed and other radionuclides detected;
- Type of measurement (e.g., lung, whole body, thyroid);
- Quantification of the amount of radionuclide(s) whether positive, negative, or zero;
- Estimates of counting uncertainty and the combined standard uncertainty (which includes counting and other random and systemic uncertainties) at a defined coverage factor (See ANSI N13.30 Table B1.);
- Values of the decision level. Values shall be in the same units as results;
- The value of the customer specified or service laboratory action level for prompt notification;
- Identification of the measurement equipment used; and
- The identification of the person responsible for the report or their designee.

(b) The indirect radiobioassay measurement report developed for the permanent record shall include, or reference the location of, the following:

- Sample identification
- Assigned number
- Total volume or weight of sample submitted
- Reference dates and times of sample collection and analysis
- Identification of radionuclides for which the sample was analyzed and other nuclides detected
- Quantification of radionuclides using the appropriate blank values, whether positive, negative, or zero
- Estimates of counting uncertainty and the combined standard uncertainty (which includes counting and other random and systemic uncertainties) at a defined coverage factor (See ANSI N13.30 Table B1.);
- Identification of specific measurement procedures;
- Values of the decision level. Values shall be in the same units as results; and
- The value of the customer specified or service laboratory action level for prompt notification;

- A description of the measurement equipment used; and
- The identification of the person responsible for the report or their designee.

APPENDIX A - REFERENCES

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

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

American National Standards Institute (ANSI). 1973. *Thyroid Radioiodine Update Measurements using a Neck Phantom* ANSI N44.3-1973. New York, NY.

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. 2013. *Records Management Program,* DOE O 243.1B, Chg 1. Washington, DC.

U.S. Department of Energy. 2018. *Department of Energy Laboratory Accreditation Program for External Dosimetry.* DOE-STD-1095-2018. Washington, DC.

APPENDIX B –PROGRAMS THAT USE SERVICE PROVIDERS

DOELAP accredited programs may purchase radiobioassay services from services providers; however, the DOELAP accredited program has the responsibility for ensuring the requirements of this technical standard are met. The purpose of this appendix is to outline the major considerations of a program that is purchasing analytical services from a commercial radiobioassay vendor or a DOE radiobioassay laboratory.

A copy of the work agreement with the service provider, including any agreed upon commitments shall be available for review. The work agreement should clearly establish

- Access to relevant documents, including technical basis documents, policies and procedures, and the documented quality assurance program;
- Timely notification of any change in a procedure or supporting quality assurance program;
- Radiobioassay data validation and verification;
- Radiobioassay reports;
- Appropriate packaging for and handling of submitted *in vitro* samples;
- Emergency Radiobioassay services, as needed; and
- *In Vitro* sample containers, if needed.

An explanation of how the DOELAP accredited technical staff have sufficient qualifications and experience to assess the capabilities and limitations of the service provider with respect to the purchased services. At minimum, the staff shall have sufficient qualifications and experience to be able to

- Sufficiently assess the capabilities and limitations of the service provider;
- Provide oversight of the service provider, including the review of quality control data and conduct on-site assessments;
- Identify error trends and anomalous data; and
- Conduct quality assurance assessments.

A technical basis for the selected performance testing categories or subcategories shall be available.

The program shall have a procedure for conducting quality assurance assessments of the service provider; that includes on-site audits, quality control reviews, and blind quality control. The procedures shall also describe how findings are identified and corrected.

APPENDIX C – Minimum Detectible Amount (MDA) and Decision Level (L_C) Testing

The ANSI/HPS N13.30 MDA/L_C tests do not calculate or estimate the process MDA or L_C. They only evaluate the hypothesis that a process L_C is no less than the claimed L_C activity, or the process MDA is no larger than the claimed MDA activity.

The MDA and L_C testing shall be completed for each radiobioassay analysis described in the DOELAP application for performance testing, and shall incorporate replicate analyses employing all analytical and computational procedures normally part of the bioassay analysis being tested. Processes for testing shall be documented in programmatic documentation.

At a minimum, testing must be performed at least once for each system/process and following significant changes to the system or processes requiring Technical Equivalence determinations.

- Each unique system/process claimed on the DOELAP application must be tested.
- Note that it is not required to test all "identical" portions of a system. For example, testing all chambers in an alpha-spectroscopy system.

MDA values tested should be those claimed on the DOELAP application or in other programmatic documentation (statements of work, technical basis documents, quality assurance program, etc.).

Nuclides used in MDA testing should be representative of those used in routine analyses.

- It is not necessary to test all nuclides if the analytical processes are the same (e.g., Pu-239/240 by alpha spectroscopy may be representative of Pu-238).
- Direct radiobioassay testing shall include nuclides in the energy ranges and configurations used in routine subject measurements (e.g., low/high energy, chest/whole body).

All tests must include the appropriate background subtraction and interferences, and the test analyses shall incorporate normal corrections for:

- Detector background subtraction;
- Reagent interferences for indirect analysis (important for U analyses); and
- K-40 continuum counts for direct measurements.

If testing of a system/process is not possible due to lack of appropriate standards or inability to produce samples at the desired MDAs, then justification shall be provided in programmatic quality assurance documentation.

Accredited Programs shall be responsible for coordinating testing with service providers.