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| **LINE OF INQUIRY** | **CRITERIA** | **REQUIREMENTS MET?** | **COMMENTS/DEMONSTRATION OF CONFORMANCE** |
| **YES** | **NO** | **N/A** |
| **Previous Assessment (PA)** |  |  |  |  |  |
| 1. Review the applicant’s prior DOELAP assessment and determine if previous concerns and deficiencies were resolved. Elevate concerns, which were not resolved, to a deficiency. Note the closure(s) or elevation(s) of prior concerns and deficiencies in the report.
 | DOE-STD-1111-2018 4.4.2 |  |  |  |  |
| **Application and Performance Testing (AP)** |  |  |  |  |  |
| 1. Proficiency shall be demonstrated on radiobioassay systems that the program intends to use to demonstrate compliance with 10 CFR 835.402.
 | 3.2a |  |  |  |  |
| 1. The testing categories selected in the application shall be representative of the evaluations that are made as part of an internal dose monitoring program, and the technical basis is documented.
 | 3.2a |  |  |  |  |
| 1. Performance testing shall be 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.
 | 3.2c |  |  |  |  |
| 1. The applicant shall review the performance testing data for potential improvements in the radiobioassay measurement system. If the applicant uses a service provider, the applicant is aware of the service providers DOELAP performance testing results and, if there were any failure(s), did the applicant and service provider investigate and take any corrective action to resolve the failure(s).
 | 3.2e |  |  |  |  |
| 1. Review processes and QA practices for nuclides indicated on the application that were not included in performance testing.
 | 3.2.2a |  |  |  |  |

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| **LINE OF INQUIRY** | **CRITERIA** | **REQUIREMENTS MET?** | **COMMENTS/DEMONSTRATION OF CONFORMANCE** |
| **YES** | **NO** | **N/A** |
| **Program Management (PM)** |  |  |  |  |  |
| 1. Managerial and technical personnel shall have the resources needed to carry out their duties, including the implementation of the Quality Assurance Program.
 | 4.2(a) |  |  |  |  |
| 1. 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.
 | 4.2(b) |  |  |  |  |
| 1. A quality assurance (QA) lead (however named) shall be assigned. (The program technical lead may function as the QA lead as long as the responsibilities are clearly defined.)
 | 4.2(c) |  |  |  |  |
| 1. The QA lead shall have the responsibility and authority to implement the quality assurance program.
 | 4.2(c) |  |  |  |  |
| 1. The QA lead shall have the authority to communicate quality assurance issues directly with the technical lead and other organizational management.
 | 4.2(c) |  |  |  |  |
| 1. Responsibilities for the implementation of the quality assurance program shall be defined, including the organizational structure and functional responsibilities of key personnel.
 | 4.2(d) |  |  |  |  |
| 1. Where quality assurance program work is delegated, the responsibility shall remain with the programmatically-assigned individual.
 | 4.2(e) |  |  |  |  |
| 1. Management and personnel shall be free from undue internal and external influences that may adversely impact the quality of their work.
 | 4.2(f) |  |  |  |  |
| 1. A formal review of the QA program shall be conducted at least one year before the accreditation end period so that it is available for the DOELAP on-site assessment.
 | 4.2(g) |  |  |  |  |
| 1. The formal review of the QA program shall be conducted by the technical lead, the QA lead, and a member of senior management who has authority for allocation of resources.
 | 4.2(g) |  |  |  |  |

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| **LINE OF INQUIRY** | **CRITERIA** | **REQUIREMENTS MET?** | **COMMENTS/DEMONSTRATION OF CONFORMANCE** |
| **Yes** | **No** | **N/A** |
| **Program Management (PM)** |  |  |  |  |  |
| 1. The formal review of the QA program shall include:
* assessing opportunities for improvement;
* need for changes to policies or processes;
* comparison of quality objectives and standards against achievements;
* 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.
 | 4.2(g) |  |  |  |  |
| 1. A program shall have a documented plan for continuity of operations. This may include service contracts, in-house maintenance, spare parts, and backup for key personnel.
 | 4.2(h) |  |  |  |  |
| 1. Responsibilities, interfaces, and authority of each organization responsible for the implementation of DOELAP requirements are clearly defined and documented.
 | 4.2(i) |  |  |  |  |
| 1. 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.
 | 4.2(j) |  |  |  |  |
| 1. External audits of a vendor or subcontractor’s quality assurance plan shall be performed initially (for new contracts) and at least once during the DOELAP accreditation period.
 | 4.2(k) |  |  |  |  |
| 1. External vendor audits shall be supplemented by an ongoing evaluation of the performance of the vendor or subcontractor.
 | 4.2(k) |  |  |  |  |

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|  **LINE OF INQUIRY** | **CRITERIA** | **REQUIREMENTS MET?** | **COMMENTS/DEMONSTRATION OF CONFORMANCE** |
| **YES** | **NO** | **N/A** |
| **Training and Qualifications (TQ)** |  |  |  |  |  |
| 1. All personnel performing accredited activities shall have the training, qualifications, and competence to perform their assigned tasks effectively.
 | 4.3(a) |  |  |  |  |
| 1. A training program commensurate with the complexity and scope of the assigned responsibilities shall be documented.
 | 4.3(b) |  |  |  |  |
| 1. Training shall be provided to achieve initial proficiency, maintain proficiency, and adapt to changes in job responsibilities, new technologies, or policies and procedures.
 | 4.3(b) |  |  |  |  |
| 1. The technical lead, or their designee, shall initially and at least annually evaluate the proficiency of each staff member authorized to perform radiobioassay related functions. This proficiency assessment shall include an observation of performance.
 | 4.3(c) |  |  |  |  |
| 1. In the event that proficiency is not achieved or maintained, any person’s work duties that impact the quality of accredited activities shall be performed under direction or supervision of a properly trained and qualified individual. Unqualified personnel shall not be the primary signatory on radiobioassay records or QA/QC reports until proficiency is demonstrated.
 | 4.3(d) |  |  |  |  |
| 1. Personnel shall be knowledgeable in methods to appropriately identify and control radioactive contamination of samples and/or subjects.
 | 4.3(e) |  |  |  |  |

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| **LINE OF INQUIRY** | **CRITERIA** | **REQUIREMENTS MET?** | **COMMENTS/DEMONSTRATION OF CONFORMANCE** |
| **YES** | **NO** | **N/A** |
| **Documents and Records (DR)** |  |  |  |  |  |
| 1. A system shall be in place which clearly describes which records are kept and practices followed through the entire radiobioassay cycle.
 | 4.4(a) |  |  |  |  |
| 1. All documents that form the quality assurance program shall be controlled to ensure that the correct documents are being employed.
 | 4.4(b) |  |  |  |  |
| 1. Documents shall be reviewed for accuracy and approved by authorized personnel in accordance with documented internal review frequencies.

(The QA program defines the document review frequency.)  | 4.4(b) |  |  |  |  |
| 1. A comprehensive record of analyses and measurements shall be maintained. Records shall contain sufficient identification to allow correlation with calibration and quality control records.
 | 4.4(c) |  |  |  |  |
| 1. Procedures shall be established and maintained for the identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records.
 | 4.4(d) |  |  |  |  |
| 1. All quality assurance and technical records shall be legible, easily retrievable, and stored in a suitable environment to prevent damage, deterioration, or loss.
 | 4.4(e) |  |  |  |  |
| 1. Records shall be available for review during the on-site assessment.
 | 4.4(e) |  |  |  |  |
| 1. Electronic records shall be protected and regularly backed-up on a pre-determined schedule to prevent unauthorized access, amendment, or loss.
 | 4.4(f) |  |  |  |  |

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| **LINE OF INQUIRY** | **CRITERIA** | **REQUIREMENTS MET?** | **COMMENTS/DEMONSTRATION OF CONFORMANCE** |
| **YES** | **NO** | **N/A** |
| **Work Processes (WP)** |  |  |  |  |  |
| 1. All accredited activities that can influence the assignment of dose to an individual are 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.
 | 4.5(a) |  |  |  |  |
| 1. Procedures control the preservation of measurements, radiobioassay records and other data on which dose is based and maintain their traceability to the individual concerned.
 | 4.5(a) |  |  |  |  |

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| **LINE OF INQUIRY** | **CRITERIA** | **REQUIREMENTS MET?** | **COMMENTS/DEMONSTRATION OF CONFORMANCE** |
| **YES** | **NO** | **N/A** |
| **Quality Improvement (QI)** |  |  |  |  |  |
| 1. The program shall have a documented quality assurance program describing the internal management structure, system of procedures, and practices to ensure radiobioassay results are accurate, repeatable, verifiable, and properly recorded.
 | 4.1(a) |  |  |  |  |
| 1. The program’s quality assurance manual or supporting documentation shall include:
* 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).
 | 4.1(b) |  |  |  |  |
| 1. Quality control procedures shall be implemented to ensure that the equipment performs at the levels of precision and accuracy defined for each measurement protocol.
 | 4.6(a) |  |  |  |  |
| 1. Quality control data shall be recorded in such a way that trends are detectable.
 | 4.6(a) |  |  |  |  |
| 1. 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.
 | 4.6(a) |  |  |  |  |
| 1. For direct radiobioassay, quality control checks shall be conducted daily when equipment is in use.
 | 4.6(a) |  |  |  |  |
| 1. 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.
 | 4.6(b) |  |  |  |  |
| 1. Reevaluation of all measurements since last acceptance shall be performed when quality control data is found to be outside pre-defined acceptance criteria.
 | 4.6(b) |  |  |  |  |
| 1. The laboratory shall use appropriate techniques to ensure the proper identification and quantification of specific radionuclides, including separating interferences and resolving a mixture of radionuclides.
 | 4.6(c) |  |  |  |  |
| 1. Blind testing shall be conducted to validate the overall performance of the radiobioassay system and the frequency of monitoring shall be documented.
 | 4.6(d) |  |  |  |  |
| 1. Blind testing samples that are submitted for analyses, over time, shall include samples that demonstrate accuracy, false positive, false negative and sensitivity evaluations.
 | 4.6(d) |  |  |  |  |
| 1. Blind testing samples shall contain chemical, matrix and radionuclide interferences common to the program’s routine samples.
 | 4.6(d) |  |  |  |  |
| 1. Procedure(s) describing steps to be taken in the event that blind testing results are outside of pre-established criteria shall be documented.
 | 4.6(d) |  |  |  |  |
| 1. The technical basis for the following system characteristics shall be documented:
* Derivation of Decision Levels (Lc);
* Methods for calculating and verifying Minimum Detectable Amounts (MDAs); and
* Estimation of measurement uncertainties.
 | 4.6(e) |  |  |  |  |
| 1. The MDA and LC testing shall be completed for each radiobioassay analysis described in the DOELAP application in accordance with Appendix C of DOE-STD-1112-2019.
 | Appendix C |  |  |  |  |

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| **LINE OF INQUIRY** | **CRITERIA** | **REQUIREMENTS MET?** | **COMMENTS/DEMONSTRATION OF CONFORMANCE** |
| **YES** | **NO** | **N/A** |
| **Quality Improvement (QI)** |  |  |  |  |  |
| 1. 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.
 | 4.6(f) |  |  |  |  |
| 1. Software version control shall be included in the program’s documented control procedures for all software.
 | 4.6(f) |  |  |  |  |
| 1. 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.
 | 4.6(g) |  |  |  |  |
| 1. The variability of test results among staff, equipment, and locations shall be assessed to ensure consistency.
 | 4.6(h) |  |  |  |  |
| 1. Internal audits shall be conducted at least annually and structured in a way to ensure that all elements of DOE-STD-1112-2019 are reviewed over the three year accreditation period.
 | 4.6(i) |  |  |  |  |
| 1. All audits and actions taken for correcting identified problems and preventative actions implemented to prevent recurrence shall be documented.
 | 4.6(i) |  |  |  |  |

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| **LINE OF INQUIRY** | **CRITERIA** | **REQUIREMENTS MET?** | **COMMENTS/DEMONSTRATION OF CONFORMANCE** |
| **YES** | **NO** | **N/A** |
| **Facilities and Equipment (FE)** |  |  |  |  |  |
| 1. Facilities and equipment shall be adequate to perform the type(s) of services(s) for which accreditation is sought.
 | 4.7(a) |  |  |  |  |
| 1. A list and description of facilities and equipment that have the potential to impact the quality of radiobioassay measurement results is available for review.
 | 4.7(a) |  |  |  |  |
| 1. Facilities shall have:
* Sufficient space to perform measurements;
* Proper shielding of areas from unwanted radiation.
* Environmental monitoring and controls, including background radiation; and
* Properly calibrated equipment.
 | 4.7(b) |  |  |  |  |

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| **LINE OF INQUIRY** | **CRITERIA** | **REQUIREMENTS MET?** | **COMMENTS/DEMONSTRATION OF CONFORMANCE** |
| **YES** | **NO** | **N/A** |
| **Maintenance and Calibration (MC)** |  |  |  |  |  |
| 1. A preventative maintenance program for radiobioassay measurement systems shall be implemented.
 | 4.8(a) |  |  |  |  |
| 1. Equipment used for radiobioassay measurements or quality control shall be calibrated periodically or whenever the accuracy of the equipment is suspect.
 | 4.8(b) |  |  |  |  |
| 1. Calibration procedures shall identify required accuracy and define the method and frequency for checking accuracy.
 | 4.8(b) |  |  |  |  |
| 1. Calibration procedures shall not be less restrictive than the manufacturer’s prescribed requirements.
 | 4.8(b) |  |  |  |  |
| 1. 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 (as appropriate).
 | 4.8(c) |  |  |  |  |
| 1. Equipment shall be properly identified to correlate with calibration records and maintenance logs.
 | 4.8(d) |  |  |  |  |
| 1. A calibration shall be performed for the specific radionuclide or energy range for each measurement system.
 | 4.8(e) |  |  |  |  |
| 1. Calibration 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.
 | 4.8(e) |  |  |  |  |
| 1. All calibrations and characterizations shall be performed using reference standards traceable to the National Institute of Standards and Technology (NIST) national standard or standards maintained by an equivalent national standards authority.
 | 4.8(f) |  |  |  |  |
| 1. 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.
 | 4.8(g) |  |  |  |  |

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| **LINE OF INQUIRY** | **CRITERIA** | **REQUIREMENTS MET?** | **COMMENTS/DEMONSTRATION OF CONFORMANCE** |
| **YES** | **NO** | **N/A** |
| **Reporting (R)** |  |  |  |  |  |
| 1. 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;
* Estimations of counting uncertainty and that combined standard uncertainty (which includes counting and other random and systemic uncertainties) at a defined coverage factor (See ANSI N13:30 Table B1, The combined standard uncertainty may be addressed in the technical documentation.);
* Values of the decision level in the same units as the results;
* The value of the customer specified or service laboratory action level for prompt notification (action levels may be specified in program documentation);
* Identification of the measurement equipment used; and
* The identification of the person responsible for the report or their designee.
 | 4.9(a) |  |  |  |  |
| 2. 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 as applicable;
* Quantification of radionuclides using the appropriate blank values, whether positive, negative or zero;
* Estimations of counting uncertainty and that combined standard uncertainty (which includes counting and other random and systemic uncertainties) at a defined coverage factor (See ANSI N13:30 Table B1, The combined standard uncertainty may be addressed in the technical documentation.);
* Identification of specific measurement procedures;
* Values of the decision level in the same units as the results;
* The value of the customer specified or service laboratory action level for prompt notification (action levels may be specified in program documentation);
* A description of the measurement equipment used; and
* The identification of the person responsible for the report or their designee.
 | 4.9(b) |  |  |  |  |

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| **LINE OF INQUIRY** | **CRITERIA** | **REQUIREMENTS MET?** | **COMMENTS/DEMONSTRATION OF CONFORMANCE** |
| **YES** | **NO** | **N/A** |
| **Guidance for Programs that use** **Service Providers (SP)** |  |  |  |  |  |
| 1. A copy of the work agreement with the service provider, including any agreed upon commitments, shall be available for review.
 | Appendix B paragraph 2 |  |  |  |  |
| 1. 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.
 | Appendix B paragraph 2 |  |  |  |  |
| 1. Staff shall have sufficient qualifications and experience to be able to sufficiently assess the capabilities and limitations of the service provider with respect to the purchased services. At a minimum, that 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.
 | Appendix B paragraph 3 |  |  |  |  |
| 1. A technical basis for the selected performance testing categories or subcategories shall be available.
 | Appendix B paragraph 4 |  |  |  |  |
| 1. The program shall have a procedure for conducting quality assurance assessments of the service provider; including on-site audits, QC reviews, and blind quality control. The procedures shall also describe how findings are identified and corrected.
 | Appendix B paragraph 5 |  |  |  |  |

Assessor Date

Assessor Date