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DOE STANDARD

THE DEPARTMENT OF ENERGY LABORATORY ACCREDITATION PROGRAM FOR RADIOBIOASSAY

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

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FOREWORD

1. This Department of Energy (DOE) standard is approved for use by all DOE Components and contractors.

2. Beneficial comments (recommendations, additions, deletions) and any pertinent data that may be of use in improving this document should be addressed to the Office of Nuclear Safety, Policy, and Standards, EH-31, U.S. Department of Energy, Washington, DC, 20585, by letter or by using the Document Improvement Proposal (DOE F 1300.3) appearing at the end of this document.

3. DOE technical standards, such as this technical standard, do not establish requirements. However, all or part of the provisions in a technical standard can become requirements under the following circumstances;

   (1) they are explicitly stated to be requirements by rule making or in a DOE requirements document; or

   (2) the organization makes a commitment to meet a standard in a contract or in a plan or program required by a DOE requirements document.

The program defined in this technical standard is the culmination of many years of effort by the Department of Energy (DOE) to provide a structured means for assuring the quality of radiobioassay measurement performance at DOE laboratories. 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, to evaluate the feasibility and technical appropriateness of the standards for application in DOE operations, and to develop and implement a routine performance testing program. The development of performance standards, blind testing programs, improvements in calibration standards, and site evaluation criteria assisted this effort. In addition, research efforts in radiobioassay calibration improvements and standards development has been supported by the DOE to enhance the quality of radiobioassay measurements.

The DOE was a strong supporter of the development of American National Standards Institute (ANSI) Standard N13.30-1996, *Performance Criteria for Radiobioassay*, and DOE and DOE contractor personnel participated in its development. The Pacific Northwest National Laboratory (PNNL) and the Radiological and Environmental Sciences Laboratory (RESL) conducted programs for DOE to evaluate draft ANSI N13.30 for use in its DOE/DOE contractor radiobioassay programs. The studies demonstrated that criteria specified in ANSI N13.30 are adequate for assessing the radiobioassay laboratories used by DOE/DOE contractor facilities.

The culmination of this work is to formally offer a DOE Laboratory Accreditation Program (DOELAP) to accredit radiobioassay laboratories that provide services to DOE and DOE contractors. The objective of the DOELAP for Radiobioassay is to maintain and improve the high quality of measurement laboratory performance through: a) performance testing; b) calibration intercomparisons; c) on-site assessment; and d) continuing applied research in areas of radiobioassay where there is a technology shortfall. DOE also expects the program to enhance cooperation and technical exchange between laboratories, which in turn will provide a more standardized and uniform radiobioassay capability.

This technical standard, which is designed to accompany the ANSI N13.30 *American National Standard for Performance Criteria for Radiobioassay* (ANSI 1996), provides the technical specifications and assessment criteria to be met by the radiobioassay program requesting accreditation. It also provides general administrative and operational information about the performance testing laboratory that administers the program. The relevant details of the ANSI N13.30 standard are also identified where necessary. It is expected that laboratories will use this technical standard, the ANSI N13.30 standard, and other technical guidance from DOE to assure that the performance of radiobioassay measurements is adequate to meet the standards of 10 CFR 835 and related requirements.

Throughout this standard, the word “shall” is used to denote actions which must be performed if the objectives of this standard are to be met. If the provisions in this standard are made requirements through one of the two ways discussed in note 3 above, then the “shall” statements would become requirements. It is not appropriate to consider that “should” statements would automatically be converted to “shall” statements as this action would violate the consensus process used to approve this technical standard.

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GLOSSARY

Accreditation - the certification through the Department of Energy Laboratory Accreditation Program (DOELAP) that a radiobioassay program meets the criteria in this standard for specified measurements. The assessment for accreditation includes testing the radiobioassay analytical performance and the evaluation of associated quality assurance, records, and calibration programs. The accreditation process includes the development of recommendations for any improvements needed to ensure continuing quality. The objective of the DOELAP is to accredit radiobioassay programs of DOE/DOE contractors, regardless of whether the radiobioassay measurements are conducted at commercial, in-house facilities, or at another DOE facility.

Accuracy - (ANSI N13.30): the characteristic of an analysis or determination that ensures that both the bias and precision of the resulting quantity will remain within specified limits.

Analyte - (ANSI N13.30): the particular radionuclide to be determined in a sample of interest.

Appropriate Blank - (ANSI N13.30): a sample, person, or phantom that is, ideally, identical in physiochemically and radiologically significant ways with the sample, person, or phantom to be analyzed. When feasible the appropriate blank should not contain environmental quantities of the analyte.

Bias - (ANSI N13.30): the deviation of a single measured value of a random variable from a corresponding expected value, or a fixed mean deviation from the expected value that remains constant over replicated measurements within the statistical precision of the measurement. (Systematic error).

Commercial Laboratory - a laboratory not on-site that performs analytical services under contract or formal agreement for the facility seeking accreditation.

Decision Level (L_c) - (ANSI N13.30): the amount of a count or final instrument measurement of a quantity of analyte at or above which a decision is made that the analyte is definitely present.

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

DOE Contractor - the DOE/DOE contractor facility eligible for accreditation.

Indirect Radiobioassay - the measurement or analysis of radionuclides in excreta or other biological samples removed from the body (also known as in vitro radiobioassay).

Minimum Detectable Activity (MDA) - (ANSI N13.30): the smallest amount of an analyte in a sample that will be detected with a probability ß of non-detection (Type II error) while accepting a probability a of erroneously deciding that a positive (non-zero) quantity of analyte is present in an appropriate blank sample (Type I error).

Minimum Testing Level (MTL) - (ANSI N13.30): the amount of radioactive material that the service laboratory should be able to measure for participation in the performance testing program, assuming the sample(s) are free of interference from other radionuclides unless specifically addressed. The MTLs should not be construed as being the appropriate MDA required for a specific internal dosimetry program, but rather an acceptable minimum testing level for radiobioassay service laboratories based on good measurement practice.

Performance Testing Laboratory - the DOE facility authorized to operate the DOELAP for Radiobioassay program.

Phantom - (ANSI N13.30): a simulated person or part of a person used for calibration of *in vivo* measurement systems. A phantom is constructed to allow placement of radionuclides in a geometry approximating internal depositions.

Precision - (ANSI N13.30): a concept employed to describe dispersion of measurements with respect to a measure of location or central tendency.

Quality Assurance - (ANSI N13.30): all those planned and systematic actions necessary to provide adequate confidence that an analysis, measurement, or surveillance program will perform satisfactorily in service.

Quality Control - (ANSI N13.30): those actions that control the attributes of the analytical process, standards, reagents, measurement equipment, components, system, or facility according to predetermined quality requirements.

Relative Bias - (ANSI N13.30): the quotient of the bias divided by the expected value.

Relative Precision - (ANSI N13.30): the quotient of the dispersion of the measurement divided by either the expected value or by the mean of the measurement.

Routine Measurements - those radiobioassay measurements (direct or indirect) which are performed to demonstrate compliance with the requirements of 10 CFR 835.

Service Laboratory - a facility performing direct or indirect radiobioassay measurements for a Department of Energy/DOE contractor.

Standard Reference Material - (ANSI N13.30): a material characterized by the National Institute of Standards and Technology (NIST) for the activity of radionuclides it contains and issued with a certificate that reports the results of the characterization .

Transfer Reference Standard - (ANSI N13.30): a material that contains radionuclide components of interest in chemical and physical forms similar to radiobioassay specimens, and is used to certify the activity present in a person or sample measured. The radionuclides used for the preparation of the Transfer Reference Standards are, when possible, related to Standard Reference Materials. The preparation procedures are verified and documented.

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ACRONYMS

ANSI	American National Standards Institute
B_r or B_R	Relative Bias Statistic
BOMAB	Bottle Manikin Absorption
CFR	Code of Federal Regulations
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation
DOELAP	Department of Energy Laboratory Accreditation Program
HQ	Headquarters, U.S. Department of Energy
INEEL	Idaho National Engineering and Environmental Laboratory
KPA	Kinetic Phosphorescence Analysis
L_c	Decision Level
MDA	Minimum Detectable Activity
MTL	Minimum Testing Level
NIST	National Institute of Standards and Technology
PEPA	Performance Evaluation Program Administrator
PNNL	Pacific Northwest National Laboratory
QA	Quality Assurance
QC	Quality Control
RESL	Radiological and Environmental Sciences Laboratory
S_B	Relative Precision Statistic
SRM	Standard Reference Material
TL	Testing Level
TRS	Transfer Reference Standard

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1.0 SCOPE

This technical standard describes the U.S. Department of Energy Laboratory Accreditation Program (DOELAP) for Radiobioassay, for use by the U.S. Department of Energy (DOE) and DOE Contractor radiobioassay programs. This standard is intended to be used in conjunction with the general administrative technical standard that describes the overall DOELAP accreditation process - DOE-STD-1111-98, *Department of Energy Laboratory Accreditation Program Administration*. This technical standard pertains to radiobioassay service laboratories that provide either direct or indirect (in vivo or in vitro) radiobioassay measurements in support of internal dosimetry programs at DOE facilities or for DOE and DOE contractors. Similar technical standards have been developed for other DOELAP dosimetry programs.

This program consists of providing an accreditation to DOE radiobioassay programs based on successful completion of a performance-testing process and an on-site evaluation by technical experts. This standard describes the technical requirements and processes specific to the DOELAP Radiobioassay Accreditation Program as required by 10 CFR 835 and as specified generically in DOE-STD-1111-98.

2.0 PURPOSE

The intent of this technical standard is to describe the program and procedures for obtaining accreditation for DOE radiobioassay programs. It also describes the administration of the DOELAP for Radiobioassay specific to the performance testing laboratory, and the process and criteria for the on-site assessment process.

To obtain accreditation, a radiobioassay program shall:

a. meet the test criteria, as modified (see Table I, footnote e and Table II, footnote c) by this technical standard, described in ANSI N13.30 *Performance Criteria for Radiobioassay* (ANSI 1996) for the applicable radiobioassay measurement procedures in use by the service laboratory; and

b. pass an on-site assessment of the documentation, quality assurance, and technical adequacy associated with an acceptable radiobioassay program.

A performance testing laboratory determines whether a contractor meets the test criteria. Members of a team of experts in radiobioassay conduct on-site assessments. The development of the testing criteria and the program requirements found in ANSI N13.30 are based on many years of performance testing of radiobioassay laboratories, and have been developed to improve the quality of radiobioassay measurements without causing undue disruption of existing satisfactory programs. This technical standard has assessment criteria which have been found by pilot testing programs to be consistent with the current capabilities of most radiobioassay laboratories. However, the criteria for passing will be reevaluated as the program evolves and improved radiobioassay capabilities become available.

3.0 APPLICABILITY

The DOELAP for Radiobioassay applies to the technical and administrative aspects of radiobioassay monitoring programs, as required in 10 CFR 835, *Occupational Radiation Protection* and recommended in DOE G 441.3-1, *Implementation Guide for use with Title 10 Code of Federal Regulations, Part 835, Occupational Radiation Protection, Internal Dosimetry Program* at DOE/DOE contractor facilities, and to the documentation of those technical aspects. During the DOELAP accreditation process for radiobioassay:

a. a performance testing laboratory evaluates the technical performance of the radiobioassay service laboratory by providing testing unknowns to be measured and reported; and

b. an on-site assessment team evaluates technical adequacy, program documentation, and quality assurance systems of the radiobioassay program(s).

Biokinetic models and internal dosimetry evaluation protocols used to determine radioactive material intake and internal dose are not included in the scope of the accreditation program. The program scope does not forbid a facility from providing additional radiobioassay services, nor does it preclude a facility from operating research programs to improve radiobioassay services. Each service laboratory shall have the option of being tested and evaluated for an entire category of radiobioassay or for a specific radionuclide within a category. If a specific radionuclide is chosen, evaluation of test results shall be for that radionuclide only. Every three years, each DOE radiobioassay program shall maintain its accreditation by demonstrating compliance with the DOELAP criteria as required in 10 CFR 835.

4.0 REFERENCES

4.1 Government Documents

Title 10, Code of Federal Regulations, part 835, *Occupational Radiation Protection*.

Title 10, Code of Federal Regulations, part 830.120, *Quality Assurance.*

U.S. Department of Energy (DOE). 1991. *Quality Assurance*. DOE Order 5700.6C, DOE, Washington, D.C.

U.S. Department of Energy. 1998. *Department of Energy Laboratory Accreditation Program Administration*. DOE-STD-1111-98, DOE, Washington, D.C.

U.S. Department of Energy. 1998. *DOE G 441.3-1 Implementation Guide for use with Title 10 Code of Federal Regulations Part 835, Occupational Radiation Protection, Internal Dosimetry Program*. DOE, Washington, D.C.

4.2 Non-Government Documents

American National Standards Institute (ANSI). 1996. *Performance Criteria for Radiobioassay*. ANSI N13.30-1996. New York: ANSI.

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

American National Standards Institute (ANSI). 1995. *American National Standard - Traceability of Radioactive Sources to the National Institute of Standards and Technology (NIST) and Associated Instrument Quality Control*. ANSI N42.22-1995. New York: ANSI.

5.0 ACCREDITATION PROCESS

The DOELAP for Radiobioassay is managed by the DOE Office of Worker Health and Safety. A HQ DOELAP Administrator is assigned to provide overall program management. A Performance Evaluation Program Administrator (PEPA) coordinates the accreditation process and administers the performance testing program. To obtain accreditation, a DOE contractor shall first submit an application through the cognizant field office. The contractor shall then satisfy both the performance testing and the on-site assessment requirements. The Performance Evaluation Program Administrator prepares an administrative report documenting the test results and recommendations for accreditation. The Oversight Board evaluates the report and the recommendations and, if approved, sends them to the HQ DOELAP Administrator. The HQ DOELAP Administrator makes the final decisions on accreditation and issues the Certificate of Accreditation. The Conditions of Accreditation accompanying the Certificate of Accreditation specifies the extent of the accreditation for the facility, including direct or indirect radiobioassay, radiobioassay matrix or measurement category, and the specific analytes and matrices for which accreditation has been granted.

5.1 Use of Commercial Laboratories

If a DOE contractor uses the services of a commercial laboratory, both the DOE contractor and commercial laboratory will be visited. If more than one DOE contractor is using the same commercial laboratory, only one site visit to the laboratory may be required. More than one DOE contractor may use performance test data for a commercial laboratory if each contractor facility is testing in the same matrix and for the same analyte. The Performance Evaluation Program Administrator shall approve combined evaluations, and the Oversight Board shall review and approve them.

5.2 Accreditation Process Description

The process of obtaining DOELAP Accreditation for Radiobioassay Programs is described in this section. Accreditation is awarded when all of the phases of the process are completed. The following sub-sections describe the process.

5.2.1 Application Phase. The contractor initiates the accreditation process by submitting the appropriate application form (Attachments A or B) to the Performance Evaluation Program

Administrator through the appropriate DOE field office. To expedite the process, a designated representative of the applying facility management should complete the application as thoroughly as possible and sign it. The designated representative(s) should be familiar with all DOELAP requirements. There may be a separate representative for each of the direct and indirect radiobioassay programs. The representative reviews all documents and acts as liaison between the radiobioassay laboratory and the Performance Evaluation Program Administrator. Other staff members may be designated to perform specific activities (e.g., handling proficiency testing or receiving assessors). However, only one designated individual should be responsible for requesting a change in the scope or nature of the accreditation of a radiobioassay type (either direct or indirect bioassay).

The application requires each DOE Contractor facility to indicate in which testing categories, matrices and analytes accreditation is desired. The application is used to:

a. enroll the DOE/DOE contractor facility in the program;
b. determine the appropriate matrices and analytes for test categories desired for accreditation;
c. determine the cognizant DOE Field Offices or Operations Office for which the radiobioassay service laboratory provides services; and
d. select on-site assessors with the appropriate technical background.

Other uses for the application information are found in the DOELAP Administration Technical Standard, DOE-STD-1111-98.

5.2.2 Performance Test Phase . Performance testing is the initial phase of the DOELAP accreditation process. If DOE contractor-specific calibration factors and data-reduction algorithms are used for routine evaluations, they shall also be used for the analyses of test unknowns and shall be made available to the performance testing laboratory. ANSI N13.30-1996 is used as the technical basis for performance testing. The recommendations contained in ANSI N13.30 are briefly highlighted in this section for direct and indirect radiobioassay.

5.2.2.1 Direct Radiobioassay. A DOE Contractor facility may choose to be accredited in one or more of the categories or radionuclides shown in Table I. Accreditation in a category is

required if routine measurements are to be performed for DOE contractors in the measurement category. This table contains the categories, radionuclides and minimum testing levels (MTLs) for direct radiobioassay measurements. For each measurement category, a set of phantom organs or phantoms will be sent to the participating laboratory to be quantitatively measured.

5.2.2.2 The performance testing laboratory will develop or procure calibration phantoms having activities within the MTL list in Table I. These phantoms will be shipped to the participating 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 thyroid neck phantom for thyroid counting.

5.2.2.3 The service laboratory may choose to analyze one or all of the radionuclides in the test phantom. For each radionuclide for which the DOE contractor 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 into the normal measurement configuration and repeating the process for a total of five times. For measurements of the lung phantoms the service laboratory is expected to provide their own LLNL torso phantom, using only the bare chest cover (no overlays) for the measurements. Repositioning shall mean the complete removal of the phantom from the chair or counting position and the reassembly and repositioning of the phantom prior to a recount. The service laboratory shall report data using the software provided by the testing laboratory.

5.2.2.4 The service laboratory shall use the counting procedure and counting times normally employed for analysis of that radionuclide in worker measurements. Any deviations from the routine measurement protocol shall be documented in the report to the performance testing laboratory.

TABLE I. Minimum Testing Levels (MTLs) for Direct Radiobioassay Performance Testing by Measurement Category and Radionuclide (Adapted from ANSI N13.30 *Performance Testing for Radiobioassay* ANSI 1996)

Measurement Category		Type	Radionuclide	MTL[b,c]
I.	Transuranium elements via L x-ray	Lung	Plutonium-238	9.0 kBq (0.24 µCi)
II.	Americium-241	Lung	Americium-241	0.10 kBq (2.7 nCi)
III.	Thorium-234	Lung	Thorium-234 in equilibrium with its parent in natural Uranium	0.50 kBq (14 nCi)
IV.	Uranium-235	Lung	Uranium-235	30 Bq (0.81 nCi)
V.	Fission and activation products	Lung	Any two of four[a]: Manganese-54 Cobalt-58 Cobalt-60 Cerium-144[e] - - - - - Plus: Cesium-134[d] Cesium-137[d]	3.0 kBq (81 nCi) 30 kBq (0.81 µCi) 3.0 kBq (81 nCi)
VI.	Fission and activation products	Total body	All of: Cesium-134 Cesium-137 Cobalt-60[d] Manganese-54[d]	3.0 kBq (81 nCi) each
VII.	Radionuclides in the thyroid	Thyroid	Iodine-131 or Iodine-125	3.0 kBq (81 nCi)

(a) Direct radiobioassay facility may elect to be tested for a specific radionuclide or may elect to be tested for the category. The testing laboratory will select the test radionuclides if a category is requested.
(b) The upper bound of the testing range shall not exceed 20 times the stated MTL.
(c) The activity of the highest and lowest radionuclides (not including Potassium-40) in any one test phantom shall be within a factor of three of each other; except for Cerium-144 in Category V, whose activity shall not exceed that of any other radionuclide by greater than a factor of 30.
(d) These radionuclides shall be present in the phantom for interference but shall not be tested.
(e) Cobalt-57 may be substituted for Cerium-144 for performance testing purposes due to difficulties in the availability of Cerium-144.

Reference: American National Standard N13.30 "Performance Criteria for Radiobioassay," 1996, American National Standards Institute, Washington, DC.

5.2.2.5 The service laboratory shall submit the report to the testing laboratory. The reporting of measurement results shall include an estimation of the total combined (overall) error for the results. The methodology for estimation of errors and a discussion of the reporting of errors are found in Section 3.0 and Appendix D of ANSI N13.30-1996.

5.2.2.6 The performance criteria used for DOELAP for Radiobioassay direct measurements results are the relative bias and relative precision statistics. A discussion of the use and acceptable limits for these criteria is found in section 5.2.3.

5.2.2.7 The service laboratories are asked to complete their counting of the phantoms in two weeks, then to ship the phantoms to the next location designated by the PEPA. Because there is only a single test phantom for each testing category (except thyroid), it is important that a service laboratory keep the phantom for no more than a maximum of 3 weeks. A letter will inform the service laboratory of the closing date for the performance testing period.

5.2.2.8 Indirect Radiobioassay. A DOE Contractor facility may choose to be accredited in one or more of the categories or radionuclides shown in Table II. Accreditation in a category is required if routine measurements are to be performed for DOE Contractors in the measurement category. This table contains the categories, radionuclides and MTLs for indirect radiobioassay measurements.

5.2.2.9 The performance testing laboratory will prepare and spike six samples in the urine and/or fecal matrix in the range of 1 to 20 times the MTL. These samples, along with five blank samples (identified as such), will be shipped to the service laboratory for analysis.

5.2.2.10 The service laboratory shall analyze at least five out of the six samples that have been spiked for the particular analyte in which the DOE laboratory is seeking accreditation. All six may be analyzed and reported, but the DOE laboratory shall report at least five. The sixth spiked sample is included to allow for lost samples or situations during analyses which would prevent the service laboratory from obtaining valid results. A Radioactive Materials label and/or any hazardous chemical labels, if needed to comply with DOE and U.S. Department of Transportation (DOT) regulations, will be attached or contained with the test samples. They will also contain an expiration date along with a reference date. The service

laboratory should report results to the Performance Evaluation Program Administrator no later than 30 days after the sample expiration date. The service laboratory may choose to analyze the blank samples or not. They are strictly for the laboratory's own use.

5.2.2.11 The service laboratory shall use the analytical procedure and counting times normally employed for routine measurement of the radionuclide for the DOE facility when analyzing the test samples. Any deviations from the routine analysis protocol shall be documented in the report to the performance testing laboratory.

5.2.2.12 The service laboratory shall submit a report to the performance testing laboratory. The reporting of measurement results from the testing analytes shall include an estimation of the total combined (overall) error for each result. The methodology for estimation of errors and a discussion of the reporting of errors are found in Section 4.0 and Appendix D of ANSI N13.30-1996.

5.2.2.13 The service laboratory shall report data using the software provided by the testing laboratory.

TABLE II. **Minimum Testing Levels (MTLs) for Indirect Radiobioassay Performance Testing by Measurement Category and Radionuclide** (Adapted from ANSI N13.30 *Performance Testing for Radiobioassay* ANSI 1996)

Measurement Category	Radionuclide[a]	MTL[b] (per L or per sample)
I. Beta activity average energy < 100 keV	Hydrogen-3	2 kBq (54 nCi)
	Carbon-14	2 kBq (54 nCi)
	Sulfur-35	20 Bq (0.54 nCi)
	Radium-228	0.9 Bq (24 pCi)
II. Beta activity average energy ≥ 100 keV	Phosphorus-32	4 Bq (0.11 nCi)
	Strontium-89/-90 or Strontium-90	4 Bq (0.11 nCi)
III. Alpha activity isotopic analysis	Thorium-228/-230 or Thorium-232	0.02 Bq (0.54 pCi)
	Uranium-234/-235 or Uranium-238	0.02 Bq (0.54 pCi)
	Neptunium-237	0.01 Bq (0.27 pCi)
	Plutonium-238 or Plutonium-239/240	0.01 Bq (0.27 pCi)
	Americium-241	0.01 Bq (0.27 pCi)
IV. Elements (mass/volume)	Elemental Uranium	1 µg (KPA)[c]
V. Gamma (photon) activity	Cesium-137	2 Bq (54 pCi)
	Cobalt-60	2 Bq (54 pCi)
	Iodine-125	0.4 kBq (11 nCi)

(a) Indirect radiobioassay facility may elect to be tested for a specific radionuclide or may elect to be tested for the category. The testing laboratory will select the test radionuclide if a category is requested.
(b) The upper bound of the testing range shall not exceed 20 times the stated MTL.
(c) This MTL differs from the ANSI N13.30 MTL which was initially based upon fluoroscopic measurements. Since KPA has mostly replaced fluoroscopic analysis, the MTL was reduce appropriately. (KPA = Kinetic Phosphorescence Analysis)

Reference: American National Standard N13.30 "Performance Criteria for Radiobioassay," 1996, American National Standards Institute, Washington, DC.

5.2.3 Performance Criteria. The performance criteria used by the testing laboratory are **relative bias** and **relative precision**. See ANSI N13.30-1996 sections 3.42, 3.43, 4.32 and 4.33 for greater detail on the bias and precision statistics development.

5.2.3.1 A **relative bias statistic** is defined in this document for the purposes of performance testing of a finite number of measurements in each category of analysis. The relative bias is individually calculated for each radionuclide in the category being tested. The individual relative bias statistic for the i^{th} measurement in a category with respect to the correct value is defined as

$$B_{ri} = (A_i - A_{ai})/A_{ai} \qquad (6.1)$$

where A_i is the value of the i^{th} measurement in a category being tested, not necessarily a replicate, but possibly a different quantity of spike for each measurement, and A_{ai} is the actual quantity in the test sample, as defined by the spike.

5.2.3.2 In order to avoid the expense of a large number of replicates at each radioactivity level in each category, the relative bias (which may be obtained at different quantity levels) for that test category is calculated from the individual relative biases (B_{ri}). The test category relative bias (B_r) is defined as:

$$B_r = \bar{B}_{ri} = \frac{\sum_{i=1}^{N} B_{ri}}{N} \qquad (6.2)$$

where N is the number of test samples measured by an individual service laboratory in a given test category. The sample size N shall be at least five. For performance testing purposes, B_r shall be within -0.25 to + 0.50 when A_{ai} is at or above the MTL to be considered acceptable.

5.2.3.3 The **relative precision** of the measurement process, selected for the purposes of this document, is the relative dispersion of the values of B_{ri} from its mean B_r. The relative precision (S_B) is defined as

$$S_B = \sqrt{\frac{\sum_{i=1}^{N} (B_{ri} - B_r)^2}{(N - 1)}} \qquad (6.3)$$

For performance testing purposes, the absolute value of the relative precision statistic, S_B, shall be less than or equal to 0.4 when A_{ai} is at or above the MTL for any given radionuclide to be considered acceptable.

5.2.4 Performance Test Conclusion. When the proficiency testing has been completed, the performance testing laboratory shall return the results of the test to the service laboratory within a period not to exceed 3 months. If the service laboratory does not demonstrate satisfactory performance in the accreditation area for which they have applied, the PEPA will send the service laboratory, as soon as feasible, a notice requiring retesting, along with the test results. Because the bias criterion (B_r) has a range of -0.25 to +0.50 and the precision criterion (S_B) is 0.4, phantom calibration uncertainties will be minimal in comparison, and will not be considered when evaluating performance results. A complete discussion on the rationales for these criteria can be found in ANSI N13.30, Appendix B.

5.3 On-site Assessment

To become accredited, a facility shall demonstrate adequate capability in administering a radiobioassay program; including the technical competency of staff, adequate training of personnel, the performance of measurements, and the record keeping and QA aspects of the program. For initial accreditation, an on-site visit is required after the performance testing has been satisfactorily completed. This visit shall assess the quality assurance, documentation, and technical aspects of the direct or indirect radiobioassay program. If a DOE Contractor uses a commercial service laboratory, an on-site assessment will also be performed of the service laboratory. Appendix A contains the assessment criteria and a checklist to be used by the assessment team. The on-site assessment is repeated at 3 year intervals, normally corresponding to the Performance Testing Phase.

5.3.1 Assignment of Assessors. Assessors are assigned to visit each facility. Assignments are based on how well the assessors' individual experience matches the radiobioassay analyses to be assessed.

Assignments also are made to avoid conflicts of interest, such as assessment by staff of a commercial laboratory's competitor. The service laboratory is notified of the assignments and has the right to appeal the assignment of an assessor to the Performance Evaluation Program Administrator. If the service laboratory and the Performance Evaluation Program Administrator cannot agree on an assessor, they may ask the Appeals Board (DOE-STD-1111-98) to resolve the difference. When the assessors have been assigned, the Performance Evaluation Program Administrator contacts the service laboratory to arrange a mutually agreeable date for the visit. The applicable DOE field office is notified of the dates of the site visit. The time needed to conduct an on-site visit varies. A two-person team typically will require a minimum of 2 to 3 days.

5.3.2 Assessors' Duties. The assessors shall perform the following activities:

a. Begin the visit by meeting with the management and the supervisory personnel responsible for the radiobioassay activities for which accreditation is being sought. The assessors acquaint management with the assessment process and set the agenda for the visit.

b. Evaluate whether the radiobioassay laboratory is following the documented quality assurance program.

c. Select and trace the history of a performance test sample from when it was received by the service laboratory until the time the test results were reported (normally for indirect radiobioassay only).

d. Review the performance testing results.

e. Examine records of the selected test samples.

f. Check sample or worker result identification and tracking procedures.

g. Determine if the samples are maintained in the appropriate environmental conditions.

h. Evaluate programmatic documentation such as procedures and management plans.

i. Conduct a close-out meeting with management and supervisory personnel to explain their findings and to clarify the contractor's responsibilities.

j. Leave a completed copy of their signed report with the service laboratory's authorized representative.

k. Completes the checklist.

l. Conduct monitoring visits between assessments as requested by the Performance Evaluation Program Administrator.

5.3.3 Findings. There are three categories of finding as described in the DOELAP Administrative Technical Standard (DOE-STD-1111-98):

Observation. This is either a suggested improvement that a radiobioasay program may incorporate at its own discretion or the highlighting of a noteworthy practice. The suggestion is offered to help "fine tune" a program. No written response is required.

Concern. This is for any aspect of a program that is considered marginal with respect to compliance with DOELAP criteria. One or more concerns will not affect a program's accreditation; however, any concern not remediated by a program's next accreditation cycle will automatically be elevated to a deficiency thereby preventing the renewal of accreditation. A remedial action plan is required.

Deficiency. This is reserved for any aspect of a radiobioassay program that an assessment team believes prevents the program from functioning competently. A deficiency will either suspend or revoke a current accreditation or suspend a new application for accreditation until the deficiency has been remediated. A remedial action plan is required. Remediation may be confirmed by an assessment team.

5.4 Quality Assurance Program

The key to a properly functioning organization is an ongoing quality assurance (QA) program. A QA program is an organization's internal system of procedures and practices to ensure the quality of

its radiobioassay services. A QA manual or QA plan shall document this program. The QA manual or plan shall be sent to the PEPA prior to the on-site assessment in order to verify that it meets the criteria of Appendix A. To qualify for accreditation, a contractor shall demonstrate during the on-site assessment adherence to the written QA program or plan. The applicable components of DOE Order 5700.6C should be included in the laboratory's QA Plan. The assessment criteria for the QA program are contained in Appendix A.

5.5 Documentation

The DOE Contractor and service laboratory shall have thorough, up-to-date documentation describing all applicable procedures and data recording methods. Written descriptions should cover, as a minimum:

a. Personnel
    1. organizational chart
    2. job/position description meeting the qualifications of the personnel
    3. procedures for training of personnel
    4. methods to assure personnel competency

b. Equipment
    1. A description of the measurement systems for which accreditation is requested
    2. practices for measurement equipment calibration and maintenance
    3. Counting protocol for measurement systems, including instructions for performing system performance checks
    4. protocols for ensuring system stability, including operating limits and failure criteria

c. Calibration
    1. calibration data, techniques, and procedures, including source traceability
    2. records of system calibration, frequency of calibrations, and verification of calibrations

d. Measurement Protocols
    1. operating procedures for routine measurement protocols
    2. documentation of non-standard results or special evaluation performance

e. Reporting
    1. data handling, storage, retrieval, and reporting
    2. actions to be implemented when measurement systems fail to meet the specified criteria.

5.6 Technical Adequacy

The DOE Contractor and service laboratory shall demonstrate technical adequacy of its staff, including adequate academic qualifications and specific operator training. The service laboratory shall also provide adequate equipment, facilities, maintenance procedures, and training.

5.6.1 Personnel Training. The service laboratory shall ensure that each new staff member is trained for the measurement systems and the specific analyses he or she is assigned to perform. On-the-job training and safety training should be accomplished and documented annually. In addition, all staff members should be retrained when measurement equipment or procedures are changed or when the staff members are assigned new or increased responsibilities. Each staff member shall receive or have received training for the assigned duties through on-the-job training, formal classroom sessions, or a technician certification program. This training should be documented in personnel files.

5.6.2 Personnel Competency. The individual(s) who has management and technical responsibilities for a radiobioassay program shall exhibit adequate technical knowledge and competent managerial control. This individual shall have the technical competence to understand all radiobioassay protocols.

5.6.2.1 The manager of the radiobioassay QA program may be the manager of the radiobioassay program or another assigned individual. This person shall demonstrate adequate knowledge and experience in quality assurance/quality control measures. He/she should communicate directly to the technical director and other organizational managers. If an individual other than the radiobioassay manager has responsibility for the QA program, that work assignment should be described in the organization description. There should be adequate trained staff members to provide program continuity.

5.6.2.2 In addition to providing for staff training, the manager should evaluate the competence of each staff member authorized to perform direct and indirect radiobioassay evaluations, preferably on an annual basis. These staff evaluations should be available for review if necessary by the DOELAP assessment team.

5.6.3 Facilities and Equipment. The service laboratory shall have facilities and equipment adequate to perform the types of service for which it requests accreditation. Facility services, alternating current (AC) power, and environmental controls shall be adequate for the measurement systems. These facilities should also be located such that background fluctuations are minimized from work operations around the facility. Adequate backup equipment or systems for key measurement systems should be available for use in case the primary systems fail. Backup systems can either include alternate electronics and instrumentation or an ability to arrange for the services of another DOELAP accredited radiobioassay service laboratory on an emergency basis.

5.6.4 Equipment Maintenance and Calibration. The laboratory shall maintain a preventive maintenance program for equipment used in measurement systems or quality control checks. When equipment used for measurements or quality control is subject to change due to use or the passage of time, it shall be calibrated periodically. Calibration is performed by measurements with a certified source, a derived source traceable to the National Institute of Standards and Technology (NIST) or with a Transfer Reference Standard (TRS). For direct radiobioassay, recalibrations shall be performed with the appropriate calibration and source geometries or with derived source calibration phantoms, however calibration checks of instrument performance can be performed without using DOELAP phantom geometries.

5.6.4.1 The proper performance of the measurement system shall be verified periodically with appropriate calibration standards. Either the contractor or an external calibration service may calibrate equipment or the measurement system. All calibrations and characterizations shall be performed using certified NIST-traceable sources, derived NIST-traceable sources, or to standards maintained by an equivalent foreign national standards authority when available. The terms used in this technical standard for traceability conform to the American National Standard ANSI N42.22-1995 *Traceability of Radioactive Sources to the National Institute of Standards and Technology (NIST) and Associated Instrument Quality Control.*

5.6.4.2 The calibration standards and any influencing environmental conditions shall be documented for all calibrations. Calibration records shall be made available for inspection during the assessors' on-site visit. The traceability of the reference standards used shall be verified during the inspection.

5.6.5 Record Keeping. The service facility shall maintain functional records on direct and indirect radiobioassay analyses. The records should be easily accessible, in logical order, and complete. Records covering the following items shall be required and are reviewed during the on-site visit:

a. staff training dates and results;
b. measurement equipment calibration and maintenance;
c. system minimum detectable activities (MDAs), sample decision levels (L_c), probabilities of Type I and Type II errors used for MDA and L_c calculations, and the data and equations used to calculate the MDA and L_c;
d. results of internal and external equipment checks, measurement QA programs, audits, etc.;
e. performance test data and reports; and
f. tracking and logging systems for indirect radiobioassay samples.

5.6.5.1 Measurement equipment calibration (or verification) records should include the following: equipment name or description; model, style, or serial number; manufacturer; notation of all equipment variables requiring calibration or verification; the range of calibration/verification; the resolution of the instrument and its allowable error; the calibration frequency; the date and result of last calibration; the identity of the laboratory individual(s) or external service responsible for calibration; and sources of the reference standards and traceability thereof.

5.6.5.2 Tracking and logging records should trace the movement of each indirect radiobioassay sample through the service laboratory from its receipt through all the analyses performed to the final report.

5.6.5.3 The measurement report the service laboratory develops for the permanent record should include or reference the location of the following information:

a. Direct Radiobioassay Information
    1. subject identification
    2. date, time, and reason for analysis

3. identification of radionuclides for which the subject was analyzed and other radionuclides detected
4. type of measurement--lung, whole body, thyroid, etc.
5 quantification of the amount of radionuclides (whether positive, negative, or zero) of each radionuclide measured in each part of the body counted
6. estimates of counting uncertainty and the total propagated uncertainty (includes counting and other random and/or systematic uncertainties) at the 1-sigma (1s) confidence level
7. value of the L_c and MDA, in the same units as results, and the expected Type I and Type II errors
8. the net count rate and standard error for measurements made for the purposes of screening only, and not for a quantitative measurement
9. the value of the customer-specified or service laboratory action level for prompt notification (this may be documented elsewhere and need not appear in the report)
10. the signature of the person responsible for the report or his/her designee.

b. Indirect Radiobioassay Information

1. sample identification
2. assigned number
3. total volume or weight of sample submitted
4. reference dates and times of sample collection and analysis
5. identification of radionuclides for which the sample was analyzed and other nuclides detected
6. quantification of radionuclides using the appropriate blank values, whether positive, negative, or zero
7. estimates of counting uncertainty and the total propagated uncertainty (includes counting, other random, and systematic uncertainties) at one sigma (1 s) level
8. identification of specific measurement procedures
9. value of the L_c and MDA, in the same units as results, and the expected Type I and Type II errors
10. the value of the customer-specified or service laboratory action level for prompt notification (this may be documented in the QA plan and need not appear in the report)
11. the signature of the person responsible for the report or his/her designee.

5.6.6 Close-Out Meeting. At the conclusion of the visit, the assessors will discuss their observations with appropriate members of management and identify any findings. A written summary of any deficiencies or concerns discussed is left with the DOE Contractor and/or service laboratory's authorized representative. The assessors forward the assessment forms and the written summary to the DOELAP Performance Evaluation Program Administrator for use in the technical evaluation.

5.6.7 Monitoring Visits. In addition to regularly scheduled on-site assessments, assessors may be assigned to make monitoring visits at any time during the 3-year accreditation period. Monitoring visits may occur for cause or on a random basis. These visits may serve to verify reported changes in the service laboratory's operations. The visits may also explore possible reasons for poor performance in proficiency testing. The scope of a monitoring visit may range from checking a few designated items to making a complete review.

5.7 Granting Accreditation

When the technical evaluation and the performance testing have been completed for the initial DOELAP accreditation or for re-accreditation at the end of the triennial re-assessment, the Performance Evaluation Program Administrator prepares an administrative report and recommendation for the Oversight Board. The Board evaluates the report and recommendation and proposes one of two options:

a. Accreditation - The HQ DOELAP Administrator completes the accreditation process by issuing a certificate and conditions of accreditation to the DOE Contractor. This certificate is current for three years. Partial accreditation may be given (see 5.7.1 below).

b. Remedial Action Required - The service laboratory is notified that remedial action is required and is given reasons for the remedial action. The service laboratory shall identify and implement a remedial action plan within 45 days of receiving the notification. This plan is sent to the HQ DOELAP Administrator through the DOE field office with a copy to the Performance Evaluation Program Administrator. A service laboratory may request an Appeals Board review (DOE-STD-1111-98).

5.7.1 Partial Accreditation. The service laboratory may be partially accredited if it has demonstrated satisfactory performance in a particular matrix and/or analyte of the DOELAP categories, and does not demonstrate program deficiencies that may affect the entire laboratory capability. If a service laboratory has not satisfactorily demonstrated compliance with the test criteria in a particular matrix and/or analyte, and if a remedial action plan is initiated, the accreditation process may continue in all other categories.

5.7.2 Changes in Systems or Procedures. The service laboratory shall inform the Performance Evaluation Program Administrator prior to implementing changes in counting systems or analytical procedures that could affect the system performance with respect to meeting DOELAP criteria or evaluations. The service laboratory shall provide evidence supporting a conclusion that the proposed changes are technically equivalent to the accredited system or procedure. The Performance Evaluation Program Administrator, with the Oversight Board's approval, shall make a determination of technical equivalence. If the determination is that the proposed changes are not technically equivalent, implementation of the proposed changes by the service laboratory will void accreditation.

5.7.3 Changes in Accredited Services. The service laboratory shall inform the Performance Evaluation Program Administrator of proposed changes in performance specifications for accredited services (e.g., changes in analytes or detection levels). The service laboratory shall also evaluate their proposed changes in service, and provide written justification either that the existing accreditation is adequate or that additional accreditation testing is required. The Performance Evaluation Program Administrator shall recommend approval or disapproval of the accreditation change request. The recommendation, with the justification, shall be forwarded to the Oversight Board for action. If the Oversight Board rules that the current accreditation does not cover the change in radiobioassay service, the facility may: a) apply to accredit the current system for the new radiobioassay service, b) apply to accredit a new or modified system for the new radiobioassay service, c) obtain the new radiobioassay services from a radiobioassay service laboratory currently accredited for that service, or d) request that the Appeals Board review the decision of the Oversight Board.

5.8 Remedial Action Plan

If a service laboratory does not pass the criteria for all the analytes for which it has applied in a given matrix, but does pass the criteria for some analytes, the service laboratory (in conjunction with the DOE Contractor if a commercial laboratory) shall prepare a remedial action plan to implement immediately. The plan is sent through the DOE field office to the HQ DOELAP Administrator with a copy to the Performance Evaluation Program Administrator. When more than one procedure or counting system is used to meet the special needs at a facility, it is possible for a procedure or counting system to receive final accreditation while other procedures or counting systems require a remedial action plan. If the service laboratory has demonstrated satisfactory performance in a radiobioassay matrix or category for a particular analyte, and if the remedial action plan is initiated, the accreditation process may continue for those analytes. Approval of partial accreditation shall only be granted with the successful completion of the on-site assessment, the approval of the Oversight Board, and the concurrence of the HQ DOELAP Administrator.

The DOE Contractor or service laboratory shall submit a written plan for resolving identified concerns and deficiencies to the cognizant field office for approval within 30 days of receipt of the assessment report. The approved plan shall be forwarded by the field office to the Performance Evaluation Program Administrator, with a copy to the HQ DOELAP Administrator, within 45 days of receipt of the assessment report.

Deficiencies identified during the initial site assessment may require some time to correct. These corrections shall be complete before accreditation is granted. Deficiencies noted during subsequent triennial site assessments of an accredited service laboratory should be corrected within 90 days of the close-out meeting. When an out-of-calibration apparatus is cited, the apparatus shall not be used for DOELAP accredited work until corrective action has been completed.

The contractor or field office may appeal an assessment finding to the DOELAP Appeals Board at any point in the accreditation process (DOE-STD-1111-98).

Appendix A: Checklist of Criteria for On-site Assessment of Radiobioassay Laboratories

The checklist included in this appendix contains assessment criteria that the on-site assessment team can use to perform an adequate evaluation of the radiobioassay laboratory. Some criteria may not apply to all laboratories, and direct and indirect radiobioassay equipment and procedures may not be comparable with every criterion in this appendix. This list does not constitute a limitation of the scope of the assessment, and the assessor team may use latitude in the application of these criteria as the conditions at each facility may dictate. To help each DOE Contractor receive a fair assessment, the assessors are provided with this list of criteria covering the main aspects of an adequate program.

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CHECKLIST FOR DOELAP SERVICE LABORATORY INDEPENDENT ASSESSMENTS

RADIOBIOASSAY LABORATORY:	
GENERAL	Accept
1. Documented, signed, approved, and controlled procedures are established for each step in the activities used to determine radioactivity concentrations or total radioactivity results for indirect radiobioassay and direct radiobioassay measurements. The procedures include: • Sample preparation and radiochemical analyses, • Data reduction, and • Data reporting.	
2. The facility/program implements an appropriate, documented QC program.	
3. The facility/program has designated a person responsible for reviewing QC data.	
4. Responsibility for review of all direct and indirect radiobioassay data rests with the individual who has technical responsibility for the program.	
PERSONNEL	Accept
1. The functional organization is consistent with the current organizational chart for the radiobioassay laboratory.	
2. The qualifications of the individual who has technical responsibility for the radiobioassay program is consistent with the position description.	
3. The individual who has technical responsibility exhibits adequate technical knowledge and management control for the program.	
4. The responsibility for maintaining and revising the QA manual or QA Plan is clearly assigned.	
5. The qualifications of the individual who has responsibility for the radiobioassay QA Program are consistent with the position description.	
6. Assigned responsibilities for the technical areas addressed in the training program are appropriate for the assigned positions..	
7. All radiobioassay program staff are familiar with and can implement the documented QC program.	
8. The responsibility for major equipment maintenance and measurement system calibrations is clearly assigned.	
9. Specialized skills required to conduct all protocols are documented annually and are included in the training program for individuals who conduct the protocols. The training includes: • a period of close supervision until competency is demonstrated, • a mechanism for evaluating and informing staff members of the adequacy of their performance in conducting assigned protocols, and • a mechanism for retraining on a periodic basis and for correcting any deficiencies in performance between retraining.	
10. Staff have adequate training and experience with the measurement systems and specific analyses they are assigned to perform.	
11. A record of training courses completed by each staff member is available for review.	
12. A record of the dates and findings of competency reviews is available for review under program management supervision.	

CHECKLIST FOR DOELAP SERVICE LABORATORY INDEPENDENT ASSESSMENTS

EQUIPMENT AND FACILITIES	Accept
1. A list and description of the facilities and measuring equipment used in all the systems and protocols for which accreditation is requested is available in the facility. The list allows measurement systems with maintenance logs to be correlated with calibration records.	
2. Procedures are established for replacing or bringing spare equipment into routine service, repairing equipment on a rapid-response basis and/or using the services of another DOELAP-accredited laboratory to ensure continuity of service when systems or personnel fail to perform as required.	
3. Adequate procedures and/or quality controls are in place to ensure the performance of measurement equipment to the levels of precision and accuracy defined by the laboratory for each measurement protocol. The procedures to be implemented when the equipment fails to meet these criteria are documented.	
4. To help in evaluating the stability of equipment performance, records of preventive maintenance and repair activities are available for each piece of critical measurement equipment.	
5. Continuity of equipment operation is adequately provided for through service contracts or through an in-house capability to maintain equipment and stock parts.	
6. Relevant environmental parameters in the counting facility, such as counting room background measurements, are measured and recorded.	
7. The calibration of equipment is verified at regular intervals determined by equipment type, manufacturing specifications, accumulated stability data, or some other reasonable plan to demonstrate the reliability of the measurements performed by the processor.	
CALIBRATION	Accept
1. Calibration and verification practices for measurement equipment or systems are described in a procedure(s). The procedure(s) identifies the calibration services, reference materials, calibration intervals, and measurement assurance programs used.	
2. Calibration and verification records for major equipment used in radiobioassay analyses include the following: • equipment name or description ____ • manufacturers name ____ • model, style, serial number, or other identifying mark ____ • identification of all equipment variables requiring calibration or verification ____ • range of energy and nuclides (or concentrations) used for calibration ____ • allowable error (taking into consideration instrument tolerance) to coincide with the requirements of each protocol ____ • date and result of last calibration/verification, including assessed uncertainty of measurement ____ • identification of staff member or position responsible for equipment calibration, or of external service performing calibrations ____ • identity of reference standard and how the individual radiobioassay calibration data relate to national standards or nationally accepted measurement systems ____	
3. Radionuclide standards or calibration phantoms used for equipment calibrations and to test the accuracy of analytical procedures and/or measurement equipment are designated as Standard Reference Material (SRM) by NIST, Transfer Reference Standards (TRS), or standards directly compared with an appropriate SRM. Care is taken to maintain a standard source geometry.	
4. Calibration procedures used are appropriate for the radionuclides of interest.	
5. Calibrations of *direct radiobioassay* measurement systems are performed with known sources of radionuclides incorporated in a suitable simulation of the body or the body part of interest, or with techniques that are technically equivalent. These calibration phantoms should have radioactivity incorporated uniformly throughout the organ of interest or the simulated body. Calibration phantoms should be anthropomorphic representations of appropriate geometries of the body whenever feasible.	
6. For each measurement system, a calibration is performed for the specific geometry and radionuclide or energy range for which accreditation is requested.	
7. The Laboratory strives to maintain system performance (check source measurements) within the range of ±10% at the 95% Confidence Level (1.96 s) of the established value for the check source.	

CHECKLIST FOR DOELAP SERVICE LABORATORY INDEPENDENT ASSESSMENTS

QUALITY ASSURANCE	Accept
1. A documented, approved quality assurance (QA) plan is in place, and addresses the following aspects of quality assurance: • organizational structure, management and operational responsibilities • instructions and procedures, including procedure validation • qualification and training of laboratory personnel • document control • procurement of materials • identification and control of material and samples (chain of custody) • inspection and testing of material and equipment • control and maintenance of calibration standards • corrective actions • review of procedures, specifications, and operating logs • observation of operations and evaluation of quality control data • quality assurance records • documentation of detector capabilities, detector background checks, relative bias, relative precision, and methods of calculating results for periodic quality control determinations • records management including any deviation from the use of established procedures, equipment, or facilities • verification, validation, and documentation of computer software used for calculations • documentation of specific customer requirements.	 ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____
2. Internal QA assessments on the use of written procedures are performed at least annually.	
3. Procedures are reviewed at least once every two years.	
4. The QA plan includes practices for ensuring staff competency.	
5. The QA plan describes the training program used to prepare staff to conduct assigned tasks (procedures), and for retraining staff when assignments or procedures are revised.	
6. Equipment used to process biological samples is procured and used in conformance with the QA plan.	
7. Results of the laboratory's participation in intercomparison programs or internal measurement assurance programs are consistent with requirements defined in the QA plan.	
8. Open lines of communication are maintained between technical and supervisory staff.	
9. Quality control protocols for measurement systems are in place and include: • use of traceable radionuclide reference standards • performance checks of measurement systems • instrument calibration • intra laboratory analyses (e.g., known quantities, replicates, and blanks) • participation in available inter-laboratory intercomparison comparison programs • computational checks • review of procedures, specifications, and operating logs • observation of operations and evaluation of quality control data • evaluating conformance to the performance criteria of ANSI N13.30 • evaluating conformance with internal performance criteria set by the QA plan • evaluating quality control data to ensure the long-term consistency of analytical results • verification of Lc, MDA, and/or MDC determinations • background counts • blind samples • measurement equipment controls such as humidity, cooling, and power fluctuation, if necessary.	 ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____
10. Laboratory staff are familiar with and implement the documented quality control program.	
11. An authorized laboratory staff member examines all daily QC results on a periodic basis, and takes timely action to correct any deficiencies before samples and sample residuals are discarded and results are reported.	
12. Quality control results are summarized on a quarterly basis.	

CHECKLIST FOR DOELAP SERVICE LABORATORY INDEPENDENT ASSESSMENTS

13. Documented, signed, approved, and controlled procedures are established for each step in the activities used to determine radioactivity concentrations or total radioactivity results for indirect and direct radiobioassay measurements. The procedures include: • Sample preparation and radiochemical analyses • Data reduction • Data reporting.	
14. The facility participates in a recognized, documented QC program.	
15. The facility has designated a person responsible for reviewing QC data.	
DIRECT RADIOBIOASSAY CRITERIA	Accept
1. The bias and precision criteria of the DOE Technical Standard and the customer's Minimum Detectable Amount (MDA) requirements are met by the *Direct radiobioassay* measurement systems (detectors, electronics support, and shielding). The Lc and MDA are calculated by techniques as described in the DOE Technical Standard and the draft ANSI N13.30 standard (ANSI 1996)	
2. Personnel shower facilities are in close proximity to the direct radiobioassay laboratory.	
3. Measurement chambers are designed to mitigate claustrophobia (may include two-way communications, remote viewing, fail-safe doors, etc.).	
4. Measurement chambers have adequate ventilation. (The use of O_2 monitors is recommended)	
5. Contamination-free clothing is used or available while the subject is counted.	
6. The laboratory is located at an appropriate distance from areas where radioactive materials are processed, stored, or transported.	
7. Periodic evaluations of chamber background measurements and Minimum Detectable Amounts (MDAs) are made.	
8. Prior to the initial radiobioassay, an orientation briefing on the measurement process are explained to the subject.	
9. The laboratory staff recognize the potential for external contamination and are able to describe appropriate investigative techniques to confirm the type of the contamination (i.e., internal or external).	
10. The direct radiobioassay program is designed to minimize measurement uncertainties and biases.	
11. An estimate of the total propagated uncertainties for the important radionuclides at the facility has been generated and documented.	
12. Direct radiobioassay spectra and associated data are retained in a retrievable format.	
INDIRECT RADIOBIOASSAY CRITERIA	Accept
1. Practices for receiving, handling, and storing samples are consistent with provisions in the QA plan.	
2. A system is in use for identifying and tracking all samples within the laboratory.	
3. Sufficient information is included with the samples to analyze and track the sample.	
4. The number of quality control samples is at least 5 percent of the total number of samples analyzed.	
5. Specific procedures to analyze biological samples from human subjects for assessment of excretion rates are validated and documented before being used.	
6. The laboratory uses appropriate techniques to ensure proper identification and quantification of specific radionuclide(s), and are capable of separating interferences or resolving a mixture of radionuclides.	
7. The laboratory determines analytical results and propagated standard errors in appropriate units. The results include appropriate volume, recovery, and decay correction. The standard error of each result is calculated and includes propagation of the estimated measurement uncertainties (e.g., calibration counting, measurement of volume or weight, losses from chemical separations, transfer, operations, and impurities).	

CHECKLIST FOR DOELAP SERVICE LABORATORY INDEPENDENT ASSESSMENTS

REPORTS	Accept
1. The **direct** radiobioassay report includes the following items:	
• subject identification	____
• date, time, and nature of examination	____
• identification of radionuclide(s) for which the subject was analyzed and other radionuclides detected	____
• identification of specific measurement procedures	____
• quantification of the amount of radionuclide(s) (whether positive, negative or zero) of each radionuclide measured in each part of the body counted	____
• estimates of counting uncertainty and, if possible, the total propagated, uncertainty (which includes counting and other random and systematic uncertainties at one sigma)	____
• value of the Lc and *a priori* MDA, in units consistent with the results	____
• the net count rate and standard error for measurements made for the purposes of screening only, and not for a quantitative measurement	____
• the value of the customer specified or service laboratory action level for prompt notification (this may be documented in the QA plan and not appear in the report)	____
• the make and model (or other unique identifier) of equipment used	____
• the identification of the person responsible for the report.	____
2. The **indirect** radiobioassay report includes the following items:	
• sample identification, including:	____
1) assigned number	
2) total volume or mass of sample submitted	
3) reference date(s), and time(s) of sample collection and analysis	
4) identification of radionuclide(s) for which the sample was analyzed and other radionuclides detected	
5) kind of sample (urine, feces, etc.)	
• quantification of the amount of radionuclide(s) in the sample using the appropriate blank values, of radionuclide(s), whether positive, negative, or zero	____
• estimates of counting uncertainty and the total propagated uncertainty (which includes counting, other random and systematic uncertainties) at one sigma	____
• identification of specific measurement procedures	____
• value of the Lc and *a priori* MDA in units consistent with the results	____
• the value of the customer specified or service laboratory action level for prompt notification (this may be documented in the QA plan and not appear in the report), and	____
• make and model (or other unique identifier) of equipment used	____
• the identification of the person responsible for the report.	____

RECORD RETENTION	Accept
1. The service laboratory retains, in retrievable form, records required by ANSI N13.30 for a minimum of 3 years or for a longer period of time as specified by federal, state, local, or contractual requirements. These records include:	
• results of all quality control performance checks	____
• results of quality assurance audits	____
• radiobioassay equipment calibrations	____
• procedures by which the measurements were made, (Direct) including generic methods and examples of calculations (or Indirect) calculations and generic examples	____
• all data used in the determination of the (Direct) person's (Indirect) sample results, including measurement spectra	____
• training received	____
• reported results (specified above in REPORTS, Direct and Indirect, as appropriate).	____

Those DOELAP participants who obtain analysis of radiobioassay samples under contract with commercial agents, are subject to all the items in the assessment checklist that pertain to routine quality assurance and quality control. The following additional items also apply to those participants.

ADDITIONAL CHECKLIST FOR DOELAP PARTICIPANTS USING RADIOBIOASSAY SERVICES UNDER CONTRACT

DOELAP PARTICIPANT:	
RADIOBIOASSAY PROVIDER:	
GENERAL	Accept
1. The contract between the radiobioassay servicing laboratory and DOELAP participant clearly establishes:: • The methods of sample preparation and radiochemical analyses • Data reduction techniques • Results of intercomparison studies • Criteria for reporting data.	
2. The DOELAP participant establishes documented, signed, approved and controlled procedures for each step in the collection of samples for indirect radiobioassay, shipment of samples for analysis and dissemination of results.	
CALIBRATION	Accept
1. Calibration and verification practices employed by the radiobioassay servicing laboratory are understood and documented by the DOELAP participant.	
QUALITY ASSURANCE	Accept
1. The radiobioassay servicing laboratory provides the DOELAP participant with sufficient QC and calibration data to assure that analytical results are accurate and samples were analyzed within the established envelope of quality.	
2. The DOELAP participant demonstrates sufficient understanding of the provided services to identify and resolve anomalous analysis results.	
3. The DOELAP participant conducts audits at least on an annual basis of the radiobioassay provider to assure that the servicing laboratory maintains established levels of quality and adheres to criteria in the servicing contract.	
4. The DOELAP participant maintains a blind audit program for providers of indirect radiobioassay services.	

APPENDIX B

SUPPORTING DOCUMENTS

Radiological Environmental Sciences Laboratory (RESL). 1992. *Performance Testing Procedure for In Vitro Radiobioassay Pilot Test Sessions, December 23, 1992, Rev. 1*. Laboratory Quality Branch Technical Procedure, LQB-TP-4.16, RESL, Idaho Falls, Idaho.

Radiological Environmental Sciences Laboratory (RESL). 1992. *Performance Testing Procedure for In Vitro Radiobioassay Pilot Test Sessions, October 30, 1992*. Laboratory Quality Branch Technical Procedure, LQB-TP-4.17, RESL, Idaho Falls, Idaho.

Pacific Northwest Laboratory (PNL). 1986. *Performance Testing of Radiobioassay Laboratories: In-Vivo Measurements,* Pilot Study Report. PNL-5840, Health Physics Department, PNL, Richland, Washington.

Pacific Northwest Laboratory (PNL). 1988. *Performance Testing of Radiobioassay Laboratories: In Vitro Measurements (Urinalysis),* Final Report, PNL-6490, PNL, Richland, Washington.

Pacific Northwest Laboratory (PNL). 1990. *Performance Testing of Radiobioassay Laboratories: In Vivo Measurements*, Final Report. PNL-7307, PNL, Richland, Washington.

Pacific Northwest Laboratory (PNL). 1988. *Recommended Procedures for Performance Testing of Radiobioassay Laboratories Volume 1: Quality Assurance,* PNL-6067, Vol. 1, PNL, Richland, Washington.

Pacific Northwest Laboratory (PNL). 1988. *Recommended Procedures for Performance Testing of Radiobioassay Laboratories Volume 2: In Vitro Samples*, PNL-6067, Vol. 2, PNL, Richland, Washington.

Pacific Northwest Laboratory (PNL). 1988. *Recommended Procedures for Performance Testing of Radiobioassay Laboratories Volume 3: In Vivo Test Phantoms*, PNL-6067, Vol. 3, PNL, Richland, Washington.

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ATTACHMENT A

DEPARTMENT OF ENERGY
APPLICATION FOR ACCREDITATION
FOR INDIRECT RADIOBIOASSAY

1. DOE site or facility:_____

2. DOE Operations/Field Office:_____

3. Other DOE facilities using your laboratory for radiobioassay:

   _____

   _____

   _____

4. Contractor laboratory identification, if outside service is used:

   _____

5. Name of authorized representative for Indirect Radiobioassay DOELAP accreditation:

   Name: _____
   Title: _____
   Department: _____
   Contractor: _____
   Address : _____
   City: _____ State:_____ Zip:_____
   Telephone: _____ Fax:_____
   e-mail: _____

   Backup Contact: _____
   Telephone: _____ e-mail: _____

6. Shipping Address: _____

   _____

   _____

   _____

   Attn:_____ Telephone:_____

7. List all measurement protocols and/or systems, by name, for which accreditation is sought and place an (x) in the box next to the appropriate category (see Table II and ANSI N13.30 for an explanation of each category).

		Indirect Radiobioassay		
Measurement Category		Test Nuclide	Fecal	Urine
I.	BETA activity:	Category Accreditation	[ ]	[ ]
	Avg. Energy <100 keV	Hydrogen-3	[ ]	[ ]
		Carbon-14	[ ]	[ ]
		Sulfur-35	[ ]	[ ]
		Radium-228	[ ]	[ ]
II.	BETA activity:	Category Accreditation	[ ]	[ ]
	Avg. Energy$100 keV	Phosphorus-32	[ ]	[ ]
		Strontium-89/-90	[ ]	[ ]
		or Strontium-90	[ ]	[ ]
III.	ALPHA activity isotopic analysis	Category Accreditation	[ ]	[ ]
		Thorium-228/-230	[ ]	[ ]
		or Thorium-232	[ ]	[ ]
		Uranium-234/-235	[ ]	[ ]
		or Uranium-238	[ ]	[ ]
		Neptunium-237	[ ]	[ ]
		Plutonium-238	[ ]	[ ]
		or Plutonium-239/240	[ ]	[ ]
		Americium-241	[ ]	[ ]
IV.	Elements (mass/volume)	Uranium		[ ]
V.	GAMMA (photon) activity	Category Accreditation	[ ]	[ ]
		Cesium-137	[ ]	[ ]
		Cobalt-60	[ ]	[ ]
		Iodine-125	[ ]	[ ]

8. For each measurement protocol and system listed above, summarize important features, describing type of counting system, counting configuration, data reduction, MDA, peak identification (if applicable), and energy calibration.

9. For each service, state whether it is processed in-house, in a commercial laboratory, or in another government facility.

10. Describe the efficiency calibration and routine counting procedures used in the indirect radiobioassay measurement.

11. Submit a QA plan or manual for the radiobioassay program in which accreditation is sought.

By authorizing this application you affirm that you are aware that if accreditation is granted to your organization, the accreditation applies to the indirect radiobioassay services using the specific measurement systems and protocols in the categories requested and using the measurement techniques that were used to demonstrate satisfactory performance in accordance with the ANSI N13.30. You will be expected to use the same system(s) and techniques in the normal measurement(s) you perform.

The contractor or service laboratory has the responsibility to inform the PEPA prior to implementing changes (e.g., in counting systems or analytical procedures) that could affect the system performance. The contractor or service laboratory shall provide evidence supporting a conclusion that the proposed changes are technically equivalent to the accredited system or procedure. The PEPA, with the Oversight Board's approval, shall make a determination of technical equivalence. If the determination is that the proposed changes are not technically equivalent, implementation of the proposed changes by the service laboratory will void accreditation.

I hereby authorize this application and attest that all statements made are true, complete, and correct to the best of my knowledge and belief and are made in good faith.

Authorized Representative:

Printed Name: _____

Title: _____

Signature: _____ Date: _____

****

Operations / Field Office Review:

In authorizing this application you declare that you commit the DOE Contractor to:

- Be examined and audited, initially and on a continuing basis during the accreditation period.
- Permit the on-site assessors to review and examine records or other documents required by the DOE Technical Standard.
- Participate in proficiency testing programs that will be required for maintaining accreditation.

Authorized Operations / Field Office Representative:

Printed Name: _____

Title: _____

Signature: _____ Date: _____

Telephone: _____ e-mail: _____

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ATTACHMENT B

DEPARTMENT OF ENERGY
APPLICATION FOR ACCREDITATION
FOR DIRECT RADIOBIOASSAY

1. DOE site or facility: _____

2. DOE Operations/Field Office: _____

3. Other DOE facilities using your laboratory for radiobioassay:

   _____

   _____

   _____

4. Contractor laboratory identification, if outside service is used:

   _____

5. Name of authorized representative for Direct Radiobioassay DOELAP accreditation:

   Name: _____
   Title: _____
   Department: _____
   Contractor: _____
   Address : _____
   City: _____ State: _____ Zip: _____
   Telephone: _____ Fax: _____
   e-mail: _____

   Backup Contact: _____
   Telephone: _____ e-mail: _____

6. Shipping Address: _____

   _____

   _____

   _____

   Attn: _____ Telephone: _____

7. List all systems by name and model number, for which accreditation is sought and place an (x) in the box next to the appropriate category (see Table I and ANSI N13.30 for explanation of each category).

Measurement Category	Direct Radiobioassay	
I. Transuranium elements via L x-ray in **Lungs**		[ ]
II. Americium-241 in **Lungs**		[ ]
III. Thorium-234 in **Lungs**		[ ]
IV. Uranium-235 in **Lungs**		[ ]
V. Fission and activation products in **Lungs**	Category Accreditation	[ ]
	Manganese-54	[ ]
	Cobalt-58	[ ]
	Cobalt-60	[ ]
	Cerium-144	[ ]
VI. Fission and activation products (Cesium-134 & Cesium-137) in **Total body**		[ ]
VII. Radionuclides in the **Thyroid**	Category Accreditation	[ ]
	Iodine-125	[ ]
	Iodine-131	[ ]

8. For each measurement protocol and system listed above, summarize important features, describing shielding, type of counting system, counting configuration, data reduction, MDA, peak identification (if applicable), and energy calibration.

9. For each service, state whether it is processed in-house, in a commercial laboratory, or in another government facility or laboratory.

10. Describe the efficiency calibration and routine counting procedures used in the direct radiobioassay measurement. Indicate protocols that may differ for different categories.

11. Submit a QA plan or manual for the radiobioassay program in which accreditation is sought.

By authorizing this application you affirm that you are aware that if accreditation is granted to your organization, the accreditation applies to the indirect radiobioassay services using the specific measurement systems and protocols in the categories requested and using the measurement techniques that were used to demonstrate satisfactory performance in accordance with the ANSI N13.30. You will be expected to use the same system(s) and techniques in the normal measurement(s) you perform.

The contractor or service laboratory has the responsibility to inform the PEPA prior to implementing changes (e.g., in counting systems or analytical procedures) that could affect the system performance. The contractor or service laboratory shall provide evidence supporting a conclusion that the proposed changes are technically equivalent to the accredited system or procedure. The PEPA, with the Oversight Board's approval, shall make a determination of technical equivalence. If the determination is that the proposed changes are not technically equivalent, implementation of the proposed changes by the service laboratory will void accreditation.

I hereby authorize this application and attest that all statements made are true, complete, and correct to the best of my knowledge and belief and are made in good faith.

Authorized Representative:

Printed Name: _____

Title: _____

Signature: _____ Date: _____

****

Operations / Field Office Review:

In authorizing this application you declare that you commit the DOE Contractor to:

- Be examined and audited, initially and on a continuing basis during the accreditation period.
- Permit the on-site assessors to review and examine records or other documents required by the DOE Technical Standard.
- Participate in proficiency testing programs that will be required for maintaining accreditation.

Authorized Operations / Field Office Representative:

Printed Name: _____

Title: _____

Signature: _____ Date: _____

Telephone: _____ e-mail: _____

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Concluding Material

Review Activity:

DOE
DP
EH
EM
ER
FM
GC
NE
RW

Operations Offices
AA
AL
AR
CH
FERMI
ID
LAAO
MAO
OAK
OH
OR
RL

Laboratories
ANL
EG&G Mound Applied Technologies
Fermi National Accelerator Laboratory
INEEL
LANL
LLNL
Lockheed Martin Energy Systems
ORNL
Pantex Plant
PNNL

External Agency
DNFSB

Preparing Activity:

DOE-EH-52

Project Number:

SAFT-0049