HPS Laboratory Accreditation Manual

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CRITERIA FOR ACCREDITATION OF CALIBRATION LABORATORIES BY THE HPS

INTRODUCTION

This document provides criteria for the accreditation of instrument and source calibration laboratories by the Health Physics Society (HPS) based on the standard ISO/IEC 17025:2005, "General requirements for the competence of testing and calibration laboratories" and ANSI N42.22-1995, "Traceability of Radioactive Sources to the National Institute of Standards and Technology (NIST) and Associated Instrument Quality Control." Included in the criteria are requirements for the accreditation of source calibration facilities. The first part of the criteria follows the general format of the 17025 standard (sections 4&5); the last part of the standard (the appendices) details specific technical requirements for various categories of calibration and the use of the accredited lab logo.

For convenience the two program areas of the accreditation program are referred to as:

- Accredited Instrument Calibration Laboratories (AICL) – survey instrument calibration laboratories
- Accredited Reference Source Calibration Laboratories (ASCL) – reference source manufacturers and calibration services.

Additional information relevant to participants in the HPS program is contained in:

- The program handbook
- Instructions for preparing a quality manual
- The application for accreditation
- The on-site assessment check list

This HPS document was written to be consistent with the relevant parts of ISO/IEC 17025 and in turn with ISO 9001:2000. Where conflicts arise between requirements in this document and the international standard the requirements in the international standard will prevail. Laboratories seeking accreditation should refer to ISO/IEC 17025 for additional information. The standard ANSI/NCSL Z540-1-1994, Part 1, which is based on the original ISO/IEC Guide 25, has requirements in addition to those in this HPS document. For laboratories wanting to claim compliance with ANSI/NCSL Z540, arrangements can be made at the time of application. Similarly, for laboratories that want to demonstrate capabilities to meet requirements in ANSI N323, arrangements can be made at the time of application.

The document is organized into scope, references, definitions, administrative requirements, technical requirements and appendices with requirements specific to the AICL and ASCL accreditation program areas.

1 SCOPE

This document provides criteria for the accreditation by the Health Physics Society (HPS) of instrument and source calibration laboratories (including source manufacturers). The current areas of accreditation are:

a) Calibration of survey instrumentation for measurements of exposure or air kerma.

b) Calibration of instruments and/or systems for measurements of exposure or air kerma at environmental levels.

c) Calibration of instruments and/or systems for measurements of exposure or air kerma in diagnostic radiology.

d) Calibration of instruments and/or systems for measurements of absorbed dose for beta particles.

e) Calibration of instruments and/or systems for measurements of neutron dose equivalent.

f) Calibration of instruments and/or systems for measurements of emission rate for alpha particle sources.

g) Calibration and/or manufacture of radioactive sources traceable to the National Institute of Standards and Technology (NIST).

There are two levels of laboratories accredited by the HPS for instrument calibration. A Secondary Accredited Laboratory (SAL) provides direct traceability to the National Institute of Standards and Technology (NIST). Tertiary Accredited Laboratories (TAL) derive their standards from a SAL and provide traceability to NIST through the secondary laboratory. Due to the increase in uncertainty from the extra step, the standards used by the TAL should only be used for the calibration of field instruments. Accredited TAL and SAL laboratories are referred to collectively as an Accredited Instrument Calibration Laboratory (AICL). Source calibration laboratories are only accredited as secondary laboratories, provided they can demonstrate direct traceability to NIST.

2 REFERENCES

Citations of references throughout this document refer specifically to the editions listed below.

- American Society for Quality. Guidelines for auditing quality systems. Milwaukee, WI: ASQ Quality Press; ANSI/ISO/ASQ Q10011-1994; 1994.

- International Organization for Standardization. General requirements for the competence of testing and calibration laboratories. Geneva: International Organization for Standardization; ISO/IEC-17025; 2005.

- International Electrotechnical Commission. Medical electrical equipment — dosimeters with ionization chambers as used in radiotherapy. Geneva: International Electrotechnical Commission; IEC 60731; 1997.

- Institute of Electrical and Electronics Engineers. American national standard — radiation protection instrumentation test and calibration, portable survey instruments. New York: Institute of Electrical and Electronics Engineers; ANSI N323A-1997; 1997.

- Institute of Electrical and Electronics Engineers. American national standard — traceability of radioactive sources to the national institute of standards and technology (NIST and associated instrument quality control. New York: Institute of Electrical and Electronics Engineers; ANSI N42.22-1995; 1995.

- International Organization for Standardization. Guide to expression of uncertainty in measurement. Geneva: International Organization for Standardization; 1995.

- International Organization for Standardization. Nuclear energy – Reference beta-particle radiation – Part 2: Calibration fundamentals related to basic quantities characterizing the radiation field. Geneva: International Organization for Standardization; 2004.

- National Conference of Standards Laboratories. US guide to the evaluation of uncertainty in measurement. Boulder, CO: National Conference of Standards Laboratories; ANSI/NCSL Z540-2-1997; 1997.

- National Conference of Standards Laboratories. Calibration Laboratories and Measuring and Test Equipment - General Requirements. Boulder, CO: National Conference of Standards Laboratories; ANSI/NCSL Z540-1-2002; 2002.

- Taylor BN, Kuyatt CE. Guideline for evaluating and expressing the uncertainty of NIST measurement results. Gaithersburg, MD: National Institute of Standards and Technology; NIST Technical Note 1297; 1993.

3 DEFINITIONS

Special word usage:
The word "shall" denotes a requirement and the word "should" denotes a recommendation.

AICL: Accredited Instrument Calibration Laboratory. A laboratory accredited by the Health Physics Society under these CRITERIA for calibration of survey instruments.

ASCL: Accredited Source Calibration Laboratory. A laboratory accredited by the Health Physics Society under these CRITERIA for the preparation and calibration of radioactive sources for reference or calibration purposes.

air kerma: Characterization of the beam of photons in terms of energy transferred per unit mass of air ($K = dE_{tr}/dm$). The special SI unit of air kerma is the Gray (Gy) and is equal to one joule per kilogram.

air kerma rate: The air kerma per unit time.

beam quality: The characteristics of a beam of ionizing radiation that define with acceptable precision the energy, penetration, target material, filtration, variation with time and duration. Examples of quality characteristics are kVp, mA, distance, beam size or area, 1st HVL, 2nd HVL, HC, time and waveform, or combinations as appropriate.

"best" uncertainty: For reporting purposes, the "best" uncertainty is the expanded uncertainty for transfer quality instruments having a coverage factor k = 2 for Co-60, Cs-137 and X-ray beams and includes the uncertainty associated with the NIST calibration of the standard chamber used in the calibration.

calibration: The set of operations that establishes, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measured value.

NOTES:
1. The result of a calibration may be recorded in a document, sometimes called a *calibration certificate* or a *calibration report*.
2. The result of a calibration is sometimes expressed as a calibration factor or as a series of calibration factors in the form of a calibration curve.
3. The result of a calibration permits the estimation of errors of indication of the measuring instrument, measuring system or material measure, or the assignment of values to marks on arbitrary scales.
4. A calibration may also determine other metrological properties.

calibration factor: The ratio of the true value of a quantity as determined by a measurement standard having a documented relation to a national standard and the indication or quantity produced by the measuring instrument being calibrated.

calibration laboratory: Laboratory that performs calibration.

calibration method: Defined technical procedure for performing a calibration.

certified reference material (CRM): A reference material with one or more property values certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation that is issued by a certifying body (ISO Guide 30–2.21).

combined standard uncertainty: Standard uncertainty of the result of a measurement when that result is obtained from the values of a number of other quantities, equal to the positive square root of a sum of terms, the terms being the variances or covariances of these other quantities weighted according to how the measurement result varies with changes in these quantities. (ANSI/NCSL Z540-2-1997, 2.3.4)

coverage factor: Numerical factor used as a multiplier of the combined uncertainty in order to obtain an expanded uncertainty. (ANSI/NCSL Z540-2-1997, 2.3.6)

design control: Design control (ASCL) is the mechanism used to ensure that traceable sources meet design specifications with respect to physical, chemical, and radiochemical characteristics: geometry, quantity, and quality assurance requirements. This is accomplished through adherence to requirements of ISO/IEC 17025.

dosimeter: For the purposes of these CRITERIA, equipment that uses ionization chambers or other radiation detectors for the measurement of air kerma, absorbed dose or exposure and/or their corresponding rates, in photon and electron beams.

dosimetry system: For the purposes of these CRITERIA, a system composed of a dosimeter (ion chamber or other radiation detector) and a readout device such as an electrometer.

expanded uncertainty: Quantity defining the interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could be attributed to the measured value. (ANSI/NCSL Z540-2-1997, 2.3.5)

exposure: The measurement of ionization in air quantified by the unit of charge (dQ) per unit mass of dry air (X = dQ/dm) and is specified in the units of roentgen (R), which is defined as 2.58×10^{-4} coulombs per kilogram. The relation between exposure and air kerma is given by

$$K_{air} = X \bullet (W/e)/(1 - g)$$

where W/e is the mean energy per unit charge expended in air by electrons (33.97 joules/coulomb) and g is the mean fraction of the energy of the secondary electrons that are lost to bremsstrahlung (g = 0 for x rays <= 300 keV, g = 0.0032 for Co-60 and g = 0.0016 for Cs-137).

intercalibration: Comparison of a standard instrument or source between laboratories to determine whether measurements are consistent. Such comparisons may be substituted for proficiency tests on a periodic basis.

influence quantity: A quantity whose value has an influence on the measured value of a quantity being measured by comparison to a standard. For example, temperature and pressure are influence quantities that must be measured during the calibration measurements of dose or air kerma.

laboratory: Body (or portion of an organization) that calibrates and/or tests. As used herein, the term "laboratory" refers to a body that carries out calibration or testing services.

manufacturer: For the purposes of these criteria, any organization that produces and distributes NIST-traceable radioactive sources that are certified with respect to radionuclide activity or a radiation emission rate.

measured value: The stated or recorded value after all appropriate adjustments and corrections, if any, have been incorporated into the observed value. (IEC 60731, 1997, 3.5)

measurand: Specific quantity subject to measurement.

national standard: A STANDARD recognized by an official national decision as the basis for fixing the value in that country of all other STANDARDS of the given quantity. (IEC 60731, 1997, 3.4.1.1)

NIST: The National Institute of Standards and Technology, the agency with legally mandated authority to maintain national physical standards in the United States of America.

proficiency testing: Determination of the laboratory calibration or testing performance by means of a Measurement Quality Assurance (MQA) test.

NOTES:
1. This can involve tests in which the laboratory measures an artifact sent by NIST, tests in which NIST measures an artifact sent by the laboratory, or tests in which an artifact is intercalibrated among accredited labs and NIST. The artifact would be a source in the case of the source calibrators or manufacturers and a reference radiation detector in the case of calibration facilities.
2. In the case of tertiary laboratories the proficiency test is conducted with a secondary laboratory.
3. Proficiency testing may be conducted with other recognized agencies for special applications or timeliness upon concurrence of the Laboratory Accreditation Policy Committee (LAPC) (see appendix K).

protocol: A document containing a complete description of a calibration laboratory's operation including the scope, uncertainty goals, management, personnel, calibration policies, record keeping, facilities and equipment, methods of achieving redundancy in measurements, methods of maintaining traceability, setup and calibration procedures, calibration report and error reporting procedures.

qualified supplier: A supplier of calibration services or reference materials that has been evaluated by the laboratory by interview, survey and/or site visit, and has been determined to have the management system components needed to provide the required services of materials within the required uncertainties.

quality manual: A document stating the quality policy, management system and quality practices of an organization.

NOTE: The quality manual may refer to other documentation relating to the laboratory's quality arrangements. The quality manual is composed of those portions of the laboratory protocol that deal specifically with the policy, management, systems, practices and procedures for quality assurance and quality control.

management system: The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

reference conditions: The standard conditions of pressure (760 mm Hg @ 0ºC, 101.325 kPa), temperature (22ºC) and relative humidity (within the range of 20–75%). Note: mercury barometers may also require gravitational corrections.

reference material: A material or substance with one or more properties that are sufficiently well established to be used for the calibration of an apparatus, for the assessment of a measurement method, or for assigning values to materials. (ISO Guide 30–2.11)

reference standard: A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. (VIM—6.081)

requirement: A translation of the needs into a set of individual quantified or descriptive specifications for the characteristics of an entity in order to enable its realization and examination.

secondary standard laboratory: A laboratory accredited by a recognized authority that has standards for ionizing radiation obtained directly from a national standards laboratory, that participates in a measurement quality assurance program with a national standards laboratory, and that possesses the capability by way of qualified personnel, management system and laboratory facilities to provide the best uncertainty available outside of a national standards laboratory.

standard: An instrument or source that defines, represents physically, maintains or reproduces the unit of measurement of a quantity (or a multiple or sub-multiple of that unit) in order to transfer it to other instruments or sources by comparison. (modified IEC 60731, 1997, 3.4.1)

standard uncertainty: Uncertainty of the result of a measurement expressed as a standard deviation. (ANSI/NCSL Z540-2-1997, 2.3.1)

tertiary laboratory: Laboratory that derives its traceability from a secondary laboratory rather than from direct comparisons with a national laboratory.

test: A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a "test report" or a "test certificate."

test method: Defined technical procedure for performing a test.

traceability: The property of a result of a measurement whereby it can be related within a stated uncertainty to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

transfer quality chamber: An ionization chamber of a high quality and stability suitable to be calibrated to a national or local standard and then used to transfer traceability to other chambers.

transmission monitor: A parallel plate ionization chamber having thin windows on each side and a thin collector to transmit a photon beam without significant alteration or attenuation. The windows and collector of the chamber are large enough or the chamber is positioned close enough to the source of radiation to intercept the entire beam. The transmission monitor is used to monitor the variations in output, field size and filtration when positioned beyond the primary collimator and added filtration.

uncertainty (of measurement): Parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measured value. (ANSI/NCSL Z540-2-1997, 2.2.3)

validation: The confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. (ISO/IEC 17025 5.4.5.1)[1]

verification: Confirmation by examination and provision of evidence that specified requirements have been met.

[1] Throughout the criteria document parenthetical references are made to the appropriate section of the ISO/IEC 17025 standard. This section of the standard generally contains the same or a similar requirement and the numbers may or may not correspond to section numbers in this document.. Where a reference is not included the HPS criteria are generally requirements specific to this program.

NOTES:

1. In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.
2. The result of verification leads to a decision either to restore to service, to perform adjustments, to repair, to downgrade, or to declare obsolete. In all cases it is required that a written trace of the verification performed be kept on the measuring instrument's individual record.

working standard: A local standard that is directly traceable to the national standard (revised IEC 60731, 1997, 3.4.1.2). A working standard is used in a laboratory to calibrate other instruments in order to reduce the wear and tear on, or the possibility of damage to, the laboratory's primary standard.

4 LABORATORY ORGANIZATION AND MANAGEMENT

4.1 ORGANIZATION

The laboratory shall be a legally identifiable organization and shall operate in such a way that its facilities meet the requirements of these CRITERIA. (ISO/IEC 17025 4.1)

4.1.1 The organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts shall be defined in writing. **(**ISO/IEC 17025 4.1.1)

4.1.2 The laboratory shall carry out its calibration activities in such a way as to meet the requirements of these CRITERIA and to satisfy the needs of the customer, the regulatory authorities or the HPS. (ISO/IEC 17025 4.1.2)

4.1.3 The management system shall cover all work carried out in the laboratory's permanent facilities as well as any temporary facilities. (ISO/IEC 17025 4.1.3)

4.1.4 If the laboratory is part of a larger organization, the responsibilities of key personnel shall be defined in order to identify potential conflicts of interest. (ISO/IEC 17025 4.1.4)

NOTES:

1. If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures that might influence their technical judgment. The third-party calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing or calibration activities.
2. If a laboratory is part of a larger organization, the organizational arrangements should be such that departments of conflicting interests do not adversely influence the laboratory's compliance with the requirements of ISO/IEC 17025.

4.1.5 The laboratory shall:

a) have managerial and technical personnel with the authority and resources needed to discharge their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures. They must be able to perform these duties despite their other responsibilities; (ISO/IEC 17025 4.1.5.a)

b) have arrangements to ensure that its personnel are free from any commercial, financial and other pressures that might adversely affect the quality of their work; (ISO/IEC 17025 4.1.5.b)

c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results; (ISO/IEC 17025 4.1.5.c)

d) be organized with appropriate policies and procedures in such a way that confidence in its independence of judgment and integrity is maintained at all times; (ISO/IEC 17025 4.1.5.d)

e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationship between management, technical operations, support services and the management system; (ISO/IEC 17025 4.1.5.e)

f) specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests; (ISO/IEC 17025 4.1.5.f)

g) provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results; (ISO/IEC 17025 4.1.5.g)

h) have a technical manager (director) who has overall responsibility for the technical operations; (ISO/IEC 17025 4.1.5.h)

i) have a quality manager (however named) who has responsibility for the management system and the authority for ensuring its implementation. The quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager; (ISO/IEC 17025 4.1.5.i)

j) appoint deputies to act in the absence of the technical or quality manager; and (ISO/IEC 17025 4.1.5.j)

k) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system. (ISO/IEC 17025 4.1.5.k)

4.1.6 Top management shall make sure that the appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system. (ISO/IEC 17025 4.1.6)

4.2 MANAGEMENT SYSTEM

4.2.1 The laboratory shall establish and maintain a management system appropriate to the type, range and volume of calibration and testing activities it undertakes. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to ensure the quality of its test and/or calibration results. The quality documentation shall be communicated to, understood by, available to and implemented by the laboratory personnel. (ISO/IEC 17025 4.2.1)

4.2.2 The laboratory's management system policies and objectives related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management reviews.. The quality policy statement shall be issued under the authority of the chief executive. It shall include at least the following:

a) the laboratory management's commitment to good professional practice and quality of its testing and calibration in servicing its customers;

b) management's statement of the laboratory's standard of service;

c) the purpose of the management system related to quality;

d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and

e) the laboratory management's commitment to compliance with these criteria and to continually improve the effectiveness of the management system.. (ISO/IEC 17025 4.2.2)

NOTE: The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents. (ISO/IEC 17025 4.2.2e)

4.2.3 Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness. (ISO/IEC 17025 4.2.3)

4.2.4 Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements. (ISO/IEC 17025 4.2.4)

4.2.5 The quality manual shall make reference to supporting procedures including technical procedures. It shall outline the structure of the documentation used in the management system. (ISO/IEC 17025 4.2.5)

4.2.6 The quality manual shall be maintained current under the responsibility of the quality manager. The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of these CRITERIA. The quality manual and related quality documentation shall also contain the following:

a) procedures for control and maintenance of documentation;

b) job descriptions of key staff and reference to the job descriptions of other staff. This shall include a description of the roles and responsibilities of technical management and the quality manager (ISO 17025 4.2.6).

c) identification of the laboratory's approved signatories (where this concept is appropriate);

d) the laboratory's procedures for achieving traceability of measurements;

e) the laboratory's scope of accredited calibrations and/or tests;

f) arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

g) reference to the calibration, verification and/or test procedures used;

h) procedures for handling calibration and test items;

i) reference to the major equipment and reference measurement standards used;

j) reference to procedures for calibration, verification and maintenance of equipment;

k) reference to relevant verification practices including inter-laboratory comparisons, standards calibration procedures, proficiency testing program and internal quality control schemes;

l) procedures to be followed for feedback and corrective action whenever testing discrepancies are detected or departures from documented policies and procedures occur;

m) the laboratory management arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications;

n) procedures for dealing with complaints;

o) procedures for protecting confidentiality and proprietary rights;

p) the objectives of the management system;

q) a requirement that all personnel concerned with calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and

r) the laboratory management's role and commitment to compliance with these CRITERIA and with ISO/IEC 17025. (ISO/IEC 17025 4.2.2)

4.2.7 Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented. (ISO/IEC 17025 4.2.7)

4.3 DOCUMENT CONTROL

4.3.1 The laboratory shall establish and maintain procedures to control all documents that form part of the management system. (ISO/IEC 17025 4.3.1)

4.3.2 All documents that are part of the management system shall be reviewed and approved for use by authorized personnel prior to their issue for use.

4.3.2.1 A master list or document control procedure shall be established (if appropriate) to identify the current revisions and distribution into the management system. This list shall be readily available to prevent the use of invalid or obsolete documents. (ISO/IEC 17025 4.3.2.1)

4.3.2.2 The procedures that are adopted shall ensure that:

a) authorized documentation shall be available at all work stations where essential to the functioning operations of the laboratory;

b) documents are periodically reviewed and revised to ensure continuing suitability and compliance to the applicable requirements;

c) invalid or obsolete documents are promptly and immediately removed from all locations to prevent unintended use; and

d) obsolete documents that are maintained for legal or preservation purposes shall be marked as such to prevent accidental use. (ISO/IEC 17025 4.3.2.2)

4.3.2.3 Management system documents generated by the laboratory shall be uniquely identified by use of page numbering, revision identification, date of issue, and total number of pages or a mark to signify the end of the document, and the issuing authorities. (ISO/IEC 17025 4.3.2.3)

4.3.3 Document changes

4.3.3.1 Changes to documents shall be reviewed and approved through the same process that was used to perform the original review, unless specifically designated otherwise. Designated reviewers shall have access to pertinent background information upon which to base their review and approval. (ISO/IEC 17025 4.3.3.1)

4.3.3.2 Where practicable, altered or new text shall be identified in the document or the appropriate attachments. (ISO/IEC 17025 4.3.3.2)

4.3.3.3 Amendments of documents by hand, pending reissue, shall be according to established procedures, identifying authorities for such amendments. These amendments shall be clearly marked, initialed and dated. A revised document shall be formally reissued as soon as possible. (ISO/IEC 17025 4.3.3.3)

4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled. (ISO/IEC 17025 4.3.3.4)

4.4 CONTRACT REVIEW

4.4.1 The laboratory shall establish procedures for the review of work requests and contracts. These procedures shall ensure that:

a) the requirements, including the methods to be used, are adequately defined, documented and understood;

b) the laboratory has the capability and resources to meet the requirements; and

c) the appropriate test and/or calibration method is selected and capable of meeting the customer's requirements.

Any differences between the request/contract shall be resolved before any work begins. Each contract shall be acceptable to the laboratory and the customer.

A contract may be any written or oral agreement to provide a customer with testing and/or calibration services. (ISO/IEC 17025 4.4.1)

4.4.2 Records of reviews shall be maintained. Records shall also be maintained of pertinent conversations with the customer regarding the customer's requirements or equipment. (ISO/IEC 17025 4.4.2)

4.4.3 The review shall also cover any work that is subcontracted by the laboratory. (ISO/IEC 17025 4.4.3)

4.4.4 The customer shall be informed of any deviation from the contract. (ISO/IEC 17025 4.4.4)

4.4.5 If a contract needs to be amended after work has begun, the same contract review process shall be repeated and any changes shall be communicated to affected personnel. (ISO/IEC 17025 4.4.5)

4.5 SUBCONTRACTING

4.5.1 When it is necessary to subcontract work, this work shall be placed with a competent subcontractor, for example one that complies with an accepted standard (e.g., ANSI N323, ISO/IEC 17025) for the work in question. (ISO/IEC 17025 4.5.1)

4.5.2 The customer shall be advised in writing and approval obtained, preferably in writing. (ISO/IEC 17025 4.5.2)

4.5.3 The laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used. (ISO/IEC 17025 4.5.3)

4.5.4 A register of all subcontractors that are used shall be maintained along with a record of evidence of compliance with the standard in question. (ISO/IEC 17025 4.5.4)

4.6 PURCHASES OF SERVICES AND SUPPLIES

4.6.1 Procedures shall be established for the selection and purchasing of services and supplies used that affect the quality of tests and/or calibrations. (ISO/IEC 17025 4.6.1)

4.6.2 The purchased supplies shall not be used until they have been inspected or otherwise verified as complying with the standard specifications or requirements. Records of actions taken to check compliance shall be maintained. (ISO/IEC 17025 4.6.2)

4.6.3 Purchasing documents for items affecting the quality of laboratory results shall describe the services and supplies ordered. The purchasing documents shall be reviewed and approved for technical content prior to release. (ISO/IEC 17025 4.6.3)

4.6.4 Laboratory consumables, supplies and services that affect the quality of testing and calibration shall be evaluated and records maintained. (ISO/IEC 17025 4.6.4)

4.6.5 Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

4.6.6 The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations or tests.

4.7 CUSTOMER SERVICE

The laboratory shall be willing to cooperate with the customer or its representatives in their efforts to monitor the laboratory's performance in relation to the work performed, to the extent that the confidentiality of other customers can be ensured.

4.7.1 The laboratory shall have documented policy and procedures for the resolution of complaints received from customers or other parties about the laboratory's activities. (ISO/IEC 17025 4.8)

4.7.2 A record shall be maintained of all complaints and of the actions taken by the laboratory.

4.7.3 Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of these CRITERIA or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited. The HPS technical director (TD) and in turn the chair of the Laboratory Accreditation Assessment Committee (LAAC) shall be notified of any findings that are contrary to established policies and procedures or adverse to the quality of the calibration results.

4.7.4 The laboratory shall seek both positive and negative feedback from the customers. The feedback results shall be used to improve the management system, testing and/or calibration activities, and customer service as applicable. (ISO/IEC 17025 4.7.2)

NOTE: Examples of feedback may include customer surveys or conferences with the customers to review data or service needs.

4.8 CONTROL OF NONCONFORMITY

4.8.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. (ISO/IEC 17025 4.9.1)

The policy and procedures shall ensure that:

a) responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates as necessary) are defined and taken when nonconforming work is identified;

b) an evaluation of the significance of the nonconforming work is made;

c) remedial actions are taken immediately, together with any decision about the acceptability of the nonconforming work;

d) where necessary, the customer is notified and work is recalled; and

e) the responsibility for authorizing the resumption of work is defined.

NOTE: Identification of nonconforming work or problems with the management system or with testing and/or calibration activities can occur at various places within the management system and technical operations. Customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits are examples.

4.8.2 The quality manager shall have the responsibility for management of nonconforming work and actions taken.

4.8.3 Notification of a significant error

4.8.3.1 For the purposes of these CRITERIA, a significant error is an error in a calibration report or certificate that exceeds the uncertainty goals of the laboratory as stated in its protocol (Section 11.1.2). The error may be in the form of an incorrect calibration factor value due to a calculation error or equipment malfunction, or a typographical or technical error in the report that is likely to cause an error in the use of the calibration results.

4.8.3.2 The error shall be corrected as soon as possible, either by sending a corrected report or by recalling and re-calibrating the equipment, as is appropriate.

NOTE: Material amendments to a calibration certificate or report after issue shall be made only in the form of a further document or data transfer including the statement "Supplement to Calibration Certificate (or Calibration Report), serial number (or as otherwise identified)," or equivalent form of wording. Such amendments shall meet all the relevant requirements of the criteria for the activity performed.

4.8.3.3 If an accredited lab (AICL/ASCL) discovers a significant error in a calibration report or calibration certificate, the person or institution that received the report shall be notified immediately by telephone.

4.8.3.4 The AICL/ASCL shall report the error to the HPS Technical Director (TD), who will, in turn, report the error to the LAAC chairperson with an explanation of how the error occurred and a description of the steps taken to prevent a repetition. This report may be provided to the full committee at the annual HPS meeting.

4.8.3.5 Where evaluation indicates that the error could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, corrective action as stated in section 4.11 shall be promptly followed. (ISO/IEC 17025 4.9.2)

4.9 NOTIFICATION OF A POTENTIAL ERROR

If an AICL or ASCL discovers a situation that has led to or might lead to a calibration error in any phase of its operation, it shall notify its potentially affected customers in writing, with a copy to the TD. This notification shall be styled to alert the LAAC to the possibility of such an error. Such notifications may be forwarded to other HPS accredited laboratories, regulatory agencies and manufacturers to alert concerned groups of generic problems that may affect the calibration or use of instruments or sources.

4.10 MANAGEMENT SYSTEM IMPROVEMENT

The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. (ISO/IEC 17025 4.10)

4.11 CORRECTIVE ACTION

4.11.1 The quality manager shall have the responsibility to implement corrective action following established procedure when nonconforming work or departures from the policies and procedures have been identified. (ISO/IEC 17025 4.11.1)

4.11.2 Investigation shall start with an investigation to determine the root cause of the problem. (ISO/IEC 17025 4.11.2)

4.11.3 Action shall be taken to eliminate the problem and to prevent recurrence. The action shall be appropriate to the magnitude and to the risk of the problem. Required changes resulting from corrective action shall be documented and implemented. (ISO/IEC 17025 4.11.3)

4.11.4 Follow-up shall be made to ensure that corrective action taken has been effective. (ISO/IEC 17025 4.11.4)

4.11.5 Where the identification of a nonconformity casts doubt on the laboratory's compliance with its own policies and procedures, an internal audit will be conducted of the appropriate area as soon as possible (ISO/IEC 17025 4.11.5).

4.12 PREVENTIVE ACTION

4.12.1 Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, an action plan shall be developed, implemented and monitored to reduce the likelihood of recurrence. (ISO/IEC 17025 4.12.1)

4.12.2 Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure the actions are effective. (ISO/IEC 17025 4.12.2)

4.13 CONTROL OF RECORDS

4.13.1 All records of measurement data and records of required comparisons shall either be recorded in ink in bound log books with pages numbered consecutively, or in some equivalent manner. As an alternative to log books, electronic data may be printed and dated or written to compact disk as a read-only archival record. These records shall be retained in a confidential manner secure from fire and degradation. (ISO/IEC 17025 4.13.1)

4.13.1.1 These records shall be kept for a period of time at least equal to that established by governmental authority, by consensus standard or as specified by HPS policy.

NOTE: HPS policy requires that for each instrument calibrated the records shall be maintained for a period of at least five years. Records regarding calibration, intercalibration, or proficiency testing of standards used shall be maintained for a period of at least 50 years.

4.13.1.2 All records shall be legible and retained in such a way that they are easily retrievable and stored to prevent damage or deterioration or loss. (ISO/IEC 17025 4.13.1.2)

4.13.1.3 All records shall be maintained securely and in strict confidence. (ISO/IEC 17025 4.13.1.3)

4.13.1.4 All records (including those pertaining to calibration measurement and test equipment), log books, computer data files, certificates and reports shall be safely stored, held securely and held in confidence to the customer. The calculations and completeness of a calibration shall be reviewed and signed or initialed by the person in charge of the laboratory or his/her designate. The records for each calibration and test shall contain sufficient information to permit their repetition.

4.13.1.5 The data to be recorded for the calibration or intercalibration of laboratory equipment shall include but need not be limited to the following: date, serial number, type, reading, reading times (if any), type and serial number of support equipment such as timers and thermometers, etc., and any deviations from the protocol.

4.13.1.6 The records shall include the identity of personnel involved in sampling, preparation, calibration or testing.

4.13.1.7 Technical records shall be maintained for a defined period. (ISO/IEC 17025 4.13.2.1)

4.13.1.8 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the task. (ISO/IEC 17025 4.13.2.2)

4.13.1.9 Written mistakes shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All corrections to records shall be signed or initialed by the person making the correction. (ISO/IEC 17025 4.13.2.3)

4.13.2 Procedures shall be established to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records (ISO/IEC 17025 4.13.1.4).

4.13.3 The procedures shall include instructions for the identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records (ISO/IEC 17025 4.13.1.1).

4.14 INTERNAL AUDITS

4.14.1 The laboratory shall arrange for internal audits of its activities at intervals not exceeding 12 months to verify that its operations continue to comply with the requirements of the management system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any customer whose work may have been affected (ISO/IEC 17025 4.14.1)

4.14.2 All audit and management review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed time scale. (ISO/IEC 17025 4.14.3)

4.14.3 In addition to periodic audits the laboratory shall ensure the quality of results provided to customers by implementing appropriate checks. These checks or audits shall be reviewed and shall include but not be limited to:

4.14.3.1 Internal quality control schemes using statistical techniques whenever possible,

4.14.3.2 Regular use of in-house quality control using secondary systems,

4.14.3.3 Replicate testing using the same or different methods,

4.14.3.4 Re-testing of nonconforming items when appropriate,

4.14.3.5 Correlation of results for different characteristics of an item.

4.14.4 Follow-up shall be made to ensure that corrective action taken has been effective. (ISO/IEC 17025 4.14.4)

4.15 MANAGEMENT REVIEWS

4.15.1 The management system adopted to satisfy the requirements of these CRITERIA shall be reviewed at least once a year by the executive management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements. (ISO/IEC 17025 4.15.1) The review should include:

a) Suitability of policies and procedures,

b) Reports from managerial and supervisory personnel,

c) The outcome of recent internal audits,

d) Corrective and preventive action,

e) Assessments by external bodies,

f) Results of intra-laboratory comparisons or proficiency tests,

g) Performance and qualification testing activities,

h) Changes in the volume and type of work,

i) Customer feedback,

j) Complaints,

k) Recommendations for improvement, and

l) Other relevant factors, such as quality control activities, resources and staff training.

NOTES:
1. Results of the review should feed into the laboratory planning system in terms of goals, objectives, and action plans.
2. A management review includes consideration of related subjects during regular management meetings.

4.15.2 Findings from the management review meetings shall be documented. Management shall ensure that those actions are carried out within an acceptable timetable.

4.16 MANAGEMENT OF SECONDARY–TERTIARY RELATIONSHIP

4.16.1 Secondary facilities that intend to service tertiary facilities shall include a statement indicating that priority shall be given to the servicing of such facilities and that all such activities will comply with HPS criteria.

4.16.2 The relationship between a secondary and tertiary laboratory shall be documented and shall be treated with independence and confidentiality.

4.16.3 In those instances where a single business entity operates both a secondary accredited laboratory and a tertiary laboratory, the two facilities shall operate with a structure that provides confidence in the independence of the operations.

NOTE: It should be easy to identify procedures and equipment related to each operation.

4.16.4 In those instances where a secondary laboratory performs operations covered under the scope of a tertiary accreditation (e.g. use of box calibrators, limited scope X-ray calibrations, etc.), the laboratory will clearly state that the scope of the activity is at a tertiary level and that the calibration is traceable to a secondary standard. The laboratory should request tertiary accreditation for such activities at the time of application.

4.16.5 In instances where a conflict of interest arises or service is felt to be inadequate a tertiary laboratory should notify the HPS (technical director and/or LAAC chair) and request that their relationship be transferred to another secondary laboratory.

4.16.6 When a secondary laboratory feels that the performance of a tertiary laboratory is inadequate they shall notify the HPS (technical director and/or LAAC chair).

5 TECHNICAL REQUIREMENTS

5.1 GENERAL

The laboratory shall take account of the factors that contribute to the total uncertainty of measurement in developing test and calibration methods and procedures, in the training and qualification of personnel and in the selection and calibration of equipment. Factors include:

5.1.1 Human factors,

5.1.2 Accommodation and environmental conditions,

5.1.3 Test and calibration methods and method validation,

5.1.4 Equipment,

5.1.5 Measurement traceability,

5.1.6 Sampling (if appropriate),

5.1.7 Handling and controlled tracking of test and calibration items.

5.2 PERSONNEL

5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment, perform calibrations, evaluate results, and sign calibration certificates. When using staff undergoing training appropriate supervision shall be provided. The laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions. Any additional personnel shall be trained so that their activities will be in accordance with the laboratory protocol. (ISO/IEC 17025 5.2.1)

5.2.2 The laboratory shall have developed goals with respect to the education, skills, and training of laboratory personnel. The laboratory shall ensure that the training of its personnel is kept up-to-date. The laboratory shall have a policy and procedures for identifying training needs and providing for the training of the employees. The training program shall be relevant to the present and anticipated needs of the laboratory. The training effectiveness shall be evaluated. (ISO/IEC 17025 5.2.2)

NOTE: The effectiveness evaluation may be in the form of a written test, observation of tasks, or by other means, or a combination of means. The evaluation, however, must be documented.

5.2.3 The person responsible for the operation of the AICL or ASCL shall be identified to the HPS and should have a position in the organizational structure of the laboratory that ensures the ability to control laboratory operation. This person shall understand the laboratory protocol and know whether it is being followed. The supervisor of the laboratory shall have at least 3 years of experience in instrument calibration, source calibration, and/or source preparation as applicable.

5.2.4 All laboratory technical personnel shall be under employment or contract to the laboratory. If contracted workers are used, they shall be required to use the laboratory's management system. Adequate supervision shall be maintained to ensure competence. Records shall be maintained on all key personnel. These records shall contain a CV on the laboratory director and the person responsible for day-to-day operations and job descriptions indicating the relevant qualifications, training, skills and experience of all technical personnel. (ISO/IEC 17025 5.2.3, 5.2.4)

5.2.5 The management shall authorize specific personnel for specific duties, such as calibrations, source preparations, interpretations, operation of equipment, etc. The laboratory shall maintain records of relevant authorization(s) competence, training, and experience of all technical personnel, including contracted personnel. This information must be readily available and must include dates on which the authorization or confirmation occurred. (ISO/IEC 17025 5.2.5)

5.2.6 The person in charge of day-to-day operations shall be identified to the HPS and should have at least a B.A. or B.S. degree in physics, chemistry, or a physical science, or equivalent knowledge, and relevant experience. The LAAC shall have the authority to determine the suitability of the qualifications of an individual proposed for this position by the laboratory. In the case of a tertiary laboratory, the technical manager shall have at least an associate degree in an appropriate technical field.

5.3 ENVIRONMENTAL CONDITIONS

The environment in which calibration, source production, and test activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement.

5.3.1 Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests. Requirements for environmental conditions that can affect measurements and/or calibrations shall be documented. (ISO/IEC 17025 5.3.1)

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5.3.2 The laboratory areas where unsealed radioactive materials are used shall include appropriate equipment, such as fume hoods, glove boxes, safety showers, etc. Adequate bench space for the number of employees working in the laboratory shall be provided. Laboratory areas shall be maintained to ensure the work areas are neat, clean, and orderly. Environmental conditions shall be maintained as appropriate for specific operations. For example, analytical balances shall be used in areas that are relatively free from dust, air currents, and vibration.

5.3.3 The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions with the calibration data as appropriate. (ISO/IEC 17025 5.3)

5.3.4 As appropriate, environmental conditions (such as temperature, pressure, and relative humidity) shall be monitored within the laboratory and recorded.

5.3.5 There shall be effective separation (e.g. radiation shielding) between neighboring areas when the activities therein are incompatible. (ISO/IEC 17025 5.3.3)

NOTES:
1. Radiation detection equipment should be physically separated from process areas for radioactive materials. If common facilities are used for both low-level and high-level radionuclide measurements, then strict contamination control procedures shall be employed before transfer of samples from production areas to the counting room(s).
2. The packing and shipping area should be separated from the production areas. All radioactive material should be monitored for removable contamination before transfer to the shipping area.

5.3.6 Access to and use of all areas affecting the quality of calibration activities shall be defined and controlled. (ISO/IEC 17025 5.3.4)

5.3.7 Suitable storage facilities shall be provided for reference standards, equipment, documented instructions, manuals, and calibration certificates and reports.

5.3.8 Although strict temperature control is not essential, it is desirable that the laboratory be kept at a reasonably uniform temperature so that the accuracy of equipment is not adversely affected, and so that an adequate stability is achieved before the start of calibration measurements. It is recommended that the laboratory temperature be maintained within the range of 18°C to 26°C.

5.3.9 The relative humidity should be within the range of 15 to 65% for laboratory operation.

5.3.10 The level of background radiation shall be as low as practicable and not subject to variations that could significantly affect the accuracy of the calibration work.

5.3.11 In uncollimated free-air calibration facilities, the radiation room should be used exclusively for calibrations to avoid variable scatter conditions.

5.3.12 A closely controlled environment is not normally necessary in a storage area, but wide temperature and humidity fluctuations should be avoided so as to protect instruments and standards temporarily held there, and to minimize the time required for an instrument to reach thermal equilibrium when brought to the calibration laboratory from the storage area.

5.3.13 The electrical power shall be appropriate to the equipment used, suitably stable, and free of switching surges and significant line noise. When necessary, local auxiliary voltage stabilizers and filters shall be provided.

NOTE: A stable source of electrical power, preferably regulated and uninterruptible, shall be available for radiation-detection instrumentation used to calibrate sources.

5.3.14 The laboratory shall be provided with an adequate grounding system. Where there is a likelihood of interference arising from equipment connected to a single grounding system, separate grounding systems shall be provided and adequate precautions taken against any possible interconnection between systems.

5.3.15 The radiation room shall be of sufficient size and design such that scattered radiation at the positions where instruments are normally placed for calibration does not introduce an error inconsistent with accuracy goals. If necessary, proper scatter corrections shall be applied.

5.3.16 Measures shall be taken to ensure good housekeeping in the laboratory. (ISO/IEC 17025 5.3)

5.3.17 Certain tests and calibrations require specific environmental conditions to exist at the time of measurements (e.g., low background radiation) that may be affected by other operations in or outside the laboratory. Procedures for such sensitive tests and calibrations shall require the evaluation of the environmental conditions (such as background radiation) prior to the commencement of such tests and the suspension or rescheduling of other activities having an adverse effect on the environmental conditions.

5.3.18 Contamination levels in laboratory areas shall be controlled to prevent contamination of sources and instruments. This will probably require control of contamination to a higher degree than required for personnel safety. Appropriate instrumentation and monitoring procedures shall be used to monitor the cleanliness of work areas utilizing radioactive material.

5.4 TEST AND CALIBRATION PROCEDURES, METHODS, AND METHOD VALIDATION

5.4.1 The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required and with any standard specifications and accreditation CRITERIA relevant to the calibrations or tests concerned. (ISO/IEC 17025 5.4.1)

5.4.1.1 The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, written standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff. Deviations from calibration methods must be documented, technically justified, authorized, and accepted by the customer. (ISO/IEC 17025 5.4.1)

NOTE: Procedures shall specify operating parameters for instruments and any specific operational limitations such as source geometry, counting rate, dead time limits, etc.

5.4.1.2 The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application. (ISO/IEC 17025 5.4.2)

5.4.1.3 Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards or those published by reputable technical organizations or in relevant scientific texts or journals. (ISO/IEC 17025 5.4.2)

5.4.1.4 Where it is necessary to employ methods that have not been established as standard, these shall be communicated to and subject to agreement with the customer, be fully documented and validated, and be available to the customer and other recipients of the relevant reports. The laboratory shall confirm that it can reliably operate the methods prior to their introduction; if the methods change, the confirmation shall be repeated. (ISO/IEC 17025 5.4.2, 5.4.4)

5.4.1.5 If a customer proposes a specific method, the laboratory shall inform the customer if the method is inappropriate or outdated. (ISO/IEC 17025 5.4.2)

5.4.1.6 Introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources. The laboratory shall ensure that plans are updated as development proceeds and that there is effective communication between all involved personnel. (ISO/IEC 17025 5.4.3)

5.4.2 The types or categories of sources and/or equipment calibrated by an AICL or ASCL shall be identified. The protocol shall describe the procedures for calibrating, reporting, and record keeping for each category as well as a means of classifying a device or source into an appropriate category.

5.4.3 New test and/or calibration methods and procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following:

a) Appropriate identification,

b) Scope,

c) Description of the type of item to be tested or calibrated,

d) Parameters or quantities and ranges to be determined,

e) Apparatus and equipment, including technical performance,

f) Required reference standards and reference materials,

g) Environmental conditions required and any stabilization period needed,

h) Description of the procedure, including:

1) affixing of identification marks, handling, transporting, storing and preparation of items,
2) checks to be made before the work is started,

3) checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,
4) the method of recording the observations and results, and
5) any safety measures to be observed.

i) Criteria and/or requirements for approval/rejection,

j) Data to be recorded and method of analysis and presentation,

k) The uncertainty or the procedure for estimating uncertainty.

5.4.4 Validation of methods

The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside the scope, and modifications of standard methods to confirm that the methods are fit for intended use. Validation should be as extensive as necessary to meet the needs of the given application. The results shall be recorded, along with the procedure used for the validation, and a statement as to whether the method is fit for the intended use. (ISO/IEC 17025 5.4.5.2)

The range and accuracy of the values obtainable from validated methods as assessed for the intended use shall be relevant to the customer's needs. (ISO/IEC 17025 5.4.5.3)

5.4.5 Estimation of uncertainty of measurement

The calibration laboratory shall have and apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations, taking into account all uncertainty components that are of importance in the given situation.

5.4.6 Control of data

5.4.6.1 Calculations and data transfers shall be subject to appropriate checks. (ISO/IEC 17025 5.4.7.1)

5.4.6.2 Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall ensure that: (ISO/IEC 17025 5.4.7.2)

5.4.6.2.1 The requirements of these CRITERIA are complied with;

5.4.6.2.2 Computer software is documented, validated and adequate for use;

5.4.6.2.3 Procedures are established and implemented for protecting the integrity of data. Such procedures shall include, but need not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

5.4.6.2.4 Computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating

conditions necessary to maintain the integrity of calibration and test data;

5.4.6.2.5 It establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records;

5.4.6.2.6 If commercial software is used for calculations, it should first be tested and approved by the director/quality manager and then protected from accidental corruption. A date and a version should be assigned so that previous versions will not be accidentally used. Test and approval of each version should be documented and retained. No changes may be made in the calculations performed by the software without approval of the director/quality manager. The software should be tested periodically to ensure that its operation and use are as intended. An alternative to this method is to check the proper operation by hand calculation after each use;

5.4.6.2.7 All tests and validations of software for the automatic acquisition of measurement data and the logging of environmental conditions shall be documented prior to initial use.

5.5 FACILITIES AND EQUIPMENT

5.5.1 An AICL or ASCL shall have, in operable condition, at least the equipment designated for each accredited function. The equipment shall be dedicated to the laboratory use with exceptions (equipment not under the direct control of the laboratory) clearly identified and justified, if appropriate. (ISO/IEC 17025 5.5.1)

5.5.2 Equipment and its software used for calibration shall be capable of achieving the accuracy required and shall comply with specifications relevant to the calibrations concerned. Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results. (ISO/IEC 17025 5.5.2)

5.5.3 Before being placed into service, equipment shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use. Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel. (ISO/IEC 17025 5.5.2, 5.5.3)

5.5.4 Each item of equipment shall, when appropriate, be labeled, marked or otherwise identified to indicate its calibration status. (ISO/IEC 17025 5.5.4)

5.5.5 Records shall be maintained of each item of equipment significant to the calibrations or tests performed. (ISO/IEC 17025 5.5.5) The records shall include:

a) the identity of the item of equipment and any software;

b) the manufacturer's name, type identification, and serial number or other unique identification;

c) tests to confirm equipment conforms to specifications or meets laboratory requirements;

d) date received and date placed in service;

e) current location, where appropriate;

f) condition when received (e.g. new, used, reconditioned);

g) copy of the manufacturer's instructions, where available;

h) dates and results of calibrations and/or verifications and due date of next calibration and/or verification;

i) details of maintenance carried out to date and planned for the future;

j) history of any damage, malfunction, modification or repair; and

k) notes on intended use and limitations, if appropriate.

5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration. (ISO/IEC 17025 5.5.6)

5.5.7 Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified limits shall be taken out of service and isolated to prevent its use or clearly marked as being out of service. (ISO/IEC 17025 5.5.7)

5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled or otherwise identified with the status and date of last calibration, with expiration date. (ISO/IEC 17025 5.5.8)

5.5.9 When laboratory procedures require outside calibration services and supplies, only those outside services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests shall be used. Each supplier of calibration services shall be selected on basis of the existence of an appropriate quality assurance program. (ISO/IEC 17025 5.5.9)

5.5.10 Intermediate checks that are needed to maintain confidence in the calibration status of the equipment shall be carried out according to a defined procedure. (ISO/IEC 17025 5.5.10)

5.5.11 Where calibrations give rise to correction factors, the laboratory shall have procedures to ensure that copies (e.g., computer software) are correctly updated. (ISO/IEC 17025 5.5.11)

5.5.12 Test and calibration equipment, including both hardware and software, shall be protected from adjustments that would invalidate the test and/or calibration results. (ISO/IEC 17025 5.5.12)

5.5.13 Instrument calibration laboratories shall have means for determining temperature and barometric pressure with ± 1% accuracy. Each device used shall have been calibrated by comparison with a reference standard. The secondary accredited laboratory shall have a device capable of monitoring relative humidity over the range 15 to 65% with an accuracy of ± 5%.

5.5.14 The laboratory barometers and thermometers should be compared at frequent intervals as specified in the laboratory protocol and should be re-calibrated or replaced whenever the tolerances established in the protocol are exceeded during the comparisons.

5.5.15 The laboratory shall have reference standards that cover the range of calibrations performed. In a secondary accredited laboratory, a working standard should be used in lieu of a reference standard for routine calibration work. In a tertiary accredited laboratory, a working standard may be used in lieu of a reference standard for routine calibration work.

5.5.16 The laboratory shall correct calibration factors for ionization chambers open to the atmosphere to the reference atmosphere of 22°C (295.15°K) and 760 mm of Hg at 0°C (101.325 kPa). Instruments that do not communicate with the atmosphere should be documented as such.

5.5.17 The laboratory shall have means for viewing instruments under calibration so they can be read from outside the radiation field.

5.5.18 In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of these CRITERIA are met.

5.5.19 The laboratory shall be designed, operated, and maintained to meet applicable federal, state, and local safety codes and regulations.

5.5.20 All AICL or ASCL laboratory equipment shall be properly maintained. Maintenance procedures shall be documented, if appropriate. Any item of the equipment that has been subjected to overloading or mishandling, or that gives suspect results or has been shown by verification or otherwise to be defective shall be taken out of service, clearly identified and, wherever possible, stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests and institute its "Control of nonconforming work" procedure (see 4.8). If this examination reveals that the defect may have had an adverse impact on any calibration results outside the uncertainty goals of the laboratory, the AICL shall notify the customer of the recall and recalibrate and/or issue a new calibration report as appropriate.

5.6 MEASUREMENT TRACEABILITY

5.6.1 The laboratory shall use appropriately calibrated reference standards. The reference standards for a secondary accredited laboratory shall be calibrated by NIST. If NIST

cannot provide the service another National Standards Laboratory (NSL) may be used subject to approval by the Laboratory Accreditation Policy Committee (LAPC). The reference standards for a tertiary accredited laboratory shall be calibrated by a secondary laboratory or by NIST.

5.6.2 The laboratory shall conduct periodic proficiency tests with a higher level laboratory (reference laboratory) to determine its calibration or testing performance and to ensure continuing measurement traceability for its reference standard(s). Secondary laboratories will interact with NIST or another NSL for its proficiency tests if NIST cannot provide the services. Tertiary laboratories will conduct proficiency tests with a secondary laboratory.

NOTE : This can involve tests in which the laboratory measures an artifact sent by the reference laboratory, tests in which the reference laboratory measures an artifact sent by the accredited laboratory, or tests in which an artifact is intercalibrated among accredited labs and NIST. The artifact would be a source in the case of the source calibrators or manufacturers and a reference radiation detector in the case of calibration facilities.

5.6.3 All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. (ISO/IEC 17025 5.6.1)

5.6.4 Calibration and Comparison of Laboratory Standards

5.6.4.1 The laboratory shall have an established program for the calibration and verification of its measuring and test equipment. (ISO/IEC 17025 5.6.1)

NOTES:
1. Verification tests shall be performed on instrumentation used for NIST-traceable calibration of sources.
2. Periodic quality control checks shall be made to demonstrate the operability and accuracy of measuring equipment. These tests shall be performed according to a defined schedule appropriate for the type of test.

5.6.4.2 The standards or equipment originally calibrated by comparison with a higher-level standard shall be recalibrated when the need is demonstrated by the results of proficiency testing or routine quality control.

5.6.4.3 The devices used to determine temperature and barometric pressure in a secondary accredited laboratory shall be intercompared with similar devices located in the laboratory as part of a documented program of quality control. The devices used to determine temperature and barometric pressure in a tertiary accredited laboratory shall be recalibrated periodically, or shall be intercompared with similar devices located in the laboratory as part of a documented program of quality control.

5.6.4.4 When such intercomparison indicates a need for recalibration, it shall be done by comparison with a reference standard.

5.6.4.5 The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards (thereby providing traceability to the International System of Units (SI) (Système International d'Unités)), whether the calibrations are performed in-house or by an external calibration service. (ISO/IEC 17025 5.6.2.1.1)

5.6.4.6 Calibration certificates of measurement and test equipment that is not calibrated by NIST shall, whenever applicable, indicate the traceability to national standards of measurement and should provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification. (ISO/IEC 17025 5.6.2.1.1)

5.6.4.7 There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as: a) the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material; b) the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned. c) Participation in a suitable program of interlaboratory comparisons is required where possible. (ISO/IEC 17025 5.6.2.1.2)

5.6.4.8 The procedure used by the laboratory to determine the estimated uncertainty of the measurements associated with the calibration result shall be consistent with the procedure established in the ISO Guide to the Expression of Uncertainty in Measurement.

5.6.5 Reference standards and reference materials

Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, except for research or other closely monitored purposes when it can be demonstrated that their performance as reference standards has not been invalidated. (ISO/IEC 17025 5.6.3.1)

5.6.5.1 Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement (thereby providing traceability to the International System of Units (SI) (Système International d'Unités)). There shall be a program of calibration and verification for reference standards, whether the calibrations are performed in-house or by an external calibration service. When proficiency testing or intercomparison indicates a need for recalibration, it shall be done by comparison with a reference standard. Reference standards shall be calibrated before and after any adjustment. (ISO/IEC 17025 5.6.3.1)

5.6.5.2 Reference materials shall, where possible, be traceable to SI units of measurement. Internal reference materials shall be checked as far as is technically and economically practicable. (ISO/IEC 17025 5.6.3.2)

5.6.5.3 Appropriate checks, comparisons and other tests shall be made in order to maintain confidence in the calibration status of local primary, transfer and reference standards and reference materials in order to prevent contamination or deterioration and preserve their integrity. (ISO/IEC 17025 5.6.3.3)

5.6.5.4 The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to protect their integrity. (ISO/IEC 17025 5.6.3.4)

5.7 SAMPLING

Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples.

5.8 HANDLING OF TEST AND CALIBRATION ITEMS

5.8.1 The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory. (ISO/IEC 17025 5.8.1)

5.8.2 The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory so as not to become confused physically or when referred to in documents. If items are subdivided within or outside of the laboratory, the system shall accommodate this practice. (ISO/IEC 17025 5.8.2)

5.8.3 Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration or test method, shall be recorded. Where there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the customer for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the customer requires preparation to be undertaken or arranged by the laboratory. (ISO/IEC 17025 5.8.3)

NOTES:
1. Instruments received for calibration should be checked for radioactive contamination and appropriate action taken if it is found to be contaminated.
2. All handling, unpacking, and packing of instruments, standards, and radioactive sources shall be done by trained staff who are familiar with the nature of the equipment.

5.8.4 The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration or test item or portion of an item is to be held secure (e.g., for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned. (ISO/IEC 17025 5.8.4)

5.9 ENSURING THE QUALITY OF TEST AND CALIBRATION RESULTS

5.9.1 The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations. The resulting data shall be recorded in a way to detect trends. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

a) Regular use of certified reference material and/or internal quality control using secondary reference materials,

b) Participation in intra-laboratory comparison or proficiency-testing,

c) Redundant measurements using different modes of measurements,

d) Frequent local comparisons of redundant standards,

e) Replicate tests or calibrations using the same or different methods,

f) Retesting or recalibration of retained items,

g) Correlation of results for different characteristics of an item

h) Quality control data shall be analyzed and, when they are found to be outside pre-defined criteria, action shall be planned and taken to correct the problem and to prevent incorrect results from being reported. (ISO/IEC 17025 5.9.2)

5.10 REPORTING

5.10.1 The results of each calibration shall be reported accurately and clearly in accordance with any specific instructions in the calibration methods. The results shall be reported, usually in a calibration certificate (sometimes called calibration reports), and shall include all the information requested by the customer and necessary for the interpretation of the calibration results and all information required by the method used. In the case of calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the customer shall be readily available in the laboratory which carried out the calibrations. (ISO/IEC 17025 5.10.1)

NOTE: Particular care and attention should be paid to the arrangement of the certificate or report, especially with regard to presentation of the calibration data and ease of assimilation by the reader. The format should be carefully and specifically designed for each type of calibration carried out, but the headings shall be standardized as far as possible.

5.10.2 Each calibration certificate shall include at least the following information (ISO/IEC 17025 5.10.2):

a) report Title,

b) report Type,

c) unique identification of the test report or calibration certificate and on each page an identification in order to ensure that the page is recognized as part of the calibration, and a clear indication of the end of the report,

d) name and address of the customer,

e) identification of the method used,

f) a description of, condition of, and unambiguous identification of the items calibrated,

g) date of receipt of the test or calibration items where it is critical to the validity and application of the results, date of performance of the test or calibration,

h) reference to a sampling plan, if applicable,

i) calibration results with SI units of measurement, as applicable,

j) names, functions and signatures or equivalent identification of persons authorizing the calibration report,

k) where relevant, a statement to the effect that the results refer only to the items calibrated,

l) an unambiguous description of any non-standard calibration methods used,

m) any deviation from, additions to, or exclusions from the calibration method, and any other information relevant to a specific calibration, such as environmental conditions,

n) measurements, examinations, and derived results, supported by tables, graphs, sketches, and photographs as appropriate, and any failures identified,

o) name and address of the laboratory, and location where the calibration was carried out if different from the address of the laboratory,

p) calibration certificates or reports including an appropriate statement clearly specifying the conditions (e.g., orientation of the detector with respect to the source) under which the calibration was performed,

q) the general condition of the instrument as received, and a warning statement for an instrument that cannot be adjusted to within a stated accuracy range shall be included in the report or certificate,

r) certificates or reports should state that the application of the calibration factors to an individual measurement is the responsibility of the user, and that care must be exercised in interpolation or extrapolation of the calibration factors, and

s) the accredited laboratory shall clearly indicate whether the calibration was performed using either an accredited or non-accredited procedure.

Notes:

1. Hard copies of the report should also include the page number and total number of pages.
2. The report should contain a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory. Internal copies made by the customer for labeling or other internal purposes are exempt from this requirement. Also exempt from this requirement are tags and miniaturized versions of data pages intended for attachment to the calibrated instrument. These are supplied by the laboratory as a convenience to the customer and are provided as an attachment to the full calibration report.

5.10.3 The calibration factors stated in the calibration report shall be corrected to standard reference conditions of 22°C and 760 mm of Hg at 0°C (101.325 kPa), unless otherwise noted (sealed ion chambers).

5.10.4 Additional calibration certificate requirements:

5.10.4.1 When test or calibration results include sampling, additional information may be necessary for the interpretation of the calibration or test results: (ISO/IEC 17025 5.10.4.1)

a) The conditions under which the calibration or test was performed,

b) The uncertainty of measurement and/or a statement of compliance with an identified metrological specification,

c) Evidence that the measurements are traceable.

5.10.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. If statements of compliance with a specification or a standard are made, the uncertainty of measurement shall be taken into account, and they this shall identify which clauses of the specification are met or not met. When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference. (ISO/IEC 17025 5.10.4.2)

5.10.4.3 When an instrument has been adjusted or repaired, the results before and after shall be reported, if available. (ISO/IEC 17025 5.10.4.3)

5.10.4.4 As requested, the as received readings for an instrument shall be taken, recorded and reported. If these readings are in error by over 20% the customer shall be notified promptly.

5.10.4.5 A calibration report shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. When calibrations are performed to a specification or specified standard with stated calibration intervals, this interval shall be specified. (ISO/IEC 17025 5.10.4.4)

5.10.4.6 The report shall be signed or initialed by the person performing the calibration or the person in charge of the day-to-day operation of the laboratory and shall be reviewed and signed by the person responsible for the laboratory or his/her designate.

5.10.4.7 Calibration results shall not be disclosed to anyone outside of the AICL or ASCL other than the individual submitting the instrument or source, except as designated in writing by that individual. Exceptions are persons authorized by a competent public authority, or representatives of the HPS when acting in an official capacity involving laboratory accreditation. In such a case, the HPS representatives will be bound by the same requirements for confidentiality as AICL or ASCL personnel. This restriction does not apply to disclosure that does not identify a particular instrument or source or institution.

5.10.4.8 The laboratory shall notify customers promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate or amendment to a report or certificate.

5.10.5 Opinions and interpretations

When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in the test report. (ISO/IEC 17025 5.10.5)

5.10.6 Testing and calibration results obtained from subcontractors (ISO/IEC 17025 5.10.6)

5.10.6.1 When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.

5.10.6.2 When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.

5.10.7 Electronic transmission of results

The laboratory shall ensure that, where customers require transmission of calibration or test results by telephone, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of this CRITERIA are met and that confidentiality is preserved (ISO/IEC 17025 5.10.7).

5.10.8 Format of certificates and reports

The format shall be designed to accommodate each type of calibration or test performed and to minimize the possibility of misunderstanding or misuse. (ISO/IEC 17025 5.10.8)

5.10.9 Amendments to calibration certificates

Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement “Supplement to Calibration Certificate, Test Report or Test Certificate, serial number...” or an otherwise identified or equivalent form of wording. Revisions or

complete replacements of calibration reports and certificates should include a reference to the original report (number or test number) and date, and shall meet all of the requirements of this standard. (ISO/IEC 17025 5.10.9)

5.11 SECONDARY–TERTIARY PROCEDURES

5.11.1 The secondary laboratory shall have a procedure for organizing its interactions with tertiary facilities. The procedure shall include:

a) Identification of the individual responsible for coordinating the activities with tertiary facilities.

b) Identification of standards to be used in proficiency testing with the tertiary laboratory and an analysis of the uncertainty of the standard with respect to national standards.

c) Procedure for handling of complaints concerning the tertiary/secondary relationship or quality of work from any involved party.

d) Identification of all parties to be involved in work with tertiary facilities including relevant training.

5.11.2 The secondary laboratory shall conduct the proficiency tests or intercalibrations with the tertiary laboratory (ISO/IEC 17025 5.6.2).

5.11.3 Results of proficiency tests shall be analyzed and reported to the HPS. Both the uncertainty with respect to the secondary laboratory standard and the derived uncertainty to the national standard shall be reported.

5.11.4 The on-site review of a tertiary laboratory may be conducted by either a secondary laboratory or by the HPS (LAAC). All on-site reviews shall be coordinated with the LAAC and shall use trained auditors. The results of the audit shall be documented and reported to the LAAC.

APPENDIX A
SPECIFIC CRITERIA FOR GAMMA-RAY CALIBRATIONS

A1 Scope

A1.1 This Part sets out specific requirements in accordance with which a laboratory has to demonstrate that it operates if it is to be accredited by the Health Physics Society for calibrations using gamma radiation. The general requirements are set forth in Sections 4 and 5.

A1.2 The criteria contained in this Part apply to calibration of portable instruments at radiation protection levels using a gamma-ray source. If this calibration service is to be included in the scope of accreditation, the laboratory shall meet the requirements set forth in Sections 4 and 5 and this Appendix.

A1.3 The criteria that apply only to the secondary level appear in the left-hand column, and those that apply exclusively to the tertiary level appear in the right-hand column. Unless a distinction is stated, an item that covers both columns applies equally to both levels.

A2 References

ISO/IEC 17025, General requirements for the competence of calibration and testing laboratories.

A3 Definitions

The relevant definitions from Section 3 of this document are applicable. Further definitions applicable for the purposes of this Appendix are given below.

A3.1 attenuator: Absorbing material intentionally placed in the path of a radiation beam to reduce its intensity.

A3.2 box-type calibrator: A system that totally encloses the radiation source, field, and instrument being calibrated in a chamber too small for occupancy by the entire human body and that provides sufficient shielding so that adjacent areas may safely be occupied while the source is exposed.

A3.3 reference value: The value of a particular quantity (e.g., exposure rate) that characterizes an accredited laboratory's radiation field. It is the "known" value to which the indicated value of an instrument under calibration is compared.

A3.4 scattered radiation: Radiation that, as the result of interaction with matter, has had its direction changed and, for some interactions, its energy decreased.

A4 Management system, audit, and review

The exposure (air kerma) rate specified by the secondary accredited laboratory as its reference value shall be within ± 5% of the actual value defined by comparison with the national standard above 100 mR/h, and within ± 7% of the actual value from 0.5 mR/h to 100 mR/h. This level of agreement with the national standard shall be demonstrated through periodic proficiency tests of the secondary accredited laboratory by NIST.	The exposure (air kerma) rate specified by the tertiary accredited laboratory as its reference value shall be within ± 5% of the actual value defined by comparison with a secondary standard above 100 mR/h, and within ± 7% of the actual value from 0.5 mR/h to 100 mR/h. This level of agreement with the secondary standard shall be demonstrated through periodic proficiency tests of the tertiary accredited laboratory by a secondary accredited laboratory. The tertiary laboratory shall determine and state the uncertainty with respect to the national standard.

Calibration and proficiency testing shall comply with sections 5.6.1 and 5.6.2.

A5 Accommodation and environment

A5.1 The source storage container shall provide sufficient shielding such that leakage radiation does not raise the background to a level where it will interfere with other calibrations performed in the vicinity.

A5.2 The contribution from scattered radiation shall not exceed 25% of the exposure (air kerma) rate at any location where a detector is placed for instrument calibration, or the effect of scattered radiation on the accuracy of the calibration of each instrument type shall be known (relative to a field in which scattered radiation contributes less than 25% of the exposure (air kerma) rate). The approximate energy spectrum of scattered radiation should be known.

A5.3 For collimated beam facilities, the gamma beam emitted from the source storage container should be collimated so that its size is limited to the minimum area consistent with calibration requirements.

A6 Equipment and reference materials

A6.1 One or more of the following sources shall be available for use in the calibration of instruments:

Radionuclide	Nominal Energy
^{241}Am	60 keV
^{137}Cs	660 keV
^{226}Ra	830 keV (mean)
^{60}Co	1.25 MeV

A6.2 The radiation fields produced by the sources shall cover a range of exposure (air kerma) rates suitable for instruments to be calibrated.

A6.3 The source storage container shall have a mechanism to control exposure in the gamma beam.

A6.4 The laboratory shall have the following operable equipment, dedicated to calibration use:

- Reference standard ionization chambers to cover the energy and intensity ranges used for calibration services, with electronic instrumentation suitable for proper utilization of the chambers.
- An independent measuring system for periodic verification of the performance of the reference standard chambers and electronics. This system should have sufficient precision to ensure that stated accuracy goals are met.

- A voltmeter capable of measuring voltages applicable to instruments being calibrated.

A positive method to define the central axis of the gamma beam. Working standard ionization chambers to cover the energy and intensity ranges used for calibration services.	

A6.5 Additional Equipment

The secondary accredited laboratory should also have available a pulser, oscilloscope, current source, and standard capacitors.	

A7 Calibration methods

A7.1 The gamma radiation field used for calibration shall be characterized in terms of exposure (air kerma) rate as a function of distance from the source. The exposure (air kerma) rate shall be known at each distance used.

A7.2 Beam Uniformity

The intensity of the gamma beam shall not vary more than 5% across the useful area of the beam.	The intensity of the gamma beam shall not vary more than 10% across the useful area of the beam.

A7.3 If the gamma beam is used for calibration of exposure-integrating instruments, appropriate time control shall be used. Any associated timing errors shall be considered, such as the transit time of the exposure control mechanism.

A7.4 Attenuators

If an attenuator is used to reduce the exposure (air kerma) rate at any location in the radiation field, its effect on the energy spectrum of the radiation shall be known, or the effect of the altered spectrum on the accuracy of the calibration of each instrument type shall be known (relative to the unattenuated field spectrum).	If an attenuator is used to reduce the exposure (air kerma) rate at any location in the radiation field, its effect on the energy spectrum of the radiation should be known.

A7.5 Working Distance

The minimum distance between the source and the detector for the instrument under calibration shall be 10 times the largest dimension of the detector.	When using a free-air facility, the minimum distance between the source and the detector for the instrument under calibration shall be 5 times the largest dimension of the detector.

A7.6 Box-Type Calibrators

	Box-type calibrators shall only be used to compare the response of an instrument under calibration with that of a reference instrument of the same manufacturer's model. The reference instrument shall have been calibrated by a secondary accredited laboratory. One reference instrument shall be under subsequent continuing quality control in the tertiary accredited laboratory. A positioning method shall be used to ensure that the reference instrument and the instrument under calibration are identically positioned in the box.

A8 Certificates and reports

A8.1 The calibration report shall include, as a minimum, the radionuclide used, the reference value of the exposure rate or exposure (air kerma rate or air kerma), the corresponding indication by the instrument, and the instrument range setting (when applicable). The orientation of the instrument or detector while under calibration shall be described or illustrated.

APPENDIX B

SPECIFIC CRITERIA FOR X-RAY CALIBRATIONS OF SURVEY INSTRUMENTS

B1 Scope

B1.1 This Part sets out specific requirements in accordance with which a laboratory has to demonstrate that it operates if it is to be accredited by the Health Physics Society for calibrations using an x-ray source. The general requirements are set forth in Sections 4 and 5.

B1.2 The criteria contained in this Part apply to calibration of portable instruments at radiation protection levels using an x-ray source. If this calibration service is to be included in the scope of accreditation, the laboratory shall meet the requirements set forth in Sections 4 and 5 and Appendix B.

B1.3 The criteria that apply only to the secondary level appear in the left-hand column, and those that apply exclusively to the tertiary level appear in the right-hand column. Unless a distinction is stated, an item that covers both columns applies equally to both levels.

B2 References

ISO/IEC 17025, General requirements for the competence of calibration and testing laboratories.

B3 Definitions

The relevant definitions from Section 3 of this document are applicable. Further definitions applicable for the purposes of this Part are given below.

B3.2 half-value layer (HVL): The thickness of a specified substance which, when introduced into the path of a given beam of radiation, reduces the value of a specified radiation quantity upon transmission through the substance by one-half.

B3.3 homogeneity coefficient: The ratio of the first HVL to the second HVL or (1st HVL)/(2nd HVL). This value may be expressed as a simple ratio or it may be multiplied by 100 and expressed as a percentage. 2nd HVL is obtained by measurement of the 25% point (quarter-value layer QVL) minus the 1st HVL or 2nd HVL = QVL – 1st HVL.

B3.4 reference value: The value of a particular quantity (e.g., exposure rate) that characterizes an accredited laboratory's radiation field. It is the "known" value to which the indicated value of an instrument under calibration is compared.

B3.5 ripple: The periodic variation in the potential difference between the cathode and anode of an x-ray tube, resulting from rectification of an alternating current. As the ripple is decreased by the use of filtering circuits, a constant potential is more nearly approached.

B3.6 scattered radiation: Radiation that, as the result of interaction with matter, has had its direction changed and, for some interactions, its energy decreased.

B4 Management system, audit, and review

The exposure (air kerma) rate specified by the secondary accredited laboratory as its reference value shall be within ± 5% of the actual value defined by comparison with the national standard above 100 mR/h, and within ± 7% of the actual value from 0.5 mR/h to 100 mR/h. This level of agreement with the national standard shall be demonstrated through periodic proficiency tests of the secondary accredited laboratory by NIST.	The exposure (air kerma) rate specified by the tertiary accredited laboratory as its reference value shall be within ± 5% of the actual value defined by comparison with a secondary standard above 100 mR/h, and within ± 7% of the actual value from 0.5 mR/h to 100 mR/h. This level of agreement with a secondary standard shall be demonstrated through periodic proficiency tests of the tertiary accredited laboratory by a secondary accredited laboratory. The tertiary laboratory shall determine and state the uncertainty with respect to the national standard. The tertiary shall determine and state the uncertainty with respect to the national standard.

Calibration and proficiency testing shall comply with sections 5.6.1 and 5.6.2.

B.5 Accommodation and environment

B5.1 The approximate energy spectrum of scattered radiation should be known.

B5.2 Scattered Radiation

The contribution from scattered radiation shall not exceed 5% of the exposure (air kerma) rate at any location where a detector is placed for instrument calibration	The contribution from scattered radiation shall not exceed 10% of the exposure (air kerma) rate at any location where a detector is placed for instrument calibration.

B5.3 The x-ray beam emitted from the tube housing should be collimated so that its size is limited to the minimum area consistent with calibration requirements.

B6 Equipment and reference materials

B6.1 X-ray Machines

The secondary accredited laboratory shall use a constant-potential x-ray machine for calibration of instruments. Its maximum ripple shall be 5%, and it shall operate at potentials from 30 to 150 kV as a minimum range.	The x-ray machine used by the tertiary accredited laboratory for calibration of instruments shall have known ripple. If the ripple is greater than 10%, its effect on the response of each type of instrument calibrated shall be known and appropriate corrections made.

B6.2 The radiation fields produced shall cover a range of exposure (air kerma) rates suitable for instruments to be calibrated.

B6.3 A shutter should be used to control emission of the x-ray beam from the tube housing. The timing uncertainty due to the shutter transit time should be known. In lieu of a shutter, appropriate corrections (either to the calibration value or to the uncertainty) shall be made for voltage ramping times, as necessary.

B6.4 The laboratory shall have the following operable equipment, dedicated to calibration use:

- Reference standard ionization chambers to cover the energy and intensity ranges used for calibration services, with electronic instrumentation suitable for proper utilization of the chambers.
- An independent measuring system for periodic verification of the performance of the reference standard chambers and electronics. This system should have sufficient precision to ensure that stated accuracy goals are met.
- A voltmeter capable of measuring voltages applicable to instruments being calibrated.
- Filters to enable production of a variety of x-ray beam qualities.

A positive method to define the central axis of the x-ray beam. Working standard ionization chambers to cover the energy and intensity ranges used for calibration services.	

B.6.5 Additional Equipment

The secondary accredited laboratory should also have available a pulser, oscilloscope, current source, and standard capacitors.	

B7 Calibration methods

B7.1 The x-ray field used for calibration shall be characterized in terms of exposure (air kerma) rate at the location where the instrument (detector) is placed for calibration.

During calibration of an instrument the exposure (air kerma) rate shall not vary by more than ± 1%.	During calibration of an instrument the exposure (air kerma) rate shall not vary by more than ± 3%.

B7.2 The x-ray beam emitted from the tube housing shall be filtered before use for calibration purposes.

B7.3 Beam Uniformity

The intensity of the x-ray beam shall not vary more than 5% across the useful area of the beam.	The intensity of the x-ray beam shall not vary more than 10% across the useful area of the beam.

B7.4 Minimum Capability

The secondary accredited laboratory shall provide calibration services using at least five of the following x-ray beams:	The tertiary accredited laboratory shall provide calibration services using at least three of the following x-ray beams:

Beam * Code	First Half-Value Layer		Homogeneity Coefficient		Added Filter**		
	Al	Cu			Al	Cu	Pb
	(mm)	(mm)	Al	Cu	(mm)	(mm)	(mm)
M30	0.36		64		0.50		
M50	1.02	0.032	66	62	1.02		
H50	4.2	0.142	92	90	4.0		0.10
L80	1.83		58		1.28		
L100	2.8		59		1.98		
M100	5.0	0.20	72	55	5.0		
H100	13.5	1.14	100	94	4.0	5.2	
M150	10.2	0.67	87	62	5.0	0.25	

*The numerical value indicates the nominal kVp.
**This information on added filtration relates specifically to the NIST beams and may provide useful guidance.

NOTE: *Accredited services are not limited to the techniques listed above, but may include other techniques supported by NIST including the ISO techniques described in the ISO 4037 series of standards.*

B7.5 Beam Quality

The first half-value layer and homogeneity coefficients for a given x-ray beam shall be within 5% and 7%, respectively, of the values shown above.	The first half-value layer and homogeneity coefficients for a given x-ray beam shall be within 10% of the values shown above.

If necessary the indicated tube voltage or added filter, or both, may be adjusted to achieve those values.

B7.6 The radiation qualities shall be checked and documented for stability at least annually, or whenever the x-ray generator is repaired or the x-ray tube is replaced. Such a check may consist of determination of the half-value layers (first and second) for the highest and the lowest tube voltages used to provide beams for calibration services.

B7.7 Calibrations

When exposure-measuring (air kerma-measuring) instruments are calibrated, the shutter shall be operated by a timer or the exposure (air by kerma) shall be controlled by use of a transmission chamber. Any associated timing errors due to shutter transit times or high voltage ramping shall be known.	When exposure-measuring (air kerma-measuring) instruments are calibrated, the shutter should be operated by a timer or the exposure (air kerma) should be controlled by use of a transmission chamber. Any associated timing errors due to shutter transit times or high voltage ramping shall be known.

B8 Certificates and reports

B8.1 The calibration report shall include, as a minimum, the x-ray beam code used, the reference value of the exposure rate or exposure (air kerma rate or air kerma), the corresponding indication by the instrument, and the instrument range setting (when applicable). The orientation of the instrument or detector while under calibration shall be described or illustrated.

APPENDIX C
SPECIFIC CRITERIA FOR X-RAY CALIBRATIONS OF INSTRUMENTS
FOR DIAGNOSTIC LEVELS

C1 Scope

C1.1 This Part sets out specific requirements in accordance with which a laboratory has to demonstrate that it operates if it is to be accredited by the Health Physics Society for calibrations using an x-ray source. The general requirements are set forth in Sections 4 and 5.

C1.2 The criteria contained in this Part apply to calibration of instruments at diagnostic radiology levels using an x-ray source. If this calibration service is to be included in the scope of accreditation, the laboratory shall meet the requirements set forth in this Appendix in addition to general requirements in Sections 4 and 5.

C1.3 The criteria contained in this Part apply only to the level of the secondary accredited laboratory.

C2 References

ISO/IEC 17025, General requirements for the competence of calibration and testing laboratories.

C3 Definitions

The relevant definitions from Parts A and B of this document are applicable. Further definitions applicable for the purposes of this Part are given below.

C3.2 half-value layer (HVL): The thickness of a specified substance which, when introduced into the path of a given beam of radiation, reduces the value of a specified radiation quantity upon transmission through the substance by one-half.

C3.3 homogeneity coefficient: The ratio of the first half-value layer to the second half-value layer, multiplied by 100.

C3.4 reference value: The value of a particular quantity (e.g., exposure rate) that characterizes an accredited laboratory's radiation field. It is the "known" value to which the indicated value of an instrument under calibration is compared.

C3.5 scattered radiation: Radiation that, as the result of interaction with matter, has had its direction changed and, for some interactions, its energy decreased.

C4 Management system, audit, and review

The exposure (air kerma) rate specified by the laboratory as its reference value shall be within ± 5% of the actual value defined by comparison with the national standard. This level of agreement with the national standard shall be demonstrated through periodic proficiency tests of the laboratory by NIST. Calibration and proficiency testing shall comply with sections 5.6.1 and 5.6.2.

C5 Accommodation and environment

C5.1 The x-ray beam emitted from the tube housing should be collimated so that its size is limited to the minimum area consistent with calibration requirements.

C5.2 The effect of room-scattered radiation (relative to a radiation field with minimal room scatter) on the accuracy of calibration of each instrument type shall be known at each location where a detector is placed for instrument calibration.

C6 Equipment and reference materials

C6.1 The laboratory shall have a constant potential x-ray machine available for calibration of instruments. It should operate at potentials from 30 to 150 kV as a minimum range.

C6.2 The radiation field produced shall cover, as a minimum range, exposure (air kerma) rates from 20 to 100 R/h (180 to 900 mGy/h), with a stability sufficient to calibrate instruments according to documented laboratory procedures.

C6.3 A shutter shall be used to control emission of the x-ray beam from the tube housing.

C6.4 The laboratory shall have the following operable equipment, dedicated to calibration use:

- Reference standard ionization chambers to cover the energy and intensity ranges used for calibration services, with electronic instrumentation suitable for proper utilization of the chambers.
- An independent measuring system for periodic verification of the performance of the reference standard chambers and electronics. This system should have sufficient precision to ensure that stated accuracy goals are met.
- A voltmeter capable of measuring voltages applicable to instruments being calibrated.
- Filters to enable production of a variety of x-ray beam qualities.
- A positive method to define the central axis of the x-ray beam, and the boundaries of the useful area of the beam shall be known.
- Working standard ionization chambers to cover the energy and intensity ranges used for calibration services.

C6.5 Additional equipment should include a pulse generator, oscilloscope, current source, precision capacitors, and precision resistors.

C7 Calibration methods

C7.1 The x-ray field used for calibration shall be characterized in terms of exposure (air kerma) rate at the location where the effective center of the instrument's detector is placed for calibration.

C7.2 During calibration of an instrument, the exposure (air kerma) rate shall not vary by more than ± 1%.

C7.3 The x-ray beam emitted from the tube housing shall be filtered before use for calibration purposes.

C7.4 The laboratory shall provide calibration services using at least five of the following x-ray beams:

Beam * Code	First Half-Value Layer		Homogeneity Coefficient		Added Filter**		
	Al	Cu			Al	Cu	Pb
	(mm)	(mm)	Al	Cu	(mm)	(mm)	(mm)
M30	0.36		64		0.50		
M50	1.02	0.032	66	62	1.02		
L80	1.83		58		1.28		
L100	2.8		59		1.98		
M100	5.0	0.20	72	55	5.0		
M150	10.2	0.67	87	62	5.0	0.25	

*The numerical value indicates the nominal kVp.
**This information on added filtration relates specifically to the NIST beams and may provide useful guidance.

C7.5 For either copper or aluminum, the first half-value layer and homogeneity coefficients for a given x-ray beam shall be within 5% and 7%, respectively, of the values shown in the above table. If necessary the indicated tube voltage or added filter, or both, may be adjusted to achieve those values.

C7.6 If a transmission chamber is used for routine beam monitoring, it shall be considered to be added filter material.

C7.7 The intensity of the x-ray beam shall not vary more than 5% across the useful area of the beam.

C7.8 The radiation quality shall be checked for stability at least annually. Whenever any part that could affect the beam quality is repaired or replaced the above requirements for radiation quality shall be met.

C7.9 When exposure (air kerma) measuring instruments are calibrated, the shutter shall be operated by a timer or a suitable charge integrating device. Any associated errors due to shutter transit times shall be documented and eliminated or compensated.

C8 Certificates and reports

C8.1 An instrument calibration report shall include, as a minimum, the x-ray beam used for calibration, the reference exposure (air kerma) rate or rates at which the instrument was calibrated, the exposure (air kerma) rate indicated by the instrument, and the correction factor at each calibration point.

C8.2 In the case of integrating instruments, in addition to the x-ray beam and exposure (air kerma) rate, the reference exposure (air kerma), instrument reading, and correction factor shall be included.

C8.3 One calibration point and a linearity check should be included for each range of the instrument, where possible.

C8.4 The orientation of the instrument with respect to the radiation beam shall be described or illustrated in the calibration report.

C8.5 For instruments that use a vented ionization chamber, the reported values shall be referenced to a temperature of 22°C and a barometric pressure of 760 mm Hg, and the equation needed to convert to other temperatures and pressures shall be provided.

APPENDIX D
SPECIFIC CRITERIA FOR BETA-PARTICLE CALIBRATIONS

D1 Scope

D1.1 This Part sets out specific requirements in accordance with which a laboratory has to demonstrate that it operates if it is to be accredited by the Health Physics Society for calibrations using a beta-particle source. The general requirements are set forth in Sections 4 and 5.

D1.2 The criteria contained in this Part apply to calibration of portable instruments used to measure dose rate from external beta sources at radiation protection levels. If this calibration service is to be included in the scope of accreditation, the laboratory shall meet the requirements set forth in this Appendix and in Sections 4 and 5.

D1.3 The criteria that apply only to the secondary level appear in the left-hand column, and those that apply exclusively to the tertiary level appear in the right-hand column. Unless a distinction is stated, an item that covers both columns applies equally to both levels.

D2 References

ISO/IEC 17025, General requirements for the competence of calibration and testing laboratories.

ISO 6980-2, 2004, Nuclear energy – Reference beta-particle radiation – Part 2: Calibration fundamentals related to basic quantities characterizing the radiation field..

D3 Definitions

The relevant definitions from Parts A and B of this document are applicable. Further definitions applicable for the purposes of this Part are given below.

D3.1 extrapolation chamber: An ionization chamber in which the separation of electrodes is variable, thereby enabling a series of measurements with decreasing separation so that the measured ion current per unit volume can be extrapolated to the case of infinitesimal volume.

D3.2 point source: A radiation source whose maximum dimension is small compared with the source-to-detector distance used for irradiation of an instrument.

D3.3 reference value: The value of a particular quantity (e.g., dose rate) that characterizes an accredited laboratory's radiation field. It is the "known" value to which the indicated value of an instrument under calibration is compared.

D3.4 residual maximum beta energy, E_{res}: The maximum energy of the beta spectrum from all beta decay branches of a radionuclide at the calibration distance.

D3.5 residual maximum beta range, R_{res}: The range in an absorbing material of a beta spectrum of residual maximum energy, $E_{res.}$

D4 Management system, audit, and review

D4.1

The dose rate specified by the secondary accredited laboratory as its reference value for each beta-particle beam shall be within 10% of the true value as defined by comparison with a national standard. This level of agreement with the standard shall be demonstrated through periodic proficiency testing by NIST.	The dose rate specified by the tertiary accredited laboratory as its reference value for each beta-particle beam shall be within 10% of the value as defined by comparison with a secondary standard. This level of agreement with the standard shall be demonstrated through periodic proficiency testing by a secondary accredited laboratory. The tertiary laboratory shall determine and state the uncertainty with respect to the national standard.

Calibration and proficiency testing shall comply with sections 5.6.1 and 5.6.2.

D5 Equipment and reference materials

D5.1 Source of beta particles

The selection of a source for beta-particle calibration of an instrument will depend upon both the nature of the radiation field in which the instrument is to be used and the anticipated energy of the beta radiation. It is recommended that both point sources and distributed sources be available for instrument calibration since they represent the extremes of measurement geometry.

The radionuclides listed below are recommended for use as reference sources for beta calibration; however, other sources may be used if they more accurately represent the beta energy spectrum in which the calibrated instrument is to be used.

Radionuclide	E_{max} (keV)	Half-Life (y)
^{147}Pm *	225	2.62
^{99}Tc	290	$\sim 2 \times 10^5$
^{85}Kr	670	10.8
^{36}Cl	710	$\sim 3 \times 10^5$
^{204}Tl	763	3.8
$^{90}Sr/Y$ **	2270	28.5
U_{nat}	2290	$\sim 4 \times 10^9$
U_{dep}	2290	$\sim 4 \times 10^9$
$^{106}Ru/Rh$	3540	1.0

* ^{147}Pm usually also contains ^{146}Pm, which has an E_{max} = 780 keV.
** The source should be sealed with 100 mg/cm^2 (nominal) filtration to remove the ^{90}Sr beta component.

The secondary accredited laboratory shall have at least these sources of beta particles: ^{204}Tl or ^{85}Kr, and $^{90}Sr/Y$ and should have ^{147}Pm. These sources shall comply with the ISO 6980 standard.	

D5.2 Source contamination

Contamination by other radionuclides may significantly change the beta or gamma radiation field emitted from a source. Small levels of beta contamination are difficult to detect but are usually accompanied by gamma contamination. The beta spectral purity is considered to be adequate if: the plot used to measure R_{res} has a linear section and the E_{res} value meets the criteria in the table below; where R_{res} is the range in an absorbing material of a beta spectrum of residual maximum energy E_{res}.

E_{max}	E_{res}/E_{max}
< 100 keV	≥ 0.6
100 to 800 keV	≥ 0.7
> 800 keV	≥ 0.8

The procedures for determining E_{res} and R_{res} are given in the ISO 6980 standard.

Measurements to determine the adequacy of beta spectral purity shall be made every 2 years or more frequently if needed.

Photon contamination of the beta field due to sources of gamma, x-ray, or bremsstrahlung radiation should contribute less than 5% of the total absorbed dose.	Photon contamination of the beta field due to sources of gamma, x-ray, or bremsstrahlung radiation should contribute less than 10% of the total absorbed dose.

D5.3 Equipment

In addition to an appropriate selection of beta-particle sources, the laboratory shall have the following minimum equipment, dedicated to calibration use:

- Reference standards consisting of a thin-window fixed-volume ionization chamber or an extrapolation chamber. The chambers shall be suitable for the range of beta energies, intensities, and depth of dose measurement point for which calibration services are offered.
- Electronic instrumentation suitable for proper utilization of the chambers.
- An independent measuring system for periodic verification of the performance of the reference standard chambers and electronics. This system should have sufficient precision to ensure that stated accuracy goals are met.
- A voltmeter capable of measuring voltages applicable to instruments being calibrated.

The secondary accredited laboratory should also have available a pulser, oscilloscope, current source, and	

standard capacitors.	

D6 Measurement traceability and calibration

D6.1

The response of the reference standard shall have been verified by NIST or by comparison to NIST or PTB calibrated beta radiation sources.	The response of the reference standard shall have been verified by NIST, by a secondary accredited laboratory, or by comparison to NIST or PTB calibrated beta radiation sources.

D7 Calibration methods

D7.1 Radiation beam control

Control of a beam (field) of beta radiation used for instrument calibration shall be achieved by means of a shutter or by moving the source to an exposed position from a shielded position.

If the radiation source is used for the calibration of fluence measuring instruments, the radiation beam shall be controlled by a timer. The timing error due to shutter or source transit time shall be documented and eliminated or compensated.

D7.2 Beam parameters

The physical size of the beta-particle beam (field) shall have been predetermined to ensure that it is sufficiently large to accommodate the instrument being calibrated. Provision shall be made for identifying the central axis, and the boundaries of the useful area of the beam shall be known.

The beta dose rate should be uniform over the detector face. The dose rate across the beam profile at a depth of 7 mg/cm^2 should not vary more than 5% from the mean dose rate for E_{res} greater than or equal to 300 keV, and not more than 10% for E_{res} less than 300 keV. If necessary, beam-flattening filters may be used to meet these requirements. The uniformity of the beta field shall be verified by measurement with a small-area detector or film.

D7.3 Characterization of the field

The beta radiation fields used for calibration shall be characterized in terms of absorbed dose rate (at a depth in tissue of 7 mg/cm^2) at a given position or distance from the source. The dose rate shall be known at each distance used. Similarly, if calibrations are to be done at other tissue depths (for example, at 300 mg/cm^2 to simulate exposure of the lens of the eye, rather than 7 mg/cm^2 for the skin), then the dose rate at these depths shall be known.

D7.4 Attenuation

To ensure that the energy of the beta radiation that reaches the detector is similar to that originating from the radionuclide, certain limits on the calibration conditions are recommended. If E_{res} refers to the residual maximum energy of a beta particle reaching the detector of an instrument and E_{max} is the energy at which the beta particle originates, then the conditions shown in the table in Section D5.2 should be met.

These conditions are recommended so that no undue attenuation from the source self-absorption, containment, or from beam flattening filters or air attenuation will significantly change the beta spectrum emitted by the radionuclide.

D8 Certificates and reports

D8.1 The instrument calibration report shall include, as a minimum, the radionuclide and radiation field type (point source or flat field) used for calibration, the reference dose rate or rates at which the instrument was calibrated, and the dose rate (or dose) indicated by the instrument at each calibration point. The orientation of the instrument with respect to the radiation beam shall be described or illustrated. The report should state whether the front face or the effective center of the detector was located at the point where the reference field was characterized.

APPENDIX E
SPECIFIC CRITERIA FOR NEUTRON CALIBRATIONS

E1 Scope

E1.1 This Part sets out specific requirements in accordance with which a laboratory has to demonstrate that it operates if it is to be accredited by the Health Physics Society for calibrations using a neutron source. The general requirements are set forth in Sections 4 and 5.

E1.2 The criteria contained in this Part apply to calibration of portable instruments used to measure dose equivalent rate from external neutron sources at radiation protection levels. If this calibration service is to be included in the scope of accreditation, the laboratory shall meet the requirements set forth in this Appendix and in Sections 4 and 5.

E1.3 The criteria that apply only to the secondary level appear in the left-hand column, and those that apply exclusively to the tertiary level appear in the right-hand column. Unless a distinction is stated, an item that covers both columns applies equally to both levels.

E2 References

ISO/IEC 17025, General requirements for the competence of calibration and testing laboratories.

ISO 8529-1989, Neutron reference radiations for calibrating neutron-measuring devices used for radiation protection purposes and for determining their response as a function of neutron energy.

E3 Definitions

The relevant definitions from Parts A and B of this document are applicable. Further definitions applicable for the purposes of this Part are given below.

E3.1 free-field quantity: A radiation quantity, such as neutron dose equivalent, that has been corrected to remove contributions from scattered radiation (e.g., air scattering and room return).

E4 Management system, audit, and review

E4.1

The dose equivalent rate specified by the secondary accredited laboratory as its reference value for each field shall be within 10% of the true value as defined by comparison with a national standard. This level of agreement with the standard shall be demonstrated through periodic proficiency testing by NIST.	The dose equivalent rate specified by the tertiary accredited laboratory as its reference value for each neutron field shall be within 10% of the value as defined by comparison with a secondary standard. This level of agreement with the standard shall be demonstrated through periodic proficiency testing by a secondary accredited laboratory. The tertiary laboratory shall determine and state the uncertainty with respect to the national standard.

Calibration and proficiency testing shall comply with sections 5.6.1 and 5.6.2.

E5 Accommodation and environment

E5.1 The neutron source should preferably be used for calibration in a low-scatter environment in an open area or at the center of a large room (for example, 10 × 10 m square with the source 4 m from both floor and ceiling). The response due to room-scattered neutrons at the point of calibration should be less than 25% of the total instrument response, and the appropriate corrections shall be made.

E6 Equipment and reference materials

E6.1 Source of neutrons

The selection of a neutron source for calibration of an instrument will depend on the nature of the radiation field in which the instrument is to be used, including the anticipated neutron energy spectrum. The radiation field produced by a neutron source used for calibration shall provide an energy spectrum and dose equivalent rates appropriate for the instrument being calibrated.

The secondary accredited laboratory shall cover a minimum dose equivalent rate range of 10 mrem/h to 1 rem/h (0.1 to 10 mSv/h).	

As a minimum, the laboratory shall have one of the sources shown in the table below:

Source	Type of Reaction	Half-Life (y)	Neutron Energy max. (MeV)	avg. (MeV)
^{238}Pu(Be)	α,n	86.4	11.3	5.0
^{239}Pu(Be)	α,n	24390	10.74	4.5→5
^{241}Am(Be)	α,n	458	11.5	5.0
^{252}Cf	SF	2.654	15	2
^{252}Cf mod*	SF	2.654	15	0.54

*Moderated with 15 cm D_2O.

If a ^{252}Cf source is used, the secondary accredited laboratory shall be capable of calibrating an instrument using both the unmoderated and moderated source configuration.	

E6.2 Field contamination

Contamination of the neutron field by other types of radiation may contribute to the response of the instrument being calibrated. If this is the case and the instrument being calibrated is sensitive to photon and/or beta radiation as well as neutrons, the extent of this type of contamination shall be known and appropriate corrections shall be made.

Photon contamination of the neutron field shall be known and should be less than 20% of the total dose equivalent rate.	Photon contamination of the neutron field shall be known and should be less than 30% of the total dose equivalent rate.

E6.3 Equipment

In addition to one or more neutron sources appropriate for the instruments being calibrated, the laboratory shall have a measuring system for periodic verification of the dose equivalent rate produced by each source used for instrument calibrations. This system should have sufficient precision to ensure that stated accuracy goals are met.

An instrument of each type calibrated should be available for the measurement of the contribution of scattered radiation to the total instrument response.

E7 Measurement traceability and calibration

The neutron source strength of each source used for calibrations shall be certified by, or be traceable to, NIST.	The neutron source strength of each source used for calibrations shall be traceable to NIST.

E8 Calibration methods

E8.1 Radiation field control

The neutron radiation field used for calibration shall be carefully monitored and controlled.

Control of a field of neutron radiation used for instrument calibration should be achieved by means of moving the source from a shielded to an exposed position.

If the neutron source is used for the calibration of integrated dose equivalent measuring instruments, the radiation field shall be controlled by a timer. Any associated systematic timing uncertainties shall be documented and eliminated or compensated.

E8.2 Characterization of the field

The neutron radiation field used for calibration shall be characterized in terms of the fluence rate (flux density) and spectral composition at the point of calibration. The dose equivalent rate shall be calculated on the basis of these characteristics as a means of setting calibration points for specific instrument types. Relevant information is given in the following table.

Source	Fluence to dose equivalent conversion factor* ($rem \cdot cm^2$)	Specific source strength ($s^{-1} \cdot Ci^{-1}$)	Specific dose equivalent rate at 1 m** ($mrem \cdot h^{-1} \cdot Ci^{-1}$)
$^{238}Pu(Be)$		2.0×10^6	
$^{239}Pu(Be)$		1.5×10^6	
$^{241}Am(Be)$	3.8×10^{-8}	2.4×10^6	2.7
		($s^{-1} \cdot mg^{-1}$)	($mrem \cdot h^{-1} \cdot mg^{-1}$)
^{252}Cf	3.4×10^{-8}	2.4×10^9	2.3×10^3
$^{252}Cfmod$	9.1×10^{-9}	2.1×10^9	5.4×10^2

* The reference for calculation of these conversion factors is ISO 8529 – 1989 (1 rem = 0.01 Sv).

** These are typical numbers. Dose equivalent rate from a particular source depends upon variable factors such as purity, internal absorption, construction details, and encapsulation (1 mrem = 0.01 mSv).

E9 Certificates and reports

E9.1 The instrument calibration report shall include, as a minimum, the radionuclide and radiation field type (moderated or unmoderated) used for calibration, the free-field dose equivalent rate or rates at which the instrument was calibrated, the scatter-corrected instrument reading at each calibration point, and the basis for any calculation of dose equivalent rate from source emission rate. At least one calibration point should be included for each decade range of the instrument, where possible. The orientation of the instrument with respect to the radiation field shall be described or illustrated in the calibration report. The value of the scatter correction shall be provided.

APPENDIX F
SPECIFIC CRITERIA FOR ALPHA-PARTICLE CALIBRATIONS

F1 Scope

F1.1 This Part sets out specific requirements in accordance with which a laboratory has to demonstrate that it operates if it is to be accredited by the Health Physics Society for calibrations using an alpha-particle source. The general requirements are set forth in Sections 4 and 5.

F1.2 The criteria contained in this Part apply to calibration of portable instruments used to measure emission rate from external alpha-particle sources at radiation protection levels. If this calibration service is to be included in the scope of accreditation, the laboratory shall meet the requirements set forth in this Appendix and in Sections 4 and 5.

F1.3 The criteria that apply only to the secondary level appear in the left-hand column, and those that apply exclusively to the tertiary level appear in the right-hand column. Unless a distinction is stated, an item that covers both columns applies equally to both levels.

F2 References

ISO/IEC 17025, General requirements for the competence of calibration and testing laboratories.

F3 Definitions

The relevant definitions from Parts A and B of this document are applicable. Further definitions applicable for the purposes of this Part are given below.

F3.1 thin source: A radiation source consisting of alpha-emitting radioactive material uniformly distributed in a thin layer over the surface of a flat, metallic backing plate so as to cause minimal degradation of the alpha energy spectrum.

F4 Management system, audit, and review

F4.1

The emission rate specified by the secondary accredited laboratory as its reference value for each source of alpha radiation shall be within 10% of the true value as defined by comparison with an appropriate reference standard. This level of agreement with the standard shall be demonstrated through periodic proficiency testing by NIST.	The emission rate specified by the tertiary accredited laboratory as its reference value for each source of alpha radiation shall be within 10% of the value as defined by comparison with an appropriate secondary standard. This level of agreement with the standard shall be demonstrated through periodic proficiency testing by a secondary accredited laboratory. The tertiary laboratory shall determine and state the uncertainty with respect to the national standard.

Calibration and proficiency testing shall comply with sections 5.6.1 and 5.6.2.

F5 Equipment and reference materials

F5.1 Source of alpha radiation

Planar or pseudo-planar alpha radiation sources shall be used to calibrate instruments used for detection of alpha contamination. A pseudo-planar source is one made up of a closely spaced array of small sources.

The spacing of smaller sources to form a pseudo-planar source array shall be such that the point-to-point distance between sources is less than the range of alpha particles in air.

The combined thickness of the source media and overburden shall be less than one-tenth the range of the least energetic alpha particle in these media.

Only the following thin sources of alpha radiation are acceptable provided their 2π emission rate (per unit area) is known and traceable to a source calibrated by NIST:

- Natural or depleted uranium
- Plutonium-238 or -239
- Natural thorium or thorium-230.

The radiation fields produced by the sources shall cover a range of at least three decades of alpha emission rates suitable for protection-level calibration. A recommended range is 100 alpha particles per minute (2π emission rate) to 10^6 alpha particles per minute.

F5.2 Equipment

In addition to radiation sources, the laboratory shall have as a minimum the following equipment:

- A source and detector support and positioning system. The system shall provide for reproducible and accurate positioning of a detector with respect to the radiation source.

- An independent measuring system used as a means of checking the sources for any degradation of their alpha emission rate.

F6 Measurement traceability and calibration

The reference standard used by the laboratory shall be traceable to NIST.

F7 Calibration methods

F7.1 Source exposure

Because of the short range of alpha particles in air, calibration measurements using an alpha source shall be made in such a way that the alpha particles emitted from the source reach the sensitive volume of the radiation detector. To ensure that this is the case, there should be no shielding material between the alpha source and the detector, other than that inherent to the detector or source itself. Additionally, the surface of the radiation detector should be no farther than 3 mm from the surface of the alpha source.

F7.2 Source characterization

The source used for calibration shall be characterized in terms of alpha emission rate per unit area. The source shall overlap the detector in all directions from their common axis.

The relative standard deviation of the emission rate averaged over every individual segment of the source shall be less than 6%. The maximum area of a segment shall be 10 cm^2, and a segment shall not exceed 10% of the total surface area of the source.

F8 Certificates and reports

F8.1 The calibration report shall include, as a minimum, the alpha radiation source used for calibration, the emission rate or rates at which the instrument was calibrated, and the instrument response at each calibration point. At least one calibration point and a linearity check should be included for each range of the instrument, where applicable.

APPENDIX G

SPECIFIC CRITERIA FOR ENVIRONMENTAL LEVEL (NEAR BACKGROUND TO 0.5 mR/h) GAMMA-RAY CALIBRATIONS

G1 Scope

Gl.1 This Part sets forth specific requirements that must be met in order to be accredited by the Health Physics Society for calibrations using gamma radiation at environmental levels. General requirements are given in Sections 4 and 5.

G1.2 The criteria contained in this Part apply to calibration of portable instruments at environmental radiation levels using a gamma-ray source. If this calibration service is to be included in the scope of accreditation, the laboratory shall meet the requirements set forth in this Appendix, in Appendix A and in Sections 4 and 5.

G1.3 The criteria that apply only to the secondary level appear in the left-hand column, and those that apply exclusively to the tertiary level appear in the right-hand column. Unless a distinction is stated, an item that covers both columns applies equally to both levels.

G2 References

ISO/IEC 17025, General requirements for the competence of calibration and testing laboratories.

G3 Definitions

The relevant definitions from Appendix A of this document are applicable. Further definitions applicable for the purposes of this Appendix are given below.

G3.1 environmental radiation levels: For the purposes of this document, environmental radiation levels are defined between natural background and 0.5 mR/h. Exposure levels above this range are covered in Appendix A.

G4 Management system, audit, and review

The exposure (air kerma) rate specified by the secondary accredited laboratory as its reference value shall be within ± 10% of the actual value defined by comparison with a national standard.	The exposure (air kerma) rate specified by the tertiary accredited laboratory as its reference value shall be within ± 10% of the actual value defined by comparison with a secondary standard.

Calibration and proficiency testing shall comply with sections 5.6.1 and 5.6.2.

G5 Accommodation and environment

G5.1 The environmental calibration range shall be located in an area away from other sources of radiation within the facility. Background levels of less than 10 μR/h are highly desirable. The impact of the use of radiation sources within the facility must be established and documented. If other uses of radiation cause a variation of more than 20% of the background in the environmental calibration area, these uses of radiation within the facility must be suspended during environmental level calibrations.

G5.2 The source storage container shall provide sufficient shielding such that leakage radiation does not raise the background to a level where it will interfere with other calibrations performed in the vicinity.

G5.3 The contribution from scattered radiation shall not exceed 25% of the exposure (air kerma) rate at any location where a detector is placed for instrument calibration, or the effect of scattered radiation on the accuracy of the calibration of each instrument type shall be known (relative to a field in which scattered radiation contributes less than 25% of the exposure (air kerma) rate). The approximate energy spectrum of scattered radiation should be known.

G5.4 For collimated beam facilities, the gamma beam emitted from the source storage container should be collimated so that its size is limited to the minimum area consistent with calibration requirements.

G6 Equipment and reference materials

G6.1 One or more of the following sources shall be available for use in the calibration of instruments:

Radionuclide	Nominal Energy
^{241}Am	60 keV
^{137}Cs	660 keV
^{226}Ra	830 keV (mean)
^{60}Co	1.25 MeV

G6.2 The radiation fields produced by the source shall cover the environmental range of exposure (air kerma) rates.

G6.3 The source storage container shall have a mechanism to control exposure in the gamma beam.

G6.4 The laboratory shall have the following operable equipment, dedicated to calibration use:

- Reference standard ionization chambers to cover the energy and intensity ranges used for calibration services, with electronic instrumentation suitable for proper utilization of the chambers.
- An independent measuring system for periodic verification of the performance of the reference standard chambers and electronics. This system should have sufficient precision to ensure that stated accuracy goals are met.
- A voltmeter capable of measuring voltages applicable to instruments being calibrated.
- A positive method to define the central axis of the gamma beam.

- A radiation detection system with a sensitivity appropriate to measure the background levels in the calibration laboratory.
- A spectroscopy system for the characterization of the energy spectrum of the background.

G7 Measurement traceability and calibration

Measurement traceability will be established with a transfer quality instrument suitable for environmental level measurements (< 0.5 mR/h) that has been calibrated at NIST at the lowest available rates for each energy offered for calibration. Measurement traceability will be confirmed through the satisfactory performance of a NIST proficiency test performed within the environmental rates offered by the laboratory.

G8 Calibration methods

G8.1 The gamma radiation field used for calibration shall be characterized in terms of exposure (air kerma) rate as a function of distance from the source. The exposure (air kerma) rate shall be known at each distance used.

G8.2 Beam uniformity

The intensity of the gamma beam shall not vary more than 5% across the useful area of the beam.	The intensity of the gamma beam shall not vary more than 10% across the useful area of the beam.

G8.3 If the gamma beam is used for calibration of exposure integrating instruments, appropriate time control, beam monitor or manual timer shall be used. Any associated timing errors shall be considered, such as the transit time of the exposure control mechanism.

G8.4 Attenuators shall not be used to establish the environmental rates.

G8.5 Calibration distance

The minimum distance between the source and the detector for the instrument under calibration shall be 5 times the largest dimension of the detector.	When using a free-air facility, the minimum distance between the source and the detector for the instrument under calibration shall be 5 times the largest dimension of the detector.

G8.6 Box-type calibrators shall not be used for environmental calibrations

G9 Certificates and reports

G9.1 The calibration report shall include, as a minimum, the radionuclide used, the reference value of the exposure rate or exposure (air kerma rate or air kerma), the corresponding indication by the instrument, the instrument range setting (when applicable) and the prevailing background at the time of calibration. The orientation of the instrument or detector while under calibration shall be described or illustrated.

APPENDIX H

RULES FOR THE USE OF THE HPS LOGO AND HPS ACCREDITATION FOR HPS-ACCREDITED CALIBRATION LABORATORIES

An AICL or ASCL shall follow HPS CRITERIA when advertising its accredited status (including the use of the AICL or ASCL logo) on letterheads, brochures, test reports, and professional, technical, trade, or other laboratory services publications.

1. The terms "AICL" and "Accredited Instrument Calibration Laboratory" and the AICL logo as attached are registered trademarks of the Health Physics Society and may be used only by an HPS-accredited laboratory.

2. Likewise, the terms "ASCL" and "Accredited Source Calibration Laboratory" and the ASCL logo as attached are registered trademarks of the Health Physics Society and may be used only by an HPS-accredited laboratory.

3. The HPS reserves the right to control the quality of the use of the terms "AICL" or "ASCL" and of the logo itself.

4. Permission for advertising HPS accreditation and the use of the logo is conditional on and limited to those cases of calibration or test reports that describe calibration or testing within the scope of HPS accreditation.

5. References to HPS accreditation and the use of the logo are not permitted in calibration reports for beams, sources, or conditions outside the scope of accreditation without clearly delineating such beams, sources or conditions. In order to prevent confusion, the following disclaimer should be stated in the report:

   "This calibration is not within the scope of the HPS accreditation."

Approved logos of the Accredited Instrument Calibration and Source Calibration Laboratories

Color Versions

BW Versions

APPENDIX I

SPECIFIC CRITERIA FOR SOURCE PRODUCTION AND/OR CALIBRATION

I1 Scope

I1.1 This Part sets out specific requirements for accreditation by the Health Physics Society of laboratories providing calibration of sources claiming to be traceable to the National Institute of Standards and Technology (NIST) or other national standardizing laboratories. The requirements are set forth in sections I4-I6.

I1.2 The criteria contained in this Part apply to manufacture and/or calibration of NIST-traceable sources. If this service is to be included in the scope of accreditation, the laboratory shall meet the requirements set forth in sections I4-I7 of this Appendix.

I2 References

Institute of Electrical and Electronics Engineers. American national standard – traceability of radioactive sources to the national institute of standards and technology (NIST and associated instrument quality control. New York: Institute of Electrical and Electronics Engineers; ANSI N42.22-1995; 1995.

I3 Definitions

I3.1 Certified sources: Sources that have been certified for radionuclide activity (Bq); concentration (Bq/g); or alpha, beta, x-, or gamma-ray emission rate (s^{-1}).

I3.2 Derived traceable sources: Sources prepared or derived from certified sources that have been calibrated in accordance with the requirements of ANSI N42.22-1995. Examples are dilutions of a liquid standard and preparation of special geometries such as charcoal cartridges, Marinelli (re-entrant) beakers, and filters with single or multiple radionuclides.

I3.3 NIST report of traceability. This is a certification that validates the manufacturer's ability to accurately determine the activity of sources received from others (NIST and suppliers) and those that the manufacturer has produced (for internal standards and distribution). NIST compares the manufacturer's reported values for product verification against its own, and if appropriate, issues a report of traceability.

I3.4 NIST source verification: The process of verifying a manufacturer's ability to accurately determine the activity of radionuclides received from NIST and those used to manufacture NIST-traceable sources. This is achieved through calibration by the manufacturer of a source distributed by NIST without disclosure of the known value. The reported value is compared with the NIST value and, if appropriate, a report of traceability is issued.

I3.5 Proficiency testing for sources (Measurements Assurance Program (MAP)): A program that allows manufacturers to verify the accuracy of their measurements through exchange and measurement of samples with NIST. This involves the analysis of blind test samples sent to the manufacturers by NIST (NIST source verification), and NIST measurement of sources certified and provided by the manufacturers (product verification).

I3.6 Product verification: proficiency testing

I3.7 Source verification: The process of relating the measurement accuracy of radionuclide sources used as input materials in the source manufacturing process to national physical standards. This includes sources provided by NIST to test the manufacturer. Traceability is achieved by demonstrating the capability to produce accurate standardized sources by participation in a MAP with linkage to NIST and production of certified materials in accordance with a quality assurance program that meets the guidance provided in this standard. Traceability of sources requires demonstrated measurement traceability as described in I5.6 and applies only to products produced in accordance with this standard.

I3.8 Total propagated uncertainty: An estimate or approximation of the accuracy of a measured value by propagation of individual uncertainties in accordance with NIST recommendations.

I4 Product quality control (ASCL)

a) The calibration of radionuclides and production of sources shall be documented so that each step of the process can be verified or checked.
b) Sources shall be clearly identified and labeled when first prepared and should retain this identity in all subsequent steps.
c) Calibration results shall be reviewed and approved by a qualified individual other than the person performing the calibration.
d) Sources derived from traceable material shall be tested prior to distribution to verify the certificate value. For certified sources made in batches, appropriate sampling of the batch is acceptable if the process has been demonstrated to produce reproducible sources or there are unlikely to be significant differences between sources.
e) Appropriate tests shall be performed to demonstrate the stability of sources when the manufacturer specifies an expected lifetime or expiration date. Examples of tests include: evaluation of radiation damage for high-level sources, plate-out of radionuclides from solution, and homogeneity of solid sources.

I5 Measurement Assurance Program (MAP)

I5.1 The production of NIST traceable radionuclide sources requires periodic verification of measurements through participation in a MAP with NIST. Manufacturers shall, when possible, utilize both product verification and NIST source verification to ensure that preparation and quality control steps are adequate to provide the traceability of radionuclide sources. The MAP and associated verification measurements constitute a proficiency test of the manufacturer.

I5.2 Verifications (proficiency tests) with NIST shall be performed at least annually for each calibration technique and instrument type involving relative or comparative calibrations. Absolute calibration techniques shall be verified with NIST every 3 years or prior to use if used less often than every 3 years.

I5.3 For calibrations utilizing the same instrument and technique over a wide energy range, verifications (proficiency tests) shall include the following:

a) Separate tests for gamma-ray emitters with energies less than 250 keV and those with energies greater than 250 keV.
b) Separate tests for beta particle emitters with average energies less than 100 keV and those with average beta energies greater than 100 keV.
c) Separate tests for alpha-particle emitters used for high-resolution spectrometry and alpha particle emitters used for measuring total alpha activity.

I5.4 Each radionuclide for which traceable sources are issued should eventually be included in the testing program. However, until that time, traceability for an untested radionuclide is assumed if the calibration technique has been demonstrated for other radionuclides with like measured radiations for the energy ranges described in I5.3. The uncertainty attached to sources with indirectly tested traceability shall include uncertainties in radiation probabilities used, in assumed energy-efficiency relations, and in corrections for differences in geometry and scattering or absorption.

I5.5 Acceptance criteria

a) Successful verification (proficiency testing) by NIST requires that the difference between the NIST value and the value (test value) of the manufacturer be less than the total propagated uncertainty of the test value with a coverage factor of three (99% confidence level).
b) If the verification test (proficiency test) of a manufacturer does not meet these criteria, the manufacturer shall investigate the cause and resolve the difference with NIST. If the difference cannot be resolved within 90 days or within a time interval agreed to by NIST and the manufacturer, the standard in question and sources calibrated with the same instrument and technique shall not be considered traceable until a successful verification test has been performed.
c) If test results from a production lot do not meet the acceptance criteria, all customers receiving standards from that lot shall be notified of the disagreement with NIST and shall be provided with test results.

I5.6 Traceability of sources can be established if the following conditions are met:

a) NIST has certified the manufacturer's ability to analyze the particular combination of radionuclide and geometry.
b) The sources are received from suppliers in the appropriate geometry or are appropriately reconfigured.
c) The manufacturer appropriately analyzes and certifies the sources.

I5.7 Traceability of derived sources can be established if the following conditions are met:

a) The derived traceable sources are prepared from material that is traceable.
b) Appropriate tests are conducted to demonstrate that the preparation process has not adversely affected the accuracy of the original calibration. Testing shall be designed to verify sample homogeneity to the level of intended use, quantitative dilutions or transfers, chemical stability, radionuclide purity, and accuracy of the derived standard.
c) If derived sources are produced in lots, testing shall include appropriate sampling of the lot to ensure product integrity. Standards that are stored for significant periods of time and that may

be subject to deterioration (e.g., plate-out or hydrolysis of liquid sources, leakage from gaseous sources) shall be periodically tested or shall be tested prior to distribution.

NIST verification of derived sources (e.g., charcoal cartridges, solids, water equivalent sources, filters, etc.) is recommended. However, due to the diversity of secondary sources, opportunities for verification with NIST may be limited due to the costs and extra resources necessary for special calibrations. In this case, the derived sources may be termed traceable provided the procedures subsequent to establishment of traceability are subjected to an internal MAP that has been examined and approved by qualified individuals. Although the term *traceable* is applied to derived sources, NIST does not accept responsibility for the accuracy of the procedures used to prepare such sources, but may certify the final product.

I6 Measurement Assurance with National Standardizing Laboratory(NSL) other than NIST

I.6.1 In special situations where NIST cannot provide measurement verification of a manufacturer's standards, traceability may be established by demonstrating traceability with a NSL of another country. This would require the NSL to verify that the manufacturer adheres to International Committee for Radionuclide Metrology (ICRM) guidelines. The NSL would provide LAAC with a report providing documentation that the manufacturer adheres to the ICRM guidelines and a summary of the NSL's testing of the manufacturer's sources.

I7 Certificates and Reports

I7.1 The manufacturer shall provide a certificate for each standard and shall include at least the following information:

- Manufacturer
- Radionuclides calibrated
- Identification number
- Calibration method
- Activities or emission rates with total propagated uncertainties (Type A and Type B uncertainties combined in quadrature and multiplied by coverage factor)
- Calibration or reference date and time (if appropriate for the half-life of the radionuclide)
- Physical and/or chemical description of the source
- Radionuclide impurities
- Statement that the source calibration did or did not take place under HPS-accredited activities

I7.2 The certificate shall include SI units for all values. Supplemental information, including preparation and intended use, may be presented in accompanying notes or attachments to the certificate or product specifications.

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I7.3 In addition to the information required above, supplemental information should be provided with the source certificate as appropriate:

a) Liquid sources to be dispensed quantitatively by the user should be described in terms of chemical composition, acidity, carrier concentration, density, and total mass in grams. Special information needed for further dilution or deposition should be given in notes. For mixtures of solid particles (soil, dried biological materials, etc.), the details of homogeneity tests and the limiting sample size for which the standard may be used should be stated. Certificates for gases should include descriptions of dilution gases used when applicable.

b) Source dimensions including active area or volume for filters and the radionuclide distribution for charcoal cartridges or other media should be specified as part of the certificate. Blank samples of construction material (e.g., Mylar covering) should be available to a user for evaluating transmission or attenuation when necessary. Resolution tests for alpha-particle or low-energy photon sources should be described in sufficient detail to permit customers to determine their applicability for their use. Large area sources (greater than 10 cm^2) should be characterized with respect to surface uniformity.

I7.4 A brief description of the calibration method shall be specified (e.g., ionization chamber, gas proportional counter, etc.). For comparative measurements both the comparison instrument and the origin of its calibration should be specified. Literature references may be given if the method is not generally used or if special corrections or calculations are required.

I7.5 All identified impurities shall be listed together with their measured activities and uncertainties. An upper limit should be indicated for other possible impurities, as inferred from the known sensitivity of the stated measuring technique, with special reference to any impurities likely to have been produced with the primary radionuclide.

I7.6 The certificate shall contain a clear and unambiguous statement of the expanded uncertainty. The major components of the combined standard uncertainty should also be given, together with a statement of the method by which they have been combined to obtain the expanded uncertainty. If the quoted uncertainty is less than the uncertainty reported in verification tests with NIST for the same radionuclide and calibration technique, then the certificate should state the justification for the lower estimate of uncertainty. Generally, the stated uncertainty should not be lower than the uncertainty specified by the manufacturer in the most recent NIST verification test.

I7.7 Each certificate should include decay data and references relevant to the calibration and intended use of the source. Notes accompanying the sources should provide warnings about any special precautions to be taken in the use of the source (such as those relating to fragility or sensitivity to moisture). Application notes dealing with common problems (cascade summing, interference from Compton edge, etc.) affecting complex applications such as gamma-spectrometry should be included.