CRITERIA FOR ACCREDITATION OF

DOSIMETRY CALIBRATION LABORATORIES

BY THE

AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE

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I. INTRODUCTION

1 HISTORICAL BACKGROUND

In 1971 the American Association of Physicists in Medicine (AAPM) formed a task group to develop guidelines for the establishment of a system of secondary standard calibration laboratories for the benefit of the AAPM membership and their institutions. The laboratories, later known as accredited dosimetry calibration laboratories (ADCLs), would be accredited by the AAPM to provide high precision dosimetry calibrations traceable to the National Bureau of Standards (now the National Institute of Standards and Technology, NIST). Pursuant to Article Three of AAPM Charter, "To promote the application of physics to medicine and biology," the secondary laboratory accreditation system was created with the following purposes:

a. To reduce the time required for precision calibrations. The growth of radiation therapy facilities in the United States had created a demand for precision calibrations of dosimetry instrumentation, which NIST was not able to satisfy in a reasonable period of time, resulting in backlogs of nearly a year in obtaining these calibrations.
b. To create a system of secondary standard laboratories (then referred to as Regional Calibration Laboratories). The high degree of accuracy and precision required for calibrations of radiation therapy instruments identified the need for the creation of not only a secondary standard laboratory system, but also the need to maintain close traceability to NIST on an ongoing basis. With the cooperation of NIST, the AAPM established its first measurement assurance program (MAP) for dosimetry instrumentation in the US, which required regular ADCL comparisons with NIST and other laboratories in the secondary system.
c. To establish a technical resource for the membership of the AAPM. The laboratory system was established to serve the AAPM membership as a technical resource by providing advice and assistance in the use of dosimetry instrumentation, the use of the calibration results and the evaluation and resolution of problems encountered by the membership.

This document was prepared, edited and refined over the years since 1971 by the efforts of members of Task Group 3, the Subcommittee on Laboratory Accreditation of the Radiation Therapy Committee of the AAPM, and its task groups. This is now known as the Calibration Laboratory Accreditation (CLA) Subcommittee, hereafter referred to as the CLA, the Subcommittee, or the CLA Subcommittee.

In 1995, the Subcommittee initiated a major revision of the accreditation protocol to bring their existing Guideline document into agreement with ISO/IEC Guide 25 which was entitled "The Criteria for Accreditation of Dosimetry Calibration Laboratories by the American Association of Physicist in Medicine." Three Task Groups were identified for the purpose of developing a protocol for dose to water (TG-1), developing a protocol for the calibration of instruments used to measure diagnostic x-ray beams (TG-2) and developing a guidance document for the rejection of instruments (TG-3). Hereafter, it may be referred to as the "Criteria," or "this document."

In 2022, the Subcommittee made major revisions to the Criteria. The AAPM fully adopted the ISO/IEC 17025:2017(ISO/IEC 17025, 2017) standard as a means to determine laboratory competency and it is referenced in its entirety in this document. This adoption serves the purpose of streamlining these AAPM Criteria and removing competing requirements that have previously existed between the AAPM and the ISO standards. It also allows the Subcommittee to focus its efforts on determining and maintaining the specific technical criteria necessary for ADCLs to competently perform dosimetry calibrations. Adherence to the ISO/IEC 17025:2017 standard is now an AAPM requirement for accreditation, in addition to the AAPM technical requirements detailed in Section 6 of this document.

2 SCOPE

This document describes requirements and procedures for laboratories to be accredited as ADCLs by the AAPM. It is intended for use by the AAPM and the laboratories in its purview to assess the competency of a laboratory to perform dosimetry calibrations and compliance with the standard established by the AAPM described in this document. This document is to be used in conjunction with ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories, Third edition 2017-11; Reference number ISO/IEC 17025:2017 (E) for this purpose.

The following sections discuss the purpose of the ADCLs and the Subcommittee that oversees these secondary standards laboratories as well as the requirements for obtaining and maintaining AAPM accreditation of calibrations under its scope. Finally, the specific criteria used to determine competency in technical work and quality management are detailed.

Laboratories may seek accreditation by the AAPM to perform calibrations of:

a. Ionization chambers and *dosimetry systems* for measurements of exposure or air kerma for radiation therapy;
b. Ionization chambers and *dosimetry systems* for absorbed dose to water for radiation therapy;
c. Ionization chambers, electrometers, *dosimetry systems* and survey meters for measurements in diagnostic radiology;
d. Well-type ionization chambers for LDR and low-dose-rate (LDR) brachytherapy sources .
e. Well-type ionization chambers for high-dose-rate (HDR) brachytherapy source calibration;
f. Well-type ionization chambers for intravascular brachytherapy (IVB) applications.

Specific requirements for a-f are discussed in Section 6 of this document. Other radiation sources and dosimetry instruments used in diagnostic radiology, radiation oncology, and nuclear medicine that require NIST-traceable calibrations require development of amendments to these criteria.

3 AAPM ACCREDITATION

The AAPM calibration laboratory accreditation process is described in the Laboratory Accreditation Program Quality Manual, Revision 9 (2022), which contains the organization, functions, and responsibilities of the accreditation body. This document describes the requirements placed on a laboratory to be AAPM accredited.

3.1 Functions of an Accredited Dosimetry Calibration Laboratory

An ADCL is expected to perform, at a minimum, the following functions:

a. Being a secondary standard calibration laboratory for medical dosimetry applications.
b. Providing NIST *traceable* calibrations of sources and/or radiation measuring devices that meet or exceed the uncertainty goals established by the CLA for areas of accreditation listed in Section 2 above.
c. Serving as a technical resource for AAPM members and the medical community at large by providing technical advice and assistance in matters relating to calibration and use of dosimetry instrumentation and/or brachytherapy sources.
d. Participating in oversight activities of the CLA Subcommittee by having a representative at all meetings of the CLA Subcommittee and by providing annual reports of the activities of the ADCL. These reports shall include:
    1. a general statement of calibration activity;
    2. any changes in key personnel or facilities;
    3. any errors in the calibrations which exceed the stated laboratory uncertainty for the calibration in question;
    4. an analysis of any significant trends, including the number of instruments received that were unfit for calibration;
    5. any other information that the CLA Chair or ADCL director deems appropriate.

3.2 Accreditation Body Organization

The accreditation body organization is described in the Laboratory Accreditation Program Quality Manual, Revision 9 (2022).

3.3 Accreditation Components

AAPM accreditation consists of the following components:

a. Application: The application as described in Section 4.4.
b. Site Assessment Team: The CLA Chair appoints an assessment team leader. The team leader and the CLA Chair will jointly choose other assessment team members.
    1. Curricula vitae of the proposed assessment team members will be sent to the laboratory for approval prior to confirmation of the team members to the assessment team.
    2. The team leader will prepare an agenda for the accreditation assessment and forward it

to the laboratory for review.

c. External Validation: The laboratory must schedule and successfully complete *proficiency tests* with NIST and, where appropriate, *ADCL intercomparisons*. This may occur before or after the site visit. The candidate laboratory will bear the expense of the *proficiency tests* and *ADCL intercomparisons*.

d. Assessment: The approved assessment team will assess the laboratory to review the facilities, personnel, organization and required resources. The team will assess the competence of the laboratory's personnel and assess the adequacy of the procedures used for calibration of a suitable instrument(s) and/or source(s) to ensure compliance with these criteria. The assessment may be on-site, or remote.

e. Accreditation:

1. Provisional Accreditation: The AAPM Calibration Laboratory Accreditation Executive committee (CLAX) may grant laboratories provisional accreditation for a period of up to one year.
   a. The initial accreditation for new laboratories will be a provisional accreditation.
   b. Provisional accreditation of the candidate laboratory may be considered by the AAPM CLAX when the laboratory meets the following:
      i. Successful completion of the NIST proficiency test(s);
      ii. A positive recommendation by the site-visit team;
      iii. All in-scope criteria contained in this document.
   c. The accreditation status of an existing ADCL can be changed to provisional when significant changes occur at the ADCL, such as changes in personnel, ownership, equipment or protocol.
   d. The performance of provisionally accredited laboratories will be evaluated at the biannual CLA and CLAX meetings. The evaluation will consider such factors as comments or complaints, turnaround time, staffing changes, any problems or calibration errors reported, and such other considerations as the CLA Subcommittee deems appropriate.
   e. Transition from provisional accreditation to full accreditation, continued provisional accreditation, or revocation of accreditation is decided by CLAX, and may require further assessment, performed at the expense of the applicant laboratory.
   f. A lab shall have no more than 3 consecutive provisional accreditations.
2. Full Accreditation: Full AAPM accreditation may be granted by the AAPM CLAX for a period of up to four years. The accreditation decision shall be based upon a review of the past performance of the ADCL, its performance in NIST *proficiency tests*, its performance on ADCL intercomparisons, upon due consideration of any client comments or complaints, and upon full compliance with these Criteria.

f. Appeal of Accreditation: An applicant laboratory can appeal an accreditation decision to the CLAX, then to the AAPM Board of Directors. The decision of the Board of Directors is final.

g. Accreditation Certificate: Upon accreditation, the AAPM shall provide a certificate and the approved scope of the accreditation and confer accreditation to the ADCL whose performance meets all the requirements of these Criteria.

h. Surveillance: Maintenance of accreditation is subject to an ADCLs participation in surveillance assessments. Surveillance assessments shall be conducted at the discretion of

the Chair of the CLA Subcommittee.

1. Generally, a surveillance assessment will be scheduled one year after an initial assessment for new ADCLs, or two years after a re-accreditation assessment.
2. The surveillance assessment team shall review:
   a. The status of responses to findings and recommendations reported from the prior assessment;
   b. Customer feedback since the prior assessment;
   c. The ADCLs most recent management review;
   d. Evidence of continuous improvement (combining all the actions, corrective and otherwise).

4 GENERAL REQUIREMENTS FOR ACCREDITATION

4.1 Purpose

The AAPM accreditation is a voluntary activity of the Association conducted for the benefit of the AAPM membership and to promote the application of physics to medicine and biology under ARTICLE 3 of its Charter. The primary goal of the AAPM accreditation is to assure the continued availability of high quality secondary standard calibrations used by the membership and their institutions in the diagnosis and treatment of patients. The use of ADCLs reduces the service time and cost in obtaining these calibrations, both of which would be significantly greater for the membership were they required to seek primary calibrations from NIST.

The CLA Subcommittee's task is to manage the AAPM ADCL accreditation program to maintain the highest level of confidence in the quality of the ADCL system, with sufficient capacity in the system to prevent undue delays in satisfying the membership's calibration needs while providing a choice of ADCLs.

The term applicant refers to a laboratory seeking initial accreditation or reaccreditation throughout this section.

4.2 Conflict of Interest

The applicant institution must be free of any conflict of interest with regard to its ownership and/or business and its responsibility to provide unbiased calibration results, technical advice, and assistance to the AAPM membership.

AAPM accreditation is not for the benefit of commercial organizations engaged in the manufacturing, marketing, distribution, or sale of dosimetry instrumentation since this would represent a conflict of interest under the ADCL's role as a technical advisor. There are other agencies, such as the National Voluntary Laboratory Accreditation Program (NVLAP) and the American Association for Laboratory Accreditation (A2LA), which currently provide accreditation programs to serve commercial interests.

If the laboratory is part of a larger organization, the organizational arrangements should be such that administrative units having conflicting interests do not adversely influence the laboratory's compliance with the requirements of these Criteria.

4.3 Ability to Serve

The applicant laboratory must have the financial and technical resources to provide sufficient staff, facilities, management and other requirements contained in these Criteria in order to provide adequate sustained service to the membership.

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

4.4 Application for Accreditation

The AAPM adopts the standards in ISO17011:2017(E) Section 7.2 for applications for accreditation.

4.4.1 Application Process

a. An organization that desires to apply for new accreditation or renewal of accreditation should contact the AAPM Secretariat. The Secretariat shall provide the applicant organization with a copy of the Criteria and the Laboratory Accreditation Program Quality Manual.
b. A new applicant shall submit objective evidence to the Secretariat that:
    1. its operation is free of conflicts of interest or financial or management influence of the other activities of its business or any other business of the owner that would adversely affect the impartiality of its ADCL activities;
    2. it can provide the proposed accredited services.
c. Applications for re-accreditation: For timely renewal, the AAPM recommends that the renewal application, along with required fees, be submitted at least 10 months prior to accreditation expiration, with an assessment completed at least 2 months prior to expiration. The AAPM makes no guarantee that applications received with less than 10 months' notice will be reviewed prior to accreditation expiration.

4.4.2 Accreditation Application Requirements

Note: The term conformity assessment body from ISO 17011:2017(E) refers to the applicant laboratory or ADCL.

The applicant shall submit a formal application to the Secretariat that includes the following:

a. As specified in ISO 17011:2017(E) 7.2.1:
    1. general features of the conformity assessment body, including legal entity, name, address(es), legal status and human and technical resources;
    2. general information concerning the conformity assessment body such as its relationship

in a larger entity if any, addresses of all its physical location(s) and, information on activities conducted at all locations including virtual site(s);

3. a clearly defined scope of accreditation as defined in ISO 17011:2017(E) 7.8.3.c) for which the conformity assessment body seeks accreditation, including limits of capability where applicable;
4. a commitment to continually fulfil the requirements for accreditation and the other obligations of the conformity assessment body;

b. Additional AAPM-specific information:

1. a description of its laboratory and support facilities related to ADCL activities;
2. the names and qualifications of the persons involved in activities related to in-scope ADCL calibrations including:
   i. the individual(s) who perform the instrument calibrations and/or source calibrations and calculations;
   ii. the laboratory quality manager;
   iii. the individual(s) who review and sign formal calibration reports;
   iv. the individual who has primary responsibility for laboratory operations;
3. The applicant shall provide to the AAPM Secretariat information demonstrating that the accreditation requirements are addressed prior to commencement of the assessment, including:
   i. a copy of the laboratory's Quality Manual and associated documentation;
   ii. demonstration of the NIST traceability for each candidate scope item;
   iii. estimated uncertainties for each candidate scope item;
   iv. an assessor checklist for the Criteria completed by the laboratory indicating the sections of the Quality Manual satisfying each Criteria requirement.
   v. a crosswalk mapping that correlates the assessment criteria contained in this document with the laboratory's documentation for each element of the scope for which the laboratory desires accreditation;
   vi. The AAPM may request additional information before agreeing to consider accreditation or re-accreditation.

4.5 Surveillance assessment requirements

ADCLs shall provide the Secretariat the materials required for the surveillance assessment team to perform its assessment. The information required includes, but is not limited to:

a. Information regarding application materials which have changed since the (re-)accreditation assessment
b. Responses to findings and recommendations from the last (re-)accreditation assessment.
c. The most recent lab management and quality reviews.
d. Customer feedback received since the last (re-)accreditation assessment.
e. A summary of activities related to continuous improvement (combining all activities, corrective and otherwise).

4.6 Accreditation Requirements

4.6.1 Requirements from ISO 17011

By accepting accreditation, the ADCL agrees to the following requirements from Section 4.2, ISO 17011 (modifications from ISO 17011 marked with *).

a. *to continually fulfill the requirements for accreditation for the scope for which accreditation is sought or granted and to provide evidence of fulfilment. This includes agreement to adapt to changes in the requirements for accreditation;
   *The requirements for accreditation are contained within these Criteria.
b. to cooperate as is necessary to enable the accreditation body to verify fulfilment of requirements for accreditation;
c. to provide access to conformity assessment body personnel, locations, equipment, information, documents and records as necessary to verify fulfilment of requirements for accreditation;
d. to arrange the witnessing of conformity assessment activities when requested by the accreditation body;
   *The AAPM may schedule surveillance assessments at any time during the period of accreditation, though they are nominally done in the second year of an accreditation interval.
e. to have, where applicable, legally enforceable arrangements with their clients that commit the clients to provide, on request, access to accreditation body assessment teams to assess the conformity assessment body's performance when carrying out conformity assessment activities at the client's site;
f. to claim accreditation only with respect to the scope for which it has been granted;
g. to follow the accreditation body's policy for the use of the accreditation symbol;

    1. *The term "ADCL", "Accredited Dosimetry Calibration Laboratory", and the ADCL logo (Appendix E) are registered trademarks of the American Association of Physicists in Medicine and may be used only by the AAPM and organizations accredited by the AAPM.
    2. *An ADCL shall not use the term *Certified* or *Registered* when referencing its AAPM accreditation or its conformance to the Criteria. The correct term is *accredited*.
    3. *The AAPM reserves the right to control the use of the term "ADCL" and the quality of the logo itself.
    4. *Reproductions of the ADCL Logo shall be legible and not combined with other graphics.
    5. *The ADCL Logo shall not be used to imply product or service endorsement by the AAPM.
    6. *The term ADCL and the ADCL Logo shall be used in combination with the conformity assessment body's mark only with reference to in-scope accredited services.

7. *If the laboratory performs calibrations not covered by the AAPM scope of accreditation, such calibration reports must not use the ADCL Logo or otherwise claim to be an AAPM accredited activity.
8. (Templates of) client reports displaying the ADCL Logo shall be subject to CLA approval.

h. not to use its accreditation in such a manner as to bring the accreditation body into disrepute;
i. to inform the accreditation body without delay of significant changes relevant to its accreditation;
NOTE Such changes can concern:
- its legal, commercial, ownership or organizational status;
- the organization, top management and key personnel;
- resources and location(s);
- scope of accreditation;
- other matters that can affect the ability of the conformity assessment body to fulfil requirements for accreditation.

*Such changes are subject to review by the accreditation body and may require an assessment (at the expense of the laboratory) before deciding whether the changes are acceptable, and whether accreditation should be retained, retained provisionally, or withdrawn.

j. to pay fees as determined by the accreditation body;
*Required fees are at available at [https://www.aapm.org/links/adcl.asp]
k. to assist in the investigation and resolution of any accreditation-related complaints about the conformity assessment body referred to it by the accreditation body.

4.6.2 **Requirements for maintenance of accreditation:**

a. to pay expenses of assessments as required by the Subcommittee, a proportionate share of the CLA Error and Omission insurance, and a proportionate share of the cost of periodic NIST proficiency tests and ADCL intercomparisons to maintain calibration traceability to the NIST for all accredited activities;
b. to operate the ADCL in accordance to the protocols, quality manual, and management system that have been approved by the ADCL and submitted to the AAPM;
c. to inform the AAPM of substantive changes in the ADCL protocols, quality manual, calibration reports, management system, key personnel, or calibration report signatories;
d. to ensure the AAPM Secretariat receives a copy of the current ADCL protocol, ADCL quality manual, and calibration report templates These documents shall be maintained confidentially by the AAPM as proprietary property of the laboratory. Redactions are allowed where necessary to comply with state or federal regulations to permit the documents to be reviewed by assessors and confidentially kept by the AAPM.
e. to provide documentation of ISO/IEC 17025:2017 (E) compliance, in the form of audit

reports (or compliance accreditation) from organizations that perform ISO 17025 audits;

f. to abide by the terms of accreditation relating to the tenure of accreditation, attendance at CLA meetings, participation in proficiency tests, submission of required reports, retention of records, surveillance visits and all other requirements contained in this Criteria document;
g. to ensure that no certificate or report, nor any part thereof, is used in a misleading manner;
h. to inform the CLA Subcommittee in writing of any intention to discontinue operation as an ADCL at a reasonable time prior to the date of discontinuance.

4.7 Suspension or Revocation of Accreditation

A calibration laboratory retains its accreditation at the discretion of the AAPM. If compliance with these Criteria for accreditation or the performance of a laboratory is found to be unacceptable, accreditation or accredited scope elements may be suspended or revoked. Upon notice of revocation of accreditation status,

a. The laboratory shall immediately suspend accredited operation for scope items that fail to meet the Criteria.
b. The laboratory shall immediately suspend claims of accreditation for calibration services related to specific scope items that fail to meet the Criteria technical requirements.
c. A laboratory will be given the opportunity to demonstrate performance that is in accordance with these Criteria.
d. The Subcommittee may, at its discretion, reassess the laboratory and/or request that the laboratory perform special calibrations to demonstrate competence and compliance with the Criteria; the reassessment expenses are to be paid by the laboratory.

4.8 Discontinuance of Accreditation

In the event of a discontinuance of accreditation, all AAPM-accredited calibration records become the property of the AAPM. The laboratory shall

a. return its certificate of accreditation;
b. cease all claims of accredited operations;
c. forward all records regarding AAPM-accredited calibrations and operations to the AAPM unless otherwise directed by the AAPM.

II. CRITERIA FOR ACCREDITATION

5 GENERAL REQUIREMENTS

5.1 Designation of International Standard as AAPM Standard

5.1.1 In conjunction with the requirements, technical and otherwise, presented in this document, for the purposes of determining the competency of a laboratory, the AAPM, hereby adopts as a supplementary standard the ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories, Third edition 2017-11; Reference number ISO/IEC 17025:2017 (E) (hereafter, this document will be referred to as the ISO 17025 standard or ISO/IEC 17025:2017).

5.1.2 The AAPM requires compliance with all sections of the aforementioned ISO/IEC 17025:2017 standard as outlined in 5.1.4, unless notable exceptions are clearly defined in 5.2 and 5.3 that supersede the expressed requirements of the published ISO/IEC 17025:2017 standard.

5.1.3 Exceptional requirements that contradict, amend or invalidate a clause of the ISO/IEC 17025:2017 standard for the purpose of AAPM accreditation must be referenced in the related clauses of current AAPM Criteria 5.2 and 5.3.

5.1.4 Structure of the ISO/IEC 17025:2017 standard document:

ISO/IEC 17025:2017	Foreword
ISO/IEC 17025:2017	Introduction
ISO/IEC 17025:2017	1 Scope
ISO/IEC 17025:2017	2 Normative references
ISO/IEC 17025:2017	3 Terms and definitions
ISO/IEC 17025:2017	4 General requirements
ISO/IEC 17025:2017	5 Structural requirements
ISO/IEC 17025:2017	6 Resource requirements
ISO/IEC 17025:2017	7 Process requirements
ISO/IEC 17025:2017	8 Management system requirements
ISO/IEC 17025:2017	Annex A (informative) Metrological traceability
ISO/IEC 17025:2017	Annex B (informative) Management system options
ISO/IEC 17025:2017	Bibliography

5.2 AAPM Supplemental Requirements

5.2.1 ISO/IEC 17025:2017 clause 4.2.1 regarding confidentiality of client information does not apply to de-identified / masked data as this data does not identify a particular instrument, client, or institution.

5.2.2 ISO/IEC 17025:2017 clause 7.10 pertains to nonconforming work with respect to the laboratory procedures and client requirements. In addition to the ISO stipulations, nonconforming work shall include work that does not conform to the requirements of these Criteria and the laboratory *protocol*.

5.2.3 The AAPM utilizes the NIST definition of nonconformance as that of nonconforming work (NIST RPD-G-07). (See glossary.)

5.2.4 In addition to ISO/IEC 17025:2017 section 7.10, if an ADCL discovers a situation that has led or might lead to a calibration error in any phase of its operation, it shall notify the Subcommittee chair and CLAX chair. The chairs shall report the situation to all other ADCLs when appropriate. This notification shall be styled to alert the other ADCLs to the possibility of such an error to include an explanation of how the error occurred and a description of the steps taken to prevent a repetition.

5.2.5 ISO/IEC 17025:2017 clause 7.10.1.e requires contacting a client regarding nonconforming work. If an ADCL discovers an error in a calibration report, the client and the AAPM (CLA Chair) shall be notified within 1 business day of the discovery and the ADCL shall document the notification as well as good-faith efforts to procure a client receipt of the notification.

5.3 AAPM Excluded Requirement

5.3.1 There are no observed exclusions to the ISO 17025: 2017 standard at this time.

6 REQUIREMENTS FOR ACCREDITED CALIBRATIONS

This Section specifies the technical requirements for laboratories to be accredited by the AAPM for the calibration of instruments and sources for use in diagnostic and therapeutic radiation applications.

6.1 General Technical Requirements

6.1.1 Equipment and Facilities

In addition to meeting the requirements of ISO/IEC 17025:2017 Section 6, an ADCL shall have at a minimum, in operable condition, the equipment and facilities designated in this section and in subsections below pertaining to specific calibration services.

a. Such equipment and facilities shall be dedicated to laboratory use (e.g., equipment under the direct control of the laboratory), with exceptions clearly identified and justified, as appropriate.
b. Wherever required in this Section, redundant equipment or facilities should be dissimilar, since dissimilar instruments are less likely to change or fail in the same way.
c. Equipment and facilities used for accredited calibrations shall have *direct traceability* to NIST where specifically required by this document, and by calibration with NIST-traceable equipment when not specified.

6.1.1.1 Environmental monitoring equipment:

a. Two barometers (resolution of 0.1 kPa or better), each with NIST-traceable calibrations.
b. Two thermometers (resolution of 0.1 °C or better), each with NIST-traceable calibrations.
c. A device to measure relative humidity (RH) having a NIST-traceable calibration with an uncertainty (k = 1) of +/-7 % RH or better.
d. A device to measure background radiation wherever background radiation may influence the accuracy or reproducibility of the measurements.

6.1.1.2 Charge and current measurement equipment:

a. Two electrometers, both shall be capable of charge and current measurements.
b. Each electrometer shall meet the requirements of IEC 60731, 2016.
c. Analog electrometers of the feedback type shall have an open-loop gain of at least 10^4 and an input offset current of less than 10^{-13} A.
d. The electrometer circuit shall be electrically guarded at the potential of the input contact point.
e. Charge-leakage and input-offset current shall not exceed 0.1 % of any measured value.
f. Electrometers may utilize analog or digital circuitry and readouts provided they meet or exceed minimum performance expectations.

6.1.1.3 Voltage measurement equipment:

a. Two 4½-digit (or more) voltmeters.
b. One shall be capable of measuring at least 600 volts.

c. The accuracy and precision of both instruments shall be 0.1 % over the range of voltages required for calibrating the laboratory electrometers (6.1.1.2).

6.1.1.4 Sources of electrical potential:

a. Two sources of electric potential.
b. For chamber polarization: with accuracy of 5 % or better and stability sufficient to achieve measurement precision of 0.1 % or better.
c. For charge measurements: with sufficient accuracy to realize uncertainty required for electrometer calibrations (section 6.2).

6.1.1.5 Time measurement equipment:

a. A device for measurement of time, with traceability to NIST frequency or period time standards.
b. The timer shall be capable of measuring one to 100 second intervals with an accuracy exceeding 0.01 %.
c. Timer accuracy must be quantified.

6.1.2 Calibration service protocols

An ADCL shall specify its quality-control procedures and conduct its technical activities according to laboratory protocols specified in one or more documents (e.g. technical manual, quality manual, etc.), requirements for which are given in this section and in the calibration-service specific sections below.

Laboratory protocols for all calibration services shall include the following:

a. The procedure for acquiring and recording calibration data, which, in addition to requirements stated in ISO/IEC 17025:2017 Section 7.5 Technical Records, shall include:
    1. The date and time of calibration;
    2. The manufacturer of the item being calibrated;
    3. The model of the item being calibrated;
    4. The serial number or other unique identifying information;
    5. The name of the institution/client submitting the item for calibration;
    6. The name of the individual(s) performing calibration;
    7. The identifying information of laboratory equipment and *working standards* used to perform calibrations, such as make, model and serial number (or the location of where this information can be found);
    8. Instrument readings, including environmental conditions (temperature, pressure, humidity) at the calibration point;
    9. All calculations of calibration-coefficient correction factors;
    10. Any observed deviations from normal behavior or normal performance

characteristics;

11. Any significant modifications to instrument performance, such as upgrades and repairs.

b. The procedure for rejection of items submitted for calibration should include consideration of the following:
   1. Mechanical problems: generally determined by visual inspection. Examples include inadequate chamber waterproofing, broken thimbles, loose stems, etc.
   2. Electrical problems: generally determined by deviations from normal operational behavior or normal performance characteristics. Examples include excessive leakage, excessive stabilization time, etc.
   3. Any problems that impact accuracy, consistency or other aspects of performance. (Guidelines for rejection presented above and in subsequent sections pertaining to specific calibration services are not intended to limit the judgment of an ADCL, but to provide consistent criteria in support of rejection of items submitted for calibration.)
   4. The reasons for rejection of an instrument or brachytherapy source should be communicated to the client in a timely fashion.

c. The procedure for monitoring and controlling environmental conditions shall comply with the following:
   1. Ambient temperature, pressure, and relative humidity shall be stable, and be measured at a frequency such that values and variations are consistent with the stated calibration uncertainty.
   2. Calibrations performed when the laboratory relative humidity is between 20 % and 80% need not be corrected for humidity. Suspension of calibrations or application of correction factors may be necessary when relative humidity is outside this range.
   3. 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 either the tests or of other activities having an adverse effect on the environmental conditions.
   4. The laboratory shall compare barometers and thermometers at least annually, and log such comparisons. Whenever the tolerances established in the laboratory protocol are exceeded during the comparisons, the appropriate instruments shall be recalibrated or replaced.

d. The procedure for reviewing calibration data and signing calibration reports;

e. The procedure for comparing and/or calibrating each piece of listed laboratory equipment, and a statement of the frequency at which this is done;

f. Procedures necessary to achieve a calibration that falls within the uncertainty limits stipulated for each accredited calibration service.

g. Procedures for laboratory instrument calibration and procedures for data recording shall be documented and should be formulated so as to reveal changes in the performance of any laboratory equipment on which calibrations depend.
h. An analysis of the way in which laboratory procedures achieve redundancy in a measurement.
i. Digital readouts should be used when available unless specified by the client.
j. With auto-ranging electrometers, calibrations should be performed within the calibrated range requested by the client or an available clinically relevant range with the concurrence of the client, but shall be limited to the range approved on the scope of accreditation.
k. The laboratory shall review their protocols at least annually and whenever changes are made to such procedures, to ensure compatibility with laboratory quality-assurance goals and AAPM accreditation requirements.
l. The laboratory shall have a procedure for updating its protocol

6.1.3 **Calibration service quality requirements:**

An ADCL shall ensure that each accredited calibration service shall meet the following quality requirements:

a. A comprehensive uncertainty budget for each calibration service shall be developed and maintained to include the combined expanded (k=2) ADCL component of the uncertainty and the total expanded uncertainty (that combines ADCL and NIST components of uncertainty). (Appendix A: Guidelines for Uncertainty Assessment furnishes an example protocol for developing an uncertainty budget.)
    1. Measurement uncertainties shall comply with limits specified for each calibration service (see tables in subsections below pertaining to specific calibration services).
    2. Measurement uncertainties shall be reassessed during laboratory document review or when changes are made pertaining to the associated calibration service (see tables in subsections below pertaining to specific calibration services).
b. Traceability to NIST of accredited calibrations shall be maintained by:
    1. Inclusion of a NIST component of uncertainty in the total uncertainty provided in calibration reports, to be derived from laboratory standards used for calibration;
    2. "Satisfactory" performance in NIST *Proficiency Test* (PT), required as scheduled by the CLA (nominal intervals for which are stipulated for relevant calibration services in appropriate subsections below). Performance is "Satisfactory" if

$$\epsilon \equiv \frac{|x-y|}{\sqrt{U_x^2+U_y^2}} \leq 1.0, \text{ where}$$

x is the ADCL measurement result;
y is the NIST measurement result;
U_x is the ADCL component of the expanded uncertainty (k=2, expressed as an absolute uncertainty to yield ϵ as a unitless quantity);
U_y is the NIST component of the expanded uncertainty in y (k=2, expressed as an absolute uncertainty to yield ϵ as a unitless quantity).

Note: U_x and U_y are independent quantities with no cross-correlation. The uncertainty associated with the NIST standard must not be included because it is common to all ADCLs and NIST. Upper limits of U_x for each calibration service are given below.

c. The ADCL participates in *ADCL intercomparisons*.
   1. The ADCL that initiates the ADCL intercomparison repeats the calibrations / measurements at the end of the comparison to make sure that the instrument / source was not damaged or altered during the comparison.
   2. All calibration results, including the repeat values from the initiating laboratory, are sent to the CLA Chair for analysis. The comparison covers the areas of accreditation of each laboratory to the same areas of the other laboratories in the system (conversion to NIST beam codes when necessary)

d. The ADCL achieves satisfactory performance in *ADCL intercomparisons* (also known as Round Robins, RR). Performance in an RR is "Satisfactory" if the following conditions are met:
   1. Repeat values from the start and end of the RR from the same ADCL indicate instrument/device consistency as evaluated via:
      $\epsilon_{R1} \equiv \frac{|x_f - x_i|}{\sqrt{2}U} < 1.0$, where
      x_i and x_f denote repeat values (initial and final, respectively);
      U denotes the ADCL component of the expanded uncertainty (k = 2, expressed as an absolute uncertainty to yield ϵ as a unitless quantity).
      Failure of this criterion invalidates the RR for all participating ADCLs and may necessitate a repeat of the RR.
   2. The agreement of an ADCL with the other participating ADCLs does not exceed unity, as determine by

      $\epsilon_i \equiv \frac{|x_i - x_j|}{U_{ij}} \leq 1.0$, where
      x_i is the ADCL measurement for ADCL i ($i \forall$ ADCLs, $i \neq j$);
      x_j is the ADCL measurement for ADCL j ($j \forall$ ADCLs $j \neq i$);
      U_{ij} is the expanded uncertainty of the difference $|x_i - x_j|$ (k=2, expressed as an absolute uncertainty to yield ϵ as a unitless quantity).

Correlated components between U_i (the expanded uncertainty in x_i) and U_j (the expanded uncertainty in x_j) shall be excluded in computing U_{ij}. E.g. for calibrations involving a NIST source, uncertainty components due to calibration of the NIST source are correlated between the calibration of the reference-standards used at ADCL i and ADCL j, while the NIST calibration measurements of the reference-standard devices used at ADCL i and ADCL j are uncorrelated. *Failure of this criterion for any of the pairwise comparisons may necessitate repeating the RR for a subset of participating ADCLs, as determined by the CLA Chair.*

e. Local ADCL *reference standards* for electrical quantities (6.1.1.4)
   1. shall be inter-compared with redundant equipment annually;
   2. at least one of the inter-compared electrical standards in each comparison set shall be calibrated at least biennially (preferably at another facility). All such calibrations shall be traceable to NIST.

f. When possible, measurement procedures shall have a redundant *method* of determining a physical quantity to backup or confirm the primary measurement *method* (e.g. calculating decay rate and comparing to measurements of dose rate, or measuring charge and charge rate with a chamber and electrometer and comparing).

g. Redundant equipment shall be compared with NIST-traceable calibrated equipment at least annually for the express purpose of identifying and quantifying significant changes that may have caused or might lead to an error in a calibration.

6.1.4 **Reporting of Calibration Results**

In addition to the requirements stated in ISO/IEC 17025:2017 Section 7.8 Reporting of Results, all calibration reports for calibrations accredited by the AAPM shall include the following:

a. Name and address of the ADCL;
b. Report date;
c. Report number;
d. Complete name and address of person or institution to whom the calibration report is issued;
e. The manufacturer of the item being calibrated;
f. The model of the item being calibrated;
g. The serial number or other unique identifier of instruments or source being calibrated;
h. The date of calibration;
i. A unique identifier to access the data used in the determination of reported results;
j. Application of all appropriate correction factors. With the exception of electrometer calibrations, the calibration coefficients stated in the calibration report shall be corrected to standard reference conditions of 22°C (295.15 kelvin), 760 millimeters of Hg (101.325 kPa), and relative humidity (within the range of 20 % to 80 %), unless otherwise noted (sealed ion chambers) or requested by the client (e.g., calibration done at 20°C).
k. A statement of any significant modifications to instrument performance, if applicable;
l. A statement of any condition that may introduce a significant potential error, if applicable;
m. The combined expanded uncertainty (with a coverage factor k=2) which includes the NIST uncertainty of the standards used in the calibration.

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6.2 Criteria for Calibration of Electrometers

This Section contains accreditation criteria for the calibration of electrometers used for the purpose of radiation dosimetry.

6.2.1 Equipment and Facilities

The laboratory shall have and use equipment and facilities described below: (italicized terms are defined in the glossary).

6.2.1.1 At least two *Working Standard* charge sources, capable of delivering NIST-traceable quantities. These may consist of calibrated, reference-class capacitors (capacitor exhibiting stability of better than 0.1% per year, and dielectric absorption of less than 0.01 % in 10 seconds) combined with a reference-class voltage source (with a stability better than 0.05% per year) and/or reference-class voltmeter (capable of displaying at least five digits, exhibit an accuracy of better than 0.03%, and be capable of measuring at least 600 volts.).

6.2.1.2 A local ADCL *Reference Standard* to calibrate charge sources. This may be one of several possible *Reference Class Devices or Working Standard* assemblages, such as:

a. an electrometer, including a coulombmeter;
b. or a set of capacitors, a voltmeter, and an electrometer;
c. or a set of resistors, a voltmeter, a timer, and an electrometer

6.2.1.3 At least two *Working Standard* current sources, capable of delivering NIST-traceable quantities. These may consist of calibrated, reference class resistors (stability of better than 0.1 % per year) combined with a means to measure an applied voltage

6.2.1.4 Local ADCL *Reference Standard* to calibrate current sources. This may be a *Reference Quality Device* or *Working Standard* assemblages, such as:

a. an electrometer, including an ammeter;
b. a set of resistors, a voltmeter, and an electrometer.

6.2.1.5 A means of providing known voltages with accuracy and precision consistent with the quality assurance goals of the laboratory.

6.2.1.6 A means for confirming adequacy in the accuracy of the ADCL's electrometer exposure timing functions.

6.2.2 Calibration service protocol

The laboratory protocol shall include the following:

a. Technical records for electrometer calibrations shall include the following:
    1. Measure of charge collection polarities;
    2. Readout linearity data, if applicable;
    3. Pre-measurement leakage (zero drift);
    4. Post-measurement leakage (holding a charge).
    5. The calibration coefficients, $P_{elec,Q}$, for charge, and $P_{elec,I}$, for current, shall be expressed in terms of charge or current per reading.

6. The range for which the calibration coefficients $P_{elec,Q}$ and $P_{elec,I}$ are valid shall be stated.

b. Rejection of items submitted for electrometer calibration should consider the following:
   1. Leakage: If the background signal is greater than 0.05 % of the indicated calibrated range for the rate mode and 0.05 % per minute of the indicated calibrated range for the charge mode, the electrometer may be subject to rejection.
   2. Scale linearity: The ratio of the electrometer output reading to the known value of input is to be constant to within 0.5 % over the central two-thirds of the calibrated range. If not, the electrometer may be subject to rejection.
   3. Digit fluctuation: When the max-to-min fluctuation of the reading on the electrometer exceeds the greater of 0.1 % of the signal or one least-significant digit on digital readouts, the electrometer may be subject to rejection.

6.2.3 **Calibration service quality requirements:**

Per Section 6.1.3, uncertainty limits and recommended intervals for PT/RRs for calibration of electrometers are shown in Table below:

Instrument and Source		Cal Coeff	Expanded (k=2) uncertainty		PT/RR
			ADCL (%)	Total (%)	Nominal Interval (y)
Electrometers	charge	$P_{elec,Q}$	≤ 0.3	≤ 0.5	4
	current	$P_{elec,I}$	≤ 0.4	≤ 0.5	4

6.2.4 **Reporting of Calibration results:**

All calibration reports for electrometer calibrations shall include:

a. List of the calibration coefficients with the appropriate scales;
b. Notation of the scale reading at which a correction or calibration coefficient applies;
c. All electrometer settings;
d. Information about instruments and settings for ADCL local standards used to calibrate the electrometer (for example, capacitance values and magnitude and polarity of the polarizing potential applied with the calibrated voltage source.

6.3 Criteria for Calibration of Diagnostic X-ray Chambers

This section contains accreditation criteria for air-kerma (N_K) calibration of dosimeters and survey meters for the measurement of radiation produced by diagnostic x-ray machines. For diagnostic dosimeters, a distinction is made between reference-class and field-class devices, as follows:

Reference-class diagnostic dosimeter: A dosimeter capable of being calibrated in diagnostic x-ay beams (50 kVp to 150 kVp) to within an uncertainty of 2.5 % (k = 2) or a mammography dosimeter capable of being calibrated in mammography beams (20 kVp to 50 kVp) to within an uncertainty of 2 % (k = 2) relative to the NIST standard as absolute (i.e. excluding uncertainties in the NIST standard) and possessing a record of long-term stability of better than 0.5 % change per year.

Field-class diagnostic dosimeter: A dosimeter used to measure levels of radiation from common medical diagnostic x-ray sources in the field that is capable of being calibrated in diagnostic beams (50 kVp to 150 kVp) to within an uncertainty of 5 % (k = 2) or a mammography dosimeter calibrated in mammography beams (20 kVp to 50 kVp) to within an uncertainty of 3 % (k = 2) relative to the NIST standard as absolute (i.e. excluding uncertainties in the NIST standard).

Laboratories may be accredited for calibrating reference-class and/or field-class diagnostic dosimeters in any one or more of the categories itemized below:

General diagnostic dosimeters: instruments used to measure radiation levels from diagnostic beams with a nominal kVp in the range of 50 kVp to 120 kVp at air kerma rates greater than 0.5 mGy per minute;

Mammographic dosimeters: instruments used to measure radiation levels from diagnostic beams with a nominal kVp in the range of 20 kVp to 50 kVp;

Computed tomographic dosimeters: instruments used to measure radiation levels from diagnostic beams with a nominal kVp in the range of 70 kVp to 150 kVp;

Low-dose-rate dosimeters: instruments used to measure radiation levels from diagnostic beams with a nominal kVp in the range of 50 kVp to 120 kVp and at air kerma rates less than 0.5 mGy per minute.

Laboratories may be accredited for calibrating diagnostic x-ray survey meters, defined as follows:

Diagnostic x-ray survey meter: An instrument used to measure levels of ambient leakage or scatter radiation produced by diagnostic x-ray beams that is capable of being calibrated to within an uncertainty of 10 % (k = 2) in diagnostic beams (20 kVp to 150 kVp) and at air kerma rates greater than 10 µGy/h.

6.3.1 **Equipment and Facilities**

The laboratory shall have and use equipment and facilities described below:

6.3.1.1 Reference-class ionization chambers for each accredited category:

For each accredited dosimeter category, the laboratory shall have two reference-class ionization chambers with the following specifications:

a. Each reference-class ionization chamber used as a laboratory standard (for accredited beam qualities) shall have been calibrated at NIST.
b. The operating range of each reference chamber (or set of reference chambers) shall cover the in-scope range of beam qualities for the applicable scope category
c. The calibration coefficient for each chamber shall be consistent with the overall accuracy goals of the laboratory
d. Each chamber shall have appropriate wall thickness or buildup cap. Table 1 of the AAPM TG-61 report (Ma et al., 2001) provides wall thicknesses to provide full buildup as a function of x-ray tube potential.
e. For each chamber, the signal stability with age and environmental conditions shall be monitored to ensure operation is consistent with the overall accuracy goals of the laboratory.
f. Any one chamber may qualify for more than one category of diagnostic-type accreditation as long as it meets the requirements of each category.

6.3.1.2 The laboratory shall have a device for testing and documenting laboratory and client ionization chamber atmospheric communication performance.

6.3.1.3 Chamber-positioning devices of a type and quality adequate to restrict chamber-positioning error to a level consistent with uncertainty goals. The calibration position should be so located that scattered radiation shall not introduce a measurement error inconsistent with uncertainty goals;

6.3.1.4 Chamber polarization device:

At least one source of electric potential suitable for chamber polarization and charge measurement is required. The electrical potential should be known to within 1 % and the impact of electrical potential variations during a measurement session is quantified and included in the uncertainty budget.

6.3.1.5 X-ray machine(s)

In all cases the laboratory shall use x-ray machines that satisfy the following requirements:

a. X-ray generator voltage waveforms shall have a voltage waveform ripple of no more than 20 % peak-to-peak (with respect to the maximum voltage) at the nominal beam qualities specified for each category of calibration.
b. Machines shall be sufficiently collimated to minimize scatter to a level consistent with the overall accuracy goals. In all directions in the reference plane of the x-ray field, the linear dimensions of the field shall be at least 1.5 times larger than the corresponding linear dimension of the active volume of the dosimeter to be calibrated.
c. The calibration field profile shall be measured parallel and perpendicular to the anode-target direction on a plane perpendicular to the beam. Over the central 80 % of the

calibration field profile measured perpendicular to the beam, the radiation field intensity shall not vary by more than 5 % from the maximum intensity.

d. All beam-quality calibration points provided by the lab shall be consistent with NIST beam qualities (i.e. first and second HVL). For this purpose, the lab shall have a set of *Certified Reference Material* aluminum filters sufficient for the determination of first and second HVL, with the following specifications: purity of at least 99.99% for calibrations of mammographic dosimeters and at least 99.9% for any other category of dosimeter.
    1. All half-value layers shall be measured with these aluminum filters to within a precision of 4% (k=2).

e. The following requirements apply for calibration of each category of diagnostic dosimeter:
    1. For general diagnostic dosimeters: a tungsten anode tube and x-ray machine operating at nominal kVp ranging from 50 kVp to 120 kVp and capable of generating beams with a first half-value layer of 1 mm to 7 mm of aluminum.
    2. For mammography dosimeters: an x-ray machine with an anode material that matches the anode material of a NIST mammography beam code, with filtration materials matching the NIST filtration materials for the anode material. (molybdenum or rhodium anode with molybdenum, rhodium, or aluminum filtration). The x-ray machines nominal tube potential shall be between 23 and 35 kVp. Molybdenum anode machines shall be capable of generating beams with a first half-value layers of 0.28 mm to at least 0.39 mm of aluminum. Rhodium anode machines shall be capable of generating beams with a first half-value layer of 0.35 to at least 0.85 mm of aluminum. Mammography HVLs shall be known to within +/- 0.01 mm.
    3. For computed tomography dosimeters: a tungsten anode tube and x-ray machine operating with nominal kVp ranging from ≤100 kVp to ≥150 kVp and capable of generating beams with a first half-value layer of ≤5 mm to ≥10 mm of aluminum. HVLs shall be known to within +/- 0.1 mm.
    4. For low-dose-rate dosimeters: a tungsten anode tube and x-ray machine operating at nominal kVp ranging from 50 kVp to 120 kVp and capable of generating beams with a first half-value layer of at least 1 mm of aluminum. HVLs shall be known to within +/- 0.01 mm.
    5. For diagnostic x-ray survey meters: a tungsten anode tube and x-ray machine operating at nominal kVp ranging from 50 kVp to 150 kVp.

6.3.1.6 Transmission monitor:

Each x-ray machine shall be equipped with a transmission monitor.

a. The transmission monitor's collector shall be large enough to intercept the entire beam
b. Vented transmission monitors shall be corrected for ambient air density in the vicinity of the monitor.
c. When applicable, monitor chamber heating from the x-ray tube usage shall be accounted for.
d. The transmission monitor shall be sufficient to monitor the radiation exposure delivered to the calibration field area and to meet the accuracy goals of the laboratory for each accredited beam quality.

6.3.1.7 Device to assess accuracy and stability of kVp:

A device is required to assess the accuracy and stability of the kVp and it shall be able to measure the kVp to within 2 % or 0.5 kVp of the intended value, whichever is larger, with a precision of 1 % (k = 2).

6.3.2 Calibration service protocol

The laboratory protocol shall include the following:

a. Technical records for diagnostic dosimeter and x-ray survey meter calibrations shall include the following:
    1. Chamber orientation with respect to beam direction by a defining mark.
    2. Special geometry considerations.
    3. Method and results of atmospheric communication verification, where appropriate. Some chambers have communication openings which may be checked with appropriate tools. Others require the use of a device for testing atmospheric communication.
    4. Full-to-half voltage charge ratio (devices with adjustable bias only).
    5. Beam quality, kVp and mA of the x-ray generator.
    6. Collection times.
    7. Results and precision findings for rate-mode measurements at an air-kerma rate within the useful range of the device being calibrated.
    8. Results of other tests performed, such as scale linearity, air communication and ion recombination.
b. Rejection of items submitted for diagnostic dosimeter and survey meter calibration should consider the following:
    1. If the calibration coefficient differs from past or expected values by more than 3.0 %, the cause should be investigated and the chamber may be subject to rejection.
    2. If the leakage of the chamber exceeds 0.5 % of the signal, a warning should be issued and if it exceeds 2.0 %, the chamber may be subject to rejection.
    3. If an air vented ionization chamber does not equilibrate with ambient pressure in one minute, it may be subject to rejection. If the chamber is designed to be sealed or pressurized and it vents to the atmosphere, it may be subject to rejection.

6.3.3 Calibration service quality requirements:

a. Per Section 6.1.3, uncertainty limits and recommended intervals for PT/RRs for calibration of dosimeters and survey meters for radiation produced by diagnostic x-ray machines:

Instrument and Source		Cal Coeff	Expanded (k=2) uncertainty		PT/RR
			ADCL (%)	Total (%)	Nominal Interval (y)
Reference-class mammography dosimeters	20 kVp-50 kVp	N_K	≤1.5	≤ 2.0	4
Reference-class for categories *other than* mammography dosimeters	50 kVp-150 kVp	N_K	≤3.2	≤ 3.5	4
Field-class mammography dosimeters	20 kVp-50 kVp	N_K	≤2.6	≤ 3.0	-
Field-class instruments for categories *other than* mammography dosimeters	50 kVp-150 kVp	N_K	≤4.6	≤ 5.0	-
Survey meters	All beam qualities	N_K	≤9.4	≤ 10	-

6.3.3.1 A procedure for establishing accredited beams and verifying beam qualities.

6.3.3.2 A procedure for measuring the thickness of the aluminum filters used to measure HVL.

6.3.4 **Reporting of Calibration Results**

All calibration reports for diagnostic dosimeter and survey meter calibrations shall include:

a. Calibration coefficients appropriately corrected for reference conditions (6.1.4);
b. Meter or scale range at which a calibration coefficient applies;
c. Electrometer settings of the calibrated instrument, if applicable;
d. Magnitude and polarity of the polarizing potential, if applicable;
e. Chamber leakage at time of calibration;

f. Beam quality;
g. Beam size;
h. Source-to-chamber distance;
i. Nominal air kerma rate;
j. Angle of the chamber axis relative to the beam axis;
k. In addition, the following are required:
    1. The *calibration coefficients* contained in the report shall be given in units of *air kerma* or air kerma rate per unit of meter reading. Other units such as units of exposure or exposure rate may also be given in the report as required by the client.
    2. When a cable-connected ionization chamber is submitted without an accompanying electrometer, the calibration coefficient shall be expressed in terms of air kerma per unit charge.
    3. For ionization chambers designed to communicate with the atmosphere, the report shall state the adequacy of the chamber communication, when atmospheric communication testing is possible. If the chamber cannot be tested for atmospheric communication, this shall be stated in the calibration report.
    4. If the wall thickness of the chamber or other performance characteristics of the dosimeter are not suitable for the calibration beam quality, a statement on how this might affect the performance of the measuring device (e.g., energy dependence due to thick wall or characteristics of the detector) shall be included in the report.
    5. The report shall include a statement regarding the applicability of the calibration for those units that have a temperature and/or a pressure sensing unit or other features that compensate for atmospheric conditions. The report shall clearly state the conditions under which the calibration was done and the limitations that apply.

6.4 Criteria for Calibration of Therapy Ionization Chambers

This Section contains accreditation criteria for air-kerma (N_K) or absorbed dose to water ($N_{D,w}$) calibrations of therapy ionization chambers in Co-60 and Cs-137 beams, and air kerma in kV x-ray beams.

6.4.1 Equipment and Facilities

The laboratory shall have and use equipment and facilities described below:

6.4.1.1 Two reference-class ionization chambers, each with calibration directly traceable to NIST for each calibration service within the laboratory's scope of accreditation. Reference-class ionization chambers shall meet the specifications in Table III of the Addendum to the TG-51 protocol for photon beam reference dosimetry (McEwen et al., 2014).

6.4.1.2 *Working standard* ionization chambers may be used for calibrations.

6.4.1.3 The laboratory shall have a device for testing and documenting ionization chamber atmospheric communication performance. When possible, the laboratory shall establish whether an ionization chamber communicates with the atmosphere. Some chambers have communication openings which may be checked with appropriate tools. Others require the use of a device for testing atmospheric communication;

6.4.1.4 Chamber-positioning device for each calibration unit (Co-60, x-ray etc.) and calibration configuration ($N_{D,w}$, N_K) of sufficient precision, accuracy and stability to meet laboratory uncertainty goals;

a. The point of calibration shall be of sufficient distance from the source of radiation such that the positioning error in distance is minimized to a level consistent with calibration uncertainty goals.
b. The calibration position should be located such that scattered radiation will not introduce a measurement error inconsistent with calibration uncertainty goals.
c. For absorbed-dose-to-water calibrations, the positioning device should allow for placement of the chamber at nominal depth of 5 cm (5 g/cm^2) in the water phantom.

6.4.1.5 For calibrations of absorbed dose to water, a water phantom having minimum filled volume with dimensions of 30 cm x 30 cm x 30 cm, with the following accommodations and requirements for use of ionization chambers in water:

a. The phantom shall be regularly monitored for water leaks to guard against water volume changes that might impact dosimetry measurements;
b. Chambers that are not inherently waterproof may be inserted in a latex sheath or PMMA sleeve of 1 mm maximum wall thickness. Use of non-client supplied sleeves or sheaths shall be noted on the calibration report;
c. Rubber or other non-PMMA or non-latex sheaths are not permitted for chamber calibrations;
d. The calibration of a chamber is to be performed by the substitution technique. There can be a number of chambers substituted in a given session between the initial and final reference or working standard chamber irradiations.

e. The beam may enter from either the top or a side of the phantom. For entrance from a side, the wall of the entrance side should not exceed 7 mm water equivalent of material with an effective atomic number of less than 10.

6.4.1.6 Requirements for beam sources:

a. For calibrations in Co-60 or Cs-137, a Co-60 unit or a Cs-137 unit (not necessarily dedicated) with intensity adequate to provide calibrations that meet the requirements of this document, including the following:
    1. The calibration distance shall be 80 cm source-to-chamber distance (SCD) or greater;
    2. The minimum distance between the measurement point and collimator, other structures, and a device, such as a transmission chamber shall be 25 cm;
    3. The collimators shall establish a 10 cm x 10 cm square field at the calibration position. The 10 cm x 10 cm field size is defined by the 50 % isodose line.

b. For calibrations in kV x-rays, an x-ray unit (not necessarily dedicated) capable of generating beams with half-value-layers of approximately 1 mm Al to at least 2.5 mm Cu. The intensity and stability of the x-ray unit must be adequate to provide calibrations that meet the requirements of this document, including the following:
    1. A set of *Certified Reference Material* copper filters having certified purities of 99.9% or greater and of appropriate thicknesses for determining half-value layers and homogeneity coefficients for all x-ray calibration beams.
    2. A set of *Certified Reference Material* aluminum absorbers having certified purities of 99.99% or greater and of appropriate thicknesses for determining x-ray beam half-value layers and homogeneity coefficients for all x-ray calibration beams.
    3. The collimators on x-ray sources shall establish suitable square or circular field sizes (e.g. a 10 cm x 10 cm square or a 10 cm diameter circular field at the calibration position (defined at the 50 % intensity level in air or FWHM)
    4. A full-beam transmission monitor with a means either to stabilize or to measure the temperature of the detection volume. The transmission monitor shall provide a precision of 0.1 % for the quantity being measured.

c. The radiation field shall be sufficiently collimated to minimize scatter to a level consistent with the overall accuracy goals.

d. In-plane and cross-plane field profiles covering the field size shall be measured using the relative response of a suitable detector (e.g., film, ion chamber, or detector array) in the plane of the calibration position.
    1. For air-kerma, field profile measurements shall be made in air, with appropriate buildup. The field profile is a measure of ionization charge or air-kerma as a function of position in the field.
    2. For dose-to-water calibrations, the field profile measurements shall be made at the calibration depth in water. The field profile is a measure of ionization chamber charge or absorbed dose-to-water as a function of position in the field.

e. Using the profiles from (d), the calibration field shall be characterized for each type of calibration (e.g., air kerma, absorbed dose to water) and (if applicable) phantom used for calibration. The characterization shall:

1. Allow determination of the beam central-axis location at the calibration distance consistent with the laboratory uncertainty goals.
2. The field size shall be determined as the distance between the two 50 % points (FWHM) on orthogonal profiles through the beam central axis for square fields, or the diameter for circular fields.
3. The beam central-axis on the calibration plane shall be defined as the geometric center of the region defined by the 50% isodose or isokerma contour.
4. Beam uniformity measurements shall be used to estimate the calibration uncertainty due to detector positioning uncertainties in a non-uniform field, or used to derive appropriate correction factors if necessary.
5. The laboratory shall utilize measurements and calculations to demonstrate and document that the field is suitable to accomplish the calibration objectives, including but not limited to accuracy, precision, and uncertainty of the calibration. This includes but is not limited to:
   i. Rigorous uncertainty analyses (propagation of errors and sensitivity tests).
   ii. Statistical analysis of measurement results.
   iii. Consideration of all relevant uncertainties in the calibration process, including but not limited to the data listed above, timer errors, fluctuations in ambient conditions, etc.
   iv. Clear and complete documentation explaining how uncertainties stated in the scope of accreditation were determined and how uncertainties in a client's calibration report are determined.

6.4.2 **Calibration Service Protocol**

The laboratory protocol shall include the following:

a. Technical records shall include the following:
   1. Beam quality;
   2. Beam intensity;
   3. Field size;
   4. Environmental conditions (pressure, temperature and humidity);
   5. Atmospheric communication findings;
   6. Polarizing potentials and polarities for charge collection;
   7. Readout linearity data, if applicable;
   8. Source-to-chamber distance;
   9. Leakage current (including stem leakage, if applicable);
   10. Orientation of the chamber;
   11. Location of chamber reference point, including depth when applicable;
   12. Ion-collection efficiency if measured;
   13. For air-kerma calibrations:
      i. Presence and material of buildup cap, if appropriate;
   14. For absorbed-dose-to-water calibrations:
      i. Temperature of the water inside the water phantom;
      ii. If a sleeve is used, information pertaining to its dimensions and material

composition.

b. Technical Procedures:
   1. Each chamber shall be calibrated to the reference point specified by the AAPM calibration protocol. For TG51 cylindrical chambers shall be calibrated to the center of the active volume and parallel-plate chambers shall be calibrated to the inside surface of the entrance window.
   2. Calibration coefficients shall be determined for negative charge collection if not specifically requested by a client.
   3. The ion recombination effect shall be measured by the full voltage and half voltage technique.(Almond et al., 1999) The final factor, $N_{D,W,\ ^{60}Co}$ or N_K, applies to 100 % collection efficiency. Thus, $N_{D,W,\ ^{60}Co}$ or N_K, shall reflect the chamber corrected to 100 % collection efficiency.
   4. The calibration coefficient, $N_{D,W,\ ^{60}Co}$ or N_K, shall be expressed in terms of absorbed dose to water per unit charge (Gy/C).
   5. For air-kerma calibrations
      i. Appropriate thickness buildup caps shall be utilized. (Ma et al., 2001)
      ii. For parallel plate chamber calibrations in low energy x-rays (tube potentials below 70 kVp), client supplied buildup caps shall be used, unless requested otherwise by the client.

c. Rejection of items submitted for therapy calibration should consider the following:
   1. If the ionization chamber calibration coefficient differs from past or expected values by more than 1.0 % for gamma ray calibrations or 2.0 % for x-ray calibrations, the cause should be investigated and the chamber may be subject to rejection.
   2. If the ionization chamber collection efficiency under calibration conditions is less than 99%, the chamber may be subject to rejection.
   3. If the ionization chamber leakage charge or current exceeds 1.0 % of the signal measured during calibration, the chamber may be subject to rejection. If the chamber leakage exceeds 0.1% of the signal, a warning or notification shall be issued to the client.
   4. If an air vented ionization chamber does not equilibrate with ambient pressure in one minute, it may be subject to rejection. If the chamber is designed to be sealed or pressurized and it vents to the atmosphere, it should be rejected.

6.4.3 **Calibration Service Quality Requirements:**

a. Per Section 6.1.3, uncertainty limits and recommended intervals for PT/RRs for calibration of therapy ionization chambers:

Instrument and Source		Cal Coeff	Expanded (k=2) uncertainty		PT/RR
			ADCL (%)	Total (%)	Nominal Interval (y)
Reference-class instruments, and ionization chambers submitted alone, suitable for calibration of other instruments with a precision of 0.1 %	^{60}Co	N_K	≤ 0.6	≤ 1.5	4
	^{137}Cs	N_K	≤ 0.6	≤ 1.5	10
	x-rays	N_K	≤ 1.0	≤ 1.5	4
	^{60}Co	$N_{D,w}$	≤ 0.8	≤ 1.4	4
Field-class digital instruments with 3 ½ or more digits, and ionization chambers submitted alone, suitable for therapy-beam calibration	^{60}Co	N_K	≤ 0.6	≤ 1.5	-
	^{137}Cs	N_K	≤ 0.6	≤ 1.5	-
	x-rays	N_K	≤ 2.2	≤ 2.5	-
Field-class digital instruments with fewer than 3 ½ digits, and analog instruments, suitable for therapy-beam calibration	^{60}Co	N_K	≤ 0.9	≤ 1.5	-
	^{137}Cs	N_K	≤ 0.9	≤ 1.5	-
	x-rays	N_K	≤ 2.2	≤ 2.5	-

6.4.4 **Reporting of Calibration Results**

All calibration reports for calibrations of therapy instruments in external beams shall include:

a. Beam quality;
b. Beam size;
c. Exposure and air kerma rate or dose rate (as applicable);
d. Electrometer settings (switch positions, meter or scale readings) at which calibration coefficient applies;
e. Potential applied and polarity of the potential, if applicable;
f. Charge polarity collected;
g. Pre-irradiation chamber leakage at the time of calibration;
h. A notation of the recombination value;
i. The measurement calibration reference point with respect to the chamber;
j. Source-to-chamber distance;
k. Depth of measurement, if applicable;
l. Angle of the chamber axis relative to the beam axis and chamber orientation;
m. The calibration coefficient shall be expressed in dimensions of absorbed dose per unit reading, air kerma per unit reading or exposure per unit reading.

6.5 Criteria for Calibration of Brachytherapy Sources and Well Chambers

This Section contains accreditation criteria for the calibration of low-dose-rate (LDR) brachytherapy sources and well chambers, electronic brachytherapy (eBT) well chambers, high-dose-rate (HDR) brachytherapy well chambers, and intravascular brachytherapy (IVBT) well chambers.

6.5.1 Equipment and Facilities

The laboratory shall have and use equipment and facilities described below:

6.5.1.1 At least one device for measuring the radiation from the sources to be calibrated. This device may be a re-entrant well-type ionization chamber or a device for measuring at a distance. This device must be equipped with positioning assemblies that will allow sources to be measured in multiple repetitions with signal reproducibility of ±0.5 % (for LDR, eBT and HDR devices) and ±2.0 % (for IVBT devices).

For IVBT calibrations, additional test equipment such as film or linear diode arrays may be used to further evaluate the source parameters, but may not be substituted for the standard well chamber in the NIST traceability chain of custody.

6.5.1.2 A redundant calibration from the *working standard* shall exist. The redundancy may be through an additional measuring device (ionization chamber) or an additional radioactive reference source. The redundant measuring device must be completely independent of the principal device such that the two would not be expected to malfunction in the same way simultaneously. A redundant source must be a different, preferably long-lived (half-life > 1 year) isotope.

6.5.1.3 For Ir-192 HDR well chamber calibrations, a reference-class thimble or spherical ionization chamber calibrated at NIST for M250 x-ray and Cs-137 radiations. Chambers shall have buildup caps as appropriate.

6.5.1.4 A timing device which provides a precision of 0.1 second and is traceable to NIST frequency or period standards.

6.5.1.5 Sources:

a. One long half-life source to be used to verify the constancy of calibration devices and instruments.
b. Seed model specific reference standard sources: All model-specific reference standard sources shall be *directly traceable* to NIST.
c. For LDR calibrations:
    1. For long half-life sources (>1 year) and LDR chamber calibrations, the laboratory shall have at least one sealed source of each isotope, manufacturer, model and encapsulation for which calibration will be offered. Each source shall have an activity within the range of activities for which routine clinical calibrations will be offered. Each source should have physical dimensions and cladding comparable to the sources routinely calibrated. Each source shall have *direct traceability* to NIST;

2. For short half-life (<1 year) sources and chamber calibrations, the laboratory shall have at least one *working standard* sealed source (at the time of a requested calibration) for the specific manufacturer and source model, which has been calibrated in the calibration device using the local standard (e.g., well chamber with calibration coefficient traceable to NIST) at the ADCL.

d. For eBT well chamber calibrations:
   1. An eBT system equivalent to the NIST eBT system used for producing x-rays for realizing the air-kerma rate of eBT miniature x-ray sources and calibrating eBT well chambers.

e. For HDR well chamber calibrations:
   1. An HDR source or access to an HDR source with the same radionuclide that was requested for calibration.

f. For IVBT calibrations:
   1. At least one sealed source of each isotope, manufacturer, model and encapsulation for which calibration will be offered. This source shall have an activity within the range of activities for which routine clinical calibrations will be offered. This source should have physical dimensions and cladding comparable to the sources routinely calibrated. This source shall have been calibrated at NIST or have traceability to NIST.
   2. For IVB source geometries, the laboratory shall have at least one *working standard* sealed source of each manufacturer and type offered for calibration which has been calibrated locally in the calibration device.

6.5.2 **Calibration Service Protocol**

The laboratory protocol shall include the following:

a. Technical records for LDR or eBT source calibrations shall include the following:
   1. For LDR seeds, description of source including isotope, physical dimensions, and identification code (e.g., manufacturer make, model and serial number). The ADCL may require the client to provide sufficient information to describe the source;
   2. Make, model and description of the instruments utilized;
   3. Description of the calibration technique;
   4. Identification of the source measurement geometry;
   5. Identification of timing device or electrometer containing the timing device;
   6. Reference date and time of calibration;
   7. Temperature in or at the laboratory well-type ionization chamber (for correction of unsealed well chambers);
   8. Barometric pressure in the measurement area (for correction of unsealed well chambers);
   9. Relative humidity (for correction of unsealed well chambers);
   10. All readings for standard source and sample source measurements;
   11. Leak test results;

12. Auto-radiograph and/or other test results of the source uniformity and length, if applicable.

b. Technical records for well-type chamber calibrations shall include the following:
   1. A complete description of each standard source used for the calibration, including the manufacturer, model, unique identifying information, isotope, encapsulation, active length, physical dimensions, and the air kerma strength (or dose to water at 2 mm for beta-emitting sources) at a reference date and time;
   2. For eBT well-type chamber calibrations, a description of eBT source, including physical dimensions and identification code (e.g., manufacturer make, model, and serial number), and the eBT source conditions used, including air-kerma rate and filament;
   3. A description of the source holder or device used to support the source;
   4. The orientation of the source and the distance from the chamber top or bottom;
   5. The method and instrumentation used to determine the exposure timing;
   6. The temperature in or at the well-chamber (for correction of unsealed well chambers);
   7. Barometric pressure in the measurement area (for correction of unsealed well chambers);
   8. Relative humidity (for correction of unsealed well chambers);
   9. The results of the atmospheric communication test, if performed (chambers sealed to atmospheric communication should be documented as such);
   10. The system leakage, if appropriate;
   11. Ion collection efficiency, if possible;
   12. Reproducibility tests on the support device;
   13. For beta-emitting IVBT sources, a description of the wall material and thickness of the source support used in the chamber;
   14. For calibrations with non-HDR sources, results of measurements with the source oriented in both vertical positions (flipped top-to-bottom).

c. Rejection of brachytherapy sources submitted for calibration should consider the following:
   1. If the source has removable radioactive contamination above accepted limits it may be subject to rejection;
   2. If the source description provided by the client is insufficient to meet the records and reporting requirements, it may be subject to rejection;
   3. If the source strength differs from expected values by more than 5.0 %, the source may be subject to rejection.

d. Rejection of brachytherapy well-type chambers submitted for calibration should consider the following:
   1. If the calibration coefficient differs from past or expected values by more than 3.0 %, the cause should be investigated and the chamber may be subject to rejection;
   2. If the collection efficiency of the ionization chamber is less than 99 %, the chamber may be subject to rejection;
   3. If the leakage of the chamber exceeds 0.5 % of the signal, a warning should be

issued and if it exceeds 2.0 %, the chamber may be subject to rejection;

4. For intravascular well-*type chambers*, the axial response of the active volume must be uniform to within ±3 % over the entire length of the source train or wire;
5. Well chambers without adequate source holders or support devices are immediately subject to rejection.

e. The calibration position should be so located that scattered radiation will not introduce a measurement error inconsistent with calibration uncertainty goals.
f. Prior to acceptance of a well-type chamber for calibration, the ADCL must ensure that the chamber design (flat axial response, for example) and the source-positioning apparatus allow calibration to be performed for the desired source to within the laboratory uncertainty goals. Calibrations shall be performed only for axial/linear source inserts.

6.5.3 **Calibration Service Quality Requirements:**

a. Per Section 6.1.3, uncertainty limits and recommended intervals for PT/RRs for calibration of LDR brachytherapy sources and well chambers, HDR brachytherapy well chambers, and well chambers for IVB are as follows:

Instrument and/or Source		Cal Coeff	Expanded (k=2) uncertainty		PT/RR
			ADCL (%)	Total (%)	Nominal Interval (y)
Brachytherapy LDR Sources	^{137}Cs	S_K	≤ 1.2	≤ 2.3	4
	^{131}Cs,^{125}I, ^{192}Ir, ^{103}Pd	S_K	≤ 1.6	≤ 2.5	4
Brachytherapy LDR Well Chambers	^{131}Cs, ^{137}Cs, ^{125}I, ^{192}Ir, ^{103}Pd	N_{SK}	≤ 1.8	≤ 2.5	4
Brachytherapy eBT Well Chambers	Consult NIST	N_K	≤ 3.6	≤ 4.0	-
Brachytherapy HDR Well Chambers	HDR ^{192}Ir	N_{SK}	≤ 2.0	≤ 3.0	4
IVBT Well Chambers		N_{Dw}	≤ 5	≤ 15	-

6.5.3.1 Regarding calibration of LDR sources:

a. An ADCL shall calibrate short half-life encapsulated radioactive sources using instruments calibrated with sources of the same isotope, manufacturer, model and encapsulation that have been calibrated by NIST.
b. An ADCL shall calibrate long half-life encapsulated radioactive sources with sources of the same isotope and similar encapsulation and geometry that have been calibrated by NIST.

6.5.4 **Reporting of Calibration Results**

a. In addition to the general information required described in Section 6.1.4, the following information is also to be recorded by the ADCL for calibrations of LDR sources:
    1. Description of source including manufacturer, isotope, physical dimensions, material and thickness of encapsulation, and model and unique identifiers (or other identifying marks), and the calibration of the source;
    2. The calibration of photon emitting sources shall be expressed in terms of air kerma strength at 1 meter from the source with units of ($\mu Gy \cdot m^2$)/h) measured in a plane which is the perpendicular bisector of the long axis of the source and reported at a reference date and time. At the discretion of the ADCL, additional calibration coefficients may be reported in other historical units.

b. In addition to the general information required described in Section 6.1.4, the following information is also to be recorded by the ADCL for calibrations of well-type ionization chambers:
    1. For LDR and HDR well-type chamber calibrations, a complete description of the standard source used for calibration including the isotope, manufacturer, model, encapsulation, active length, serial number or lot number, and the air kerma strength on the date of chamber calibration with the associated uncertainties;
    2. For eBT well-type chamber calibrations, a complete description of eBT source used for calibration, including identification code (e.g., manufacturer make, model, and serial number), and the eBT source conditions used, including air-kerma rate and filament current;
    3. An indication of whether the chamber is sealed or open to the atmosphere;
    4. A description of the source holder or support device and axial location of source placement during calibration;
    5. A description of any special conditions (e.g. shield, etc.);
    6. The ion collection efficiency, if possible;
    7. The polarizing potential, if available for measurement;
    8. The system pre-irradiation leakage or background current, if appropriate;
    9. A complete description of the calibration coefficient and its use:
        i. The calibration coefficient for the well-type ionization chamber for radioactive sources shall be expressed in terms of air kerma strength at 1 meter from the source with units of $\mu Gy.m^2/h$;
        ii. The calibration coefficient for the well-type ionization chamber for eBT sources shall be expressed in terms of air-kerma rate (μGy/min) at 50 cm per ampere, μGy/min/A.
    10. Appropriate log references;
    11. Such other information as may be deemed appropriate;

III. APPENDICES

Appendix A Guidelines for Uncertainty Assessment

Estimations of uncertainty for ADCL calibrations shall be determined according to “Uncertainty of calibrations in accredited dosimetry calibration measurements.” (Ibbott, Attix, Slowey, Fontenla, & Rozenfeld, 1997) and “A dosimetric uncertainty analysis for photon-emitting brachytherapy sources: Report of AAPM Task Group No. 138 and GEC-ESTRO” (DeWerd et al., 2011).

Appendix B Calibration Report Handling Requirements

Purpose:

In accordance with AAPM and ISO 17025 requirements, calibration reports must be archived in a secure manner, which is readily accessible. The requirements for electronic storage of signed calibration reports are as follows:

Report Storage and Archive:

1. Reports will be signed and sent to the client.
2. Digital copies of signed reports will be archived.
3. Archived reports shall not be edited.
4. Reports shall be stored in such a way that they can be recalled on demand for a period of 10 years after the report signature date.
5. Report storage/archive systems shall maintain client confidentiality.

Appendix C AAPM Recommendations for Components of Non-Standard Methods

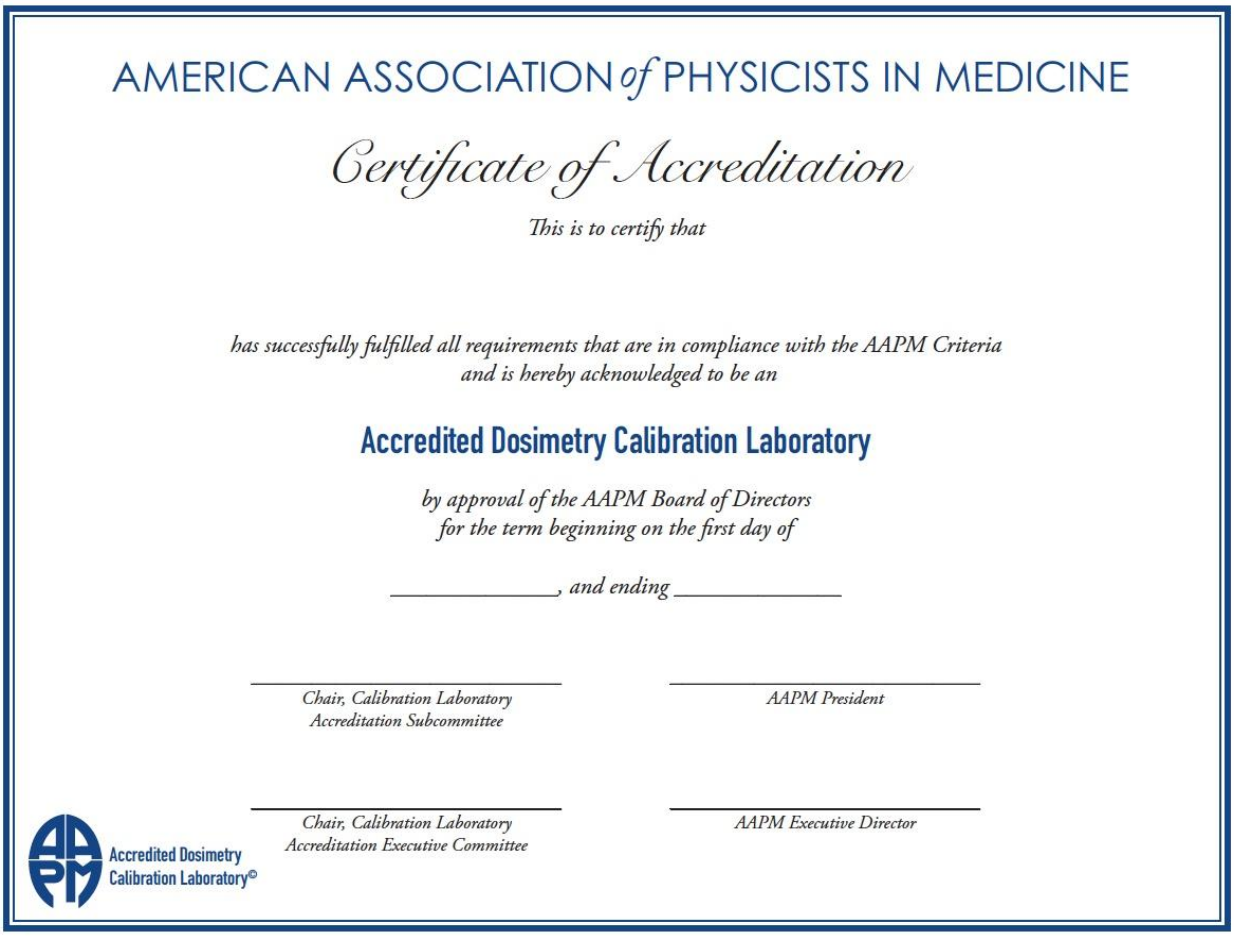
Purpose:

Situations occur in which an ADCL is requested to perform an in-scope calibration, however, the calibration cannot be accomplished using standard operating procedures. This section provides supplemental requirements for in-scope calibrations accomplished with non-standard operating procedures.

Requirements:

a. In-scope calibrations which cannot be performed with standard operating procedures shall have the alternative operating procedures developed prior to calibration.
b. The uncertainty analysis of the alternative procedure shall be documented.
c. The alternative procedure shall be appended to the laboratory's operating procedures.
d. The procedure and associated documentation should contain at least the following:
    1. appropriate identification;
    2. scope;
    3. description of the type of item to be tested or calibrated;
    4. parameters or quantities and ranges to be determined;
    5. apparatus and equipment, including technical performance requirements;
    6. reference standards and reference materials required;
    7. environmental conditions required and any stabilization period needed;
    8. description of the procedure including:
        1) affixing of identification marks, handling, transporting, storing and preparation of items
        2) checks to be made before 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
        5) any safety measures to be observed
    9. criteria and/or requirements for approval/rejection;
    10. data to be recorded and method of analysis and presentation;
    11. the uncertainty or procedure for measuring uncertainty.

Appendix D AAPM Accreditation Certificate



AMERICAN ASSOCIATION *of* PHYSICISTS IN MEDICINE

Certificate of Accreditation

This is to certify that

has successfully fulfilled all requirements that are in compliance with the AAPM Criteria and is hereby acknowledged to be an

Accredited Dosimetry Calibration Laboratory

by approval of the AAPM Board of Directors for the term beginning on the first day of

_____, *and ending* _____

_____ *Chair, Calibration Laboratory Accreditation Subcommittee*

_____ *AAPM President*

_____ *Chair, Calibration Laboratory Accreditation Executive Committee*

_____ *AAPM Executive Director*

Accredited Dosimetry Calibration Laboratory©

Appendix E AAPM ADCL Logo

The AAPM Logo is shown below. The AAPM Policy for the accreditation symbol's use is given in the sub-points of 4.6.1 g.

Appendix F GENERAL TERMS AND DEFINITIONS

AAPM Secretariat

The AAPM employed liason whose responsibilities are outlined in the Laboratory Accreditation Program Quality Manual.

Accredited Dosimetry Calibration Laboratory (ADCL)

A laboratory accredited by the American Association of Physicists in Medicine under these Criteria whose secondary standards are *directly traceable* to NIST.

ADCL Comparison / ADCL Intercomparison

A comparison of similar calibration standards maintained by each ADCL to the other AAPM ADCLs.

Note 1: The ADCL Comparison is also referred to as a round robin (RR).

Air Kerma, *K*

The quotient of dE_{tr} by dm where dE_{tr} is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dm. (IEC 60731, 2016)(3.31)

Note 1: The unit of air kerma is Gy (where 1 Gy = 1 J-kg^{-1}).

Note 2: This definition is derived from the definition in C.6 of ICRU 33 (ICRU 33, 1987),

Air Kerma Rate

The *air kerma* per unit time.

Beam Quality

A descriptor or series of descriptors sufficient to distinguish an x-ray/photon energy spectrum.

Note 1: For x-ray beams, the descriptor(s) shall distinguish incident electron energy on target (including waveform time dependence), x-ray target material, and x-ray beam filtration.

Note 2: Descriptors may include kVp, waveform, 1st and 2nd HVLs of a stated *Certified Reference Material*, homogeneity coefficient, isotope, or other relevant quantities.

Calibration Range / Calibrated Range

The region within which the *calibration coefficient* of a measured quantity is valid, expressed by stating the lower and upper values.

Calibration

The set of operations that establishes, under specified conditions, the *calibration coefficient*.

Calibration Coefficient

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 at the time of calibration.

Calibration Laboratory

A laboratory that performs calibrations, accredited or otherwise.

Certified Reference Material (CRM)

(A) *reference material*, characterized by a metrologically valid approach for one or more specified properties, accompanied by an RM certificate that provides the values of the specified properties, associated uncertainties, and statements of metrological traceability. ((JGCM 200, 2012) (JGCM WG2-CD-01, 2021))

Directly Traceable / Direct Traceability

Traceable with a single step in the calibration chain.

Note 1: Directly traceable to NIST indicates that the instrument or source was calibrated at NIST with respect to NIST primary standards.

Dosimeter

Equipment that uses ionization chambers or other radiation detectors to measure air kerma, absorbed dose or exposure and/or their corresponding rates.

Dosimetry System

A system composed of a *dosimeter* and a readout device such as an electrometer.

Electronic Brachytherapy

Electronic brachytherapy is a form of radiotherapy delivered locally, using a miniaturized electronic x- ray source which is inserted into the body.

Exposure, X

(The) quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in air of mass dm are completely stopped in air. (IEC 60731, 2016) (3.32)

Note 1: This quantity is expressed in coulombs per kilogram (C/kg). Formerly it was expressed in roentgens R (1 R = 2.58×10^{-4} $C\cdot kg^{-1}$).

Field Class

An instrument (dosimeter, ionization chamber, or electrometer) whose performance and stability are sufficient for it to be used to make ordinary routine measurements.

High Dose Rate (HDR) Brachytherapy Source

Gigabecquerel (GBq) or curie levels of activity producing microgray per second air kerma rates at one meter. These sources are intended to be remotely inserted through a catheter into the patient for a relatively short period of time.

Homogeneity Coefficient (HC)

The ratio of the first HVL to the second HVL, expressed as a fraction or percentage.

Intravascular Brachytherapy (IVB)

The treatment of a blood vessel wall with a beta or gamma emitting source for the purpose of reducing the rate of re-stenosis of the vessel after PTCA (balloon angioplasty).

IVB Source

A beta or gamma emitting source used for IVB characterized by a small diameter, used over an extended active length (>20 mm) or remotely controllable position and physically attached to a catheter, wire or other device to position the source within the active target region of the vessel wall.

Intravascular Well-type Chamber

A well type chamber for IVB source calibrations.

kilo-Voltage peak (kVp)

A specification of the voltage applied across a diagnostic x-ray tube

Low Dose Rate (LDR) brachytherapy source

Brachytherapy sources intended to be implanted permanently or for a period of days and then removed at a prescribed time.

Management System

(S)et of interrelated or interacting elements of an organization to establish policies and objectes and processes to achieve those objectives. (ISO 9000, 2015)

Note 1: The manage system elements establish the organization's structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs,objectives and processes to achieve those objectives. (Note 2 in (ISO 9000, 2015))

Measured Value

Best estimate of the true value of a quantity, being derived from the indicated value of an instrument together with the application of all relevant correction factors and the calibration factor ((IEC 60731, 2016), 3.5)

Method

A documented systematic technical procedure.

National Standard

(A) standard recognized by an official national decision as the basis for fixing the values and uncertainties in that country of all other standards of the given quantity. ((IEC 60731, 2016), 3.4.1.1)

Nonconformance

(A)ny deviation from standard practice or operation that renders the quality of a calibration/test unacceptable(NIST RPD-G-07).

Note 1: nonconformance includes typographical or technical error(s) in a calibration report which could cause an error in the use of the calibration results, an error in a calibration report or certificate exceeds the laboratory uncertainty goals, an error due to equipment malfunction, a calculation error, and related errors which affect calibration results.

Note 2: AAPM supplemental requirements (section 5.2.2) include deviations from the resource, process, management, or technical requirements of ISO/IEC 17025:2017 (e), these Criteria, the laboratory quality manual, and laboratory technical manual in its definition of non-conformance.

Proficiency Test

Evaluation of the laboratory calibration or testing performance by means of an interlaboratory comparison, with NIST as the reference standard.

Protocol

The set of laboratory documents and records that cover accredited technical operations, including but not limited to the scope of accreditation, the quality manual, the technical manual, and any other technical or customer-related procedures used for accredited operations."

Quality Manual

(S)pecification of the quality management system of an organization (ISO 9000, 2015).

Note 1: The quality manual document includes portions of the organization's protocol which deal specifically with the policy, management, systems, practices and procedures for quality assurance and quality control. The quality manual may refer to other documentation relating to the organization's quality arrangements.

Redundant / Redundancy

Provision of alternative (identical or diverse) elements in a system that enable the required function regardless of the state of other operational elements.

Note 1: Practically, redundancy is the systematic duplication of reference standards, measurements and/or procedures for the express purpose of obtaining independent calibration and/or ADCL comparison results that validate and confirm the continued use of the initial results.

Reference-Class Device or Instrument

A device or instrument having sufficient accuracy, precision, and long-term stability for it to be used to calibrate other (field-class) instruments within a specified uncertainty interval.

Reference Standard

(A) standard generally of the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived (IEC 60050, 2022).

Note 1: ADCL reference standards are calibrated at NIST.

Reference Material (RM)

(M)aterial, sufficiently homogeneous and stable with reference to one or more specified properties, which has been established to be fit for its intended use in measurement or in examination. (JGCM 200, 2012) (JGCM WG2-CD-01, 2021)

Note 1: Reference materials can be *certified reference materials* or reference materials without a certified property value.

Note 2: For a reference material to be used as a measurement standard for calibration purposes it needs to be a *certified reference material*

Note 3: In a given measurement, a given reference material can only be used for either calibration or quality assurance.

Round Robin (RR)

See ADCL Comparison

Secondary Standard

(M)easurement standard established through calibration with respect to a primary measurement standard for a quantity of the same kind (JGCM 200, 2012) (JGCM WG2-CD-01, 2021).

Secretariat

An AAPM employee whose roles and responsibilities are defined in the AAPM Quality Manual of the Laboratory Accreditation Program

Standard

(An) instrument 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 comparison. ((IEC 60731, 2016), 3.4.1)

Note 1: a radiation source can be a standard

Traceable / Traceability

(P)roperty of the result of a measurement or of the value of a standard such that it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties. (IEC 60050, 311-01-15)

Note 1: Unless otherwise noted, traceable utilizes NIST as the national standard.

Working Standard

A standard which, usually calibrated against a reference standard, is used routinely to calibrate or check material measures, measuring instruments or reference materials (https://www.electropedia.org/).

Note 1: The working standard device will have operational characteristics (stability, reproducibility) of a reference-class device.

Note 2: A Working Standard is referred to as a Transfer Standard in prior Criteria revisions.

Appendix G UNCERTAINTY TERMS AND DEFINITIONS

ADCL Component of the Uncertainty

The portion of the expanded combined uncertainty that arises solely at the ADCL. The component arising from the NIST calibration of the ADCL reference or working standard is not included in this value.

Measurement Uncertainty

(N)on negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used. (JGCM 200, 2012)

Standard Measurement Uncertainty / Standard Uncertainty

(M)easurement uncertainty expressed as a standard deviation. (JGCM 200, 2012)

Combined Standard Measurement Uncertainty / Combined Standard Uncertainty

(S)tandard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model.

Note: In case of correlations of input quantities in a measurement model, covariances must also be taken into account when calculating the combined standard measurement uncertainty (JGCM 200, 2012).

Expanded Measurement Uncertainty / Expanded Uncertainty

(P)roduct of a combined standard measurement uncertainty and a factor larger than the number one

Note 1: The factor depends upon the type of probability distribution of the output quantity in a measurement model and on the selected coverage probability.

Note 2: The term “factor” in this definition refers to a coverage factor.

(JGCM 200, 2012)

Coverage Factor k

(N)umber larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty (JGCM 200, 2012)

Measurand

(Q)uantity intended to be measured (JGCM 200, 2012)

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[1]Criteria for Accreditation of Absorbed Dose to Water Calibrations with Ionization Chambers for Radiation Therapy
[2]Criteria for Accreditation of Air Kerma Calibrations for Diagnostic X-ray Systems
[3]Criteria for Accreditation of Electrometer Calibrations
[4]Guidelines for Rejection of Instruments

The 2023 Criteria Revision

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