

Laboratory Accreditation Program  
Quality Manual

American Association of Physicists in Medicine

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AAPM Laboratory Accreditation Program  
Quality Manual

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by membership of CLA and CLAX in 2021

**AAPM Laboratory Accreditation Program  
Quality Manual**

Calibration Laboratory Accreditation Subcommittee  
of the Therapy Physics Committee

And

Calibration Laboratory Accreditation Executive Committee  
American Association of Physicists in Medicine

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Quality Manual

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## INTRODUCTION

This Quality Manual describes the American Association of Physicists in Medicine (AAPM) Laboratory Accreditation Program. The area of accreditation focuses on the calibration of equipment used to measure ionizing radiation used in medicine.

Medical physics is an applied branch of physics concerned with the application of the concepts and methods of the physical sciences to the diagnosis and treatment of human disease. Information on medical physics can be found at <https://w3.aapm.org/media/index.php>.

A key responsibility of a medical physicist is to ensure the safety and quality of medical procedures involving ionizing radiation. This includes the calibration of diagnostic and therapeutic radiation machines and radiation sources used in the diagnosis and treatment of patients using instruments and sources traceable to a national primary standard maintained by a national metrology institute (e.g., in the United States, the National Institute of Standards and Technology (NIST)).

The AAPM is a scientific, educational, and professional organization of more than 9,500 members devoted to the discipline of physics in medicine. As a leading professional society, the AAPM has rights and responsibilities in the medical dosimetry field as part of its mission to serve its members, their institutions, and the patients they serve. The AAPM is uniquely qualified to be an accreditation body for medical dosimetry calibration laboratories. The accreditation and calibration activities have contributed to an outstanding record of safety and quality in medical procedures that use ionizing radiation.

For the reader's convenience, we briefly review the background and scope of the AAPM's dosimetry calibration-laboratory accreditation program here. In 1971 the 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 would be accredited by the AAPM to provide high precision dosimetry calibrations outside of the National Bureau of Standards (subsequently renamed the National Institute of Standards and Technology). Pursuant to Article Three of the AAPM Charter (<https://peat.aapm.org/govdocs/articles.php>), "To promote the application of physics to medicine and biology," the secondary laboratory accreditation system was created with the following purposes:

1. To increase the capacity of calibration providers to meet the needs of AAPM members for timely calibrations. The need for increased capacity was driven by growth in the utilization of radiation therapy in the US. This growth in demand outstripped NIST's capacity, which resulted in backlogs of nearly a year.
2. To create a system of *secondary* standard laboratories (then referred to as Regional Calibration Laboratories). The high degree of 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's primary standards on an ongoing basis. With the cooperation of NIST, the first measurement assurance program (MAP) was established for dosimetry instrumentation in the US (<https://nvlpubs.nist.gov/nistpubs/Legacy/SP/nbsspecialpublication603.pdf>). The MAP required periodic comparisons with NIST and among laboratories in the secondary system.

3. 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 technical 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 user relating to calibration and use of dosimetry instrumentation and/or brachytherapy sources.

The secondary standard laboratories accredited by the AAPM are now known as Accredited Dosimetry Calibration Laboratories (ADCLs). The number of secondary standard laboratories has varied from two to five over the years since 1971. At the time of this document update (2022), there were three ADCLs. The accreditation program supplies the need for precision medical calibration services in the US through the close support of NIST.

The first edition of this Quality Manual was written by a Task Group of the Calibration Laboratory Accreditation Subcommittee for the purpose of satisfying the requirements of ISO/IEC Guide 58, "Calibration and testing laboratory accreditation systems-General requirements for operation and recognition" (<https://www.iso.org/standard/21678.html>). It was revised in January 2007 to satisfy ISO/IEC 17011:2004, "Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies," which replaced ISO/IEC Guide 58. This Quality Manual underwent a major revision in 2021 make it consistent with ISO/IEC 17011:2017 and to improve the organization and clarity of the document. The AAPM makes no claim that this document is fully compliant with ISO 17011:2017.

This Quality Manual was prepared to be consistent with the AAPM's Rules and Bylaws. In the unforeseen event that an inconsistency is identified, the AAPM Rules and Bylaws take precedence over this Quality Manual.

## 1 Scope

*This document specifies requirements for the competence, consistent operation and impartiality of accreditation bodies assessing and accrediting conformity assessment bodies.*

*NOTE In the context of this document, activities covered by accreditation include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification.*

This Quality Manual describes the quality system that governs the AAPM Laboratory Accreditation Program, which operates primarily under the Calibration Laboratory Accreditation subcommittee (CLA) and Calibration Laboratory Accreditation Executive (CLAX) committee. Laboratories accredited by the AAPM are known as ADCLs. The function of an ADCL is as follows:

- 1.1 To be a *secondary* standard calibration laboratory for medical dosimetry.
- 1.2 To calibrate radiation sources and/or radiation measuring devices by comparing them with NIST-traceable secondary standards.
- 1.3 To calibrate reference-class as well as field-class diagnostic and therapy dosimetry instruments and/or brachytherapy sources that satisfy the uncertainty goals established by the CLA Subcommittee for each item in an accreditation scope.
- 1.4 To serve as a technical resource for AAPM members, other health care professionals and managers of medical institutions by providing technical advice and assistance in matters relating to calibration and use of dosimetry instrumentation and/or brachytherapy sources.
- 1.5 To participate in the CLA Subcommittee by having a representative at all CLA Subcommittee meetings and by providing annual reports of the ADCL activities to the CLA.

## 2 Normative References

*The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.*

[ISO/IEC 99:2007](#), *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

[ISO/IEC 17000:2020](#), *Conformity assessment — Vocabulary and general principles*

[ISO/IEC 17011:2017](#), *Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies*

[ISO/IEC 17025:2017](#), *General requirements for the competence of testing and calibration laboratories*

[ISO/IEC 19011:2018](#), *Guidelines for Auditing Management Systems*

*Criteria for accreditation of dosimetry calibration laboratories, American Association of Physicists in Medicine, 2021.*



### 3 Definitions

*For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the following apply.*

*ISO and IEC maintain terminological databases for use in standardization at the following addresses:*

- *ISO Online browsing platform: available at <https://www.iso.org/obp>*
- *IEC Electropedia: available at <http://www.electropedia.org/>*

*Any use of the defined terms within this document is limited to the meaning given below. Modifications and additions from ISO/IEC 17011:2017 are identified with a \*.*

#### 3.1 **accreditation**

*third-party attestation related to a conformity assessment body (3.4) conveying formal demonstration of its competence to carry out specific conformity assessment tasks*

*[SOURCE: ISO/IEC 17000:2004, 5.6]*

#### 3.2 **accreditation body**

*authoritative body that performs accreditation (3.1)*

*Note 1 to entry: The authority of an accreditation body is generally derived from government.*

*[SOURCE: ISO/IEC 17000:2004, 5.6]*

*\*The AAPM is the accreditation body.*

#### 3.3 **accreditation body logo**

*logo used by an accreditation body (3.2) to identify itself*

#### 3.4 **conformity assessment body**

*body that performs conformity assessment activities (3.5) and that can be the object of accreditation (3.1)*

*Note 1 to entry: Whenever the term “conformity assessment body” is used in the text, it applies to both the applicant and accredited conformity assessment bodies, unless otherwise specified.*

*\*Existing and applicant ADCLs are the conformity assessment bodies.*

**3.5 conformity assessment activity**

activity conducted by a conformity assessment body (3.4) when assessing conformity

*Note 1 to entry: In the context of this document, activities covered by accreditation (3.1) include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provisions of proficiency testing, production of reference materials, validation and verification. For simplicity, these are referred to as conformity assessment activities (3.5) being performed by conformity assessment bodies (3.4).*

**3.6 scope of accreditation**

specific conformity assessment activities (3.5) for which accreditation (3.1) is sought or has been granted

**3.7 flexible scope of accreditation**

scope of accreditation (3.6) expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the conformity assessment body (3.4) as confirmed by the accreditation body (3.2)

**3.8 accreditation scheme**

rules and processes relating to the accreditation (3.1) of conformity assessment bodies to which the same requirements apply

*NOTE Accreditation scheme requirements include, but are not limited to ISO/IEC 17020, ISO/IEC 17021, ISO/IEC 17025, ISO/IEC 17024, ISO/IEC 17034, ISO/IEC 17043, ISO/IEC 17065, ISO 15189, and ISO 14065.*

**3.9 accreditation activity**

Individual operational tasks of the accreditation process (3.11)

*Note 1 to entry: See Clause 7*

**3.10 impartiality**

Presence of objectivity

*Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the accreditation body (3.2)*

*Note 2 to entry: Other terms that are useful in conveying the element of impartiality include "independence", "freedom from conflict of interests", "freedom from bias", "lack of prejudice", "neutrality", "fairness", "open-mindedness", "even-handedness", "detachment", "balance".*

*[SOURCE: ISO/IEC 17021-1:2015, 3.2, modified — The words "certification body" have been replaced by "accreditation body" in Note 1 to entry.]*

- 3.11 accreditation process**  
*activities from application through to granting and maintenance of accreditation (3.1) as defined by the accreditation scheme (3.8)*
- 3.12 accreditation symbol**  
*symbol issued by an accreditation body (3.2) to be used by accredited conformity assessment bodies to indicate they are accredited*
- 3.13 accreditation decision**  
*decision on granting (3.14), maintaining (3.15), extending (3.16), reducing (3.17), suspending (3.18), and withdrawing (3.19) accreditation (3.1)*
- 3.14 granting accreditation**  
*awarding accreditation (3.1) for a defined scope of accreditation (3.6)*
- 3.15 maintaining accreditation**  
*confirming the continuance of accreditation (3.1) for a defined scope*
- 3.16 extending accreditation**  
*adding conformity assessment activities to the scope of accreditation (3.6)*
- 3.17 reducing accreditation**  
*cancelling part of the scope of accreditation (3.6)*
- 3.18 suspending accreditation**  
*putting temporary restriction in place for all or part of the scope of accreditation (3.6).*
- 3.19 withdrawing accreditation**  
*cancelling accreditation (3.1) for the full scope.*
- 3.20 complaint**  
*expression of dissatisfaction, other than appeal (3.21) by any person or organization, to an accreditation body (3.2), relating to the activities of that accreditation body or of an accredited conformity assessment body (3.4), where a response is expected.*
- 3.21 appeal**  
*request by a conformity assessment body (3.4) for reconsideration of any adverse accreditation decision (3.13) related to its desired accreditation (3.1) status.*
- 3.22 assessment**  
*process undertaken by an accreditation body (3.2) to determine the competence of a conformity assessment body (3.4), based on standard(s) and/or other normative documents and for a defined scope of accreditation (3.6).*
- 3.23 reassessment**  
*assessment (3.22) performed to renew the accreditation (3.1) cycle*

**3.24 assessment technique**

method used by an accreditation body (3.2) to perform an assessment (3.22)

*Note 1 to entry: assessment techniques can include, but are not limited to:*

- on-site assessment
- remote assessment (3.26)
- witnessing (3.25)
- document review
- file review
- measurement audits
- review of performance in proficiency testing and other interlaboratory comparisons
- validation audits
- unannounced visits
- interviewing

**3.25 witnessing**

observation by the accreditation body (3.2) of a conformity assessment body (3.4) carrying out conformity assessment activities within its scope of accreditation (3.6)

**3.26 remote assessment\***

assessment (3.22) of the physical location or virtual site of a conformity assessment body (3.4), using electronic means \*without the assessors being physically present at the assessment site.

*Note 1 to entry: A virtual site is an online environment allowing an assessor to execute the process, e.g. using \*virtual meeting tools.*

**3.27 assessment program**

Set of assessments (3.22) consistent with a specific accreditation scheme (3.8) that the accreditation body (3.2) performs on a specific conformity assessment body (3.4) during an accreditation (3.1) cycle.

**3.28 assessment plan**

description of the activities and arrangements for an assessment (3.22)

**3.29 accreditation body personnel**

internal or external individuals carrying out activities on behalf of the accreditation body (3.2)

**3.30 assessor**

person assigned by an accreditation body (3.2) to perform, alone or as a part of an assessment team, an assessment (3.22) of a conformity assessment body (3.4)

**3.31 team leader**

assessor (3.30) who is given the overall responsibility for the management of an assessment (3.22)

**3.32 technical expert**

*person assigned by an accreditation body (3.2), working under the responsibility of an assessor (3.30), who provides specific knowledge or expertise with respect to the scope of accreditation (3.6) to be assessed and does not assess independently*

*Note 1 to entry: A technical expert is not expected to have assessor qualifications and training*

**3.33 interested party**

*person or organization with a direct or indirect interest in accreditation (3.1)*

*Note 1 to entry: Direct interest refers to the interest of those who undergo accreditation; indirect interest refers to the interests of those who use or rely on accreditation conformity assessment bodies.*

*Note 2 to entry: Interested parties can include the accreditation body, conformity assessment bodies, their associations and their clients, industry services, trade associations, scheme owners, governmental regulatory bodies or other governmental services, or non-governmental organizations, including consumer organizations.*

**3.34 consultancy**

*Participation in any of the activities of a conformity assessment body (3.4) subject to accreditation (3.1)*

*Example 1: Preparing or producing manuals or procedures for a conformity assessment body.*

*Example 2: Participating in the operation or management of a conformity assessment body.*

*Example 3: Giving specific advice or specific training towards the development and implementation of the management system, operational procedures and/or competence of a conformity assessment body.*

**3.35** \*primary standard <https://www.iso.org/obp/ui#iso:std:iso-iec:guide:99:ed-1:v2:en:term:5.4>

measurement standard established using a primary reference measurement procedure, or created as an artifact, chosen by convention

Example 1: Primary measurement of absorbed dose to water done with a water calorimeter in a Co-60 standard reference beam.

Example 2: Primary measurement of air kerma for therapy beams done with a cavity ionization chamber in a Co-60 reference beam.

Example 3: Primary measurement of air kerma for diagnostic x-ray beams done with a free air chamber in standard reference x-ray beams.

Example 4: The international prototype of the kilogram as an artifact, chosen by convention.

- 3.36 \*secondary standard (ISO 99:2007, <https://www.iso.org/obp/ui#iso:std:iso-iec:guide:99:ed-1:v2:en:term:5.5>)  
measurement standard established through calibration with respect to a primary measurement standard for a quantity of the same kind

Note 1 to entry: Calibration may be obtained directly between a primary measurement standard and a secondary measurement standard, or involve an intermediate measuring system calibrated by the primary measurement standard and assigning a measurement result to the secondary measurement standard.

Note 2 to entry: A measurement standard having its quantity value assigned by a ratio primary reference measurement procedure is a secondary measurement standard.

## 4 General requirements

### 4.1 Legal entity

*The accreditation body shall be a legal entity, or a defined part of a legal entity such that it is legally responsible for its accreditation activities.*

*NOTE 1 Governmental accreditation bodies are deemed to be legal entities on the basis of their status within their government.*

*NOTE 2 An accreditation body that is part of a larger body can operate under a different name.*

The American Association of Physicists in Medicine is a not-for-profit organization that incorporated in the District of Columbia, on November 10, 1965.

### 4.2 Accreditation agreement

*The accreditation body shall establish a legally enforceable arrangement with each conformity assessment body that requires the conformity assessment body to conform to at least the following:*

- a) to commit to fulfill continually the requirements for accreditation for the scope for which accreditation is sought or granted and to commit to provide evidence of fulfillment. This includes agreement to adapt to changes in the requirements for accreditation;*
- b) to cooperate as is necessary to enable the accreditation body to verify fulfillment of requirements for accreditation;*
- c) to provide access to conformity assessment body personnel, locations, equipment, information, documents and records as necessary to verify fulfillment of requirements for accreditation;*
- d) to arrange the witnessing of conformity assessment activities when requested by the accreditation body;*
- 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 commit to follow the accreditation body's policy for the use of the accreditation symbol;*
- 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.*
- j) *to pay fees as determined by the accreditation body;*
- 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.*

ADCLs are required to fulfill these requirements as a condition of accreditation as given in the AAPM Criteria 4.5.

### **4.3 Use of accreditation symbols and other claims of accreditation**

- 4.3.1 *The accreditation body shall take measures to ensure that the accredited conformity assessment body;*
- a) *fully conforms to the requirements of the accreditation body for claiming accreditation status, when making reference to its accreditation in communication media;*
  - b) *does not make any misleading or unauthorized statement regarding its accreditation;*
  - c) *upon withdrawal of its accreditation, discontinues its use of any reference to that accreditation;*
  - d) *does not refer to its accreditation in a way so as to imply that a product, process, service, management system or person is approved by the accreditation body;*
  - e) *informs its affected clients of the suspension, reduction or withdrawal of its accreditation and the associated consequences without undue delay.*

ADCLs are required to fulfill these requirements as a condition of accreditation as given in the AAPM Criteria 4.5.

- 4.3.2 *When an accreditation body has an accreditation symbol, the accreditation body shall have the legal right to use it and the accreditation symbol shall be legally protected.*

The accreditation symbol is a registered trademark owned by the AAPM.

- 4.3.3 *The accreditation body shall have a documented policy governing the use of the accreditation symbol and claims of accreditation status. This policy shall specify at a minimum:*
- a) *requirements for the use and monitoring of the accreditation symbol in combination with any conformity assessment body mark;*
  - b) *that the accreditation symbol is not affixed on its own or used to imply that a product, process or service (or any part of it) has been certified or approved by the accreditation body;*
  - c) *requirements for reproduction of the accreditation symbol;*
  - d) *requirements for any reference to accreditation;*
  - e) *requirements for the use of the accreditation symbol and claims of accreditation status in communication media;*



- f) *that the conformity assessment body only uses the accreditation symbol and claims of accreditation status for the specific activities covered by the scope of accreditation.*

The AAPM policy regarding use of the accreditation symbol is:

- Only organizations that are accredited as dosimetry calibration laboratories by the AAPM may refer to themselves as an “Accredited Dosimetry Calibration Laboratory” or “ADCL.”
- The AAPM will monitor the use of the ADCL Logo.
- The ADCL Logo shall be used only in combination with the conformity assessment body’s mark with reference to in-scope accredited services.
- The ADCL Logo shall not be used on its own.
- The ADCL Logo or accreditation status shall not be used to imply AAPM product or service certification or approval.
- 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*.
- Reproductions of the ADCL Logo shall be legible and not combined with other graphics.
- The ADCL Logo can be used in ADCL communication media with respect to in-scope services.

4.3.4 *The accreditation symbol shall have, or be accompanied by, a clear indication as to which conformity assessment activity the accreditation is related.*

4.3.5 *The accreditation body shall take suitable action to deal with incorrect or unauthorized claims of accreditation status, or misleading or unauthorized use of accreditation symbols and the accreditation body logo.*

*NOTE Suitable actions can include requests for corrective action, suspension, withdrawal of accreditation, publication of the transgression and, if necessary, legal action.*

The AAPM will take action on inappropriate uses of the ADCL Logo. Such action may include a request for corrective action, suspension or revocation of accreditation, or legal action.

#### **4.4 Impartiality requirements**

The AAPM accreditation program adheres to the AAPM Code of Ethics, Policy PP-24 (<https://www.aapm.org/org/policies/details.asp?id=519&type=PP>).

CLA voting members and assessors shall not provide or have previously provided consultation services to the candidate laboratory which might compromise their impartiality in the accreditation process and decisions. (Voting members, defined in

Section 5.2.1.f.ii, exclude individuals who have a potential conflict of interest, such as laboratory employees.)

4.4.1 *Accreditation shall be undertaken impartially.*

The AAPM ADCL Accreditation Program shall be administered in a fair and objective manner. It shall be administered without consideration of the size of the laboratory or its staff. The administration of the program shall be conducted in a manner to avoid conflicts of interest (COI) wherever possible; in cases where COI are unavoidable, they will be managed in a manner in keeping with the AAPM's Code of Ethics.

4.4.2 *The accreditation body shall be responsible for the impartiality of its accreditation activities and shall not allow commercial, financial or other pressures to compromise impartiality. Where an accreditation body, including a governmental accreditation body, is part of a larger entity, the accreditation body shall be organized so that accreditation is provided impartially.*

The Accreditation Program management system (Section 9), through execution of the duties and responsibilities (Section 5.6), is responsible for ensuring impartiality of accreditation activities. Commercial, financial, and other pressures are handled by the confidentiality agreement form and the AAPM COI policy (PP-15 <https://www.aapm.org/org/policies/details.asp?id=520>).

4.4.3 *The accreditation body shall have top management commitment to impartiality. It shall document and make public an impartiality policy which includes the importance of impartiality in carrying out its accreditation activities, managing conflict of interest and ensuring objectivity of its accreditation activities.*

This Quality Manual states the commitment to impartiality and is publicly available.

4.4.4 *All accreditation body personnel and committees who could influence the accreditation process shall act objectively and shall be free from any undue commercial, financial and other pressures that could compromise impartiality. The accreditation body shall require all personnel and committee members to disclose any potential conflict of interest whenever it may arise.*

The confidentiality agreement form and the AAPM COI policy act to ensure objectivity and impartiality.

- 4.4.5 *The accreditation body shall document and implement a process to provide opportunity for effective involvement by interested parties for safeguarding impartiality. The accreditation body shall ensure a balanced representation of interested parties with no single party predominating.*

The CLA subcommittee structure and AAPM's open meeting access policy are structured to involve interested parties and safeguard impartiality in the accreditation process.

- 4.4.6 *The accreditation body shall have a process to identify, analyze, evaluate, treat, monitor and document on an ongoing basis the risks to impartiality arising from its activities including any conflicts arising from its relationships or from the relationships of its personnel. The process shall include identification of and consultation with appropriate interested parties as described in 4.4.5 to advise on matters affecting impartiality including openness and public perception.*

*NOTE 1 Sources of risks to impartiality of the accreditation body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, outsourcing, training, marketing and payment of a sales commission or other inducement for the referral of new clients, etc.*

*NOTE 2 One way of fulfilling the consultation with the Interested parties is by the use of a committee.*

The AAPM processes with respect to impartiality risk are covered by the notification requirements of the accreditation agreement, the assessor selection process, annual management reviews, and CLA subcommittee discussions.

CLAX committee members shall be free from conflict of interest that could impact the accreditation program and/or accreditation decisions.

- 4.4.7 *Where any risks to impartiality are identified, the accreditation body shall document and demonstrate how it eliminates or minimizes such risks and document any residual risk. The demonstration shall cover all potential risks that are identified, whether they arise from within the accreditation body or from the activities of other persons, bodies or organizations.*

AAPM's impartiality risk is minimized via the assessor selection process, annual management reviews, CLA subcommittee discussions, appeals process, and consultation with the Executive Director.

- 4.4.8 *Top management shall review any residual risk to determine if it is within the level of acceptable risk.*

The AAPM Executive Director shall review residual risk.

4.4.9 *When an unacceptable risk to impartiality is identified and which cannot be mitigated to an acceptable level, then accreditation shall not be provided.*

4.4.10 *The accreditation body's policies, processes and procedures shall be non-discriminatory and shall be applied in a non-discriminatory way. The accreditation body shall make its services accessible to all applicants whose application for accreditation falls within the scope of its accreditation activities as defined within its policies and rules. Access shall not be conditional upon the size of the applicant conformity assessment body or membership of any association or group, nor shall accreditation be conditional upon the number of conformity assessment bodies already accredited.*

*NOTE It is not considered discriminatory when an accreditation body refuses services to a conformity assessment body because of proven evidence of fraudulent behavior, falsification of information or deliberate violation of accreditation requirements.*

AAPM's policies, processes, and procedures as described in this Quality Manual and the AAPM Criteria are designed to meet these requirements.

4.4.11 *The accreditation body and any part of the same legal entity shall not offer or provide any service that affects its impartiality, such as:*

- a) conformity assessment activities covered by accreditation which include but are not limited to testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification;*
- b) consultancy.*

The AAPM, as an organization, shall not provide conformity assessment activities or consultancy services to the conformity assessment body. This does not preclude individual AAPM members who do not have a conflict of interest with respect to accreditation body activities from providing such activities or services to the conformity assessment body.

4.4.12 *In case the accreditation body is linked to a body offering consultancy or undertaking those conformity assessment activities mentioned in 4.4.11 bullet a), the accreditation body shall have:*

- a) different top management (see 5.7);*
- b) different personnel performing the accreditation decision-making processes (see Clause 5);*
- c) distinctly different name, logos and symbols;*
- d) effective mechanisms to prevent any influence on the outcome of any accreditation activity.*

The AAPM is not linked to any such body, therefore this is not applicable.

- 4.4.13 *The accreditation body's activities shall not be presented as linked with consultancy or other services that pose an unacceptable risk to impartiality. Nothing shall be said or implied that would suggest that accreditation would be simpler, easier, faster or less expensive if any specified person(s) or consultancy were used.*

*NOTE Accreditation bodies can carry out, for example, the following duties that are not considered a risk to impartiality:*

- *arranging and participating as a lecturer in training, orientation or educational courses, provided that these courses confine themselves to the provision of generic information that is freely available in the public domain, i.e. they cannot provide specific solutions to a conformity assessment body in relation to the activities of that organization;*
- *adding value during assessments, e.g. by identifying opportunities for improvement as they become evident during the assessment without recommending specific solutions;*
- *advising other accreditation bodies on development of accreditation process;*
- *advising scheme owners on accreditation requirements, including requirements within relevant conformity assessment standards.*

The AAPM and its activities and the assessors and their activities shall not be linked to consultancy or other services that pose an unacceptable risk to impartiality.

## **4.5 Financing and liability**

- 4.5.1 *The accreditation body shall have the financial resources, demonstrated by records and/or documents, required for the operation of its activities. The accreditation body shall have a description of the source(s) of its income.*

The AAPM publishes an annual financial report that describes the sources of income. Records and other documents are maintained.

- 4.5.2 *The accreditation body shall evaluate the risks arising from its activities and have arrangements to cover liabilities arising from its activities.*

The AAPM maintains legal counsel to aid in risk assessment. The AAPM purchases liability insurance to protect against claims resulting from the activities of the Association.

## **4.6 Establishing accreditation schemes**

The competence of an applicant laboratory shall be assessed by the accreditation body against all of the requirements of the Criteria for Accreditation of Dosimetry Calibration Laboratories (Criteria), which requires ISO/IEC 17025 compliance.

The technical requirements for accreditation are described in Section 6 of the AAPM Criteria document, which was developed and maintained by the CLA Subcommittee. The CLA Subcommittee (composition described elsewhere in this document) oversees the activities of the Laboratory Accreditation Program.

- 4.6.1 *The accreditation body shall develop or adopt accreditation schemes. The accreditation body shall document the rules and processes for its accreditation schemes referring to the relevant International Standards and/or other normative documents.*

The AAPM has developed the AAPM Criteria as the accreditation scheme. The AAPM Criteria and the AAPM Quality Manual (this document) establish the rules and processes related to accreditation.

- 4.6.2 *The accreditation body shall ensure that any guidance, application or normative documents it uses have been developed by committees or persons possessing the necessary competence and with participation of appropriate interested parties. These documents shall not contradict or exclude any of the requirements included in the relevant international standards and/or other normative documents.*

*NOTE 1 Where international application or guidance documents are available, these can be used.*

*NOTE 2 The accreditation body can adopt and/or develop application or guidance documents, normative documents and/or participate in their development.*

This Quality Manual and the AAPM Criteria were developed by the CLA subcommittee and align with the international standards listed in the normative references.

- 4.6.3 *The accreditation body shall have a policy and documented procedures to determine the suitability of the conformity assessment schemes and standards for accreditation purposes.*

The AAPM policy is to base its accreditation schemes, in part, upon relevant ISO standards and to involve technical experts in the scheme development to ensure that the schemes ensure traceability to appropriate primary standards within stated uncertainties for in-scope calibrations, as needed by the AAPM stakeholders.

The schemes developed by the CLA subcommittee are deemed suitable as the schemes use methods accepted by standards organizations and developed through a consensus of technical experts in relevant metrology, quality systems, dissemination of primary standards, and quality assurance procedures relevant to medical physics.

- 4.6.4 *The accreditation body shall establish, document, implement and maintain a process for developing and extending its accreditation schemes. The following shall be considered:*
- a) feasibility of launching or extending an accreditation scheme;*
  - b) analysis of its present competence and resources;*
  - c) accessing and employing expertise;*
  - d) the need for application or guidance documents;*

- e) *training of accreditation body personnel;*
- f) *implementation or transition arrangements;*
- g) *views of interested parties.*

The AAPM, through the activities of the CLA, has established, documented, implemented, and maintains its accreditation schemes in consideration of points a)-g) above. Extensions of accreditation schemes and scope may be accomplished through action of the CLA with due consideration of points a)-g).

4.6.5 *Before an accreditation body discontinues an accreditation scheme in part or in full, at least the following shall be considered:*

- a) *views of interested parties;*
- b) *contractual duties;*
- c) *transition arrangements;*
- d) *external communication regarding the discontinuation;*
- e) *information published by the accreditation body.*

The AAPM shall consider points a)-e) prior to discontinuing an accreditation scheme in part, or in full.

## 5 Structural requirements

**5.1** *The accreditation body shall be structured and managed so as to safeguard impartiality.*

The AAPM accreditation program is structured and managed as described in the following sections to safeguard impartiality in its activities.

**5.2** *The accreditation body shall document its entire organizational structure, including lines of authority and responsibility.*

The AAPM Organization as it applies to the Laboratory Accreditation Program is shown in Figure 1.

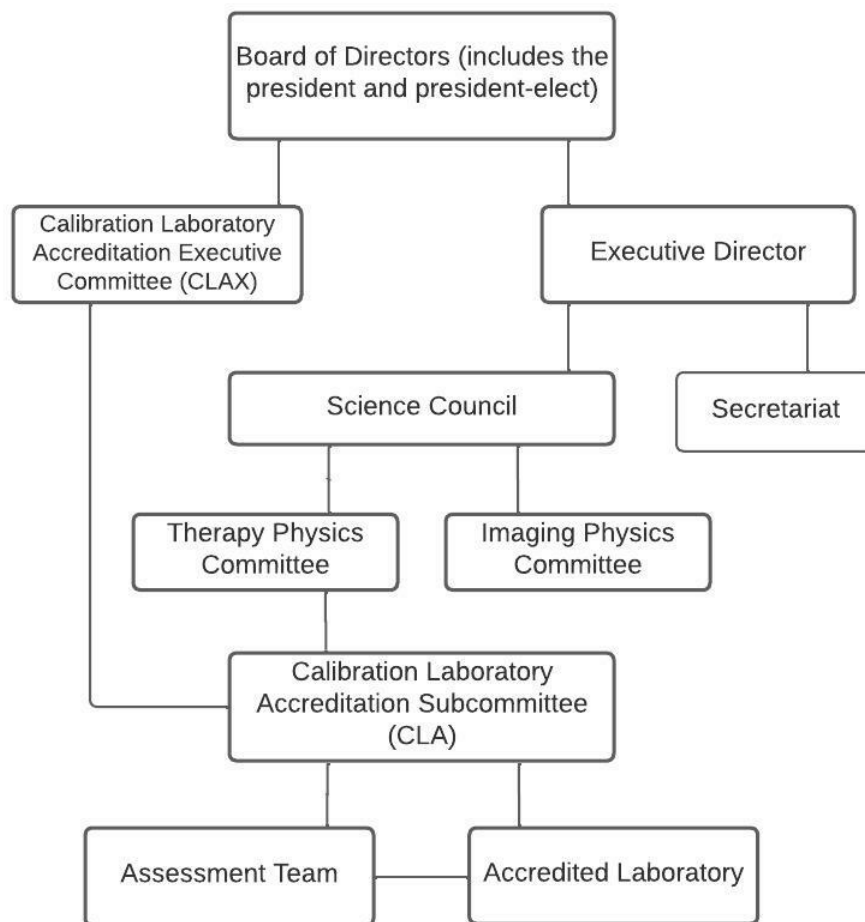


Figure 1: The AAPM Laboratory Accreditation Program Organization. The line of authority is from top-down. See Section 5.1 for appointment and committee makeup as it applies to the accreditation program, and Section 5.6 for duties and responsibilities.



- a) The Board of Directors appoints the Executive Director to have overall responsibility for the accreditation program.
- b) The Executive Director appoints a Secretariat.
- c) The President is the principal administrative officer of the AAPM. The President appoints the Chair of CLAX.
- d) CLAX comprises the CLAX Chair and voting members of the CLA Subcommittee who have no COI with an ADCL or prospective ADCL, the Chair of the CLA, and the Executive Director (ex officio).
- e) The Therapy Physics Committee appoints the CLA Chair and approves CLA members.
- f) The CLA subcommittee consists of voting and non-voting members.
  - i. Appointed members include the CLA Chair, the CLA Vice Chair, the CLAX Chair, at least 4 AAPM Members, and Chairs of Working Groups and Task Groups affiliated with CLA.
  - ii. Ex-officio members include the Directors of each ADCL, a representative from NIST, and an Imaging and Radiation Oncology Core (IROC) representative.
  - iii. Voting members must be AAPM members who are free from a COI.
- g) The CLA Chair appoints an assessment team leader.
- h) The team leader and the CLA Chair will jointly decide on the other members of the assessment team.
- i) An accreditation assessment team is composed of three or more assessors: a team leader (usually a member of the CLA Subcommittee), a representative from NIST to serve as a technical expert in calibration metrology similar to the calibrations requested for accreditation, and a person to assist in the assessment as assigned by the team leader. The assistant may be an assessor in training for reaccreditation teams.
- j) A surveillance team is composed of a team leader, and at least one additional assessor. An assessor in training can serve as the additional assessor.

**5.3** *If the accreditation body is part of a larger entity, the accreditation body shall be identified.*

The AAPM is not part of a larger entity. The accreditation body organization is given in Figure 1.

**5.4** *The accreditation body shall have a description of its legal status, including the names of its owners if applicable, and, if different, the names of the persons who control it.*

The AAPM is a not-for-profit organization incorporated in the District of Columbia, on November 10, 1965.

**5.5** *The accreditation body shall have authority and be responsible for its accreditation decisions which shall not be subject to approval by any other organization or person.*

The AAPM has sole authority for its accreditation decisions.

- 5.6** *The accreditation body shall document the duties, responsibilities and authorities of top management and other personnel associated with the accreditation body who are involved in the accreditation process.*

The duties and responsibilities of those involved in the AAPM accreditation process include, but are not limited to the following:

a) The Board of Directors

- i. is the governing body of the Society and exercises control over all funds, properties, activities, and policies of the Society in accordance with the Articles of Incorporation, By-Laws, and Rules of the Society;
- ii. delegates authority to committee or individuals, as required, to undertake defined activities. Specific duties have been delegated to the CLA, CLAX, and the Executive Director;
- iii. has overall authority and responsibility for the laboratory assessment program and approves the Criteria, Quality Manual, relevant procedures, and budget;
- iv. hears appeals of accreditation decisions and has final authority to approve or reject the laboratory accreditation when appealed.

b) The Executive Director

The Executive Director has the authority and responsibility:

- i. to assure the implementation of AAPM policies and procedures;
- ii. to assure that objectivity and impartiality are safeguarded in accreditation activities;
- iii. to provide financial oversight for the accreditation body;
- iv. to approve contractual arrangements on the recommendations of CLAX and CLA;
- v. to report to the Board on the performance of the management system and any need for improvement;
- vi. to serve as ex-officio, non-voting member of CLAX;
- vii. to appoint and supervise the Secretariat.

c) The Secretariat

The Secretariat has the authority and responsibility:

- i. to complete duties as assigned by the Executive Director;
- ii. to maintain an up-to-date set of the Criteria and Quality Manual for each ADCL (4.2.p);
- iii. to receive the formal application for accreditation from the authorized representative of the laboratory (7.2.1);
- iv. to notify the CLA Chair that the application and fee has been received.
- v. to review applicant documents (with the CLA Chair) to determine the suitability of accreditation (7.2.3);
- vi. to provide assessment team access to an up-to-date set of the Criteria and Quality Manual;
- vii. to prepare and transmit the certificate and scope of accreditation to the laboratory and maintain copies in the AAPM records (7.8);

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- viii. to obtain the records of any ADCL that voluntarily or involuntarily ceases operation as an ADCL (7.11.1.b);
  - ix. to advise the ADCL to return its certificate of accreditation, and cease all claims in advertising of accreditation upon suspension (7.11.1.c)
  - x. to receive written complaint(s) when uninvolved, acknowledge that the complaint(s) is/are received and relevant, and once resolved sends a written response to complainant (7.12.10);
  - xi. to keep the records of the accreditation body in the AAPM Headquarters files in accordance with AAPM policy (7.14.2);
  - xii. to receive and retain the confidentiality agreement from anyone having access to confidential information (8.1.4);
  - xiii. to complete annual review checklist (Appendix 6)
  - xiv. to organize annual management reviews with the accreditation program leadership (9.2.2);
  - xv. to maintain current versions of The Criteria and this Quality Manual and mark obsolete documents as such (9.3);
  - xvi. to keep the minutes of the CLA meetings according to the AAPM Headquarters policy (9.5)
- d) The President (President-elect for appointments coincident with the President-elects term as President)  
The President/President-elect has the authority and responsibility:
- i. to appoint the Chair of the CLAX Committee for a term of three years;
  - ii. to be the Board's point-of-contact for accreditation appeals;
  - iii. to appoint technical subject matter experts to review changes in Criteria and Quality Manual documents (See Section 9.3)
- e) The Therapy Physics Committee  
The Therapy Physics Committee has the authority and responsibility:
- i. to appoint the chair of the CLA Subcommittee;
  - ii. to approve members of the CLA Subcommittee;
  - iii. to approve the Criteria and Quality Manual after review by technical subject matter experts (See Section 9.3).
- f) The Science Council
- i. to approve the Criteria and Quality Manual after review by the Therapy Physics Committee (See Section 9.3)
- g) The Calibration Laboratory Accreditation Executive Committee (CLAX)
- i. shall meet at least twice per year, with one meeting coinciding with the AAPM annual meeting;
  - ii. shall decide accreditation of calibration laboratories assessed under the Dosimetry Calibration Laboratory assessment program;
  - iii. shall ensure confidentiality in the accreditation decision process;
  - iv. shall report directly to the Board;
  - v. shall make accreditation decisions in executive session to assure confidentiality of the accreditation evaluation process;
  - vi. shall review proficiency test results submitted to the CLA Subcommittee;

- vii. shall review site visit reports from assessment teams approved by the CLA Subcommittee;
  - viii. shall review any other appropriate material;
  - ix. shall evaluate the performance of dosimetry calibration laboratories against the AAPM Criteria for Accreditation of Dosimetry Calibration Laboratories,
  - x. shall approve the Quality Manual and the Criteria;
  - xi. shall review the CLA findings and make the final decision on laboratory accreditation as described in section 4.6, but elevates that responsibility to the Board if indicated;
  - xii. shall hear initial accreditation-decision appeals.
- h) The CLAX Chair
- i. presides over CLAX Committee activities;
  - ii. ensures that each decision on accreditation is taken by competent individuals;
  - iii. reports accreditation decisions and CLAX activities to the Board;
  - iv. develops and manages the CLAX budget.
- i) The CLA Chair
- i. presides over CLA meetings;
  - ii. schedules CLA meetings;
  - iii. liaises with ADCLs;
  - iv. ensures that a sufficient number of competent personnel (internal, external, temporary, or permanent, full time or part time) have the education, training, technical knowledge, skills and experience necessary for handling the type, range and volume of work performed by CLA and CLAX. This list of personnel will include assessors and other experts, as well as assessors in training;
  - v. ensures that each individual's duties are made clear to them (limits, responsibilities and authorities);
  - vi. appoints each assessment team leader;
  - vii. develops and manages the CLA budget;
  - viii. calculates reimbursements owed by each ADCL to the AAPM for errors and omissions insurance (E&O) it acquires each year;
  - ix. analyzes round robin and proficiency test results;
  - x. responds to complaints and appeals in a timely manner;
  - xi. reports CLA activities to the Therapy Physics Committee (TPC);
  - xii. Represents CLA interests to other AAPM committees (TPC, BTSC)
- j) The Calibration Laboratory Accreditation Subcommittee
- i. shall meet at least twice per year, with one meeting coinciding with the AAPM annual meeting;
  - ii. oversees the development of policies and procedures governing the operation of the accreditation program, including maintenance of the Criteria and this Quality Manual;
  - iii. administers the accreditation program in an objective and impartial manner;
  - iv. provides the opportunity of involvement by interested parties;
  - v. makes accreditation services accessible to all applicants whose request fall within its policies and rules;
  - vi. prevents or properly manages COIs pertaining to its members;

- k) The Assessment Team
  - i. liaises with laboratory regarding assessment and surveillance activities;
  - ii. performs accreditation assessments;
  - iii. performs surveillance assessments;
  - iv. generates a report of laboratory performance with respect to the Criteria.
- l) Assessor
  - i. completes AAPM assessor training modules;
  - ii. reviews laboratory performance with respect to the Criteria and in compliance with this Quality Manual;
- m) Assessment Team Leader
  - i. appoints assessment team with CLA chair;
  - ii. liaises with laboratory regarding assessment and surveillance activities;
    - 1. creates assessment agenda,
    - 2. delegates site visit responsibilities,
    - 3. leads report writing,
    - 4. receives laboratory response to assessment report,
  - iii. leads assessment team meetings,
  - iv. performs the laboratory assessment and presents its findings to CLAX.
  - v. submits assessment report to CLA and CLAX chairs;
- n) Assessor in training
  - i. completes AAPM assessor training modules;
  - ii. assists with review of laboratory performance with respect to the Criteria and in compliance with this Quality Manual;
  - iii. will report on the performance of the assessment for monitoring purposes.

**5.7** *The accreditation body shall identify the top management having overall authority and responsibility for each of the following:*

- a) *development of policies relating to the operation of the accreditation body;*
- b) *supervision of the implementation of the policies, processes and procedures;*
- c) *supervision of the finances of the accreditation body;*
- d) *development or adoption of activities for the schemes for which it provides accreditation;*
- e) *decisions on accreditation;*
- f) *performance of assessments and accreditation processes;*
- g) *responding to complaints and appeals in a timely manner;*
- h) *contractual arrangements;*
- i) *provision of adequate resources;*
- j) *delegation of authority to committees or individuals, as required, to undertake defined activities on behalf of top management;*
- k) *safeguarding of impartiality.*

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The AAPM accreditation program addresses the criteria of this section via the organizational structure and responsibilities as given in Sections 5.2 and 5.6 of this document.

- 5.8** *The accreditation body shall have formal rules for the appointment, terms of reference and operation of committees that are involved in the accreditation process, and shall identify the interested parties participating.*

The AAPM accreditation program rules for appointment, terms, operations are as given in Section 3.0 Committees of the AAPM Rules, <http://peat.aapm.org/govdocs/compendiumDoc.php>, and Sections 5.2 and 5.6 of this document.

## 6 Resource requirements

### 6.1 Competence of personnel

#### 6.1.1 General

*The accreditation body shall have processes to ensure its personnel have appropriate knowledge and skills relevant to the accreditation schemes and geographic areas in which it operates.*

#### 6.1.2 Determination of competence criteria

6.1.2.1 *The accreditation body shall have a documented process for determining and documenting the competence criteria for personnel involved in the management and performance of assessments and other accreditation activities. Competence criteria shall be determined with regard to the requirements of each accreditation scheme and shall include the required knowledge and skills for performing accreditation activities.*

Personnel competence criteria are documented in the assessor training checklist (Appendix 7). Knowledge and skills are addressed in 6.1.2.6.

6.1.2.2 *The accreditation body shall ensure the assessment team, and the accreditation body personnel who review documents, review assessment reports and make accreditation decisions, demonstrate knowledge of the following:*

- *assessment principles, practices and techniques;*
- *general management system principles and tools,*

as embodied in this Quality Manual and The AAPM Criteria.

6.1.2.3 *The accreditation body shall ensure the assessment team, and the accreditation body personnel who review applications, select assessment team members, review documents, review assessment reports, make accreditation decisions and manage accreditation schemes, demonstrate knowledge of the following:*

- *accreditation body's rules and processes;*
- *accreditation and accreditation scheme requirements and relevant guidance and application documents;*
- *conformity assessment scheme requirements, other procedures and methods used by the conformity assessment body,*

as embodied in this Quality Manual and The AAPM Criteria.

6.1.2.4 *The accreditation body shall ensure the assessment team, and the accreditation body personnel who review assessment reports, make accreditation decisions and manage accreditation schemes, demonstrate knowledge of risk-based assessment principles.*

6.1.2.5 *The accreditation body shall ensure the assessment team, and the accreditation body personnel who review documents, review assessment reports, make accreditation decisions and manage accreditation schemes, demonstrate knowledge of general regulatory requirements related to the conformity assessment activities.*

6.1.2.6 *The accreditation body shall ensure the assessment team demonstrates the following knowledge and skills:*

- *knowledge of practices and processes of the conformity assessment body business environment;*
- *communication skills appropriate to interact with all levels within the conformity assessment body;*
- *note-taking and report-writing skills;*
- *opening and closing meeting skills;*
- *interviewing skills;*
- *assessment-management skills.*

Assessors shall:

- a) have knowledge of radiation metrology and calibration practices;
- b) have knowledge of applicable radiation regulations;
- c) have communication skills appropriate to interact with all levels within the conformity assessment body;
  - i. note-taking and report-writing skills;
  - ii. opening and closing meeting skills;
  - iii. interviewing skills;
- d) possess the characteristics outlined in section 7.2.2 of ISO 19011:2018 (Guidelines for Auditing Quality Systems),
  - i. ethical, i.e., fair, truthful, sincere, honest and discreet.
  - ii. open-minded, i.e., willing to consider alternative ideas or points of view;
  - iii. diplomatic, i.e., tactful in dealing with individuals;
  - iv. observant, i.e., actively observing physical surroundings and activities;
  - v. perceptive, i.e., aware of and able to understand situations;
  - vi. versatile, i.e., able to readily adapt to different situations;
  - vii. tenacious, i.e., persistent and focused on achieving objectives;
  - viii. decisive, i.e., able to reach timely conclusions based on logical reasoning and analysis;
  - ix. self-reliant, i.e., able to act and function independently while interacting effectively with others;
  - x. able to act with fortitude, i.e., able to act responsibly and ethically, even though these actions may not always be popular and may sometimes result in disagreement or confrontation;
  - xi. open to improvement, i.e., willing to learn from situations;
  - xii. culturally sensitive, i.e., observant and respectful to the culture of the auditee;
  - xiii. collaborative, i.e., effectively interacting with others, including audit team members and the auditee's personnel.
- e) have assessment-management skills, such as: planning, communication, decision making, delegation, problem solving and motivating.

6.1.2.7 *The accreditation body shall ensure the accreditation body personnel who review documents demonstrate note-taking and report-writing skills.*



6.1.2.8 *The group or individual that takes the accreditation decisions shall understand the applicable accreditation scheme requirements and shall have competence to evaluate the outcomes of the assessment, including, where appropriate, related recommendations of the assessment team.*

*NOTE Annex A of ISO 17011:2017 summarizes 6.1.2.2 to 6.1.2.8.*

6.1.2.9 *Where additional specific competence criteria have been established for a specific accreditation scheme, these shall be applied.*

- a) Each Assessor shall:
- i. have appropriate technical knowledge for the task assigned by the CLA Subcommittee Chair or assessment team leader;
  - ii. have working knowledge of the AAPM Criteria for accreditation, the AAPM Quality Manual, and AAPM accreditation procedures;
  - iii. have undergone training relevant to accreditation assessor duties, methods, and requirements via in-person training and training handouts;
  - iv. have signed the AAPM Confidentiality Agreement Form (Appendix 1) prior to performing the assessment;
  - v. have familiarity with ISO/IEC 17025:2017;
  - vi. have working knowledge with the relevant legal regulations regarding the licensing, registration and safe (and secure) use of radiation machines and sources;
- b) The Assessment Team leader shall have participated in at least one prior CLA laboratory assessment in a non-leadership role.

### **6.1.3 Competence management**

The requirements of Quality Manual sections 6.1.3.1-6.1.3.6 are covered in the assessor training in Appendix 7 of this document.

6.1.3.1 *The accreditation body shall:*

- a) *establish and implement a documented process for the initial evaluation and on-going monitoring of all personnel involved in accreditation processes;*
- b) *ensure that its evaluation methods are effective to demonstrate competence of accreditation body personnel;*
- c) *prior to undertaking accreditation activities, authorize personnel to perform those activities of the accreditation process.*

6.1.3.2 *The accreditation body shall have documented processes for selecting, training and formally authorizing assessors. The accreditation body shall have documented processes for selecting and authorizing technical experts and familiarizing them with relevant requirements and procedures used in the accreditation process. The initial competence evaluation of an assessor shall include determining the ability to apply required knowledge and skills during assessments.*

*NOTE One method of evaluating an assessor is to have competent individuals observing the assessor conducting an assessment.*

- a) Assessors are selected from CLA members and technical experts (e.g., from Standards Laboratories or other accreditation bodies).
- b) Assessors are trained using materials maintained by the CLA chair.
- c) New Assessors are authorized by the team leader and the CLA chair.
- d) Existing Assessors are continually assessed by the ADCL and the CLA chair.

- 6.1.3.3 *The accreditation body shall identify training needs and shall provide access to specific training to ensure all personnel involved in accreditation processes are competent for the accreditation activities they perform.*
- 6.1.3.4 *There shall be a documented process for monitoring competence and performance of all personnel involved in the assessment activities based on the frequency of their involvement and the level of risk linked to the accreditation activities they perform. In particular, the accreditation body shall review and record the competence of its personnel taking into account their performance in order to take any necessary corrective action.*
- 6.1.3.5 *The accreditation body shall monitor each assessor considering each accreditation scheme for which the assessor is authorized. The documented monitoring process of assessors shall include a combination of on-site evaluation, review of assessment reports and feedback from personnel, conformity assessment bodies or from other interested parties.*
- 6.1.3.6 *Each assessor shall be observed during an assessment at regular intervals. This shall be at least every three years, unless there is sufficient supporting evidence that the assessor is continuing to perform competently. If the interval is extended, justification shall be made.*

## **6.2 Personnel involved in the accreditation process**

- 6.2.1 *The accreditation body shall have access to a sufficient number of competent personnel to manage and support all its accreditation activities for all accreditation schemes.*

This is part of the Executive Director Responsibilities, section 5.6.b. of this document.

- 6.2.2 *The accreditation body shall have enforceable arrangements requiring all personnel to conform to applicable policies and implement processes as defined by the accreditation body. The arrangements shall address aspects relating to confidentiality and impartiality and shall require all personnel to notify the accreditation body of any existing, prior or foreseeable relationships which may compromise impartiality.*

This is covered under section 8.1 of this document, Confidentiality information.

- 6.2.3 *The accreditation body shall give assessors and technical experts access to an up-to-date set of documented procedures giving assessment instructions and all relevant information on the accreditation processes.*

Covered under section 5.6.c, Duties and Responsibilities of the Secretariat.

### 6.3 Personnel records

*The accreditation body shall maintain records, including qualifications, training (Appendix 7), competence, results of monitoring, work experience, experience in laboratory assessment, assessor evaluation forms, signed confidentiality agreement, professional status and professional affiliations for personnel managing or performing accreditation activities.*

The Secretariat maintains the accreditation body records.

### 6.4 Outsourcing

6.4.1 *The accreditation body shall itself normally undertake the accreditation activities.*

6.4.2 *Accreditation decisions shall not be outsourced. The person(s) assigned by the accreditation body to make an accreditation decision shall be employed by, or shall be under enforceable arrangements with the accreditation body.*

When accreditation activities are outsourced, standard processes for decision making and appeals remain in force, CLAX maintains Accreditation decisions.

6.4.3 *The accreditation body shall describe the conditions under which outsourcing may take place and when applicable shall have a documented procedure for outsourcing.*

Contract assessors may be used to perform all or part of an assessment when deemed appropriate by the CLA Chair or AAPM Board of Directors.

Outsourcing any part of the assessment requires written consent of the CLA Chair.

6.4.4 *The accreditation body shall have an enforceable arrangement covering the outsourcing arrangements, including confidentiality and conflicts of interests, with each body that provides outsourced services.*

Each body that provides outsourced services shall agree to:

- a) commitment to comply with the rules defined by the accreditation body, including this Quality Manual and the Criteria for accreditation;
- b) a confidentiality agreement;
- c) provide a disclosure statement regarding commercial and other interests;
- d) provide a full disclosure of any prior association with the laboratory to be assessed.

6.4.5 *The accreditation body shall:*

- a) *take responsibility for all activities outsourced to another body and assure the adequacy of the assessment to meet the requirements of the accreditation;*
- b) *ensure that the body that provides outsourced services, and the individuals that it uses, conform to requirements of the accreditation body and also to the applicable provisions of this document, including competence, impartiality and confidentiality;*
- c) *obtain the consent of the conformity assessment body to use a particular provider of any outsourced parts of the assessment.*

- 6.4.6 *The accreditation body shall have a documented process for the approval and monitoring of all bodies that provide outsourced services used for accreditation processes, and shall ensure that records of the competence of all personnel involved in accreditation processes are maintained.*

*NOTE 1 Where the accreditation body engages individuals or employees of other organizations to provide additional resources or expertise, the use of these individuals does not constitute outsourcing provided they are individually contracted to operate under the accreditation body's management system (see 6.2.2).*

*NOTE 2 Mutual recognition arrangements based on this document can fulfil some of the requirements in 6.4.4. 6.4.5 and 6.4.6.*

## **7 Accreditation Process Requirements**

### **7.1 Accreditation Requirements**

*The general requirements for accreditation of conformity assessment bodies shall be those set out in the relevant International Standards and/or other normative documents for the operation of conformity assessment bodies.*

The general requirements for laboratory accreditation are given in the Criteria, which required compliance with ISO 17025:2017.

### **7.2 Applications for accreditation or re-accreditation**

7.2.1 *The accreditation body shall require an authorized representative of the applicant conformity assessment body to make a formal application that includes the following:*

- a) general features of the conformity assessment body, including legal entity, name, address(es), legal status and human and technical resources;*
- b) general information concerning the conformity assessment body such as its relationship in a larger entity if any, addresses of all its physical locations and, information on activities conducted at all locations including virtual site(s);*
- c) a clearly defined scope of accreditation as defined in 7.8.3 for which the conformity assessment body seeks accreditation, including limits of capability where applicable;*
- d) a commitment to continually fulfil the requirements for accreditation and the other obligations of the conformity assessment body.*

The AAPM shall require an authorized representative of the applicant to make a formal application to the Secretariat that includes the items listed in 3.3 of the AAPM Criteria.

7.2.2 *The accreditation body shall require the applicant conformity assessment body to provide information demonstrating that the accreditation requirements are addressed prior to commencement of the assessment.*

The AAPM shall require the applicant conformity assessment body to provide information regarding the applicant laboratory's self-assessed compliance with the requirements of the AAPM Criteria that are relevant to each item in their requested scope of accreditation with their application for (re)accreditation.

7.2.3 *The accreditation body shall review the information supplied by the conformity assessment body to determine the suitability of the application for accreditation to initiate an assessment.*

The Secretariat and CLA Chair shall review the information supplied by the applicant to determine the suitability of the application for accreditation to initiate an assessment and may request additional information from the applicants before agreeing to consider accreditation.

Upon receipt of the application, the Secretariat will acknowledge receipt and provide a copy of the application to the Chair of the CLA Subcommittee along with acknowledgement of the payment of the fee.

- 7.2.4 *At any point in the application or initial assessment process, if there is evidence of fraudulent behavior, if the conformity assessment body intentionally provides false information or if the conformity assessment body conceals information, the accreditation body shall reject the application or terminate the assessment process.*
- 7.2.5 *Where the accreditation body conducts a preliminary visit before the initial assessment, it shall be conducted with the agreement of the conformity assessment body. The accreditation body shall have clear rules for the conduct of preliminary visits and shall exercise due care to avoid consultancy.*

If the AAPM conducts a preliminary visit before the initial assessment, it shall be conducted with the agreement of the candidate conformity assessment body. The AAPM, CLA, and the assessment team shall exercise due care to avoid consultancy in preliminary accreditation review activities.

### **7.3 Resource Review**

- 7.3.1 *The accreditation body shall review its ability to carry out the assessment of the applicant conformity assessment body, in terms of its own policy and procedures, its competence and the availability of personnel suitable for the assessment activities and decision making.*
- 7.3.2 *The review shall also include the ability of the accreditation body to carry out the initial assessment in a timely manner. Where the initial assessment cannot be conducted in a timely manner, this shall be communicated to the conformity assessment body.*

### **7.4 Preparation for assessment**

- 7.4.1 *The accreditation body shall appoint an assessment team consisting of a team leader and, where required, a suitable number of assessors and/or technical experts for the scope to be assessed. When selecting the assessment team, the accreditation body shall ensure that the expertise brought to each assignment is appropriate. In particular, the team as a whole:*
- a) shall have appropriate knowledge of the specific scope of accreditation;*
  - b) shall have understanding sufficient to make a reliable assessment of the competence of the conformity assessment body to operate within its scope of accreditation.*

The CLA Chair shall appoint an assessment team consisting of a team leader and, a suitable number of assessors and/or technical experts for the scope to be assessed.

- The Chair of the CLA Subcommittee will qualify assessment team leaders based on the requirements of section 6.1.
- The CLA Subcommittee Chair and the team leader will jointly qualify the other members of the team according to the requirements of 6.1 and the required technical knowledge needed by the technical expert to assess the laboratory.

- Trainee team members are exempt from required qualifications for which the Trainee will gain experience during the assessment.
- The CLA Subcommittee Chair may consider Laboratory Evaluations of the assessment team leader and team members in evaluating qualifications.

7.4.2 *The accreditation body shall inform the conformity assessment body of the names of the members of the assessment team and any observers, and the organization(s) they belong to, sufficiently in advance to provide the conformity assessment body the opportunity to lodge an objection to the appointment of any particular team members or observers with supporting justification. The accreditation body shall have a policy for dealing with such objections.*

The CLA Chair shall inform the applicant of the names of the members of the assessment team and any observers, and the organization(s) with which they are affiliated, sufficiently in advance to provide the applicant/ADCL the opportunity to lodge an objection to the appointment of any team member or observer with supporting justification.

The CLA Subcommittee Chair shall attempt to settle any objection with the applicant. Even if applicant objections remain unresolved, the CLA Subcommittee Chair has final authority to set and approve the assessment team.

7.4.3 *The accreditation body shall clearly define the assignment given to the assessment team.*

The general assignment shall be to assess the laboratory performance with respect to the Criteria on items in the laboratory's scope.

7.4.4 *The accreditation body shall establish documented procedures to assess the competence of a conformity assessment body to perform all activities in its scope of accreditation irrespective of where these activities are performed. These procedures shall describe the manner in which the scope of a conformity assessment body is covered through the use of a combination of on-site assessments and other assessment techniques sufficient to provide confidence in the conformity with the relevant accreditation criteria.*

The AAPM meets this requirement with three documents, namely, the AAPM Criteria, the Quality Manual (this document), and the AAPM CLA Assessor Guidance Document. The latter is derived from the former two documents and supplemented with additional operational guidance, e.g., sequence of events, scheduling, points of contact, critical path items, etc.

7.4.5 *The procedures shall ensure that the assessment team assesses the performance of a sample of the conformity assessment activities representative of the scope of accreditation. The assessment shall cover a sample of locations and personnel to determine the competence of the conformity assessment body to perform the activities covered by its scope of accreditation.*

7.4.6 *In selecting the activities to be assessed the accreditation body shall consider the risk associated with the activities, locations and personnel covered by the scope of accreditation.*

7.4.7 *The accreditation body shall develop an assessment plan to cover the activities to be assessed, the locations at which activities will be assessed, the personnel to be assessed where applicable and the assessment techniques to be utilized including witnessing where appropriate or applicable. The accreditation body shall justify where witnessing is not appropriate or applicable.*

The AAPM provides a procedure for the items in this Quality Manual, the AAPM Criteria and the AAPM CLA Assessor Guidance Document. Assessors may review calibration processes in lieu of observing actual calibration activities, at the assessors' discretion, as review may allow a more thorough assessment of calibration process conformance.

7.4.8 *The accreditation body shall confirm with the conformity assessment body the date(s) and plan for the assessment.*

The assessment date shall be set by mutual agreement between the assessment team leader and the laboratory.

The assessment team leader shall coordinate the assessment agenda with the laboratory, then provide the agenda to the Secretariat and the Chair of the CLA Subcommittee in advance of the assessment.

7.4.9 *The accreditation body shall ensure that the assessment team is provided with the appropriate requirements documents, previous assessment records, if applicable, and the relevant documents and records of the conformity assessment body.*

Documents to be provided by the AAPM to the assessment team (no later than 2 months prior to the scheduled assessment) include:

- a) the AAPM Criteria, Quality Manual, and the AAPM CLA Assessor Guidance Document
- b) the application, as described in the Criteria, Section 3.3;
- c) results of most recent proficiency test or round robin inter-comparison results (initial accreditations require proficiency tests);
- d) for re-accreditations, reports from the most recent accreditation and surveillance assessments;
- e) an evaluation form to be provided to the applicant for the purpose of evaluating the performance of the assessment team to the CLA Chair or to the CLAX Chair when the CLA Chair is on the assessment team.

## **7.5 Review of documented information**

The team leader will review the application, including the submitted protocol, laboratory quality manual and checklist and resolve any major questions concerning the submission.



- 7.5.1 *The assessment team shall review all relevant documented information supplied by the conformity assessment body to evaluate its system for conformity with the relevant standard(s) and other requirements for accreditation.*
- 7.5.2 *The accreditation body can decide not to proceed with further assessment based on the review of the documented information. In such cases, the results with their justification shall be reported in writing to the conformity assessment body.*

If the AAPM decides not to proceed with a requested assessment, justification shall be reported in writing by the CLA Chair to the conformity assessment body.

## **7.6 Assessment**

- 7.6.1 *The accreditation body shall have documented procedures for describing the assessment techniques used, the circumstances in which they are to be used and the rules for determining assessment durations. The procedures shall include how the accreditation body will report the assessment findings to the conformity assessment body.*

a) Assessment techniques used:

The “Guidelines for Auditing Quality Systems”, ISO 19011:2018, shall be used as a guide in conducting the site visit.

During the assessment, the assessment team will review the facilities, personnel, organization and required resources and observe laboratory personnel performing calibration activities to demonstrate the competence of the laboratory’s personnel and procedures through the calibration of suitable instrument(s) and/or source(s).

The AAPM CLA Assessor Guidance Document should be used to guide the assessment process.

- b) Circumstances: As needed for accreditation and maintaining accreditation.
- c) Rules for determining assessment duration: Assessments shall be of sufficient duration to carry out assessment activities; expected to be 4 days for an initial assessment, and typically 2 days for re-assessment and 1 day for a surveillance assessment.
- d) Assessment findings: A preliminary summary report will be provided to the applicant at the conclusion of the assessment. A written report, meeting the criteria of 7.6.6, will be provided to the conformity assessment body following the assessment.

- 7.6.2 *For an assessment, whether performed on-site or remotely, the assessment team shall commence the assessment with an opening meeting at which the purpose of the assessment and accreditation requirements are clearly defined, and the assessment plan as well as the scope for the assessment are confirmed.*

- 7.6.3 *The assessment team shall conduct the assessment based on the assessment plan.*

7.6.4 *The assessment team shall analyze all relevant information and objective evidence gathered prior to and during the assessment to determine the competence of the conformity assessment body as determined through its conformity with the requirements for accreditation.*

7.6.5 *Where the assessment team cannot reach a conclusion on a finding, the team shall refer back to the accreditation body for clarification.*

When the assessment team cannot reach a conclusion on a finding, the team shall consult with the CLA Chair.

7.6.6 *The accreditation body's documented reporting procedures shall require the following.*

a) *For an assessment, whether performed on-site or remotely, a meeting shall take place between the assessment team and the conformity assessment body at the end of the assessment. At this meeting, the assessment team shall report on the preliminary findings identified during the assessment and detail in writing any nonconformities. An opportunity shall be provided for the conformity assessment body to seek clarification on the findings including the nonconformities, if any, and their basis.*

The report shall describe the status of compliance with the accreditation requirements and a list of any deficiencies that will need to be corrected for full compliance.

A draft of the scope of accreditation will be reviewed by the assessment team and the laboratory representative during the end-of-assessment meeting.

b) *A written report on the outcome of the assessment shall be provided to the conformity assessment body without undue delay and within a defined timeframe. This assessment report shall contain comments on competence as determined through conformity, the scope assessed and shall identify nonconformities, if any, to be resolved in order to conform to all of the requirements for accreditation. Comments on competence as determined through conformity included in the assessment report shall be adequate to support the conclusions arising from the assessment. The team's observations on areas for possible improvement may also be presented to the conformity assessment body but shall not recommend specific solutions.*

The assessment team leader will provide a written report within 10 business days of the completion of the assessment to the conformity assessment body.

c) *If the report on the outcome of the assessment [see bullet b) above] differs from the outcome delivered at the close of the assessment [see bullet a) above], the accreditation body shall provide an explanation to the assessed conformity assessment body, in writing.*

7.6.7 *The accreditation body shall be responsible for the content of all of its assessment reports.*

- 7.6.8 *When nonconformities are identified, the accreditation body shall define time limits for correction and/or corrective actions to be implemented. The accreditation body shall require the conformity assessment body to provide an analysis of the extent and cause (e.g., root cause analysis) of the nonconformities and to describe within a defined time the specific actions taken or planned to be taken to resolve the nonconformities.*

The AAPM requires that the ADCL provide an analysis of the extent and cause of nonconformities and the timeline for their resolution. Timelines should be consistent with international standards for corrective actions.

- 7.6.9 *The accreditation body shall ensure that the responses of the conformity assessment body to resolve nonconformities are reviewed to determine if the actions are considered to be sufficient and appropriate. Where the conformity assessment body's responses are found not to be sufficient, further information shall be requested. Additionally, evidence of effective implementation of actions taken may be requested, or a follow-up assessment may be carried out to verify effective implementation of corrective actions.*

The AAPM will review the ADCL response, request clarifications and/or modifications, and further assessment as needed. The resolution plan is to be approved by the AAPM prior to reaccreditation.

## **7.7 Accreditation decision-making**

Accreditation of a candidate conformity assessment body / calibration laboratory occurs by action of the CLAX based upon a laboratory's compliance with the Criteria.

- 7.7.1 *The accreditation body shall describe its process for all types of accreditation decisions.*
- a) Decision process:
    - i. The CLA assessment team will perform a laboratory assessment to determine the laboratories' ability to adhere to the Criteria for items in its requested scope, operate in conformance with the criteria, and perform satisfactorily on proficiency tests.
    - ii. The final assessment report, which includes laboratory responses, will be provided to the Secretariat as well as the CLA and CLAX Chairs.
    - iii. CLAX will review the report and make accreditation decisions based upon adherence to the scope and operation in conformance with the criteria.
    - iv. Accreditation is granted by a majority vote of CLAX voting members.
    - v. Votes on appeals to the Board of Directors are governed by the Board rules.
  - b) Types of accreditation decisions: (Described in Criteria, Section 3.4)
    - i. Provisional Accreditation: Provisional accreditation may be granted for a period of up to one year.

- ii. Full Accreditation: Full AAPM accreditation may be granted after one year or more of satisfactory performance or as prescribed by CLAX.

7.7.2 *The accreditation body shall ensure that each decision on granting, maintaining, extending, reducing, suspending and withdrawing accreditation is taken by competent person(s) or committee(s) different from those who carried out the assessment. However, where maintaining is not related to a reassessment (see 7.9.4) and there is no modification to the scope, or where the reduction, suspension or withdrawal is requested by the conformity assessment body, then the accreditation body can implement a process which does not require an independent decision.*

7.7.3 *The information provided to the accreditation decision-maker(s) for review shall include the following:*

- a) *unique identification of the conformity assessment body;*
- b) *date(s) and type(s) of assessment(s) (e.g., initial, reassessment);*
- c) *name(s) of the assessor(s) and, if applicable, technical expert(s) involved in the assessment;*
- d) *unique identification of all locations assessed;*
- e) *scope of accreditation that was assessed;*
- f) *the assessment report(s);*
- g) *a statement on the adequacy of the organization and procedures adopted by the conformity assessment body to give confidence in its competence, as determined through its fulfilment of the requirements for accreditation;*
- h) *sufficient information to demonstrate the satisfactory response to all nonconformities;*
- i) *where relevant, any further information that may assist in determining the competence of the conformity assessment body as determined through conformity with requirements;*
- j) *where appropriate, a recommendation as to the accreditation decision for the proposed scope.*

7.7.4 *The accreditation body shall, prior to making a decision, be satisfied that the information is adequate to decide that the requirements for accreditation have been fulfilled.*

7.7.5 *The accreditation body shall, without undue delay, make the accreditation decision on the basis of an evaluation of all information received and any other relevant information. Without undue delay, the conformity assessment body shall be notified in writing of the decision including justification where relevant.*

The accreditation body shall confine its requirements, assessment and decision on accreditation to those matters specifically related to the scope of the accreditation being considered.

7.7.6 *Where the accreditation body uses the results of an assessment already performed by another accreditation body, it shall have assurance that the other accreditation body was operating in accordance with the requirements of ISO 17011:2017.*

## 7.8 Accreditation information

Upon approval of accreditation, the Secretariat shall prepare a certificate of accreditation and a scope of accreditation and transmit these documents to the laboratory. A copy of the certificate and scope will be retained by the AAPM Secretariat.

- a) A sample certificate is shown in Appendix 4.
- b) A sample scope of accreditation is shown in Appendix 5.

7.8.1 *The accreditation body shall provide information on the accreditation to the accredited conformity assessment body that shall identify the following:*

- a) *the identity and, where relevant, the accreditation body logo;*
- b) *the name of the accredited conformity assessment body and the name of the legal entity, if different;*
- c) *scope of accreditation;*
- d) *locations of the accredited conformity assessment body (ADCL) and, as applicable, the conformity assessment activities performed at each location and covered by the scope of accreditation;*
- e) *the unique accreditation identification of the accredited conformity assessment body;*
- f) *the effective date of accreditation and, if applicable, its expiry or renewal date;*
- g) *a statement of conformity and a reference to the international standard(s) and/or other normative documents), including issue or revision used for assessment of the conformity assessment body.*

*NOTE: The information can be provided in an accreditation certificate or other suitable means (e.g., electronic media).*

7.8.2 *The effective date of accreditation shall be the date of or a date after the accreditation decision.*

7.8.3 *The scope of accreditation shall, at least, identify the following:*  
(Only relevant section of ISO17011:2017 included here)

- *the calibration and measurement capability (CMC) expressed in terms of:*
  - *measurand or reference material;*
  - *calibration or measurement method or procedure and type of instrument or material to be calibrated or measured;*
  - *measurement range and additional parameters where applicable, e.g., frequency of applied voltage;*
  - *measurement uncertainty.*
  
- *a statement on traceability to NIST*

A template of the accreditation scope is given in Appendix 5.

- 7.8.4 *When the accreditation body uses a flexible scope of accreditation, it shall have documented procedures on how it addresses and manages flexible scopes. The procedure shall include how the accreditation body addresses 7.8.3 bullets a) to h), including specifying how the information required for bullets a) to h) shall be maintained and made available on request. (Not applicable)*

## **7.9 Accreditation cycle**

- 7.9.1 *An accreditation cycle shall begin at or after the date of the decision for granting the initial accreditation or decision after reassessment (see 7.9.4) and shall not be longer than five years.*

Accreditation is awarded for a period of up to four years, at which time it must be renewed.

The AAPM/CLAX Committee shall have the authority to grant a one-year administrative extension of the ADCL accreditation.

- 7.9.2 *The accreditation body shall apply an assessment programme for assessing the conformity assessment body activities during the accreditation cycle to ensure that the conformity assessment activities representative of the scope of accreditation at the relevant locations are assessed during the accreditation cycle (see 7.4.4). Factors such as knowledge obtained by the accreditation body about the conformity assessment body's management system and activities and the performance of the conformity assessment body shall be considered by the accreditation body when establishing the assessment programme.*
- a) The performance of the laboratory will be evaluated at subsequent meetings of the CLAX. The evaluation will consider such factors as comments or complaints from AAPM members or other interested parties, turn-around time, staffing changes, any problems or calibration errors reported and such other considerations as the CLAX deems appropriate.
  - b) The calibration laboratory retains its accreditation at the discretion of the AAPM. The AAPM will normally have no reason to consider revocation as long as the performance on proficiency tests are satisfactory, the procedures of the laboratory are in accordance with its protocol and its personnel, performance, or ownership are not significantly changed. When laboratory performance or laboratory changes indicate, the CLA Subcommittee may, at its option, perform an on-site or remote laboratory assessment and/or request that the laboratory complete specific proficiency tests and/or perform specific calibrations to confirm laboratory performance.
  - c) The AAPM may re-evaluate the remaining accreditation tenure when significant changes occur at the ADCL, such as changes in personnel, ownership, equipment or protocol. The AAPM may direct the laboratory to limit or cease its activity as an ADCL until further notice. The AAPM may require a site visit (at the expense of the laboratory) before deciding whether the changes are acceptable, and whether accreditation should be retained, retained provisionally, or withdrawn.

- d) The ownership of the accredited laboratory is a condition of the accreditation granted by the AAPM. A change in ownership of the laboratory shall require the AAPM to approve accreditation to the new owner. Upon notification of a change in ownership, the CLAX Committee may grant temporary provisional approval for the laboratory to continue accredited operation until the approval process has been completed. If, however, the nature of the business or the ability of the new owner to operate an accredited laboratory is questionable or unlikely to be approved, the CLAX Committee may give notice to suspend operation as an accredited laboratory.

7.9.3 *The assessment programme shall ensure that the requirements of the international standards and other normative documents containing requirements for conformity assessment bodies and the scope of accreditation shall be assessed taking risk into consideration. A sample of the scope of accreditation shall be assessed at least every two years. The time between consecutive on-site assessments shall not exceed two years. However, if the accreditation body determines that an on-site assessment is not applicable, it shall use another assessment technique to achieve the same objective as the on-site assessment being replaced and justify the use of such techniques (e.g. remote assessment).*

Surveillance assessments shall be conducted at the discretion of the Chair of the CLA Subcommittee.

- a) Generally, a surveillance assessment will be scheduled one year after an initial assessment for new ADCLs, or two years after a re-accreditation assessment.
- b) The surveillance assessment team will determine the status of corrective actions taken to address deficiencies found on the prior assessment and to monitor laboratory compliance with the Criteria.

7.9.4 *Before the end of the accreditation cycle, a reassessment shall be planned and performed taking into consideration the information gathered from assessments performed over the accreditation cycle. The reassessment shall confirm the competence of the conformity assessment body and cover all the requirements of the standard(s) for which the conformity assessment body is accredited. An accreditation decision shall be made after the reassessment.*

7.9.5 *The accreditation body may conduct extraordinary assessments as a result of complaints or changes, or other matters that may affect the ability of the conformity assessment body to fulfil requirements for accreditation. The accreditation body shall advise conformity assessment bodies of this possibility.*

## **7.10 Extending accreditation scope**

7.10.1 *The accreditation body shall have a documented procedure for extending the scope of accreditation. Based on the risk associated with the activities or locations to be covered in the scope extension, the accreditation body shall define the appropriate assessment technique(s) to apply and consider the corresponding requirements defined in 7.3. to 7.9.*

The AAPM shall apply the following procedure for extending an ADCL's scope of accreditation:

- a) the ADCL requests an extension of scope to the AAPM via an application for accreditation with the procedures for the new scope item clearly indicated;
- b) if the scope extension is for a calibration method that is not in the current AAPM Criteria:
  - i. The ADCL shall include a justification for the new scope item in its application;
  - ii. the AAPM shall review the justification for the new scope item;
  - iii. if justified, the AAPM shall amend the AAPM Criteria to include the new scope item;
  - iv. the AAPM shall assess the laboratory in its ability to adhere to the AAPM Criteria Amendment for the new scope item.
- c) when the scope extension is for a calibration method described in the current AAPM Criteria, the AAPM shall assess the laboratory in its ability to adhere to the AAPM Criteria for the new scope item.

7.10.2 *The accreditation body shall take into account extensions granted when reviewing the assessment programme and planning the subsequent assessment.*

## **7.11 Suspending, withdrawing or reducing accreditation**

7.11.1 *The accreditation body shall have documented procedure(s) and criteria to decide in which circumstances the accreditation shall be suspended, withdrawn or reduced when an accredited conformity assessment body has failed to meet the requirements of accreditation or to abide by the rules for accreditation or has voluntarily requested a suspension, withdrawal or reduction.*

- a) An ADCL can voluntarily reduce its scope of accreditation at any time, with notification to the AAPM.
- b) The AAPM can reduce an ADCL's scope when the ADCL does not meet the requirements of that scope item in the AAPM Criteria
- c) Laboratory accreditation denial, revocation, or discontinuance may occur by action of the AAPM when the performance of the laboratory does not meet one or more requirements in the AAPM Criteria.
- d) If a laboratory voluntarily or involuntarily ceases operation as an ADCL, the Secretariat will obtain the laboratory records regarding ADCL calibrations and operations as required in 4.8 of the AAPM Criteria.
- e) Upon suspension of accreditation, the Secretariat shall advise the laboratory to return its certificate of accreditation and cease all claims in advertising of accredited operation.

7.11.2 *Where there is evidence of fraudulent behavior, or the conformity assessment body intentionally provides false information or conceals information, the accreditation body shall initiate its process for withdrawal of accreditation.*

7.11.3 *The accreditation body shall have a documented procedure and criteria for lifting suspension of accreditation.*



- a) Appeal of any CLAX decision regarding accreditation may be undertaken at the discretion of the laboratory.
- b) Accreditation decisions may be reconsidered when items which resulted in accreditation suspension are addressed and the laboratory demonstrates compliance with the Criteria.

## **7.12 Complaints**

- 7.12.1 *The accreditation body shall have a documented process to receive, evaluate and make decisions on complaints. The accreditation body shall, where appropriate, ensure that a complaint concerning an accredited conformity assessment body (ADCL) is first addressed by the conformity assessment body.*
- 7.12.2 *A description of the handling process for complaints shall be available to any interested party.*
- 7.12.3 *Upon receipt of a complaint, the accreditation body shall confirm whether the complaint relates to accreditation activities that it is responsible for and, if so, shall deal with it.*
- 7.12.4 *The handling process for complaints shall include at least the following elements and methods:*
  - a) *a description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;*
  - b) *tracking and recording complaints, including actions undertaken to resolve them;*
  - c) *ensuring that any appropriate action is taken in a timely manner.*
- 7.12.5 *The accreditation body shall acknowledge receipt of the complaint and provide the complainant with progress reports and the outcome.*
- 7.12.6 *The accreditation body shall be responsible for gathering and verifying all necessary information to validate the complaint.*
- 7.12.7 *The accreditation body shall be responsible for all decisions at all levels of the handling process for complaints.*
- 7.12.8 *The decision to be communicated to the complainant shall be made by, or reviewed and approved by, the individual(s) not involved in the activities in question.*
- 7.12.9 *The accreditation body shall give formal notice of the end of the complaint handling process to the complainant.*

- 7.12.10 *Investigation and decision on complaints shall not result in any discriminatory actions against the complainant.*

Written complaints regarding the accreditation body (AAPM) or the conformity assessment body (ADCLs) shall be received by an uninvolved party of the accreditation body leadership (the Secretariat, CLA Chair, CLAX Chair, or Executive Director). The Secretariat will send the complaint resolution procedures to the interested parties upon request. The party receiving the complaint will acknowledge that it is received and relevant. The uninvolved party(ies) from accreditation body leadership will investigate the complaint and send a written response to the complainant when resolved.

Records of the complaint and actions will be kept in the AAPM/CLA files.

### **7.13 Appeals**

- 7.13.1 *The accreditation body shall have a documented process to receive, evaluate and make decisions on appeals.*
- 7.13.2 *A description of the handling process for appeals shall be available to any interested party.*
- 7.13.3 *The accreditation body shall be responsible for all decisions at all levels of the handling process for appeals.*
- 7.13.4 *Investigation and decision on appeals shall not result in any discriminatory actions.*
- 7.13.5 *The handling process for appeals shall include at least the following elements and methods:*
- a) a description of the process for receiving, validating, investigating the appeal and deciding what actions are to be taken in response to it;*
  - b) tracking and recording appeals, including actions undertaken to resolve them;*
  - c) ensuring that any appropriate action is taken in a timely manner.*
- 7.13.6 *The accreditation body receiving the appeal shall be responsible for gathering and verifying all necessary information to validate the appeal.*
- 7.13.7 *The accreditation body shall acknowledge receipt of the appeal and provide the appellant with progress reports and the outcome.*
- 7.13.8 *The decision to be communicated to the appellant shall be made by, or reviewed and approved by, the individual(s) not involved in the activities in question.*
- 7.13.9 *The accreditation body shall give formal notice of the end of the appeals handling process to the appellant.*

Appeals may be made with respect to accreditation decisions or other decisions.

A laboratory's initial appeal regarding an accreditation decision is to the CLAX chair. Following the appeal, the laboratory will be eligible for either provisional accreditation, full accreditation, or denial of accreditation.

If a disagreement persists following an initial appeal, the ADCL or applicant laboratory may subsequently appeal the decision to the AAPM Board. The Board shall appoint an Ad Hoc group of three members to investigate the decision and report its findings to the Chair of the Board. Such findings shall be reviewed by legal counsel. Upon review and advice of counsel, the Chair of the Board shall request a special meeting or conference with the Chairs of CLA and CLAX and other involved parties as necessary. The outcome of the appeal is decided by a Board vote. The decision of the Board shall be final.

#### **7.14 Records on conformity assessment bodies**

- 7.14.1 *The accreditation body shall maintain records on conformity assessment bodies to demonstrate that requirements for accreditation have been effectively fulfilled.*
- 7.14.2 *The accreditation body shall have a documented policy and documented procedures on the retention of records. Records of the conformity assessment body shall be retained at least for the duration of the current cycle plus the previous full accreditation cycle.*

Conformity assessment body records shall be kept by AAPM in accordance with the records controls described in section 9.4.

## **8 Information Requirements**

### **8.1 Confidential information**

- 8.1.1 *The accreditation body shall be responsible through legally enforceable agreements for the management of all information obtained or created during the accreditation process. The accreditation body shall inform the conformity assessment body, in advance, of the information it intends to place in the public domain. Except for information that the conformity assessment body makes publicly available, or when agreed between the accreditation body and the conformity assessment body (e.g. for the purpose of responding to complaints), all other information obtained during the accreditation process is considered proprietary information and shall be regarded as confidential.*
- 8.1.2 *When the accreditation body is required by law or authorized by contractual arrangements to release confidential information, the conformity assessment body shall, unless prohibited by law, be notified of the information provided.*
- 8.1.3 *Information about the conformity assessment body obtained from sources other than the conformity assessment body (e.g., complainant, regulators) shall be confidential between the conformity assessment body and the accreditation body. The provider (source) of this information shall be confidential to the accreditation body and shall not be shared with the conformity assessment body, unless agreed by the source.*
- 8.1.4 *Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the accreditation body's behalf, shall keep confidential all information obtained or created during the performance of the accreditation body's activities, except as required by law.*

All individuals having access to confidential information regarding the operation of an accredited laboratory or a prospective one shall sign a confidentiality agreement (Appendix 1) and submit it to the Secretariat.

Access to confidential information relating to applications, assessments, ownership, facilities, methods of operation, manuals and protocols and other accreditation information of the laboratories shall be restricted to the CLA and CLAX chairs, the appointed and approved assessment team, the Executive Director and the Secretariat of the AAPM. Files containing the above information shall be maintained securely to prevent unauthorized access.

### **8.2 Publicly available information**

This Quality Manual and the AAPM Criteria are available to the public on the open access area of the AAPM website (<https://www.aapm.org/links/adcl.asp>). These documents describe the accreditation process, the requirements for accreditation and the duties and rights of the accredited laboratory. The AAPM web site information describes the Accreditation Program and provides contact information for interested parties to obtain additional information.

- 8.2.1 *The accreditation body shall make publicly available through publications, electronic media or other means, without request, and update at adequate intervals, the following:*
- a) *information about the accreditation body:*
    - i. *information about the authority under which the accreditation body operates (this Quality Manual);*
    - ii. *a description of the accreditation body's rights and duties (This Quality Manual);*
    - iii. *general information about the means by which the accreditation body obtains financial support (this Quality Manual);*
    - iv. *information about the accreditation body's activities, other than accreditation (<http://aapm.org>);*
    - v. *information about international recognition arrangements in which it is involved (none at present time);*
  - b) *information about accreditation process:*
    - i. *detailed information about its accreditation schemes, including its assessment and accreditation processes (both this Quality Manual and the Criteria);*
    - ii. *reference to the documents containing the requirements for accreditation (the Criteria);*
    - iii. *general information about the fees relating to accreditation (<https://www.aapm.org/links/adcl.asp>);*
    - iv. *a description of the rights and obligations of conformity assessment bodies (both this Quality Manual and the Criteria);*
    - v. *information on procedures for lodging and handling complaints and appeals (this Quality Manual);*
    - vi. *information on the use of the accreditation symbol or other claims of accreditation (this Quality Manual).*
- 8.2.2 *As a minimum the accreditation body shall make publicly available without request, information on conformity assessment bodies as described in 7.8.1 and, where applicable, information on suspension or withdrawal of accreditation, including dates and scopes.*

*NOTE: In exceptional cases, access to certain information can be limited upon the request of the conformity assessment body (e.g. for security reasons).*

- 8.2.3 *The accreditation body shall give due notice of any changes to its requirements for accreditation. It shall take account of views expressed by interested parties before deciding on the precise form and effective date of the changes.*
- 8.2.4 *Following a decision on and publication of the changed requirements, the accreditation body shall verify that each accredited body conforms to the changed requirements.*

## 9 Management system requirements

### 9.1 General

9.1.1 *The accreditation body shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document. In addition to meeting the requirements of clauses in this document, the accreditation body shall implement a management system in accordance with option A (see 9.1.4) or with option B (see 9.1.5).*

The AAPM CLA accreditation body management system is in accordance with option A of ISO17011:2014. The accreditation body management system is described in this Quality Manual.

9.1.2 *The accreditation body's management shall establish and document policies and objectives related to competence, consistency of operation and impartiality. The management shall provide evidence of its commitment to the development and implementation of the management system in accordance with the requirements of this document. The management shall ensure that the policies are understood, implemented and maintained at all levels of the accreditation body's organization.*

The AAPM utilizes this Quality Manual to satisfy this requirement.

The AAPM has documented policies and procedures governing the operation of committees as published on the AAPM website (<http://peat.aapm.org/govdocs/compendiumDoc.php>).

9.1.3 *The accreditation body's top management shall assign responsibility and authority for:*

- a) *ensuring that policies and processes needed for the management system are established, implemented and maintained;*
- b) *reporting to top management on the performance of the management system and any need for improvement.*

The AAPM CLA utilizes this quality manual to satisfy these requirements.

9.1.4 *Under option A, as a minimum, the management system of the accreditation body shall address the following, as elaborated in 9.2 to 9.8:*

- *management system;*
- *document control;*
- *records control;*
- *nonconformities and corrective actions;*
- *improvement;*
- *internal audits;*
- *management reviews.*

The AAPM CLA utilizes this quality manual to satisfy these requirements.

- 9.1.5 *Under option B, an accreditation body that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of this document, fulfils at least the management system section requirements.*

Not applicable. AAPM uses option A.

## **9.2 Management system**

- 9.2.1 *The accreditation body shall operate a management system appropriate to the type, range and volume of work performed. All applicable requirements of this document shall be addressed either in a manual or in associated documents. The accreditation body shall ensure that the manual and relevant associated documents are accessible to its personnel and shall ensure effective implementation of the management system's processes.*
- 9.2.2 *The accreditation body shall continually improve effectiveness of its management system in accordance with the requirements of this document.*

Periodic reviews of the Criteria and Quality Manual, annual management review, feedback from ADCLs, assessor evaluations, timeliness of feedback.

## **9.3 Document control**

*The accreditation body shall establish documented procedures to control all documents (internal and external) that relate to its accreditation activities. The procedures shall define the controls needed:*

- a) to approve documents for adequacy prior to issue;*
- b) to review and update as necessary and re-approve documents;*
- c) to ensure that changes and the current revision status of documents are identified;*
- d) to ensure that relevant versions of applicable documents are available at points of use;*
- e) to ensure that documents remain legible and readily identifiable;*
- f) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose;*
- g) to safeguard, where relevant, the confidentiality of documents.*

Documents (the Criteria and this Quality Manual) are approved prior to use by the following structure

- a) AAPM leadership, in consultation with CLA and CLAX leadership appoints at least two technical subject matter experts to review the updated documents;
- b) the technical subject matter experts review and provide comments on the documents;
- c) the document authors reply to the comments until the technical subject matter experts approve the documents;
- d) the CLA subcommittee votes to approve the updated documents;

- e) the CLA presents the documents to the Therapy Physics Committee and Science Council for approval. Note: The technical subject matter expert reviews in step b) are intended to avoid the need for TPC or SC technical review;

The Documents are reviewed prior to laboratory assessments and as otherwise necessary. The Documents are updated as needed. The revision status and number are given at the top of this document. Document changes area identified in the revision history at the end of this document. Current versions are maintained and distributed by the Secretariat. Controlled copies of obsolete documents are so marked. The Quality Manual and Criteria notes the location of the official copy to reduce unintended use.

## 9.4 Records control

- 9.4.1 *The accreditation body shall establish documented procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records.*

These requirements are satisfied by:

- a) Identification: All records related to accreditation activities will be clearly titled.
- b) Storage: All records related to accreditation activities will be stored in electronic format on AAPM computer file storage.
- c) Retrieval: Records not publicly available will be retrieved by the Secretariat.
- d) Protection: Files will be secured, backed up and archived using standard AAPM computer file storage techniques.
- e) Retention time: Records will be retained for at least 10 years.
- f) Disposition: Records will be stored or archived by the Secretariat. Records may be deleted after the retention time at the discretion of the Executive Director.

- 9.4.2 *The accreditation body shall establish documented procedures for retaining records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality arrangements.*

The AAPM records shall be kept in accordance with contractual obligations and confidentiality agreements.

## 9.5 Nonconformities and corrective actions

The accreditation body shall establish documented procedures for the identification and management of nonconformities in its own operations. The accreditation body shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the impact of the problems encountered. The procedures shall cover the following:

- a) identifying nonconformities (from complaints, internal audits or other sources);
- b) determining the causes of nonconformity;
- c) correcting nonconformities;
- d) evaluating the need for actions to ensure that nonconformities do not recur;
- e) determining the actions needed and implementing them in a timely manner;



- f) recording the results of actions taken;
- g) reviewing the effectiveness of corrective actions.

Non-conformities can be identified by the post-assessment survey completed by the laboratory, internal audits, and complaints. Identified nonconformities will undergo a causal analysis by the CLA leadership or a sub-committee so appointed. The same group shall identify the required corrective action for the identified nonconformity and actions to prevent reoccurrence of the identified nonconformity in a timely manner. Records of actions taken are recorded in the minutes of the CLA meeting, which are then kept by the Secretariat. The effectiveness of the corrective action(s) will be discussed at subsequent CLA meetings, and the annual management review.

## 9.6 Improvement

*The accreditation body shall establish documented procedures to identify opportunities for improvement and to identify risks and take appropriate actions (see also 4.4).*

The AAPM accreditation body shall discuss opportunities for improvement during the CLA and CLAX meetings and act on such improvement as appropriate, with documentation in this Quality Manual and/or the AAPM Criteria. Risk shall be discussed at CLA, CLAX, and annual management review meetings, particularly with respect to maintaining impartiality as discussed in 4.4.

## 9.7 Internal audits

- 9.7.1 *The accreditation body shall establish documented procedures for internal audits to verify that the accreditation body conforms to the requirements of this document and that the management system is implemented and maintained.*

Internal audits are performed by the accreditation body management post assessment laboratory evaluation of assessors and the assessment process, as well as a part of the annual management review. Internal audits shall comply with the criteria of 9.7.4.

- 9.7.2 *Internal audits shall be performed normally once a year. An audit program shall be established, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits.*

The AAPM performs internal audits as part of its annual management review.

- 9.7.3 *The frequency of internal audits may be reduced if the accreditation body demonstrates that its management system has been effectively implemented according to this document and has proven stability.*

- 9.7.4 *The accreditation body shall ensure that:*

- a) *internal audits are conducted by competent personnel knowledgeable in accreditation, auditing and the requirements of this document;*
- b) *internal audits are conducted by personnel different from those who perform the activity to be audited;*
- c) *personnel responsible for the area audited are informed of the outcome of the audit;*

- d) *actions are taken in a timely and appropriate manner;*
- e) *any opportunities for improvement are identified.*

## **9.8 Management reviews**

- 9.8.1 *The accreditation body's management shall establish documented procedures to review its management system at planned intervals to ensure its continuing adequacy and effectiveness in satisfying the relevant requirements, including this document and the stated policies and objectives. These reviews shall be conducted at least once a year.*
- 9.8.2 *Inputs to management reviews shall include, current performance and opportunities for improvement related to the following:*
- a) *results of audits;*
  - b) *results of peer evaluation, where relevant;*
  - c) *participation in international activities, where relevant;*
  - d) *safeguarding impartiality;*
  - e) *feedback from interested parties;*
  - f) *new areas of accreditation;*
  - g) *trends in nonconformities;*
  - h) *status of corrective actions;*
  - i) *the status of actions to address risks and opportunities;*
  - j) *follow-up actions from earlier management reviews;*
  - k) *fulfilment of objectives;*
  - l) *changes that could affect the management system;*
  - m) *analysis of appeals;*
  - n) *analysis of complaints.*
- 9.8.3 *The outputs from the management review shall include actions related to:*
- a) *improvement of the management system and its processes;*
  - b) *improvement of services and accreditation process in conformity with the relevant standards and expectations of interested parties;*
  - c) *need for resources;*
  - d) *defining or redefining policies, goals and objectives.*

## Appendix 1 Confidentiality Agreement Form

This is to acknowledge that I understand my responsibilities as a member of an Accredited Dosimetry Calibration Laboratory (ADCL) Assessment Team of the American Association of Physicists in Medicine (AAPM). Sections 4.4 and 8.1 of this Quality Manual discuss impartiality and confidential information.

I, the undersigned, do acknowledge and agree to the following:

1. I agree to comply with the policies, procedures and rules established by AAPM and the CLA Subcommittee while serving on a Laboratory Assessment Team.
2. I will maintain confidentiality of all information relating to applications and assessments of laboratories accredited by AAPM.
3. I will hold in strict confidence all information, proprietary or otherwise, obtained in the course of my service on an Assessment Team.
4. I understand that I may reveal information about an individual laboratory only to the Chairperson of CLAX Committee, Chairperson of CLA Subcommittee, the Secretariat of the CLA Subcommittee, the laboratory itself or other members of a CLA Assessment Team.
5. I will not offer consultancies or services to any laboratory that might compromise my impartiality during any phase of the assessment process.
6. For each laboratory that I assess, I agree to either be free of any commercial, financial or other pressures or conflicts of interest that might cause me to act in other than an impartial and nondiscriminatory manner or to excuse myself from such activity in the event of a real or perceived conflict of interest.
7. For each laboratory that I assess, I will keep the Chairperson of the CLA Subcommittee informed, in a timely manner, of any activities, affiliations or relationships that might compromise my adherence to commitments made in this agreement. This includes informing the Chairperson of any existing, former or envisaged link or competitive position / association with any laboratory to be evaluated.

NOTE: Please send to the CLA Secretariat, with this signed form, a listing of any possible conflict-of-interest affiliations, and the nature of each.

\_\_\_\_\_  
SIGNATURE DATE: \_\_\_\_\_

PRINT NAME: \_\_\_\_\_

SIGNATURE: \_\_\_\_\_

## **Appendix 2 Laboratory Assessment Fees**

Fees for the administration and maintenance of the Accreditation Program will be assessed to the accredited laboratories and will consist of:

1. Fees to cover E & O Insurance Coverage:  
The cost of the Errors & Omissions insurance premium will be shared among the accredited laboratories on the basis of the ratio of the number of chambers and sources calibrated by the individual laboratory in a 12-month period divided by the total number of chambers and sources calibrated by all the laboratories combined.
2. Other fees as required to recover the cost of the program.
  - a. Assessment costs

The current fee schedule can be found at <https://www.aapm.org/links/adcl.asp>

**Appendix 3 ADCL Logo**



**Appendix 4 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 AAPM  
for the term beginning on the first day of*

\_\_\_\_\_, and ending \_\_\_\_\_

_____ <i>Chair, Calibration Laboratory Accreditation Subcommittee</i>	_____ <i>AAPM President</i>
_____ <i>Chair, Calibration Laboratory Accreditation Executive Committee</i>	_____ <i>AAPM Executive Director</i>

 Accredited Dosimetry  
Calibration Laboratory®

## Appendix 5 Example Scope of Accreditation

Scope of Accreditation  
 Criteria for Accreditation of Dosimetry Calibration Laboratories  
 Revision XX, Revision Date  
 American Association of Physicists in Medicine  
 Granted to  
 Institution Name  
 Address  
 Contact Representative  
 Accredited Dosimetry Calibration Laboratory

Valid To: Date of expiration

Certificate Number:XXXX

Instrument or Material Calibrated	Reference Material and/or Measurand	Measurement Range and Parameters <sup>1</sup>	Measurement Uncertainty <sup>2</sup>	NIST-traceable Calibration Method
Electrometers	Charge, $P_{elec,Q}$	25 pC – 10 $\mu$ C	0.25 %	Measurement of NIST-traceable charge sources; comparison to NIST-traceable voltmeters
Diagnostic X-ray Chambers – Reference-Class	X-rays M-Series Air Kerma, $N_K$	20 kVp -250 kVp	1.9 %	Comparison to NIST-traceable ionization chambers
Therapy Ionization Chambers - Field-Class	<sup>60</sup> Co Dose to Water, $N_{Dw}$	Up to 150 cGy/min	1.3 %	Comparison to NIST-traceable ionization chambers
HDR Well Chambers	HDR <sup>192</sup> Ir Air Kerma Strength, $N_{SK}$	Up to 50 mGy m <sup>2</sup> /hr	2.8 %	Measurement of NIST-traceable Cs-137 brachytherapy sources; comparison to NIST-traceable ionization chambers
LDR Well Chambers	LDR <sup>103</sup> Pd, <sup>125</sup> I Air Kerma Strength, $N_{SK}$	Up to 500 $\mu$ Gy m <sup>2</sup> /hr	2.2 %	Measurement of NIST-traceable brachytherapy sources for <sup>103</sup> Pd, <sup>125</sup> I

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LDR Sources	LDR $^{103}\text{Pd}$ , $^{125}\text{I}$ Air Kerma Strength, $S_K$	Up to 500 $\mu\text{Gy m}^2/\text{hr}$	2.3 %	Measurement of NIST-traceable brachytherapy sources for $^{103}\text{Pd}$ , $^{125}\text{I}$
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<sup>1</sup> Include additional parameters where applicable, e.g., magnitude and polarity of bias voltages.

<sup>2</sup> Measurement Uncertainty is the expanded combined uncertainty with a coverage factor  $k=2$  and includes the NIST uncertainty of the standard used.

AAPM Cert# XXXX, Date

Page x of y



## Appendix 6 Annual Management Quality Review Checklist

The following checklist is to be utilized in the annual management review of the AAPM Accreditation Program.

Date: \_\_\_\_\_

By: \_\_\_\_\_

### Secretariat Procedures & Records

- Applications Outstanding
- Pending Accreditations
- Outstanding Invoices
- Cost and Budget Records
- Current Committee Minutes
- Current Outstanding Action Items
- Printed Current Criteria
- Printed Current Certificate
- Logo Artwork
- Printed Current Quality Manual
- Complaints

### Headquarters Procedures

- Records Maintenance
- Security & Confidentiality
- Interviews & Observations

### Historical Records

- Subcommittee Minutes

### Accredited Laboratory Records

- Application
- Agreement
- Personnel
- Submitted Documents
  - Lab Quality Manual
  - Lab Procedures
- Payment History
- Assessments
- Proficiency Test History

### Assessor Records:

- Qualifications
- Training

AAPM Laboratory Accreditation Program  
Quality Manual

Assessment Participation

Performance Evaluations

Assessor Documents

Quality Manual Review:

Deficiencies

Updates

Standards Compliance

Criteria Review:

Deficiencies

Updates

Standards Compliance

## **Appendix 7 Assessor Training Checklist**

(See requirements of 6.1.3)

To be completed by prospective assessors and reviewed and approved by the CLA Chair

Trainee:

Evaluator (CLA Chair):

Date

Completed:

Review Quality Manual

Review Criteria

Review slide deck

Review prior assessment reports

Participate in assessment as a trainee

Understands risk-based assessment principles

Is able to assess scope item with respect to criteria.

Technical competence

Management competence

Non-consultancy

## Appendix 8 Document Revision History

<b>Date</b>	<b>Who</b>	<b>Comments</b>
1997		Original Created
12/7/01	GS (George Starkshall)	Task Group on ISO Guide 58 Compliance
05/12/02	TS (Tom Slowey)	
8/5/02	GS	
8/17/02	TS	
8/7/03	TS	
7/21/04	TS	to include comments from Geoff Ibbott and Frank Cerra
11/22/05	TS	for ISO 17011:2004 requirements
07/22/06	TS	for ref to ISO 17025:2005 and date
01/26/07	TS	revised organization and formatting
10/2021	J. Siebers R. Tosh J. Moton	Major revision for alignment with ISO17011(2017). Individual changes were too extensive to track individually.