Laboratory Accreditation Program
Quality Manual

American Association of Physicists in Medicine

Revision 8

January 2007

Original Prepared by the
Task Group on ISO Guide 58 Compliance

Revised to Comply with
ISO/IEC 17011

AAPM Laboratory Accreditation Program Quality Manual

Subcommittee on Laboratory Accreditation
of the
Therapy Physics Committee
American Association of Physicist in Medicine

Formal adoption of quality manual and **quality** policy statement

The policy of the American Association of Physicists in Medicine is to operate the very highest quality accreditation system for dosimetry calibration laboratories through the commitment of appropriate personnel, voluntary committees and financial resources and the application of policies and procedures that satisfy national and international standards and guides relating to the operation of accreditation systems and the accreditation of competent calibration and testing laboratories. **It is also our policy to ensure that all policies and procedures are understood and maintained at all levels.**

(**Original** Approval by the Board of Directors and signed by President.)

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INTRODUCTION

Medical physics is an applied branch of physics concerned with the application of the concepts and methods of physics to the diagnosis and treatment of human disease. It is allied with medical electronics, bioengineering, and health physics. Most medical physicists have an M.S. or Ph.D. in medical physics, physics, radiation biology, or a related discipline, and training in clinical medical physics. Clinical training may be obtained through a residency traineeship or a postdoctoral program of one or two years in a hospital. Clinical medical physicists are employed in medical schools, hospitals or clinics, or are in private practice. These physicists divide their time between clinical service and consultation, research and development, and teaching. Some medical physicists work in industrial or research positions, and have no clinical responsibilities.

A key element in the activities of a medical physicist is 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 standard (e.g. in the United States, the National Institute of Standards and Technology-NIST).

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

1. To reduce the time required for precision calibrations. The growth of radiation therapy facilities in the US had created a demand for precision calibrations of dosimetry instrumentation which NIST was not able to satisfy in a reasonable period of time and resulted in backlogs of nearly a year in obtaining these calibrations.

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 on an ongoing basis. With the cooperation of NIST the first measurement assurance program (MAP) was established for dosimetry instrumentation in the US. The MAP required regular accredited laboratory comparisons with NIST and other 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.

The laboratories accredited by the AAPM are now known as Accredited Dosimetry Calibration Laboratories (ADCL). The number of laboratories has varied from two to five over the years since 1971. The accreditation program supplies the need for precision medical calibration services in the US through the close support of the National Institute of Standards and Technology (NIST).

This document was prepared 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". The numbers in parentheses after selected sentences and paragraphs refer to the section in Guide 58.

This document has been revised January 2007 to satisfy ISO/IEC 17011:2004, "Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies"

1.0 SCOPE

This document describes the quality system that governs the operation of the accreditation of laboratories by the American Association of Physicists in Medicine. Laboratories accredited by the AAPM are known as Accredited Dosimetry Calibration Laboratories. The function of an ADCL is as follows:

1. To be a *secondary* standard calibration laboratory for medical dosimetry.

2. To calibrate radiation sources and/or radiation measuring devices by comparing them with standards that have been calibrated at NIST or other acceptable national standards laboratory.

3. To provide, for reference-class as well as field class diagnostic and therapy instruments and/or long lived brachytherapy sources, calibrations that meet or exceed the uncertainty goals established by the Calibration Laboratory Accreditation Subcommittee (CLA Subcommittee) for each area of accreditation.

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.

5. To participate in oversight activities of the CLA Subcommittee by having a representative at all meetings of the CLA Subcommittee and by providing annual reports of the activities of the ADCL. These reports shall include, as a minimum, a.) a report on the number of calibrations performed in each area, including the type of calibrations performed, b.) a report on any changes in key personnel or facility, c.) a report of any errors in the calibrations which exceed the laboratory uncertainty goals, d.) a report of the number of instruments received that were unfit for calibration and e.) such other information that the chairman of the Subcommittee deems appropriate.

2.0 REFERENCES

"Guidelines for Auditing Quality Systems", ANSI/ISO/ASQ Q10011-1-1994, Q10011-2-1994, Q10011-3-1994, ASQ, Milwaukee, WI

"General Requirements for the Competence of Testing and Calibration Laboratories", ANSI/ISO/IEC 17025:2000, NCSL, Boulder, CO.

"Calibration and testing laboratory accreditation systems – General requirements for operation and recognition", ISO/IEC Guide 58:1993, ISO, Geneva

"CRITERIA FOR ACCREDITATION OF DOSIMETRY CALIBRATION LABORATORIES", AAPM, April, 2003

"General Requirements for the competence of Testing and Calibration Laboratories", ANSI/ISO/IEC 17025:2005, NCSL, Boulder, CO

ISO/IEC 17011:2004, "Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies"

ISO 9000:2000, Quality managements systems – Fundamentals and vocabulary

ISO/IEC 17000:2004, Conformity assessment – Vocabulary and general principles

3.0 DEFINITIONS

3.1 accreditation
third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks

3.2 accreditation body
authoritative body that performs accreditation
NOTE The authority of an accreditation body is generally derived from government.

3.3 accreditation body logo
logo used by an accreditation body to identify itself

3.4 accreditation certificate
formal document or a set of documents, stating that accreditation has been granted for the defined scope

3.5 accreditation symbol
symbol issued by an accreditation body to be used by accredited labs to indicate their accredited status

NOTE “Mark” is to be reserved to indicate direct conformity of an entity against a set of requirements.

3.6 appeal
request by a CAB for reconsideration of any adverse decision made by the accreditation body related to its desired accreditation status

NOTE Adverse decisions include
- refusal to accept an application,
- refusal to proceed with an assessment,
- corrective action requests,
- changes in accreditation scope,
- decisions to deny, suspend or withdraw accreditation, and
- any other action that impedes the attainment of accreditation .

3.7 assessment
process undertaken by an accreditation body to assess the competence of a CAB, based on particular standard(s) and/or other normative documents and for a defined scope of accreditation

NOTE Assessing the competence of a lab involves assessing the competence of the entire operations of the lab, including the competence of the personnel, the validity of the methodology and the validity of the calibration or test results.

3.8 assessor
person assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a lab

3.9 complaint
expression of dissatisfaction, other than appeal, by any person or organization, to an accreditation body, relating to the activities of that accreditation body or of an accredited lab, where a response is expected

3.10 conformity assessment body
CAB - body that performs conformity assessment services and that can be the object of accreditation

3.11 consultancy
participation in any of the activities of a lab subject to accreditation

EXAMPLES:
- preparing or producing manuals or procedures for a lab;
- participating in the operation or management of the system of a lab;
- giving specific advice or specific training towards the development and implementation of the management system and/or competence of a lab;

- giving specific advice or specific training for the development and implementation of the operational procedures of a lab.

3.12 expert
person assigned by an accreditation body to provide specific knowledge or expertise with respect to the scope of accreditation to be assessed

3.13 extending accreditation
process of enlarging the scope of accreditation

3.14 interested parties
parties with a direct or indirect interest in accreditation
NOTE Direct interest refers to the interest of those who undergo accreditation; indirect interest refers to the interests
of those who use or rely on accredited conformity assessment services.

3.15 lead assessor
assessor who is given the overall responsibility for specified assessment activities

3.16 reducing accreditation
process of cancelling accreditation for part of the scope of accreditation

3.17 scope of accreditation
specific conformity assessment services for which accreditation is sought or has been granted

3.18 surveillance
set of activities, except reassessment, to monitor the continued fulfilment by accredited labs of requirements for accreditation
NOTE Surveillance includes both surveillance on-site assessments and other surveillance activities, such as the following:

a) enquiries from the accreditation body to the lab on aspects concerning the accreditation;
b) reviewing the declarations of the lab with respect to what is covered by the accreditation;
c) requests to the lab to provide documents and records (e.g. audit reports, results of internal quality control for verifying the validity of lab services, complaints records, management review records);
d) monitoring the performance of the CAB (such as results of participating in proficiency testing).

3.19 suspending accreditation
process of temporarily making accreditation invalid, in full or for part of the scope of accreditation

3.20 withdrawing accreditation
process of cancelling accreditation in full

3.21 witnessing
observation of the laboratory carrying out test and calibration services within its scope of accreditation

4.0 ACCREDITATION BODY

4.1 General Requirements

4.1.1 The AAPM accreditation program shall be administered in a non-discriminatory manner and shall not be dependent upon the size of the laboratory or membership of the laboratory or its leadership in the AAPM. (4.1.1.)

4.1.2 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 is based on ISO/IEC 17025. (4.1.2)

4.1.3 The technical requirements for accreditation described in the Appendix of the Criteria are developed by the CLA Subcommittee. This CLA Subcommittee (composition described elsewhere in this document) oversees the activities of the Accreditation Program and is considered an impartial body representing the interest of the consumers of the accredited services as well as the interest and goals of the AAPM. (4.1.3.)

4.1.4 As described in the General Requirements for Accreditation of the Criteria, accredited laboratories are required to maintain impartiality and integrity.

4.1.5 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. (4.1.5.)

4.1.6 The accreditation body will make publicly available, and update at regular intervals, the following:

a. detailed information about its assessment and accreditation processes, including arrangements for granting, maintaining, extending, reducing, suspending and withdrawing accreditation

b. a document of reference documents containing requirements for accreditation, including technical requirements specific to each field of accreditation, where applicable

c. general information about the fees relating to the accreditation

d. description of the rights and obligations of accredited laboratory

e. information on the accredited laboratory, such as

name and address of each accredited laboratory

dates of granting accreditation and expiry dates, as applicable

scopes of accreditation, if condensed, information on how to obtain the full scope

f. information on procedures for lodging and handling complaints and appeals

g. information and the authority under which the accreditation program operates

h. description of its rights and duties

i. general information about the means by which it obtains financial support

j. information about its activities and stated limitations under which it operates

k. information about related bodies

4.2 Organization of the accreditation body

4.2.1 Legal Entity

The American Association of Physicists in Medicine is a not-for-profit organization incorporated in the District of Columbia, November 10, 1965. (4.2.1.a.)

4.2.2 Organization

The AAPM is a scientific, educational, and professional organization of more than 4,500 medical physicists devoted to the discipline of physics in medicine. In 1971, the AAPM established the accreditation of dosimetry calibration laboratories for the purpose of assisting the membership and other health professionals in obtaining high quality traceability to national standards of dosimetry in a timely manner. As a leading professional society, the AAPM has rights and responsibilities in the medical dosimetry field. With many years of experience in the operation of a laboratory accreditation system, the AAPM is uniquely qualified to be an accreditation body for medical dosimetry calibration laboratories. (4.2.1.b., 4.2.1.d.)

4.2.3 Headquarters

Headquarters are located at the American Center for Physics in College Park, MD, with a staff of 16; Annual budget is over $5M. (4.2.1.d.) Publications include a scientific journal (*Medical Physics*), technical reports, and symposium proceedings.

4.2.4 Insurance

The AAPM purchases liability insurance to protect against claims resulting from the activities of the society. (4.2.1.c.)

4.2.5 Sources of Income

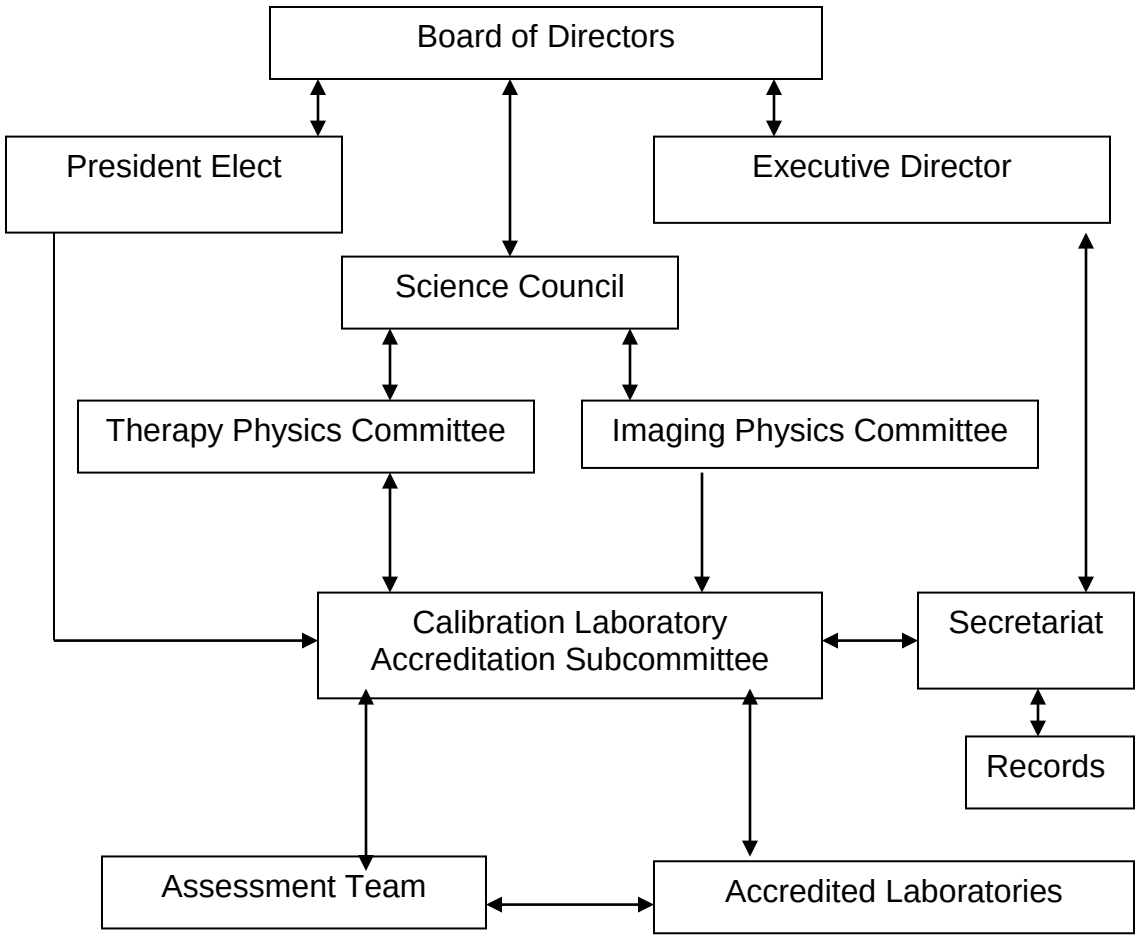
The AAPM publishes an annual financial report that describes the sources of income. Records and other documents are maintained. (4.2.1.e.)

4.2.6 Committee Operation

The AAPM has documented policies and procedures governing the operation of committees as published in the AAPM Membership Directory. (4.2.1.j.)

4.2.7 Organizational Structure

(4.2.1.f, 4.2.1.g, 4.3.2.b, 4.2.7.h)



4.2.8 Program Organization

a. The Board of Directors (Board) 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.

b. The President is the principal administrative officer of the Society. The President appoints a Chair of the CLA Subcommittee for a term of three years.

c. The Board appoints the Executive Director to have overall responsibility for the accreditation program.

d. The Board has overall authority and responsibility for the LAP and approves the LAP Criteria, Quality Manual, relevant procedures, budget, and initial accreditation decisions.

e. The CLA Subcommittee makes the final decision on appeals of initial LAP accreditation decisions, but elevates that responsibility to the Board if indicated.

f. The Board appoints a Secretariat to be the initial point of contact for all communications regarding the accreditation program and to maintain all accreditation program records.

g. Refer to section 4.3.3 for duties and responsibilities of the President and Executive Committee.

4.3.3 Duties and Responsibilities

a. The Board of Directors
The Board has overall responsibility for the Society. The Board approves all accreditation program actions based on the recommendations of the CLA Subcommittee, the Therapy Physics Committee and the Executive Director. The Board appoints the Executive Director to have overall authority and responsibility for the management of the accreditation program (ISO 17011:4.2.4, 4.2.5):

b. The Executive Director
The Executive Director has the authority and responsibility,

1. to approve policies relating to the operation of the accrediting body.

2. to assure the implementation of the policies and procedures

3. to safeguard objectivity and impartiality of the accreditation activities

4. to supervise the finances of the accreditation body

5. to prevent discriminatory practices.

4. to make recommendations on decisions on accreditation

5. to approve contractual arrangements on the recommendations of the CLA Subcommittee

6. to delegate the authority to committee or individuals, as required, to undertake defined activities on behalf of the board of directors. Specific duties have been delegated to the Calibration Laboratory Accreditation Subcommittee, Accreditation Program Secretariat.

7. to ensure 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. This list of personnel will include assessors and experts.

8. to ensure that each individual's duties are made clear to them (limits, responsibilities and authorities).

11. to require each individual to make a formal commitment by signature or equivalent means that they will comply with the rules of the AAPM.

12. to report to the Board on the performance of the management system and any need for improvement.

c. President

1. to appoint the Chair of the CLA Subcommittee for a term of three years.

2. to review and make recommendations to the Board regarding accreditation decisions.

d. The Calibration Laboratory Accreditation Subcommittee

The voting members of the Subcommittee are made up of a Chairman, a representative from NIST, one or more representatives from the Imaging Physics Committee and other interested persons who may or may not be members of the AAPM. Members are appointed for a period of three years by the President Elect. Members may succeed themselves for one additional term. The Directors of each Accredited Dosimetry Calibration Laboratory (ADCL) are non-voting ex-officio members of the Subcommittee. (4.3.2.b., 4.2.1.h.)
Voting members of the Subcommittee must be free from any commercial pressure that might influence their ability to make unbiased decisions. (4.2.1.i.)

The CLA Subcommittee is responsible for

1. the development of policies and procedures governing the operation of the accreditation program,

2. administer the accreditation program in an objective and impartial manner.

3. provide the opportunity of involvement by interested parties.

4. make accreditation services accessible to all applicants whose request falls within its policies and rules

5. prevent undue pressure to influence its members and decisions

6. ensure that each decision on accreditation is taken by competent person(s) or committee(s) different from those who carried out the assessment.

7. prevent the offering consultancies or services by Subcommittee members that might affect the Subcommittee's impartiality.

4.2.9 Approval of Accreditation

Accreditation of a candidate calibration laboratory occurs by action of the Board of Directors of the AAPM and may be granted and renewed for a period of up to four years. The action of the Board is based on the recommendations of the Radiation Therapy Committee (RTC). The Therapy Physics Committee makes its recommendations to the Board on the basis of findings and recommendations of the Calibration Laboratory Accreditation Subcommittee (also known as the CLA Subcommittee). The CLA Subcommittee oversees all activities regarding the operation of the ADCLs.

4.2.10 Appeal of Denial of Accreditation

In the event of a disagreement between an ADCL or applicant laboratory regarding a decision of the CLA Subcommittee to deny accreditation, the ADCL or applicant laboratory may appeal the decision to the Therapy Physics Committee. The Chair of TPC shall appoint a Task Group of three members to investigate the decision to deny accreditation and report its findings to the Chair. Such findings shall be reviewed by legal council. Upon review and advice of council, the Chair shall request a special meeting or conference with the Chair of the CLA Subcommittee and the AAPM Executive Committee (EXCOM). The decision of EXCOM shall be final. (4.2.1.h.)

4.2.11 Meetings

The Subcommittee has two regular annual meetings, one at the annual AAPM meeting in mid-summer and one at the Radiological Society of North America meeting in late November or early December. Other meetings may be scheduled at the discretion of the Chairman.

Whenever a site assessment is necessary either for initial accreditation or renewal of accreditation, the Chairman appoints a team leader. The team is generally composed of a team leader (usually a member of the Subcommittee), a technical representative from NIST and a person familiar with the technical aspects or area of service that the candidate laboratory provides.

4.2.12 Use of Accreditation Symbol

Only organizations that have been accredited as dosimetry calibration laboratories by the American Association of Physicists in Medicine may refer to themselves as "Accredited Dosimetry Calibration Laboratories" or "ADCLs." (4.2.2.)

4.3 Impartiality

4.3.1. The AAPM is a professional society providing accreditation activities as a service to its members and to health care professionals. Such accreditation services generally complement the standard setting activities in which the AAPM is engaged and do not pose a conflict of interest on the part of members engaged in multiple activities.

4.3.2 The appointment and operation of all technical committees are governed by the rules of the society. Appointments of members shall be made with due consideration for any perceived or actual commercial, financial or other pressures or conflicts of interest. (4.2.1.j.)

4.3.3 In order to avoid any compromise in the objectivity of members of the ADCL Subcommittee, voting members shall not offer to consult with or provide services to any existing or prospective laboratory. (4.2.1.l.)

4.4 Confidentiality

4.4.1 All documents and information relating to the operation, policies and procedures of the laboratory application for accreditation, renewal of accreditation or information submitted by laboratories not accredited by the AAPM shall be maintained in strict confidence. (4.4)

4.4.2 All individuals having access to confidential information regarding the operation of an accredited lab or a prospective shall sign a nondisclosure statement and submit it to the Secretariat.

4.4.3 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 Chair of the ADCL Subcommittee, the appointed and approved assessment team leader, the Executive

Director of the AAPM and the Secretariat. Files containing the above information shall be maintained locked to prevent unauthorized access.

4.4.4 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 re-approval of the accreditation to the new owner. Upon notification of a change in ownership, the ADCL Subcommittee 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 lab is questionable or unlikely to be approved, the ADCL Subcommittee may give notice to suspend operation as an accredited lab until the AAPM Board can consider the new accreditation. Upon suspension of accreditation, the laboratory shall be advised to return its certificate of accreditation and cease all claims in advertising of accredited operation. The laboratory shall forward all records to the AAPM. (4.4.3.)

4.5 Full disclosure

All individuals participating in the assessment of laboratories, as voting members of the ADCL Subcommittee and executive staff, shall have submitted a disclosure statement describing ownership or affiliations with any organization or entities that may represent or be perceived as a conflict of interest.

4.6 Accreditation Activity

4.6.1 Accreditation Actions by the AAPM

a. Accreditation of a candidate calibration laboratory occurs by action of the Board of Directors of the AAPM and may be granted and renewed for a period of up to four years. The action of the Board is based on the recommendations of the Therapy Physics Committee, which is a standing committee of the AAPM. The Therapy Physics Committee makes its recommendations to the Board on the basis of findings of the CLA Subcommittee. The CLA Subcommittee oversees all activities regarding the operation of the ADCLs.

b. The voting members of the CLA Subcommittee are made up of a Chairman, a representative from NIST, one or more representatives from the Diagnostic Imaging Committee, members of the Radiation Therapy Committee and other interested persons who may or may not be members of the AAPM. Members are appointed for a period of three years by the President Elect. Members may succeed themselves for one additional term. The Directors of each ADCL are non-voting ex-officio members of the CLA Subcommittee.

c. The CLA Subcommittee has two regular annual meetings, one at the annual AAPM meeting in mid-summer and one at the Radiological Society of North America meeting in late November or early December. Other meetings may be scheduled at the discretion of the Chairman.

d. Whenever a site visit is necessary either for initial accreditation or renewal of accreditation, a three-member team is appointed by the Chairman. The team is generally composed of a team leader (usually a member of the CLA Subcommittee), a representative from NIST and a person familiar with the technical aspects or area of service that the candidate laboratory provides.

4.6.2 Tenure of accreditation

a. Accreditation is awarded by the AAPM for a period of four years, at which time it must be renewed. Renewal of accreditation generally requires a site visit during the third year. Surveillance visits may be scheduled at any time during the period of accreditation as required by the Subcommittee.

b. 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 and the procedures of the laboratory are in accordance with its protocol and its personnel or performance are not significantly changed.

c. The laboratory shall report significant changes in personnel, equipment or protocol to the Subcommittee. 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. (4.4.1.)

4.6.3 Revocation or discontinuance of accreditation

a. Evaluation of the performance of an ADCL will be based on such considerations as the acceptable performance of the periodic NIST proficiency tests, representation at the appropriate committee meetings, other indications of the acceptable uncertainty of calibration, comments offered by individuals or institutions concerning the ADCL, the adequacy of turn-around time for calibrations, and the ability of the ADCL to provide calibrations at a reasonable cost. A major factor in this evaluation will be the review at the periodic site visits.

b. If the Subcommittee believes the performance of a laboratory to be unacceptable, accreditation may be revoked. Normally this will be temporary, allowing the laboratory to demonstrate its ability to perform according to these CRITERIA. The Subcommittee may, at its option, make a site visit to the laboratory and/or request that the laboratory perform special calibrations, the expenses of either normally to be paid by the laboratory. Following demonstration judged by the Subcommittee as successful, the laboratory will be eligible for either provisional or full accreditation. (4.4.2.)

c. Discontinuance of operation as an accredited laboratory: By acceptance of accreditation, the laboratory agrees to inform the Subcommittee in writing of any intention to discontinue operation as an ADCL, at a reasonable time prior to the

date of discontinuance. The laboratory also acknowledges that all calibration records become the property of the AAPM upon discontinuance of ADCL operation and agrees to keep records in accordance with these CRITERIA following the discontinuance, unless authorized by the Subcommittee to transfer or otherwise dispose of the records. (4.4.3.)

4.7 Public Informational Documentation describing the accreditation

4.7.1 Document entitled “Criteria for Accreditation of Dosimetry Calibration Laboratories by the American Association of Physicists in Medicine,” which is available from the American Association of Physicists in Medicine, describes the accreditation process, the requirements for accreditation and the duties and rights if the accredited lab. The AAPM web site has information readily available that describes the Accreditation Program and provides contact information for interested parties to obtain additional information. (4.5 a-f)

5.0 LABORATORY ASSESSORS

On-site assessments of candidate laboratories are conducted to evaluate compliance with the requirements of the accreditation Criteria. For initial or renewal accreditation assessments, the ADCL Subcommittee Chair and a team leader identify a team composed of a minimum of three assessors. For periodic surveillance assessments, usually one assessor is sufficient. After each assessment, a report of visit is submitted to the Subcommittee describing the observations along with recommendations for initial, renewal of accreditation. This section describes the requirements for assessors, the makeup of the site visit team, the procedures for assessor qualification and the records required to document assessors. The specific scope for each assessor will be identified. This scope will be only for the area in which the assessor has demonstrated competence.

5.1 Requirements for assessors

5.1.1 Minimum requirements for all assessors

All laboratory assessors shall:

a. have appropriate technical knowledge for the task assigned by the ADCL Subcommittee or assessment team leader which includes a familiarity with the accreditation procedures, accreditation criteria and other relevant requirements (5.1.c.)

b. be able to communicate effectively, both in writing and orally, (5.1.d.)

c. be free of any commercial, financial or other pressures or conflicts of interest that might cause assessor(s) to act in other than an impartial or non-discriminatory manner, (5.1.e.)

d. not have previously offered or provided consultation services to the candidate laboratory which might compromise their impartiality in the accreditation process and decisions. (5.1.f.)

e. sign an agreement to maintain the confidentiality of all information obtained in the performance of the assessment.

f. have personal characteristics consistent with guidance of ISO 10011, clause 7.2

g. have undergone training relevant to accreditation assessor duties and requirements

h. have a thorough knowledge of relevant assessor methods

5.1.2 Assessment Team

The assessment team for initial or renewal of accreditation shall be composed of at least 3 members - a team leader, a technical expert in calibration metrology similar to the calibrations requested for accreditation and a third member to assist in the assessment as assigned by the team leader, to observe the conduct of the assessment and to gain assessor experience for future team leadership. Surveillance assessments may be composed of one person who is qualified as a team leader.

5.1.3 Assessment Team Leader

The assessment team leader is appointed by the Chair of the ADCL Subcommittee. This individual shall:

a. have an understanding of the general requirements for accreditation as described in the Criteria and be familiar with the technical requirements of the Appendix of the Criteria as it applies to the calibrations and tests of the candidate laboratory

b. be selected from the ADCL Subcommittee

c. have prior training in ISO/IEC 17025

d, have participated in at least one prior laboratory assessment

e. demonstrate familiarity with the relevant legal regulations regarding the licensing, registration and safe use of radiation machines, ISO 10011 (Guidelines for Auditing Quality Systems), the AAPM Criteria for accreditation, the AAPM procedures for accreditation and accreditation requirements (5.1.a.)

f. have a working knowledge of the AAPM assessment method and assessment documents (5.1.b.)

5.2 Assessor Qualification Procedures (5.2.)

The Chair of the ADCL Subcommittee will evaluate the training and experience of prospective assessor team leaders. Assessor team leaders are qualified on the basis of the requirements of section 5.1.1 and 5.1.2. Once a team leader is qualified and agrees to conduct the assessment in the required time interval, the Subcommittee Chair and the team leader will jointly qualify the other members of the team according to the requirements of 5.1.1 and the required technical knowledge needed by the technical expert to assess the laboratory. The last member of the team will also be a joint decision based not only on the above referenced qualifications sections but also on fulfilling the need for training of additional team leaders. The third team member will also have the responsibility to report on the performance of the assessment for monitoring purposes. (4.3.2)

For additional monitoring, the Chair of the Subcommittee may contact the laboratory for an evaluation of the assessment.

5.3 Contracting of assessors (5.3.)

Contract assessors will not be used unless qualified assessors are not available. In the event that it becomes necessary to engage the services of contract assessors, a signed contract will be require the following:

5.3.1 a commitment to comply with the rules defined by the accreditation body,

5.3.2 a confidentiality agreement,

5.3.3 a disclosure statement those relating to independence from commercial and other interests and

5.3.4 a full disclosure of any prior association with the laboratory to be assessed.

5.4 Assessor records

The AAPM Secretariat shall possess and maintain up-to-date records on assessors consisting of

5.4.1 name and address (5.4.a)

5.4.2 organization affiliation and position held (5.4.b)

5.4.3 educational qualification and professional status (5.4.c)

5.4.4 work experience (5.4.d)

5.4.5 training in ISO/IEC 17025, quality assessment, calibration and testing (5.4.e)

5.4.6 experience in laboratory assessment, together with field of competence (5.4.f)

5.4.7 signed confidentiality agreement

5.4.8 date of most recent updating of record (5.4.g)

5.5 Procedures for Assessors

Assessors shall be provided with an up-to-date set of procedures giving assessment instructions and all relevant information on accreditation arrangements. (5.5)

5.6 Assessor Documents

The assessment team shall be furnished the following documents prior to the assessment:

5.6.1 Current version of the AAPM Criteria

5.6.2 Assessor checklist for the Criteria completed by the candidate lab indicating the sections of the quality manual satisfying each Criteria requirement.

5.6.3 Copy of the application for accreditation or renewal of accreditation describing the laboratory with address and contact information, scope of accreditation and a copy of the report of prior assessment (if appropriate)

5.6.4 Copy of the lab quality manual and/or protocol (if version on file at AAPM is current)

5.6.5 A guideline agenda

5.6.6 Requested or proposed dates of assessment.

5.6.7 Results of most recent proficiency test or round robin inter-comparison results.

5.6.8 An evaluation form will be provided to the candidate laboratory for the purpose of evaluating the performance of the assessment team to the Subcommittee.

6.0 ACCREDITATION PROCESS

6.1 Application for accreditation

An organization that desires to apply for new or renewal accreditation should contact the Secretariat. The Secretariat shall provide the applicant organization with a copy of these Criteria. (6.1.1.)

6.1.1 New Application for Accreditation

The new applicant organization shall submit a formal application with the following information along with any required application fee:

a. the location of the proposed or existing laboratory,

b. a complete description of its laboratory and support facilities,

c. the scope of the calibration work it intends to provide, (6.1.3.a)

d. The application shall include an agreement by the applicant's representative to the following:

1) fulfill all requirements of accreditation procedures,

2) allow an assessment team access to laboratory facilities,

3) pay all additional fees (charges for assessment, proficiency tests, annual maintenance fees, etc.) (6.1.3 b)

e. The applicant agrees to comply with requirements for accreditation and to supply any additional information as needed for the evaluation. (6.1.2., 6.1.3c)

f. The applicant agrees to provide the names and qualifications of the persons who will be responsible for the laboratory (6.1.4.a)

g. The applicant shall provide the following general information prior to the on-site assessment:

1) Name, address, legal status, human and technical resources,

2) General information regarding primary function, relationship in a larger corporate entity and ownership, (6.1.4.b.)

3) Definitions of the type, range and best uncertainties of measurements performed, (6.1.4.c.)

4) A copy of the laboratory's quality manual and associated documentation. (6.1.4.d.)

h. The applicant agrees to provide the names and qualifications of the persons who will perform the instrument calibrations and/or source calibrations and calculations and

i. The applicant agrees to provide the names and qualifications of the persons who will review and sign the formal reports.

j. The Chair of the ADCL Subcommittee will review the application for completeness and may request additional information from new applicants before agreeing to consider accreditation.

k. The committee will review its ability to carry out the assessment in terms of its own policy, competence and the availability of assessors and experts.

l. This review will also include the ability of the accreditation body to carry out the initial assessment in a timely manner.

6.1.2 Renewal of Accreditation

The renewal applicant organization shall submit a letter requesting renewal of accreditation and asserting its compliance with the general requirements for accreditation along with any required renewal application 6 months fee prior to the expiration date of the accreditation. The process of renewal will proceed as follows:

a. AAPM accreditation is granted for a period of four years. During the third year, the ADCL should submit a letter requesting renewal of the accreditation to the Secretariat with the appropriate fee.

b. The site visit should be completed at least two months prior to the summer AAPM meeting or the RSNA meeting. Ideally the site visit should take place by the end of May of the year before the expiration of accreditation.

c. In the event that the necessary approvals of the RTC, Science Council and Board of Directors does not occur prior to the expiration of the laboratory's accreditation, the ADCL Subcommittee shall have the authority to grant a one year administrative extension of the accreditation of the ADCL to provide the time necessary to complete the approval process.

Upon receipt of the application, the Secretariat will acknowledge receipt and send copies to the Chair of the ADCL Subcommittee along with acknowledgement of the payment of the fee.

6.2 Satisfy general requirements:

The Secretariat will advise the new applicant laboratory to submit objective evidence that it satisfies the general requirements for accreditation in all of the following areas:

6.2.1 The laboratory must establish that it can satisfy a need that is not presently satisfied by the existing accredited laboratories.

6.2.2 The laboratory must establish that its operation is free of a conflict of interest or financial or management influence of the other activities of its business or the business

of the owner that would adversely affect the impartiality of its calibration and/or test results.

6.2.3 The laboratory must establish its ability to provide the proposed accredited services.

6.2.4 The laboratory must agree to allow access to records and facilities by AAPM assessors.

6.2.5 The laboratory must agree to pay all fees and expenses assessed by AAPM.

6.2.6 The laboratory must establish its compliance with the accreditation Criteria.

6.2.7 The laboratory must agree to all the terms of accreditation relating to the tenure of accreditation, attendance at meetings, required reports, retention of records, notification of changes in ownership and key personnel, surveillance visits and all other requirements contained in the Criteria.

6.2.8 The laboratory agrees to immediately suspend accredited operation upon notice of revocation or discontinuance of accreditation status.

6.2.9 The laboratory must agree to perform all accredited calibrations according to the submitted laboratory protocol and quality manual

6.2.10 The laboratory agrees to maintain redundant standards and perform redundant measurements whenever possible.

6.2.11 The laboratory standards for dosimetry must have been calibrated by the National Institute of Standards and Technology (NIST) or other acceptable national standards laboratory.

6.2.12 The laboratory must agree to limit the scope of its accredited calibrations to those approved in the scope of accreditation

6.2.13 The laboratory must agree to submit a copy of the current protocol and quality manual to the AAPM Secretariat. The ADCL protocol and quality manual shall be maintained confidential by the AAPM as a proprietary property of the laboratory.

6.2.14 The laboratory agrees to follow the rules for use of ADCL logo

6.3 Subcontracting of assessment:

In the event that the ADCL Subcommittee decides to delegate part or all of the assessment of a laboratory to a third party, the Subcommittee accepts full responsibility for the adequacy of the assessment to meet the requirements of the accreditation and will not subcontract the decision-making. .(6.3.1) The Subcommittee shall ensure that

the assessment organization or individual is competent and qualified to perform the assessment and familiar with AAPM policies and procedures and the Criteria and the requirements of ISO 17011. (6.3.2) The committee will obtain consent from the accredited laboratory for the specific contractor. A list of subcontractors to be used will be maintained. The committee will have means for assessing and monitoring their competence and for recording the results.

6.4 Appointment of assessment team:

6.4.1 Upon receipt of the lab submission, the Chair of the ADCL Subcommittee shall appoint an assessment team leader. The team leader and the Chair will jointly decide on the other members of the assessment team. Selection of the assessment team will be based on the requirements of Section 5.2. The list of prospective assessors will be sent to the laboratory to be assessed for approval. If requested, CV's of members of the assessment team will be also be provided to the laboratory for approval. (6.2.1., 6.2.4.)

6.4.2 Each assessor shall be provided with the appropriate working documents.(6.2.2) Each assessor will inform the accreditation body, prior to the assessment, of any existing, former or envisaged link or competitive position between themselves or their organization and the accredited laboratory to be assessed.

6.4.3 The assessment date shall be set by mutual agreement between the AAPM and the laboratory. The AAPM shall provide to the laboratory a list of the names and, if appropriate, the background of each member of the proposed assessment team. The laboratory shall have the opportunity to appeal for replacement of any member. Such appeal shall include a reasonable and appropriate justification for such replacement. (6.2.3)

6.4.4 The assessment team may not subcontract any part of its responsibilities without the written consent of the ADCL Subcommittee.

6.5 Assessment team approval:

The Subcommittee Chair will notify the team members after approval is received from the laboratory. The team leader and the Chair of the Subcommittee review the submission and, if incomplete, advise the Secretariat to send the Criteria checklist and request a copy of the laboratory quality manual and protocol.

6.6 Review of protocol, quality manual and Criteria checklist:

6.6.1 The team leader will review the application, the submitted protocol, quality manual and checklist and resolve any major questions concerning the submission. If, in the opinion of the team leader, the laboratory is ready for an assessment, an assessment date is proposed to the lab. Upon mutual agreement on the date, the team leader will prepare an agenda and send it to the Secretariat and the Chair of the Subcommittee.

6.7 Initial Assessment Visit and Preliminary Proficiency Test:

6.7.1 The approved assessment team will visit the laboratory and review the facilities, personnel, organization and required resources and conduct a preliminary proficiency test designed to demonstrate the competence of the laboratory's personnel and procedures through the calibration of a suitable instrument or source. The "Guidelines for Auditing Quality Systems", ASQ Q10011, will be used as a guide in conducting the site visit. Upon completion of the assessment, the team will submit all expenses to the Secretariat for billing to the laboratory.

6.7.2 Prior to the completion of the site assessment, a draft of the scope of the accreditation will be prepared by the assessment team and the laboratory representative according to the form shown in appendix 9. Each entry in the scope shall include a statement of the "best" uncertainty for the entry. The laboratory shall prepare an uncertainty budget for each stated uncertainty entry in the scope.

6.8 NIST Proficiency Test:

The laboratory must schedule and successfully complete a proficiency test with NIST covering the scope of calibrations offered by the laboratory. This may occur before or after the site visit. The candidate laboratory will bear the expense of the proficiency test directly with NIST. (6.8.)

6.9 Assessment Reports:

6.9.1 The assessment team shall provide a written or oral report to the laboratory management at the final meeting after the assessment describing the status of compliance with the accreditation requirements and a list of any deficiencies that will need to be corrected for full compliance. (6.4.1a)

6.9.2 The assessment team shall provide to the AAPM a detailed written assessment report containing all relevant information concerning the applicant laboratory's compliance with the accreditation requirements and any unresolved deficiencies and any known proficiency test issues. (6.4.1b)

6.9.3 The assessment team and the Subcommittee Chair shall review the report and promptly inform the applicant laboratory of all deficiencies that require resolution and the laboratory will be invited to respond to the deficiencies by describing an action plan to remedy any outstanding non-compliance. (6.4.1c)

6.10 Accreditation Actions

6.10.1 Provisional Accreditation: Upon successful completion of the NIST proficiency test, a positive report by the site visit team and if the AAPM Subcommittee finds the laboratory complies with these CRITERIA and eligible for accreditation, provisional accreditation may be recommended by the Subcommittee to the Radiation Therapy

Committee. Upon approval of the recommendation by the Radiation Therapy Committee, a recommendation is made to the Executive Committee and the AAPM Board of Directors for provisional accreditation. Upon approval of the AAPM Board of Directors, the provisional accreditation is granted for a period of one year. (6.5.1.)

6.10.2 Granting accreditation: Upon approval of accreditation, the Secretariat shall prepare a certificate of accreditation and a scope of accreditation and transmit these documents to the laboratory after a complete copy has been made for headquarters files. (6.6.1.)

a. A sample certificate is shown in the appendix.

b. A sample scope of accreditation is shown in the appendix . (6.6.1.b.)

6.10.3 Performance Evaluation: The performance of the laboratory will be evaluated at subsequent meetings of the Subcommittee. The evaluation will consider such factors as comments or complaints from members, turn-around time, staffing changes, any problems or calibration errors reported and such other considerations as the Subcommittee deems appropriate. If another site visit is required, it also will be performed at the expense of the applicant institution.

6.10.4 Full Accreditation: Full AAPM accreditation may be granted by the AAPM Board of Directors upon the recommendation of the Subcommittee and the Radiation Therapy committee after one year or more of satisfactory performance or as prescribed by the Subcommittee.

6.10.5 Surveillance assessments will be scheduled at the discretion of the Chair of the Subcommittee. Generally, a surveillance assessment will be scheduled one year after the initial assessment for the purpose of determining the status of corrective action for deficiencies found on the initial assessment. If all deficiencies have been satisfactorily corrected and no further deficiencies are found, subsequent assessments will not be necessary unless new information suggests that the need for such assessment. Usually, only the team leader from the previous full assessment is assigned this task since the team leader is most familiar with the lab. (6.7)

7.0 RELATIONSHIP BETWEEN AAPM AND LABORATORY

7.1 Access to Records

The AAPM shall have arrangements to ensure that the calibration laboratory and its representatives afford such accommodation and cooperation as is necessary to enable the AAPM to verify compliance with the requirements for accreditation. These arrangements shall include provision for examination of documentation and access to all calibration and testing areas, records and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints. (7.1.)

7.2 Laboratory Requirements

The AAPM shall require that an accredited calibration laboratory

7.2.1 at all times complies with the relevant provisions of this document; (7.2.a.)

7.2.2 claims that it is accredited only in respect of services for which it has been granted accreditation and which are carried out in accordance with these conditions; (7.2.b.)

7.2.3 pays such fees as shall be determined by the AAPM; (7.2.c.)

7.2.4 does not use its accreditation in such a manner as to bring the AAPM into disrepute and does not make any statement relevant to its accreditation which the AAPM may consider misleading or unauthorized; (7.2.d.)

7.2.5 upon suspension or withdrawal of its accreditation forthwith discontinues its use of all advertising matter that contains any reference thereto and returns any certificates of accreditation to the AAPM; (7.2.e.)

7.2.6 does not use its accreditation to imply product approval by the AAPM; (7.2.f.)

7.2.7 endeavors to ensure that no certificate or report nor any part thereof is used in a misleading manner; (7.2.g.)

7.2.8 in making reference to its accreditation status in communications media such as advertising, brochures, or other documents, complies with the requirements of the AAPM. (7.2.h.)

7.3 Notification of change

7.3.1 The accredited calibration laboratory shall notify the AAPM in writing without delay of changes in any aspect of the laboratory's status or operation that affects the laboratory's

a) legal, commercial or organizational status;

b) organization and management, e.g., key managerial staff;

c) policies or procedures, where appropriate;

d) premises

e) personnel, equipment, facilities, working environment or other resources, where significant;

f) authorized signatories;

or other such matters that may affect the laboratory's capability or scope of accredited activities, or compliance with the requirements in this document or any other relevant criteria of competence specified by the AAPM. (7.3.1.)

7.3.2 Upon receipt of written notice of any intended changes relating to the requirements of this documents, the relevant criteria of competence and any other requirements prescribed by the AAPM, the AAPM shall ensure that the laboratory carries out the necessary adjustments to its procedures within such times as, in the opinion of the AAPM, is reasonable. The laboratory shall notify the AAPM when such adjustments have been made. (7.3.2.)

7.4Directory of accredited laboratories

The AAPM shall publish in its annual directory and on the AAPM web site, a directory of accredited laboratories, describing the accreditation granted. (7.4.)

APPENDIX

1. Confidentiality Agreement Form
2. Laboratory fees
3. ADCL logo
4. ADCL certificate of accreditation
5. ADCL scope of accreditation

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).

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 Accreditation Subcommittee while serving on an ADCL 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 Accreditation Subcommittee, the Secretariat of the AAPM, the laboratory itself or other members of a ADCL 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 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 prior association with any laboratory to be evaluated.

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

_____

SIGNATURE DATE: _____

PRINT NAME: _____

SIGNATURE: _____

Laboratory Administration Fees
January, 2007

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

1. New or renewal application Fee

2. Annual Administrative Fee

3. Fees to cover E & O Insurance Coverage:

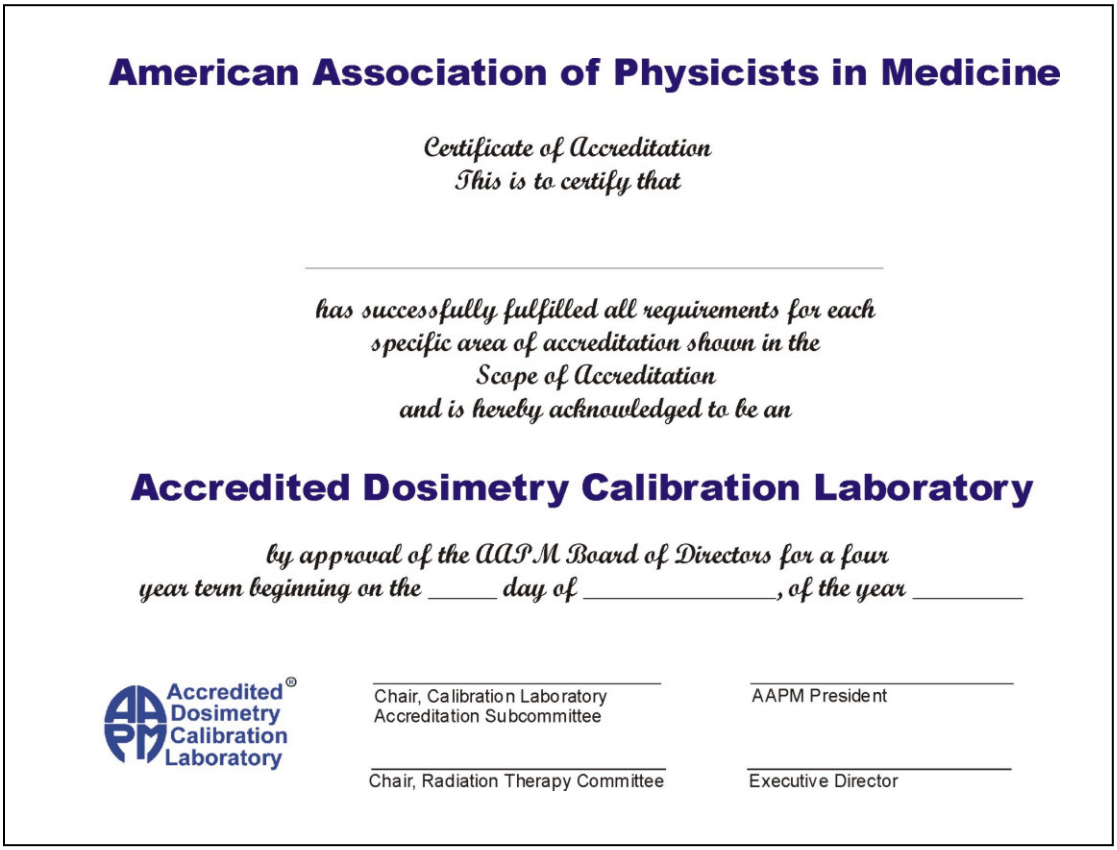
    The cost of the Errors & Omissions insurance premium will be shared between the accredited laboratories on the basis of the ratio of the number of chambers and sources calibrated by the individual lab in a 12 month period divided by the total number of chambers and sources calibrated by all the laboratories combined.

Other fees as required to recover the cost of the program.

Contact the AAPM Secretariat for the current fee schedule.

4. ADCL LOGO

ACCREDITATION CERTIFICATE



American Association of Physicists in Medicine

Certificate of Accreditation
This is to certify that

_____

has successfully fulfilled all requirements for each specific area of accreditation shown in the Scope of Accreditation and is hereby acknowledged to be an

Accredited Dosimetry Calibration Laboratory

by approval of the AAPM Board of Directors for a four year term beginning on the _____ day of _____, of the year _____

Accredited® Dosimetry Calibration Laboratory

Chair, Calibration Laboratory Accreditation Subcommittee

AAPM President

Chair, Radiation Therapy Committee

Executive Director

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/Parameter	Range	Best Uncertainty*	Comments
Ionization Chambers-Therapy class			By comparison to a reference ionization chamber
^{60}Co			
Air Kerma	up to XX cGy/min	1.2%	
Dose to water	up to XX cGy/min	1.3%	
X-rays			
M-Series	up to XX cGy/min	1.2%	

* Best uncertainty is the expanded combined uncertainty with a coverage factor k=2 and includes the NIST uncertainty of the standard used. Best uncertainty is the smallest uncertainty of measurement that a laboratory can achieve within its scope of accreditation when performing a routine calibration of a typical instrument with nearly ideal precision, resolution and reproducibility in a nearly ideal laboratory environment. The user is cautioned that larger uncertainties may result with instruments of less than ideal precision, resolution or reproducibility or when used in less than ideal environmental conditions.

AAPM Cert# XXXX, Date Page x of y

Internal Audit Checklist

Date: _____

By: _____

Location: _____

OUTLINE

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

Subcommittee Historical Records:
- Subcommittee Minutes

Accredited Laboratory Records:
- Application
- Personnel
- Submitted Documents
- Payment History
- Assessments
- Proficiency Test History

Assessor Records:
- Qualifications
- Training
- Assessment Participation
- Performance Evaluations
- Assessor Documents

Revision History ”

Revised by GS 12/7/01
Revised by TS 05/12/02
Revised by GS 8/5/02
Revised by TS 8/17/02
Revised by TS 8/7/03
Revised by TS 7/21/04 to include comments from Geoff Ibbott and Frank Cerra
Revised by TS 11/22/05 for ISO 17011:2004 requirements
Revised by TS 07/22/06 for ref to ISO 17025:2005 and date.
Revised by TS 01/26/07 revised organization and formatting