CRITERIA FOR ACCREDITATION OF DOSIMETRY CALIBRATION LABORATORIES BY THE AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE

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I. INTRODUCTION

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 (now referred to as the National Institute of Standards and Technology - NIST). Pursuant to Article Three of AAPM Charter, "To promote the application of physics to medicine and biology", the secondary laboratory accreditation system was created with the following purposes:

a) To reduce the time required for precision calibrations. The growth of radiation therapy facilities in the 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.

b) 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, which required regular ADCL comparisons with NIST and other laboratories in the secondary system.

c) To establish a technical resource for the membership of the AAPM. The laboratory system was established to serve the AAPM membership as a technical resource by providing 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.

This document was prepared, edited and refined over the years since 1971 by the efforts of members of Task Group #3, the Subcommittee on Laboratory Accreditation of the Radiation Therapy Committee of the AAPM, and its task groups.

At the summer meeting of the AAPM In 1995, the Subcommittee initiated a major revision of the accreditation protocol for the purpose of bringing the Guideline document into agreement with ISO/IEC Guide 25. Three Task Groups were identified for the purpose of developing a protocol for dose to water (TG-1), developing a protocol for the calibration of instruments used to measure diagnostic x-ray beams (TG-2) and developing a guidance document for the rejection of instruments (TG-3). In addition, this document now conforms to ISO 17025:2005.

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A. AAPM ACCREDITATION

1. Function of an Accredited Dosimetry Calibration Laboratory (ADCL)

   a) It is the function of an ADCL to be a *secondary* standard calibration laboratory for medical dosimetry.

   b) It is the function of an ADCL 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.

   c) It is the function of an ADCL to provide, for reference-class instruments and/or long lived brachytherapy sources, calibrations that meet or exceed the uncertainty goals established by the Subcommittee on Calibration Laboratory Accreditation (the Subcommittee) for each area of accreditation (see appendices).

   d) It is the function of an ADCL 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.

   e) It is the function of an ADCL to participate in oversight activities of the Subcommittee by having a representative at all meetings of the 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. Accreditation Body Organization

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, which is a standing committee of the AAPM. The Radiation Therapy Committee makes its recommendations to the Board on the basis of findings of the Subcommittee. The Subcommittee oversees all activities regarding the operation of the ADCLs.

The voting members of the 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 Subcommittee.

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 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 or the chair of the Subcommittee), a representative from NIST and a person familiar with the technical aspects or area of service that the candidate laboratory provides.

3. Application for Accreditation.

An organization that desires to apply for accreditation should contact the Chairman of the Subcommittee. The following information should be provided:

a. the location of the proposed laboratory,
b. a complete description of its laboratory and support facilities,
c. the scope of the calibration work it intends to provide,
d. the names and qualifications of the persons who will be responsible for the laboratory
e. the names and qualifications of the persons who will perform the instrument calibrations and/or source calibrations and calculations and
f. the names and qualifications of the persons who will review and sign the formal reports.

The AAPM may request additional information before agreeing to consider accreditation.

4. Accreditation Components

a. Application: The application includes the name, address, description of facilities.

b. Protocol and Quality Manual: Following notification that the Subcommittee has agreed to consider accreditation, the candidate laboratory must submit its Laboratory Protocol and Quality Manual (if the quality manual is not included in the protocol). The quality manual shall address how the candidate laboratory will comply with the paragraphs in this criteria.

c. Site Assessment Team: After the resolution of all questions relative to the application, the submitted protocol and quality manual, the Subcommittee will normally select an assessment team leader to review the documentation and nominate other team members to conduct the site assessment. Curriculum vitae of all members of the assessment team will be sent to the laboratory for approval prior to confirmation of the team members to the Subcommittee. The team leader will prepare an agenda and forward it to the laboratory for approval.

d. Initial Assessment Visit and Preliminary Proficiency Test: The approved assessment team will visit the laboratory to 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. The candidate laboratory shall re-reimburse the site team for all expenses related to the site visit.

e. 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 initial site visit. The candidate laboratory will bear the expense of the proficiency test.

f. Provisional Accreditation: Provisional accreditation of the candidate laboratory may be recommended by the Subcommittee to the Radiation Therapy Committee when the laboratory meets the following goals:

1. Successful completion of the NIST proficiency test;
2. A positive recommendation by the site visit team;
3. Full compliance with the CRITERIA contained in this document;
4. Upon approval of 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. This provisional accreditation will remain in force until review at the next meeting of the Subcommittee. At this time, full accreditation may be proposed to the Radiation Therapy Committee or provisional accreditation extended for another year, or accreditation may be revoked.

g. Performance Evaluation: The performance of the laboratory will be evaluated at each subsequent meeting 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.

h. 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. The recommendation for full accreditation by the Subcommittee shall require a two-thirds majority vote of the members and shall be based on a review of the past performance of the provisional ADCL, on the provisional ADCL's performance in subsequent NIST and intralaboratory comparisons and upon due consideration of any customer comments or complaints.

B. GENERAL REQUIREMENTS FOR ACCREDITATION

1. Purpose

The AAPM Accreditation is a voluntary activity of the Association conducted for the benefit of the AAPM membership. The primary goal of the AAPM accreditation is to assure the continued availability of high quality secondary calibrations used by the membership and their institutions in the diagnosis and treatment of patients. The second goal is to minimize the cost to the membership. The Subcommittee's task is to accredit, supervise and maintain the highest level of confidence in the quality of the ADCL system, with sufficient capacity in the system to prevent undue delays in satisfying the membership's calibration needs while providing a choice of ADCLs. Thus, the number of laboratories for which AAPM accreditation is available may be determined by the AAPM membership's need for additional calibration laboratories as perceived by the Subcommittee.

2. Free of conflict of interest

The applicant institution must be free of any conflict of interest with regard to its ownership and/or business and its responsibility to provide unbiased calibration results, technical advice, and assistance to the AAPM membership. The applicant must comply with the requirements of paragraphs 4.1.4 and 4.1.5 later in this document.

The AAPM accreditation is a voluntary activity of the association conducted for the benefit of the AAPM membership and to promote the application of physics to medicine and biology under ARTICLE 3 of its Charter. Its primary objective is to establish and maintain the highest quality *secondary* standard dosimetry system in the US. It is not established for the benefit of commercial organizations engaged in the manufacture, marketing, distribution or sale of dosimetry instrumentation, since this would represent a conflict of interest under the ADCL's role as technical advisor and since there are other agencies, such as the National Voluntary Laboratory Accreditation Program (NVLAP) and the American Association for Laboratory Accreditation (A2LA), which currently provide accreditation programs to serve commercial interests.

3. Ability to serve

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

4. Access to records and facilities

By accepting accreditation, the ADCL agrees to make its calibration records, facilities, and personnel available to official representatives of the AAPM at any reasonable time so that the AAPM may review the status of the ADCL.

5. Fees and expenses

By accepting accreditation, the laboratory agrees to be subject to and pay all administrative fees and expenses of site visits as required by the Subcommittee, and to pay a proportionate share of the cost of periodic NIST proficiency tests.

6. Compliance with the accreditation CRITERIA

The applicant laboratory must comply with these CRITERIA for accreditation.

7. Tenure of accreditation

Accreditation is awarded by the AAPM for a period of four years, at which time it must be renewed. For timely renewal, the laboratory should request a renewal of accreditation the year prior to the four year anniversary date for scheduling of the site visit. Surveillance visits may be scheduled at any time during the period of accreditation as required by the Subcommittee.

A 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 approved protocols, and its personnel or performance are not significantly changed.

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.

The AAPM shall provide a certificate that will identify the scope of the accreditation and confer continued accreditation to the ADCL whose performance meets all the requirements of these CRITERIA after favorable review by the site visit team.

8. Revocation or discontinuance of accreditation

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.

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.

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.

9. Laboratory Protocol and Quality Manual

A major factor in obtaining accreditation will be the laboratory protocol and Quality Manual. Maintenance of accreditation will require continued adherence of the ADCL operation to its own approved protocols and management system. Section II, Criteria for Accreditation, describes in detail the required components of the protocol and management system.

10. Redundancy in Standards and Measurements

Redundancy in standards and measurements is an important characteristic of the AAPM accreditation program.

a. Redundancy in standards: The AAPM accreditation requires redundant standards to be compared in a gamma radiation beam (^{60}Co or ^{137}Cs) on a frequent basis for the express purpose of identifying and quantifying significant changes that may have caused or might lead to an error in a calibration.

b. Redundancy in measurements: Measurement procedures designed to provide a redundant method of determining a physical quantity to backup or confirm the primary measurement method (calculating decay rate and comparing to measurements of dose rate, measure charge and charge rate and compare).

New applicants for accreditation are required to submit an analysis of the way in which the candidate laboratory's policies and procedures achieve redundancy in standards and measurements.

11. Traceability of Standards

All dosimetry standards used in the performance of an accredited calibration must be obtained directly from the National Institute of Standards and Technology (NIST) or other acceptable national standards laboratories.

12. Accredited Calibrations Limited to Scope

An ADCL shall not provide any accredited calibration for which the beam qualities and intensities as well as the calibration procedures are not described in the laboratory protocol and the scope of accreditation. The laboratory may perform calibrations not covered by the accreditation, provided such calibrations are clearly identified in the calibration report as not within the scope of AAPM accreditation.

13. Amendments to Protocol

An ADCL may amend its protocol to reflect improvements in procedures or services. The laboratory shall have a procedure for protocol revisions, a mechanism for dating and approvals by the Director or his/her designate. A revision history should be maintained.

14. Maintain Current Protocol and Quality Manual Updates

A copy of the latest revision of each ADCL protocol and quality manual shall be on file with the AAPM. The ADCL shall submit a copy of the current protocol annually to the Subcommittee chairman or state in writing that the protocol on file is the current protocol in use. The ADCL protocol and quality manual shall be maintained confidential by the AAPM as a proprietary property of the laboratory.

15. Rules for use of ADCL logo

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

b. The term “ADCL”, “Accredited Dosimetry Calibration Laboratory”, and the ADCL logo as attached are registered trademarks of the American Association of Physicists in Medicine and may be used only by the accredited laboratory.

c. The AAPM reserves the right to control the quality of the use of the term “ADCL” and of the logo itself.

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

e. References to AAPM accreditation and the use of the logo is not permitted in calibration reports for beams or conditions outside the scope of accreditation. In order to prevent confusion, the following disclaimer should be clearly stated and emphasized in the report:

“This calibration is not within the scope of the AAPM accreditation.”

16. Appeals

In the event of a disagreement between an ADCL or applicant laboratory regarding a decision of the Subcommittee, the ADCL or applicant laboratory may appeal the decision to the Radiation Therapy Committee.

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II. CRITERIA FOR ACCREDITATION

1. SCOPE

This document describes accreditation of dosimetry calibration laboratories by the American Association of Physicists in Medicine (AAPM). The current program areas of accreditation are:

a. Calibration of ionization chambers and dosimetry systems for measurements of exposure or air kerma for radiation therapy,

b. Calibration of ionization chambers and dosimetry systems for absorbed dose to water for radiation therapy,

c. Calibration of ionization chambers, electrometers, dosimeter systems and survey meters for measurements in diagnostic radiology,

d. Calibration of low dose rate (LDR) brachytherapy sources and the calibration of well type LDR ionization chambers

e. Calibration of high dose rate Ir-192 (HDR) brachytherapy well type ionization chambers.

f. Calibration of well type ionization chambers for intravascular brachytherapy applications

The only type of laboratory accredited by the AAPM is a secondary standard laboratory with the capability of providing direct traceability to the National Institute of Standards and Technology (NIST). Such a laboratory is referred to as an Accredited Dosimetry Calibration Laboratory (ADCL)

2. REFERENCES

ISO/IEC 17025, 2005, “General requirements for the competence of testing and calibration laboratories”,

IEC 60731, Ed.2 , Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy, 1997

“Uncertainty of calibrations at the accredited dosimetry calibration laboratories”, G.S. Ibbott, F.H. Attix, T.W. Slowey, D.P. Fontenla and M. Rozenfeld, Med. Phys. 24: #8, 1249-1254 (1997)

“Guideline for Evaluating and Expressing the Uncertainty of NIST Measurement Results”, B.N. Taylor and C.E. Kuyatt, NIST Technical Note 1297 (1993)

“Guide to the Expression of Uncertainty in Measurement”, ISO / TAG 4, WG 3, (1992)

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

“US Guide to the Evaluation of Uncertainty in Measurement”, ANSI/NCSL Z540-2-1997, NCSL, Boulder, CO.

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

“Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments”, ANSI N323A-1997

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

Kramer, H.M., Selbach, H-J, Iles, W.J, “The practical peak voltage of diagnostic X-ray generators”, British Journal of Radiology, 71, (1998)

IEC 61676: SC 62C, WG3, “Medical Electrical Equipment – Instruments used for the non-invasive measurement of x-ray tube voltage in diagnostic radiology”, May, 2000

3. DEFINITIONS

ADCL: Accredited Dosimetry Calibration Laboratory. A laboratory accredited by the American Association of Physicists in Medicine under these CRITERIA.

ADCL comparison: (referred to as round robins) A comparison of similar calibration standards maintained by each ADCL to the other ADCLs in the AAPM secondary system. This comparison is conducted by the Subcommittee on an alternate year basis covering the range of energies and sources within the scope of each laboratory as specified by the Subcommittee. The comparison covers the areas of accreditation of each laboratory to the same areas of the other laboratories in the system (conversion to NIST beam codes when necessary).

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

air kerma rate: The air kerma per unit time.

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

calibration: The set of operations that establishes, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measured value. The result of a calibration may be recorded in a document, sometimes called a calibration certificate or a calibration report. The result of a calibration is sometimes expressed as a calibration coefficient or as a series of calibration coefficients.

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

calibration laboratory: Laboratory that performs calibration .

calibration method: Defined technical procedure for performing a calibration.

certified reference material {CRM}: A reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body. (ISO Guide 30—2.21)

directly traceable: The property of a result of a measurement in which the standard used to obtain the result was calibrated by NIST.

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

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

exposure: The measurement of ionization in air quantified by the unit of charge (dQ) per unit mass of dry air (X= dQ/dm) and is specified in the units of Roentgen (R) which is defined as 2.58×10^{-4} Coulombs per kilogram. The relation between exposure and air kerma is given by $K_{air} = X \cdot (W/e)/(1-g)$ where W/e is the mean energy per unit charge expended in air by electrons (33.97 joules/Coulomb) and "g" is the mean fraction of the energy of the secondary electrons that are lost to bremsstrahlung (g=0 for x-rays<=300 keV, g=0.0032 for Co-60 and g = 0.0016 for Cs-137).

field class dosimeter: A dosimeter whose performance and stability are sufficient for it to be used to make ordinary routine measurements. (IEC 60731, 1997, 3.23)

field-class Instrument: A chamber or chamber and electrometer system suitable for measurement of a radiation quantity but not having the precision, reproducibility and/or long term stability to be used for the calibration of other chambers or chamber and electrometer systems.

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

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

kVp: (kilo-Voltage peak) A specification of the voltage impressed across a diagnostic x-ray tube (see Practical Peak Voltage for a proposed IEC definition). The x-ray tube voltage may be constant during the exposure (constant potential) or time varying during the exposure (single phase, half or full wave rectified, three phase half or full wave rectified or high frequency).

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

management system: The quality, administrative, and technical systems that govern the operation of the calibration laboratory as defined by the International Standard.

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

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

practical peak voltage (PPV): The practical peak voltage U is defined as :

$$U = \frac{\int_{U_{min}}^{U_{max}} p(U)FW(U)[UdU}{\int_{U_{min}} \text{with } \int p(U)dU = 1 \int p(U)3v(U)CdU}$$

where $p(U)$ is the distribution function for the voltage U and $w(U)$ is a weighting function. Umax is the highest voltage in the interval, and Umin is the lowest voltage in the interval. The unit of the quantity Practical Peak Voltage is the volt(V). (see reference)

proficiency testing: Determination of the laboratory calibration or testing performance by means of NIST Measurement Quality Assurance test.

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

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

quality manual: A document stating the quality policy, management system and quality practices of an organization. The quality manual may refer to other documentation relating to the laboratory's quality arrangements. The quality manual is composed of those portions of the laboratory protocol which deal specifically with the policy, management, systems, practices and procedures for quality assurance and quality control.

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

redundant standard ADCL comparison system: A system of maintaining traceability through the use of two or more systems of comparable quality that are compared at frequent intervals and substantiated with periodic ADCL COMPARISON with NIST and other laboratories in the secondary system.

reference conditions: The standard conditions of pressure (760mmHg @ 0 ° C, 101.325 kPa), temperature (22 degrees Celsius) and relative humidity (within the range of 20-75%). Note: mercury barometers may also require gravitational corrections.

reference-class dosimeter: A dosimeter whose performance and stability are sufficiently well known for it to be used to calibrate other instruments. (IEC 60731, 1997, 3.22)

reference-class Instrument: A high quality chamber or chamber and electrometer system having the precision, reproducibility and long term stability to be used for the purpose of calibrating other chambers or chamber and electrometer systems (e.g. Field-class instruments) to an acceptable degree of uncertainty.

> NOTE: A field class instrument may be of such high quality and have sufficient history of constancy and stability to be considered a reference class instrument. This history must be established prior to use as a reference instrument.

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

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

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

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

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

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

test method: Defined technical procedure for performing a test.

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

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

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

validation: The confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled (ISO 17025:2005, 5.4.5.1)

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

UNCERTAINTY DEFINITIONS

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

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

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

expanded uncertainty: Quantity defining the interval about the result of a measurement that may be expected to encompass a large fraction of the

distribution of values that could be attributed to the measured value. (ANSI/NCSL Z540-2-1997, 2.3.5)

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

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

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

x-ray tube voltage: The difference of potential between the anode and cathode of an x-ray tube. This potential may be constant potential, single phase (half or full wave rectified), three phase (6 or 12 pulse) or high frequency. Presently, no national or international standard exists for the method of interpretation (peak, average of the peaks, effective, practical peak voltage, etc.) or the method of measurement of this voltage (invasive vs non-invasive). The measurement and method of interpretation should be specified.

4. MANAGEMENT REQUIREMENTS

4.1 Organization

4.1.1 The laboratory shall be a legally identifiable organization and shall operate in such a way that its facilities meet the requirements of these CRITERIA. The organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts shall be defined in writing. The laboratory can be held legally responsible. (ISO17025:2005, 4.1.1)

4.1.2 The laboratory shall carry out its testing and calibration activities in such a way as to meet the requirements of these CRITERIA and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition. (ISO17025:2005, 4.1.2)

4.1.3 The management system shall cover all work carried out in the laboratory's permanent facilities as well as any temporary facilities. (ISO17025:2005, 4.1.3)

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

NOTE 1: If the laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests do not adversely influence the laboratory's compliance with the requirements of this standard (ISO17025:2005, 4.1.4).

NOTE 2: If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures that might influence their technical judgment. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing or calibration activities.

4.1.5 The laboratory shall:

4.1.5.a Have managerial and technical personnel who, irrespective of their other responsibilities have the authority and resources needed to discharge their duties, including the implementation, maintenance and improvement of the management system. Personnel shall identify the occurrence of departures from the management system or from procedures for performing tests and/or calibrations, and shall initiate actions to prevent or minimize such departures; (ISO 17025:2005, 4.1.5.a)

4.1.5.b Have arrangements to ensure that its personnel are free from any commercial, financial and other pressures that might adversely affect the quality of their work; (ISO 17025:2005, 4.1.5.b)

4.1.5.c Have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results; (ISO 17025:2005, 4.1.5.c)

4.1.5.d Be organized with appropriate policies and procedures in such a way that confidence in its independence of judgment and integrity is maintained at all times; (ISO 17025:2005, 4.1.5.d)

4.1.5.e Define the organization and management structure of the laboratory, its place in any parent organization, and the relationship between quality management, technical operations, support services. ; (ISO 17025:2005, 4.1.5.e)

4.1.5.f Specify and document the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of calibrations and tests; (ISO 17025:2005, 4.1.5.f)

4.1.5.g Provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results; (ISO 17025:2005, 4.1.5.g)

4.1.5.h Have a technical manager (director) who has overall responsibility for the technical operations; (ISO 17025:2005, 4.1.5.h)

4.1.5.i Have a quality manager (however named) who has responsibility for the management system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager; (ISO 17025:2005, 4.1.5.i)

4.1.5.j Nominate deputies for key managerial personnel; (ISO 17025:2005, 4.1.5.j)

4.1.5.k Ensure that personnel are aware of the relevance and importance of their activities and how they contribute to the objectives and effectiveness of the overall management system. (ISO 17025:2005, 4.1.5.k)

4.1.6 Top management shall ensure the appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

4.2 MANAGEMENT SYSTEM

4.2.1 The laboratory shall establish and maintain a management system appropriate to the type, range and volume of calibration and testing activities it undertakes. The elements of this system shall be documented. The management system documentation shall be available for use by the laboratory personnel. (ISO 17025:2005, 4.2.1)

4.2.2 Top management shall authorize the laboratory quality policies, including a quality policy statement, and its commitment to good laboratory practice and quality of calibration or testing services in a quality manual (however named). Top laboratory management shall ensure that these quality objectives are established and reviewed during management review. (ISO 17025:2005, 4.2.2)

4.2.3 Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness. (ISO 17025:2005, 4.2.3)

4.2.4 Top management shall communicate to the laboratory the importance of meeting customer, statutory, and regulatory requirements.

4.2.5 The quality manual shall include or reference supporting documentation including technical procedures. The structure of the management system documentation shall be outlined in the quality manual.

4.2.6 The quality manual shall define the roles and responsibilities of the quality manager and technical management to ensure compliance with this standard.

4.2.7 Top management shall guarantee the integrity of the management system when changes to the management system are planned and implemented.

4.3 DOCUMENT CONTROL

4.3.1 The laboratory shall establish and maintain procedures to control all documents that form part of the management system. (ISO 17025:2005, 4.3.1)

4.3.2 Document approval and use

4.3.2.1 All documents that are part of the management system shall be reviewed and approved for use by authorized personnel prior to implementation. A master list or document control procedure shall be established to identify the current revisions and distribution into the management system. This list shall be readily available to prevent the use of invalid or obsolete documents. (ISO 17025:2005, 4.3.2.1)

4.3.2.2 The procedure(s) that are adopted shall ensure that:

a. Authorized editions of documents shall be available at all work stations where essential to the functioning operations of the laboratory;
b. Documents are periodically reviewed and revised to ensure continuing suitability and compliance to the applicable requirements;
c. Invalid or obsolete documents are promptly and immediately removed from all locations to prevent unintended use.
d. Obsolete documents that are maintained for legal or preservation purposes shall be marked as such to prevent accidental use. (ISO 17025:2005, 4.3.2.2)

4.3.2.3 Management system documents generated by the laboratory shall be uniquely

identified. Identification shall include: the issuing authority, revision identification, date of issue, page numbering and total number of pages or a mark to signify the end of the document. (ISO 17025, 4.3.2.3)

4.3.3 Document changes

4.3.3.1 This document may be amended in accordance with the constitution, bylaws, and official procedures of the AAPM and the Subcommittee. Changes to documents shall be reviewed and approved through the same process that performed the original review, unless specifically designated elsewhere. (ISO 17025:2005, 4.3.3.1)

4.3.3.2 Where practicable, altered or new text shall be identified in the document or the appropriate attachments. (ISO 17025: 2005, 4.3.3.2)

4.3.3.3 Amendment of documents by hand, pending re-issue, shall be according to defined, established procedures. These amendments shall be clearly marked, initialed and dated. Authority for these changes shall be identified. (ISO 17025: 2005, 4.3.3.3)

4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled. (ISO 17025:2005, 4.3.3.4)

4.4 REVIEW OF REQUESTS, TENDERS, AND CONTRACTS

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

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

4.4.1.b The laboratory has the capability and resources to meet the requirements;

4.4.1.c The appropriate test and/or calibration method is selected and capable of meeting customer requirements. Any differences between the request/contract shall be resolved before work begins. Each contract shall be acceptable to the laboratory and the customer.

NOTE 1: The request, tender and review shall be conducted in a practical and efficient manner. Legal, financial, and time schedule considerations shall be taken into account.

NOTE 2: The review shall establish the laboratory resources available to perform the calibrations in question. The review may encompass results from interlaboratory comparisons or proficiency tests to determine measurement uncertainties, detection limits, confidence limits, etc.

NOTE 3: A contract may be any written or oral agreement to provide a customer with testing and/or calibration services. (ISO 17025:2005, 4.4.1)

4.4.2 Records of reviews shall be maintained. Records shall also be maintained of pertinent conversations with the customer regarding the client's requirements or equipment or the results of work during the period of execution of the contract. (ISO 17025:2005, 4.4.2)

4.4.3 The review shall also cover any work that is subcontracted by the laboratory. (ISO 17025:2005, 4.4.3)

4.4.4 The customer shall be informed of any deviation from the contract. (ISO 17025:2005, 4.4.4)

4.4.5 If a contract needs to be amended after work has begun, the same contract review process shall be repeated. (ISO 17025:2005, 4.4.5)

4.5 Subcontracting of tests and calibrations

4.5.1 If it is necessary to subcontract work, then this work shall be placed with a competent subcontractor. A competent subcontractor is, for example, one that complies with this standard for the work in question. (ISO 17025:2005, 4.5.1)

4.5.2 The customer shall be advised of the arrangement in writing and approval obtained, preferably in writing. (ISO 17025:2005, 4.5.2)

4.5.3 The laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies the subcontractor to be used. (ISO 17025:2005, 4.5.3)

4.5.4 A register of all subcontractors that are used shall be maintained along with a record of evidence of compliance with the standard in question. (ISO 17025:2005, 4.5.4)

4.6 PURCHASING SERVICES AND SUPPLIES

4.6.1 Procedures shall be established for the selection and purchasing of services and supplies it uses that affect the quality of tests and/or calibrations. (ISO 17025:2005, 4.6.1)

4.6.2 The purchased supplies shall not be used until they have been inspected or otherwise verified as complying with the standard specifications or requirements. Records of actions taken to check compliance shall be maintained. (ISO 17025:2005, 4.6.2)

4.6.3 Purchasing documents for items affecting the quality of laboratory results shall describe the services and supplies ordered. The purchasing documents shall be reviewed and approved for technical content prior to release. (ISO 17025:2005, 4.6.3)

4.6.4 Laboratory consumables, supplies and support services which affect the quality of testing and calibration shall be evaluated. Records of these evaluations shall be

made. An approved supplier list shall be maintained. (ISO 17025:2005, 4.6.4)

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

4.7 SERVICE TO THE CUSTOMER

4.7.1 The laboratory shall be willing to cooperate with the customer or its representatives to monitor the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to all other customers.

4.7.2 The laboratory shall seek feedback from its customers. This feedback shall be evaluated and used to improve the management system, customer service, and calibration activities.

4.8 COMPLAINTS

The laboratory shall have documented policies and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

4.9 CONTROL OF NONCONFORMING TESTING AND/OR CALIBRATION WORK

4.9.1 The laboratory shall implement defined policies and procedures when testing and/or calibration work, including results, do not conform to its own procedures or the customers' requirements. (ISO 17025:2005, 4.9.1) The policies and procedures shall ensure that:

a) the responsibilities and authorities for the management of nonconforming work shall be designated. Actions taken when nonconforming work arises shall be defined;
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b) an evaluation of the significance of the nonconforming work, or significant error, is made:

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

c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work;

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

d) where necessary, the customer and the appropriate AAPM committee shall be notified;

NOTE 1: If an ADCL discovers in a calibration report a significant error, the person or institution that received the report shall be notified immediately by telephone.

NOTE 2: The ADCL shall report the error to the chairman of the Subcommittee with an explanation of how the error occurred and a description of the steps taken to prevent a repetition. This report may be made to the full Subcommittee in the annual report at the AAPM meeting.

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

4.9.2 Where evaluation indicates that the error could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, corrective action as stated shall be promptly followed. (ISO 17025:2005 4.11)

NOTE: Notification of a potential error
If an ADCL discovers a situation that has led or might lead to a calibration error in any phase of its operation, it shall notify all other ADCLs in writing, with a copy to the Subcommittee. This notification shall be styled to alert the other ADCLs to the possibility of such an error.

4.10 IMPROVEMENT

The laboratory shall continually improve the effectiveness of its management system through the use of quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

4.11 CORRECTIVE ACTION

4.11.1 General

The laboratory shall have a policy and procedures that designate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures have been identified. (ISO 17025:2005, 4.11.1)

4.11.2 Cause Analysis

Corrective action procedures shall start with investigations to determine the root cause(s)

of the problem. (ISO 17025:2005, 4.11.2)

4.11.3 Selection and implementation of corrective actions

When corrective action is needed, the laboratory shall investigate and identify potential corrective actions. Based upon the magnitude and risk of the problem, it shall choose the appropriate action(s) that will most likely eliminate the problem and prevent its recurrence.

4.11.4 Monitoring of corrective actions

The laboratory shall monitor the results to ensure that corrective action(s) taken are effective.

4.11.5 Additional Audits

Where the identification of a nonconformance casts doubt on the laboratories compliance with its own policies and procedures, an internal audit will be conducted of the appropriate area as soon as possible. (ISO 17025:2005, 4.11.5)

4.12 PREVENTIVE ACTION

4.12.1 Potential sources of nonconformities and needed improvements shall be identified. When improvements opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of opportunities for improvement. (ISO 17025:2005 4.12.1)

4.12.2 Procedures shall include the initiation and application of controls to ensure the action is effective. (ISO 17025:2005, 4.12.2)

4.13 CONTROL OF RECORDS

4.13.1 General

The laboratory shall establish and maintain procedures for the identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical documents. All records of measurement data and records of required comparisons shall either be recorded in ink in bound log books with pages numbered consecutively, or in some equivalent manner. As an alternative to log books, electronic data may be printed and dated or written to compact disk as a read-only archival record. These records shall be retained in a confidential manner secure from fire and degradation. (ISO 17025:2005 4.13.1)

4.13.1.2 All records shall be legible, retained in such a way that they are easily retrievable and stored to prevent damage or deterioration or loss. (ISO 17025:2005, 4.13.1.2)

4.13.1.3 All records shall be maintained in strict confidence. (ISO 17025:2005, 4.13.1.3)

4.13.1..4 Procedures shall be established to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.

4.13.2 Technical records

4.13.2.1 The laboratory shall retain records (including those pertaining to calibration measurement and test equipment, log books, computer data files, certificates of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate) for a defined period. The records for each calibration and test shall contain sufficient information to permit their repetition.

The records shall include the identity of personnel involved in sampling, preparation, calibration or testing. The calculations and completeness of a calibration shall be reviewed and signed or initialed by the person in charge of the laboratory or his/her designate.

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

4.13.2.2 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the task. (ISO 17025:2005, 4.13.2.2)

4.13.2.3 Written mistakes shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All corrections to records shall be signed or initialed by the person making the correction. (ISO 17025:2005, 4.13.2.3)

4.14 INTERNAL AUDITS

4.14.1 The laboratory shall arrange for internal audits of its activities at intervals not exceeding 12 months to verify that its operations continue to comply with the requirements of this Standard and the management system. The quality manager shall plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. (ISO 17025: 4.14.1)

4.14.2 Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any customerwhose work may have been affected (ISO 17025:2005, 4.14.2)

4.14.3 All audit and review findings and any corrective actions that arise from these activities shall be documented. The quality manager shall ensure that these actions are discharged within the agreed time scale. (ISO 17025:2005, 4.14.3)

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

a) Internal quality control schemes using statistical techniques;

b) Regular use of in-house quality control using secondary systems;

c) Replicate testing using the same or different methods;

d) Re-testing of nonconforming items when appropriate;

e) Correlation of results for different characteristics of an item.

4.14.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken. (ISO 17025:2005, 4.13.4)

4.15 MANAGEMENT REVIEWS

4.15.1 The management system adopted to satisfy the requirements of these CRITERIA shall be reviewed at least once a year by the top management to ensure its continuing suitability and effectiveness, and to introduce any necessary changes or improvements. .The review shall include:

- suitability of policies and procedures;
- reports from managerial and supervisory personnel;
- the outcome of recent internal audits;
- corrective and preventive actions;
- assessments by external bodies;
- results of intra-laboratory comparisons or proficiency tests;
- changes in the volume and type of work;
- customer feedback;
- complaints;
- recommendations for improvement;
- other relevant factors, such as quality control activities, resources and staff training.

NOTE 1: Results shall include the goals and objectives and action plans for the coming year.

NOTE 2: Management reviews shall include related subjects at regular management meetings.

4.15.2 Findings from management reviews and the actions that arise from them shall be

recorded. Management shall ensure that actions are carried out within an acceptable timetable.

5. TECHNICAL REQUIREMENTS

5.1 GENERAL

The laboratory shall take account of factors that contribute to the total uncertainty of measurement in developing test and calibration methods and procedures. These factors include contributions from:

- human factors
- accommodation and environmental conditions;
- test and calibration methods and method validation;
- equipment;
- measurement traceability;
- sampling (if appropriate);
- handling and controlled tracking of test and calibration items.

5.1.2 The extent to which these factors contribute to the overall uncertainty of calibrations varies considerably between tests and calibrations. The laboratory shall consider these factors in training personnel, developing test and calibration methods, and in the selection, calibration, and use of related equipment. (ISO 17025:2005, 5.1.2)

5.2 PERSONNEL

5.2.1 The laboratory management shall ensure the competence of all personnel to perform calibrations, evaluate results, and sign calibration reports. Personnel shall be trained and supervised when appropriate so that their activities will be in accordance with the laboratory protocol. Personnel shall have the necessary education, training, technical knowledge and experience for their assigned functions. (ISO 17025:2005, 5.2.1)

The person responsible for the operation of the ADCL shall be identified to the AAPM and should have a position in the organizational structure of the laboratory that assures their competence and ability to work in accordance with the management system. Personnel shall understand and follow the laboratory protocol.

5.2.2 The laboratory shall ensure that the training of its personnel is kept up-to-date. The laboratory shall have a policy and procedures for identifying training needs and providing for the training of its employees. The effectiveness of the training actions taken shall be evaluated. (ISO 17025:2005, 5.2.2)

5.2.3 The laboratory shall use personnel who are employed, or under contract to, the laboratory. If contracted help is used, management shall ensure that they are supervised and competent to work according to the laboratory's management system.

5.2.4 The laboratory shall maintain records that include current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations. These records shall contain a CV on the laboratory director and key support personnel responsible for day-to-day operations,, indicating the relevant qualifications, training, skills and experience of all other the technical personnel. (ISO 17025:2005, 5.2.4)

5.2.5 The management shall authorize specific personnel for specific duties, such as calibrations, interpretations, operation of equipment. The laboratory shall maintain records of relevant authorization(s) competence, including contracted personnel. (ISO 17025:2005, 5.2.5)

The person in charge of day-to-day operations shall be identified to the AAPM and should have at least a B.A. or B.S. degree in physics or a physical science, or equivalent knowledge, and relevant experience. The Subcommittee shall have the authority to determine the suitability of the qualifications of an individual proposed for this position by the laboratory.

5.3 ACCOMODATION AND ENVIRONMENTAL CONDITIONS

5.3.1 Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

The environment in which calibration and test activities are undertaken shall not invalidate the results or adversely affect the quality or required accuracy of measurement. (ISO 17025:2005 5.3.1)

5.3.2 The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions with the calibration data as appropriate. (ISO 17025:2005 5.3.2)

5.3.3 There shall be effective separation between neighboring areas when the activities therein are incompatible. (ISO 17025:2005 5.3.3)

5.3.4 Access to and use of all areas affecting the quality of these activities shall be defined and controlled. (ISO 17025:2005 5.3.4)

5.3.5 Measures shall be taken to ensure good housekeeping in the laboratory. (ISO

17025:2005, 5.3.5)

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

5.4 TEST AND CALIBRATION METHODS AND METHOD VALIDATION

5.4.1 General

The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its scope. These include sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement, and analysis of calibration and/or test data. They shall be consistent with the accuracy required, and with any standard specifications and accreditation CRITERIA relevant to the calibrations or tests concerned. (ISO 17025:2005, 5.4.1)

The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, written standards, manuals and reference data relevant to the work of the laboratory shall be kept up-to-date and be readily available to the staff. Deviations from calibration methods shall only be made if technically justified, documented, authorized, and accepted by the customer. (ISO 17025:2005 5.4.1)

5.4. 2 Selection of methods

The laboratory shall use methods and procedures for all calibrations and tests and related activities that meet the needs of the customer and are appropriate for the calibrations it undertakes. They shall be consistent with the accuracy required, and with any standard specifications and accreditation CRITERIA relevant to the calibrations or tests concerned.

Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations or in relevant scientific texts or journals. (ISO 17025:2005, 5.4.2)

5.4.3 Laboratory-developed methods

The introduction of test and calibration methods developed by the laboratory shall be planned and carried out by qualified personnel equipped with adequate resources.

5.4. 4 Non-standard methods

Where it is necessary to employ methods not covered by standard methods, these shall be subject to agreement with the customer, be fully documented and validated, and include a clear specification of the customer's requirements and the purpose of the test and/or calibration. ISO 17025:2005, 5.4.4)

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

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

a) appropriate identification;
b) scope;
c) description of the type of item to be tested or calibrated;
d) parameters or quantities and ranges to be determined;
e) apparatus and equipment, including technical performance requirements;
f) reference standards and reference materials required;
g) environmental conditions required and any stabilization period needed;
h) description of the procedure including:

- affixing of identification marks, handling, transporting, storing and preparation items
- checks to be made before work is started
- checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use
- the method of recording the observations and results
- any safety measures to be observed

i) criteria and/or requirements for approval/rejection;
j) data to be recorded and method of analysis and presentation;
k) the uncertainty or procedure for measuring uncertainty.

.4.5Validation of methods

5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

5.4.5.2 The laboratory shall validate non-standard methods, laboratory designed/ developed methods, standard methods used outside the scope, and modifications of standard methods to confirm that the methods are fit for intended use. Validation should be as extensive as necessary to meet the needs of the given application. The results shall be recorded, along with the procedure used for the validation, and a statement as to whether the method is fit for the intended use. (ISO 17025:2005, 5.4.5.2) Methods applied to new clinical treatment techniques shall be approved by the subcommittee prior to implementation.

5.4.5.3 The range and accuracy of the values obtainable from validated methods as assessed for the intended use, shall be relevant to the customers' needs. (ISO 17025:2005, 5.4.5.3)

5.4.6 Estimation of uncertainty of measurement

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

5.4.7 Control of data

5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner. ISO17025, 5.4.7.1)

5.4.7.2 Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall ensure that:

a) computer software developed by the user is documented in sufficient detail and is validated as being adequate for use;

b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, security, integrity and confidentiality of data entry and collection, data storage, data transmission and data processing;

c) computers and automated equipment are maintained to ensure proper functioning and are provided with environmental and operating conditions necessary to maintain the integrity of data.

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

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

5.5 EQUIPMENT

5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment for the correct performance of the tests and/or calibrations. (ISO 17025:2005, 5.5.1)

An ADCL shall have, in operable condition, at least the equipment designated in Appendix A for each accredited function. The equipment shall be dedicated to the calibration laboratory use with exceptions (equipment not under the direct control of the laboratory) clearly identified and justified, if appropriate.

Redundant equipment should, whenever possible, be dissimilar, since dissimilar instruments are unlikely to change in the same way.

5.5.2 Equipment and its software for testing and calibration shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations. Before being placed into use, equipment shall be calibrated or checked to establish that it meets requirements and complies with relevant standard specifications.

Documented procedures shall exist for the purchase, receipt and storage of consumable materials used for the technical operations of the laboratory.

5.5.3 Equipment shall be operated by authorized personnel. Up-to-date instructions shall be readily available to the appropriate laboratory personnel.

5.5.4 Each item of equipment and its software shall, when appropriate, be labeled, marked or otherwise uniquely identified.

5.5.5 Records shall be maintained of each item of equipment significant to the calibrations or tests performed. (ISO 17025:2005, 5.5.5) The records shall include:

a) the identity of the item of equipment and the condition when received (e.g. new, used, reconditioned);

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

c) Date received and date placed in service;

d) current location, where appropriate;
e) copy of the manufacturer's instructions, where available;

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

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

h) history of any damage, malfunction, modification or repair;

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

5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in

order to prevent contamination or deterioration. (ISO 17025:2005, 5.5.6)

5.5.7 Equipment that has been subjected to overloading or mishandling, gives questionable results or has been shown to be defective or outside specified limits shall be taken out of service and isolated to prevent its use or clearly marked as being out of service. (ISO 17025:2005, 5.5.7)

5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled or otherwise identified with the status and date of last calibration, with expiration date. (ISO 17025:2005, 5.5.8)

5.5.9 When laboratory procedures require outside calibration services and supplies, only those outside services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests shall be used. Each supplier of calibration services shall be selected on basis of the existence of an appropriate quality assurance program. The laboratory shall ensure that the function and calibration status of equipment are checked and confirmed satisfactory before the equipment is returned to service. (ISO 17025:2005, 5.5.9)

5.5.10 Intermediate checks that are needed to maintain confidence in the calibration status of the equipment shall be carried out according to a defined procedure. (ISO 17025:2005, 5.5.10)

5.5.11 Where calibrations give rise to correction factors, the laboratory shall have procedures to ensure that copies (e.g. computer software) are correctly updated. (ISO 17025:2005, 5.5.11)

5.5.12 Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results. (ISO 17025:2005, 5.5.12)

5.5.13 The laboratory shall have at least two high-quality barometers (resolution of 0.5 mm Hg or better) and two high-quality thermometers (resolution of 0.1°C or better). At least one barometer and one thermometer shall have a calibration documented as traceable to NIST.

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

5.5.15 The laboratory shall have a device to measure relative humidity (RH). The device shall have a calibration traceable to NIST with an uncertainty of +/- 7% RH or better. Calibrations performed when the laboratory relative humidity is between 20 percent and 80 percent need not be corrected for humidity. Suspension of calibrations or corrections may be necessary when relative humidity is outside this range.

5.5.16 The laboratory shall correct calibration coefficients for ionization chambers open

to the atmosphere to the reference atmosphere of 22 degrees Celsius (295.15 degrees Kelvin) and 760 millimeters of mercury at 0 degrees Celsius (101.325 kPa). Instruments that do not communicate with the atmosphere should be documented as such.

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

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

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

5.6 MEASUREMENT TRACEABILITY

5.6.1 General

All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established program and procedure for the calibration of its equipment. (ISO17025, 5.6.1)

5.6.2 Specific requirements

5.6.2.1 Calibration (and ADCL comparison of laboratory standards) .

5.6.2.1.1 The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards. (ISO 17025:2005, 5.6.2.1.1)

5.6.2.1.2 Calibration certificates of measurement and test equipment which is not calibrated by NIST shall, whenever applicable, indicate the traceability to national standards of measurement and should provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

5.6.3 Reference standards and reference materials

5.6.3.1 Reference standards

The laboratory shall have a program and procedure for calibration and verification of its reference standards. Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, except for research or other closely monitored purposes when it can be demonstrated that their performance as reference standards has not been invalidated. (ISO 17025:2005, 5.6.3.1)

5.6.3.2 Reference materials

Reference materials shall, where possible, be traceable to SI units of measurement. Internal reference materials shall be checked as far as is technically and economically practicable. (ISO 17025:2005, 5.6.3.2)

5.6.3.3 Intermediate checks

Appropriate checks, comparisons and other tests shall be made in order to maintain confidence in the calibration status of local primary, transfer and reference standards and reference materials in order to prevent contamination or deterioration and preserve their integrity. (ISO 17025:2005, 5.6.3.3)

5.6.3.4 Transport and storage

The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to protect their integrity. (ISO 17025:2005, 5.6.3.4)

5.7 Sampling

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

5.8 Handling of test and calibration items

5.8.1 The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity and interests of the laboratory and the customer. (ISO 17025:2005, 5.8.1)

5.8.2 The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory so as not to become confused physically or when referred to in documents. (ISO 17025:2005, 5.8.2)

5.8.3 Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration or test method, shall be recorded. Where there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the customer for further instruction before proceeding

and shall record the discussion. The laboratory shall establish whether the item has received all necessary preparation, or whether the customer requires preparation to be undertaken or arranged by the laboratory. (ISO 17025:2005, 5.8.3)

5.8.4 The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration or test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned. (ISO 17025:2005, 5.8.4)

5.9 Assuring the quality of test and calibration results

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

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

b) participation in intra-laboratory comparison or proficiency-testing;

c) replicate tests or calibrations using same or different methods;

d) retesting or recalibration of retained items;

e) correlation of results for different characteristics of an item;

f) frequent local comparisons of redundant standards.

5.9.2 Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.

5.10 Reporting the results

5.10.1 General

The results of each calibration shall be reported accurately and clearly in accordance with any specific instructions in the calibration methods. (ISO 17025:2005, 5.10.1)

5.10.2 Test reports and calibration certificates

Each calibration certificate shall include at least the following information (ISO 17025:2005, 5.10.2):

a) a title;

b) the name and address of the laboratory, and the location where the calibration was performed, if different from the laboratory address;

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

d) name and address of the customer;

e) identification of the method used;

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

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

h) reference to a sampling plan, if applicable;

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

j) name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the calibration report;

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

note 1: Hard copies of the report should also include the page number and total number of pages.

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

note 3: The calibration coefficients stated in the calibration report shall be corrected to standard reference conditions of 22 degrees Celsius and 760 millimeters of Hg at 0 degrees C (101.325 kpa), unless otherwise noted (sealed ion chambers).

5.10.3 Test reports

5.10.3.1 When test or calibration results include deviations from, or additions to, or exclusions from the calibration method, additional information shall be included in test or calibration reports.

5.10.3.2 When test or calibration results include sampling, additional information may be necessary for the interpretation of the results and shall be included in test or calibration reports.

5.10.4 Calibration certificates

5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, when necessary for the interpretation of calibration results:

a) the conditions under which the calibration or test was performed;

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

c) evidence that the measurements are traceable.

5.10.4.2If statements of compliance are made, the uncertainty of measurement shall be taken into account. (ISO 17025:2005, 5.10.4.2)

5.10.4.3 When an instrument has been adjusted or repaired, the calibration results before and after shall be reported, if available. (ISO 17025:2005, 5.10.4.3)

5.10.4.4 A calibration report shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. (ISO 17025:2005, 5.10.4.4)

The Report shall be signed or initialed by the person performing the calibration or the person in charge of the day to day operation of the laboratory, and shall be reviewed and signed by the person responsible for the laboratory or their designate.

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

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

5.10.5 Opinions and interpretations

When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in the test report (ISO17025, 5.10.5).

5.10.6 Testing and calibration results obtained from subcontractors

When the test report contains results of tests performed by subcontractors, these results shall be clearly identified.
When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory. (ISO 17025:2005, 5.10.6)

5.10.7 Electronic transmission of results

The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of this CRITERIA are met and that confidentiality is preserved (ISO 17025:2005, 5.10.7).

5.10.8 Format of reports and certificates

The format shall be designed to accommodate each type of calibration or test performed and to minimize the possibility of misunderstanding or misuse. (ISO 17025:2005, 5.10.8)

5.10.9 Amendments to test reports and calibration certificates

Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Calibration Certificate, Test Report or Test Certificate, serial number..." or as otherwise identified or equivalent form of wording. Revisions to calibration reports and certificates should include a reference to the original report (number or test number) and date. When it is necessary to issue a new calibration report, reference to the original report it replaces shall be included. (ISO 17025:2005, 5.10.9)

5.10.10 Report storage

Reports may be filed and stored as a hard copy of the original. The copy should be marked copy. Otherwise, the original report may be electronically archived according to the procedure in Appendix F.

6 REVISION HISTORY

This document is an expanded and updated version of a statement of the minimum requirements, equipment, and procedures for Regional Calibration Laboratories accredited by the AAPM, prepared in 1971 by J. G. Holt.

August, 1981: Original document.
January, 1983: Title changed, Section 2.2 revised, reference supplied in Section 3.9.1.2, and an error corrected on page 1.

September, 1989: Added "calibration of ionization chamber instruments" in title and body. Changed NIST to NIST, Sections 3.2.3 and 5.1.3 added, and Section 5.2.1 revised. Air kerma added in Sections 3.8.4, 3.8.5.2 and 3.8.5.3.

Draft for ISO Guide 25, November, 1995
Table of Contents , Scope, References , Definitions , Outline of Original Guideline , 3.1. Organization and management , 3.3.1.2.1, 3.3.3.1 , 3.3.3.2, 3.3.3.3, 3.4.01, 3.4.02, 3.4.03 , 3.4.04, 3.4.1.2 , 3.4.1.3, 3.4.2, 3.5.01, 3.5.4 , 3.5.5, 3.7.6, 3.7.7, 3.7.8, 3.8.5.4 , 3.8.5.5, 3.8.5.6 , 3.8.5.7, 3.10 Management system, audit and review, 7 COMPLAINTS, 8 REVISION HISTORY

Revision #1: Revised for consistency with ISO Guide 25, November, 1996
- Revise wording and remove technical sections to the appendix Add brachytherapy section to appendix
- Add place mark for diagnostic and uncertainty sections

Revision #2: Revised as follows:
- Revised Reference for IEC 60731,
- Added Introduction, Accreditation Body Structure,
- Added definitions from IEC 60731
- Added section 1.3, 1.4
- moved common statements from appendix to main document section 3

Revision #3: November 1997: Revised as follows:
- Replaced “Guideline” with “CRITERIA” in the document title.
- Added note under reference class instruments.
- Revise definition of proficiency test,
- Added ADCL comparison definition,

Renumbered b, c and d and revised b and d of Section 2.3 Accreditation Process Section
- Revised wording of Section 3.5
- Guideline has been replaced by CRITERIA,
- revised name & added commercial spreadsheets to Section 8.
- Renumbered appendix

REVISION #4: July 28, 1998; Revised as follows:
- Replaced “Draft” with “Revision” on cover and in history
- All sections: typographical / editorial corrections
- References: Added references 3,4 & 5.
- Definitions: Added definition of calibration coefficient, combined

uncertainty, uncertainty of measurement, sigma, kVp, measured value, added line to quality manual definition.
Added 5.7, correction for temp/press
Added 2 sentences to 11.3
Revised Table of Contents: revised order of appendices,

REVISION #4A: July 30, 1998; Last minute revisions
Definitions: transmission monitor
Reordered Appendix and added Appendix C Guideline for Rejection
Revised Table of Contents: revised order of appendices,
Renumbered Appendix A1, A2, A5 to be consistent

REVISION #5: November, 1998
Moved revision and date to inside cover
Added copyright notice
Replaced "ADCL" Subcommittee with "Accreditation" Subcommittee
SCOPE: Renumbered program areas
Replaced Guideline with CRITERIA
Added reference to ANSI Z540-2-1997
Replaced intercomparison with COMPARISON and revised definition
Added definition for air kerma, air kerma rate, Ampere, Coulomb, exposure, qualified supplier, reference conditions, secondary standard laboratory
Revised definition of DOSIMETER to include other detectors.
Deleted RADIOTHERAPY DOSIMETER definition
Combined all uncertainty terms under uncertainty using ANSI/NCSL definitions.
Added "best" uncertainty definition
Added x-ray tube voltage definition.
Added section 18, Appeals
Moved Rules for use of logo from appendix to new section.
Added 5.7
Revised 9.1
Added 10.8
Replaced "overall" with "expanded" uncertainty, A3.7.2.2, A3.6.3.8

REVISION #6: July 22, 1999
Revised wording under Scope, 2
Revised wording of Section 2.1
Added dosimeter systems and survey meters under Scope # 3
Revised 5.6
Revised 5.17
Revised wording of section 9.1
Revised wording of section 10.1
Revised wording of section 10.5
Revised wording of section 10.8
Revised wording of section 12.3
Revised wording of section 14.2.3
Revised wording of section 17.4

Revision # 7: September, 1999

Definitions:

Replaced "measurand" with " measured value" in "calibration" definition.
Replaced "quotient" with "ratio" in "calibration coefficient" definition.
Added definition for HC
Added definition for "transfer quality chamber"
Replaced "measurand" with " measured value" in "uncertainty" and "expanded uncertainty" definition.
Revised definition of "x-ray tube voltage"

Revised wording 2.2.2
Revised wording 2.3.3
Revised wording 2.3.5
Revised wording 3.2
Revised wording 4.2.7
Revised wording 5.1
Revised wording 5.5
Revised wording 5.15
Revised wording 5.17.7
Revised wording 6.7

Revision # 8, July, 2000
Revised for ISO/IEC 17025

Revised Introduction, deleted last sentence
Revised References, added ISO/IEC 17025 reference
Revised Definitions, Air Kerma, deleted reference to neutrons EXPOSURE, qualified g=0 for x-rays "<=300keV" Traceability, added "within a stated uncertainty" "best" uncertainty, added "Cesium 137"
Revised 1.3, added "(see appendix)" to the end of the paragraph.
Revised 1.5, corrected " oversight"
Revised 2.4.3, added "AAPM", "provisional", " for a period of one year"
Revised 2.3.6, replaced "will" with "may' and replaced "six months" with "one year".
Revised 3.2, added quote from ISO/IEC 17025.
Revised 5.6, added phrase
Revised 5.7, added "Celsius"
Revised 5.12, added phrase
Added 5.17.10
Revised 11.5, added phrase Revised
12.2.19, added "internal" Revised
12.6.4, to clarify

November, 2000

Revised definitions for consistent case and underline, page 8-14
Revised definition of exposure and g values
Revised definition of homogeneity coefficient
Revised definition of reference conditions add note
Revised 5.6, added (RH)

Revision #9, July 2001:

Page 9: Added site assessment team
Page 10: added A2LA
Page 12: Payment of expenses: added administrative fees.
Page 12: Tenure of accreditation: Revised to four year term and added surveillance visits to comply with ISO/IEC Guide 58.
Page 12: added quality manual to documentation.
Page 12: expanded Redundancy description.
Page 12: added traceability statement.
Page 12: scope of accreditation added.
Page 17: Added references
Page 37: Added 5.3.6

Page 46: Added 5.9.3, 5.9.4
All sections revised to comply with ISO 17025

September, 2001
Revised layout pages and numbers to agree with PDF version

Revision #10, January, 2002:

Revision for ISO 17025, Revise A1 for TG-61, new appendix A7 for IVB technical requirements,
Edited by: L.A. DeWerd, W.F. Hanson, M.S. Huq, T.W. Slowey
Revised dates on and inside cover
Added names of edit committee
Revised Copyright year
Regenerated TOC
Page 5, Numbered introduction
Page 7, Numbered sections and minor editorial changes
Page 8, numbered sections
Page8, revised accreditation period from five to four and added “or the cair” in forth paragraph
Page9-16, Re-numbered paragraphs and numerous editorial changes
Page9, Section I, 4.b, added last sentence
Page9, Section I, 4.c, spelled out CV
Page9, Section I, 4.f, Revised wording
Page10, Section I, 4.h, added last sentence
Page12, Section I, 7, revised wording of first paragraph
Page18, Section II,1a & 1b, added dosimetry systems; II, 1e, deleted sources.
Page18, Section II, 1f, added
Page19, Section II, 2, Deleted reference to ISO Guide 25, Added two references at the bottom of the list.
Page25, deleted “sigma” definition.
Page20-26, Definitions, misc. editorial changes, added “dosimetry system”, expanded HC definition, revised kVp, removed Guide 25 references, added “practical peak voltage”.
Page30-53, misc. typographical corrections.
Page 30, Section 4.3.2.1, added phrase “(if appropriate)”

Page35, Section 4.12.1, revised to allow CD archive
Page36, Section 4.12.2.3, added “Written” at the beginning of the sentence.
Page 39, Section 5.1.7, added “and controlled tracking”
Page43, Section 5.4.4, added last sentence in first paragraph, 5.4.7.2.2, added “validated”.
Page46, Section 5.5.15, revised RH uncertainty to 7%; 5.5.16, added last sentence and corrected kP
Page50, 5.10.2.1, added “Report” to title; 5.10.2.2, replaced name with “Report Type”
Page51, Section 5.10.2.11, note 2, added last two sentences
Page59, Revised summary of “Appendices” as follows:

A1, replaced “for” with “of” and revised appendix A1 to conform with x-ray air kerma calibrations
A2, Removed IVB from A2 title
A3, revised title
A4, replaced “for” with “of”
A5, removed “Sources” and revised title
A6, revised title Added Appendix A7 on Intravascular brachytherapy well calibrations

Revision 11, July, 2005:
Revised for ISO 17025:2005, new Appendix F for electronic records storage

The term “calibration factor” has been replaced with “calibration coefficient.”
The terms “quality system” and “laboratory management system” have been changed to “management system.”
The term “client” has been changed to “customer.”
The term “nonconformances” has been changed to “nonconformities.”
Page 18, “Management system” is defined.
Page 23, Changed “LABORATORY ORGANIZATION AND MANAGEMENT” to “MANAGEMENT REQUIREMENTS” to match the standard.
Page 23, 4.1.1, added statement, “The laboratory can be held legally responsible.”
Page 23, 4.1.4, NOTE 1, condensed text.
Page 23, 4.1.5.a, Revised text to emphasize that personnel have the authority and resources needed to implement, maintain, and improve the management system, irrespective of other responsibilities.
Page 24, 4.1.5.k, added text, “Ensure that personnel are aware of the relevance and importance of their activities and how they contribute to the objectives and effectiveness of the overall management system.”
Page 24, 4.1.6, new requirement added, “Top management shall ensure the appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.”
Page 25, 4.2.2, Revised text related to the quality manual and quality policies, “quality objectives are established and reviewed during management review.”
Page 25, 4.2.3 New section from the ISO standard added, “Top

management shall provide evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness."

Page 25, 4.2.4 New section from the ISO standard added, "Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements."

Page 25, 4.2.5 Moved former section 4.2.3 to this section to match the standard, "The quality manual shall include or reference supporting documentation including technical procedures. The structure of the management system documentation shall be outlined in the quality manual."

Page 25, 4.2.6, New section added to comply with the standard, "The quality manual shall define the roles and responsibilities of the quality manager and technical management to ensure compliance with this standard."

Page 25, 4.2.7, New section from the ISO standard added, "Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented."

Page 25, 4.3.2.2, Added "editions of" documents….

Page 26, 4.3.2.3, Added text to this section to clarify document requirements as specified by the standard.

Page 26. 4.3.3. Added text to this section to comply with the standard, "Authority for these changes shall be identified."

Page 26, 4.4, Changed "CONTRACT REVIEW" to "REVIEW OF REQUESTS, TENDERS, AND CONTRACTS" to match the standard.

Page 26, 4.4.1.c, Added "NOTE 1" and "NOTE 2" to comply with the standard.

Page 27, 4.4.2, Added text to this section to comply with the standard, "…or the results of work during the period of execution of the contract."

Page 27, 4.5, Changed "SUBCONTRACTING" to "Subcontracting of tests and calibrations" to match the standard.

Page 27, 4.6, Changed "PURCHASES" to "PURCHASING" to match the standard.

Page 28, 4.6.4, Added text to this section to comply with the standard, "Records of these evaluations shall be made. An approved supplier list shall be" maintained.

Page 28, 4.6.5 has been changed to a "NOTE" to comply with the standard.

Page 28, 4.7, Changed "CLIENT SERVICE' to "SERVICE TO THE CUSTOMER" to match the standard.

Page 28, 4.7.1, Added text to comply with the standard, The laboratory shall "be willing to" cooperate with customers in clarifying requests and in monitoring the laboratory's performance related to their work.

Page 28, 4.7.2, New text added to comply with the standard, "The laboratory shall seek feedback from its customers. Feedback shall be used and analyzed to improve the management system…."

Page 28, 4.8, Changed "CONTROL OF NONCONFORMANCE" to "COMPLAINTS" to match the standard.

Page 28, 4.8, Moved what was formerly section 4.7.2 in the AAPM standard to 4.8 to comply with the ISO 17025 standard.

Page 28, 4.9, Changed "Notification of potential error" to "Control of

nonconforming testing and/or calibration work" to match the standard.
Page 28, 4.9.1, New section added to match the standard.
4.10 Improvement. "The laboratory shall continually improve the effectiveness of its management system…."
Page 28, 4.9.1.a and 4.9.1.b, New sections added to match the standard.
Pages 28 and 29, 4.9.1.b NOTE, Moved what was formerly section 4.8.3.1 in the AAPM standard to this section.
Page 29, 4.9.1.c, New section added to match the standard.
Page 29, 4.9.1.c NOTE, Moved what was formerly section 4.8.3.2 in the AAPM standard to this section.
Page 29, 4.9.1.d, New section added with reference to the AAPM to comply with both standards, "where necessary, the customer and the appropriate AAPM committee shall be notified;"
Page 29, 4.9.1.d NOTE 1, Moved what was formerly section 4.8.3.3 in the AAPM standard to this section.
Page 29, 4.9.1.d NOTE 2, Moved what was formerly section 4.8.3.4 in the AAPM standard to this section.
Page 29, 4.9.1.e, New section added to match the ISO standard.
Page 29, 4.9.2 Moved text from what was formerly section 4.8.3.5 in the AAPM standard to this section.
Page 29, 4.9.2 NOTE, Moved text from what was formerly section 4.9 in the AAPM standard to this section.
Page 29, 4.10, Changed "CORRECTIVE ACTION" to "IMPROVEMENT." Added text to match the ISO standard, "The laboratory shall continually improve the effectiveness of its management system through the use of quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review."
Page 29, 4.11, Changed 4.11, "PREVENTIVE ACTION" to "CORRECTIVE ACTION" to match the standard.
Page 29, 4.11.1 Revised text in what was formerly section 4.10.1 in the AAPM standard to comply with the ISO standard.
Page 30, 4.11.2, Cause Analysis, New section added to comply with the ISO standard.
Page 30, 4.11.3, Selection and implementation of corrective actions, New section added to comply with the standard. Moved text from what was formerly section 4.11.1 in the AAPM standard to this section.
Page 30, 4.11.4, Monitoring of corrective actions, New section added to comply with the standard. Moved text from what was formerly section 4.11.2 in the AAPM standard to this section.
Page 30, 4.11.5, Additional audits, New section added to match the standard. Moved text from what was formerly section 4.10.4 in the AAPM standard to this section.
Page 30, 4.12, Changed "CONTROL OF RECORDS" to "PREVENTIVE ACTION" to match the standard.
Page 30, 4.12.1, Revised text to comply with ISO standard.
Page 30, 4.12.2, Moved text from what was formerly section 4.11.2 in the AAPM standard to comply with the ISO standard.
Page 30, 4.13, Changed "INTERNAL AUDITS" to "CONTROL OF RECORDS" to match the ISO standard.
Page 30, 4.13.1, Added text to this section to comply with the standard, "The laboratory shall establish and maintain procedures for the

identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical documents." Moved text from what was formerly section 4.12.1 in the AAPM standard to this section.
Pages 30 and 31, 4.13.1.2, Moved text from what was formerly section 4.12.1.2 in the AAPM standard to this section to comply with the ISO standard.
Page 31, 4.13.1.3, Moved text from what was formerly section 4.12.1.3 in the AAPM standard to this section to comply with the ISO standard.
Page 31, 4.13.1.4, Moved text from what was formerly section 4.12.2 in the AAPM standard to this section to comply with the ISO standard.
Page 31, 4.13.2, New section, "Technical records," added to match the standard.
Page 31, 4.13.2.1, New text added to comply with the standard. Moved text from what was formerly section 4.12.1.5 in the AAPM standard to this section to comply with the ISO standard.
Page 31, 4.13.2.2. Moved text from what was formerly section 4.12.2.2 in the AAPM standard to this section to comply with the ISO standard.
Page 31, 4.13.2.3, Moved text from what was formerly section 4.12.2.3 in the AAPM standard to this section to comply with the ISO standard.
Page 31, 4.14, Changed "MANAGEMENT REVIEWS" to "INTERNAL AUDITS" to match the ISO standard.
Page 31, 4.14.1, New text added to comply with the ISO standard. Moved text from what was formerly section 4.13.1 in the AAPM standard to this section to comply with the ISO standard.
Page 31, 4.14.2, Moved text from what was formerly section 4.13.1 in the AAPM standard to this section to comply with the ISO standard.
Page 32, 4.14.3, New text added to comply with the ISO standard. Moved text from what were formerly sections 4.13.2 and 4.13.3 in the AAPM standard to this section to comply with the ISO standard.
Page 32, 4.14.4, New text added to match the standard, "Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken."
Page 32, 4.15, New section added, MANAGEMENT REVIEW, to match the ISO standard. Moved text from what was formerly section 4.14 in the AAPM standard to this section to comply with the ISO standard. Added "recommendations for improvement" to match the ISO standard.
Page 33, 4.15, NOTE 1, Moved text from section 4.14.11 in the AAPM standard to this section.
Page 33, 4.15, NOTE 2, Moved text from section 4.14.12 in the AAPM standard to this section.
Page 33, 4.15.2, New text added to comply with the standard. Moved text from what was formerly section 4.14.13 in the AAPM standard to this section to comply with the ISO standard.
Page 33. 5.1, Reformatted text from the section 5.1 in the AAPM standard to a bulleted list to match the ISO standard.
Page 33. 5.1.2, New text added to comply with the standard, "The extent to which these factors contribute to the overall uncertainty of calibrations varies considerably between tests and calibrations. The laboratory shall consider these factors in training personnel, developing test and calibration methods, and in the selection, calibration, and use of related equipment."
Page 33, 5.2.1, New text added to comply with the standard.

Page 34. 5.2.1, Moved text from what was formerly section 5.2.3 in the AAPM standard to this section to comply with the ISO standard.
Page 34, 5.2.2, Moved text from what was formerly section 5.2.2 in the AAPM standard to this section to comply with the ISO standard. New text added to comply with the standard.
Page 34. 5.2.3, New text added to comply with the standard, "The laboratory shall use personnel who are employed, or under contract to, the laboratory. If contracted help is used, management shall ensure that they are supervised and competent to work according to the laboratory's management system."
Page 34, 5.2.4, New text added to comply with the standard. Moved text from what was formerly section 5.2.4 in the AAPM standard to this section to comply with the ISO standard.
Page 34, 5.2.5, Moved text from what was formerly section 5.2.6 in the AAPM standard to this section.
Page 34, 5.3, Changed "ENVIRONMENTAL CONDITIONS" to "ACCOMODATION AND ENVIRONMENTAL CONDITIONS" to match the standard.
Page 34, 5.3.1, Added text to comply with the standard, "The environment in which calibration and test activities are undertaken shall not invalidate the results or adversely affect the quality or required accuracy of measurement."
Page 35, 5.4.1, Moved text from what was formerly section 5.4.1.1 in the AAPM standard to this section.
Page 35, 5.4.2, "Selection of methods," Created this section to match the ISO standard. Moved text from what was formerly section 5.4.1.2 in the AAPM standard to this section. Added text to comply with the ISO standard," … that meet the needs of the customer and are appropriate for the calibrations it undertakes."
Page 36, 5.4.3, "Laboratory-developed methods," Created this section to match the ISO standard. New text added to match the ISO standard.
Page 36, 5.4.4, "Non-standard methods," Created this section to match the ISO standard. Moved text from what was formerly section 5.4.1.4 in the AAPM standard to this section. Added text to comply with the standard,"…include a clear specification of the customer's requirements and the purpose of the test and/or calibration."
Page 36, 5.4.4, Moved what was formerly section 5.4.2 to this section.
Page 36, 5.4.4, NOTE, Moved what was formerly section 5.4.3 in the AAPM standard to this section. Formatted text as a list to comply with the ISO standard.
Page 37, 5.4.5, "Validation of methods," Created this section to match the ISO standard.
Page 37, 5.4.5.1, Added text to match the ISO standard, "Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled."
Page 37, 5.4.5.2, Moved what was formerly section 5.4.4 in the AAPM standard to this section.
Page 37, 5.4.5.3, Moved what was formerly section 5.4.4 in the AAPM standard to this section.
Page 37, 5.4.7.1, Added text to comply with the ISO standard, "…in a systematic manner."

Page 37, 5.4.7.2.a), Moved text from what was formerly section 5.4.7.2.2 in the AAPM standard to this section. Added text for validation requirements to comply with the ISO standard.
Page 37, 5.4.7.2.b), Moved text from section 5.4.7.2.3 in the AAPM standard to this section. Added text for confidentiality requirement to comply with the ISO standard.
Page 37, 5.4.7.2.c), Moved text from what was formerly section 5.4.7.2.4 in the AAPM standard to this section.
Pages 37 and 38, 5.4.7.2, Moved text from what were formerly sections 5.4.7.2.6 and 5.4.7.2.7 to this section.
Page 38, 5.5.1, Added text to comply with the ISO standard, "The laboratory shall be furnished with all items of sampling, measurement and test equipment for the correct performance of the tests and/or calibrations."
Page 38, 5.5.1, Moved text from what was formerly section 5.5.2 in the AAPM standard to this section.
Page 38. 5.5.2, Added text to comply with the ISO standard, "Equipment and its software for testing and calibration shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations. Before being placed into use, equipment shall be calibrated or checked to establish that it meets requirements and complies with relevant standard specifications."
Page 38, 5.5.2, Moved text from what was formerly section 5.5.3 in the AAPM standard to this section.
Page 38, 5.5.3, Added text to comply with the ISO standard, "Equipment shall be operated by authorized personnel. Up-to-date instructions shall be readily available to the appropriate laboratory personnel."
Page 38, 5.5.4, Added text to comply with the ISO standard, "...and its software…uniquely…."
Page 38, 5.5.5, Formatted text as a lettered list to comply with the ISO standard.
Page 38, 5.5.5.a, Changed "name" to "identity" to comply with the ISO standard. Moved section 5.5.5.5 in what was formerly the AAPM standard to this section.
Page 39, 5.5.9, Added text to comply with the ISO standard, "The laboratory shall ensure that the function and calibration status of equipment are checked and confirmed satisfactory before the equipment is returned to service."
Page 39, 5.5.12, Changed "protected" to "safeguarded" to match the ISO standard.
Page 40, 5.6.1, Added text to comply with the ISO standard, "The laboratory shall have an established program and procedure for the calibration of its equipment."
Page 41, 5.6.2, "Specific requirements," Created new section to match the ISO standard.
Page 41, 5.6.2.1, Moved what was formerly section 5.6.2 title in the AAPM standard to this section.
Page 41, 5.6.2.1.1, Moved what was formerly section 5.6.2.2 in the AAPM standard to this section.
Page 41, 5.6.2.1.2, Moved what was formerly section 5.6.2.3 in the AAPM standard to this section.
Page 41, 5.6.3.1, Added text to comply with the ISO standard, "The

laboratory shall have a program and procedure for calibration and verification of its reference standards. Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement."
Page 41, 5.6.3.3, "Intermediate checks," Added title to match the ISO standard.
Page 41, 5.6.3.4, "Transport and storage," Added title to match the ISO standard.
Page 42, 5.8.1, Added text to comply with the ISO standard, "…and interests…and the customer."
Page 42, 5.8.3, Added text to comply with the ISO standard, "…and shall record the discussion."
Page 42. 5.9.1, Moved text from what was formerly section 5.9 in the AAPM standard to this section. Added "not" to correct sentence.
Page 42, 5.9.1, Formatted text as a lettered list to match the ISO standard.
Page 42, 5.9.1.a, Moved text from what was formerly section 5.9.1 in the AAPM standard to this section.
Page 42, 5.9.1.b, Moved text from what was formerly section 5.9.2 in the AAPM standard to this section.
Page 43, 5.9.1.c, Replaced text from what was formerly section 5.9.3 on the AAPM standard to match the ISO standard, "replicate tests or calibrations using same or different methods;"
Page 43, 5.9.1.d, Moved text from what was formerly section 5.9.5 in the AAPM standard to this section.
Page 43. 5.9.1.e, Moved text from what was formerly section 5.9.7 in the AAPM standard to this section.
Page 43. 5.9.1.f, Moved text from what was formerly section 5.9.4 in the AAPM standard to this section.
Page 43, 5.9.2, Added text to match the ISO standard, "Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported. "
Page 43, 5.10, Changed "REPORTING" to "Reporting the results" to match the ISO standard.
Page 43, 5.10.1, Added new title, "General," to match the ISO standard.
Page 43, 5.10.2, Added new title, "Test reports and calibration certificates," to match the ISO standard.
Page 43, 5.10.2, Formatted text as a lettered list to match the ISO standard.
Page 43, 5.10.2.a, Moved text from what was formerly 5.10.2.1 in the AAPM standard to this section.
Page 43, 5.10.2.b, Added text from what was formerly 5.10.2.2 in the AAPM standard to this section,"… and address of the laboratory, and the location where the calibration was performed, if different from the laboratory address;"
Page 43, 5.10.2.c, Moved text from what was formerly section 5.10.2.3 in the AAPM standard to this section.
Page 43, 5.10.2.d, Moved text from what was formerly section 5.10.2.4 in the AAPM standard to this section.
Page 43, 5.10.2.e, Moved text from what was formerly section 5.10.2.5 in the AAPM standard to this section.
Page 43, 5.10.2.f, Moved text from what was formerly section 5.10.2.6 in the

AAPM standard to this section.
Page 43, 5.10.2.g, Moved text from what was formerly section 5.10.2.7 in the AAPM standard to this section.
Page 43, 5.10.2.h, Moved text from what was formerly section 5.10.2.8 in the AAPM standard to this section.
Page 43, 5.10.2.i, Moved text from what was formerly section 5.10.2.9 in the AAPM standard to this section.
Page 44, 5.10.2.j, Moved text from what was formerly section 5.10.2.10 in the AAPM standard to this section.
Page 44, 5.10.2.k, Moved text from what was formerly section 5.10.2.11 in the AAPM standard to this section.
Page 44, 5.10.2, note 3: Moved text from what was formerly section 5.10.3 in the AAPM standard to this section.
Page 44, 5.10.3, Added new title, “Test reports,” to match the ISO standard.
Page 44, 5.10.3.1, Created text to comply with the ISO standard, “When test or calibration results include deviations from, or additions to, or exclusions from the calibration method, additional information shall be included in test or calibration reports.”
Page 44, 5.10.3.2, Moved text form what was formerly section 5.10.4.1 in the AAPM standard to this section. Added text to this section to comply with the ISO standard,”… and shall be included in test or calibration reports.”
Page 44, Added new title, “Calibration certificates,” to match the ISO standard.
Page 44, 5.10.4.1, Added new text to match the ISO standard, “In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, when necessary for the interpretation of calibration results:”
Page 44, 5.10.4.1, Formatted text as a lettered list to match the ISO standard.
Page 44, 5.10.4.1.a, Moved text from what was formerly section 5.10.4.1.1 in the AAPM standard to this section.
Page 44, 5.10.4.1.b, Moved text from what was formerly section 5.10.4.1.2 in the AAPM standard to this section.
Page 44, 5.10.4.1.c, Moved text from what was formerly section 5.10.4.1.3 in the AAPM standard to this section.
Page 44, 5.10.4.3, Added “calibration” to comply with the ISO standard.
Page 45, 5.10.4.4, Moved text from what were formerly sections 5.10.4.5, 5.10.4.6, and 5.10.4.7 to this section.
Page 45, 5.10.8, Changed title from “Format of certificates and reports” to “Format of reports and certificates” to match the ISO standard.
Page 46, 5.10.8, Added text, “…or misuse.” to comply with the ISO standard.
Page 46, 5.10.9, Changed title from “Ammendments to calibration certificates” to “Ammendments to test reports and calibration certificates” to match the ISO standard.
Page 46, 5.10.9, Added text to comply with the ISO standard, “When it is necessary to issue a new calibration report, reference to the original report it replaces shall be included.”
Page 46, 5.10.10, Added new section, “Report storage,” with reference to the new procedure in Appendix F.

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APPENDICES:

Appendix A: Technical Specifications for Accreditation

A1. CRITERIA for Accreditation of Air Kerma Calibrations for Ionization Chambers for Radiation Therapy

A2. CRITERIA for Accreditation of Low Dose Rate (LDR) Brachytherapy Sources and Well-type Chamber Calibration

A3. CRITERIA for Accreditation of Air Kerma Calibrations for Diagnostic X-ray Chambers, Dosimeter Systems and Survey Instruments

A4. CRITERIA for Accreditation of Absorbed Dose to Water Calibrations with Ionization Chambers for Radiation Therapy

A5. CRITERIA for Accreditation of High Dose Rate (HDR) Brachytherapy Well-type Chamber Calibrations

A6. CRITERIA for Accreditation of Electrometer Calibrations

A7. CRITERIA for Accreditation of Intravascular Brachytherapy (IVBT) Well type Chamber Calibrations

B: Guideline for Uncertainty Assessment

C: Guideline for Rejection of Instruments

D: Example of Certificate of Accreditation

E: ADCL Logo

F: Report Storage

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A1. CRITERIA for Accreditation of Air Kerma Calibrations for Ionization Chambers and Electrometers for Radiation Therapy

by the
American Association of Physicists in Medicine

This appendix was developed from the former "Guidelines for Accreditation of Dosimetry Calibration Laboratories" by the Subcommittee (formerly Task Group 3 of the Radiation Therapy Committee) and provides the minimum requirements for accreditation for ionization chambers and electrometers for radiation therapy. The following technical requirements are in addition to those contained in the body of these Criteria

A1.1 Scope

This appendix specifies the technical requirements for laboratories to be accredited by the American Association of Physicists in Medicine (AAPM) for the calibration of instruments used to measure exposure or air kerma produced by therapeutic radiation machines.

A1.2 References

A1.2.1 "A protocol for the determination of absorbed dose from high-energy photon and electron beams", Task Group 21, Radiation Therapy Committee, Med. Phys. 10 (6), 741-771 Nov/Dec 1983.

A1.2.2 Gastorf, R. Humphries, L., Rozenfeld, M., "Cylindrical chamber dimensions and the corresponding values of A_{wall} and $N_{gas}/(N_x . A_{ion})$", Med Phys.13 (5), 751-754, Sep/Oct 1986.

A1.2.3 Schulz, R.J., Almond, P.R.,Kutcher, G., Lovoevinger, R., Nath, R., Rodgers, D.W.O., Suntharalingam, N., Wright, K.A.,, "Clarification of the AAPM Task Group 21 protocol", Med Phys. 13 (5), 755-759, Sep/Oct 1986.

A1.2.4 Almond, P.R., "Use of a Victoreen 500 electrometer to determine ionization chamber collection efficiencies", Med. Phys. 8 (6), 901-904, Nov/Dec, 1981.

A1.2.5 Ma, C.-M., Coffey, C. W. DeWerd, L. A.,. Liu, C., Nath, R. seltzer, S.M., and Seuntjens, J. P., "AAPM protocol for 40-300 kV x-ray beam dosimetry in radiotherapy and radiobiology," Med. Phys. 28 (6), 868-893, June 2001.

A1.2.6 Almond, P.R., Biggs, P.J., Coursey, B.M., Hanson, W.F.,Huq, M.S., Nath, R., Rodgers, D.W.O., "AAPM TG-51 protocol for clinical reference dosimetry of high-energy photon and electron beams", Med. Phys. 26 (9), 1847-1870, Sept.,1999

A1.2.7 Almond, P.R., Xu, Z., Li, H., Park, H.C., "The calibration and use of plane-parallel ionization chambers for dosimetry of electron beams", Med. Phys. 22 (8), 1307-1314, August 1995

A1.3 Definitions

A1.3.1 Air kerma calibration coefficient: Response of a given ionization chamber compared with a NIST calibrated ionization chamber. Generally the units are Gy/C.

A1.3.2 Cable connected chamber: An ionization chamber having a cable that connects directly with an electrometer or measuring device.

A1.4 Traceability of Calibrations

An ADCL shall calibrate therapeutic radiation measuring devices by comparing them with secondary standard ionization chambers that have been calibrated at the National Institute of Standards and Technology (NIST), in conformity with the requirements of these CRITERIA.

The ADCL shall maintain traceability to NIST by satisfactory performance of the following:

A1.4.1. NIST MQA Performance: The required ADCL performance on the NIST measurement quality assurance (MAP) proficiency test for reference class instruments is 0.5 percent for Cobalt-60 and Cesium-137 and 1 percent for x-rays.

A1.4.2. ADCL comparison Performance: The required ADCL performance on the ADCL comparison for a reference class instrument is 0.5 percent for Cobalt-60 and Cesium-137 and 1 percent for x-rays as compared to the average of all ADCLs for each energy in the test.

A1.4.3. The ADCL shall meet the following uncertainty requirements:

A1.4.3.1 ADCL component of uncertainty: The ADCL component of uncertainty expressed as an expanded uncertainty with a coverage factor k=2 and does not include the NIST uncertainty associated with the standard used is 0.5 percent for Cobalt-60 and Cesium-137 gamma beams and 1 percent for x-rays.

A1.4.3.2 Reported Uncertainty: The ADCL shall state in the calibration report the "best" expanded uncertainty which includes the NIST uncertainty of the standard used. This uncertainty shall not exceed 1.2 percent for Cobalt-60 (and Cesium-137) gamma beams and 1.5 percent for x-rays (coverage factor k= 2).

A1.5 Equipment and facilities

A1.5.1. Minimum requirements for general equipment and facilities

A1.5.1.1 The laboratory shall have two capacitors for electrometer calibration, each with a stability of at least one part in 10^3 per year and a time constant of at least 10^{-5} s.

A1.5.1.2 Two 4 1/2 digit (or more) voltmeters shall be available. One should be capable of measuring at least 600 volts. Their accuracy shall be 0.1 percent. The two should be capable of use over the ADCL charge measurement range.

A1.5.1.3 Two sets of reference-class ionization chambers that provide a useful operating range from approximately 1 mm Al HVL through cobalt-60 radiation shall be available. Each chamber shall have an appropriate equilibrium wall thickness. Each shall have calibration coefficients as a function of energy that are consistent with the uncertainty goals of the laboratory. The chambers shall have high stability and should be ruggedly constructed of material suitable to minimize change of response with age, temperature, humidity, or moderate mechanical force.

A1.5.1.4 Two electrometers to measure charge shall be available. If the electrometers are of the feedback type, they shall have an open-loop gain of at least 10^4 and an input offset current of less than 10^{-13} A. The electrometer circuit shall be electrically guarded at the potential of the input contact point. The charge measurement system shall retain a charge with a decay time constant of at least 10^6 s. Digital electrometers employing charge digitization may also be used, provided they meet or exceed the minimum performance expectations of the analog electrometers given above.

A1.5.1.5 The laboratory shall have a device for testing and documenting atmospheric communication performance. When possible, the laboratory shall establish whether a ion chamber communicates with the atmosphere. Some chambers have communication openings which may be checked with appropriate tools. Others require the use of a device for testing atmospheric communication.

A1.5.1.6 The laboratory shall have at least two source of electric potential accurate to 5 percent and with a short-term stability (10 Min) of 0.1 percent, suitable for chamber polarization and charge measurement.

A1.5.1.7 Each calibration unit (Cobalt 60, x-ray, etc.) shall be equipped with a chamber positioning device of a type and quality adequate to restrict chamber-positioning error to a level consistent with calibration uncertainty goals.

A1.5.1.8 The point of calibration shall be of sufficient distance from the source of radiation such that the positioning error in distance is minimized to a level consistent with calibration uncertainty goals.

A1.5.1.9 The calibration position should be so located that scattered radiation will not introduce a measurement error inconsistent with calibration uncertainty goals.

A1.5.1.10. Ambient conditions at the calibration position and at the monitor detector shall be stabilized or measured with a frequency such that variations are consistent with the calibration uncertainty goals.

A1.5.1.11 The laboratory standard ionization chambers, voltmeters, and capacitors should be compared frequently in accordance with the laboratory protocol and calibrated in accordance with the following:

A1.5.1.11.1 At least one of the laboratory standard ionization chambers for each energy range shall be calibrated by NIST over the full range of energies for which it is used.

A1.5.1.11.2 At least one of the laboratory standard voltmeters and one of

the capacitors used for charge measurement, shall be calibrated at least biennially at another facility. Alternatively, an electrometer with a precision and stability of 0.1% or better may be calibrated biennially by NIST. These calibrations shall be documented as traceable to NIST.

A1.5.1.12 The ionization chambers shall be calibrated to the center of the cavity for all radiation therapy beams.

A1.5.1.13 A determination of the ion collection efficiency during calibration shall be determined for all chambers if possible.

A1.5.2 Minimum requirements for Cobalt 60 calibration equipment and facilities

A1.5.2.1 A cobalt-60 gamma-ray source (not necessarily dedicated) with an intensity adequate to provide calibrations that meet the requirements of this document.

A1.5.2.2 The collimators on cobalt-60 source(s) shall establish either a 10cm x 10cm square or a 10 cm diameter circular field at the calibration position (defined at the 50% intensity level in air or FWHM). Within the central 8 cm diameter circle of the 10 cm x 10 cm field, the difference between the maximum and minimum dose divided by the average of these values, expressed as a percentage, shall not exceed 3.0%. Within the central 4cm diameter , the ratio of difference to average shall not exceed 1.5%. This shall be verified by measurements along at least two major axis.

A1.5.3 Minimum requirements for x-ray calibration equipment and facilities

A1.5.3.1 An x-ray generator (not necessarily dedicated) capable of generating beams with half-value-layers of approximately 1 mm Al to at least 2 mm Cu. with an intensity and stability adequate to provide calibrations that meet the requirements of this document.

A1.5.3.2 The laboratory shall have a set of copper filters having a certified purity of 99.9% of appropriate thickness to permit the precise determination of half-value layers and homogeneity coefficients for all appropriate x-ray calibration beams.

A1.5.3.3 The laboratory shall have a set of aluminum absorbers having a certified purity of 99.99% of appropriate thickness to permit the precise determination of x-ray beam half-value layers and homogeneity coefficients for all appropriate x-ray calibration beams.

A1.5.3.4 The collimators on x-ray sources shall establish suitable field sizes (e.g. a 10cm x 10cm square or a 10 cm diameter circular field at the calibration position (defined at the 50% intensity level in air or FWHM). Attention should be given to the heel effect and the uniformity of the beam across the area of the x-ray field.

A1.5.3.5 Each x-ray unit will be equipped with a full-beam transmission monitor with a means either to stabilize or to measure the temperature of the detection volume. The transmission monitor should provide a precision of 0.1 % for the parameter being measured.

A1.5.3.6 For low energy x-rays with tube potentials below 70 kV, the user shall supply buildup of the appropriate thickness as given in Ma et.al. 2001 (AAPM TG-61) for the calibration of any parallel plate chamber. The chamber shall be calibrated to the center of the active volume with this buildup on the chamber.

A1.5.4 General Data Recording

A1.5.4.1 The procedures for calibration and data recording, as specified in the laboratory protocol, should be formulated so as to reveal changes in the performance of any laboratory equipment on which calibrations depend, through the comparison of redundant systems.

A1.5.4.2 The information to be recorded for the calibration of a medical therapy chamber shall include but need not be limited to the following: date, manufacturer, model, serial number, type, buildup cap (if appropriate), temperature at the chamber, barometric pressure at the chamber, instrument reading, beam quality, beam intensity, field size, atmospheric communication findings, polarizing potentials and polarities, name of person performing the calibration, readout linearity data (if applicable), source-to-chamber distance, all calculations leading to correction or calibration coefficients, and any observed deviations from normal behavior and performance characteristics.

A1.6 Protocol

The laboratory protocol shall include at least the following:

A1.6.1. A statement of the scope of the laboratory work including the energies and intensities at which calibrations are provided, as well as other tests such as stem leakage and scale linearity.

A1.6.2. The protocol shall state the estimates of the ADCLs component of uncertainty. These uncertainties shall be expressed as expanded uncertainties with a coverage factor k=2 and exclude the NIST uncertainty associated with the standard chamber used by the laboratory. For reference class instruments, the uncertainties shall be less than 0.5% for Cobalt-60 and Cesium-137 and 1% for x-rays.

A1.6.3. The protocol shall state the estimated expanded uncertainty for each class of instrument calibrated. The expanded uncertainties are expressed with a coverage factor k=2 and include the NIST uncertainty associated with the standard chamber used by the laboratory.

The expanded uncertainties shall not exceed the following:

	Cobalt-60 Cesium-137 radiation	x-rays
Reference-class instruments, and submitted alone suitable for calibration of other instruments with a precision of 0.1%	1.2% 1.5% ionization chambers	
Field-class digital instruments with 3 1/2 or more digits, and ionization chambers submitted alone, suitable for therapy-beam calibration	1.2%	2.5%
Field-class digital instruments with fewer than 3 1/2 digits, and analog instruments, suitable for therapy-beam calibration	1.5%	2.5%

A1.7 Calibration Report

A1.7.1 In addition to the requirements of Section 10, the calibration report shall include, in succinct form, at least the following information:

A1. 7.1.1 Name and address of the ADCL,

A1. 7.1.2 Report date,

A1. 7.1.3 Report number,

A1. 7.1.4 Person or institution submitting the instrument for calibration, A1.

7.1.5 Type and serial number of instruments calibrated,

A1. 7.1.6 Correction or calibration coefficients normalized to 22°C and 1 standard atmosphere pressure,

A1. 7.1.7 Approximate meter or scale reading at which the calibration coefficient applies,

A1. 7.1.8 Electrometer switch positions (if applicable),

A1. 7.1.9 Beam quality,

A1. 7.1.10 Beam size,

A1.7.1.11 Source-to-chamber distance,

A1.7.1.12 Exposure, air kerma,rate,

A1.7.1.13 Magnitude and polarity of the polarizing potential (if applicable), and the specific electrode polarizing geometry

A1.7.1.14 Pre-irradiation chamber leakage at time of calibration,

A1.7.1.15 Angle of the chamber axis relative to the beam axis.

A1.7.2 The calibration report shall also state the "best" uncertainties offered by the laboratory for Cobalt 60 and X-ray energies (and for Cesium 137 if offered).

A1.7.3 The report may include other information such as type of source used (e.g., kVp, first HVL, HC), temperature and pressure correction tables, rotational orientation of the chamber, relative humidity at the calibration location, etc.

A1.7.4 When a cable-connected ionization chamber is submitted, the calibration coefficient shall be expressed in terms of air kerma or exposure per unit charge. The calibration for the associated electrometer shall be expressed as charge per reading.

A1.7.5 The calibration coefficient may also be given as a system factor which includes a cable-connected ionization chamber and an electrometer. The calibration shall be expressed in one of three ways:

A1.7.5.1 The system can be assigned a dimensionless calibration coefficient for a specified range if the electrometer indicates air kerma or exposure.

A1.7.5.2 The system can be given a calibration coefficient having dimensions of air kerma or exposure per unit of reading, with the switch positions or full-scale reading specified for each calibration coefficient.

A1.7.5.3 The cable-connected chamber can be calibrated in terms of air kerma per or exposure unit charge, and the electrometer calibrated in terms of charge per unit of reading, with the switch positions or full-scale reading specified for each calibration coefficient.

A1.8 Revision History

July 24, 1998: Main Document Revision #4, Revised as follows: Editorial/typographical
3.2 added "overall" and edited sentence
3.3 rewrite of first sentence,
added revision history

November 1998: Revised as follows:
A1.2 revised traceability statements and added uncertainty A1.3 added statement
A1.3.9 replaced beam specification with the same as dose to water

A1.3.10 revised wording
A1.3.13 replaced "beam" with "transmission"
A1.3.23 replaced "correction" with "calibration"
A1.4.2 Revised for expanded uncertainty A1.4.3 Revised statement
A1.5 Spread out report requirements
A1.4.2 Added

July, 1999, Revisions as noted

Revised wording in A1.3.10
Revised wording in A1.3.20
Revised wording in A1.3.21 - removed reference to absorbed dose
Revised wording in A1.3.22.1 - removed reference to absorbed dose
Revised wording in A1.3.22.2 and A1.3.22.3
Renumbered A1.5
Revision #8 July 2000:
Renumbered sections beginning with A1.4
Revised A1.5.9, added words for clarification
Revised A1.5.19, added manufacturer, model, buildup cap
Revised A1.5.21, added "per unit charge"
Revised A1.7.1.14, added "pre-irradiation"

Revision 10, December 2001
Reorganized and Modified for x-ray air kerma calibrations for TG-61
Page 62, replaced "FOR" with "OF" in title, updated References for AAPM TG-39, TG-51 and TG-61, added page numbers to selected references.
Page64, deleted phrase "for reference class instruments" Pages 64-67, replaced wording of entire Section A1.5 Page66, Modified A1.5.2.2 to clearify the region of uniformity Page67, A1.5.3.6-revised reference, A1.5.4.1-deleted "chamber" Page72, A1.7.1.12-added "air kerma" and removed "or absorbed dose to water", A1.7.1.13-added "and the specific electrode polarizing geometry", Added A1.7.3, A1.7.4 and A1.7.5

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A2. CRITERIA for Accreditation of Low Dose Rate (LDR) Brachytherapy Source and Well-Type Chamber Calibration

by the
American Association of Physicists in Medicine

This appendix was developed from the former "Guidelines for Accreditation of Dosimetry Calibration Laboratories (For Brachytherapy Calibrations)" by the Subcommittee (formerly Task Group 3 of the Radiation Therapy Committee) and provides the minimum requirements for accreditation for the calibration of brachytherapy sources and well type chambers used for the measurement of Low Dose Rate brachytherapy sources. The following technical requirements are in addition to those contained in the body of these Criteria.

A2.1 Scope

This document is concerned with calibration laboratories being accredited by the American Association of Physicists in Medicine (AAPM) to provide brachytherapy source and well-type chamber calibrations directly traceable to the National Institute of Standards and Technology (NIST). This document was originally generated by Task Group #22 of the Radiation Therapy Committee of the AAPM.

A2.2 References

Nath, R., Anderson, L.L., Meli, J.A., Olch, A.J., Stitt, J.A., Williamson, J.F.,"Code of practice for brachytherapy physics: Report of the AAPM Radiation Therapy Committee Task Group No. 56", , Med. Phys. 24, (10), 1557-1598, 1997

Nath, R., Anderson, L.L., Luxton, G., Weaver, K.A., J.A., Williamson, Meigooni, A.S., "Dosimetry of Interstitial brachytherapy sources: Recommendations of the AAPM Radiation Therapy Committee Task Group No. 43", Med. Phys. 22 (2), 209-234, 1995

Loftus, T.P., "Standardization of Iridium 192 Gamma Ray Sources in Terms of Exposure,", J. Res. NIST , 1980

Williamson, J.W., Nath, R., "Clinical implementation of AAPM Task Group 32 recommendations on brachytherapy source strength specification", Med. Phys. 18 (3), 439-448, 1991

A2.3 Definitions

A2.3.1 Low intensity source: For the purposes of these Criteria, sources of less than 37 GBq, and/or less than 4 U ($\mu Gy.h^{-1}.m^2$) are considered low intensity sources.

Short half lived source: Half lives less than one year.

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

A2.4 Traceability of calibrations

A2.4.1 Standard Source Traceability: The ADCL shall obtain all model-specific calibrations of standard sources used as reference standards for calibrations directly from NIST.

A2.4.2 NIST MQA Performance: The required performance on the NIST measurement quality assurance proficiency test for photon emitting brachytherapy sources is 2 percent for long half-life sources and 3 percent for short half-life sources. For well-type chamber calibrations, the performance criteria is 3 percent for photon emitting LDR sources.

A2.4.3 An ADCL shall calibrate short half-life encapsulated radioactive sources using instruments calibrated with sources of the same radionuclide, manufacturer, model and encapsulation that have been calibrated by NIST, in conformity with the specifications of this CRITERIA.

A2.4.4 An ADCL shall calibrate long half-life encapsulated radioactive sources with sources of the same radionuclide and similar encapsulation and geometry that have been calibrated by NIST, in conformity with the specifications of this CRITERIA.

A2.5 Equipment and Facilities

A2.5.1 An ADCL shall have, in operable condition, at least the equipment designated in this section, dedicated to calibration laboratory use except as noted. Whenever possible, redundant items should be dissimilar, since dissimilar items are unlikely to change in the same way.

A2.5.2 For long half-life sources and chamber calibrations the laboratory shall have at least one sealed source of each radionuclide, manufacturer, model and encapsulation for which calibration will be offered. This source shall have an activity within the range of activities for which routine clinical calibrations will be offered. This source should have physical dimensions and cladding comparable to the sources routinely calibrated. This source shall have direct traceability to NIST.

A2.5.3 For short half-life sources and chamber calibrations, the laboratory shall have at least one working standard sealed source of each manufacturer and type offered for calibration which has been calibrated locally in the calibration device, and a long half-life radionuclide which is to be used to determine the constancy of the calibration device as detailed in Section A2..5.4.

A2.5.4 At least one device for measuring the intensity of the radiation emanating from the sources to be calibrated. This device may be a reentrant well-type ionization chamber or a device for measuring intensity at a distance. This device must be equipped with positioning assemblies which will allow sources to be measured in multiple repetitions with signal reproducibility of +/- 0.5%.

A2.5.5 Provisions must be made to provide redundancy in the transfer calibration from the working standard source. This redundancy device may be an additional intensity measuring device (ionization chamber) or an additional radioactive reference source. The redundancy intensity measuring device must be completely independent of the principal device such that the two would not be expected to malfunction in the same way simultaneously. A redundant source must be a different, preferably long-lived radionuclide.

A2.5.6 A timing device which provides a precision of 0.1 second, and is traceable to NIST frequency or period standards.

A2.5.7 The calibration position will be so located that scattered radiation will not introduce a measurement error inconsistent with calibration uncertainty goals.

A2.5.8 Ambient conditions at the calibration position shall be stabilized or measured with a frequency such that variations are consistent with the calibration uncertainty goals.

A2.5.9 Calibration of laboratory standards and comparison of measurement equipment.

A2.5.9.1 The laboratory standard equipment should be compared frequently in accordance with the laboratory protocol.

A2.5.9.2 Calibration traceability to NIST dosimetry standards shall be maintained by participating periodically in NIST measurement quality assurance tests. When possible the period should be annually.

A2.5.10. When possible, the laboratory shall establish whether a well chamber communicates with the atmosphere. Some well chambers have communication openings, which may be checked with appropriate tools. Others require the use of a device for testing atmospheric communication which the laboratory shall have available. Chambers sealed to atmospheric communication should be documented in the report.

A2.6 Protocol

A2.6.1 Prior to acceptance of a well-type chamber for calibration, the ADCL must insure that the chamber design (flat axial response for example), and the source positioning apparatus will allow calibration to be performed for the desired source / source train to within the laboratory uncertainty goals. Calibrations will be performed only for axial / linear source inserts.

A2.6.2 The ADCL shall state in the protocol the estimated laboratory component of uncertainty which is the combined expanded uncertainty with a coverage factor k=2 and does not include the NIST uncertainty for the standard.

A2.6.3 The procedures for calibration and data recording, as specified in the laboratory protocol, should be formulated so as to reveal changes in the performance of any laboratory equipment on which calibration depends, through the comparison of redundant Systems.

A2.6.4 Brachytherapy Source Calibration Records: The data to be recorded for the calibration of a brachytherapy source shall include, but need not be limited to the following:

A2.6.4.1 Description of source including radionuclide, physical dimensions, and identification code (e.g. manufacturer make, model and serial number), Make, model, and description of ADCL transfer instrument (or technique), and electrometer.

A2.6.4.2 Identification of the standard source measurement geometry,

A2.6.4.3 Identification of timing device or electrometer containing the timing device, date and time of calibration and the reference date and time of the report

A2.6.4.4 Temperature and pressure and relative humidity (for correction of unsealed well chambers),

A2.6.4.5 Name of person performing the calibration,

A2.6.4.6 All readings for standard source and sample source,

A2.6.4.7 All calculations leading to the calibration coefficient,

A2.6.4.8 Leak test results,

A2.6.4.8 Any deviating conditions from those expected,

A2.6.4.9 Auto-radiograph and/or other test results of the determination of the uniformity and length of the source, if applicable.

A2.6.5 Well-Type Ionization Chamber Calibration Records: The data to be recorded for calibration of ionization chambers shall include but need not be limited to the following:

A2.6.5.1 The chamber manufacturer, model and serial number,

A2.6.5.2 A complete description of each standard source used for the calibration including the manufacturer, model, serial/lot number, radionuclide, encapsulation, active length, physical dimensions, and the air kerma strength .,

A2.6.5.3 A description of the source holder or device used to support the source,

A2.6.5.4 The orientation of the source and the distance from the chamber top or bottom,

A2.6.5.5 The method or instrumentation used to determine the exposure timing, the date and time of the calibration,

A2.6.5.6 The temperature, pressure and relative humidity at the time of calibration,

A2.6.5.7 The results of the atmospheric communication test,

A2.6.5.8 The system leakage (if appropriate),

A2.4.5.9 Ion collection efficiency (if possible) and

A2.6.5.10 Reproducibility tests on the support device.

A2.7 Calibration Report

In addition to the requirements of Section 10,

A2.7.1 The calibration report for brachytherapy sources shall include, in succinct form, at least the following information:

A2.7.1.1 Name and address of the ADCL,

A2.7.1.2 Report date, report number,

A2.7.1.3 Person and/or institution submitting the source for calibration,

A2.7.1.4 Description of source including manufacturer, radionuclide, physical dimensions, material and thickness of encapsulation, and model and serial number or other identifying marks and the calibration of the source. It is the customers responsibility to provide sufficient information to characterize the source.

A2.7.2 The calibration of the photon emitting sources shall (when available) be expressed in terms of air kerma rate at 1 meter from the source with units of ($\mu Gy \cdot m^2 h^{-1}$) measured in a plane which is the perpendicular bisector of the long

axis of the source. At the discretion of the ADCL, additional calibration coefficients may be reported in other historical units.

A2.7.3 The calibration report for well-type ionization chambers shall include at least the following:

A2.7.3.1 The name and address of the ADCL,

A2.7.3.2 The report date and report number,

A2.7.3.3 The complete name and address of the person and/or institution submitting the instrument for calibration,

A2.7.3.4 The manufacturer, model and serial number of the ionization chamber or system,

A2.7.3.5 The calibration date,

A2.7.3.6 A complete description of the standard source used for calibration including the radionuclide, manufacturer, model, encapsulation, active length serial number or lot number, the air kerma strength, or the activity on the date of chamber calibration with the associated uncertainties, and an indication of whether the chamber is sealed or open to the atmosphere,

A2.7.3.8 A description of the source holder or support device,

A2.7.3.9 A description of any special conditions (e.g. shield, etc.),

A2.7.3.10 The ion collection efficiency (if possible), the polarizing potential (if available for measurement),

A2.7.3.11 The system pre-irradiation leakage or background current (if appropriate),

A2.7.3.12 A complete description of the calibration coefficient and its

use, A2.7.3.13 An indication of the uncertainty of the calibration,

A2.7.3.14 Appropriate log references and

A2.7.3.15 Such other information as may be deemed appropriate.

A2.7.4 Reported uncertainty: The ADCL shall state in the calibration report the "best" combined expanded uncertainty (with a coverage factor k=2) which includes the NIST uncertainty of the standard source used in the calibration.

A2.8 Revision History

October, 1985: Original Document

September 1989: Added " calibration of brachytherapy sources" in title. Changed ABCL to ADCL, changed NIST to NIST, Sections 3.2.3 and 5.1.3 added, and Section 5.2.1 revised. Sections 3.8.1.2 revised to require calibration in terms of air kerma in Section 3.9.1.2.

October 1990: Added 1.1.2, 3.7.3.2, 3.8.1.3, and changed title, introduction, 1.1.1, 1.2, 3.3.1.1, 3.3.1.2, 3.3.1.2.b, 3.4.2, 3.6, 3.8.1.1 to allow for the calibration of ion chambers and make other minor modifications.

August, 1992:
Modified introduction, 1.1.1, 1.1.2, 1.2, and 3.8.1.1 and added 1.1.3 and 3.3.1.2.c to include HDR calibrations.

November, 1996: Revised for ISO 25

July, 1997: Revised Brachytherapy in appendix, revised section numbers.

November 1997: Revised to correct typographical errors.

July 24, 1998:
Revised to correct typographical errors,
Replaced Chronology with Revision History
Renumbered July 30, 1998 for Rev 4A

November, 1998:

- Added AAPM at top under A2 title
- Added introductory section below title
- Added Reference section and TG-43 reference
- Added Definition section and definitions
- A2.2.2 inserted "and well chamber", revised percentages
- A2.2.3 revised percentages
- A2.2.4 moved to report section
- New A2.2.4 revised wording
- New A2.2.5 revised wording
- A2.3.3 revised wording
- A2.3.7 added "second"
- A2.4.1 added "expanded" and k
- A2.4.2 added "expanded" and k
- A2.4.4 renumbered
- A2.5.3 renumbered
- A2.5.4 expanded uncertainty with k and well chambers

July 22, 1999, Revisions as noted;

Revised wording A2.4.4
Revised wording A2.4.5
Revised wording A2.5.2
Added A2.5.10
Added A2.6.3.8
Revised wording of A2.7.2
Revised wording of A2.7.4

Revision #8, July 6, 2000

Revised A2.5.4, clarify local working standard for short lived.
Revised A2.6.3.4, revised wording
Revised A2.7.2, added units

Revision # 9, July 1, 2001

Revision #10, January 2002

Remove IVB from LDR to new appendix, revise and edit.
Page75, delete “INTERSTITIAL AND INTRAVASCULAR” form title and add “(LDR), delete “and intravascular” from first paragraph.
Page75, A2.2, Added authors and pages in references,
Page76, A2.2, removed the TG-60 reference.
Page76, A2.3.1, revised Low intensity definition, LDR brachytherapy, removed IVB definitions.
Page76, A2.4.2, removed the second sentence regarding IVB and “and HDR” from last sentence.
Page77, A2.5.3, removed “or IVB” in first sentence.
Page78, A2.6.1, removed second sentence regarding IVB sources and added “combined” to A2.6.2.
Page79, A2.6.4.9, added “if applicable”. At the end of the sentence and deleted A2.6.4.10 (IVB refrence) and added “and” to A2.6.5.2 Page80, A2.6.5.2, deleted “(or dose to water at ….calibration.”, deleted A2.7.1.5 and the second sentence in A2.7.2 “For beta emitting sources…model.” (IVB references)
Page81, A2.7.3.6-deleted “(and uniformity for IVB sources)” and “absorbed dose to water”

A3. CRITERIA for Accreditation of Air Kerma Calibrations for Diagnostic X-ray Systems

by the
American Association of Physicists in Medicine

This appendix was prepared by the AAPM task group on Guidelines for ADCL Calibration of Ionization Chambers for Diagnostic X-ray Applications (Task Group No. 2) of the Calibration Laboratory Subcommittee of the Radiation Therapy Committee, consisting of the following persons:

- Louis K. Wagner, University of Texas Houston Medical School, Houston, Texas, Chairman
- Frank Cerra, Center for Devices and Radiological Health, Rockville, Maryland
- Larry DeWerd, University of Wisconsin ADCL, Madison, Wisconsin
- Tom Heaton, Center for Devices and Radiological Health, Rockville, Maryland
- Michelle O'Brien, National Institute of Standards and Technology, Gaithersburg, Maryland
- Bill Simon, Sun Nuclear, Melbourne, Florida
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A3.1 Scope

This appendix itemizes requirements for laboratories that are accredited by the American Association of Physicists in Medicine (AAPM) in the calibration of dosimeters used to measure radiation levels produced by diagnostic machines. Laboratories may be accredited in any one or more of the categories itemized in section A3.4.2

A3.2 References

A3.2.1 Wagner LK, Fontenla DP, Kimme-Smith C, Rothenberg LN, Shepard J, Boone JM. Recommendations on the performance characteristics of diagnostic exposure meters: Report of AAPM Diagnostic X-Ray Imaging Task Group No. 6, Med Phys 19 (1), 231-241, 1992

A3.2.2 Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments. ANSI N323A-1997, IEEE, New York, NY.

A3.3 Definitions

A3.3.1 Calibration of a diagnostic dosimeter: The comparison of the air kerma or air kerma rate response of a dosimeter to that of a secondary diagnostic reference class dosimeter at diagnostic beam qualities, including the maintenance of records and a report specifying the results.

A3.3.2 Diagnostic Field Class Dosimeter: A dosimeter used to measure levels of radiation from common medical diagnostic x-ray sources in the field and capable of being calibrated to within an uncertainty of 5% (k=2) for the conventional x-ray range

(50kVp-150kVp) and within an uncertainty of 3% (k=2) for mammography dosimeters (23kVp-50kVp).

A3.3.3 Diagnostic Reference Class Dosimeter: A dosimeter capable of being calibrated in diagnostic beams (50kVp-150kVp) to within an uncertainty of 2.5% (k=2) or for mammography dosimeters calibrated in a mammography beam (20kVp-50kVp) to within an uncertainty of 2% (k=2) relative to the NIST standard as absolute (i.e., excluding uncertainties in the NIST standard) and possessing a record of long term stability of better than 0.5% change per year.

A3.3.4 Diagnostic X-ray Survey Meter: An instrument used to measure levels of ambient leakage or scatter radiation produced by diagnostic beams and capable of being calibrated to within an uncertainty of 10% (k=2).

A3.4 Function of a Laboratory Accredited for Calibration of Diagnostic Dosimeters

A3.4.1 A calibration laboratory accredited to calibrate dosimeters for measurement of radiation levels at diagnostic beam qualities:

A3.4.1.1 Shall maintain reference class chambers that have been calibrated at NIST in conformity with standards set forth in this document and over the range of beam qualities appropriate for each type of calibration for which they apply,
A3.4.1.2 May perform accredited calibrations only at beam qualities established by a protocol approved by the accrediting body,
A3.4.1.3 Shall maintain records of and reports on calibrations and quality control tests as defined below,
A3.4.1.4 Shall participate in proficiency tests as required by the accrediting body (AAPM).

A3.4.2 Laboratories shall perform accredited calibrations of reference class and/or field class dosimeters and/or survey meters in at least one or more of the following categories:

A3.4.2.1 General diagnostic dosimeters - instruments used to measure radiation levels from diagnostic beams in the range of 50 kVp to 120 kVp.
A3.4.2.2 Mammographic dosimeters - instruments used to measure radiation levels from diagnostic beams in the range of 20 kVp to 50 kVp.
A3.4.2.3 Computed tomographic dosimeters - instruments used to measure radiation levels from diagnostic beams in the range of 100 kVp to 150 kVp.
A3.4.2.4 Low-dose-rate dosimeters - instruments used to measure radiation levels from diagnostic beams in the range of 50 kVp to 120 kVp and at air kerma rates less than 0.5 mGy per minute.
A3.4.2.5 Diagnostic x-ray survey meters – instruments used to measure radiation levels of ambient x-rays, typically resulting from scatter or leakage radiation, from diagnostic beams in the range of 20 to 150 kVp and at air kerma rates of 10 uGy/h and up.

A3.4.3 The ADCL shall be capable of the following:

A3.4.3.1 Reference-class instruments - providing calibrations for diagnostic beams (50kVp-150kVp) with an expanded uncertainty not exceeding 3.5% (k=2) and mammography beams (20kVp-50kVp) with an expanded uncertainty not exceeding of 2% (k=2),

A3.4.3.2 Field class instruments - an expanded uncertainty not exceeding 5% (k=2) for in categories A3.4.2.1, A3.4.2.3 and A3.4.2.4, an expanded uncertainty not exceeding 3% for mammography calibrations for categories A3.4.2.2 and an expanded uncertainty not exceeding 10% (k=2) for field class instruments in category A3.4.2.5.

Note: The expanded uncertainty above includes those related to the calibration by the absolute standard from NIST and those of the calibration laboratory. All uncertainties are specified with a coverage factor k=2 (k=2).

A3.5 Equipment and Facilities

In addition to the requirements of the criteria of which this is an appendix, an ADCL shall have, in operable condition, at least the equipment designated in the following subsections and dedicated to use in the calibration laboratory.

A3.5.1 X-ray Machine(s)

In all cases the laboratory shall use x-ray machines dedicated to calibration laboratory use. All voltage waveforms of generators shall have a voltage waveform ripple of no more than 20% peak-to-peak at the nominal beam qualities specified for each category of calibration. All machines shall be capable of providing a calibration x-ray field as specified in section A3.5.5. The range of beam quality calibration points provided by the laboratory shall be sufficiently consistent with NIST beam qualities (i.e., first and second HVL) to ensure compliance with A3.6.1.6.

A3.5.1.1 For general diagnostic dosimeters: a tungsten anode tube and x-ray machine operating at nominal kVp ranging from 50 to 120 and capable of generating beams with a first half-value layer of 1 mm to 7 mm of aluminum. The laboratory shall provide at least three beam quality calibration points within the range defined for this type of calibration.

A3.5.1.2 For mammography dosimeters: a molybdenum anode tube with molybdenum filtration and x-ray machine capable of generating beams with a first half-value layer of approximately 0.28 mm to at least 0.39 mm of aluminum. The laboratory shall provide at least two beam quality calibration points within the range defined for this type of calibration.

A3.5.1.3 For computed tomography dosimeters: a tungsten anode tube and x-ray machine operating at nominal kVp ranging from 100 to 150 and capable of generating beams with a first half-value layer of 5 mm to 10 mm of aluminum.

The laboratory shall provide at least two beam quality calibration points within the range defined for this type of calibration.

A3.5.1.4 For low-dose-rate dosimeters: a tungsten anode tube and x-ray machine operating at nominal kVp ranging from 50 to 120 and capable of generating beams with a first half-value layer of 1 mm of aluminum and up. The laboratory shall provide at least two beam quality calibration points within the range defined for this type of calibration.

A3.5.1.5 For survey meters: a tungsten anode tube and x-ray machine operating at nominal kVp ranging from 50 to 150. The laboratory shall provide at least two beam quality calibration points within the range defined for this type of calibration.

A3.5.2 A Device to Assess the Accuracy and Stability of the kVp
A device is required to assess the accuracy and stability of the kVp and it shall be able to measure the kVp to within 2% or 0.5 kVp of the intended value, whichever is larger, with a precision of 1% (k=2).

A3.5.3 Transmission Monitor
A transmission monitor, correctable for ambient air density if vented, is required. If necessary, temperature correction shall be suitable to account for effects resulting from heat that is generated from the x-ray tube. This transmission chamber shall be sufficient to monitor the radiation exposure delivered to the calibration field area and to meet the accuracy goals of the laboratory for each accredited beam quality.

A3.5.4 Aluminum Filters for Measurement of HVL
A set of aluminum filters having certified purity of at least 99.99% for calibrations in category A3.4.2.2 and at least 99.9% for all other categories is required. A sufficient supply shall be available for the determination of the first and second HVL.

A3.5.5 Collimators
The x-ray field shall be sufficiently collimated to minimize scatter to a level consistent with the overall accuracy goals. In all directions in the reference plane of the x-ray field, the linear dimensions of the field shall be at least 1.5 times larger than the corresponding linear dimension of the active volume of the dosimeter to be calibrated. Over the central 80% of the calibration field profile measured perpendicular to the beam, the radiation field intensity shall not vary *by* more than 5% from the maximum intensity.

A3.5.6 Reference-Class Ionization Chambers for Each Accredited Category For each accredited category, the laboratory shall have two reference-class ion chambers. Each reference chamber (or set of reference chambers) shall provide a useful operating range of beam qualities applicable to all beam qualities approved for that accreditation category. Each chamber shall have appropriate wall thickness and calibration coefficients consistent with the overall accuracy goals of the laboratory. The chambers shall have high stability and should be ruggedly constructed of material suitable to minimize change of response with age, temperature, humidity, or

moderate mechanical force. Any one chamber may qualify for more than one category of diagnostic-type accreditation as long as it meets the requirements of each category.

A3.5.7 Chamber Polarization Device

At least one source of electric potential suitable for chamber polarization and charge measurement is required. The voltage output should be known to within 1%. Short-term stability should be within 1mV/s.

A3.5.8 A Device for Testing Atmospheric Communication of Ionization Chambers

A device to measure atmospheric communication of ionization chambers is required.

A3.5.9 Chamber-Positioning Devices

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

A3.5.10 Electrometers to Measure Charge

At least two electrometers to measure charge and current are required. Each shall be of sufficient quality to meet the laboratory's accuracy goals for calibration of reference-class ionization chambers at all accredited diagnostic-type beam qualities.

A3.5.11 Capacitors for Electrometer Calibration

Two hermetically sealed capacitors are required, each with a stability of at least one part in 10^4 per year and a time constant of at least 10^5 s.

A3.5.12 DC Voltage Source for Electrometer Calibration

The DC voltage source shall be stable to within 0.05% (k=2).

A3.5.13 Voltmeters

Two voltmeters of at least 4 1/2 digits are required. One should be capable of measuring at least 600 volts. The two should be capable of comparison over the charge measurement range.

A3.6 Protocol

A3.6.1 Maintenance of Calibration Quality

A3.6.1.1 The laboratory shall have a protocol manual (Section A3.7) providing quality assurance measurement procedures and specifying frequency of performance.

A3.6.1.2 Each reference class ionization chamber, which serves as the laboratory's standard for accredited beam qualities, shall be calibrated by NIST. The laboratory must have standard ionization chambers calibrated at beam qualities sufficient to cover the laboratory's accredited beam qualities.

A3.6.1.3 At least one of the laboratory standard voltmeters, and one of the capacitors used for charge measurement, shall be calibrated at least biennially at another facility. These calibrations shall be documented as traceable to NIST. The uncertainty of the calibration shall be within 0.05% (k=2).

A3.6.1.4 The laboratory standard ionization chambers, voltmeters, and capacitors shall be compared frequently in accordance with the laboratory protocol.

A3.6.1.5 All half-value-layers shall be measured with the filters specified in A3.5.4 to within a precision of 4% (k=2).

A3.6.1.6 Calibration traceability to NIST dosimetry standards shall be maintained by participation in NIST measurement quality assurance tests and in ADCL intercomparisons at intervals prescribed by the Subcommittee. For the purposes of the NIST proficiency test and ADCL intercomparisons, the ADCL shall be capable of calibration of a transfer quality chamber at each accredited beam quality used for the intercomparison to within an uncertainty of 2.5% (k=2), excluding the NIST uncertainty of the ADCL standard that is used for the calibration.

A3.6.2 Calibration of Field Class Dosimeters and Survey Class Meters

A3.6.2.1 The equipment calibrated by an ADCL that is accredited for diagnostic calibrations shall be instruments of the type suitable for measurement of radiation levels produced from diagnostic x-ray machines.

A3.6.2.2 Each ion chamber submitted for calibration shall be tested for atmospheric communication if possible.

A3.6.2.3 The laboratory should have the capability to measure the accuracy of a dosimeter in the rate mode at air kerma rates of approximately 10 mGy per minute and 100 mGy per minute for general diagnostic dosimeters and 10 uGy per minute and 0.5 mGy per minute for low-dose-rate meters. The accuracy of the test shall be indicated.

A3.6.2.4 The laboratory should have the capability to measure the accuracy of a dosimeter in the air kerma mode at air kerma rates of approximately 1 Gy per minute and 10 Gy per minute for the purpose of evaluating rate dependence of general diagnostic dosimeters. The accuracy of the test shall be indicated.

A3.6.3 Calibration report

A3.6.3.1 The calibration report shall provide calibration coefficients and the other information that makes them meaningful and useful.

A3.6.3.2 The calibration report shall include, in succinct form, at least the following information:

a) name, address and telephone number of the ADCL,

b) person or institution submitting the instrument for calibration,
c) calibration date, report number, model and serial numbers of the calibrated instrument,
d) calibration coefficients appropriately corrected for reference conditions, meter or scale range at which a calibration coefficient applies,
e) electrometer settings of the calibrated instrument (if applicable), magnitude and polarity of the polarizing potential (if applicable), chamber leakage at time of calibration,
f) beam quality, beam size, source-to-chamber distance, air kerma rate, a statement of the calibration uncertainties, and angle of the chamber axis relative to the beam axis.

A3.6.3.3 The calibration coefficients contained in the report shall be given in units of air kerma or air kerma rate per unit of meter reading. Other units such as units of exposure or exposure rate may also be given in the report as required by the owner or user of the instrument.

A3.6.3.4 When a cable-connected ionization chamber is submitted without an accompanying electrometer, the calibration coefficient shall be expressed in terms of air kerma per unit charge.

A3.6.3.5 For ionization chambers designed to communicate with the atmosphere, the report shall state the adequacy of the chamber communication. If the chamber cannot be tested for atmospheric communication, this shall be stated in the calibration report.

A3.6.3.6 If the wall thickness of the chamber or other performance characteristics of the dosimeter are not suitable for the calibration beam quality, a statement on how this might affect the performance of the measuring device (e.g., energy dependence due to thick wall or characteristics of the detector) shall be included in the report.

A3.6.3.7 The report shall include a statement regarding the applicability of the calibration for those units that have a temperature and/or a pressure sensing unit or other features that compensate for atmospheric conditions. The report shall clearly state the conditions under which the calibration was done and the limitations that apply.

A3.6.3.8 The report shall include a statement of the "best" combined expanded uncertainty (k=2) including the NIST uncertainty of the standard for the calibration coefficient for each category and class of instrument included in the report.

A3.7 The Protocol Manual

A3.7.1 The procedures for laboratory instrument calibration and data recording shall be specified in the laboratory protocol manual and should be formulated so as to reveal changes in the performance of any laboratory equipment on which calibrations depend, through the comparison of redundant systems.

A3.7.2 The ADCL's protocol shall include at least the following:

A3.7.2.1 A statement of the scope of the laboratory work including the beam qualities and intensities at which calibrations are provided, as well as other tests such as scale linearity, air communication and ion recombination.

A3.7.2.2 A statement of laboratory goals for calibration uncertainty for each category of calibration offered by the ADCL (A3.4.2.1 – A3.4.2.5). These goals should include a calculation for uncertainty expected for each category using the appropriate reference standard and calculated on the basis of the calibration of the reference class instrument. The uncertainty must represent an estimate of the maximum uncertainties anticipated in direct comparisons with NIST or other ADCL's. The uncertainties shall also include those stated by NIST for the transfer chamber calibration and this may be itemized separately. The combined expanded uncertainty shall fall within the following (coverage factor k=2):

Type of instrument	Combined ExpandedUncertainty (k=2)
Reference-class instruments suitable for calibration of other instruments in categories A3.4.2.1,A3.4.2.3 – A3.4.2.5.	3.5%
Reference-class instruments suitable for calibration of other instruments in mammography category ,A3.4.2.2.	2%
Field-class dosimeters (50kVp-150kVp)	5%
Field-class mammography dosimeters (20kVp-50kVp)	3%
Survey meters	10%
Electrometers	1%

A3.7.2.3 A procedure for establishing accredited beams and verifying beam qualities.

A3.7.2.4 Type and serial number of each piece of equipment used in any calibration or the location of where this information can be found.

A3.7.2.5 Procedures that allow a knowledgeable person to reproduce a particular calibration technique repeatedly to a precision consistent with the goals of the laboratory.

A3.7.2.6 A procedure for electrometer calibration.

A3.7.2.7 A procedure for acquiring and recording calibration data.

A3.7.2.8 A procedure for measuring the thickness of the aluminum filters used to measure HVL.

A3.7.2.9 A procedure for reviewing calibration data and signing reports.

A3.7.2.10 The form of the calibration report.

A3.7.2.11 An analysis of the way in which laboratory procedures achieve redundancy in measurement.

A3.7.2.12 The laboratory's quality control procedures.

A3.7.2.13 A procedure for comparing and/or calibrating each piece of listed laboratory equipment, and a statement of the frequency at which this is done, with provision to conform to the main CRITERIA document.

A3.7.2.14 A procedure for updating the protocol.

A3.7.2.15 Any other procedures necessary to achieve a calibration that falls within the uncertainty limits of A3.7.2.2.

A3.8 Revision History

November, 1998:

A3.4.3, A3.7.2.2 Replaced "overall" with "expanded" and added coverage factor

July, 1999:

Revised font Section A3.5.11
Revised wording Section A3.6.3.8

September, 1999:

Revised wording of A3.6.2.4

Revision #8, July 6, 2000:

Revised A3.3.2 definition to include mammography instruments as field class dosimeters.
Revised A3.3.3 definition to include reference class mammography dosimeters.
Revised A3.4.3, rewritten to separate field class and reference class and to set mammography to 3% uncertainty.
Revised A3.7.2.2, added mammography category to table

Revision #10, January 2002

Page86, title edited by deleting "dosimetry calibrations in the", inserting "Air Kerma", adding "s" to Calibration" and deleting "of instruments used to measure radiation produced by" and inserting "for"
Page86, A3.3.2, delete "6 " and insert "k=" before the "2"
Page87, A3.3.3, A3.3.4, delete "6 " and insert "k=" before the "2"
Page88, A3.4.3.1, A3.4.3.2-delete "6 " and insert "k=" before the "2"
Page 89, A3.5.2 -delete "6 " and insert "k=" before the "2"
Page90, A3.5.12 - delete "6 " and insert "k=" before the "2"

Page91, A3.6.1.3, A3.6.1.5, A3.6.1.6 - delete “6 “ and insert “k=” before the “2”
Page93, A3.6.3.8- added “combined” before “expanded” and “(k=2) including the NIST uncertainty of the standard for” and deleted “of”
Page93, A3.7.2.2 – added “combined” and “(k=2)”
Pages 86-93, misc. typographical corrections

A4. CRITERIA for Accreditation of Absorbed Dose to Water Calibrations with Ionization Chambers for Radiation Therapy

by the
American Association of Physicists in Medicine

This appendix was prepared by a Task Group of the Subcommittee of the Radiation Therapy Committee of the AAPM consisting of the following persons:

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A4.1. Aims & Scope

This appendix is concerned with the accreditation of a laboratory for the calibration of ionization chambers for absorbed dose to water pursuant to the recommendations of Task Group #51 of the AAPM Radiation Therapy Committee. It is intended that the ADCL will assign a value of $N_{D,W}^{Co}$ that is directly traceable to NIST. The ADCL component of the relative expanded uncertainty (k=2) will be no greater than 0.7%. This includes a coverage factor of two, which defines an interval having a level of confidence of approximately 95 percent.

A4.2. Laboratory Traceability

The laboratory will calibrate instruments in a radiation field quantified with a transfer instrument carrying a valid NIST calibration coefficient maintained according to Section A4.5.7.

A4.3. References

A4.3.1 Almond, P.R.,chair, Biggs, P.J., Coursey, B.M., Hanson, W. F., Huq, M. S., Nath, R., Rogers, D.W.O., “AAPM’s TG-51 Protocol for clinical Reference Dosimetry of High-Energy Photon and Electron Beams,” Med. Phys. 26 (9), 1847-1870, 1999.

A4.3.2 Lillicrap, S. C., Owen, B., Williams, J. R., Williams, P.C., “Code of Practice for high-energy photon therapy dosimetry based on the NPL absorbed dose calibration service,” , Phys. Med. Biol. 35: 1355-1360 (1990).

A4.3.3 Ross, C. K., Shortt, K.R.,"The effect of waterproofing sleeves on ionization chamber response," Phys. Med. Biol. 37: 1403-1411 (1992).

A4.3.4 Ibbott, G.S., Attix, F.H., Slowey, T.W., Fontenla, D.P., Rozenfeld, M., "Uncertainty of calibrations at the accredited dosimetry calibration laboratories," Med. Phys. 24: #8, 1249-1254 (1997).

A4.3.5 Taylor, B.N., Kuyatt, C.E., "Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results," NIST Technical Note 1297, (1993)

A4.3.6 "Guide to the Expression of Uncertainty in Measurement," ISO/TAG 4/WG 3, (1992)

A4.3.7 Boag, J.W., "Ionization Chambers, The Dosimetry of Ionizing Radiation," in Radiation Dosimetry II, pp. 169-244, ed. F. H. Attix and W. Roesch (1987)

A4.3.8 Hanson W. F., Dominguez Tinoco J. A., "Effects of Plastic potective caps on the calibration of therapy beams in water", Med Phys 12; p 243 - 248, 1985

A4.4. Definitions

A4.4.1 Absorbed Dose To Water calibration coefficient, N_{60wo}: The factor N_{60wo} converts the charge released in the chamber to absorbed dose to water at the reference point in a ^{60}Co beam in the absence of the chamber. The factor is based on a comparison of responses of the chamber to be calibrated and a secondary standard chamber, which has been calibrated at NIST in conformity with sections A4.2 and A4.5.8. The point of measurement is the centroid of the collecting volume of the cylindrical chamber, which is oriented with its axis of symmetry perpendicular to the beam axis. For a plane-parallel ionization chamber, the point of measurement is at the inside surface of the window of the air cavity and oriented with the window pointed toward the beam. For a vented ionization chamber the calibration coefficient applies for reference conditions of temperature, pressure, and relative humidity, as defined in Section 10.8 of the Criteria Document.

A4.4.2 ADCL component of the combined expanded uncertainty: that portion of the uncertainty that arises solely at the ADCL. The component arising from the NIST calibration of the transfer standard is not included in this value.

A4.5. Equipment and Facilities

In addition to meeting the requirements of Section 10 of the CRITERIA, of which this is an Appendix, the candidate laboratory shall have and use the following:

A4.5.1 A cobalt-60 gamma-ray source (not necessarily dedicated) of a strength adequate to provide calibrations that meet the requirements of this document.

A4.5.2 Two reference class (Section 1 of CRITERIA) ionization chambers, each with a valid NIST absorbed dose to water calibration coefficient for cobalt-60. Chambers that are not inherently waterproof may be inserted in a PMMA sleeve of 1 mm maximum wall

thickness. Although a thin latex sheath may be substituted for the PMMA sleeve, rubber

sheaths are not permitted for chamber calibrations. Note that transfer chambers used for these calibrations should have a proven history of reliability, as described below. Reliability and constancy of these ionization chambers is to be demonstrated by comparisons either in air or in water at maximum intervals of six months.

A4.5.3 Collimators on cobalt-60 sources to establish a 10 cm x 10 cm square field at the calibration position. The cobalt-60 unit should provide a uniform field. The resulting field shall meet the following requirements for uniformity, as determined by measurements of dose in water in the plane of the calibration position. Within the central 8 cm x 8 cm area of the 10 cm x 10 cm field, the difference between the maximum and minimum dose divided by the average of these values, expressed as a percentage, shall not exceed 3.0%. Within the central 4 cm x 4 cm area, the ratio of difference to average shall not exceed 1.5%. The calibration distance should be 80 cm Source to Chamber Distance (SCD) or greater. The minimum distance between the measurement point and collimator, other structures, and a device, such as a transmission chamber is to be 25 cm. No additional scatter materials should be in the beam.

A4.5.4 A device for testing atmospheric communication of ionization chambers. See section A1.5.1.5

A4.5.5 Chamber-positioning devices of a type and quality adequate to restrict chamber-positioning error to a level consistent with expanded goals for calibration uncertainty. The chamber should be positioned at a nominal depth of 5 cm (5 g/cm^2) in a water phantom having minimum dimensions of 30 cm x 30 cm x 30 cm. The calibration of a chamber is to be performed by the substitution technique. However, there can be a number of chamber substitutions in a given run before the transfer chamber should be used again to verify constancy of the calibration field. The beam may enter from either the top or a side of the phantom. For entrance from a side, the wall of the entrance side should not exceed 7 mm of plastic in thickness.

A4.5.6 Stabilization of environmental conditions. Ambient conditions at the calibration position shall be stabilized and measured with a frequency such that variations are consistent with the expanded goals for calibration uncertainty.

A4.5.7 Maintenance of Traceability. Calibration traceability to NIST dosimetry standards shall be maintained by the laboratory through frequent comparisons of local laboratory standards and by participation in NIST measurement quality assurance program. On years when the NIST program is not performed, the laboratory will participate in ADCL comparisons. These mandated comparisons are given in the CRITERIA of which this is an appendix.

A4.6. Protocol

The protocol for laboratories carrying out these calibrations shall include the following:

A4.6.1 A statement of the scope of the laboratory work including a description of the phantom used for calibrations, as well as all tests performed such as leakage, scale linearity, etc.

A4.6.2. A statement of laboratory goals for calibration uncertainty. The uncertainty statement shall include two goals for uncertainty: 1. The ADCL component of the uncertainty and 2. The combined expanded uncertainty that includes the NIST uncertainty. Both values will always have a coverage factor of 2, which defines an interval having a level of confidence of approximately 95 percent. The reported combined expanded uncertainty will include the ADCL uncertainties and all NIST uncertainties, both Type A and B of the whole chain. These laboratory goals must fall within the following limits: ADCL component of the uncertainty must be within 0.7%; the combined expanded uncertainty that includes NIST must be within 1.3%.

A4.6.3 The information to be recorded for the calibration of a medical therapy chamber includes the following: date of measurements, model and serial number, temperature of the water phantom, barometric pressure in the room, rotational orientation of the chamber, instrument reading, beam quality, beam intensity, field size, atmospheric communication findings, charge collection polarities, name of person performing the calibration, readout linearity data (if applicable), source-to-chamber distance, all calculations leading to calibration coefficients, and any deviations from normal.

A4.6.4 The calibration coefficient, $N_{D}W_{\circ}$, shall be expressed in terms of absorbed dose to water per unit charge (Gy/C). The ion recombination effect will be measured by the full voltage and half voltage technique. The final factor, $N_{Dw\ \circ}$ applies to 100% collection efficiency. Thus, $N_{DW\ \circ}$ will reflect the chamber corrected to 100% collection efficiency. The value of the recombination effect (expressed as $A_{ion)}$ or the magnitude of the effect (ratio of currents) for the chamber being calibrated will be given in a comment section of the report.

A4.6.5 Calibration coefficients will be determined only for negative charge collection on the collector electrode. The user must specify polarity if negative charge collection is not desired.

A4.7. Calibration Report

The calibration report shall include, in succinct form, at least the following information:

A4.7.1 Information on the report, such as name and address of the ADCL, report date, report number, laboratory notebook pages or electronic location of original data, person or institution submitting the instrument for calibration, type and serial number of instruments

calibrated

A4.7.2 Information on the chamber, such as calibration coefficients normalized to reference conditions. The calibration coefficient shall be corrected for full collection efficiency. Also included will be a notation of the recombination value, approximate meter or scale reading at which a correction or calibration coefficient applies, electrometer switch positions (if applicable). The magnitude and polarity of the polarizing potential and electrode

geometry (if applicable), charge polarity collected, difference of positive and negative polarities if measured, chamber leakage at time of calibration shall be included.

A4.7.3 Information on the irradiation conditions, such as beam quality, beam size, source-to-chamber distance, water phantom dimensions, depth of measurement, dose rate, chamber orientation, and angle of the chamber axis relative to the beam axis.

A4.7.4 A statement of the ADCL component of the relative expanded uncertainty and the relative expanded uncertainty shall be included.

A4.8 Revision History

July 22, 1999
Revised wording of Section A4.6.4
Revision #8, July 2000:
Revised A4.1, added “(k=2)”
Revised A4.3.1, deleted “(to be published…)”

Revision #10, January 2002
Page94, Revised title, added “Accreditation of”, deleted “of”, added “with”, deleted “IN A COBALT 60 BEAM”, deleted “APPLICATIONS” Page94, A4.1-deleted “determine” and replaced with “assign” Page94-95, A4.3.1-A4.3.7-reorganized references
Page95, deleted non-standard uncertainty definitions(see definitions in section 3 of the Criteria.
Pae96, A4.4.4, replaced “relative” with “combined”
Page97, A4.6.2, replaced “relative” with “combined”, added “that includes the NIST uncertainty” to qualify one of the uncertainties. Page97, A4.6.4-replaced “P”ion with “A”
Page98, A4.7.1-replaced”floppy disk” with “electronic”
Page98, A4.7.2-added “and electrode geometry” to third sentence.

A5. CRITERIA for Accreditation of High Dose Rate (HDR) Brachytherapy Well-type Chamber Calibrations

by the
American Association of Physicists in Medicine

This appendix was developed from the former "Guidelines for Accreditation of Dosimetry Calibration Laboratories (For Brachytherapy Calibrations)" by the Subcommittee and provides the minimum requirements for accreditation for the calibration of High Dose Rate (HDR) Iridium-192 well type chambers used for the measurement of HDR Iridium-192 sources. The following technical requirements are in addition to those contained in the body of these Criteria

A5.1 Scope

This document is concerned with accreditation of calibration laboratories for the calibration of well type chambers for HDR Iridium-192 sources. Until such time as a national standard for HDR Iridium-192 is established, calibrations of HDR Iridium-192 shall conform to interim interpolated standard approved by the AAPM in consultation with NIST.

A5.2 References

Goetsch, S.J., Attix,F.H., Pearson,D.W., Thomadsen,B.R., “Calibration of 192Ir High Dose Rate afterloading systems”, Med. Phys. 18 (3), 462-467, 1991

Podgorsak, M.B., DeWerd, L.A., Thomadsen, B.R., Paliwal, B.R., “Thermal and scatter effects on the radiation sensitivity of well chambers used for high dose rate Ir-192 calibrations”, Med. Phys. 19 (5), 1311-1314, 1992

Verhaegen, F.E., van Dijk, H., Thierens, A. Aalbers, "Calibration of Low Activity Ir-192 brachytherapy Sources in Terms of Reference Air Kerma Rate with Large Volume Spherical Ionization Chambers," Phys. Med. Biol. 37 (11), 2071-2082, 1992

A5.3 Definitions

A5.3.1 _ HDR brachytherapy: High Dose Rate brachytherapy. Gigabecquel (GBq) or Curie levels of activity producing microGray per second air kerma rates at one meter. These sources are intended to be remotely inserted through a catheter into the patient for a relatively short period of time.

A5.4 Traceability of Calibrations

A5.4.1 An ADCL shall obtain calibration coefficients on a transfer quality thimble or spherical ionization chamber for Cesium-137 and M250 with an appropriate buildup cap directly from NIST. An interim standard has been established which uses a specific interpolation method between the NIST Cesium-137 and the M250 beam (using sufficient buildup for Cesium-137 during both calibrations). The calibration coefficient for the Iridium-192 point is presumed to be midway between the calibration coefficients for Cs-137 and M250. A correction is then applied for excess attenuation at the average energy for Ir-192 per the technique in reference A5.2.1.

A5.4.2 ADCL comparison Performance: The required performance on the ADCL comparison of HDR Iridium-192 well chambers is within 2 percent of the average of all ADCLs in the comparison.

A5.4.3 Calibration uncertainty. The ADCL component of uncertainty in the calibration of HDR well chambers shall not exceed 2 percent when expressed as an expanded uncertainty with a coverage factor k=2.

A5.5 Equipment and Facilities

A5.5.1 An ADCL shall have, in operable condition, at least the equipment designated in this section, dedicated to calibration laboratory use except as noted. Whenever possible, redundant items should be dissimilar, since dissimilar items are unlikely to change in the same way.

A5.5.2 At least one sealed source of a long half lived radionuclide(greater than 1 year), which is to be used to determine the constancy of the calibration device.

A5.5.3 An ADCL that calibrates chambers to be used *with* high activity sources shall have, or have access to, such a source.

A5.5.4 At least one device for measuring the intensity of the radiation emanating from the sources to be calibrated. This device may be a reentrant device or a device for measuring intensity at a distance. This device must be equipped with positioning devices which will allow sources to be repositioned so the measured signal is reproducible to within 0.5%.

A5.5.5 Redundancy device: Provisions must be made to provide redundancy in the transfer of the calibration from the calibrated source. This redundancy device may be an additional intensity measuring device (ionization chamber) or an additional radioactive reference source. The redundancy intensity measuring device must be completely independent of the principal device.

A5.5.6 A timing device and method which provides a precision of 0.1 second.

A5.5.7 The calibration position will be so located that scattered radiation will not introduce a measurement error inconsistent with uncertainty goals.

A5.7 Calibration Report

In addition to the requirements of Section 5.10 of the Criteria, the calibration report for ionization chambers shall include at least the following:

A5.7.1 The name and address of the

ADCL, A5.7.1 The report date and the

report number,

A5.7.2 The complete name and address of the person or institution submitting the instrument for calibration,

A5.7.3 The manufacturer, model and serial number of the chamber or system,

A5.7.4 The calibration date,

A5.7.5 T complete description of the source used for calibration including the radionuclide, manufacturer, model, encapsulation, serial number or lot, the air kerma rate at one meter and/or the activity on the date of chamber calibration,

A5.7.6 Indication of whether the chamber is sealed or open to the atmosphere,

A5.7.7 A description of the source support device and the axial location of source placement during calibration,

A5.7.8 A description of any special conditions (e.g. shield, etc.),
A5.7.9 The ion collection efficiency (if appropriate),

A5.7.10 The polarizing potential (if appropriate),

A5.7.11 The chamber leakage (if appropriate),

A5.7.12 A complete description of the calibration coefficient and its use,
A5.7.13 An indication of the expanded uncertainty of the calibration,
A5.7.14 Appropriate log references,

A5.7.15 The "best" expanded uncertainty with a coverage factor k=2 including the NIST uncertainty of the standard chamber used and

A5.7.15 Such other information as may be deemed appropriate.

A5.6 Revision History

August, 1992: Modified introduction, 1.1.1, 1.1.2, 1.2, and 3.8.1.1 and added 1.1.3 and 3.3.1.2.c to include HDR calibrations.

November, 1996: Revised for ISO 25

July, 1997: Revised Brachytherapy in appendix, revised section numbers.

November 1997: Revised to correct typographical errors.

July 30, 1998: Rev. 4A,
renumbered
Added Appendix for Guideline for Rejection

November, 1998
Added intro
Revised scope
Added references and definitions
Revised traceability
A5.3.9 revised wording
Renumbered A5.4.2 subparts
Added A5.5.15 uncertainty statement in calibration report

July 22, 1999,
Revised wording Section A5.5.15

Revision #8, July 2000:
Revised A5.3.9, added “current”
Revised A5.3.11, deleted “an” before ADCL.

Revision # 10, January 2002
Page100, revised title, replaced “for” with “of”, added “(HDR)”, deleted “iridium-192”, added “Brachytherapy”, deleted “brachytherapy sources and”, added “Calibrations”
Page100, A5.1-deleted “HDR Iridium 192 sources and”, deleted “calibrations”
Page100, A5.3-added “Gigabecquel(GBq) or” and deleted “or GBq”
Page101-103-revised section numbers A5.4, A5.5, A5.6, A5.7 Page 100-103-misc typographical corrections

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A6. CRITERIA for Accreditation of Electrometer Calibrations

by the
American Association of Physicists in Medicine

This appendix was prepared by a Task Group of the Subcommittee of the Radiation Therapy Committee of the AAPM consisting of the following persons:

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A6.1. Scope

This appendix is concerned with the accreditation of a laboratory (ADCL) for the calibration of electrometers for the purpose of radiation measurement. It is intended that the ADCL will determine a value of a multiplicative electrometer correction factor, $P_{elec.}$ The ADCL component of uncertainty will be no greater than the values given in Section A6.6.2. This includes a coverage factor of two, which defines an interval having a level of confidence of approximately 95 percent.

A6.2. Laboratory Traceability

The laboratory will have the ability to calibrate instruments for both charge and current modes, using devices that have a NIST traceable calibration coefficient maintained according to Section A4.5.7. In addition, digital voltmeters may be calibrated using NIST traceable voltage standards and time or frequency standards should also be available for calibration of electrometers in timed exposure modes.

A6.3. References

A6.3.1 Ibbott, G.S., Attix, F.H., Slowey, T.W., Fontenla, D.P., Rozenfeld, M.,"Uncertainty of calibrations at the accredited dosimetry calibration laboratories," Med. Phys. 24: #8, 1249-1254 (1997).

A6.3.2 Taylor, B.N., Kuyatt, C.E.,"Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results," , NIST Technical Note 1297, (1993)

A6.3.3 "Guide to the Expression of Uncertainty in Measurement," ISO/TAG 4/WG 3, (1992)

A6.4. Definitions

A6.4.1 CHARGE CALIBRATION COEFFICIENT: The factor P_{elec} converts the charge read by the electrometer to the true charge.

A6.4.2 CURRENT CALIBRATION COEFFICIENT: The factor Pe_{ec} converts the current read by the electrometer to the true current.

A6.4.3 VOLTAGE CALIBRATION COEFFICIENT: The factor PdcV converts the DC voltage read by the voltmeter to the true DC voltage.

A6.4.4 ADCL component of the uncertainty: that portion of the expanded combined uncertainty that arises solely at the ADCL. The component arising from the NIST calibration of the transfer standard is not included in this value.

A6.5. Equipment and Facilities

In addition to meeting the requirements of Section 5.10 of the Criteria, of which this is an Appendix, the candidate laboratory shall have and use the following:

A6.5.1 A means of delivering a known charge and current, e.g. a calibrated set of reference quality capacitors or resistors and a known voltage. There should be a redundant set of standards to provide adequate quality, for example, two sets of capacitors.

A6.5.2 A means of providing known voltages with accuracy and precision consistent with the quality assurance goals of the laboratory.

A6.5.4 (Optional) A means for confirming accuracy of electrometer exposure timing functions, with traceability to NIST frequency or period time standards.

A6.5.5 Stabilization of environmental conditions. Ambient conditions at the calibration position shall be stabilized and measured with a frequency such that variations are consistent with the overall goals for calibration uncertainty.

A6.5.6 Maintenance of Traceability. Calibration traceability to NIST standards shall be maintained by the laboratory through frequent comparisons of local laboratory standards or electrometers and by participation in the NIST Measurement Quality Assurance program. On years when the NIST program is not performed, the laboratory will participate in ADCL comparisons of electrometers. These mandated comparisons are described in the body of the Criteria of which this is an appendix. In addition, at least one of the standard reference capacitors, one of the voltage standards (e.g.. DMM, precision voltage supply, etc.) and other laboratory standards (e.g.. temperature, pressure, time, etc.) shall be calibrated at least biennially at another facility providing direct traceability to NIST with an appropriate level of uncertainty.

A6.6. Protocol

The protocol for laboratories carrying out these calibrations shall include the following:

A6.6.1 A statement of the scope of the laboratory work including a description of all tests performed such as leakage, scale linearity, etc.

A6.6.2. A statement of laboratory goals for calibration uncertainty. The uncertainty statement shall include two goals for uncertainty: 1. The ADCL component of the expanded uncertainty and 2. The expanded uncertainty. Both values will always have a coverage factor of 2, which defines an interval having a level of confidence of approximately 95 percent. The expanded uncertainty will include the ADCL uncertainties and all NIST uncertainties, both Type A and B of the whole chain. These laboratory goals must fall within the following limits: ADCL component of the expanded uncertainty must be within 0.3% for charge calibrations 0.4% for current calibrations and 0.1% for voltage calibrations.

A6.6.3 The information to be recorded for the calibration of a medical electrometer will include the following: date of measurements, institutions/users' name, the manufacturer, model and serial number, measure of charge collection polarities, name of person performing the calibration, readout linearity data (if applicable), all calculations leading to calibration coefficients, and any deviations from normal. Pre-measurement leakage (zero drift) and Post-measurement leakage (holding a charge) shall be stated. Any significant modifications to instrument performance shall be recorded. Any condition that represents a significant potential error during routine use shall be recorded.

A6.6.4 The calibration coefficients, PeQc for charge and Pelec for current, shall be expressed in terms of true Charge or Current per reading.

A6.6.5 The range for which the calibration coefficients $P_{elec,Q}$ and $P_{elect,I}$ are valid shall be stated.

A6.7. Calibration Report

The calibration report shall include, in succinct form, at least the following information:

A6.7.1 Information, such as name and address of the ADCL, report date, report number, laboratory notebook pages or location of electronic storage of original data, person or institution submitting the instrument for calibration, manufacturer, type and serial number of instruments calibrated

A6.7.2 Information on the electrometer. A list of the calibration coefficients with the appropriate scales. Also included will be a notation of the scale reading at which a correction or calibration coefficient applies, and all electrometer settings (if applicable). The magnitude and polarity of the polarizing potential shall be stated including the connector geometry. The polarity of the input signal used for calibration and readout polarities shall also be stated.

A6.7.3 A statement of the overall expanded uncertainty shall be included.
A6.7.4 Any significant modifications to instrument performance shall be included.

A6.7.5 Any condition that represents a significant potential error during routine use shall be included.

A6.8 History of Document

November 28, 1999, Formation of Task Group
February 22, 2000, First Draft prepared May 24,
2000, Revised First Draft distributed July 14,
2000, Second Draft distributed August 16, 2000,
Final Draft distributed September 22, 2000,
Final to Task Group
September 29, 2000, Final to Geoffrey Ibbott for Subcommittee

Revision #10, January 2002

Page106, revised title, deeted “the”, added “Accreditation”, deleted “Calibrations”
Page106, A6.1-deleted “the relative expanded”
Page106, A6.3-reorganized references
Page107, deleted A6.4.4, A6.4.5, renumbered A6.4.4, A6.5.4-added “or period time”
Page109, A6.7.1-replaced “magnetic or optical” with “electronic”, A6.7.2-“including the connector geometry”

A7. CRITERIA for Accreditation of Intravascular Brachytherapy (IVBT) Well-type Chamber Calibrations

by the
American Association of Physicists in Medicine

This appendix provides the minimum requirements for accreditation for the calibration of well type chambers used for the measurement of intravascular brachytherapy sources. The following technical requirements are in addition to those contained in the body of these Criteria

A7.1 Scope

This document is concerned with calibration laboratories being accredited by the American Association of Physicists in Medicine (AAPM) to provide intravascular brachytherapy well-type chamber calibrations directly traceable to the National Institute of Standards and Technology (NIST).

A7.2 References

A7.2.1 "Intravascular brachytherapy physics: Report of the AAPM Radiation Therapy Committee Task Group No. 60", Nath, R., et al, Med. Phys. 26, (2), 119-152, 1999

A7.3 Definitions

A7.3.1 Short half lived source: half lives less than one year.

A7.3.2 Intravascular Brachytherapy (IVBT): For the purposes of these Criteria, IVBT is the treatment of the wall of a blood vessel with a beta or gamma emitting source for the purpose of reducing the rate of re-stenosis of the vessel after PTCA (balloon angioplasty).

A7.3.3 IVBT source: A beta or gamma emitting source used for IVBT characterized by a small diameter, used over an extended active length (>20mm) or remotely controllable position and physically attached to a catheter, wire or other device to position the source within the active target region of the vessel wall.

A7.3.4 Intravascular well type chamber: a typical well type chamber with an appropriate length uniform sensitive area and appropriate linear holders for long train sources

A7.4 Traceability of calibrations

A7.4.1 Standard Source Traceability: The ADCL shall obtain traceability for all reference standards directly from NIST.

A7.4.2 NIST MQA Performance: The required performance on the NIST measurement quality assurance proficiency test for well type ionization chambers is 3 percent for photon emitting intravascular brachytherapy sources. For beta emitting IVB sources, the criteria is 6 percent.

A7.4.3 ADCL comparison Performance: The required ADCL uncertainty performance on the ADCL comparison of well-type chambers are the same as in section A7.4.2.

A7.4.4 An ADCL shall calibrate well type ionization chambers using with sources of the same radionuclide, manufacturer, model and encapsulation that have been calibrated by NIST, in conformity with the specifications of this CRITERIA.

A7.5 Equipment and Facilities

A7.5.1 An ADCL shall have, in operable condition, at least the equipment designated in this section, dedicated to calibration laboratory use except as noted. Whenever possible, redundant items should be dissimilar, since dissimilar items are unlikely to change in the same way.

A7.5.2 For chamber calibrations the laboratory shall have at least one sealed source of each radionuclide, manufacturer, model and encapsulation for which calibration will be offered. This source shall have an activity within the range of activities for which routine clinical calibrations will be offered. This source should have physical dimensions and cladding comparable to the sources routinely calibrated. This source shall have direct traceability to NIST.

A7.5.3 For IVBT source geometries, the laboratory shall have at least one working standard sealed source of each manufacturer and type offered for calibration which has been calibrated locally in the calibration device and a long half-life radionuclide which is to be used to determine the constancy of the calibration device as detailed in Section A7.3.5.

A7.5.4 At least one device for measuring the intensity of the radiation emanating from the sources to be calibrated. This device shall be a reentrant well-type ionization chamber, The well type standard chamber must be equipped with positioning assemblies which will allow sources to be measured in multiple repetitions with signal reproducibility of +/- 2 % (one standard deviation). Additional test equipment such as film blocks or linear diode arrays may be used to further evaluate the source parameters, but may not be substituted for the 4 π geometry of the standard well chamber in the NIST traceability chain of custody.

A7.5.5 Redundancy device: Provisions must be made to provide redundancy in the transfer calibration from the working standard source. This redundancy device may be an additional intensity measuring device (ionization chamber) or

an additional radioactive reference source. The redundancy intensity measuring device must be completely independent of the principal device such that the two would not be expected to malfunction in the same way simultaneously. A redundant source must be a different, preferably long-lived radionuclide.

A7.5.6 A timing device which provides a precision of 0.1 second, and is traceable to NIST frequency or period standards.

A7.5.7 The calibration position will be so located that scattered radiation will not introduce a measurement error inconsistent with calibration uncertainty goals.

A7.5.8 Ambient conditions at the calibration position shall be stabilized or measured with a frequency such that variations are consistent with the calibration uncertainty goals.

A7.5.9 Calibration of laboratory standards and comparison of measurement equipment.

A7.5.9.1 The laboratory standard equipment should be compared frequently in accordance with the laboratory protocol.

A7.5.9.2 Calibration traceability to NIST dosimetry standards shall be maintained by participating periodically in NIST measurement quality assurance tests. When possible the period should be annually.

A7.5.10. When possible, the laboratory shall establish whether a well chamber communicates with the atmosphere. Some well chambers have communication openings which may be checked with appropriate tools. Others require the use of a device for testing atmospheric communication which the laboratory shall have available.

A7.6 Protocol

A7.6.1 Prior to acceptance of a well-type chamber for calibration, the ADCL must insure that the chamber design (flat axial response for example), and the source positioning apparatus will allow calibration to be performed for the desired source / source train to within the laboratory uncertainty goals. This criteria must be applied on a case by case basis, with special consideration for calibration of beta emitting IVB sources. Calibrations will be performed only for axial / linear source inserts.

A7.6.2 The ADCL shall state in the protocol the estimated laboratory component of uncertainty which is the expanded uncertainty with a coverage factor k=2 and does not include the NIST uncertainty for the standard.

A7.6.3 The procedures for calibration and data recording, as specified in the laboratory protocol, should be formulated so as to reveal changes in the performance of any laboratory equipment on which calibration depends, through the comparison of redundant Systems.

A7.6.4 Well-Type Ionization Chamber Calibration Records: The data to be recorded for calibration of ionization chambers shall include but need not be limited to the following:

A7.6.4.1 The chamber manufacturer, model and serial number,

A7.6.4.2 A complete description of each standard source used for the calibration including the manufacturer, model, serial/lot number, radionuclide, encapsulation, active length, physical dimensions, the air kerma strength (or dose to water at 2mm for beta emitting sources) and/or the apparent activity on the date of calibration,

A7.6.4.3 A description of the source holder or device used to support the source,

A7.6.4.4 The orientation of the source and the distance from the chamber top or bottom,

A7.6.4.5 The method or instrumentation used to determine the exposure timing, the date and time of the calibration,

A7.6.4.6 The temperature, pressure and relative humidity at the time of calibration,

A7.6.4.7 The results of the atmospheric communication test,

A7.6.4.8 The system leakage (if appropriate),

A7.4.4.9 Ion collection efficiency (if possible) and

A7.6.4.10 Reproducibility tests on the support device.

A7.6.4.11 For beta-emitting IVBT sources, a description of the wall material and thickness of the source support used in the chamber.

A7.7 Calibration Report

A7.7.1 The calibration coefficient for the well type ionization chamber for the photon emitting sources shall be expressed in terms of air kerma rate at 1 meter from the source with units of $((\mu Gy \cdot m^2)h^{-1})/A$ measured in a plane which is the perpendicular bisector of the long axis of the source. For beta-emitting sources or wires, the contained activity and/or the average absorbed dose to water at a depth of 2mm may be reported depending on the source of NIST traceability for that particular source model. At the discretion of the ADCL, additional calibration coefficients may be reported in other convenient units.

A7.7.2 The calibration report for well-type ionization chambers shall include at least the following:

A7.7.2.1 The name and address of the ADCL, A7.7.2.2 The report date and report number,

A7.7.2.3 The complete name and address of the person and/or institution submitting the instrument for calibration,

A7.7.2.4 The manufacturer, model and serial number of the ionization chamber or system,

A7.7.2.5 The calibration date,

A7.7.2.6 A complete description of the standard source used for calibration including the radionuclide, manufacturer, model, encapsulation, active length, serial number or lot number, the air kerma strength, absorbed dose to water or the activity on the date of chamber calibration with the associated uncertainties, and an indication of whether the chamber is sealed or open to the atmosphere,

A7.7.2.8 A detailed description of the source holder or support device and geometry,

A7.7.2.9 A description of any special conditions (e.g. shield, etc.),

A7.7.2.10 The ion collection efficiency (if possible), the polarizing potential (if available for measurement),

A7.7.2.11 The system pre-irradiation leakage or background current (if appropriate),

A7.7.2.12 A complete description of the calibration coefficient and its use, A7.7.2.13 An indication of the uncertainty of the calibration, A7.7.2.14 Appropriate log references and

A7.7.2.15 Such other information as may be deemed appropriate.

A7.7.3 Reported uncertainty: The ADCL shall state in the calibration report the "best" combined expanded uncertainty (with a coverage factor k=2) which includes the NIST uncertainty of the standard source used in the calibration.

A7.8 Revision History

Revision # 9, July 1, 2001
Title, added INTRAVASCULAR
Revised A2.3 Definitions, added IVBT & IVBT sources Revised

A2.4.2, added uncertainty for IVBT
Revised A2.3.3, added IVBT performance
Revised A2.5.2, “direct traceability to NIST”
Revised A2.5.3, added “or IVBT”
Revised A2.5.4, added “(when possible)”
Added A2.6.3.9 & 10, IVBT requirements
Added A2.7.1.4, IVBT
Revised A2.7.2, “when possible” & corrected air kerma units
Revised A2.7.3.6, “active length (and uniformity for IVBT sources)”
Title, replaced “for” with “of”, added “INTERSTITIAL”, added “CALIBRATION”

Appendix B: GUIDELINES FOR UNCERTAINTY ASSESSMENT

ESTIMATION OF UNCERTAINTY AT THE AAPM-ACCREDITED DOSIMETRY CALIBRATION LABORATORIES, Draft No. 3, December 18, 1989

Uncertainty Committee:

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Presented in part at the annual meeting of the American Association of Physicists in Medicine, July 21-25, 1991, San Francisco, CA. The authors were members of an ad-hoc group formed at the request of the Task Group-3 of the Radiation Therapy Committee. This is not an official report of the AAPM.

I. INTRODUCTION

AAPM Task Group 3 oversees the operation of the ADCLs, and makes recommendations concerning accreditation. The Task Group believes that there should be uniformity in the assessment, evaluation, and reporting of the uncertainty in the ion-chamber calibrations provided by the ADCLs. To accomplish this, each lab should undertake to systematically estimate each of the contributions to calibration uncertainty. These should be combined into a single figure or group of figures representing the uncertainty for each class of instrument calibrated (or each range of beam qualities used). These estimates of uncertainty may be instructive to the labs, and should indicate the influence on calibration uncertainty introduced by procedures or instrumentation. The estimates determined at individual labs would not be publicized, although large differences would likely stimulate further investigation. Instead, provided comparable results are obtained, a single figure or group of figures might be chosen as representing the upper bound of uncertainty among the labs.

The approach to be used is described below. It is adopted from a procedure recommended by NIST (in concert with BIPM in Paris), and described in the NIST Publication “NIST Measurement Services: Calibration of x-ray and Gamma-Ray Measuring Instruments”, March 1988. Further information on uncertainty assessment techniques can be found in NIST Technical Note 1297: Guidelines for Uncertainty Assessment *(please confirm reference).*

II. PROCEDURE

Uncertainties are of two types - Type A are random uncertainties derived 2-sigma

standard deviations of the mean of quantities that are repeatedly measured (i.e., Eq.1.4b in Attix text), while Type B are best estimates of the uncertainties in the other parameters that influence the calibration. (Type A uncertainty is called “precision” or “reproducibility” while Type B is often called “accuracy” or “bias”). Both types are to be expressed as percentage standard deviations (i.e. at the 67% confidence level, or1-sigma). This is straightforward and objective for Type A. For Type B, however, the experience and judgment of the laboratory personnel come into play. A consistent method for evaluating Type B certainties is to estimate their maximum value (which corresponds approximately to 3 sigma, or 99% confidence level) and divide by 3 to get the 1-sigma value.

Type A and Type B uncertainties are each combined by taking the quadratic sum - the square-root of the sum of their squares.

The two resulting figures are then combined by the same method to obtain the 1-sigma percentage uncertainty for A and B types together. This result is doubled to yield the expanded uncertainty of the measurement, that is, its percentage uncertainty at the 2-sigma or 95% confidence level (coverage factor k=2). TG-3 (Subcommittee) proposes that the laboratories report this figure to the Subcommittee on Uncertainty.

Note that in this approach the Type B uncertainties are treated as if they were just as random as the Type A, whether they are or not. This simplifying assumption is at the core of the BIPM-NIST recommendation, and is based on the idea that the Type B uncertainties may influence the calibration in either the positive or negative direction. There is certainly room for philosophical argument about this, but we recommend its acceptance by the ADCLs for consistency with NIST.

Consider next the specific application of this approach to the calibration of ion chambers by the ADCLs. This is done in two steps: First the gamma or x-ray beam at the ADCL is calibrated by means of a NIST-calibration ion chamber, and then the customer’s ion chamber is calibrated in that beam. The foregoing analysis of uncertainties should be applied separately to each of these two operations, paying attention, however, to possible correlation that may reduce or eliminate the Type B uncertainty of a given parameter in both operations. The following two tables list the parameters that control the expanded uncertainties in establishing the exposure (or air kerma) rate and in calibrating the customer’s chamber, respectively:

TABLE I - Uncertainty Analysis of Exposure (or Air Kerma) Rate at an ADCL

1. NIST Calibration of N_x or N_k:
   Type A and Type B uncertainties combined have an expanded uncertainty of 1.0%, or 0.5% at the 1-sigma level.
2. Charge:
   Type A: Derived. from repeated measurements.
   Type B: Derived from electrical calibrations of each electrometer scale. (Note that if the same electrometer and scale are used for calibrating the beam and the customer’s chamber, this uncertainty = 0.)
3. Timing:
   Type A: Ordinarily = 0, since effect of fluctuations appears as charge variation.
   Type B: Depends on irradiation time duration, and calibration of timer. Goes

to zero if the beam and the customer's chamber are both calibrated with the same timer and irradiation time duration. (Shutter error must be measured and corrected for.)

4. Air Density:

   Type A: Depends on the variability of the temperature and pressure as measured during the calibration procedure. A start-to-finish density change greater than some limiting value (say, 0.1%) should call for repeating the calibration. Humidity variations are not taken into account as noted below

   Type B: Depends on calibration uncertainties of the barometer and thermometer. These must be located close enough to the ion chamber to represent conditions in it. Humidity is to be ignored, assuming, it is 50% RH +/-25%, thus simulating the NIST conditions under which the ion chamber calibration applies.

5. Ionic Recombination:

   Type A: Assume = 0 .

   Type B: Assume = 0 if chamber voltage and polarity are the same as used in the NIST calibration of N_x or N_k, and if beam intensity is the same.

6. Distance from Source:

   Type A: Assume = 0.

   Type B: Uncertainty depends on the distance from the source to the desired point on the beam axis, and on an estimate of how close to it the chamber ' s mid-point will be positioned by the technique used.

7. Beam Cross-sectional Uniformity:

   Type A: Assume = 0.

   Type. B: Based on scanning a small volume detector across the beam. Observed variations of the exposure rate within the area occupied by the standard chamber in its calibration position permits estimation of the resulting uncertainty. In this case, however, it would be preferable to use

UNCERTAINTY ESTIMATION

Table I: Exposure or Air Kerma Rate Calibration

	Type A	Type B
1. Charge		
2. Timing		
3. Air Density		
4. Ionic Recombination		
5. Distance from Source	0% ----------	
6. Beam Uniformity	0% ----------	
(Quadratic Sum)		
(Quadratic Sum)		
7. NIST Calibration		
(Quadratic Sum)		
Expanded Uncertainty		

Table II: Calibration of ION Chamber

	Type A	Type B
1. Charge or Scale Reading		
2. Timing	0% ----------	
3. Air Density		
4. Ionic Recombination	N.A.----------	
5. Distance from Source	0% ----------	
6. Beam Uniformity	0% ----------	
(Quadratic Sum)		
(Quadratic Sum)		
7. Exposure (Air Kerma) Rate		
(Quadratic Sum)		
Expanded Uncertainty		

Revision #8, July 2000

Added “III. Revision History”

Revised “II Procedure”, paragraph 1, sentence 3, replaced “8” with “%” and “ - 16” in “(i.e. at the 67% confidence level – 1 6)”

Revised “II Procedure”, paragraph 6, “TABEL I” typos

Appendix C: Guidelines for Rejection of Instruments

by the
American Association of Physicists in Medicine

This appendix was prepared by a Task Group of the Subcommittee of the Radiation Therapy Committee of the AAPM consisting of the following persons:

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C1. Aims & Scope

This appendix presents guidance for rejection of instruments and brachytherapy sources from the calibration process of the AAPM Accredited Dosimetry Calibration Laboratories (ADCLs). These Guidelines are not intended to limit the judgement of an ADCL but to provide consistent criteria in support of rejection of instruments and brachytherapy sources from the calibration process. The criteria are based upon accuracy, consistency, and other aspects of performance. The criteria apply to therapy and diagnostic instrumentation systems and brachytherapy sources.

C2. References

Reserved

C3. Definitions

C3.1 CALIBRATED RANGE: The lowest to highest values, for a given polarity, displayed on an electrometer and for which the electrometer is to be calibrated. For example, a request may be made for calibration for collection of negative charge over the CALIBRATED RANGE of 0.1 nC to 20 nC.

C4. General Criteria

There are two major causes of malfunction that may result in rejection of an instrument.

1. Mechanical problems: generally determined by visual inspection. Examples include inadequate chamber waterproofing, broken thimbles, and loose stem.
2. Electrical problems: generally determined by poor operational behavior of instrument. Examples include excessive leakage and excessive stabilization time.

C5. Electrometer Calibration Rejection:

C5.1 Measurements:

All measurements for digital instruments should be based upon the readings of the front panel of the electrometer, unless the user specifically requests otherwise. On certain electrometers, readings from external back panel connectors can differ by 1% or more from the front panel. With auto ranging electrometers, calibrations should be performed within the CALIBRATED RANGE requested by the user or an available clinically relevant CALIBRATED RANGE with the concurrence of the user.

C5.2 Non-signal Criteria such as Leakage:

If the background signal is greater than 0.1% of half the indicated CALIBRATED RANGE for the rate mode and 0.1 % per minute of half the indicated CALIBRATED RANGE for the charge mode, the electrometer may be subject to rejection.

C5.3 Linearity of Electrometers:

The ratio of the electrometer output reading to known value of input is to be constant to within 0.5 % over the central two-thirds of the CALIBRATED RANGE. If not, the electrometer may be subject to rejection.

C5.4 Digit Fluctuation of Electrometer Scale:

When the fluctuation of the reading on the electrometer exceeds the greater of 0.1% of the signal or one least significant digit, the electrometer may be subject to rejection.

C6 Ionization Chambers:

C6.1 Therapy External Beam Ionization Chambers:

If the calibration coefficient differs from past or expected values by more than 1.0% for gamma ray calibrations or 2.0% for x-ray calibrations, the cause should be investigated and the chamber may be subject to rejection. If the collection efficiency of the ionization chamber under calibration conditions is less than 99%, the chamber may be subject to rejection. If the leakage of the chamber exceeds 0.1% of the signal, a warning should be issued and if it exceeds 1.0%, the chamber may be subject to rejection.

C6.2 Brachytherapy Well Chambers

If the calibration coefficient differs from past or expected values by more than 3.0%, the cause should be investigated and the chamber may be subject to rejection. If the collection efficiency of the ionization chamber is less than 99%, the chamber may be subject to rejection. If the leakage of the chamber exceeds 0.5% of the signal, a warning should be issued and if it exceeds 2.0%, the chamber may be subject to rejection. For intravascular well type chambers, the axial response of the active volume must be

uniform to within +/-3% over the entire length of the source train or wire. Well chambers without adequate source holders or support devices are immediately subject to rejection.

C6.3 Diagnostic Ionization Chambers

If the calibration coefficient differs from past or expected values by more than 3.0%, the cause should be investigated and the chamber may be subject to rejection. If the leakage of the chamber exceeds 0.5% of the signal, a warning should be issued and if it exceeds 2.0%, the chamber may be subject to rejection.

C6.4 Air Communication Test of Ionization Chambers

If an air vented ionization chamber does not equilibrate with ambient pressure in one minute, it may be subject to rejection. If the chamber is designed to be sealed or pressurized and it vents to the atmosphere, it should be rejected.

C7. Brachytherapy Sources

If the source has removable radioactive contamination above accepted limits it may be subject to rejection.

If the source strength differs from expected values by more than 5.0%, the source may be subject to rejection. Measurements should include the orientation of the source in both vertical positions.

C8. Notification

The reasons for rejection of an instrument or brachytherapy source should be communicated to the user in a timely fashion.

C9. Revision History

September 28, 1999: Added to Criteria
Prior Document history:

Draft 1 Initial draft
Draft 2 Revision of draft for discussion at RSNA 11/97
Draft 3 Major revision of draft for format and discussion at AAPM 8/98
Draft 4 Revision for discussion at RSNA 11/98
Draft 5 Complete revision for discussion at AAPM 7/99
Draft 6 Revision for final draft discussion at AAPM 7/99- Approval to move to Subcommittee
Draft 7 Final draft before being sent to Subcommittee
Final 8 Sent to Subcommittee

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Appendix D: ACCREDITATION CERTIFICATE

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Appendix F: Procedure for Archiving Signed Reports in Electronic Format

Purpose:
In accordance with AAPM and ISO 17025 requirements, calibration reports must be archived in a secure manner, which is readily accessible. Meeting this requirement is becoming a greater challenge as appropriate storage for paper reports becomes limited. This procedure details the method for electronic storage of signed calibration reports.

Report Storage and Archive:

1. Hard copy (original) reports will be signed and sent to physicist. This original report will be scanned and then stored to a data storage device. Archived reports will be stored such that editing of the archived pdf files will not be allowed. This feature would be set as a password-protected property of the file. Printing of the reports would only be permitted.

2. Report Storage
    a. Reports would be stored on a File Server (FS) in the current Fiscal Year directory. (FY2004, FY2005….). The report ***date*** determines the period in which the report is stored (***x:\Archive 2005\Q1\reported.pdf***).
    b. The file server will be backed up (using standard backup capabilities) on a daily basis.
    c. A monthly or quarterly backup of current reports using optical storage (e.g. CD) would be done. The CD will be dated and stored in a fire-safe located in the laboratory.

3. Archiving
    a. Reports are archived using optical storage (DVD or other nonvolatile device or media). According to the Council on Library and Information Resources and NIST (http://www.clir.org/pubs/reports/pub121/contents.html), the estimated longevity of a DVD stored at 25C and 50% RH is 30 years.
    b. Reports are archived in both incremental and annual fashion.
        i. Quarterly Backup (QB) – Reports generated during any given quarter are backed up. Two copies are generated. A sample (5 – 10) of the scanned reports is reviewed to insure that the images of the reports are intact.
        ii. Complete Annual Archive (CAA) – Two copies of the entire library of stored report images are copied to storage medium (DVD, or other nonmagnetic medium). At least 10 of the archived reports are checked to verify integrity.
        iii. One copy each of the Quarterly Backup and the Complete Annual Archive for the past calendar year is kept on site in a fireproof box. The second copy of each plus the new complete Annual Archive is kept off site in a secure controlled environment facility. (e.g. a safe deposit box in a commercial bank). Quarterly Backups will be kept until the Annual Archive for the most recent complete calendar year is created. The Quarterly Backups for that year can then be destroyed if desired.

c. Old reports would be archived by year over a time period as the laboratory has time.

Hardware to accomplish storage:

1. An automatic feed scanner capable of storing the scanned documents to a separate data storage device as an Adobe Portable Document Format (.pdf) file.
2. A file server (FS) (e.g. Windows-based) for storage of report files.
3. A system utilizing removable data storage medium for backup of report files.
4. Personal Computers capable of archiving report files to an optical storage media
5. A secure off-site storage facility that does not have environmental extremes.