



ACCREDITATION CRITERIA FOR CALIBRATION LABORATORIES

Fifth Edition

May 2010

Published by
Conference of Radiation Control Program Directors, Inc.
www.crcpd.org

[This page is intentionally blank.]

ACCREDITATION CRITERIA FOR CALIBRATION LABORATORIES

Fifth Edition

**Developed by CRCPD's
Committee on Ionizing Measurements (G-2)**

Donald Parry
Chairperson, Michigan
Lynn Albin (Washington)
Charles Ditmer (South Carolina)
Robert Lommler (Illinois)

May 2010

Published by
Conference of Radiation Control Program Directors, Inc.
1030 Burlington Lane, Suite 4B
Frankfort, Kentucky 40601
www.crcpd.org

CRCPD: A Partnership Dedicated to Radiation Protection

CRCPD's mission:

- ▶ **to promote consistency in addressing and resolving radiation protection issues,**
- ▶ **to encourage high standards of quality in radiation protection programs,**
- ▶ **and to provide leadership in radiation safety and education.**

This publication was supported in part by grant number FD-U-000005 from the Food and Drug Administration.

The information contained in this document is for guidance. The implementation and use of the information and recommendations contained in this document are at the discretion of the user. The implications from the use of this document are solely the responsibility of the user.

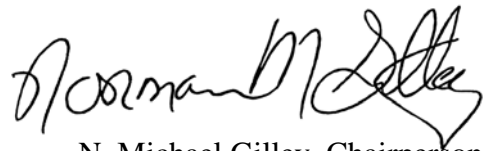
This document has been developed by a working group of the Conference of Radiation Control Program Directors, Inc. (CRCPD) and accepted by the Board of Directors for publication. The contents contained herein, however, may not necessarily represent the views of the entire membership of the CRCPD or any federal agency supporting the work contained in this document. The mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by the CRCPD or any federal agency.

FOREWORD

The Conference of Radiation Control Program Directors, Inc. (CRCPD) is an organization made up of the radiation control programs in each of the 50 states, the District of Columbia, and Puerto Rico, and of individuals, regardless of employer affiliation, with an interest in radiation protection. CRCPD was formed in 1968.

CRCPD's mission is "to promote consistency in addressing and resolving radiation protection issues, to encourage high standards of quality in radiation protection programs, and to provide leadership in radiation safety and education." The primary purpose and goal of CRCPD is to assist its members in their efforts to protect the public, radiation worker, and patient from unnecessary radiation exposure. CRCPD also provides a forum for centralized communication on radiation protection matters between the states and the federal government, and between the individual states.

One method of providing assistance to the states, as well as to other interested parties, is through technical and administrative publications. Most technical publications of CRCPD are written by various committees, task forces or special working groups. Most administrative publications are written by staff of the Office of Executive Director (OED).



N. Michael Gilley, Chairperson
Conference of Radiation Control
Program Directors, Inc.

[This page is intentionally blank.]

PREFACE

This publication, *Accreditation Criteria for Calibration Laboratories, Fifth Edition*, describes the principles and processes under which CRCPD accredits laboratories that calibrate instruments used for measurement of ionizing radiation. Such laboratories are operated by state radiation control programs, state universities, or other agencies. Their function is calibration of instruments used by state and local radiation control programs to determine compliance with regulations or guidelines that limit exposure of the public to ionizing radiation.

This document was developed for the CRCPD by the Committee on Ionizing Measurements (G-2). CRCPD's accreditation of calibration laboratories began in 1984.

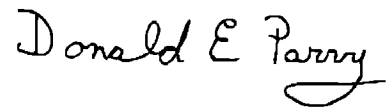
The Board of Directors initially adopted this criteria document July 2, 1997 (CRCPD Publication 99-4). The first revised criteria document, *Accreditation Criteria for Calibration Laboratories, Revised Edition*, was published January 2001 (CRCPD Publication 01-2). In that document, the section on x-ray calibration of diagnostic and survey instruments was totally replaced. Additional criteria were added to this section to add accreditation criteria for molybdenum-anode x-ray beams. These beams are used to calibrate instruments used to inspect mammography x-ray machines. The *Revised Edition* replaced the previously published CRCPD Publication 99-4.

The *Third Edition* (CRCPD Publication E-03-3) contained modifications under Renewal, Accreditation Decision and Notification, the X-ray Beam Quality Parameters table, Radiation Quality, and Accuracy. The *Third Edition* replaced CRCPD Publication 01-2.

This *Fourth Edition* (CRCPD Publication E-07-5) contained only one change from the Third Edition. On page 15, under CALIBRATION REPORT, the sentence that read "At least one calibration point should be included for each range of the instrument, where applicable" was revised to read "One calibration point and a linearity check should be included for each range of the instrument, where possible." The *Fourth Edition* replaced CRCPD Publication E-03-3.

The *Fifth Edition* (CRCPD Publication E-10-3) allows laboratories to use lab intercomparison tests as part of their program to document traceability to NIST when applying for accreditation. If the laboratory has participated in an intercomparison and hasn't participated in a NIST MQA test yet, the modified criteria allows CRCPD to accredit the laboratory, but requires the laboratory to participate in a NIST MQA test within one year of approval by CRCPD.

The changes bring CRCPD accreditation criteria in line with other accrediting bodies and reduce the initial cost for applying for accreditation. The *Fifth Edition* replaces CRCPD Publication E-07-05.

A handwritten signature in black ink that reads "Donald E. Parry". The signature is written in a cursive style with a large, looping 'P' at the end.

Don Parry, Chairperson
Committee on Ionizing Measurements

CONTENTS

Foreword	iii
Preface	v
Abstract	ix
General Criteria	1
Introduction.....	1
Scope of Accreditation.....	1
Definition of Accreditation.....	1
Operational Information and Requirements.....	2
Accreditation.....	2
Renewal.....	2
Additions to Scope of Accreditation.....	2
Termination.....	2
Revocation.....	2
Notice of Change.....	3
The Accreditation Process.....	3
Application for Accreditation.....	3
Basic Conditions for Accreditation.....	4
On-site Assessment.....	4
Monitoring Visits.....	4
Laboratory Intercomparisons and Proficiency Testing.....	5
Technical Evaluation.....	5
Accreditation Decision and Notification.....	6
Suspension.....	6
Revocation.....	6
Technical Requirements.....	6
Scope of the Program.....	6
Quality Systems.....	7
Documentation.....	7
Organizational Structure and Staff.....	7
Laboratory director.....	7
Technical staff.....	8
Quality assurance.....	8
Staff training.....	8
Staff competency.....	8
Facilities and Equipment.....	8
Effect of external conditions.....	8
Equipment changes.....	9
Laboratory Equipment Calibration.....	9
Records.....	9
Calibration Reports.....	10
Proficiency Testing.....	11

Uncertainty Analysis.....	11
On-Site Assessment	12
Gamma-ray Calibration of Survey Instruments.....	13
Introduction.....	13
Sources of Gamma Radiation	13
Radiation Control.....	13
Shielding	13
Beam Collimation	14
Source Exposure	14
Exposure Control	14
Equipment	14
Characterization of the Radiation Field	15
Exposure Rate (Air Kerma Rate).....	15
Scattered Radiation	15
Use of Attenuators	15
Accuracy	15
Calibration Report.....	15
X-ray Calibration of Diagnostic and Survey Instruments	16
Introduction.....	16
Source of X-rays	16
Control of the Radiation Beam	17
Radiation Production	17
Beam Collimation	17
Exposure Control	17
Equipment	17
Characterization of the Radiation Field	18
Exposure Rate	18
Scattered Radiation	18
Radiation Quality	18
Accuracy	18
Calibration Report.....	18
Index.....	20

TABLES

Table 1. Gamma Radiation Sources.....	13
Table 2. X-ray Beam Quality Parameters	16

ABSTRACT

Conference of Radiation Control Program Directors, Inc.'s Committee on Ionizing Measurements (G-2), *Accreditation Criteria for Calibration Laboratories, Fifth Edition*, CRCPD Publication E-10-3 (May 2010) (22pp). This document supersedes CRCPD Publication E-07-5.

This criteria document describes the principles and processes under which CRCPD accredits laboratories that calibrate instruments used for measurement of ionizing radiation. Such laboratories are operated by state radiation control programs, state universities, or other agencies. Their function is calibration of instruments used by state and local radiation control programs to determine compliance with regulations or guidelines that limit exposure of the public to ionizing radiation.

[This page is intentionally blank.]

ACCREDITATION CRITERIA FOR CALIBRATION LABORATORIES

GENERAL CRITERIA

INTRODUCTION

This document describes the principles and processes under which the Conference of Radiation Control Program Directors, Inc. (CRCPD) accredits laboratories that calibrate instruments used for measurement of ionizing radiation. Such laboratories are operated by state radiation control programs, state universities, or other agencies. Their function is calibration of instruments used by state and local radiation control programs to determine compliance with regulations or guidelines that limit exposure of the public to ionizing radiation.

SCOPE OF ACCREDITATION

A laboratory may be accredited to calibrate instruments over a range of ionizing radiation types, energies, and intensities. An individual laboratory is accredited for a particular set of radiation types, energies, and intensities, as requested by the laboratory and specified in its Scope of Accreditation.

DEFINITION OF ACCREDITATION

Accreditation is a formal recognition of a laboratory's competence. This means that all of the necessary elements are present at a laboratory for carrying out the calibration functions for which accreditation is granted, in terms of staff, equipment, procedures, quality control, and all of the other items covered by these criteria. Accreditation does not guarantee that a laboratory's services are or always will be provided within the level of uncertainty it has claimed and for which the laboratory is accredited. The CRCPD does not monitor the daily operations of an accredited laboratory, and therefore is not responsible for the quality of the work performed.

Accreditation provides verification that a laboratory's measurement process is under statistical control and produces results that are consistent with the national physical standards maintained by the National Institute of Standards and Technology (NIST). This consistency is demonstrated by participation in measurement quality assurance (MQA) services provided periodically by NIST. Participation in MQA services is required for accreditation under the criteria. The extent of participation depends on the scope of calibrations for which the laboratory desires accreditation.

The process of evaluation described in this document has the purpose of determining and recognizing the soundness of a laboratory's calibration procedures and performance. A laboratory is expected to follow scrupulously the procedures demonstrated during evaluation for

every type of calibration for which accreditation is granted, and must recognize that failure to do so during routine operations may be cause for the revocation of accreditation.

OPERATIONAL INFORMATION AND REQUIREMENTS

Accreditation

Accreditation is granted for a specified period, usually one year. Based on the recommendation of the assessment team, a decision will be made by the CRCPD Board of Directors to grant or deny initial accreditation for an applicant laboratory or renewal of a currently accredited laboratory. The laboratory will be notified of the decision by letter from the Executive Director of the CRCPD. If accreditation is denied, the notification will state the reason.

Renewal

Renewal of accreditation will be issued annually, assuming that a proficiency test has been successfully completed at some point in the preceding twelve months, the laboratory has paid its accreditation fee during the previous billing cycle, and any on-site visit was satisfactory. Renewal dates may be reassigned to provide benefits to the laboratory and/or CRCPD. If the CRCPD Board of Directors changes the renewal date, the laboratory will be notified in writing of the change and any related adjustment of fees.

Additions to Scope of Accreditation

During the accreditation period, a laboratory may request the addition of test methods or services to its Scope of Accreditation. The laboratory must meet all the criteria for the additional test methods or services. The need for an additional on-site assessment will be determined on a case-by-case basis.

Termination

An accredited laboratory may voluntarily terminate its accreditation at any time. Likewise, an applicant laboratory may voluntarily withdraw its request at any time prior to the completion of action on the request.

Revocation

If the CRCPD Board of Directors finds that an accredited laboratory has violated the basic conditions for accreditation, the Executive Director may, after consultation with the laboratory, notify the laboratory that revocation of its accreditation is proposed. The laboratory will have 30 days in which to appeal a proposed revocation by requesting a hearing before the CRCPD Board

of Directors. A proposed revocation will specify to whom a request for a hearing should be sent. If a hearing is not requested, the revocation becomes final.

Notice of Change

A laboratory shall inform the CRCPD within 30 days:

- Of any major changes involving the location, ownership, management structure, critical personnel, or facilities;
- If it wishes to delete an accredited capability from the scope of accreditation; or
- If it is no longer capable of performing an accredited service.

Failure to notify the CRCPD of any of these items may result in revocation of the laboratory's accreditation.

THE ACCREDITATION PROCESS

Accreditation will be granted upon successful completion of the following process: submission of a request by the laboratory; evaluation of the laboratory's resources and procedures, including an on-site assessment; proficiency testing of the laboratory's performance through MQA services; resolution of deficiencies; payment of any applicable fees; technical evaluation and administrative review. This process will be repeated for each accreditation renewal.

Application for Accreditation

A laboratory interested in becoming accredited should address a formal request to the Executive Director of the CRCPD. The request should specify the scope of calibrations for which accreditation is sought and state that the basic conditions for accreditation will be satisfied. The laboratory must also submit five copies of their protocol and procedure manual, to be reviewed by CRCPD's Ionizing Measurement Committee, a representative from the Food and Drug Administration's Center for Devices and Radiological Health (CDRH), and a representative from NIST. Requests received from state operated laboratories in radiation control programs, universities, or other state agencies will be considered. Requests from universities or other state agencies shall be co-signed by the Director of the State Radiation Control Program. Requests from other laboratories will be considered at the discretion of the CRCPD Board of Directors.

Basic Conditions for Accreditation

The laboratory management must agree to the following basic conditions:

1. To be evaluated and audited initially and on a periodic basis.
2. To offer, with highest priority, its services to state and local radiation control programs in the host and other states.
3. To claim or imply accreditation only for those procedures listed within the "Scope of Accreditation."
4. To advertise its accredited status only on its letterhead, brochures, and test reports, and in CRCPD publications.
5. To meet and maintain compliance with the current version of the accreditation criteria.
6. To participate in laboratory intercomparisons and proficiency testing that may be required for achieving or maintaining accreditation.
7. To pay, in full, any fees assessed by the CRCPD for the purpose of accreditation of the laboratory.

On-site Assessment

Visits to the laboratory's facilities are conducted prior to initial accreditation, and thereafter on a regularly scheduled basis. The assessment may be conducted by one or more CRCPD assessors. The laboratory will be advised in advance who the assigned assessor will be. The laboratory will be contacted to arrange a mutually agreeable date for the assessment. The laboratory will be notified of any additional information that must be supplied, and any applicable proficiency testing requirements that must be met prior to the assessment. An assessment generally takes one to three days depending on the extent of the review. Every effort will be made to conduct an assessment with as little disruption as possible to the normal operations of the laboratory.

Monitoring Visits

In addition to scheduled on-site assessments, monitoring visits of limited scope may be conducted to ensure that an accredited laboratory continues to comply with the general criteria. Monitoring visits may be conducted randomly or in response to problems perceived by the CRCPD. A laboratory may or may not be contacted in advance of a monitoring visit.

Laboratory Intercomparisons and Proficiency Testing

Participation in laboratory intercomparisons and proficiency testing is an integral part of the accreditation process. CRCPD has determined that in order to apply for accreditation, a laboratory must participate in laboratory intercomparisons or a NIST MQA test to demonstrate traceability to NIST for the scope of accreditation desired. The nature of the MQA service must

be commensurate with the scope of accreditation desired. If a laboratory intercomparison is used to demonstrate traceability to NIST, the laboratory will be evaluated based on the test if it specifically requests that in its accreditation application. All testing must be commensurate with the scope of accreditation desired. Within one year of approval by CRCPD, the laboratory must participate in an MQA service provided by NIST or lose its accreditation.

To determine calibration proficiency during laboratory intercomparisons or MQA test, the usual method is for NIST to send a well-characterized NIST calibrated instrument to the participating laboratory for calibration. The calibration coefficients determined by the laboratory are sent to the intercomparisons controller or NIST, where the data are analyzed to determine if the laboratory's results are within acceptable limits of uncertainty as stated in the criteria. The frequency with which proficiency testing is conducted depends upon the performance history of the participating laboratory. Normally a laboratory is required to participate in a proficiency test each year so that all accredited beams have a proficiency test a minimum of once every three years. Molybdenum beams are tested a minimum of once every two years to comply with federal regulations. Intercomparisons are scheduled as needed by the Ionizing Radiation Measurements (G-2) Committee.

Laboratory intercomparisons and proficiency testing are processes for checking actual laboratory testing performance. Information obtained from testing these processes helps to identify problems in a laboratory. When problems are found, CRCPD works with the laboratory to solve them.

Technical Evaluation

The assessment team will use the following information to review an applicant laboratory:

- Written information supplied by the laboratory;
- Results of quality system documentation review;
- On-site assessment reports;
- Actions taken by the laboratory to correct deficiencies;
- Results of laboratory intercomparisons and proficiency testing; and
- Information from any monitoring visits made to the laboratory.

If deficiencies are identified in the review, the laboratory will be given written notification of these deficiencies and a reasonable period in which to correct or resolve them. All deficiencies must be corrected before accreditation can be granted or renewed. Upon completion of the review of the above information, and the laboratory's response to any notification of deficiencies, the assessment team will make an accreditation recommendation to the CRCPD Board of Directors.

Accreditation Decision and Notification

Based on the recommendation of the assessment team, a decision will be made by the CRCPD Board of Directors to grant or deny initial accreditation for an applicant laboratory or renewal for a currently accredited laboratory. The laboratory will be notified of the decision by letter from the Executive Director of the CRCPD. If accreditation is denied, the notification will state the reason. A laboratory is granted accreditation for a specified period, usually one year.

Suspension

Suspension is a temporary removal of the accredited status of a laboratory when it is found to be out of compliance with the terms of its accreditation. The laboratory will be notified of the reasons for and conditions of the suspension and the action(s) that the laboratory must take to have the accreditation reinstated. Reasons for suspension include: loss of key personnel, loss of major equipment, damage to laboratory by fire, changing laboratory location, failure to pay the required fees, and proficiency test failure.

Revocation

Revocation is the removal of the accredited status of a laboratory when it is found to have violated the terms of its accreditation. The laboratory may be given the option of voluntarily terminating the accreditation. If accreditation is revoked, the laboratory must return its Certificate of Accreditation. Reasons for revocation include: obtaining accreditation through falsification, deceit, or misrepresentation; refusal to resolve deficiencies; changing types of accredited services provided without notifying CRCPD and receiving approval.

TECHNICAL REQUIREMENTS

This section outlines the criteria to be followed for operation of State Regional Calibration Laboratories.

Scope of the Program

To be granted accreditation, a laboratory must satisfy all required criteria and demonstrate proficiency in calibrating each type of instrument for which accreditation is desired. The laboratory's Scope of Accreditation will specify the instruments, sources, the radiation type(s), and any applicable measurement uncertainties for which accreditation has been granted.

Laboratories may utilize calibration techniques of their choice. However, once accredited, the technique(s) used to provide accredited services to the clients must be those for which the laboratory is accredited. If a laboratory adopts new calibration techniques, it will be

the responsibility of the laboratory to provide evidence to CRCPD that such changes lead to results that are technically equivalent to the accredited activities. Such techniques shall not be used for accredited calibrations until reviewed and approved by CRCPD. If the changes or deviations in the techniques are not considered to provide results that are technically equivalent, the new techniques will not be covered by the accreditation.

Quality Systems

To qualify for accreditation, a laboratory must have a documented system of procedures and practices that assure the quality of services performed. During the on-site assessment, an applicant must demonstrate that the quality system ensures the technical integrity of all work performed.

Documentation

All documentation must be up-to-date and thoroughly describe all procedures and practices. The written descriptions should contain, as applicable, such items as the approach to maintain quality, the method of implementation, responsible personnel, recordkeeping system utilized, operating procedures, procedures used in the event of unusual or non-standard circumstances, and scheduling methods used. The documentation must be arranged in such a way that it is readily accessible to all staff members. Preferably, it should be in the form of a single manual that can be distributed to various locations throughout the facility. If parts are distributed among several manuals, then a central reference document must be available to number and identify individual procedures. The documentation must be in a format and style that can be easily understood by all staff members.

Organizational Structure and Staff

The laboratory shall be free from any external influence that could adversely affect the quality or impartiality of the service it offers. The laboratory shall maintain a list of personnel designated to fulfill the criteria requirements including the laboratory director and key technical personnel in the laboratory. CRCPD must be informed of changes to this list of personnel within 30 calendar days of such changes.

Laboratory director

The laboratory technical director shall be a professional experienced in applied radiation measurements who is knowledgeable in calibration and measurement techniques currently utilized. This individual should have the technical competence and the supervisory capacity to direct the work of professionals and technicians.

Technical staff

The laboratory shall maintain a staff that is technically capable of conducting the required functions and is of sufficient number to adequately handle the quantity of work expected. The person in charge of day-to-day operations shall possess adequate qualifications and experience in measurement principles and practice appropriate to his responsibilities. Staff employed in calibration work shall have appropriate training, be adequately supervised, and follow fully documented procedures. All laboratory personnel shall maintain resumes that include a description of the experience in measurement principles and practice gained at the current and any other laboratory.

Quality assurance

Responsibility for the quality assurance program may reside with the technical director or with another individual having knowledge and experience in quality assurance and who has a direct line of communication to the technical director and other appropriate members of management.

Staff training

Each new staff member must be trained for assigned duties and existing staff members must be retrained when calibration equipment and/or procedures are changed or they are assigned new responsibilities. Each staff member must receive (or have had) training for assigned duties either through on-the-job training, formal classroom sessions, or through appropriate technician certification programs.

Staff competency

In addition to training, the competency of each staff member must be evaluated by observing him/her perform all calibration procedures he/she is authorized to conduct. The performance observation and evaluation must be conducted at least annually by the immediate supervisor or his designee.

Facilities and Equipment

A laboratory must have adequate facilities and equipment to perform the services for which capability is claimed. This includes adequate space, proper shielding of areas from unwanted radiation, environmental controls, adequate measurement equipment and radiation sources, adequate safety systems, and properly calibrated laboratory standard equipment for verifying system performance. All equipment used to calibrate instruments and to perform quality control must be adequately maintained in order to accomplish the required function(s).

Effect of external conditions

The effect of external conditions on the internal environment of the laboratory must be considered in selection of the site.

The laboratory should be sited away from, or otherwise isolated from, sources of mechanical vibration and shock, sources of electrical and electromagnetic interference, and other sources of interference. The laboratory space shall be used exclusively for maintenance, repair, and calibration of instruments, and related activities.

Equipment changes

When an accredited laboratory changes the calibration system including procedures, equipment, software, etc., for which it was accredited, CRCPD must be notified. Depending on the nature and extent of the changes, the laboratory will be advised as to the evaluation steps required in order to maintain accreditation, such as the need for an additional on-site assessment, etc.

Laboratory Equipment Calibration

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 for the calibration and verification of its measuring and test equipment. The program will ensure the recall or removal from service of any standard or equipment that has exceeded its calibration interval or is otherwise judged to be unreliable.

Equipment calibration records should include the following: equipment name or description; model, style, or serial number; manufacturer; notation of all equipment variables requiring calibration or verification of the range of calibration/verification; the resolution of the instrument and its allowable error; calibration/verification date and schedule; date and result of last calibration; identity of the laboratory individual or external service responsible for calibration; source of reference standard and traceability.

Records

A comprehensive and readily available recordkeeping system shall be maintained by the laboratory and shall include at least the following information:

- Laboratory equipment calibration and maintenance records, including calibration reports, for all laboratory reference standards and instruments.
- Inventory of all laboratory equipment and certification data for items requiring periodic recalibration.
- Procedures used for providing calibration services.
- General laboratory instructions.
- A bound day-book, or equivalent shall be kept in which is recorded the date, customer, description of the instrument, its serial number, details of the test required, and certificate

number and invoice or other accounting number. If an instrument has no serial number, it shall be marked with an identifying number, e.g., job number.

- A record of routine quality control actions and resultant control charts.
- Copies of all calibration reports issued.
- Results of all proficiency testing.

All records shall have the name or initials of the person collecting the data and be kept for a minimum of five years, or at least until such time as the appropriate time limitations for all applicable local, state, and federal legal requirements have been satisfied. Adequate precautions shall be taken to protect and preserve laboratory records.

Calibration Reports

The laboratory shall issue calibration reports that accurately indicate the calibration conditions, set-up, calibration results, and all other required information. The calibration report should provide all information necessary to permit the same or another laboratory to repeat the test and obtain comparable results. The calibration report shall be signed by the person responsible for the operation of the laboratory.

The final report to the client must include:

- Name and address of the calibration laboratory.
- Pertinent dates and identification of instrument including client and corresponding identification codes.
- Client name.
- Description or identification of each instrument calibrated.
- "Instrument Calibration Report" or a similar title.
- An explanation of any deviation from the procedures routinely used in instrument calibration that may affect the reported results.
- Identification of anomalies.
- Orientation of the detector.
- Beam codes, exposure rates.
- Range of calibration.

- Application of correction factor.
- Environmental conditions.
- Signature of person responsible for the operation of the laboratory.
- Adequately defined data resulting from the calibration.

The calibration report shall include the following statement: "This calibration was performed using a procedure that is (or is not) included in the Scope of Accreditation issued by the Conference of Radiation Control Program Directors, Inc." in a prominent location between the heading and the signature. The calibration report shall not include any other statement that may imply or make reference to accreditation by the Conference of Radiation Control Program Directors, Inc.

Proficiency Testing

In order to be eligible for accreditation, each laboratory must demonstrate satisfactory performance for the calibration areas in which accreditation is desired. Satisfactory proficiency must be demonstrated prior to initial accreditation, and every year thereafter. NIST and CRCPD will determine appropriate proficiency testing requirements for the program. It is not feasible that an annual proficiency test for a particular radiation quantity should attempt to cover the entire range of exposure (air kerma) rates or dose rates of interest. Instead, each annual test will involve only a representative part of the possible range, with the intent of covering the complete range over a period of years. If a laboratory establishes a new type of calibration procedure, and wishes to perform a proficiency test for that new procedure, the cost for that proficiency test shall be borne entirely by that laboratory.

If an accredited laboratory fails a proficiency test, it must perform a retest. Accreditation will not be suspended for one failure of a test; the laboratory will be able to retest after the initial failure to successfully pass the proficiency test.

If the laboratory fails the second attempt, accreditation will be suspended for that portion of the accredited services. Accreditation can be reinstated once competency has been reestablished. This may require an additional on-site assessment.

If a laboratory fails a proficiency test, any costs associated with retesting shall be borne by the laboratory failing the test.

Uncertainty Analysis

Each laboratory is required to perform an assessment of uncertainty associated with the calibration of each instrument. This includes an analysis of the systematic and random error

associated with each type of calibration. The percentage of error used in determining the accuracy of the measurement should be stated with the calibration.

On-Site Assessment

On-site assessment is based upon this document. A checklist for on-site assessments has been developed for use by the assessment committee to ensure that all laboratories receive comparable assessments. The agenda for a typical on-site visit is as follows:

- The assessment committee meets with management and supervisory personnel responsible for the laboratory's activities to review the assessment process with the individuals involved.
- The committee reviews the quality control system employed by the laboratory. The committee may select and trace the history of one or more instruments from receipt to final issuance of the calibration report.
- The committee examines notebooks or records, checks tracking procedures, determines whether the appropriate environmental conditions are maintained, and examines copies of completed calibration reports.
- The committee reviews records of periodic internal audit and use of quality control items.
- The committee reviews personnel records including resumes and job descriptions of key personnel and competency evaluations for all staff members who routinely perform the calibration for which accreditation is sought.
- The committee observes demonstrations of calibration techniques and discusses them with the technical personnel to assure their understanding of the procedures.
- The committee examines major equipment, apparatus, and facilities for appropriateness, capability, and adherence to specifications.

At the conclusion of the assessment, an exit briefing is held with the laboratory manager and staff to discuss the committee's findings. Deficiencies are discussed, and resolutions are planned. The committee will identify those deficiencies that must be addressed before initial accreditation or renewal of accreditation can be granted. Items that have been corrected during the on-site assessment are also specifically noted. Recommendations for change not identified as deficiencies should be given serious consideration, but are taken at the laboratory's discretion. Any disagreement between the laboratory and the committee should be referred to CRCPD for further evaluation.

If deficiencies are identified during the on-site review, the laboratory will be given written notification of these deficiencies, and a reasonable period in which to correct or resolve them. Upon completion of the on-site review and the laboratory's response to any notification of

deficiencies, the committee will make an accreditation recommendation to CRCPD's Board of Directors.

GAMMA-RAY CALIBRATION OF SURVEY INSTRUMENTS

INTRODUCTION

The criteria contained in this part apply to the calibration of health physics instruments at radiation protection levels using one or more gamma-ray sources. These criteria are supplementary to the general criteria. Both the general criteria and these specific criteria shall be followed if this gamma-ray calibration service is offered and its inclusion in the Scope of Accreditation is desired.

SOURCES OF GAMMA RADIATION

One or more of the following radiation sources in the following table shall be available for use in the calibration of health physics instruments:

Table 1. Gamma Radiation Sources

Radionuclide	Nominal Energy
Am 241	60 keV
Cs 137	660 keV
Co 60	1.25 MeV

The radiation fields produced by the sources shall cover a range of exposure (air kerma) rates suitable for protection-level calibration. A minimal range is 9 μ Gy to 40 mGy/h (1 mR/h to 5 R/h); and, a more desirable range is 4 μ Gy/h (0.5 mR/h) to at least 0.9 Gy/h (100 R/h).

RADIATION CONTROL

Shielding

Radiation barriers and/or storage containers for sources shall provide sufficient shielding so that radiation added to natural background radiation in the calibration area is sufficiently low as to not interfere with ongoing calibration work. Added background radiation and leakage radiation from all sources in the calibration area should not contribute more than 1 percent of the total exposure (air kerma) rate at which an instrument is calibrated.

Beam Collimation

The gamma radiation beam emitted from a source that has been exposed for calibration shall be collimated so that its size is limited to an area consistent with calibration requirements. An exception to this requirement is calibration facilities sufficiently large to provide a low room scatter radiation environment for instrument calibration, e.g., an uncollimated source in a low scatter room.

Source Exposure

The source storage container shall have a mechanism to control exposure in the gamma beam. If the radiation source is used for calibration of exposure (air kerma) measuring (as contrasted with exposure-rate (air kerma rate) measuring) instruments, the shutter or source transit time and its effect on the total radiation exposure (air kerma) shall be known.

Exposure Control

If the radiation source is used for the calibration of exposure (air kerma) measuring instruments (see Source Exposure above), the shutter or source transfer shall be initiated and terminated by a timer or the exposure (air kerma) shall be controlled by use of a transmission chamber. Any associated systematic timing uncertainties shall be documented and eliminated or compensated.

EQUIPMENT

In addition to one or more radiation sources and associated control devices, the laboratory shall have as a minimum the following equipment:

- a. Secondary standard ionization chambers suitable for the photon energy and intensity ranges for which calibration services are offered.
- b. An electrometer to measure the charge produced in the ionization chambers.
- c. A voltage source suitable for chamber polarizing potential.
- d. An independent measuring system for verification of the performance of the secondary standard ionization chambers and electrometer.
- e. An instrument and ionization chamber support and positioning system. The system should provide for reproducible and accurate positioning of an instrument or chamber with respect to the radiation source. For beam type irradiation configurations, the positioning system should define the central axis of the gamma beam.

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

CHARACTERIZATION OF THE RADIATION FIELD

Exposure Rate (Air Kerma Rate)

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

Scattered Radiation

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

Use of Attenuators

If an attenuator is used to reduce the exposure (air kerma) rate at any location in the radiation field, the effect of the altered radiation spectrum (relative to an unattenuated radiation spectrum) on the accuracy of calibration of each instrument type shall be known. The approximate energy spectrum of the attenuated radiation field should be known. Secondary electron equilibrium at the calibration position shall be documented.

Accuracy

The exposure (air kerma) rate specified by the laboratory as its reference value for each source of radiation shall be within 5 percent of the true value as defined by comparison with a national standard above 90 $\mu\text{Gy/h}$ (10 mR/h), and within 7 percent of the true value from 4 $\mu\text{Gy/h}$ (0.5 mR/h) to 90 $\mu\text{Gy/h}$ (10 mR/h). This level of agreement with the standard shall be demonstrated through periodic proficiency testing by NIST.

CALIBRATION REPORT

An instrument calibration report shall include, as a minimum, the radionuclide or photon energy used, the reference exposure (air kerma) rate or rates at which the instrument was calibrated, the exposure (air kerma) rate indicated by the instrument, and the correction factor at each calibration point. In the case of integrating instruments, in addition to the radionuclide and exposure (air kerma) rate, the reference exposure (air kerma), instrument reading, and correction factor shall be included. One calibration point and a linearity check should be included for each range of the instrument, where possible. The orientation of the instrument with respect to the

radiation beam shall be described or illustrated in the calibration report, and the use of a build-up cap shall be noted. For instruments that use a vented ionization chamber, the reported values shall be referenced to a temperature of 22 °C and a barometric pressure of 760 mm Hg, and the equation needed to convert to other temperatures and pressures shall be provided.

X-RAY CALIBRATION OF DIAGNOSTIC AND SURVEY INSTRUMENTS

INTRODUCTION

The criteria contained in this part apply to the calibration of diagnostic and survey x-ray instruments using an x-ray source. These criteria are supplementary to the General Criteria contained in this document. Both the general criteria and these specific criteria should be followed if these x-ray services are offered and included in the Scope of Accreditation.

SOURCE OF X-RAYS

Constant potential x-ray generators shall be used. Maximum ripple shall not exceed 2 percent and it should be operable over a minimum range of 30 to 100 kV. For tungsten-anode tube x-ray machines, a minimum of three tungsten-anode beams from Table 2 below shall be available if this service is included in the laboratory scope of accreditation. The range of mA available for tungsten-anode x-ray machines should, as a minimum, cover 1 to 11 mA. For molybdenum-anode tube x-ray machines, a minimum of two Mo beam codes from Table 2 shall be available and used for calibration of diagnostic instruments used for mammography if this service is included in the laboratory scope of accreditation. The range of mA available for molybdenum-anode x-ray machines should, as a minimum, cover 1 to 20 mA.

Table 2. X-ray Beam Quality Parameters

Beam Code	Tube Voltage (kVp)	Anode Material	Added Filter (nominal mm)	Half-Value Layer (mm Al)	Homogeneity Coefficient (Al)
Mo/Mo25	25	molybdenum	0.03 Mo	0.296	n/a
Mo/Mo28	28	molybdenum	0.03 Mo	0.332	n/a
Mo/Mo30	30	molybdenum	0.03 Mo	0.351	n/a
Mo/Mo35	35	molybdenum	0.03 Mo	0.392	n/a
M30	30	tungsten	0.5 Al	0.36	64
M50	50	tungsten	1 Al	1.02	66
L80	80	tungsten	1.3 Al	1.83	58
M80	80	tungsten	3 Al	2.97	67
L100	100	tungsten	2 Al	2.8	59
M100	100	tungsten	5 Al	5.0	72
M120	120	tungsten	7 Al	6.79	77

CONTROL OF THE RADIATION BEAM

Radiation Production

The production of a useful beam of radiation may be by means of the application of high voltage to the x-ray tube or the opening of a mechanical shutter (which normally acts as a shield to the x-ray beam).

Beam Collimation

The x-ray beam emitted from the tube housing shall be collimated so that its size is limited to an area consistent with calibration requirements. Provision shall be made for identifying the central axis, and the boundaries of the useful area of the beam shall be known.

Exposure Control

If the radiation source is used for the calibration of exposure (air kerma) measuring instruments, the radiation beam shall be controlled by a timer or the exposure (air kerma) shall be controlled by use of a transmission chamber. The timing error due to the shutter transit times or high voltage ramping shall be known.

EQUIPMENT

In addition to one or more x-ray machines and associated control devices, the laboratory shall have the same minimum equipment as that required for gamma ray calibration (see "Equipment" in the section entitled "Gamma-Ray Calibration of Survey Instruments) with the following exception—the secondary standard ionization chambers shall be appropriate to the energy and intensity of x-rays for which calibration services are offered.

Additionally, the laboratory shall be equipped with filters to permit the production of a variety of x-ray beam qualities (see "Radiation Quality" below under the heading "Characterization of the Radiation Field").

CHARACTERIZATION OF THE RADIATION FIELD

Exposure Rate

The x-ray radiation field used for calibration shall be characterized in terms of exposure rate at a given position or distance from the anode of the x-ray tube. The exposure rate shall be known at each distance used. During calibration of an instrument, the exposure rate shall not vary by more than 2 percent from the nominal rate when it is 10 mR/s or higher, and shall not vary by more than 4 percent from the nominal rate when it is below 10 mR/s.

Scattered Radiation

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

Radiation Quality

The x-ray beam emitted from the tube housing shall be filtered before use to provide the appropriate radiation quality for calibration purposes. If a transmission chamber is used for routine beam monitoring, it shall be considered to be added filter material.

The first half-value layer for a given x-ray beam shall be within 5 percent of the values listed in Table 2. For tungsten x-ray beams the homogeneity coefficient for a given x-ray beam shall be within 7 percent of the values listed in Table 2. If necessary the indicated tube voltage or added filter, or both, may be adjusted to achieve those values.

The intensity of the x-ray beam shall not vary more than 5 percent across the useful area of the beam. The radiation quality shall be checked for stability at least annually. Whenever any part that could affect the beam quality is repaired or replaced the above requirement for radiation quality shall be met.

Accuracy

The exposure rate specified by the laboratory as its reference value for each tungsten x-ray beam shall be within 5 percent of the true value as defined by comparison with a national standard above 10 mR/h and within 7 percent of the true value below 10 mR/h. For Mo/Mo beams, an expanded uncertainty not exceeding 3.5% (2σ) for calibrations of reference-class instruments (e.g., Exradin A15) and 5% (2σ) for field-class instruments (e.g., MDH 1015 and 1515 w/10X5-6M probe) shall be attained. This level of agreement with the standard shall be demonstrated through periodic proficiency testing by NIST.

CALIBRATION REPORT

An instrument calibration report shall include, as a minimum, the x-ray beam used for calibration, the reference exposure (air kerma) rate or rates at which the instrument was calibrated, the exposure (air kerma) rate indicated by the instrument, and correction factor at each calibration point. In the case of integrating instruments, in addition to the x-ray beam and exposure (air kerma) rate, the reference exposure (air kerma), instrument reading, and correction factor shall be included. At least one calibration point should be included for each range of the instrument, where possible. The orientation of the instrument with respect to the radiation beam shall be described or illustrated in the calibration report. For instruments that use a vented ionization chamber, the reported values shall be referenced to a temperature of 22 °C and a

barometric pressure of 760 mm Hg, and the equation needed to convert to other temperatures and pressures shall be provided.

INDEX

Accreditation	
Additions to scope.....	2
Application.....	3
Basic conditions.....	3
Decision and notification.....	6
Definition.....	1
Notice of change.....	3
Process.....	3-6
Suspension.....	6
Renewal.....	2
Revocation.....	2, 6
Scope of accreditation.....	1
Termination.....	2
Accuracy	
Gamma.....	15
X-ray.....	18
Attenuation.....	15
Beam collimation	
Gamma.....	14
X-ray.....	17
Beam sources for calibrations	
Gamma.....	13
X-ray.....	16
Calibration criteria	
Gamma-ray survey instruments.....	13-16
X-ray instruments.....	16-19
Calibration of laboratory equipment.....	9
Calibration records requirement.....	9
Calibration reports	
General requirements.....	10
Requirements for gamma calibrations.....	15
Requirements for x-ray calibrations.....	18
Calibration system changes	
Calibration technique changes.....	6-7
Equipment changes.....	9
Personnel changes.....	7
Calibration techniques	
Review by CRCPD.....	7
Selection by the laboratory.....	7
Characterization of the radiation field	
Gamma.....	15
X-ray.....	17
Documentation.....	7
Effect of external conditions.....	8

Equipment	
Changes.....	9
For gamma calibrations.....	14
For x-ray calibrations.....	17
Exposure control	
Gamma.....	14
X-ray.....	17
Exposure rate	
Gamma.....	15
X-ray.....	17
Facilities and equipment.....	8
Gamma-ray	
Calibration of survey instruments.....	13-15
Source exposure.....	14
General laboratory requirements	
Basic conditions.....	3
On-site assessment.....	4, 12
Monitoring visits.....	4
Proficiency testing.....	4, 11
Laboratory director.....	7
Laboratory equipment	
Calibration requirement.....	9
General requirements.....	8
Gamma requirements.....	14
X-ray requirements.....	17
Laboratory facilities.....	8
Laboratory notifications to CRCPD	
30-day notifications	
Changes in critical staff.....	3, 7
Changes in facilities.....	3
Changes in location.....	3
Changes in management structure.....	3
Changes in ownership.....	3
Deletion of accredited capability.....	3
No longer capable of accredited service.....	3
Calibration system change notification.....	9
On-site assessment.....	4, 12
Operational information and requirements.....	2
Organizational structure.....	7
Proficiency testing.....	5, 11
Quality assurance.....	8
Quality systems.....	7
Radiation control	
Gamma.....	13
X-ray.....	17

Radiation field characterization	
Gamma.....	15
X-ray	17
Radiation sources	
Gamma.....	13
X-ray	16
Records	9
Scattered radiation	15, 18
Shielding	13
Source of gamma radiation.....	13
Source of x-ray radiation	16
Staff	
Competency	8
Laboratory director	7
Quality assurance	8
Technical staff.....	8
Training.....	8
Technical evaluation	5
Technical requirements.....	6
Technical staff.....	7
Uncertainty analysis.....	11
X-ray	
Instrument calibration criteria.....	16
Radiation production.....	17
Radiation quality.....	18

CRCPD'S MISSION: A PARTNERSHIP DEDICATED TO RADIATION PROTECTION.

The Conference of Radiation Control Program Directors, Inc. (CRCPD) is a nonprofit organization made up of individuals in state and local government who regulate and control the use of radiation sources, and of individuals, regardless of employer affiliation, who have expressed an interest in radiation protection. CRCPD was formed in 1968.

The objectives and purposes of the organization are: to promote radiological health in all aspects and phases, to encourage and promote cooperative enforcement programs with federal agencies and between related enforcement agencies within each state, to encourage the interchange of experience among radiation control programs, to collect and make accessible to the membership of the CRCPD such information and data as might be of assistance to them in the proper fulfillment of their duties, to promote and foster uniformity of radiation control laws and regulation, to encourage and support programs that will contribute to radiation control for all, to assist the membership in their technical work and development, and to exercise leadership with radiation control professionals and consumers in radiation control development and action.

CRCPD
205 Capital Avenue
Frankfort, KY 40601
502/227-4543
Web Site: www.crcpd.org