

# Ionizing Radiation Division Quality Manual

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## 1. Introduction

### 1.1 Division Commitment to Quality

This Quality Manual defines the quality system of the Ionizing Radiation Division (IRD) of the Physics Laboratory (PL) at the National Institute of Standards and Technology (NIST). It describes the processes by which the IRD achieves and maintains high standards of quality in maintaining the U.S. national measurement standards for photon, electron, neutron and alpha radiations. Included are a description of the Division, its policies, procedural structure and organization along with an overview of the various processes used to assure that radiometric standards are used and maintained in an accurate manner that is consistent with international standards and practices. This Quality Manual (IRD-QM-II) defers to the NIST Quality Manual (NIST-QM-I) institutional policies and procedures where applicable (see Section 1.5), and refers to other quality-assurance documents, where appropriate.

This Quality Manual is intended to document policies and practices necessary to comply with the NIST Quality System (QS). The IRD commits that its quality system be, to the extent allowed by statute and regulation, in conformity with the international standard ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, and the relevant requirements of ISO Guide 34, *General requirements for the competence of reference material producers*, as they apply to the Standard Reference Materials<sup>®</sup> (SRMs<sup>®</sup>) and the related services that the IRD delivers.

Signed:

\_\_\_\_\_, date \_\_\_\_\_.

Division Chief  
Ionizing Radiation Division  
Physics Laboratory  
National Institute of Standards and Technology

### 1.2 Scope

This Quality Manual covers the IRD calibration services that are listed in the *NIST Calibration Services Users Guide*, NIST SP 250 (see Appendix A). It covers testing and calibrations performed using standard methods, non-standard methods and laboratory-developed methods. The scope of calibration services provided by the IRD varies from Group to Group as described below. This Quality Manual also covers the IRD SRM services. The IRD personnel, to assure that clients receive ionizing radiation calibrations and SRMs of the highest accuracy, follow the practices documented in NIST-QM-I and IRD-QM-II.

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The services offered by the IRD (see Section 5.1) and within the scope of this Quality Manual pertain to the following areas:

- Activity measurements of alpha-particle and gamma-ray emitting sources;
- Preparation and certification of radionuclide Standard Reference Materials
- X-ray and gamma-ray dosimetry, and beta-particle dosimetry; and,
- Calibration of neutron sources and radiation-protection instruments for neutron fields.

While committed to quality work and many of the policies included in this document, other activities (i.e., special tests/measurements, research and development, contract, CRADA, or other cooperative activities) of the Division are not within the scope of this quality manual.

## 1.3 Outline of IRD Quality Manual for Calibration Services

The IRD Quality Manual is organized in two levels.

- The first level (NIST-QM-I) contains NIST-wide policies and procedures stemming (primarily) from the executive leadership of NIST, i.e., the NIST Director and Laboratory Directors. Many of these policies and procedures govern all activities at NIST and thereby are controlling in so far as these activities are part of providing calibration services.
- The second level, this document (IRD-QM-II), contains policies, protocol guides (see Section 4.3) and technical procedures (see Section 5.1) established and maintained by the Ionizing Radiation Division to meet its technical needs. The IRD-QM-II explicitly references NIST-QM-I where appropriate.
- The specific protocols to carry out IRD-QM-II policies are contained in its Guides. Examples of Guide protocols include: the acquisition of materials and supporting services; complaints; nonconformance, corrective and preventive action; internal audits; and training.
- The specific procedures to carry out IRD-QM-II services are contained in its Procedures. Procedure contents include: technical procedures for calibrations; handling and storage of calibration items; quality-assurance procedures; and, creation, storage, and control of technical records of all types.

## 2. References

The documents described in this section are used as references to help ensure the highest quality in the calibration and SRM services offered by the IRD. These documents are available to all calibration/testing personnel and are implemented by the appropriate personnel. A complete list

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of publications pertaining to the IRD calibration and SRM services can be found in Appendix A. A list of informative references is contained in NIST-QM-I Section 2.1.

## 3. Definitions

Acronyms and terms requiring definitions to assure the consistency and clarity of the IRD-QM-II are provided in Appendix B. Those not listed in Appendix B are listed in NIST-QM-I.

## 4. Management Requirements

### 4.1 The Ionizing Radiation Division

#### 4.1.1 Description

The Ionizing Radiation Division (IRD) is one of six Divisions within NIST's Physics Laboratory (PL); the organizational chart describing this is shown in NIST-QM-I Figure 4.1. Three Groups within the IRD maintain the national ionizing-radiation standards. These standards, in turn, are used in the calibration of ionizing-radiation detection equipment, the calibration of radiation sources, and the preparation of standard reference materials (SRM). The organizational structure of the IRD is arranged in a way that preserves independence of judgment in matters concerning radiological calibrations and services.

The Division Chief has the overall responsibility for the development and implementation of proper calibration and quality-control procedures. The Group Leaders are responsible for the day-to-day operation of their calibration programs and ensure that adequate resources are provided so that at no time is the quality of the calibration service jeopardized. These responsibilities cover work conducted in the IRD's permanent facilities and at sites away from its permanent facilities.

#### 4.1.2 Physical Locations

Located on the NIST, Gaithersburg campus, Buildings 245 (Radiation Physics) and 235 (Reactor) contain the offices and laboratories of IRD personnel.

#### 4.1.3 Organizational Structure for Scientific and Technical Research and Services; Responsibilities and Authorities

##### 4.1.3.1 Organization Charts

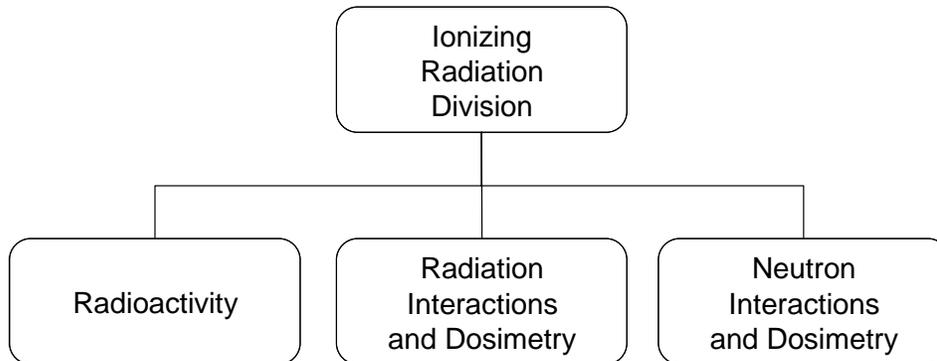
Calibration and SRM services are part of the efforts of the Ionizing Radiation Division. All three Groups within this Division are directly involved with the provision of the calibration reports and

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measurement certificates covered by this manual. IRD-QM-II Figure 4.1 provides a schematic representation of this part of the NIST organization.



**Figure 4.1 Organization chart for the three Groups that comprise the Ionizing Radiation Division**

The technical effort required to prepare a SRM or conduct a calibration or special test is made by scientific and technical staff within each Group. The NIST Information System to Support Calibrations (ISSC) in Technology Services (NIST-QM-I Figure 4.1) provides business, administrative, and customer support for all calibrations. The ISSC also provides liaison with external organizations with specific interests in NIST calibration services. Many other parts of the NIST organization have functions that impact in some way the provision of calibration services. For a complete description see NIST-QM-I Section 4.1.3.1 and the associated schematic representation in NIST-QM-I Figure 4.2.

### 4.1.3.2 Responsibilities, Authorities, and Delegations

The responsibilities of the NIST Director and Laboratory Directors are documented in NIST-QM-I Section 4.1.3.2.

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The Ionizing Radiation Division Chief, acting through his/her leadership staff, is responsible for the technical and scientific work involved in the development, maintenance and provision of national standards of measurement and the associated calibration services. The IRD Chief authorizes resource allocations (personnel, fiscal, equipment, and space) specifically for these efforts. The IRD Chief is also responsible for ensuring the institutional competency needed to provide a calibration or SRM service. The IRD Chief, or his/her designees, sign reports of calibration or certificates in the name of the NIST Director.

Requirements for the position of Division Chief are set forth by the NIST Physics Laboratory. Requirements for the Group Leader positions are set forth by the Division Chief. Requirements for the staff positions are set forth by the respective Group Leaders.

## 4.2 NIST Quality System for IRD Calibration and SRM Services

### 4.2.1 IRD Quality Policy

The IRD abides by the NIST Quality Policy stated in NIST-QM-I Section 4.2.1.

### 4.2.2 IRD Quality Objectives

The Ionizing Radiation Division's principal quality goal is to consistently meet or exceed customer needs and expectations and provide high value, continually improving services. IRD's quality objectives support this goal.

#### 4.2.2.1 Realization of Units

The IRD develops and maintains U.S. national realizations of the International System of Units (SI) for ionizing radiation. These realizations will have measurement uncertainties appropriate to current and anticipated needs of U.S. industry and Government.

#### 4.2.2.2 Comparisons

To the extent permitted by resources, the IRD participates in comparisons of its national standards with those of other National Measurement Institutes (NMIs), both as a means of assuring the quality of its measurement services and to satisfy the requirement that the U.S. standards are consistent with those of other NMIs and with the SI within stated uncertainties. Special priority is given to key comparisons conducted under the auspices of the International Committee on Weights and Measures (CIPM) in support of the CIPM Mutual Recognition Arrangement.

#### 4.2.2.3 Dissemination

The IRD provides calibration services for ionizing radiation and radionuclide SRMs that are customer focused and, at a minimum, are:

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- marked by clear and open communication with customers to assure mutual understanding of customer needs and IRD capabilities
- technically consistent with customer needs
- timely and cost effective

## 4.2.2.4 Improvement

The IRD expects continuous improvement in the provision of calibration and SRM services and encourages identification of opportunities for improvement from all staff.

## 4.2.2.5 Strategic Planning and Peer Review

The IRD employs a variety of mechanisms to assess its performance and impact to stakeholders, as well as the future needs of the communities it serves by:

- Participating in client surveys as directed by the MSAG.
- Hosting the annual meeting of the Council on Ionizing Radiation Measurements and Standards (CIRMS) as an independent, non-profit council that draws together experts involved in all aspects of ionizing radiation to discuss, review and assess developments and needs in this field. CIRMS draws upon expertise from government and national laboratories, agencies and departments, from the academic community and from industry, to issue a triennial report on national needs in ionizing radiation measurements and standards.
- Hosting workshops on topics relating to its services and activities as needed.
- Actively participating in organizations that prepare documentary standards relating to IRD services.
- Periodic peer review by the National Academy of Science Board of Assessment.
- Contracting for economic assessment studies of its services.
- Permitting external audits of the IRD Quality System by qualified reviewers (while ensuring client confidentiality; see Section 4.3.4.3).

## 4.2.3 Organizational Structure of the NIST QS: Responsibilities and Authorities

### 4.2.3.1 Organization Chart

The organizational hierarchy of the NIST QS includes that of the IRD and is shown in NIST-QM-I Figure 4.3.

### 4.2.3.2 Responsibilities, Authorities, and Delegations

The responsibilities of the NIST Director and Laboratory Directors are documented in NIST-QM-I Section 4.2.3.2.

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## 4.2.3.2.1 IRD Chief

The IRD Chief has the overall responsibility to assure that the statement of policy and the quality-assurance procedures in the Quality Manual are being implemented and followed. The IRD Chief is also responsible for assuring completion of assessments and reviews in a timely manner, and for implementing actions resulting from the findings of these assessments and reviews. The IRD Chief will keep the NIST Director and the Physics Laboratory Director informed of issues that affect the quality of calibrations performed by the Division.

The IRD Chief will participate in policy reviews related to revising the Quality Manual and/or documentation procedures for calibration or quality control implementation. He/she will work with professional and technical groups interested in promoting quality calibration and SRM services of the type offered by the Division, and will participate in technical activities affecting the ability of the Division to perform quality calibrations. The Division Chief authorizes a staff member to perform a specific calibration or SRM service. The authorization and its effective date are established through written notification from the Division Chief to the Quality Manager.

The IRD Chief approves the IRD-QM-II, which, when so approved, becomes the official version.

The Division Chief appoints a Division Quality Manager and Deputy.

In the absence of the Division Chief, the Deputy Division Chief will carry out the responsibilities in his/her absence. When both are absent, an Acting Division Chief will be designated from within the Division to carry out the responsibilities.

## 4.2.3.2.2 Group Leaders

The Group Leaders are responsible for the overall technical operations of their Groups. They will ensure that the staff meets minimum requirements to perform the required calibrations and that adequate training is provided as needed to protect the integrity of the calibration program. Staff members that are determined to be competent to perform a specific calibration or SRM service will be recommended for authorization by the Group Leader in writing to the Division Chief. They will also be responsible for assuring that adequate resources are available for calibration personnel to carry out their duties in a manner consistent with the quality goals of the Division. It is also their responsibility to ensure that calibration and SRM activities (see IRD-QM-II Section 4.2.3.2.4) are carried out in such a way as to satisfy the requirements of the NIST Quality System and the needs of its clients.

Group Leaders will work with professional and technical groups interested in promoting quality calibration services of the type offered by the Division and will participate in technical activities affecting the ability of the Division to perform quality calibrations. They will ensure that comparisons, or similar programs, are carried out with other national/international laboratories periodically to assure the quality of the calibration services provided.

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In addition, Group Leaders serve as liaisons for laboratory capabilities and the needs of potential clients, including U.S. government and industry and foreign parties. This responsibility involves issues of policy and comparability of the various programs and/or entities. The Group Leaders are also responsible for providing independent arbitration and oversight in various activities (including the development of technical procedures and methods, self-assessments, etc.).

In the absence of a Group Leader, an Acting Group Leader will be designated from within the Division to carry out his or her responsibilities.

## 4.2.3.2.3 Quality Manager

The Quality Manager is responsible for the development, implementation and maintenance of the quality system. It is the Quality Manager's responsibility to ensure that calibration and SRM activities are carried out in such a way as to meet the requirements of the NIST Quality System. The Quality Manager must be well versed in the properties and characteristics of radiation standards, calibration methods, capabilities and limitations of radiation-measurement/detection instruments and uncertainty analysis. He/she shall have direct access to the highest level of management at which decisions are made regarding Division policy or resources, and to the Group Leaders. The Quality Manager has the authority to stop work in the event that poor-quality practices are identified or suspected.

The Quality Manager must have at least a B.S. in health physics or a related field with five years of ionizing-radiation measurements experience. He or she must have experience in calibrations, radiation measurements, instrument evaluation, computer record keeping, and a wide range of radiation applications. He or she must also have good communication skills, both written and oral, and shall be familiar with both government and private industry needs.

In the absence of the Quality Manager, the Deputy Quality Manager will carry out his/her responsibilities.

## 4.2.3.2.4 Calibration and SRM Personnel

Responsibilities of the Calibration and SRM Personnel may include providing support in the calibration, characterization and troubleshooting of national radiological standards (sources and/or measurement equipment), calibration of instrumentation, preparation of SRMs, and the maintenance, preparation and analysis of specialized dosimetry services. Calibration and SRM Personnel may also have assigned duties as custodians of radiation sources, Radiation Generating Devices, or Special Nuclear Materials.

Calibration and SRM Personnel obtain direction from the Group Leaders for all technical activities. They are responsible for the operation of all calibration equipment within their area of expertise, and following established procedures for both safety and operations. They must

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properly record calibration data on established data sheets or in approved notebooks as required by the specific task.

Calibration Personnel must be trained radiation workers and must be familiar with the operation of radiation-generating devices when applicable. They must have basic computer skills and should be familiar with a wide range of radiation-measurement instruments. Familiarity with laboratory procedures and calibration techniques is also required.

A senior Radioactivity Group member (generally a radiochemist or someone trained in chemistry) is designated by the Radioactivity Group Leader to coordinate the production of all Radioactivity SRMs. The SRM Coordinator is responsible for providing the necessary coordination and overall oversight for the production, calibration, and documentation of the SRMs. More specifically, the functions of this SRM Coordinator are: (i) to schedule and approve the production of renewal (out of stock) and new SRMs, based on identified needs; (ii) to approve the experimental design and production process; (iii) to obtain the necessary funding; (iv) to arrange for the necessary facilities, materials, equipment and personnel; (v) to assist in the preparation of the SRM Certificate and to initiate and finalize a technical review; (vi) to assure the proper collection and storage of the record file; (vii) to complete all of the necessary transfers to SRM stock and to provide inventory control; (viii) and, more generally, to assist any other Radioactivity Group members in the production, standardization and certification of the SRMs. An authorized Radioactivity Group staff member is designated by the SRM Coordinator as the principal investigator that is primarily responsible for producing, standardizing, and certifying that SRM. All other SRM staff working on that SRM are expected to assist the principal investigator in assembling and providing the required documentation. The principal investigator is responsible for all technical aspects leading to completion of the SRM described in the steps below except those steps that are explicitly identified as being the responsibility of the Group Leader and/or the SRM Coordinator. The SRM Coordinator is responsible for informing the Group Leader of all aspects of SRM planning activities. The Radioactivity Group Leader is responsible for notifying the IRD Division Chief and Quality manager of any change in the SRM Coordinator designee. This designation is documented in IRD-QM-II Appendix E.

## 4.3 Control of Documents, Records, and Data

### 4.3.1 Scope

This section of IRD-QM-II describes the guides and protocols for identification, collection, indexing, access, filing, storage, maintenance, and disposal (including retention times) of all Division-level quality and technical records. The IRD-QM-II provides up-to-date references for the IRD organization, capabilities, policies, and practices that are updated as necessary. IRD staff members responsible for calibration work are provided with a copy, are required to read the Quality Manual, and are expected to utilize it for reference as necessary.

IRD-QM-II has two classifications of instructional documents, Guides and Procedures. IRD-QM-II Guides contain policy-based protocols that apply to all persons within the Division, and

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copies are distributed to all persons involved in calibration work. IRD Guides are referenced throughout IRD-QM-II and are appended to the IRD-QM-II in a separate section. A list of these Guides is shown in Table 4.3.

IRD Guide No.	IRD Guide Title
01	Protocol for Guide and Procedure writing
02	Control of quality-system documentation
03	Purchasing of services and supplies
04	Complaints
05	Protection of clients' confidentiality
06	Laboratory notebooks
07	Nonconformance
08	Corrective action
09	Preventive action
10	Internal audits and management reviews
11	Training
12	Changes to disseminated values
13	Customer comments

IRD-QM-II Procedures contain protocols for performing specific calibration services. IRD Procedures are developed as needs arise or new calibration services are established. Established Procedures will be reviewed by IRD staff on a biannual basis to assure that practices remain valid and practicable. Procedures may be revised at any time if it is found that existing methods are inadequate or that better protocols have been identified. Procedures will be reviewed by appropriate staff including, but not limited to, the Quality Manager, the Group Leader and, if applicable, an independent reviewer. A list of these Procedures is shown in Section 5.1.

## 4.3.2 Document Approval and Issue

The official version of IRD-QM-II is maintained by the IRD Quality Manager. The master copy is secured in a locked cabinet of the IRD Quality Office. A single shelf copy also located in the IRD Quality Office is the only other controlled copy. The IRD Quality System is disseminated to IRD staff via the Internet. An uncontrolled (read/print-only) copy of the IRD Quality Manual and associated documents are available on the NIST external website through a link on the IRD home page: {<http://www.physics.nist.gov/Divisions/Div846/QualMan/index.html>}.

## 4.3.3 Document Changes

The IRD Quality Manager is responsible for coordinating updates to the manual. Changes may be performed incrementally, by subsection or appendix numbers, or by a general revision to the entire document. The Quality Managers, Group Leaders, and Division Chief will review the manual in its entirety every 2 years.

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After a revision of IRD-QM-II is approved as the official version, the IRD Division Quality Manager will notify all IRD staff that a revised version of IRD-QM-II is now official and available on the IRD Quality System intranet. This notice shall indicate those sections of IRD-QM-II that have been revised. A copy of the official version as well as historical records pertaining to, and copies (clearly marked as obsolete) of all previous versions of IRD-QM-II shall be maintained on a separate backup system. These documents are official parts of the NIST QS documents.

## 4.3.4 Control of Records

Records are generated as part of the quality and calibration systems. Each IRD Procedure that generates a record includes procedures for the identification, handling, filing, storage, maintenance, and disposal of the records. This includes both calibration and quality procedures.

The Quality Manager shall hold all quality documentation that is generated by this manual and its procedures (not calibration records, see Section 4.3.4.2 below) secure. All records shall be maintained in appropriately marked notebooks or files.

### 4.3.4.1 Maintenance of Computer Records

All official records, at this time, are kept only as hard copy. Electronic records are maintained only to facilitate data processing and report generation. If, in the future, it is decided to maintain electronic or computer records, procedures incorporating the Physics Laboratory policy (see below and Guide IRD-G-06) shall be developed prior to the implementation of such a program.

### 4.3.4.2 Calibration Records

Each calibration/SRM service shall maintain detailed technical records that include, but are not limited to, 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 issued. Records for each SRM or calibration shall contain sufficient information to enable the test or calibration to be repeated under conditions as close as possible to the original.

The records shall include the identity of personnel responsible for sampling, performance of each test and/or calibration and checking of results. They shall also contain sufficient information to identify the factors affecting the uncertainties. Guidelines of IRD-G-06 should be used for all records to the extent possible.

Records may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, clients' notes, papers, and feedback. Records may be kept in laboratory and research notebooks (see next section and IRD-G-06) or in client files. All data shall be recorded in a timely manner and shall be identifiable.

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Records for each calibration/SRM are kept in accordance with the procedure set for that calibration or SRM service. Each calibration/SRM service determines the facilities in which its records are stored. The facilities are included as part of the calibration and/or testing procedures. The retention time for calibration records is three years, in accordance with the policy set by the NIST Technology Services. The calibration documentation shall be handled by the calibration/SRM personnel in such a way that its integrity is not jeopardized in any way and that client confidentiality is maintained.

### 4.3.4.3 Confidentiality

All staff of the IRD shall strive to maintain the confidentiality of the results of calibrations (see Guide IRD-G-005). Results will be dispensed only to those persons who are duly authorized by the customer to receive them.

Official results are not electronically transmitted, therefore policies or procedures have not been written for protecting the confidentiality of such transmissions.

Electronic files containing information pertaining to a customer calibration (communications, experimental design, results, etc.) are stored such that access to these files is restricted to all except the relevant IRD staff. The confidentiality of stored files on personal computers maintained by IRD staff or servers dedicated to IRD staff are assured through IRD adherence to the *NIST Policy on the Management and Use of Passwords to Control Access to Information Technology Resources* {[http://www-i.nist.gov/cio/itsd/pp\\_nist/policy/policy\\_passwd.html](http://www-i.nist.gov/cio/itsd/pp_nist/policy/policy_passwd.html)}

### 4.3.4.4 Laboratory Notebooks

The Physics Laboratory, of which the Ionizing Radiation Division is a part (NIST-QM-I, Figure 4.1), maintains a policy on laboratory and research notebooks. This policy extends to keeping records of electronic and computer files.

In a Memorandum dated 24 May 1994, the Physics Laboratory established its minimal practices for technical record keeping in accordance with the NIST Policy on Research Notebooks of 21 August 1992. This policy is stated below and ensures that measurement and research activities are properly documented in order to: preserve the institutional memory embodied within its staff; establish the basis for published outputs; and, safeguard the intellectual property of NIST, the Physics Laboratory, and our customers.

The research notebook consolidates a chronological record of scientists' work into a single document that captures their thoughts and ideas, and establishes a "road map" to research records either contained within the notebook or located elsewhere. The implementation of the Physics Laboratory policy is contained in procedure IRD-G-06.

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- All Physics Laboratory staff engaged in measurement and in research and development activities are responsible for maintaining a thorough and accurate record of their work by keeping a laboratory or research notebook
- Staff using electronic media in such activities are responsible for indexing electronic work files so that experimental data and results are retrievable.
- All laboratory and technical unit managers are responsible for ensuring that the technical activities of their staff are fully documented and that appropriate control measures are in place so that either paper or electronic records of data and results are retrievable.
- Managers are responsible for instructing their staff on appropriate procedures for their unit.
- All technical records, including laboratory research notebooks, journals, electronic records, data, calculations, etc., pertaining to NIST activities are official files of the U.S. Government and are the property of the Government, not the employee.
- Laboratory and technical unit directors are responsible for ensuring that these records are not destroyed or removed from NIST without proper authority even when an employee transfers, retires, or otherwise separates from NIST.

## 4.4 Administrative Requirements

Provision of a NIST-IRD calibration or certification generally involves the following steps:

1. The customer communicates with a technical contact responsible for the calibration/SRM service (the customer can find technical contacts listed under the heading Ionizing Radiation Measurements at { <http://ts.nist.gov/ts/htdocs/230/233/calibrations/ionizing-rad/index.htm> }).
2. This contact initiates a process to determine the customer's needs and the ability of the IRD to address them. Agreement between the customer and the IRD technical contact leads to acceptance of a customer's purchase order (PO).
3. Authorized IRD personnel enter the PO data into the ISSC database and fax the PO to the NIST Measurement Services Division (MSD).
4. The ISSC assigns the calibration or test an official Test Folder number. The customer is notified of acceptance and provided a password (unique to the Test Folder number) to allow monitoring the progress of the calibration via internet access to the ISSC.
5. Calibration items are received at NIST by the Logistics Group in the Acquisition and Logistics Division and delivered to the IRD. Unpacking and inspection of the calibration items is done by IRD calibration personnel.
6. Calibrations typically involve data gathering, data analysis, report preparation, technical review of the report, and approval for signature. After the report is signed, it is sent to the customer, the Test Folder is closed and returned to the MSD, and the IRD Administrative Officer notifies the NIST Finance Officer to invoice the customer.
7. If applicable, the IRD prepares the calibration item for shipping, and the Logistics Group arranges for pick up by the shipping agency.

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Additional information about the activities within this general framework and the staff responsible for various steps are presented for each IRD procedure and described in IRD-QM-II Section 5.

## 4.4.1 Review and Approval of Requests for Calibrations

The IRD abides by the NIST policies pertaining to requests for calibration services (see NIST-QM-I Section 4.4.1). Any additional criteria and procedures specific to IRD calibrations are described in IRD-QM-II Section 5.

## 4.4.2 Procuring Products and Services, External Sources

The IRD abides by the NIST policies pertaining to procurement of products and services from external sources (see NIST-QM-I Section 4.4.2). Any additional criteria and procedures specific to IRD calibrations are described in IRD-G-03 or IRD-QM-II Section 5.

## 4.4.3 Interaction with NIST Supporting Divisions

The IRD strives to communicate concisely and clearly the actions desired/required of NIST supporting services to allow quality goals to be achieved.

## 4.4.4 Subcontracting of Tests, Calibrations and Reference Material Certifications

The IRD abides by the NIST policy on subcontracting (see NIST-QM-I Section 4.4.4).

## 4.4.5 Reference Materials Production Planning and Control

The IRD abides by the NIST policy on reference material planning and control (see NIST-QM-I Section 4.4.5).

## 4.5 Corrective and Preventive Actions

### 4.5.1 Nonconformity

The IRD is committed to NIST QS policies regarding management of nonconformity events (see NIST-QM-I Section 4.5.1).

The IRD has attained extensive experience in performing calibrations of radiation reference fields, radiological instrumentation, the preparation of SRMs and the performance of dosimeter irradiations. Despite this experience, discrepancies and, in some cases, incorrect measurements are possible. There are various sources of discrepancies that might possibly be identified internally by laboratory staff or externally by clients. The IRD Guide IRD-G-07 identifies the various levels of discrepancies, conditions requiring client notification, and the IRD procedures applicable to dealing with items of nonconformance. Complaint forms (see IRD-G-04) may or

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may not be initiated as part of the discrepancy. The IRD Guide IRD-G-12 describes the protocol used to make changes in disseminated calibration or measurement values.

Any person, be it a staff member, management, or client, may call attention to a matter that may require corrective action. The person(s) with responsibility for the calibration or test, equipment, or quality system has the responsibility for implementing corrective actions. The corrective action may be carried out by anyone with the proper experience to perform the required action (see IRD Guide IRD-G-08). The Group Leader and/or Quality Manager may be requested to verify results prior to commencing with routine calibration and/or testing.

## 4.5.2 Customer Complaints

Customer feedback/concerns categorized as “complaints” (see NIST-QM-I Section 4.5 and IRD Guide IRD-G-04) specifically regarding the technical aspects of any IRD calibration service that includes, but is not limited to, the characterization of reference fields, performance of measurements or irradiations, preparation of SRMs, reporting issues, personnel qualifications, etc., are documented and investigated promptly (see IRD Guide IRD-G-04). The Quality Manager maintains an IRD complaint file.

The person receiving the complaint is responsible for initiation of a Customer Complaint Report (IRD-G-04) and completion of the Complaint section. The customer is strongly encouraged to submit the complaint with enough supporting documentation to facilitate a thorough investigation of the technical issues. Applicable processes will be audited, and investigations will be documented.

IRD staff members are encouraged to work closely with the customer to resolve the complaint.

## 4.5.3 Preventive Actions

At times, potential sources of nonconformance or opportunities for needed improvement may be identified either in the technical or quality systems. This can result in modification to procedures, modification to or purchase of new equipment, etc. The IRD management encourages all calibration and testing staff to continually seek opportunities to identify system improvements. If preventive action is required, action plans shall be developed, implemented, and monitored in accordance with IRD-G-09.

## 4.5.4 Customer Comments

Customer feedback regarding any aspect of an IRD calibration service that are offered as suggestions for consideration as future improvements are documented and disseminated promptly (see IRD Guide IRD-G-13). The Quality Manager maintains an IRD comment file.

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The person receiving the comment is responsible for submitting it to the Quality Manager with a Customer Comment Form (IRD-G-13.A). The comment is distributed to IRD management and calibration staff as appropriate.

IRD staff members are encouraged to work closely with the customer to ensure the customer statement is interpreted correctly as a comment (see IRD Guide IRD-G-13 for more details).

## 4.6 Internal Assessments and Management Reviews

### 4.6.1 Assessments

The IRD abides by the NIST-level assessments organized by the MSAG (see NIST-QM-I Section 4.6.1).

In order to verify continued compliance with the requirements of the quality system, the IRD conducts internal audits periodically in accordance with Guide IRD-G-10. The Quality Manager will prepare a schedule to ensure that all quality system elements are audited over the course of one year. The audits will be planned and organized by the Quality Manager, and carried out by trained and qualified personnel who, resources permitting, are independent of the activity being audited.

### 4.6.2 Management Reviews

The IRD abides by the NIST-level executive management reviews organized by the MSAG (see NIST-QM-I Section 4.6.2).

Management reviews will be conducted once every twelve (12) months. The quality system and testing and/or calibration activities will be reviewed to ensure their continuing suitability and effectiveness and to introduce necessary changes or improvements. The results of these reviews will feed into the laboratory planning system and will include the goals, objectives and action plans for the coming year.

## 4.7 Service to the Client

The IRD abides by the NIST client service policy (see NIST-QM-I Section 4.7). One of the primary modes of client communication is through CIRMS (see IRD-QM-II Section 4.2.2.5).

## 5 Technical Requirements

### 5.1 Introduction

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This Quality Manual covers the IRD calibration services that are listed in the *NIST Calibration Services Users Guide*, NIST SP 250. It covers testing and calibrations performed using standard methods, non-standard methods and laboratory-developed methods. The scope of calibration services provided by the IRD varies from Group to Group as described below. The calibration services personnel, to assure that clients receive ionizing-radiation calibrations of the highest accuracy, follow the practices documented in this Quality Manual. The seventeen services offered by the IRD and within the scope of this Quality Manual are listed in Table 5.1.

IRD Procedure	NIST Service Code	Service Title
01	43010C	Gamma-Ray-Emitting Radionuclides in Solution (Half Lives Greater than 15 Days)
01	43020C	Gamma-Ray-Emitting Radionuclides in Solution (Half Lives Less than 15 Days)
02	43030C	Alpha-Particle-Emitting Solid Sources, NIST 2 $\pi$ alpha Proportional Counter
02	43040C	Alpha-Particle-Emitting Solid Sources, NIST 0.8 $\pi$ alpha Defined-Solid-Angle Counter
02	43050C	Alpha-Particle-Emitting Solid Sources, Using Both Counting Systems
03	46011C	Calibration of X-Ray Radiation Detectors
04	46010C	Calibration of Gamma-Ray Radiation Detectors
05	46020C	Passive Dosimeters—Irradiation of Up to Six, One Beam Quality at One Set-Up
06	46110C	Absorbed-Dose-To-Water Calibrations For Ionization Chambers
07	47010C	Gamma-Ray Sources, Co-60, Cs-137, Ir-192
08	47020C	Low-energy Photon Brachytherapy Seeds, <sup>125</sup> I, <sup>103</sup> Pd
09	47030C	Beta-Particle Sources Calibrated for Surface Dose Rate
10	47035C	Beta-Particle Sources Calibrated for Radiation Protection
	47036C	Ionization Chambers Calibrated with Beta-Particle Sources for Radiation Protection
11	49010C	Calibration Irradiations of Customer Supplied Dosimeters with <sup>60</sup> Co Gamma-Rays
12	49020C	Dose Interpretation of NIST Transfer Dosimeters Irradiated by Customer
13	44010C	Radioactive Neutron Sources Emission Rates (10 <sup>5</sup> /s to 10 <sup>8</sup> /s)
13	44020C	Radioactive Neutron Sources Emission Rates (10 <sup>8</sup> /s to 10 <sup>10</sup> /s)
14	44060C	Personnel Protection Instrumentation, Californium Source Bare and Moderated
15	SRM 4xxx	Radioactivity Standard Reference Materials
16	SRM 4xxx	Natural-Matrix Radionuclide Standard Reference Materials

While committed to quality work and many of the policies included in this document, other activities (i.e., special measurements/tests, research and development, contract, CRADA, or

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other cooperative activities) of the IRD are not within the scope of this quality manual. The NIST Service Codes for special tests not included in the IRD Quality Manual are: 43060S; 43070S; 43090S; 44070C; 44080C; 44090C; 44100S; 46030S; 46040S; 46050S; 47040S; 48020S; and, 49050S. The service listed as 48010M, *Dose Interpretation of NIST-Packaged Dosimeters Irradiated by Customer -- Two Dosimeters*, is temporarily inactive while its procedures are undergoing revision. A procedure for this service will be included at the appropriate time.

## 5.1.1 Establishment/Termination of an IRD Calibration Service

The policies that govern the decision to either establish or terminate an IRD calibration service are developed and maintained by the NIST Measurement Services Advisory Group (MSAG). The MSAG guidelines for the establishment of an IRD calibration service are shown in Appendix C. The MSAG guidelines for the establishment of an IRD calibration service are shown in Appendix D.

## 5.2 Personnel

Personnel in the IRD have responsibility for carrying out NIST's overall mission. As a result, official position descriptions are broader in scope than those required for calibration duties. Appendix E lists all personnel currently associated with the various calibration, testing and SRM programs. The Group Leaders maintain the specific job description/performance plan for each person in their group.

All IRD personnel have the authority needed to carry out their duties and to determine the resources necessary to do so. Authority is extended to include the identification of departures from the quality system or from the procedures for performing tests and/or calibrations, to initiate actions to prevent or minimize such departures, and to identify training that is necessary to maintain or improve their skills.

Support from collaborators (non-NIST laboratories and personnel) in the development and certification of a SRM is provided in accordance with the policies set forth in NIST-QM-I Section 5.2.4. The Division Chief authorizes a collaborator to prepare SRMs. The authorization and its effective date are established through written notification from the Division Chief to the Quality Manager. See IRD-QM-II Section 5.2.4.

### 5.2.1 Competence

Assuring competence is the direct responsibility of the management chain for scientific research and services of the IRD, as described in IRD-QM-II Section 4.1.3.2. The competence of an IRD staff member is achieved through demonstrated proficiency of a specific service. The Group Leader declares the competence of a staff member to perform a specific calibration service in a written notification to the Division Chief. The staff member is authorized to perform a calibration service through a written notification from the Division Chief to the Quality Manager.

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Group Leaders must have at least a M.S. degree in a related field with at least ten years of ionizing radiation experience. They must have experimental or theoretical experience in calibrations, radiation measurements, and a wide range of radiation applications. They must also be familiar with both government and private industry needs. The NIST Physics Laboratory sets other requirements for the position.

The Quality Manager must have at least a B.S. in health physics or a related field with five years of ionizing-radiation measurements experience. He/she must have experience in calibrations, radiation measurements, instrument evaluation, computer record keeping, and a wide range of radiation applications. He/she must also have good communication skills, both written and oral, and shall be familiar with both government and private industry needs.

Calibration/SRM Personnel must be trained radiation workers and must be familiar with the operation of radiation-generating devices when applicable. They must have basic computer skills and should be familiar with a wide range of radiation-measurement instruments. Familiarity with laboratory procedures and calibration techniques are also required.

Contract personnel are supervised by IRD staff members to ensure that they are competent and work in accordance with the IRD Quality System.

## 5.2.2 Education and Training Goals

The IRD recognizes the importance of education and training of calibration personnel and of Division management to maintain the quality goals of this manual. Calibration/SRM personnel are encouraged to have a bachelors degree or higher. Management encourages educational development of calibration and SRM personnel and fully supports higher education.

Calibration procedures are developed by the calibration personnel through experience and personal contacts with staff of other calibration laboratories. Calibration personnel who write procedures are considered fully trained on their procedures once they are placed in the appropriate procedure manual. If other personnel are to learn the calibration procedure, they work closely with the person responsible for the calibration procedure until they can maintain the same level of quality service.

Management and calibration personnel are encouraged to expand their education and training by reviewing technical journals, attending meetings of technical societies, attending classes, workshops, seminars and technical meetings dealing with related issues, and actively participating with organizations developing and implementing ionizing radiation standards.

## 5.2.3 Ethics

NIST maintains policies and procedures for personnel to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity,

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i.e., participation in political party activities, financial disclosures, etc. Ethics training is conducted by NIST on an annual or biannual basis, depending on job function, to keep personnel informed on the policies.

## 5.2.4 Collaborators

The IRD abides by the NIST collaborator policy (see NIST-QM-I Section 5.2.4). Collaborators (non-NIST laboratories and personnel), typically research associates and contractors, are authorized by the Division Chief to perform specific supporting functions (IRD-QM-II Section 5.2). IRD staff members responsible for an IRD Service Procedure oversee collaborator performance. At the discretion of the IRD Quality manager, collaborators may be required to attend an IRD QS training session.

## 5.3 Accommodations and Environmental Conditions

The IRD determines the requisite conditions, and, working in collaboration with the Plant Division, Facilities Services Division, and Engineering Safety, Maintenance and Support Division, is responsible for assuring that environmental conditions do not adversely affect the quality of calibration services. Specific requirements and methods are defined in the IRD Procedures.

## 5.4 Calibration and Certification Procedures

### 5.4.1 Calibrations and Certification

Detailed descriptions of the calibrations and certifications offered (see Section 5.1), and the associated procedures, methods of validation, and measurement uncertainty, are documented in the IRD Procedures.

### 5.4.2 Reference Materials

The IRD uses appropriate, documented methods and procedures when preparing and certifying SRMs. The general policies governing these activities (see NIST-QM-I Section 5.4.2) are adhered to by IRD SRM personnel.

### 5.4.3 Estimation of Uncertainty

The IRD uses the NIST approach to quantitative statements of uncertainty described in NIST-QM-I Section 5.4.2 and NIST-QM-I Appendix D. The uncertainty analysis for each calibration service is described in each of the IRD Procedures.

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## 5.5 Equipment

All IRD calibration services included in the IRD-QM-II Procedures section are conducted in Building 245, Radiation Physics, on the NIST campus in Gaithersburg, MD. The building also houses parts of two other divisions of the Physics Laboratory and the Health Physics Group of the Occupational Safety and Health Division.

Calibration facilities for each service are described in full in the appropriate calibration service documentation or in the IRD-QM-II Procedure specific to that calibration service. This documentation is listed in Appendix A.

Equipment used in association with calibration services is listed in the appropriate service documentation. This list includes equipment currently in use, back-up equipment and associated calibration schedules and/or procedures. Equipment maintenance is performed as needed based on staff expertise and monitoring of performance data. Equipment requiring calibration with a fixed periodicity are labeled, coded or otherwise identified to indicate the status of the calibration, including the date when last calibrated and its expiration date. Equipment may also be calibrated on an as-needed basis through the monitoring of performance data. Equipment requiring calibration outside the direct control of the IRD is checked upon return to ensure that it is operating within expected limits.

Persons not associated with the IRD often use the radiological resources within these facilities. National and international guest researchers, students, and calibration customers often use the national standards for purposes other than calibration work. Another user of the IRD resources is the Health Physics Group of the Occupational Health & Safety Division (OHSD). The Health Physics Group provides external dosimetry to NIST employees and guests using the NIST radiological facilities. The IRD does not depend on any specific technical product or service from any outside user in attaining a quality process. IRD calibration services take precedence over any other usage of the national standards.

## 5.6 Measurement Traceability

The IRD uses the NIST definition of traceability described in NIST-QM-I Section 5.6.

### 5.6.1 Policy

It is IRD policy to establish traceability of the results of its own measurements and values of its own standards and of results and values provided to customers in IRD calibrations.

#### 5.6.1.1 Radioactivity

The SI unit of radioactivity is the Becquerel (Bq). The efficiency points for all secondary measurement systems are obtained, for each radionuclide measured, using NIST Standard Reference Materials (SRMs), which are, in turn, validated through intercomparisons with other

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National Metrology Institutions and the periodic submission of measured sources to the International Reference System (SIR) for gamma-ray emitting sources at the BIPM (<http://www.bipm.org/en/scientific/ionizing/radionuclides/sir/>). Efficiency curves for point sources (solids), 5 mL ampoules (liquids) and 33 cm<sup>3</sup> spheres (gas), where appropriate, for gamma-ray emitting sources for the covered energy range are available for impurity and activity calibration measurements.

## 5.6.1.2 Radiation Interactions and Dosimetry

The Radiation Interactions and Dosimetry Group maintains the national standards for one of the International System of Units (SI) units, the gray for radiation dosimetry. The gray is the unit for the (derived) quantities kerma and absorbed dose. These quantities generally apply to any absorbing medium, but – in conformance with international practices in metrology – our standards are centered on air kerma and absorbed dose to water, as outlined below.

- Absorbed dose to water from suitable <sup>60</sup>Co beams: direct realization by a water calorimeter.
- Air kerma from suitable <sup>192</sup>Ir, <sup>137</sup>Cs and <sup>60</sup>Co beams: direct realization by graphite-walled, air-filled ionization chambers.
- Air kerma from suitable x-ray beams with maximum energies from 10 keV to 300 keV: direct realization by free-air ionization chambers.
- Absorbed dose to water from suitable beta emitters: direct realization of absorbed dose to air by an air-ionization extrapolation chamber, then corrected to absorbed dose to water.

## 5.6.1.3 Neutron Interactions and Dosimetry

The emission rates of neutron sources (neutrons per second) are measured relative to that of the National Standard Neutron Source NBS-I by comparison of activation of manganese in a totally absorbing manganese bath. The emission rate of NBS-I is known from absolute beta-gamma coincidence counting of induced manganese activity with corrections for neutron capture in other bath constituents, and from other independent methods (SP250-18). The dose-equivalent rate from a bare <sup>252</sup>Cf sources is based on the spectral fluence rate from the source and fluence-to-dose conversion factors recommended by the International Commission on Radiation Protection (ICRP Publication 21, 1973). The spectral fluence from a bare <sup>252</sup>Cf source is known from an evaluation of a large body of experimental data (ISO 8529-1). For the dose-equivalent rate from a D<sub>2</sub>O moderated <sup>252</sup>Cf source, the spectral fluence is based an evaluation of Monte Carlo calculations (also in ISO 8529-1), beginning with the spectral fluence from the bare source, and the same fluence-to-dose conversion factors. The emission rates of the <sup>252</sup>Cf sources are known by comparison to NBS-I.

## 5.6.2 Traceability Services

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To assist IRD customers in establishing traceability of results of measurements or values of standards, the IRD provides calibrations, standard reference materials, standard reference data, measurement quality assurance programs, and laboratory accreditation services.

## 5.7 Sampling

### 5.7.1 Calibrations

IRD calibration services and calibrations of individual instruments do not use sampling.

### 5.7.2 Certification of Standard Reference Materials

Authorized IRD staff designated as principal investigators for SRM Procedures are required to develop an SRM development sampling plan in cooperation with the Statistical Engineering Division. Principal investigators are responsible for ensuring that the sampling operations conform to this plan. The details of the preparation, homogeneity and stability assessment specific to each SRM are documented in SRM production records and/or certificates.

## 5.8 Handling of Test and Calibration Items

The diversity of the calibration services offered by the IRD precludes a uniform method for the handling of calibration items. Therefore, each calibration service shall provide this information in their described Procedure.

All items sent in for calibration will be inspected by calibration personnel to verify that all items are included based on the customer's documentation. Items will also be inspected for defects or damage. If it is determined that the calibration requirements can not be achieved, the calibration personnel will contact the customer and follow Nonconformance Guide IRD-G-07. Customers will also be consulted in the event that any instructions are unclear. All customer contacts pertinent to the calibration shall be recorded and kept in the calibration logbook or the customer's file.

## 5.9 Quality Assurance Practices

IRD calibration and SRM services make use of quality assurance practices to ensure the validity of calibration and certification results and their uncertainties. Such practices can include:

- repeat measurements/calibrations compared over many time intervals
- comparison of results obtained using multiple reference standards
- use of check standards and control charts
- use of redundant experimental designs
- comparison of results obtained using two or more different measurement approaches

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- results of national and international comparisons, including CIPM key comparisons
- correlation of results for different characteristics of an item

The IRD Procedures detail the quality assurance practices for specific calibration/SRM services.

## 5.9.1 Bilateral comparisons

Interlaboratory comparisons with other national standards laboratories have long been used to ensure that the NIST standards maintain equal status with those of its peers worldwide. Bilateral comparisons are generally carried out between two national laboratories. Any participating party may initiate the comparison. Protocols are generally written, but can also be oral. The results are presented in a report prepared by the testing laboratory and are sometimes published. When the IRD serves as the testing laboratory, all information and documentation pertaining to the comparison is maintained in a manner similar to the calibration service that is being compared. Bilateral comparisons are listed or referenced in the service Procedure documents.

## 5.9.2 Key comparisons

A group of National Metrology Institutes (NMIs) belonging to the Comité International des Poids et Mesures (CIPM) has signed a Mutual Recognition Arrangement (MRA) "to establish the degree of equivalence of national measurement standards maintained by NMI's, to provide for the mutual recognition of calibration and measurement certificates issued by NMI's, [and] thereby to provide governments and other parties with a secure technical foundation for wider agreements related to international trade, commerce and regulatory affairs." Key comparisons are selected by the relevant Consultative Committee of the CIPM to test the principal techniques and methods in the field among the NMIs as part of the MRA. A key comparison database is maintained by the Bureau International des Poids et Mesures (BIPM). NIST Technology Services maintains an International Comparisons Database.

## 5.10 Reporting Results

### 5.10.1 Reports of Calibration or Certification

IRD Reports of Calibration or Certification are in accord with the NIST-QM-I requirements (see Sections 5.10.1 and 5.10.2). Report examples are included in each IRD Procedure. Additional requirements include:

- Opinions and/or interpretations shall be clearly marked as such. Documents supporting the basis for any opinions and/or interpretations shall be included.
- Only complete, signed paper versions of certificates shall be considered official. The transmission of results by telephone, facsimile, or electronically shall not be considered official.
- Amendments to a calibration or certification shall be a separate document and clearly marked as such.

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- If a replacement report of calibration or certification is issued it shall be uniquely identified (See Guide IRD-G-12) and contain a reference to the original that it replaces.

## 5.10.2 Signatory Authority

All Reports of Calibration or Certification are signed “for the Director of the National Institute of Standards and Technology” by the IRD Chief or his/her designate. Those designated with the authority to sign a report (*i.e.*, an Acting Division Chief or Acting Group Leader) must have attended an IRD Quality System training session.

The calibration personnel, Group Leader and the Division Chief sign calibration reports. Calibration personnel have the responsibility to sign off on reports they have written or reviewed as an independent reviewer. Calibration personnel and managers who sign reports must have attended an IRD Quality System training session.

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## Appendix A. References

### SP 250 Publications

NOTE: These are a collection of documents written to support the NIST SP250 Calibration Services Guide. These documents explain the various calibration services including, but not limited to, the procedures and facilities used for the calibration. These documents describe the realization and measurement traceability aspects of the calibration service in greater detail than the IRD-QM-II Procedures. However, the methodologies and operational aspects for the individual services described in the IRD-QM-II Procedures supersede those published in SP250 publications. These documents are available on the NIST website {[http://ts.nist.gov/ts/htdocs/230/233/calibrations/Publications/sp250\\_series.htm](http://ts.nist.gov/ts/htdocs/230/233/calibrations/Publications/sp250_series.htm)}.

- NBS Special Publication 250-4 – *Fricke dosimetry in high-energy electron beams*
- NBS Special Publication 250-5a – *Alpha-particle calibrations*
- NBS Special Publication 250-9 – *Calibration of beta-particle-emitting ophthalmic applicators*
- NBS Special Publication 250-10 – *Radioactivity calibrations with the “4 $\pi$ ” gamma ionization chamber, and other radioactivity calibration capabilities*
- NBS Special Publication 250-12 – *Neutron personnel dosimetry*
- NBS Special Publication 250-13 – *Activation foil irradiation with californium fission sources*
- NBS Special Publication 250-14 – *Activation foil irradiation by reactor cavity fission sources*
- NBS Special Publication 250-16 – *Calibration of x-ray and gamma-ray measuring instruments*
- NBS Special Publication 250-18 – *Neutron source strength calibrations*
- NBS Special Publication 250-19 – *Calibration of gamma-ray emitting brachytherapy sources*
- NBS Special Publication 250-21 – *Calibration of beta-particle radiation instrumentation*
- NIST Special Publication 250-40 – *Absorbed-dose calibration of ionization chambers in a <sup>60</sup>Co gamma-ray beam*
- NIST Special Publication 250-44 – *Radiation Processing Dosimetry Calibration Services and Measurement Assurance Program*
- NIST Special Publication 250-45 – *Radiation Processing Dosimetry Calibration Services: Manual of Calibration Procedures*
- NIST Special Publication 250-58 – *Calibration of X-Ray and Gamma-Ray Measuring Instruments*

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## Appendix B. Definitions & Acronyms

### Definitions

**calibration method:** defined technical procedure for performing a calibration.

**check standard:** a standard that is used routinely to ensure measurement correctness.

**client (customer):** person (corporate or individual) who requests a calibration or test. This is usually someone external to NIST, but may be another NIST calibration service or researcher who will use the measurement results/data for their own reporting of official results.

**measurand:** a quantity subjected to measurement.

**national standard:** a standard recognized by an official national decision to serve in a country as the basis for fixing the value of all other standards of the quantity concerned.

**primary standard:** a standard that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity.

**quality manual:** a document stating the quality policy, quality system, and quality practices of an organization.

**quality system:** the organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

**reference standard:** a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

**secondary standard:** a standard whose value is assigned by comparison with a primary standard of the same quantity.

**test folder:** the document that indicates an official calibration or test has been requested by a client (external to NIST). This document must be created before any measurements are to be conducted on a client's test item.

**transfer standard:** a standard used as an intermediary to compare standards. Note: the term "transfer device" should be used when the intermediary is not a standard.

**working standard:** a standard that is used routinely to calibrate or check material measures, measuring instruments or reference materials. Notes: 1) A working standard is usually

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calibrated against a reference standard. 2) A working standard used routinely to ensure that measurements are being carried out correctly is called a “check standard.”

## Acronyms

BIPM	Bureau International des Poids et Mesures
CIPM	Comité International des Poids et Mesures
DOC	(United States) Department of Commerce
IRD	Ionizing Radiation Division
ISO	International Organization for Standardization
ISSC	Information System to Support Calibrations
MRA	Mutual Recognition Arrangement
NIST	National Institute of Standards and Technology
NMI	National Metrology Institute
NRC	(United States) Nuclear Regulatory Commission
NRCC	National Research Council – Canada
PL	Physics Laboratory
SRM	Standard Reference Material

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## Appendix C. Establishment of an IRD Calibration Service

Approved by Measurement Services Advisory Group

January 29, 2002

### Establishment of NIST Calibration Services

The decision to provide a new NIST calibration service requires a careful assessment of the role the service will play for NIST's customers. The following policy documents the procedures and roles and responsibilities in reaching that decision. This policy applies to Regular Calibration Tests (as listed in SP250), Special Tests, and Measurement Assurance Programs. In this policy, the phrase "calibration service" refers to all three types of service.

A Laboratory proposing to establish a new NIST calibration service will inform the NIST Measurement Services Advisory Group (MSAG) of the intended new service. The Laboratory should do this early in the process of developing the new service. This will ensure that the proposed service does not conflict with existing or planned measurement services of other Laboratories.

It is the responsibility of the individual Laboratories to ensure that the new calibration service is in compliance with the *NIST System for Assuring Quality in the Results of Measurements Delivered to Customers in Calibration and Measurement Certificates*.

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## Appendix D. Termination of an IRD Calibration Service

Approved by Measurement Services Advisory Group

January 29, 2002

### Termination of NIST Calibration Services

The decision to terminate a NIST calibration service requires a careful assessment of the role the service plays for NIST's customers and of the potential impact of the termination. The following policy documents the procedures and roles and responsibilities in reaching that decision. This policy applies to Regular Calibration Tests (as listed in SP250), Special Tests, and Measurement Assurance Programs. In this policy, the phrase "calibration service" refers to all three types of service.

The responsibility for terminating measurement services belongs to the individual Laboratories. It is recognized, however, that the customers of the terminated service might include other NIST Laboratories. Therefore, when a Laboratory has decided to begin the process of terminating a service, the Laboratory Director should inform MSAG members of that decision along with an identification of known NIST customers of that service in order that arrangements can be made to meet the needs of these customers.

The NIST Laboratories have the responsibility of assessing the impact of a proposed termination. In order to do this they should notify customers of the last five years informing them of the proposed service termination, proposed alternatives for the customers, and including a request for comments. When appropriate, the letter should also be sent to standards writing and similar organizations potentially affected by the service termination.

Service termination should not take effect until at least one year after the Laboratory has notified the affected parties.

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## Appendix E. IRD Calibration Service Personnel

Title	Name	Authorized Service Functions	Date
<b>Ionizing Radiation Division</b>			
Division Chief	B.M. Coursey		
Acting Chief	as assigned		
Deputy Chief	L.R. Karam		
Quality Manager	M. F. Desrosiers	(see below)	
Deputy Quality Manager	J. M. Puhl	(see below)	
Administrator Officer	M. A. Dewese	Billing	1/1/04
Division Secretary	W. M. Lease	ISSC database entry; Test folder management	1/1/04
<b>Radiation Interactions and Dosimetry Group</b>			
Group Leader	S.M. Seltzer		
Acting Group Leader	as assigned		
Physical Science Technician	S. L. Cooper	49010C; 49020C	1/1/04
Physicist	H. H. Chen-Meyer	46110C	1/1/04
Group Secretary	D. Copeland	Mailing; Filing	4/16/04
Research Chemist	M. F. Desrosiers	49010C; 49020C	1/1/04
Physicist	C. M. O'Brien	46010C [Procedure 4]	1/1/04
Physical Science Technician	J. M. Puhl	49010C	1/1/04
Physicist	R. Minniti	46010C [Procedure 3]; 46020C; 46110C	1/1/04
Physicist	M. G. Mitch	47010C; 47020C; 47030C; 47035C; 47036C	1/1/04
Physicist	C. G. Soares	47030C; 47035C; 47036C	1/1/04
<b>Neutron Interactions and Dosimetry Group</b>			
Group Leader	M. Arif		
Acting Group Leader	as assigned		
Physicist	D.M. Gilliam		
Physicist	M. S. Dewey	44010C; 44020C	1/1/04
Physicist	A. K. Thompson	44060C	1/1/04
Physicist	C. R. Heimbach	44060C	1/28/05
<b>Radioactivity Group</b>			
Group Leader	L.R. Karam		
Acting Group Leader	as assigned		
Physicist	J. T. Cessna	42010C; 42020C	1/1/04
Research Chemist	R. Collé	SRM 4xxxx [SRM Coordinator and Lead Staff for Procedure 15]	9/12/05
Research Associate	D. Golas	42010C; 42020C	1/1/04

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Title	Name	Authorized Service Functions	Date
Research Chemist	K. G. W. Inn	SRM 4xxxx [Procedure 15]	9/12/05
		SRM 4xxx [Lead Staff for Procedure 16]	3/1/05
Contractor	H. Kurosaki	SRM 4xxx [Procedure 16]	9/12/05
Physical Science Technician	M. M. Hammond	42010C; 42020C	1/1/04
Technician	L. King	42010C; 42020C; 42030C	1/1/04
Contractor	S. Nour	SRM 4xxx [Procedure 16]	9/12/05
Physical Scientist	B. R. Norman	42010C; 42020C	9/13/05
Contractor	I. Outola	SRM 4xxx [Procedure 16]	9/12/05
Research Associate	O. Palabrica	42010C; 42020C	1/1/04
		SRM 4xxxx [Procedure 15]	9/12/05
Physicist	L. Pibida	42010C; 42020C	1/1/04
Physicist	M. P. Unterweger	42010C; 42020C; 42030C	1/1/04

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