Radiation and Biomolecular Physics Division
Quality Manual

1. Introduction

1.1 Division Commitment to Quality

This Quality Manual defines the quality system of the Radiation and Biomolecular Physics Division (RBPD) of the Physical Measurement Laboratory (PML) at the National Institute of Standards and Technology (NIST).[1] It describes the processes by which the RBPD achieves and maintains high standards of quality in maintaining the U.S. national measurement standards for photon, electron, neutron and alpha-particle 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 (RBPD-QM-II) defers to the NIST Quality Manual (NIST-QM-I) institutional policies and procedures where applicable, 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 RBPD 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® (SRMs®) and the related services that the RBPD delivers.

Signed:

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1.2 Scope

This Quality Manual covers the RBPD 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.

[1] Quality system documents established prior to 2011 refer to the Ionizing Radiation Division (IRD) and the Physics Laboratory (PL) respectively.

The scope of calibration services provided by the RBPD varies from Group to Group as described below. This Quality Manual also covers the RBPD SRMs. The RBPD personnel, to assure that clients receive ionizing radiation calibrations and SRMs of the highest accuracy, follow the practices documented in NIST-QM-I and RBPD-QM-II.

The services offered by the RBPD (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 (SRMs);
- X-ray and gamma-ray dosimetry, and beta-particle dosimetry; and,
- Calibration of neutron sources and radiation-protection instruments for neutron fields.

Though not within the scope of this quality manual, other Division activities (*i.e.*, special tests/measurements, research and development, contract, CRADA, or other cooperative activities) are committed to quality.

1.3 Outline of RBPD Quality Manual for Calibration Services

The RBPD 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, Associate Director for Laboratory Programs, and laboratory Directors) through the NIST Quality Management System (QMS). 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 (RBPD-QM-II), contains policies, protocol guides (see Section 4.3), and technical procedures (see Section 5.1) established and maintained by the Radiation and Biomolecular Physics Division to meet its technical needs. The RBPD-QM-II explicitly references NIST-QM-I where appropriate.

- The specific protocols to carry out RBPD-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 RBPD-QM-II services are contained in its Procedures. Procedure contents include: technical procedures for calibrations and SRMs; handling and storage of calibration/SRM 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 RBPD. These documents are available to all calibration/testing personnel and are implemented by the appropriate personnel. A complete list of publications pertaining to the RBPD calibration and SRM services can be found in Appendix A. A list of informative references is contained in NIST-QM-I Section 2.1.

NIST policies on environmental-, safety-, and health-related activities are documented elsewhere (see NIST-QM-I Section 2).

3. Definitions

Acronyms and terms requiring definitions to assure the consistency and clarity of the RBPD-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 Radiation and Biomolecular Physics Division

4.1.1 Description

The Radiation and Biomolecular Physics Division (RBPD) is a Division within NIST's Physical Measurement Laboratory (PML) that provides calibration services and SRMs; the organizational chart describing this is shown in NIST-QM-I Figure 4.1. Three Groups within the RBPD 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 radioactive standard reference materials (SRMs). The organizational structure of the RBPD 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 RBPD's permanent facilities and at sites away from its permanent facilities.

4.1.2 Physical Locations for Quality System Activities

Located on the NIST Gaithersburg campus, Buildings 245 (Radiation Physics) and 235 (NIST Center for Neutron Research) contain the offices and laboratories of RBPD service 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 Radiation and Biomolecular Physics Division. Three of the four Groups within this Division are directly involved with the provision of the calibration reports and measurement certificates covered by this manual. RBPD-QM-II Figure 4.1 provides a schematic representation of this part of the NIST organization.

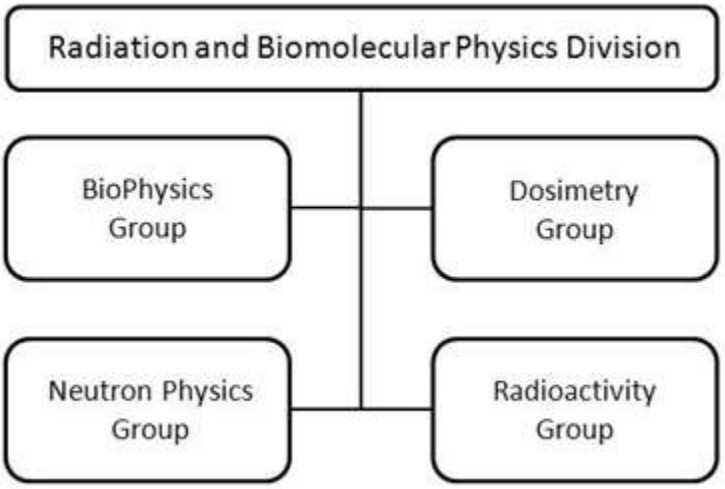

Figure 4.1. Organization chart for the four Groups that comprise the Radiation and Biomolecular Physics Division

The technical effort required to prepare an SRM or conduct a calibration or special test is made by scientific and technical staff within each Group. The NIST Calibrations Support System (CSS) in Technology Services provides business, administrative, and customer support for all calibrations. The CSS 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.

4.1.3.2 Responsibilities, Authorities, and Delegations

The responsibilities of the NIST Director, Associate Director for Laboratory Programs, Laboratory Directors and NIST Quality Manager are documented in NIST-QM-I Section 4.1.3.2 and Section 4.2.3.2).

The Radiation and Biomolecular Physics 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 RBPD Chief authorizes resource allocations (personnel, fiscal, equipment, and space) specifically for these efforts. The RBPD Chief is also responsible for ensuring the institutional competency needed to provide a calibration or SRM service. The RBPD Chief, or his/her designee, signs reports of calibration or certificates for the NIST Director.

Requirements for the position of Division Chief are set forth by the NIST Physical Measurement 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 RBPD Calibration and SRM Services

4.2.1 RBPD Quality Policy

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

4.2.2 RBPD Quality Objectives

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

4.2.2.1 Realization of Units

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

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

4.2.2.4 Improvement

The RBPD 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 RBPD 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 NIST QMS.
- 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 RBPD 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 RBPD 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 RBPD and is shown in NIST-QM-I Figure 4.3.

4.2.3.2 Responsibilities, Authorities, and Delegations

The responsibilities of the NIST Director, Associate Director for Laboratory Programs, Laboratory Directors and NIST Quality Manager are documented in NIST-QM-I Section 4.1.3.2 and Section 4.2.3.2).

4.2.3.2.1 RBPD Chief

The RBPD 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 RBPD 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 RBPD Chief will inform the NIST Director and the Physical Measurement Laboratory Director of issues that affect the quality of calibrations performed by the Division.

The RBPD 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 RBPD Chief approves the RBPD-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 by written authorization from the Group Leader to the Division

Chief. Group Leaders 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 RBPD-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. 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. The Calibration and SRM Personnel are responsible for the operation of all calibration equipment within their area of expertise, and for following established procedures for both safety and operations. They must 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 RBPD Division Chief and Quality Manager of any change in the SRM Coordinator designee. This designation is documented in RBPD-QM-II Appendix C.

4.3 Control of Documents, Records, and Data

4.3.1 Scope

This section of RBPD-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 RBPD-QM-II provides up-to-date references for the RBPD organization, capabilities, policies, and practices that are updated as necessary. RBPD staff members responsible for calibration and SRM work are required to read the Quality Manual and are expected to utilize it for reference as necessary.

RBPD-QM-II has two classifications of instructional documents, Guides and Procedures. RBPD-QM-II Guides contain policy-based protocols that apply to all calibration service and SRM personnel within the Division. RBPD Guides are referenced throughout RBPD-QM-II and are appended to the RBPD-QM-II in a separate section. A list of these Guides is shown in Table 4.3. RBPD-QM-II Procedures contain protocols for performing specific calibration services. RBPD Procedures are developed as needs arise or new calibration services are established. Established Procedures may be revised at any time if the need has been identified. A list of these Procedures is shown in Section 5.1. Guides and Procedures will be reviewed according to the protocol described in Guide RBPD-G-01.

RBPD Guide No.	RBPD 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

4.3.2 Document Approval and Issue

The official versions of the RBPD-QM-II, and its Guides, Procedures, forms and supporting documents, are maintained by the RBPD Quality Manager. The controlled versions of these quality documents are in electronic portable document format (PDF) located on the NIST servers and disseminated through the external website by a hypertext link on the RBPD home page

{http://www.nist.gov/pml/div682/qualitysystem.cfm }. Printed versions or electronic versions residing elsewhere (*i.e*., other physical locations or storage media) are uncontrolled.

4.3.3 Document Changes

The RBPD 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. Changes that are purely editorial (*i.e*., grammar, syntax) may be made immediately and without notification. The Quality Manager, Group Leaders, and Division Chief will review the manual in its entirety halfway through the five year RBPD Quality System assessment cycle (see Guide RBPD-G-01).

A draft version (with changes identified) of the Quality Manual is prepared by the Quality Manager and distributed to the RBPD staff, Group Leaders and the Division Chief. The draft version is reviewed for consistency with common practices, services, and policy. The Division Chief approves the Quality Manual by email or written notification to the Quality Manager.

After a revision of RBPD-QM-II is approved as the official version, the RBPD Division Quality Manager will notify all RBPD staff that a revised version of RBPD-QM-II is now official and available on the RBPD Quality System website. Notice of the revised RBPD-QM-II will be posted on the Document Revisions page of the RBPD Quality System website. A copy of the deleted document will be retained in the RBPD Quality System Office files.

4.3.4 Control of Records

Records are generated as part of the quality and calibration systems. Each RBPD 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 (but not calibration records; see Section 4.3.4.2) secure. All records shall be maintained in appropriately marked notebooks or files.

4.3.4.1 Maintenance of Computer Records

All official Quality Manual files are electronic. It is the responsibility of the Quality Manager to maintain the original files, including working versions (*e.g*., Word "doc" files) and associated graphic files. A backup of all documents are archived on RBPD internal servers. Records generated by Quality System activities (*i.e*., meeting notes, completed forms, etc.) are archived as hard copies in the Quality System Office files. For additional information, see Guide RBPD-G-02.

4.3.4.2 Calibration Records

Each calibration 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 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 RBPD-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 RBPD-G-06) or in client files. All data shall be recorded in a timely manner and shall be identifiable.

Records for each calibration are kept in accordance with the procedure set for that calibration service. Each calibration 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 NIST Technology Services. The calibration documentation shall be handled by the calibration personnel in such a way that its integrity is not jeopardized in any way and that client confidentiality is maintained.

4.3.4.3 SRM Records

Each SRM service shall maintain detailed technical records that include, but are not limited to, the radioactivity SRM production plan, detailed descriptions of the certification methods and procedures, measurement uncertainty, and sampling plans. Records for each SRM shall contain sufficient information to enable the production to be repeated under conditions as close as possible to the original. These documents are archived together and stored in Building 245, Room E103. The production information is retained for as long as the SRM is available for sale to the public, plus at least an additional 10 years.

For natural matrix SRMs, data, analysis printouts and copies of the SRM certificate are stored in folders identified by SRM number and held in the custody of the principal investigator. Folders of these SRM certificates are maintained in Building 245, Room C10 during the time of the SRM's availability. When the SRM becomes unavailable, a copy of the SRM certificate remains in that location.

4.3.4.4 Confidentiality

All staff of the RBPD shall strive to maintain the confidentiality of the results of calibrations (see Guide RBPD-G-05). Results will be dispensed to only those persons who are duly authorized by the customer to receive them.

Official results are not electronically transmitted, and 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 only the relevant RBPD staff. The confidentiality of stored files on personal computers maintained by RBPD staff or servers dedicated to RBPD staff are assured through RBPD adherence to the NIST information technology security policies.

4.3.4.5 Laboratory Notebooks

The Physical Measurement Laboratory, of which the Radiation and Biomolecular Physics 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 Physical Measurement Laboratory (known then as 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 Physical Measurement 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 Physical Measurement Laboratory policy is contained in procedure RBPD-G-06.

- All Physical Measurement 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.
- 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.

- 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.
- Managers 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-RBPD calibration or certification generally involves the following steps:

1. The customer communicates with a technical contact responsible for the calibration service (the customer can find technical contacts listed under the heading Ionizing Radiation Measurements at {http://www.nist.gov/calibrations/ }).
2. This contact initiates a process to determine the customer's needs and the ability of the RBPD to address them. Agreement between the customer and the RBPD technical contact leads to acceptance of a customer's purchase order (PO).
3. Authorized RBPD personnel enter the PO data into the CSS database and fax or email the PO to the NIST Measurement Services Division (MSD).
4. The CSS 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 CSS.
5. Calibration items are received at NIST by the Logistics Group in the Acquisition and Logistics Division and delivered to the RBPD. Unpacking and inspection of the calibration items is done by RBPD 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 RBPD Administrative Officer notifies the NIST Finance Officer to invoice the customer.
7. If applicable, the RBPD prepares the calibration item for shipping, and the Logistics Group arranges for pick up by the shipping agency.

Provision of a NIST-RBPD SRM request generally involves the following steps:

1. The customer communicates with a representative of the Standard Reference Materials Group responsible for customer service (srminfo@nist.gov) to request a radioactive SRM. Request for orders can be accepted only via fax or email.
2. This contact determines the customer's needs and provides a quote for the radioactivity SRM material requested. Customer approval of this quote constitutes an agreement with the customer and establishes acceptance of the customer's PO.
3. Authorized MSD personnel enter the PO data into the SRM order system and provide the appropriate paperwork to the RBPD to begin the shipping process. Upon receipt of the paperwork, authorized RBPD personnel package the SRM(s) in accordance with the appropriate regulations and accompanied by any additional required paperwork.

4. The NIST Radiation Safety Division checks the package for proper preparation and for the absence of any radioactive contamination. Once approved by Radiation Safety, the package is taken to the NIST Shipping and Receiving Group for pickup by the carrier.
5. Authorized RBPD personnel acknowledge the shipment of the order to the SRM order system; this action initiates shipment tracking notification and order billing to the customer.
6. The NIST Certificate for a radioactivity SRM contains information about the composition, the properties, and the proper use of the SRM and additional required information, as stated in NIST-QM-I Sections 5.10.2 and 5.10.3.

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

4.4.1 Review and Approval of Requests for Calibrations

The RBPD 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 RBPD calibrations are described in RBPD-QM-II Section 5.

4.4.2 Procuring Products and Services, External Sources

The RBPD 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 RBPD calibrations are described in RBPD-G-03 or RBPD-QM-II Section 5.

4.4.3 Interaction with NIST Supporting Divisions

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

The RBPD has attained extensive experience in performing calibrations of radiation reference fields, radiological instrumentation, the preparation of radioactive 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 RBPD Guide RBPD-G-07 identifies the various levels of discrepancies, conditions requiring client notification, and the RBPD procedures applicable to dealing with items of nonconformance. Complaint forms (see RBPD-G-04) may or may not be initiated as part of the discrepancy. The RBPD Guide RBPD-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 RBPD Guide RBPD-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 RBPD Guide RBPD-G-04) specifically regarding the technical aspects of any RBPD calibration service that includes, but is not limited to, the characterization of reference fields, performance of measurements or irradiations, preparation of radioactive SRMs, reporting issues, personnel qualifications, etc., are documented and investigated promptly (see RBPD Guide RBPD-G-04). The Quality Manager maintains an RBPD complaint file.

The person receiving the complaint is responsible for initiation of a Customer Complaint Report (RBPD-G-04) and completion of the Complaint description. 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.

RBPD 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 RBPD 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 RBPD-G-09.

4.5.4 Customer Comments

Customer feedback regarding any aspect of an RBPD calibration service that are offered as suggestions (*e.g*., service improvements) are documented and disseminated promptly (see RBPD Guide RBPD-G-13). The Quality Manager maintains an RBPD comment file.

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

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

4.6 Internal Assessments and Management Reviews

4.6.1 Assessments

The RBPD abides by the NIST-level assessments organized by the MSAG once every five years (see NIST-QM-I Section 4.6.1). In order to verify continued compliance with the requirements of the quality system, the RBPD conducts internal audits at least every two years in accordance with Guide RBPD-G-10.

4.6.2 Management Reviews

The RBPD 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 12 to 24 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 RBPD 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 RBPD-QM-II Section 4.2.2.5).

5 Technical Requirements

5.1 Introduction

This Quality Manual covers the RBPD calibration services that are listed in the *NIST Calibration Services Users Guide*, NIST SP 250 and radioactivity SRM services. It covers testing and calibrations performed using standard methods, non-standard methods and laboratory-developed methods. The scope of calibration services provided by the RBPD 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 services offered by the RBPD and within the scope of this Quality Manual are listed in Table 5.1.

Certain commercial equipment, instruments, or materials are identified in RBPD Procedures. Such identification does not imply recommendation or endorsement by the National Institute of Standards and Technology, nor does it imply that the products identified are necessarily the best available for the purpose.

RBPD 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 π alpha Proportional Counter
02	43040C	Alpha–Particle–Emitting Solid Sources, NIST 0.8 π 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, ^{60}Co, ^{137}Cs, ^{192}Ir

RBPD Procedure	NIST Service Code	Service Title
08	47020C	Low-energy Photon Brachytherapy Seeds, ^{125}I, ^{103}Pd, ^{131}Cs
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 ^{60}Co Gamma–Rays
12	49020C	Dose Interpretation of NIST Transfer Dosimeters Irradiated by Customer
13	44010C	Radioactive Neutron Sources Emission Rates (10^5/s to 10^8/s)
13	44020C	Radioactive Neutron Sources Emission Rates (10^8/s to 10^{10}/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
17	SRM 2xxx	Passive Calibration Artifacts for Imaging Systems Using Ionizing Radiation and Related Imaging Systems

Though not within the scope of this quality manual, other Division activities (*i.e.*, special tests/measurements, research and development, contract, CRADA, or other cooperative activities) are committed to quality. The NIST Service Codes for special tests not included in the RBPD 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 RBPD Calibration Service

The policies that govern the decision to either establish or terminate an RBPD calibration service are developed and maintained by the NIST Measurement Services Advisory Group (MSAG). The MSAG guidelines for the establishment of an RBPD calibration service are found at {http://www-i.nist.gov/ts/tsintranet/calibrations/start_policy.htm}. The MSAG guidelines for the termination of an RBPD calibration service are found at {http://www-i.nist.gov/ts/tsintranet/calibrations/termination_policy.htm}.

5.2 Personnel

Personnel in the RBPD 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 C lists all personnel currently associated with the various calibration, testing, and

SRM programs. Personnel in Appendix C that are not assigned to a specific service code may share equipment/facilities that are part of the RBPD Quality System. The Group Leaders maintain the specific job description/performance plan for each person in their group.

All RBPD 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 radioactive or natural matrix 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 RBPD-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 RBPD, as described in RBPD-QM-II Section 4.1.3.2. The competence of an RBPD 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 declaration of staff member competence should address the period of evaluation/training, the expert(s) that provided oversight, and the completeness of the training that include, but are not limited to, the Quality System training and other associated aspects of the service (*i.e.*, shipping and billing). The staff member is authorized to perform a calibration service through a written notification from the Division Chief to the Quality Manager.

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 Physical Measurement 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 measurement 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 is also required.

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

5.2.2 Education and Training Goals

The RBPD 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 the educational development of calibration and SRM personnel and fully supports higher education.

Calibration procedures are developed by the calibration personnel through experience and knowledge of the state-of-the-art. Calibration personnel who write procedures are considered to be fully trained on the procedure they author. If other personnel are to learn the calibration procedure, they work closely with the person authorized for the calibration procedure until they can demonstrate a consistent 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, *i.e.*, participation in political party activities, financial disclosures, etc. Ethics training is conducted by NIST as appropriate, depending on job function, to keep personnel informed on the policies.

5.2.4 Collaborators

The RBPD 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 (RBPD-QM-II Section 5.2). RBPD staff members responsible for an RBPD Service Procedure oversee collaborator performance. At the discretion of the RBPD Quality Manager, collaborators may be required to attend an RBPD QS training session.

5.3 Accommodations and Environmental Conditions

The RBPD 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 RBPD 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 RBPD Procedures.

5.4.2 Reference Materials

The RBPD 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 RBPD SRM personnel.

5.4.3 Estimation of Uncertainty

The RBPD uses the NIST approach to quantitative statements of uncertainty described in NIST-QM-I Section 5.4.2 and NIST-QM-I Section 5.4.3. The uncertainty analysis for each calibration service is described in each of the RBPD Procedures.

5.5 Equipment

All RBPD calibration services included in the RBPD-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 Physical Measurement Laboratory, and the Radiation Safety Division of the Office of Safety, Health & Environment.

Calibration facilities for each service are described in full in the appropriate calibration service documentation or in the RBPD-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 RBPD is checked upon return to ensure that it is operating within expected limits.

Authorized persons not associated with the RBPD may use the radiological resources within these facilities. National and international guest researchers, student interns, and calibration customers often use the national standards for purposes other than calibration work. Another user of the RBPD resources is the Radiation Safety Division of the Office of Safety, Health & Environment. The Radiation Safety Division provides external dosimetry to NIST employees and guests using the NIST radiological facilities. The RBPD does not depend on any specific technical product or service from any outside user in attaining a quality process. RBPD calibration services take precedence over any other usage of the national standards.

5.6 Measurement Traceability

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

5.6.1 Policy

It is RBPD 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 of RBPD 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 comparisons with other National Metrology Institutes 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^3 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 (derived) unit for the 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 ^{60}Co beams: direct realization by a water calorimeter.
- Air kerma from suitable ^{192}Ir, ^{137}Cs, and ^{60}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-1 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 ^{252}Cf source 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 ^{252}Cf source is known from an evaluation of a large body of experimental data {International Organization for Standardization, Reference neutron radiations-part 1: characteristics and methods of production. ISO 8529-1 (ISO: Geneva) (2001)}. For the dose-equivalent rate from a D_2O moderated ^{252}Cf source, the spectral fluence is based on 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 ^{252}Cf sources are known by comparison to NBS-I.

5.6.2 Traceability Services

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

5.7 Sampling

5.7.1 Calibrations

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

5.7.2 Certification of Standard Reference Materials

Authorized RBPD 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 RBPD precludes a uniform method for the handling of calibration items. Therefore, each calibration service shall provide this information in the associated Procedure.

All items sent in for calibration will be inspected by calibration personnel to verify that the items received are consistent with the customer's documentation. All items will also be inspected for defects or damage. If it is determined that the calibration requirements cannot be achieved, the calibration personnel will contact the customer and follow Nonconformance Guide RBPD-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

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

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

5.9.1 Bilateral comparisons

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 RBPD 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 enable an assessment (or evaluation) of the comparability of measurement results so as to provide technical support for international commerce and trade. A key component in this evaluation is the successful participation in interlaboratory comparisons among NMIs. 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 CIPM 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

RBPD 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 RBPD 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 physically issued by the RBPD 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.
- If a replacement report of calibration or certification is issued it shall be uniquely identified (See Guide RBPD-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 RBPD 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 RBPD Quality System training session within the previous 12 months.

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 RBPD Quality System training session within the previous 12 months.

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. They describe the realization and measurement traceability aspects of the calibration service in greater detail than the RBPD-QM-II Procedures. However, the methodologies and operational aspects for the individual services described in the RBPD-QM-II Procedures supersede those published in SP250 publications. These documents are available on the NIST website {http://ts.nist.gov/MeasurementServices/Calibrations/sp250_series.cfm}.

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 "4π" 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 ^{60}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*

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

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
CIRMS	Council on Ionizing Radiation Measurements and Standards
CSS	Calibrations Support System
DOC	(United States) Department of Commerce
RBPD	Radiation and Biomolecular Physics Division
ISO	International Organization for Standardization
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
PML	Physical Measurement Laboratory
SRM	Standard Reference Material

Appendix C. RBPD Calibration Service Personnel

Title	Name	Authorized Service Functions	Authorization Date
Radiation and Biomolecular Physics Division			
Division Chief	L.R. Karam		
Acting Chief	as assigned		
Quality Manager	M. F. Desrosiers	(see below)	
Deputy Quality Manager	L. Laureano-Perez	(see below)	
Administrative Officer	M. A. Dewese	Billing	1/1/04
Division Secretary	W. M. Lease	CSS database entry; Test folder management	1/1/04
Radiation Interactions and Dosimetry Group			
Group Leader	M. G. Mitch		
Acting Group Leader	as assigned		
Group Secretary	D. Copeland	Mailing; Filing	4/16/04
Research Chemist	M. F. Desrosiers	49010C; 49011C; 49015C; 49016C; 49020C-49022C; 49030C-49032C	1/1/04
Physicist	C. M. O'Brien	46010C [Procedure 4]	1/1/04
Physicist	A. M. Forney	49010C; 49011C; 49015C; 49016C	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	J. Walia	47030C; 47035C; 47036C	3/22/10
Neutron Interactions and Dosimetry Group			
Group Leader	M. Arif		
Acting Group Leader	as assigned		
Research Associate	D.M. Gilliam		
Physicist	M. S. Dewey	44010C; 44020C	1/1/04
Physicist	A. K. Thompson	44060C	1/1/04
Research Associate	C. R. Heimbach	44060C	1/28/05

Title	Name	Authorized Service Functions	Authorization Date
Radioactivity Group			
Group Leader Acting Group Leader	M. P. Unterweger as assigned	43010C; 43020C; 43030C	1/1/04
Physicist	J. T. Cessna	43010C; 43020C	1/1/04
Physicist	H. Chen-Mayer	SRM 2xxxx [Procedure 17]	6/3/11
Research Chemist	R. Collé	SRM 4xxxx [SRM Coordinator and Lead Staff for Procedure 15]	9/12/05
Research Associate	D. Golas	43010C; 43020C SRM 4xxxx [Procedure 15]	1/1/04 9/12/05
Research Chemist	K. G. W. Inn	SRM 4xxx [Lead Staff for Procedure 16]	3/1/05
Physical Scientist	L. King	43010C; 43020C; 43030C	1/1/04
Research Chemist	J. LaRosa	SRM 4xxx [Procedure 16]	01/01/09
Chemical Engineer	L. Laureano-Perez	SRM 4xxxx [SRM Coordinator and Lead Staff for Procedure 15]	01/29/10
Physicist	Z. Levine	SRM 2xxxx [Procedure 17]	6/3/11
Research Chemist	L. Lucas	SRM 4xxx Packaging and Shipping [Procedure 15]	01/27/10
Contractor	S. Nour	SRM 4xxx [Procedure 16]	9/12/05
Physical Scientist	B. R. Norman	43010C; 43020C	9/13/05
Physicist	L. Pibida	43010C; 43020C	1/1/04
Physical Science Technician	J. Stann	SRM 4xxx Packaging and Shipping [Procedure 15]	01/27/10
Research Chemist	B. Zimmerman	SRM 4xxx [Procedure 15]	01/01/09