Radiation Physics Division Quality Manual

Introduction

This Quality Manual defines the quality management system of the Radiation Physics Division (RPD) of the Physical Measurement Laboratory (PML) at the National Institute of Standards and Technology (NIST).[1] This Manual describes the processes by which the RPD achieves and maintains high standards of quality in maintaining and disseminating the U.S. national measurement standards for photon, electron, neutron and alpha-particle radiations. Included in the Manual are a description of the Division structure and organization, its policies and procedures, and an overview of the various processes used to assure that radiological standards are used and maintained in an accurate manner that is consistent with international standards and practices. This Quality Manual (RPD-QM-II) complies with the NIST Quality Manual (NIST-QM-I) and institutional policies and procedures where applicable and refers to other quality-assurance documents where appropriate. All RPD staff members whose activities affect the quality of the measurement services are to be familiar with the NIST QMS and implement it into all RPD measurement services.

This Quality Manual documents policies and practices necessary to comply with the NIST Quality Management System (QMS). The RPD commits that its quality management system is, 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 17034, *General requirements for the competence of reference material producers*, as they apply to the Standard Reference Materials® (SRMs®). The ISO/IEC 17043:2010 *Conformity assessment – General requirements for proficiency testing* is used for the related services that the RPD delivers for proficiency testing.

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[1] Quality management system documents established prior to 2015 refer to the Ionizing Radiation Division (IRD) or the Radiation and Biomolecular Physics Division (RBPD), and the Physics Laboratory (PL) respectively.

1 Scope

This Quality Manual covers RPD calibration services that are listed in the *NIST* SP 250 Measurement Services (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 RPD varies from Group to Group as described below. This Quality Manual also covers some aspects of Radioactivity and Complex-Matrix Radionuclide SRM's. Additional NIST policy requirements related to the production and handling of reference materials that are not fully addressed by the requirements of ISO 17025 are specifically stated in the NIST-QM-I, Appendix E. The additional NIST policy requirements for proficiency testing in accordance with ISO 17043:2010 are in the NIST-QM-I, Appendix F. The RPD personnel, to assure that clients receive ionizing radiation calibrations and SRMs of the highest accuracy, follow the practices documented in NIST-QM-I, RPD-QM-II, RPD Procedures and RPD Guides.

This document is organized as follows:

- Sections 2 to 8 and Appendices A to C address the requirements of testing and calibration laboratories in accordance with ISO 17025:2017
- Appendix A References
- Appendix B Definitions and acronyms
- Appendix C RPD calibration service personnel

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 RPD. These documents are available to all calibration/testing personnel and are implemented by the appropriate personnel. A complete list of NIST SP250 Calibration Services Guide publications pertaining to the RPD calibration and SRM services can be found in Appendix A.

3 Definitions

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

4 General Requirements

4.1 Impartiality

Impartiality, confidentiality, objectivity and ethical conduct are discussed in the RPD QM-II, RPD Procedures and RPD Guides, but the complete NIST expectations are found in the NIST-QM-I. In accordance with the NIST-QM-I, the RPD conducts its ***measurement services*** in a fair and open-minded manner that is free of conflicts of interest, bias, or prejudice ensuring

impartiality in the operations and measurements of the laboratory. All perceived or actual risks to impartiality, as identified by the measurement service staff, shall be eliminated or minimized as an essential obligation to its customers.

4.2 Confidentiality

NIST is legally obligated to provide protection of confidential or proprietary information obtained or created during the performance of laboratory measurement service activities. All staff of the RPD shall ensure the confidentiality of the results of calibrations and measurement tests. The Guide RPD-G-05 addresses confidentiality. Results will be dispensed to only those persons who are duly authorized by the customer to receive them.

Official results may be signed electronically and transmitted to the customer. The policies that protect the confidentiality and safe handling of the data also applies to the transmission of the report in PDF format. Some technical procedures include the transmission of copies of signed reports for record retention purposes to Calibration Services and to the NIST technical contact. Electronic copies may be provided to customers, upon request, or as deemed necessary by the author.

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 RPD staff. The confidentiality of stored files on personal computers maintained by RPD staff or servers dedicated to RPD staff is assured through RPD adherence to the NIST information technology security policies.

5 Structural Requirements

5.1 The Radiation Physics Division

The Radiation Physics Division (RPD) is a Division within NIST's Physical Measurement Laboratory (PML) that provides calibration services and SRMs. Three Groups within the RPD maintain the national ionizing-radiation measurement 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 RPD is arranged in a way that preserves independence of judgment in matters concerning radiological calibrations and services.

5.2 Laboratory Management Responsibilities

The Division Chief has the overall responsibility for the development and implementation of proper calibration and quality-control procedures. The Deputy Division Chief works cooperatively with the Division Chief on all duties and is authorized to stand-in for the Division Chief if the Division Chief is not available. Group Leaders can stand-in for the Division Chief when authorized specifically to do so. 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 RPD's permanent facilities and at sites away from its permanent facilities.

5.3 RPD Measurement Services

The services offered by the RPD and within the scope of this Quality Manual pertain to the following areas:

- Activity measurements of alpha- and/or β- particle and gamma-ray emitting sources;
- Preparation and certification of radioactivity SRMs;
- X-ray and gamma-ray dosimetry, and beta-particle dosimetry; and,
- Calibration of neutron sources and radiation-protection instruments for neutron fields.

As stated in the NIST-QM-I section 5.3, special tests are so designated for one or more of the following reasons: (1) the specific type of ***calibration*** is seldom requested, thus precluding the maintenance of a large statistical base for characterizing the measurement process; (2) the test requested is unique; or (3) the service is still under development - meaning the measurement or ***calibration methods*** are still being perfected, or all the quality-control documentation has not been completed.

The RPD QM-II covers the RPD calibration services that are listed in the *NIST Calibration Services Users Guide*, NIST SP 250 and radioactivity SRM services. The scope of calibration services provided by the RPD varies from Group to Group as described below. The services offered by the RPD and within the scope of this Quality Manual are listed below.

Procedure	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-and Beta-Particle-Emitting Solid Sources, NIST 2 π Alpha/Beta Proportional Counter
02	43040C	Beta-Particle-Emitting Solid Sources, NIST 2 π Alpha/Beta Proportional Counter
02	43050C	Mixed-Alpha-Particle-Emitting Solid Sources, NIST 2 π Alpha/Beta Proportional Counter in Conjunction with a Solid-State Detector
03	46011C	Calibration of X-Ray Radiation Detectors
04	46010C	Calibration of Gamma-Ray Radiation Detectors
05	46020C 46021C	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, ^{137}Cs, ^{192}Ir

Procedure	Service Code	Service Title
08	47020C 47021C	Low-energy Photon Brachytherapy Seeds, ^{125}I, ^{103}Pd, ^{131}Cs
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
12	49030C	Dose Measurement Session
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 435x	Complex-Matrix Radionuclide Standard Reference Materials
18	46012C	Well Ionization Chamber Calibrations with Electronic Brachytherapy Sources

Research and development work, CRADAs, contracts and other cooperative activities used in the development of new calibration opportunities for radioactivity and/or SRM development follow the quality guidance described in Procedures 15 and 16. The RPD Special Tests meet the requirements described in NIST-QM-I 7.2.1.1 and a verification and validation process is reviewed for each test during the report review process. Reports for RPD Special Tests must meet all report requirements in NIST-QM-I 7.8.2. The RPD NIST Service Codes for special tests are: 43031S, 43060S, 43090S, 44100S and 46050S. NIST ID 47010C is temporarily unavailable pending changes to the procedure. The policies that govern the decision to either establish, suspend or terminate a RPD calibration service are referenced in the NIST Directives Management System (Order O 5901.00 and accompanying suborders).

SRMs may be discontinued for various reasons (e.g., existence of other suitable materials, technical obsolescence, measurements that do not meet the required standards, etc.). The decision to terminate a NIST SRM requires a careful assessment of the role it plays for NIST's customers and of the potential impact of the termination. In addition, reasonable alternatives to current customers, if appropriate should be provided. This step is normally carried out by, or in cooperation with, the SRM Coordinator and with the concurrence of the Radioactivity Group (RG) leader. The RG leader confers with the RPD division chief and inform ORM that the SRM will be discontinued. ORM with the assistance of the radioactivity SRM coordinator will then complete the steps necessary for discontinuation or the SRM.

5.4 Physical Locations for Quality Management 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 RPD service personnel. All RPD calibration services included in the RPD-QM-II Procedures section are conducted in Building 245, Radiation Physics, on the NIST campus in Gaithersburg, MD. The building also houses parts of one other division of the Physical Measurement Laboratory and the Radiation Safety Division (RSD) 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 RPD-QM-II Procedure specific to that calibration service. This documentation is listed in Appendix A. Facilities for Special Tests are documented in individual test reports.

5.5 Organizational Structure for Scientific and Technical Research and Services

a) Organizational structure

Calibration and SRM services are part of the efforts of the Radiation Physics Division. The Groups within this Division are directly involved with the provision of the calibration reports and measurement certificates covered by this manual. RPD-QM-II Figure 5.1 provides a schematic representation of this part of the NIST organization.

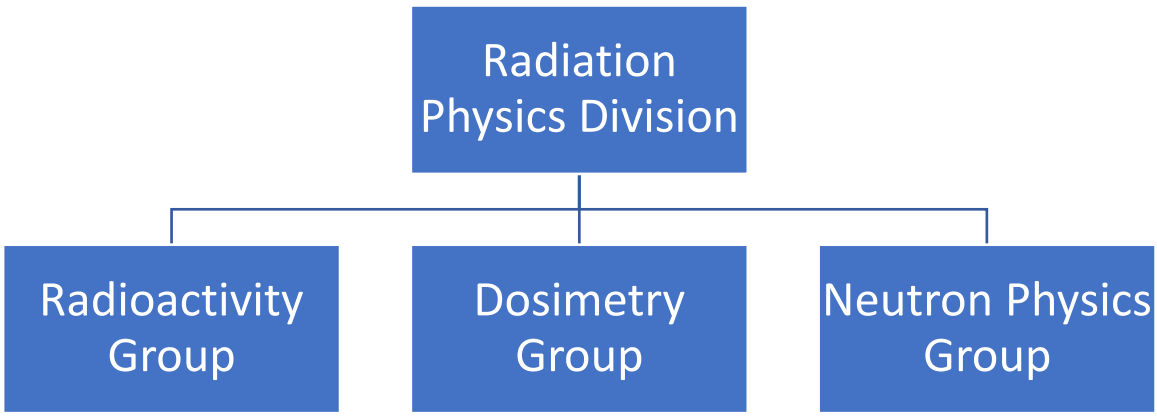

Figure 5.1. Organization chart for the Groups that comprise the Radiation Physics Division

b) Laboratory staff responsibilities, authorities, and delegations

The responsibilities and the organizational hierarchy of the NIST Director, Associate Director for Laboratory Programs, Laboratory Directors and NIST Quality Managers are documented in NIST-QM-I. Requirements for the position of Division Chief are set forth by the NIST Physical Measurement Laboratory. Requirements for the Deputy Division Chief and the Group Leader positions are set forth by the Division Chief. Requirements for the staff positions are set forth by the respective Group Leaders.

Personnel in the RPD have the 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 RPD Quality Management System.

All RPD 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 management 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.

c) Documentation of QMS procedures

- The 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 (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.

- RPD-QM-II contains policies, protocol guides, and technical procedures established and maintained by the Radiation Physics Division to meet its technical needs. The RPD-QM-II explicitly references NIST-QM-I where appropriate.

- The specific protocols to carry out RPD-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 RPD-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.

5.6 Quality Management System Personnel

a) Division Chief

The Division 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 Division Chief approves the RPD-QM-II, which, when so approved, becomes the official version. The Division Chief appoints a Division Quality Manager and Deputy Quality Manager. The Division 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 Division 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 Division 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.

b) Group Leaders

Group Leaders 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 are performed to satisfy the requirements of the NIST Quality Management System and the needs of its clients. The Radioactivity Group Leader will designate a senior Radioactivity Group member (generally a radiochemist or someone trained in chemistry) as the SRM Coordinator. The Radioactivity Group Leader is responsible for notifying the RPD Division Chief and Quality Manager of any change in the SRM Coordinator designee, as described below. This designation is documented in RPD-QM-II Appendix C.

c) Quality Manager

The Quality Manager is responsible for the development, implementation, and maintenance of the quality management 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 Management 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 if poor-quality practices are identified or suspected. In the absence of the Quality Manager, the Deputy Quality Manager will carry out his/her responsibilities.
The Quality Manager must have at least a B.S. in radiation 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. Upon the receipt of the Division Chief's authorization for a staff member to perform a specific service, the Quality Manager will notify Calibration Services or the SRM Coordinator who will notify the SRM services of the additional authorized staff.

5.7 RPD Measurement Service communication

The Quality Manager and Division Chief ensure that there is open communication within and between all levels of NIST ***measurement services*** concerning the effectiveness of the QMS, including maintaining the integrity of the QMS when changes are planned and implemented. RPD quality communication occurs through: NIST-level assessments every 5 years, RPD quarterly quality reports and RPD internal audits, conducted at least every two years.

6 Resource Requirements

6.1 General

The necessary policy and technical requirements for personnel, facilities, equipment, systems and support services are documented within the RPD-QM-II, Procedures, and Guides to meet the technical requirements of ISO 17025.

6.2 Personnel

6.2.1 Competence and Impartiality

Assuring competence and impartiality is the direct responsibility of the management chain for scientific research and services of the RPD. The competence of an RPD staff member is achieved through demonstrated proficiency of a specific service. Mentoring and training with an expert are the preferred method for assessing competence, should resources allow this level of training. The procedure implemented by management to assess competence involves knowledge of the

education, experience, demonstrated skills, published research and training. The acquired knowledge of each staff scientist is discerned through discussions between managers and scientific staff of measurements and also the review process for all calibrations and published measurements. The information exchanged to establish and monitor competence is varied, including group and division presentations, professional meeting involvement, and group level meetings to solve measurement service challenges. The assessment of skills of personnel, determined by management and/or fellow scientists, are based upon demonstration of competence specific to each measurement service. The required competence skills are those needed to perform the technical procedures. The demonstration of the understanding and independent application of each technical procedure, under the guidance of a NIST staff expert, contributes to the management's assessment of the competence level. Personnel may only generate measurement service data independently after competence is declared through the formal authorization process documented in RPD-QM-II 6.2.6. Personnel training is documented in, but not limited to: management reviews, internal audits, external assessments, measurement comparisons, and performance evaluations. The extensive review process of measurement data for all services for all customer reports, measurement comparisons, and published data is the most important verification of competence and impartiality performed by management. NIST maintains policies and procedures for personnel to avoid involvement in any activities that would diminish confidence in their 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. The RPD meets the NIST-QM-I requirement of national and internationally recognized experts in the field of radiation metrology as demonstrated by involvement with measurement comparisons, standard and professional organizations, staff serving as technical assessors for calibration laboratories, active membership on standards committees, and published references.

6.2.2 Job descriptions

Employee records and job descriptions are stored and maintained by the NIST Office of Human Resources Management offices at the NIST laboratories in Gaithersburg, Maryland. Included in these records are the employee's current version of the Federal Job Application: SF 171, OPM 118, College and Education, Experience, and completed training forms. These records provide information regarding each NIST employee's skills, qualifications, training, and experience.

Job descriptions are written by group leaders and the Division Chief (in consultation with appropriate members of the scientific staff, as needed) to include skills and knowledge specific to calibration and SRM services. The job descriptions that are associated with each measurement service position are reassessed upon each new hire. This process involves collaboration within management and precisely identifies the needs of each position. Job descriptions are reestablished for new positions based on current duties and available technologies. The staff skills are identified and described individually and maintained as part of publicly accessible PML web site staff biographies. The published scientific data, that validates and describes the specific staff experience associated with measurement services, is available to customers and online through the references associated with each measurement service and each member of the scientific staff. The references, including recent measurement comparisons, which further provide details of job

description requirements, are routinely included in calibration and SRM reports.

General job descriptions are provided here, with specific technical duties identified in the technical procedures.

a) Division Chief and Deputy Division Chief

The Radiation Physics Division Chief (and the Deputy Division Chief, for duties designated by the 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 Division Chief authorizes resource allocations (personnel, fiscal, equipment, and space) specifically for these efforts. The Division Chief is also responsible for ensuring the institutional competency needed to provide a calibration or SRM service. The Division Chief, or his/her designee, signs report of calibration or certificates on behalf of the NIST Director. In the absence of the Division Chief, the Deputy Division Chief (acting on behalf of the 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.

b) Group Leaders

The Group Leaders are responsible for the overall technical operations of their Groups. The Group Leaders maintain the specific job description/performance plan, and any needed historical records of both, for each person in their group. Group Leaders must have at least a M.S. degree or equivalent academic 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 additional requirements for the position.

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. Only quality management system trained Group Leaders can approve and sign measurement service reports.

c) Calibration and SRM Personnel

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. 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 meticulously following established written 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, following RPD-G-06 and any task-specific guidance.

Calibration/SRM Personnel must be trained radiation workers and must be familiar with the safe operation of radiation-generating devices and the safe use of radioactive materials, 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.

d) SRM Coordinator

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 the 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 coordinate 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. The SRM Coordinator is responsible for informing the Radioactivity Group Leader of all aspects of SRM planning activities. The SRM Coordinator will designate an authorized Radioactivity Group staff member as the principal investigator primarily responsible for all technical aspects of the SRM to include the production, standardization, and certification of 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, except for explicitly identified responsibilities of the Group Leader and/or the SRM Coordinator. The SRM Coordinator will inform the Office of Reference Materials of newly authorized staff, upon receipt of the authorization from the Division Chief and Quality Manager.

6.2.3 Education and Training

The RPD recognizes the importance of education and training of calibration/SRM personnel and of Division management to maintain the quality goals of this manual. Calibration/SRM personnel are encouraged to have a bachelor's degree or higher. Management encourages the educational development of calibration and SRM personnel and fully supports higher education. Guide 11 is available for the protocol of training.

Calibration procedures are developed by the calibration personnel through experience and knowledge of state-of-the-art techniques. Calibration personnel who write procedures are fully trained on the procedures they author. If other personnel are to learn the calibration procedure, they work closely with someone authorized for the calibration procedure until they can demonstrate a consistent level of quality service.

Management and calibration/SRM 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. The documentation of participation in technical meetings, travel related to measurement services, calibration laboratory exchanges, professional training and assessments are included in the quarterly reports to NIST management. The laboratory employees involved in laboratory activities have access to consensus standards, equipment manufacturers' manuals, safety guidance, and specific laboratory facilities procedures where applicable to support training goals.

The management review plan for education and training is monitored during the job performance plan development and annual staff review which involves the topic of professional development and includes the discussion of education and training. If education and training improvements are requested or deemed required, then the plan is documented in the employee's performance evaluation.

6.2.4 Delegation of duties, responsibilities and authorities

The official Position Descriptions and individual Performance Plans document all duties, responsibilities, and authorities for all management, administrative, support, scientific, and technical staff. Management meets with each employee at least biannually to review their Performance Plans to ensure their duties, responsibilities, and authorities.

6.2.5 Management of personnel

The hiring records for each position, including competence requirements, questionnaires, and notes are kept in the Division Chief's and group leader's electronic personnel records. Electronic copies of the staff's mid-year and annual performance reviews and subsequent records are kept electronically in the Division Office's records. Training records for radiation, safety training, and other NIST provided training are maintained by NIST databases and supervisors are responsible

for monitoring the completion. The training records of the authorization training process will be developed by the scientist performing the training and provided to the group leader for documentation of the complete authorization and maintained electronically with the approving memo of authorization.

6.2.6 Authorization of personnel

The calibration and SRM staff are authorized by the Division Chief through the group leader to perform specific service ID's and SRM's including, but not limited to, the development, modification, verification and validation of methods, analysis of results, and report review authority. The procedure for the authorization of staff within the RPD follows. 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 shall address the period of evaluation/training, the expert(s) that provided oversight, and the completeness of the training that includes, but is not necessarily limited to: Quality Management System training, training on all technical/scientific aspects of each service, and training on associated aspects of each service (*e.g.*, shipping and billing, calibrations tracking software, etc.). The staff member is authorized to perform a calibration service through a written notification from the Division Chief to the Quality Manager. Upon the receipt of the Division Chief's authorization for a staff member to perform a specific service, the Quality Manager will notify Calibration Services or the SRM Coordinator who will notify the Office of Reference Materials of the additional authorized staff. The authorization memo circulated by email is converted into a document and retained in the division's quality system. The authorization date for each staff, including the services associated with the authorization are documented in the QMII appendix C.

6.2.6.1 Interaction with NIST supporting divisions

If the RPD staff needs services performed by another NIST Division, the service personnel are responsible for ensuring that the measurements in the supporting division are covered by a quality system.

6.2.6.2 Subcontracting of tests, calibrations, and reference material certifications

The RPD does not sub-contract calibration work or reference material certification.

6.2.6.3 Collaborators

Support from collaborators (non-NIST laboratories and personnel) in the development and certification of a radioactive or complex-matrix SRM is provided in accordance with the policies set forth in NIST-QM-I Section 6.2. The Division Chief may authorize a collaborator to prepare SRMs. The authorization and its effective date are established through written notification from the Division Chief to the Quality Manager. RPD staff members responsible for a RPD Service Procedure oversee collaborator performance. At the discretion of the RPD Quality Manager, collaborators may be required to complete RPD QMS training.

Guest researchers may provide support for measurement work or be involved in auxiliary research that uses or develops equipment common to the calibration services but an authorized calibration or SRM staff supervises these activities. The authorized staff is responsible for the validation of work developed by a contractor or guest researcher for measurement services.

6.3 Facilities and Environmental Conditions

The RPD determines the requisite conditions. Working in collaboration with the Office of Facilities and Property Management (OFPM), RPD is responsible for assuring that environmental conditions do not adversely affect the quality of calibration services. Specific requirements and methods are defined in the RPD Procedures.

6.4 Equipment

The RPD is responsible for the maintenance, calibration, storage, safe and proficient operation, quality assurance, and documentation of all equipment supporting calibration services and standard reference materials program. This includes software validation and data storage. The details of the RPD processes for selection, handling, and maintenance of equipment are documented in the NIST sub-level quality documents. The RPD-G-07 addresses nonconformance of equipment. Certain commercial equipment, instruments, or materials are identified in RPD Procedures. Such identification is for informational purposes only and 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.

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 is 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 RPD is checked upon return to ensure that it is operating within expected limits.

Authorized persons not associated with the RPD may use the radiological resources within these facilities. National and international guest researchers, student interns, and calibration customers occasionally use the national standards for purposes other than calibration work. Another user of the RPD resources is the RSD of the Office of Safety, Health & Environment. The RSD provides external dosimetry to NIST employees and guests using the NIST radiological facilities. RPD calibration services take precedence over any other usage of the national standards and radiological facilities.

6.5 Metrological traceability

The RPD uses the NIST-QM-I definition of metrological traceability. It is RPD 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 RPD calibrations. To assist RPD customers in establishing traceability of results of measurements or values of standards, the RPD provides calibrations, standard reference materials, measurement quality assurance programs, and supports laboratory accreditation services. The RPD 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.

a) Radioactivity

The SI unit of activity is the becquerel. Primary measurements within the Radioactivity Group are considered direct realizations of the becquerel. All secondary measurements are directly related to primary standards through direct comparison or calibration with sources whose activity was determined with primary measurement methods. International equivalence of NIST primary standards to those of other National Metrology Institutes is generally established though comparisons, key or bilateral, such as participation in the International Reference System (SIR) at the BIPM for gamma-ray-emitting radionuclides (http://www.bipm.org/en/scientific/ionizing/radionuclides/sir/).

b) Dosimetry

The 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 − NIST dosimetry 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.

c) Neutron Physics

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 74, 1996, and, as needed, 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.

6.6 Externally provided products and services

The RPD Procedures document all aspects of products or services used for a calibration service or measurement. Federal Procurement Policy and Regulations govern procurement of products and services from sources external to NIST. RPD-G-03 explains the purchasing of services and supplies from external sources and addresses the NIST-QM-I required procedure.

7 Process Requirements

The RPD provides calibration services for ionizing radiation and radioactivity 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 RPD capabilities
- technically consistent with customer needs
- timely and cost effective

7.1 Review of requests, tenders and contracts

The E-commerce solution replaces the NIST Calibration Support System (CSS) and provides business, administrative, and customer support for all calibrations. E-commerce also provides liaison with external organizations with specific interests in NIST calibration services.

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

1. The customer communicates with a technical contact responsible for the calibration service. The RPD technical contacts are listed on the NIST calibration website.

2. Typically, initial contact is to determine which SP250 calibration service is needed and the ability of the RPD to provide that service. If the customer initiates the quote request prior to contacting RPD staff, E-commerce will contact the primary contact of the service.
3. E-commerce assigns an official order number and issues an email to the NIST primary contact for the service. Following the technical procedure, the NIST 364 is completed prior to shipment of sources. The NIST primary contact informs NIST Calibration Services of the receipt date of the instrument to be calibrated or item preparation readiness.
4. Calibration instruments or sources delivered to the RPD, are unpacked, handled and inspected by RPD calibration personnel, according to NIST-QM-I.

Upon completion of the requested calibration, the final calibration report is reviewed and signed by the Division Chief. The group secretary or the technical staff scans the official report as required for the order closure. E-commerce processes the closure of the customer's order. The official NIST calibration report is sent to the customer either by mail or within the container of the returned equipment/source. The customer is invoiced electronically as described by the E-commerce webpage. The RPD technical staff repackages the calibration instrument/source in the original container, or a more suitable one, for return shipping. A Shipping Request Form is prepared, or the shipping authorization from E-commerce is printed and attached to the box and sent with the instrument/source to the NIST Shipping Department. For alpha and beta source calibration, package has to be checked and cleared by RSD before shipping.

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

1. The customer communicates with a representative of the NIST Office of Reference Materials responsible for customer service (srminfo@nist.gov) to request a radioactive SRM. Requests 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. License verification is performed following Interdivisional Procedure IP1-1 (maintained by RSD) before quote is completed and offered to the customer. Customer approval of this quote constitutes an agreement with the customer and establishes acceptance of the customer's purchase order (PO) and order billing to the customer. Authorized personnel enter the PO data into the SRM order system and provide the appropriate paperwork to the RPD to begin the shipping process. Upon receipt of the paperwork, authorized RPD personnel package the SRM(s) in accordance with the appropriate regulations and accompanied by any additional required paperwork.
3. The NIST Radiation Safety Division (RSD) checks the package for proper preparation and for the absence of any radioactive contamination. RSD also verifies the regulatory compliance of the transfer, if needed. Once approved by RSD, the package is taken to the NIST Shipping and Receiving Group for pickup by the carrier.
4. Authorized RPD personnel acknowledge the shipment of the order to the SRM order system, this action initiates shipment tracking notification and order billing to the customer.

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

If there is a deviation from a NIST measurement service procurement contract, the customer must be informed. This information shall be documented and retained in the customer's file, either electronically of or on paper copy. If a NIST measurement service procurement contract is amended after work has commenced, the contract review is repeated, and any amendments are communicated to all affected personnel. If the customer requests cooperation for a calibration, such as monitoring the performance or the preparation, packaging, and dispatch of the calibration item, that request must be clearly identified in the initial request and documented by the NIST technical lead. All discussions with customers are documented in the customer file.

7.2 Selection, verification and validation of methods

The RPD QM-II covers the RPD 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 calibration service personnel, to assure that clients receive ionizing-radiation calibrations of the highest accuracy, follow the practices documented in this Quality Manual. To meet the QMI requirements for section 7.2 the policies that govern the decision to either establish, suspend or terminate a RPD calibration service are referenced in the NIST Directives Management System.

7.3 Sampling

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

7.4 Handling of Test and Calibration Items

The diversity of the calibration services offered by the RPD precludes a uniform method for the handling of calibration items. The specific procedures for identifying, preparing, packaging, handling, storing, and shipping of calibration items and reference materials are addressed in the RPD Procedures.

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. Unambiguous identification of test or

calibration items will be made to ensure that items will not be confused physically or when referred to in records or other documents. 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 RPD-G-07. Customers will also be consulted if 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. The environmental requirements for the storage of calibration items and testing conditions are documented in the RPD Procedures.

7.5 Technical records

QMI section 7.5.1 describes technical records and the requirements for the associated data plans for discoverability and preservation.

a) Calibration Records

Each calibration service shall maintain detailed technical records that include, but are not limited to, original observations, derived data, and enough 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 enough 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 performing each test and/or calibration and checking of results. They shall also contain sufficient information to identify the factors affecting the uncertainties. Guidelines of RPD-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 RPD-G-06) or in client files. All data shall be recorded in a timely manner and shall be identifiable.

b) SRM Records

Each SRM calibration 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 when applicable. Records for each SRM shall contain sufficient information to enable the production to be repeated under conditions as close as possible to the original. 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 the NIST-QM-I. These documents are archived together and stored in Building 245, Room E103. The production information is retained for the SRM while available for sale to the public, plus at least an additional 10 years.

For complex-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, E103 during the time of the SRM's availability. When the SRM becomes unavailable, a copy of the SRM certificate remains in that location.

7.6 Estimation of Uncertainty

The RPD uses the NIST approach to quantitative statements of uncertainty described in NIST-QM-I. The uncertainty analysis for each calibration service is described in each of the RPD Procedures.

7.7 Ensuring the validity of results

To the extent permitted by resources, the RPD 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.

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

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 written documents. The results are presented in a report prepared by the testing laboratory and are sometimes published. When the RPD serves as the testing laboratory, all information and documentation pertaining to the comparison is maintained in a

manner like the calibration-related information for the calibration service that is being compared. Bilateral comparisons are listed or referenced in the service Procedure documents.

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 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).

7.8 Reporting of results

Detailed descriptions of the calibrations and certifications offered, and the associated procedures, methods of validation, and measurement uncertainty, are documented in the RPD Procedures. The RPD uses appropriate, documented methods and procedures when preparing and certifying SRMs. The general policies governing these activities are adhered to by RPD SRM personnel. Particular attention shall be paid to the following:

- NIST Measurement Services do not issue opinions of interpretations.
- Only complete, signed versions, either ink on paper or electronically, are official. The transmission of draft results is not official and must be unambiguously marked as draft results.
- Dissemination of customer-related draft data must be approved and coordinated through the technical reviewer and the associated Group Leader. The written approval shall be maintained with the procedure level customer records.
- Measurement service data used for other purposes such as internal reports, presentations and comparisons must be reviewed and approved through the associated Group Leader for customer privacy.
- Amendments to a calibration report or certification shall be a separate document or an amendment to the revision history, and clearly marked, including the reason for the change when appropriate.
- Amended reports shall be uniquely identified (See Guide RPD-G-12) and contain a reference to the original that it replaces.
- Reissue of a measurement report to the original customer is permitted.

All Reports of Calibration or Certification are signed by the Division Chief or his/her designate, with the phrase “for the Director of the National Institute of Standards and Technology” appearing under the signature, according to QMI 7.8.1.1. Those designated with the authority to sign a report (*i.e.*, a Deputy Division Chief, an Acting Division Chief or associated Group Leader) must have received training on the RPD Quality Management System.

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 received training on the RPD Quality Management System.

In accordance with government policy (for example, *OSTP Memorandum "Increasing Access to the Results of Federally Funded Scientific Research", dated 22 February 2013*, and *Open, Public, Electronic and Necessary (OPEN) Government Data Act* of 2019), all NIST research data are publicly accessible unless their release is specifically prohibited by law for National Security reasons or for the protection of proprietary information.

7.9 Customer Complaints

Customer feedback/concerns categorized as "complaints" (see NIST-QM-I Section 7.9 and RPD Guide RPD-G-04) specifically regarding the technical aspects of any RPD 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 RPD Guide RPD-G-04). The Quality Manager maintains an RPD complaint file.

The person receiving the complaint is responsible for initiation of a Customer Complaint Report (RPD-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. RPD staff members are encouraged to work closely with the customer to resolve the complaint.

7.10 Nonconforming work

The complete requirements of QMI nonconforming work are found in QMI section 7.10. The following RPD guides address all the components of the QMI requirements: RPD-G-07, Nonconformance, RPD-G-08, Corrective action, and RPD-G-09, Preventive action. When nonconforming work is identified, first inform the group leader and the quality manager for guidance on the steps within the RPD quality system. According to QMI the RPD process for nonconforming work must include a full root cause analysis, identified and documented on a corrective action form. The purpose of RPD-G-08 is to define the steps necessary in carrying out corrective actions when nonconforming work or departures from the policies and procedures in the quality management system have been identified.

7.11 Control of data and information management

See NIST-QM-I for information. In the RPD procedures, the technical staff identifies the location of stored data which is required to conduct calibrations and measurements.

8 Management system requirements

8.1 RPD quality management system

The Radiation Physics Division's principal quality goal is to consistently meet or exceed customer needs and expectations and provide high value, while striving to continually improve services. RPD's quality objectives support this goal and adopt the NIST Quality Policy stated in NIST-QM-I. All staff members whose activities affect the quality of NIST *measurement services* are to be familiar with the NIST-QM-I and in the RPD-QM-II and *sub-level quality documents,* and to implement it in their work. The complete quality system is located at the following website: http://www.nist.gov/pml/div682/qualitysystem.cfm.

8.2 Management system documentation

RPD-QM-II has two classifications of instructional documents, Procedures and Guides. RPD-QM-II Procedures contain protocols for performing specific calibration services. RPD Procedures, listed in section 5.3, are developed, revised or created as needed. RPD-QM-II Guides contain policy-based protocols that apply to all calibration service and SRM personnel within the Division. RPD Guides are referenced throughout RPD-QM-II. A list of these Guides is shown below.

RPD Guide No.	RPD 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 and electronic records
07	Nonconformance
08	Corrective action
09	Preventive action
10	Internal audits and management reviews
11	Training
12	Changes to disseminated values and amended reports and certificates
13	Customer comments

8.3 Control of management system documents

The official versions of the RPD-QM-II, and its Guides, Procedures, forms and supporting documents, are maintained by the RPD 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 RPD 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.
The RPD 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 Deputy Division Chief and Division Chief will review the manual and the guides in their entirety halfway through the five-year RPD Quality Management System assessment cycle (see Guide RPD-G-01).

The review process for the QMII follows. A draft version (with changes identified) of the Quality Manual is prepared by the Quality Manager and distributed to the RPD staff, Group Leaders, Deputy Division Chief 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 RPD-QM-II is approved as the official version, the RPD Division Quality Manager will notify all RPD staff that a revised version of RPD-QM-II is official and available by posting on the RPD Quality Management System website. Notice of the revised RPD-QM-II will be posted on the Document Revisions page of the RPD Quality Management System website. A copy of the deleted document will be retained in the RPD Quality Management System Office files (see Guide RPD-G-02).

8.4 Control of Records

Records are generated as part of the quality and calibration systems. Each RPD 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 handling of the calibration and quality documentation must maintain client confidentiality.

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 record retention time is set by the NIST Data Retention Policy or the needs of the service, see RPD-G-06. The RPD supports a calibration record retention of at least 3 years but not more than 20 years, unless the technical procedure requires a longer retention. SRM/SRD-related documents could be transferred to the National Archives 20 years after the SRM/SRD is obsoleted or superseded however, all SRM records are retained on NIST campus, building 245. The technical details for the production of SRMs contained in these records are used as reference in the preparation of future SRMs
The research notebooks and the electronic records consolidate a chronological record of scientists' work, capturing thoughts and ideas. The RPD supports a records policy which ensures that measurement and research activities are properly documented 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 customers, in accordance with previously established PML policy, which includes the following.

- 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, research or electronic notebook or log.
- 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.

The following describes the controls of both QMS documents and QMS records. The Quality Manager shall hold all quality documentation that is generated by this manual and its procedures secure. All records shall be maintained in appropriately marked notebooks or files.
All QMS records are electronic with paper versions being stored in the Quality office. 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 for both documents and records. Backup copies of all documents and tracked records are archived on RPD internal servers. Records generated by QMS are archived as hard copies in the QMS Office files as well as stored electronically on the RPD access-controlled quality site. The RPD QMS document management webpage provides the file location of all RPD QMS documents and records. https://www.nist.gov/pml/radiation-physics/quality-system-services/quality-system-document-management. Electronic copies of RPD Manuals, Guides, Procedures, and associated documents that reside on the NIST server are controlled. Document versions found elsewhere are uncontrolled. Approval records for all RPD Manuals, Guides, and Procedures are maintained in the RPD Quality System Office or on the RPD access-controlled quality site at L:\internal\ridshare\QUALITY\QUALITY\2017Obrien along with other quality records. Electronically tracked records are noted in the Management Document Binder. For additional information, see Guide RPD-G-02 on QMS document control. RPD ***measurement services*** information and data are managed and maintained on-site.

8.5 Risks and Opportunities

Assurance is given that the QMS achieves its intended results while enhancing opportunities to achieve the purpose and objectives of the NIST measurement services. Risk will be assessed to prevent or reduce undesired impacts and potential failures in the NIST measurement service

activities. Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results. Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs. The RPD-G-09 explains the use of RPD Preventive Forms to monitor risk. The RPD Preventive Form documents the preventive action and risk assessment plan and integrates it into the management review system since each new form is identified in the NIST quarterly reports. Any change to a technical procedure that results from a preventive action and risk assessment, is documented in the sub-level quality documents.

8.6 Improvements and Preventive actions

The RPD expects continuous improvement in the provision of calibration and SRM services and encourages identification of opportunities for improvement from all staff. Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results. At times, potential sources of nonconformance or opportunities for needed improvement may be identified either in the technical or quality management systems. This can result in modification to procedures, modification to or purchase of new equipment, etc. The RPD 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 RPD-G-09.
Customer feedback, both positive and negative, shall be analyzed and used to improve the management system, laboratory activities and customer service. Feedback regarding any aspect of an RPD calibration service that are offered as suggestions (*e.g.*, service improvements) are documented and disseminated promptly (see Guide RPD-G-13). The Quality Manager maintains an RPD comment file.

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

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

8.7 Corrective actions

The RPD is committed to NIST policies regarding management of nonconformity events according to the NIST-QM-I. The RPD 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 RPD Guide RPD-G-07 identifies the various levels of discrepancies, conditions requiring client notification, and the RPD procedures applicable to dealing with items of nonconformance. Complaint forms (see RPD-G-04) may or may not be initiated as part of the discrepancy. The RPD Guide RPD-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 management 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 RPD Guide RPD-G-08). The Group Leader and/or Quality Manager may be requested to verify results prior to commencing with routine calibration and/or testing. All incidents of nonconforming work are documented in the Division's/Office's quarterly quality report.

8.8 Internal audits

The RPD abides by the NIST-level assessments organized once every five years, as described in NIST-QM-I 8.8. To verify continued compliance with the requirements of the quality management system, the RPD conducts internal audits at least every two years in accordance with Guide RPD-G-10.

The RPD 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 or participating with 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 reports 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 RPD services.
- Periodic peer review by the National Academy of Sciences Board of Assessment.
- Contracting for economic assessment studies of its services.
- Permitting external audits of the RPD Quality Management System by qualified reviewers.

8.9 Management Reviews

The RPD abides by the NIST-level management reviews. These reviews are based on the analysis of the quarterly reports that Divisions submit through their respective Laboratories to the NIST Quality Manager. The quality management 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. The Quality Manager writes the report based on input from the Group Leaders and the Division Chief. Section 8.9.2 of the NIST-QM-I has the requirements for the quarterly quality reports.

Appendix A. References

SP 250 Publications

NOTE: These are a collection of documents written to support the services described in this quality system. 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 RPD-QM-II Procedures. However, the methodologies and operational aspects for the individual services described in the RPD-QM-II Procedures supersede those published in SP250 publications. These documents are available on the NIST website or by request.

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 and Acronyms, complete list found in the QMI

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.

E-commerce: The platform that allows measurement services customers to place online orders. It implements fulfillment practices and manages invoicing and payment processes. The E-commerce solution is being rolled out in Fiscal Year 2019.

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.

order number: Order number previously known as test folder number, starting with the letter "O" this is a unique 10-digit number that is issued by NIST that indicates that an official calibration or test has been requested by a customer. The accepted format is (Div; Group; E-Commerce generated Order Number; Fiscal Year) 682.0#/O-0000000###-2#

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

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

quality management 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 that 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. Test folders have been phased out for the implementation of unique order numbers in the E-commerce system. The term, if used in any level of this quality document can be defined as the order number.

transfer standard: a standard used as an intermediary to compare standards. Note: the term "transfer device" should be used when the intermediary is not classified as 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	Calibration Support System replaced by E-commerce solution in March of 2019
DOC	(United States) Department of Commerce
RPD	Radiation 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
QMS	Quality Management System
SRM	Standard Reference Material

Appendix C. RPD Calibration Service Personnel

Title	Name	Authorized Service Functions	Authorization Date
Radiation Physics Division			
Division Chief	J. M. Adams		10/1/18
Acting Chief	as assigned		
Deputy Division Chief	A.K. Thompson	(see below)	
Quality Manager	C. M. O'Brien	(see below)	
Deputy Quality Manager	A.K. Thompson	(see below)	
Administrative Officer	R. Abrom	Billing	
Dosimetry Group			
Group Leader Physicist	M. G. Mitch		
Acting Group Leader	as assigned		
Physicist	R. Minniti	46010C; 46020C; 46021C;46110C;46050S	1/1/04
Physicist	C. M. O'Brien	46010C - 46013C 46020C;46021C;46050S	1/1/04
Physicist	M. G. Mitch	47010C; 47020C; 47021C; 47035C; 47036C	1/1/04
Physicist	L. T. Cumberland	49010C; 49011C; 49015C; 49016C; 49020C-49022C; 49030C-49032C	6/28/13
Research Chemist	I. M. Pazos	49010C; 49011C; 49015C; 49016C; 49020C-49022C; 49030C-49032C	11/2/17
Physicist	R. E. Tosh		9/19/17

Neutron Physics Group

Group Leader Physicist	J. S. Nico	44100S	10/8/14
Acting Group Leader	as assigned		
Physicist	M. S. Dewey	44010C; 44020C	1/1/04
Physicist	A. K. Thompson	44060C; 44100S	1/1/04
Physicist	T.R. Gentile	44060C	10/8/14
Physicist	S. F. Hoogerheide	44100S	12/4/17
Physicist	Hans Pieter Mumm	44010C; 44020C; 44100S	7/20/21

Radioactivity Group

Group Leader Research Chemist	B. Zimmerman	SRM 4xxx [Procedure 15] 43010C- 43050C; 43031S 43060S; 43090S	5/18/09
Acting Group Leader	as assigned		
Physicist	J. T. Cessna	43010C; 43020C; 43060S; 43090S	1/1/04
Research Chemist	R. Collé	SRM 4xxxx [Procedure 15]; 43010C; 43020C	9/12/05
Physical Scientist	L. King	43030C; 43040C; 43050C 43031S	1/1/04
Research Chemist	J. LaRosa	SRM 435x [Procedure 16]	5/18/09
Chemical Engineer	L. Laureano-Perez	SRM 4xxxx and SRM 435x [SRM Coordinator for Procedure 15 and 16]; 43010C; 43020C	1/29/10
Research Chemist	L. Lucas	SRM 4xxx [Procedure 15]	1/27/10
Research Chemist	S. Nour	SRM 435x [Procedure 16]	9/12/05
Physicist	L. Pibida	43010C; 43020C	1/1/04
Physical Science Technician	J. Stann	SRM 4xxx [Procedure 15] and SRM 435x [Procedure 16]	1/27/10
Physical Scientist	M. A. Tyra	SRM 4xxx [Procedure 16]	7/27/15
Physicist	R. P. Fitzgerald	SRM 4xxx [Procedure 15]; 43010C; 43020C	7/27/15
Research Chemist	D. E. Bergeron	43010C; 43020C; SRM 4xxx [Procedure 15]	7/27/15
Physical Scientist	R. M. Essex	SRM 4xxx [Procedure 16]	7/27/15