Purpose

This protocol outlines the elements necessary to write or revise Guides, Procedures, and the Radiation Physics Division Quality Manual (RPD-QM-II) within the Radiation Physics Division (RPD).

Scope

This protocol applies to Guides, Procedures, and the RPD-QM-II, all of which are written and maintained in support of the RPD calibration, measurement quality assurance, and standard reference material programs.

Definitions

Guide – Information and instructions for the operational aspects of the RPD Quality Management System.

Procedure – A set of principles and practices that describe the requirements for calibrations, certifications, measurement quality assurance, or standard reference material production.

RPD-QM-II - A document stating the quality policy, quality management system, and quality practices of an organization.

Protocol

Part 1 - *RPD Guides*

1. The Guide templates are obtained from the Quality Manager.

2. The obligatory sections to be included are as follows: Purpose, Scope, Protocol, Acceptance Criteria, Records, Filing, and Retention. If any of these sections do not apply, a "N/A" must be entered.

3. Optional sections may include: Definitions, Equipment, Health & Safety Precautions, References, and Appendices. If these do not apply, they may be omitted from the Guide.

4. Additional sections may be added as needed.

5. Specific guidelines may be obtained from the Quality Manager.

Review of RPD Guides

1. The Guide may be distributed to RPD staff for review for consistency with common practices. Comments should be directed to the Quality Manager.

2. The Guide is reviewed by each of the Group Leaders to ensure that it does not conflict with the operational aspects of RPD services. Comments should be directed to the Quality Manager.

3. The Quality Manager reviews the Guide to ensure that all items dealing with quality (documents, records, etc.) are handled in the correct manner.

4. The RPD Division Chief reviews the Guide to ensure that it adheres to Division policy.

5. The Division Chief approves the Guide by email or written notification to the Quality Manager.

Distribution

Once a Guide is approved, the Quality Manager will assign it a number and will add it to the master list of controlled documents. The master list of controlled documents will be updated to reflect any revisions. The Quality Manager will notify the RPD staff of the Guide's status and availability.

The Quality Manager is under no obligation to provide updated Guides to bearers of uncontrolled quality management system documentation.

Guide Revision

1. The Quality Manager will initiate the review process, as needed, at the discretion of the Quality Manager or the Division Chief.

2. Guides are to be revised when a change is warranted.

3. The Guide revision review and approval process is identical to that described above in *Review of RPD Guides*.

4. The Quality Manager is responsible for updating all controlled documents.

5. The Quality Manager has the option of issuing errata notifications rather than revised protocols in the interim between official revisions.

Deleted Guides

1. A Guide will be deleted when:

   - it is no longer in effect
   - there is a change of name and/or number

2. The Quality Manager shall remove the deleted Guide from the RPD files and place it in the specific Guide, Previous Versions- Archive Folder.

Part 2 – *Technical Service Procedures*

1. There is no set format for calibration service Procedures. They should be written in an easy-to-understand format appropriate to the particular service.

2. The obligatory section headings to be included are: Purpose, Scope, Definitions, Equipment, Safety, Procedures, Uncertainty Analysis, Records, References, Filing, and Retention. Other sections may be added as deemed appropriate.

3. Authors are strongly encouraged to consider the NIST-QM-I and RPD-QM-II as guidance in preparing the content of their (calibration or SRM) service Procedure. The following sections from NIST-QM-I are of particular relevance: (6.0) Resource requirements, (7.0) Process requirements, and (8.4) Control of records.

4. The Procedure shall be consistent with all requirements of the NIST Quality Management System.

Review of Procedures

1. The relevant Group Leader shall name an independent reviewer.

2. The independent reviewer reviews the Procedure.

   2.1 This person should be familiar, but not necessarily intimately involved, with the calibration/testing program in the Procedure.

   2.2 If possible, the independent reviewer should visit the measurement facility to either perform the Procedure or simulate the steps involved.

3. The Group Leader shall review the Procedure to ensure that it meets Group policy and operational requirements.

4. The Quality Manager shall review the Procedure to ensure that quality requirements are being met.

5. The RPD Division Chief reviews the Procedure to ensure that it adheres to Division policy.

6. The Division Chief approves the Procedure by email or written notification to the Quality Manager.

Distribution

Once a Procedure is approved, it shall be given to the Quality Manager, who will assign it a unique number and add it to the master list of controlled documents. The Quality Manager will notify the RPD staff of the Procedure's status and availability.

The Quality Manager is under no obligation to provide updated Procedures to bearers of uncontrolled quality management system documentation.

Procedure Revision

1. The Quality Manager will initiate the review process, as needed, at the discretion of the Quality Manager or the Division Chief.

2. Procedures are to be revised when a change is warranted.

3. The Procedure revision review and approval process is identical to that described above in *Review of RPD Procedures,* with the exception that steps 1 & 2 are optional.

4. The Quality Manager is responsible for updating all controlled documents.

Deleted Procedures

3. A Procedure will be deleted when:

   - it is no longer in effect
   - there is a change of name and/or revision number

4. The Quality Manager shall remove the deleted Procedure from the RPD files and place it in the specific Procedure, Previous Versions- Archive Folder.

Part 3 - *RPD QM-II*

1. There is no set format for the RPD-QM-II, but following the format of the NIST QM-I provides clarity.

2. The RPD-QM-II must be consistent with the NIST-QMI.

Review of RPD-QM-II

1. A draft version (with changes identified) of the Quality Manual is prepared by the Quality Manager and distributed to the RPD Group Leaders, Deputy Division Chief, and the Division Chief.

2. The draft version is reviewed for consistency with common practices, services, and policy by management.

3. The RPD Division Chief reviews the RPD-QM-II to ensure that it adheres to Division policy.

4. The Division Chief approves the Quality Manual by email or written notification to the Quality Manager.

Distribution

After a revision of the RPD-QM-II is approved as the official version, the RPD Division Quality Manager will have it posted on the RPD Quality Management System website as the official version. Notice of the revised RPD-QM-II will be posted on the Document Revisions page of the RPD Quality Management System website.

RPD-QM-II Revision

1. The Quality Manager will initiate the review process, as needed, at the discretion of the Quality Manager, RPD staff request, or RPD management.

2. The RPD-QM-II will have a completed documentary review during internal audits, during which the staff is requested to review the RPD-QM-II.

3. The RPD-QM-II will be revised when a change is warranted.

4. The RPD-QM-II revision review and approval process is identical to that described above in *Review of RPD RPD-QM-II*.

5. The Quality Manager is responsible for updating all controlled documents.

6. The Quality Manager has the option of issuing errata notifications in the interim between official revisions.

Deleted RPD-QM-II

5. An old version of the RPD-QM-II will be deleted when a new version is created.

6. The Quality Manager shall remove the deleted RPD-QM-II from the RPD files and place it in the QM-II, Previous Versions- Archive Folder.

Acceptance Criteria

The Division Chief approves the RPD-QM-II, Guide, or Procedure by email or written notification to the Quality Manager.

Schedule

Guides and Procedures will be reviewed at least every two years. The RPD-QM-II will be reviewed whenever changes are made.

Records

Master list of controlled documents
RPD Guides
RPD Procedures
RPD-QM-II
Deleted Documents file

Filing and Retention

The master list of controlled documents is available on the RPD Quality Management System website and shall be retained only until the next list is prepared.

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 stored as portable document format (PDF) electronic files located on the NIST servers and disseminated through the external website via 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.*, in other physical locations or storage media) are uncontrolled.

All deleted RPD-QM-II, Guides, and Procedures (including old revisions) shall be placed in their respective Previous Versions- Archive Folder. The Quality Manager shall maintain these files. All old revisions shall be maintained until it is decided to delete the Guide or Procedure altogether. Once the decision has been made to delete the Guide or Procedure, only the last revision must be maintained in its respective Previous Versions-Archive Folder.