Purpose

This protocol provides an outline of elements necessary to write Guides and Procedures within the Ionizing Radiation Division (IRD).

Scope

This protocol applies to all Guides and Procedures written in support of the IRD calibration, measurement quality assurance, and standard reference material programs.

Definitions

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

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

Protocol

Part 1 - *IRD 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 IRD Guides

1. The Guide is distributed to IRD 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 IRD 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 IRD 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 IRD staff of the Guide's status and availability.

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

Guide Revision

1. The Quality Manager will initiate the review process at least every two years or 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 IRD Guides*.

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

5. The Quality Manager has the option of issuing errata notifications rather than revised procedures 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 IRD files and place it in the Deleted Documents file.

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 encouraged to consider the NIST-QM-I and IRD-QM-II as guidance in preparing the content of their (calibration or SRM) service Procedure. The following list of sections from NIST-QM-I and IRD-QM-II are of particular relevance: (4.3) Control of Documents, Records, and Data; (5.4) Calibration and Certification Procedures; (5.5) Equipment; (5.6) Measurement Traceability; (5.7) Sampling; (5.8) Handling of Test and Calibration Items; (5.9) Quality Assurance Practices; and, (5.10) Reporting Results.

4. The Procedure shall be consistent with the NIST Quality System.

Review of Procedures

1. An independent reviewer shall be named by relevant Group Leader.

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

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

Procedure Revision

1. The Quality Manager will initiate the review process at least every two years, or 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 IRD Procedures* with the exception that steps 1 & 2 are optional.

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

Acceptance Criteria

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

Schedule

Guides and Procedures will be reviewed at least every two years.

Records

Master list of controlled documents
IRD Guides
IRD Procedures
Deleted Documents file

Filing and Retention

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

The official versions of the IRD-QM-II, and its Guides, Procedures, forms and supporting documents, are maintained by the IRD 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 by a hypertext link on the IRD home page {http://www.physics.nist.gov/Divisions/Div846/QualMan/index.html}. Printed versions or electronic versions residing elsewhere (*i.e.*, other physical locations or storage media) are uncontrolled.

All deleted Guides and Procedures (including old revisions) shall be placed in the Deleted Documents file. The Quality Manager shall maintain this file. All old revisions shall be maintained until such time as 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 shall be maintained in the Deleted Documents file.