

## **Purpose**

This Guide provides instruction for the control of the quality system documentation of the Ionizing Radiation Division (IRD).

## **Scope**

The documents covered in this Guide include IRD-QM-II, IRD Guides, and IRD Procedures. These documents will be issued as Controlled Documents unless otherwise marked.

This Guide does not cover other documents that form part of the IRD quality system including, but not limited to NIST-QM-I, regulations, standards, other normative documents, calibration charts, drawings, software, specifications, instructions, and manuals. Instructions for addressing these items can be found in the NIST-QM-I, IRD Procedures, or elsewhere in this manual.

## **Protocol**

### *General*

The Quality Manager will maintain a master list identifying the current revision status and distribution of documents (currently doc\_control.xls).

All quality system documentation shall be uniquely identified. This includes the date of issue and/or revision, page numbering, total number of pages, and the issuing authority(ies).

### *Distribution*

The Quality Manager shall retain the master copy of all distributed documents.

All quality system documents covered by this Guide shall be reviewed and approved for use by authorized personnel prior to issue. Authorized editions of appropriate documents shall be available to all personnel involved in calibration and testing work. Other authorized editions may be made available upon the request of the Division Chief or the Technical Managers.

Unauthorized editions of documents may be distributed once the master document has been signed and dated by the individual with authority over the content. An unauthorized edition is a copy of the master document with the words “Uncontrolled Copy” stamped on each page in ink or other permanent medium.

### *Revision of documents*

Quality system documents shall be reviewed at least every two years, sooner if needs dictate. The Quality Manager shall maintain a revision schedule and track all revisions. The master copy of the revised page or document will be marked “retired” on each page and placed in the Deleted Documents notebook by date. The revision shall take its place in the Master Quality System Documentation notebook.

For revisions that are strictly editorial, it is sufficient to replace only the pertinent pages. These changes do not require a revision number change. Complete documents will be replaced when there is any change to content, whether methodology, ordering of procedures, or other matters.

Changes to documents shall be reviewed and approved by the same person who originated the document unless designated otherwise. Where practicable, the altered text shall be identified in the document.

It is the responsibility for authorized personnel to notify the Quality Manager immediately when a Guide/Procedure is no longer in effect and needs to be removed from the IRD-QM-II. The obsolete procedure will be marked “retired” on each page and placed in the Deleted Documents notebook by date.

As revisions are made, the Quality Manager will issue corrected pages, complete documents, or a list of deleted documents to all controlled-copy holders. They, in turn, will remove the expired sections and replace them with the corrected documents as applicable. The removed sections must be recycled or discarded by the controlled-copy holder.

Uncontrolled copies are not required to be updated when revisions are produced.

#### *Recalling a controlled copy*

The controlled copy to be recalled shall be returned to the Quality Manager. If the copy is to be reissued, the Quality Manager will make the appropriate entries in the Controlled Document spreadsheet, *i.e.* date copy was removed from the first party and date and to whom it was reissued.

If the copy is not to be reissued, it shall be noted on each page that the copy was recalled. The copy will then be recycled or discarded.

#### *Electronic version of quality system documentation*

The official master copy and all controlled copies of the quality system documentation will be maintained in hard-copy format. The unofficial master copy will be available in electronic format mainly for ease in making revisions.

If it is decided to place any or all of the documentation on the internet, all pages shall be clearly marked with a watermark or other “stamp” that states “Uncontrolled Copy”.

### **Acceptance Criteria**

N/A

### **Records**

Master list of controlled documents  
Deleted Documents notebook  
Master Quality System Documentation notebook

### **Filing and Retention**

The master list of controlled documents, the Deleted Documents notebook, and the Master Quality System Documentation notebook shall be maintained continuously by the Quality Manager.