

**Purpose**

The purpose of this Guide is to outline the steps to conduct internal audits and management reviews.

**Scope**

This Guide applies to all activities of the Ionizing Radiation Division that pertain to the calibration and testing services.

**Definitions**

N/A

**Equipment**

N/A

**Health & Safety Precautions**

N/A

**Protocol***Internal audits*

1. At least every two years or at the discretion of the Quality Manager and/or Division Chief, the Quality Manager will develop an audit schedule that will verify that the IRD operations continue to comply with the requirements of this quality system and the NIST Quality System.
2. The audit schedule will be provided to the Group Leaders at least one month prior to the proposed audit. The audits shall be conducted by the Quality Manager and/or the Deputy Quality Manager. The Group Leaders may designate someone within their Group to participate in each audit.
3. Unscheduled audits may be performed at any time at the discretion of the Quality Manager, Group Leader or Division Chief.
4. Based on the compliance requirements for an activity, the auditor should develop a checklist for the audit. This checklist should include:
  - 4.1 A list of objective requirements based on the quality system documentation and the scope of the audit.

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- 4.2 A means of noting acceptability for each checklist item (i.e., pass/fail, yes/no or N/A, etc.)
- 4.3 A section for notes to document the basis for acceptability (or unacceptability) of a checklist item.
- 4.4 Pages numbered to ensure that each page is traceable to the rest of the checklist and notes.
- 4.5 The date of the audit and a place for the signature of the auditor on each page.
5. Using the checklist, the auditor may evaluate compliance with requirements by observing activities in progress, interviewing personnel, reviewing documentation or records, and reviewing procedures.
6. The auditor brings any conditions identified as requiring corrective actions during the assessment to the attention of the Group Leader and the individual(s) involved.
7. Appropriate personnel must notify any clients in writing if investigations show that their laboratory results may have been affected.
8. Upon completion of the assessment, the auditor reviews the results with the Group Leader and/or the Division Chief as appropriate.
9. The auditor documents any findings (including those corrected during the audit) and initiates Corrective Action Plans (IRD-G-08) or Preventive Actions (IRD-G-09) as appropriate.
10. After completion of the audit, the auditor prepares a written summary that includes:
  - 10.1 The inclusive dates of the audit.
  - 10.2 The scope of the audit.
  - 10.3 The auditors name.
  - 10.4 Key persons contacted during the course of the audit.
  - 10.5 A summary of the results of the audit, including any exemplary practices, and any findings noted including corrective or preventive actions taken.

11. The summary is then signed by the auditor, dated, and given to the Quality Manager who notifies the Division Chief of the findings and files signed document appropriately.

#### *Management reviews*

Management review requirements are set by the NIST-QM-I; see Section 4.6.2 of that document.

#### *Follow-up audits and reviews*

1. Follow-up actions on audit and review findings shall begin in a timely fashion.
2. If neither a corrective action plan nor preventive action form were initiated, the individual involved shall respond in writing to all findings that require additional information.
3. The auditor will check the response to ensure that the finding is addressed properly. A follow-up audit or review may be conducted if necessary.
4. Once the auditor is satisfied, the response is given to the Division Chief and the Quality Manager to file appropriately.

#### **Acceptance Criteria**

N/A

#### **References**

IRD Quality System Documentation

#### **Documentation**

Audit schedule

Audit or review checklist

Internal audit or management review report and attachments

#### **Filing and Retention**

The Quality Manager shall file all documents by date of audit. The retention time for audit files will be ten years.