

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 Radiation Physics Division (RPD) 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 initiate an internal assessment to verify that the RPD operations continue to comply with the requirements of this quality system and the NIST Quality System.
2. The audit activity shall be conducted by qualified Division members assigned by the Group Leaders and the Quality Manager and confirmed by the Division Chief. The assessors will be knowledgeable of the Division's Quality System.
3. Unscheduled audits may be performed at any time at the discretion of the Quality Manager, Group Leader or Division Chief.
4. The internal audit shall begin with the drafting of a schedule that includes the documentary review of the Quality Manual and associated documents as well as a proposed date range for the technical service reviews.
 - 4.1 The Quality Manager shall prepare the internal assessment schedule and be responsible for ensuring its completion in a timely manner.

INTERNAL AUDITS AND MANAGEMENT REVIEWS

- 4.2 The Quality Manager may participate in each technical service area review if desired. The Deputy Quality Manager may participate in technical service area reviews as schedules permit.
 - 4.3 The Quality Manager shall be responsible for the review of QM-II level documents for accuracy and adherence to current policies and procedures. These documents include, but are not limited to, the Division Quality Manual and all Guides.
 - 4.4 The Quality Manager shall be responsible for the review of the administrative records for the Quality System maintained by the Quality Manager. The review shall include the maintenance of records, both written and electronic, for accurate and timely archiving.
 - 4.5 The Quality Manager shall prepare a summary of findings to be combined with the internal assessment findings for the technical service reviews (see number 11 in this section).
- 5. Based on the compliance requirements for an activity, the auditor should develop a checklist for the audit. This checklist should include:
 - 5.1 A list of objective requirements based on the quality system documentation and the scope of the audit.
 - 5.2 A means of noting acceptability for each checklist item (i.e., pass/fail, yes/no or N/A, etc.)
 - 5.3 A section for notes to document the basis for acceptability (or unacceptability) of a checklist item.
 - 5.4 Pages numbered to ensure that each page is traceable to the rest of the checklist and notes.
 - 5.5 The date of the audit and a place for the signature of the auditor on each page.
 - 6. Using the checklist, the auditor may evaluate compliance with requirements by observing activities in progress, interviewing personnel, reviewing documentation or records, and reviewing procedures.
 - 7. The auditor brings any conditions identified as requiring corrective actions during the assessment to the attention of the Quality Manager, Group Leader and the individual(s) involved.
 - 8. Appropriate personnel must follow the Change in Disseminated Values Guide (RPD-G-12) to notify any clients if investigations show that their results may have been affected.

INTERNAL AUDITS AND MANAGEMENT REVIEWS

9. Upon completion of the assessment, the auditor reviews the results with the Group Leader and/or the Division Chief as appropriate.
10. The auditor documents any findings (including those corrected during the audit) and initiates Corrective Action Plans (RPD-G-08) or Preventive Actions (RPD-G-09) as appropriate.
11. After completion of the audit, the auditor prepares a summary that includes:
 - 11.1 The inclusive dates of the audit.
 - 11.2 The scope of the audit.
 - 11.3 The auditor's name.
 - 11.4 Key persons contacted during the course of the audit.
 - 11.5 If necessary, a summary of the results of the audit may be prepared, including any exemplary practices, and any findings noted including corrective or preventive actions taken.
12. The Division Chief is notified of the findings and the document(s) are filed appropriately.

Management reviews

Management review requirements are set by the NIST-QM-I; see Section 4.6.3 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

RPD Quality System Documentation

Documentation

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 indefinite.