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 management system and the NIST Quality Management System; see QMI 8.8 and Appendix B.

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 Management 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.

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 Management 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 or use the spreadsheet provided by the quality manager. A sample checklist is found in Appendix A. This checklist should include:

5.1 A list of objective requirements based on the quality management system documentation and the scope of the audit.

5.2 Each finding should be clearly identified using the following four categories, taken from the NIST Peer Review/Assessments Report template:

5.2.1 **Nonconformity (NC)** – stated with reference to the ISO standard, the NIST-QM-I, or to sublevel quality documents – evidence is described when the requirements are not being met or the documentation is silent. Per NIST-QM-I, the RPD has a maximum of 90 days to correct the nonconformity or to produce its action plan. Cause of the nonconformity will also be identified and described.
5.2.2 **Comment (C)** – when the requirement is met, but opportunities for improvement may be present. NIST will consider the cost-benefit and consider risks associated in determining whether an action will be taken. A formal response to the comment will be provided. Comments are considered actionable.
5.2.3 **Editorial (E)** – often the reviewers find opportunities for improving and clarifying the information in the documentation that is under the scope of review. NIST will consider including these notations if captured on the findings spreadsheet and will leverage the updates if revisions are required in the documentation, particularly for the quality manuals and procedures.

5.2.4 **Notes (N) -** will be included in the spreadsheet, if time permits for the reviewers. These notations will include complimentary observations for the measurement service providers and their measurement systems and procedures.

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 and Report Amendments Guide (RPD-G-12) to notify any clients if investigations show that their results may have been affected.

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) on the spreadsheet provided by the quality manager or the auditor's preferred checcklist 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, which can be accomplished on the provided checklist, 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 any findings through a report generated by the quality mananger using a format resembling the NIST Corrective Action Log, an example of which is found in Appendix B. The document(s) are filed appropriately for later use in the 5-year audit

Management reviews

Management review requirements are set by the NIST-QM-I 8.9.

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 Management System Documentation

Documentation

Audit or review checklist
Internal audit or management review report

Filing and Retention

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

Appendix RPD-G-10. A

CHECKLIST FOR AUDITOR

This is an example of a spreadsheet that can be used for the internal audit, provided by the quality manager at the commencement of the audit. The auditor can use a preferred checklist, providing the required items from RPD-G-10 section 5 are included.

NIST QS INTERNAL AUDIT CHECKLIST AND SUMMARY (see RPD QMII Guide 10 section 5 and 11)						
Procedure number (Scope of Audit): Use Procedure number 1 through 18.						Inclusive Dates of Audit:
NIST ID: Use the Calibration Service Identifier						Auditor(s) and signature(s): Use an electronic signature or initials.
Objective requirements (RPD QMII Guide 10 section 5.3 & 11.5): technical review of the procedure (add to this if necessary or specify the approach taken).						Key persons contacted during audit:
Item No.	**Section**	**Guide # & Page**	**Procedure # & Page**	**NC,C,E or N**	**Findings (Notes) (RPD QMII Guide 10 section 5.3 & 11.5)**	**Corrections (RPD QMII Guide 10 section 11.5)**
1						
2						
3						

Add rows as necessary.

From RPDG-10 5.5.2

5.5.2.1 Nonconformity (NC) – stated with reference to the ISO standard, the NIST-QM-I, or to sublevel quality documents – evidence is described when the requirements are not being met or the documentation is silent. Per NIST-QM-I, the RPD has a maximum of 90 days to correct the nonconformity or to produce its action plan. Cause of the nonconformity will also be identified and described.

5.5.2.2 Comment (C) – when the requirement is met, but opportunities for improvement may be present. NIST will consider the cost-benefit and consider risks associated in determining whether an action will be taken. A formal response to the comment will be provided.

5.5.2.3 Editorial (E) – often the reviewers find opportunities for improving and clarifying the information in the documentation that is under the scope of review. NIST will consider including these notations if captured on the findings spreadsheet and will leverage the updates if revisions are required in the documentation, particularly for the quality manuals and procedures.

5.5.2.3 Notes (N) - will be included in the spreadsheet, if time permits for the reviewers. These notations will include complimentary observations for the measurement service providers and their measurement systems and procedures.

Appendix RPD-G-10. B

Example of a NIST CORRECTIVE ACTION LOG FY 20

CAR #	Date Issued	Assigned to	Requirement Reference	Brief Description	Risk[1] and Impact[2]	Reply Request Date	Expect Comp. Date	Reply OK? Y/N	Status and Comments	Date Closed
1	19 August 2019 – Carry over from FY19	Sally Bruce	NIST-QM-I, 8.3	Comment 4 from the Internal audit: review of the NIST Quality Manager handbook is needed.	In the event a backup NIST Quality Manager is needed, the Handbook is a guide to the duties and responsibilities – Medium impact	19 August, 2019	31 December 2019		Agreed, schedule for FY20	

Format 2017-11-22 provide by Sally Bruce and implemented in August of 2019.

[1] Risk can be positive or negative effect of the nature of the action item/finding, consider the probability of this happening.
[2] Impact is a consideration of what is at stake to the QMS, the operations, or the services (high or low impact).