This procedure addresses ISO 9001:2015 clause 9.2 Internal audit. It represents a classic and well-established approach to internal auditing.

If internal auditing is new in your company and you don't have any established practices, you should incorporate this procedure without too many changes, and then review it, say, a year later when you get your own experience with operating this system.

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for conducting internal audits of the quality management system.

II APPLICATION

This procedure applies to all processes and activities of the quality management system, and to all areas where the QMS is implemented.

I PROCESS

Purpose: The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for conducting internal audits of the quality management system.

Application: This procedure applies to all processes and activities of the quality management system, and to all areas where the quality system is implemented.

Process owners: <Quality>

II PROCESS ACTIVITIES AND PROCEDURE

1 Audit plan

1.1 <Quality> is responsible for planning and scheduling internal audits of the quality system, manufacturing processes and products. Audit frequency is based on the status and importance of the processes, products and areas to be audited, as well as results of previous audits, internal/external nonconformities, and customer complaints. Each quality system process is audited at least once a year.

An audit plan where all processes and activities are audited with the same frequency (for example, annually) is not acceptable. There must be some variation in audit frequency to demonstrate that audits are scheduled on the basis of the status and importance of the audited area or activity.

1.2 Internal audits cover all quality management system processes; are conducted in all relevant departments, functions and areas; and cover all relevant shifts.

Be sure that your audit plan reflects this requirement for covering all shifts.

1.3 Quality system audit plan and schedule is documented in IMSXpress > Qlty Audit module. The audit plan lists processes of the quality system to be audited and the planned audit dates and assigned auditors.

1.4 Internal audit plans and cycles are synchronized with management reviews of the quality system (refer to process procedure QPP-093-1 Management Review), so that complete results from the full auditing cycle are available in time for the management review meeting.

2 Audit team

2.1 <Quality> is responsible for qualifying, training and assigning internal auditors. Personnel assigned to carry out internal audits are independent of those having direct responsibility for the audited activity.

Edit this as appropriate to your company, but be sure to clearly communicate the requirement for objectivity and impartiality of the auditor.

2.2 Internal auditors are qualified on the basis of their education, experience and training. Minimum requirements are:

- **Education:** High School graduation
- **Experience:** Two years in the industry
- **Training:** 16 hours external or in-house training

The training can be by an external course or seminar provided by a qualified institution (such as a registrar, accredited training organization, etc.), or in-house training provided by a qualified consultant/trainer. If training is provided in-house, the trainer must have documented qualifications as a Lead Auditor.

The standard explicitly requires that internal auditors must be qualified, but does not state any particular qualification criteria. The criteria defined in this clause are just an example.

3 Preparing for audit

3.1 Auditors prepare for an audit by:

- Reviewing the Internal Audit Checklist (form QPPF-092-1);
- Refreshing their knowledge of the quality manual and relevant process procedures;
- Reviewing nonconformity reports, customer complaints, and corrective action files; and
- Customizing and augmenting (as necessary) the Internal Audit Checklist.

4 Conducting and reporting the audit

4.1 The manager responsible for the area scheduled for audit is contacted at least one week in advance with the proposed audit date. The manager responds with a confirmation, or proposes an alternative date.

4.2 In conducting the audit, auditors generally follow the Internal Audit Checklist (form QPPF-092-1). The checklist defines the minimum scope criteria (requirements) for the audit and provides examples of relevant questions and auditing techniques. The checklist is also used for referencing reviewed evidence and keeping audit notes.

4.3 When a nonconformity is noted, it is brought to the attention of, and discussed with, the responsible manager. Before the end of the audit each noted nonconformity is documented in the IMSXpress system > Quality Audit module using electronic form EF-140-3 Audit

Finding. Auditors fill out only the top block (references and particulars) and the Finding block of the audit finding form, describing the noted nonconformity. The form is then processed by the Assignee who uses its second and third block to determine root causes and document the corrective action.

5 Correcting audit finding

5.1 The person identified in the 'Assigned to:' field (form EF-140-3 Audit Finding) is responsible for implementing actions to address the audit finding. This person is referred to as Assignee.

5.2 The first step in addressing the finding is the review and analysis of the noncompliance and determination of its causes. The results of the analysis and the causes are documented in form EF-140-3.

5.3 After the root causes are determined, one or several corrective and preventive actions are implemented to:

- Correct the noncompliance
- Prevent recurrence of the noncompliance
- Prevent occurrence of similar noncompliances elsewhere

Corrective actions taken are documented in form EF-140-3.

5.4 Any implemented changes are reviewed with respect to their impact on other processes and documents. Related processes and documents are updated as needed.

6 Closing out audit finding

6.1 On, or immediately after, the due date for correcting audit finding, the Auditor or the <Quality> determines if appropriate actions to correct the finding have been implemented. If the actions are deemed to be fully implemented, the finding record (form EF-140-3) is closed out and the follow up due date is set. If more time is needed to fully implement the actions, the due date can be extended, as necessary.

7 Follow Up Review

7.1 On, or immediately after, the follow up due date, the Auditor or the <Quality> follows up with an inquiry or an audit to determine if the implemented corrective actions are effective. If the actions are deemed to be effective, the follow up (form EF-140-3) is closed out. If the actions are not effective, additional actions are implemented to add new, or further strengthen existing controls.

7.2 Results of the follow up review are documented in form EF-140-3.

8 Managing, monitoring and reviewing the audit

8.1 Progress and status of the Internal Audit process is managed and monitored in the IMSXpress system > Quality Audits module using electronic form EF-140-2 Audit Plan Item. For each completed item, the ‘Actual Date’ and ‘Status’ are recorded in the plan.

8.2 The internal audit is completed when all items of the audit plan are completed and all audit findings are closed out.

8.3 At the end of an auditing cycle, all findings are compiled and analyzed, and are presented at the management review meeting (refer to process procedure QPP-093-1 Management Review).