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QOP-82-02	Internal Quality Audits (full text)		
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This procedure 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 quality system is implemented.

III   PROCEDURE

1   Audit plan

1.1   Planning of internal audits is based on the Quality System Process Map diagram and the Quality System Process Matrix documented in the Quality Manual Section 4, and on the Internal Audit Checklist documented in form QOP-82-02-F1. The process map, matrix and the audit checklist define all major quality system processes, and for each process specify:

- Sequence and interrelation between the processes (process map),
- Process purpose, owners and sub-processes (process matrix),
- QMS requirements (audit checklist),
- Questions to ask and auditing techniques (audit checklist)
- Relevant sections and clauses in the ISO 13485 standard (audit checklist).

1.2   <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.

1.3   Internal audits cover all quality management system processes and sub-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.

1.4   Quality system audit plan and schedule is documented in the IMSXpress system > Internal

Audits module (select the audit in the grid, and click the Audit Plan button in the top menu). The audit plan lists processes of the quality system to be audited and the planned audit dates and assigned auditors. More detailed scope and reference for the audit, to include relevant sub-processes, procedures, areas/functions and reference clauses of ISO 9001 standard, are provided in the Quality System Process Map diagram (QM 4.1.1), the Quality System Process Matrix (QM 4.1.1), and the Internal Audit Checklist (form QOP-82-02-F1).

Note that the Audit Plan in the IMSXpress system is actually just the schedule component of the internal audit plan. The actual scope and reference for the internal auditing program are defined in the Quality System Process Map diagram, the Quality System Process Matrix, and the Internal Audit Checklist.

1.5 Internal audit plans and cycles are synchronized with management reviews of the quality system (refer to operational procedure QOP-56-01 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 Quality System Process Map diagram, the Quality System Process Matrix (documented in the Quality Manual Section 4), and the Internal Audit Checklist (documented in QOP-82-02-F1);
- Refreshing their knowledge of the quality manual and relevant operational 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 (QOP-82-02-F1). The checklist defines the minim 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 > Internal Audits > Audit Findings. 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 responsible manager who uses its second and third block to determine root causes and document the corrective action.

5   Corrective action and follow up

In this procedure, the process for requesting and implementing corrective actions resulting from audit findings is incorporated into the Audit Finding form in the IMSXpress system. Thus, the general Corrective and Preventive Action procedure and form do not apply to audits. While, in theory, the general Corrective and Preventive Action system could be used for internal audit findings, it is not a good idea. Audit findings must always be addressed as a priority, and within a specified time frame; because an open finding means that the quality system is technically in default.

5.1   Once a nonconformity is identified and documented, further processing of the audit finding form is similar to the corrective action requests (operational procedure QOP-85-03 Corrective and Preventive Action). The responsible manager investigates the root causes of the problem noted as a nonconformity, and implements and documents appropriate corrective action.

5.2   On, or immediately after the due date for implementation of corrective action, the auditor follows up with an inquiry or an audit to determine if the corrective action has been implemented and if it is effective. When there is objective evidence that the corrective action is effective, the audit finding is closed out. If more work is needed to fully implement the action, the due date may be extended by up to 30 days.

6   Managing, closing out, and reviewing the audit

6.1   Progress and status of the Internal Audit process is managed and monitored in the IMSXpress system > Internal Audits module (select the audit in the grid, and click the Audit Plan button in the top menu). For each completed item, the 'Actual Date' and 'Status' are recorded in the plan.

6.2   The internal audit is closed when the whole audit plan is completed and all audit findings are closed out. The status of the audit is recorded in the IMSXpress system > Internal Audits

form.

6.3   At the end of an auditing cycle, all nonconformity reports established during the cycle are compiled and analyzed, and are presented at the management review meeting (refer to operational procedure QOP-56-01, Management Review).

IV   ASSOCIATED DOCUMENTS

- Form QOP-82-02-F1 Internal Audit Checklist
- Operational Procedure QOP-42-03 Control of Records
- Operational Procedure QOP-56-01 Management Review
- Operational Procedure QOP-85-03 Corrective and Preventive Action

Records associated with this procedure may include:

- ***Internal audit plans:*** *Plans for quality management system audits. Maintained in the IMSXpress system > Internal Audits module.*

- ***Internal Audit Checklists:*** *Checklist filled out with comments and references noted by auditors during the audit. Established using form QF-82-02-3, Internal Audit Checklist.*

- ***Audit Finding Reports:*** *Reports with audit findings and records of corresponding corrective actions. Established and maintained in the IMSXpress system > Internal Audits > Audit findings module.*