Procedure: Internal Quality Audit

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# Purpose

This procedure describes a system, provides instructions and assigns responsibilities for conducting internal Quality audits at [Company].

# Scope

The scope of this procedure includes internal audits performed to verify the company’s compliance with regulatory codes, guidelines and standards. (Refer to QM001: Quality Manual sections 2.1 and 2.2 for complete listing)

# Responsibilities

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| Role | Responsibility |
| Quality Manager | * Ensures this procedure is implemented and followed. * Initiates all internal audits and ensures they are conducted in an efficient and timely manner. * Maintains and files documentation generated from internal audits. * Ensures documents and reports are filed in a safe and secure manner. * Documents results of audits and communicates the results to appropriate personnel. * Documents and monitors corrective actions * Ensures internal audit non-conformances are addressed in a timely and effective manner. |
| Audit Team Members | * Have been trained in this SOP * Perform or contribute to audits in their area of expertise * Provide all findings to the Quality Manager |
| Area Managers | * Oversee the corrective actions resulting from internal audits * Ensure that corrective actions are completed in a timely and effective manner. |
| Staff/ contractors | Provide truthful and useful information to the auditors. |

# Procedure

Internal audits are performed at planned intervals to confirm that the quality management system (QMS):

* conforms to the regulatory requirements
* is effectively implemented and maintained.

The internal audit program is planned taking into consideration the status and importance of the processes and the areas audited, as well as the results of previous audits.

## Internal audit team

The Quality Manager is responsible for selecting the audit teams, ensuring that there is no conflict of interest. Ideally, an audit team should comprise of two to three auditors.

The audit team can include:

* an experienced auditor, preferably the Quality Manager or delegate
* staff member(s) from a department not being audited
* a suitably qualified and experienced specialist consultant.

The Quality Manager or delegate is responsible for co-ordinating the internal audit including:

* planning the scope, objectives, criteria, duration and resources
* determining the method of auditing (documentation review, interviewing staff, review of non-conformances)
* selection of auditors (including consultants)
* organising the timing of the audit with the relevant department manager
* advising the relevant department of the scope of the internal audit
* reporting the results of the audit to the relevant department head and senior management
* organising follow-ups to the audit in response to non-conformances observed
* leading the audit process (where there is no conflict of interest).

The other internal audit team members are responsible for:

* making themselves available for the audit
* preparing for the audit by reviewing the relevant procedures, regulatory requirements and other documents as directed by the quality manager
* identifying non-conformances within the area under review
* aiding in the completion of the audit report and presenting the findings.

## Scope of internal audits

The scope for each audit will include as a minimum:

* a review of the previous audits results. This will be used to determine the scope of the current audit
* verification of actions taken to rectify non-conformances from the previous audit
* review of non-conformance reports, customer complaints and corrective actions
* confirmation of results from corrective actions.

The scope will be determined by the area being audited and will reflect the requirements of the appropriate section of the QMS.

## Frequency of internal audits

Auditing frequency is dependent on:

* the results of the previous audits
* the status and importance of the processes
* the area being audited
* the length of time the QMS has been in operation at the time the audit is carried out
* non-conformities
* customer complaints.

Audits will be performed every six months (as a minimum). Critical areas may be audited more frequently depending on the results of previous audits and at the discretion of the Quality Manager.

The Quality Manager is responsible for documenting an audit schedule for each department. A proforma is provided for this purpose; Form FP802-1 Internal Audit Register.

## Conducting the internal audit

The Quality Manager or delegate notifies the area supervisors of the audit. Audit team members are briefed on the audit process and the areas under audit.

Checklists are used where possible to prompt the auditors to examine certain aspects and all findings are recorded thereon.

During the audit, the auditors aim to seek objective evidence to demonstrate whether the process conforms to the requirements of the QMS. When a non-conformance is noted, this is brought to the attention of the department manager and discussed.

## Reporting the internal audit

At the conclusion of an audit, an informal, verbal report is provided to the department manager. The manager is given the opportunity to refute, correct, comment or further clarify any observations. The Quality Manager’s decision is final regarding any disputed findings between the area manager and the auditor.

Within one week from the completion of the audit, the Quality Manager (or delegate) prepares a formal audit report that details all observations and their criticality.

|  |  |
| --- | --- |
| Criticality | Description |
| Critical | The observation is a non-compliance with the QMS or will affect product quality. |
| Major | The observation may result in a non-compliance with the QMS or may affect product quality. |
| Minor | The observation is a deviation from a procedure that is unlikely to affect product quality. |
| Comment | The observation is a suggested improvement to the system or procedure. |

The audit report indicates the period in which the department manager should resolve and respond to reported observations; usually this is four weeks.

## Responding to the internal audit

The department manager resolves and responds to all observations noted in the formal audit report within the specified period. The audit response includes:

* outcomes of simple deficiencies that have been resolved immediately
* references to corrective actions if the deficiencies are more complex.

Documented evidence is attached where appropriate. The auditor follows up all deficiencies to determine if they have been resolved appropriately.

## Audit Metrics

The Quality Manager or delegate enters the audit summary into a spreadsheet, database or document and monitors the audit performance of each area. Non-conformances relating to audit findings are also used to track the performance of each area.

Appendices

Amend as required or delete WS-look for an audit checklist.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QM001 | Quality Manual |
| FP802-1 | Internal Audit Register |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
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List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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