# internal audits

## Purpose

Internal audits are systematic and independent examinations (by direct observation or records) for monitoring the operation of (*Insert manufacturer’s name*), to verify work practice compliance with operational policies and procedures, check compliance with regulatory requirements and identify opportunities for improvement.

## Auditor Training

1. The Quality Coordinator is responsible for selecting and training internal auditors.
2. Personnel are selected for auditor training on the basis of their communication skills, technical knowledge and interest in quality management.
3. Auditors may be trained externally (e.g. NATA Internal Audits course) or in-house.
4. In-house trainees attend a theory course to gain an understanding of accreditation standards and the operation of a quality management system. The course covers auditing concepts, techniques and procedures, including conducting an audit, recording findings and identifying non-conformances.
5. Course notes are provided to trainees.
6. To complete their training, personnel conduct an audit under the supervision of the Quality Coordinator (or suitably qualified designee).
7. Auditors are required to conduct at least one audit every two years to maintain competency.

## Audit Schedule

1. An annual schedule of audits is planned to ensure critical elements are regularly addressed. The program includes audits of external facilities performing critical contracted services (suppliers).
2. The schedule includes, but is not restricted to:

**Horizontal audits** of systems or processes. Horizontal audits of the facility, equipment, personnel, storage, materials, suppliers, management/product reviews and the quality system should be conducted at a minimum every 3 years, preferably every 2 years.

**Vertical audits** of products: including (where applicable) collection, receipt, processing, storage, release, labels, distribution, transport, therapy administration, disposal. A minimum of three different product types should be audited each year. If a vertical audit identifies serious deficiencies in a particular process, a horizontal audit of that process should be scheduled.

1. Schedule audits for a specified month. Refer to *(Insert name of quality software application)* DOCXX for audit registration instructions.
2. The audit should be conducted within the scheduled timeframe, taking into consideration work commitments of both the auditor and auditee. If the audit is significantly delayed, the Quality Coordinator is to be informed and the reason for the delay recorded in *(Insert name of quality software application)*.
3. The planned schedule may be amended to include audits scheduled in response to external assessments or non-conformances.
4. If audits raise concerns about continuing non-compliance with documented procedures or regulatory requirements, the relevant activity will be audited more frequently.

## Audit Preparation and Conduct

1. The selected auditor must have sufficient expertise to identify problems but must not be solely responsible for the processes being audited.
2. The Quality Coordinator is to provide the auditor with an explanation of the scope of the audit, who to contact to arrange the audit (auditee), an audit checklist and other relevant documents.
3. The auditor is responsible for contacting the auditee and arranging a suitable time for the audit.
4. During the audit, the auditor is to:

* gather and evaluate information as effectively and efficiently as possible about the activity.
* select a representative sample of records, where appropriate
* check work practice against documented procedures either by direct observation and/or records
* record findings on the audit checklist and attach photocopies of key records and documents.

## Audit Reports

The auditor is to write the report in consultation with the Quality Coordinator. This partnership approach facilitates standardised audit practice and continued mentoring and review of auditing competency.

1. Use the Audit Word template to assist reporting.
2. Report an overview of the audit findings in the Observations section of the Word report template. Include positive feedback where applicable.
3. Identify any recommendations and non-conformances.
4. Raise a non-conformance if the audit identified a failure to comply with regulatory requirements or a failure to follow documented procedures. It should be possible to express the non-conformance in the words of the relevant standard or documented procedure. Record the non-conformance in the Non-conformances sections of the report template.
5. Raise a recommendation for an issue identified by the audit which was not a non-conformance but where improvement is desirable. Record it in the Recommendations sections of the report template.
6. Record the audit findings in *(Insert name of quality software application)*. Refer to *(Insert name of quality software application)* for detailed instructions. If possible, record the findings and related non-conformances and recommendations directly through the electronic Checklist function. *(Insert name of quality software application)* only allows findings to be expressed as non-conformances or observations. We use the observation function to record audit recommendations.
7. Record the non-conformances as Compliance Managements using the Audit Non-conformance template. Identify the Source as Audit Internal.
8. Record the recommendations as observations in the Findings field.
9. Print a hard copy of the audit Word report and attach the completed checklist, copies of any non-conformances raised and relevant source information.
10. Discuss the audit findings with the auditee and, where applicable, management.
11. The auditor and auditee are to sign the report.
12. The Quality Coordinator is to review, sign and file the hard copy report and embed an electronic copy of the audit Word report in the *(Insert name of quality software application)* record.

## Audit Review and Closure

1. Action each non-conformance within the time frame specified.
2. Review the audit findings at the monthly (*Insert manufacturer’s name*) Management Meeting and, where appropriate, at other meetings such as the (*Insert manufacturer’s name*) Staff Meeting and the relevant clinical program meeting.
3. Use the findings to recognise potential problems, detect trends and identify improvement opportunities.
4. Closure of the internal audit requires:

* Acceptance (by signature on the hard copy report) of the internal audit report by the auditor, auditee and the Quality Coordinator (audit program manager). Record acceptance by the auditee in *(Insert name of quality software application)*.
* Completion of the audit response. All non-conformances must be completed. Actions taken in response to the recommendations must be recorded and accepted by the Quality Coordinator. The date and forum of the management review must be recorded. Supporting documentation may be attached to the response.

1. Once the closure requirements have been met, the Quality Coordinator may authorise closure of the audit by signing the response and recording the audit closure date.
2. The Quality Coordinator is to:

* Attach the hard copy response to the audit report on file and embed an electronic copy in *(Insert name of quality software application)*.
* Print the completed *(Insert name of quality software application)* Audit Report and attach it to the audit documents as a coversheet.

1. Operation of the audit program is to be reviewed at each (*Insert manufacturer’s name*) Management Review Meeting.

## Procedure History

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| --- | --- | --- | --- | --- |
| **Revision** | **Date** | **Modification** | Approved By | Implemented |
| 1.0 | *(Insert date)* | Originally drafted by *(Insert name)* | *(Insert name)* | *(Insert date)* |
| 2.0 | *(Insert date)* | Revised by *(Insert name & description of changes)* | *(Insert name)* | *(Insert date)* |