INTERNAL AUDITS

Internal audits are an organisations own process for monitoring the correct implementation of its management system. Internal audits serve three basic purposes:

- To provide assurance to management that the system is operating as intended;
- To investigate the cause of noted problems, determine how the system allowed such problems to occur, and implement corrective action to prevent recurrence;
- To identify opportunities to improve the system or the manner in which it is implemented.

Essentially, internal audits give an organisation assurance regarding the effective operation of its management system and identify opportunities for continuous improvement.

Internal audit procedures apply to all aspects of the management system, i.e., Quality Management System, Environmental Management System, OH&S Management System etc. Internal audits should be conducted as a scheduled series of detailed examinations to verify that the organisation's operation complies with the requirements of the integrated quality system. All system work instructions, documents, records and accreditation are included in such audit.

Additionally, unscheduled audits may be carried out to satisfy a specific Corrective & Preventive Action Request. The scope of each such audit may be determined by the importance of the activity that is being audited.

Types of Audits

There are two basic methodologies that are commonly used for conducting compliance audits and these can be used separately or in combination.

"Horizontal" Audits (procedure based)

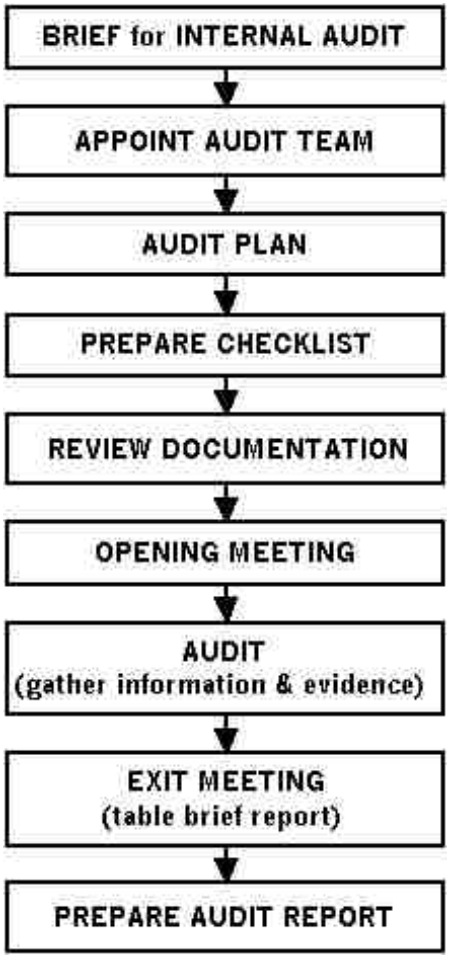
In this audit approach the audit examines a particular procedure across an organisation; for example document control, calibration, training, purchasing, traceability, etc. As this type of audit focuses on one procedure only it is examined in great depth and can reveal different interpretation or application of the procedure in different departments of an organisation. Since this audit approach only examines one procedure at a time the interaction between procedures and processes is not revealed.

"Vertical" Audits (process based)

This audit approach involves tracking a particular process from one end to the other, that is, all steps in the process are examined and the inputs into each step. This type of audit allows the auditor to examine all the factors affecting the implementation of the process but does not allow identification of inconsistencies in the application of procedures. Vertical audits often do not examine the management components of the quality management system.

Audit Processes

The processes involved in undertaking an audit:



Audit Brief

For internal audits, the audit brief should include, as a minimum:

- Identification of the work area to be audited,
- Contact person in that area (auditee),
- Purpose(s) of the audit,
- Scope of the audit (usually in terms of standards, procedures, work instructions, activities),
- Timeframe for completion of the audit,
- Expected duration (hours, days),
- Identity of audit team leader,
- Number of auditors in the team (and who is to select them),
- Relevant outcomes from previous audits to be taken into account,
- Any previous corrective actions to be followed-up, and
- Any other pertinent issues (customer complaints, product/process problems).

Before contacting the auditee about an impending audit, obtain whatever information about operations and activities that must be taken into account for planning and conducting the audit, for example:

- The normal working hours of the work group to be audited,
- Any daily/weekly cycles in the work being performed,
- The identity of the staff members who normally perform the activities to be audited
- Any leave arrangements for key staff that could coincide with the audit,
- The possible need for personal protective equipment for members of the audit team,
- Any special health and safety issues to be taken into account, and
- Any other circumstances or factors that might interfere with the audit.

Even when you think that you are familiar with the operations and activities of the work group you will be auditing, you should still explore these issues with the auditee just in case you have overlooked something or perhaps circumstances have changed.

After advising the auditee of the timeframe for completion of the audit, discuss possible dates and times and reach a mutually acceptable agreement on the date(s) and time(s) for the conduct of the audit

Selection and Training of Auditors

While the Quality Manager may play the key role in audits it will often be necessary to draw company personnel into the internal audit program as auditors. The requisite personal qualities include:

- Understanding of quality management system concepts,
- Knowledge of the quality management system itself,
- Appropriate technical knowledge,
- Ability to investigate and analyse situations,
- Good judgement and communication skills, and
- Positive attitude toward the quality management system.

For the audit program to be successful, chosen personnel will need specific audit training. The requisite skills and expertise will include:

- Understanding of the auditing **concepts**,
- Understanding of the audit **program objectives** and **procedures**,
- Knowledge of how to **plan** and **conduct** an audit,
- Knowledge of **what to audit** in various audit situations,
- Knowledge of the most effective information gathering techniques, and
- Understanding of the **human relations** aspects of auditing.

The Quality Manager must acquire the necessary training skills through participating in one of the comprehensive auditing trainer courses.

Audit Plan

Now that the scope of the audit is defined and the assistant auditor selected, it is time to think through how to will conduct the audit in the time available, what roles auditors will play in the audit, what activities auditors will audit together and what activities will be audit separately. In other words, prepare an audit plan. Developing the audit plan is generally the responsibility of the audit team leader, even if done in consultation with fellow members of the audit team.

The guidance on content of audit plans given in the auditing standards is mainly directed to external audits. Audit plans for internal audits can be simplified somewhat and should include the following:

- Audit identification number,
- Identification of the work unit to be audited,
- Name & title of the auditee representative for this work unit,
- Purpose and scope of the audit,
- Identity of members of the audit team,
- Date(s) on which the audit to be conducted,
- Structure of the audit, including the expected starting and finishing times of the Opening and Closing Meetings, and any planned team meetings, and
- The planned sequence and timing of the audit activities, and identification of the member of the audit team who will be undertaking them.

The Audit Plan is the key guiding document for the audit team. It ensures that team members know what is expected of them, especially in terms of the sequence and timing of their auditing activities. The Audit Plan tells the auditee how the audit will be conducted, enabling them to prepare more effectively and reschedule non-essential work activities.

Preparing Audit Checklists

A process-oriented checklist is the most suitable for internal audits, it draws the auditor's attention to the key facets of the process/activity under examination, and allows the detail to reside in the documented procedure or work instruction. The process-oriented checklist emphasis is on outcomes, and they can do this all on one page. The benefits of checklists in an audit are:

- Encourage a structured approach to the audit,
- Ensure that important issues are covered,
- Ensure nothing important is overlooked,
- Assist in time management throughout the audit,
- Convenient place to record any pre-audit concerns,
- Convenient place to record audit evidence and observations, and

- Record of what auditor examined and what was found

Review Briefing Documents

Study current copies of all management system documents related to the scope and subject of the audit, including previous audit reports, both internal and external, as well as all non-conformances and preventive actions

Information and Evidence in Audits

An audit is essentially a fact-finding mission with the focus on the system rather than blaming the staff. The auditor's task is to gather evidence about compliance (or otherwise) with the management system the organisation claims to be following. To do all this in the time allotted, the auditor must gather the information as **efficiently** and **effectively** as possible whilst also being sufficiently **thorough** and **objective**. There are six techniques commonly available to auditors for gathering information and evidence during an audit:

- *Discussing issues,*
- *Asking questions,*
- *Listening to responses,*
- *Observing activities,*
- *Examining facilities, and*
- *Examining records*

The first three of these techniques normally give information. If what is being discussed or heard is important to the outcome of the audit, then seek confirming evidence, even if the same information is coming from multiple sources.

The second three techniques normally provide evidence and will usually be used in combination with one another and the information gatherers. For many audit tasks, (for example, performance of a test in a laboratory), *observation of activities* will be part of an approach that could also involve discussing the test with the technician and examining the test records, including quality control records. Depending upon the type of laboratory, *examining facilities* could include test equipment, ancillary equipment, accommodation and testing environment, essential laboratory services, storage and clerical areas, and anything else essential to the proper performance of the work. In every audit, *examining records* will be a key evidence gatherer.

The records of interest to an auditor will include:

- System records (e.g., management review, corrective action, document control, etc),
- Operational records (e.g., purchasing, subcontracting, staff training, calibration, etc),
- Test-related records (e.g., test results, quality control records, nonconforming work, reports, etc), and
- Archived records (depending on scope and timescale of audit).

The Final Team Meeting

On completion of audit activities the audit team will use a final team meeting to review findings and achieve consensus on the audit outcome. Even as a solo auditor, it is likely the auditor will need a short period of time to review the information and evidence collected and decide the outcome of the audit. In doing this:

- Review all of the significant information and evidence collected,
- Decide the areas of compliance and noncompliance,
- Decide the significance of any noncompliances (major or minor),
- Identify any improvement opportunities that you wish to raise with the auditee, and
- Assemble your thoughts in readiness for the Closing Meeting with the auditee(s)

In some organisations, auditors are encouraged to prepare a handwritten report on the audit during this team meeting, so that a copy can be passed to the auditee during the Closing Meeting.

Remember, to be a noncompliance, your audit finding must meet two criteria:

- Based on evidence, and not just information; and
- In breach of a specific requirement in the standard or the organisation's quality system.

When a noncompliance is discovered in an audit or assessment, its significance should be evaluated so that appropriate levels of remedial and corrective action can be taken. The auditing standards give no guidance on how to classify noncompliances, but NATA advises its laboratory assessors to classify deficiencies as

conditions or ***minor conditions***; these classifications are consistent with the terms **major nonconformity** and **minor nonconformity** as used by certification bodies auditing quality management and environmental management systems.

Audit Reports

A free-form format audit report is commonly used within small and medium size organisations. In this type of report the auditor initially summarise the audit findings on the report "cover page", and then provides more details (including links to the corrective actions raised) in the follower pages. Corrective action requests should be attached, one for each of the significant noncompliances raised as a result of the audit. It does not matter in which order these are written, but most experienced auditors find it easier to write the noncompliance statements before writing the actual report.

Reports should be:

- Concise - but not cryptic,
- Positive - but not patronising, and
- Constructive - but not directing.

Reports that are likely to be well received by auditees will include:

- Recognition of activities that are being done well,
- Clear descriptions of the problems that need attention, and
- Improvement opportunities for consideration.

Corrective & Preventive Action Requests arising from audits

Although not mentioned in the auditing standards, it is the accepted practice amongst certification bodies to write formal noncompliance statements (corrective action requests) only against major noncompliances. Usually the minor noncompliances are merely mentioned in the body of the audit report.

The rationale of this approach is to ensure that primary attention is directed to serious issues that directly affect the quality of the output or the integrity of the quality system. By definition, minor noncompliances do not fall into either of these categories and may justifiably be given lower priority. Lodging a Corrective & Preventive Action Request indiscriminately on every minor matter that goes wrong will flood the Corrective & Preventive Action system with so many minor matters that the serious issues may suffer. Justification for this approach can be found within both ISO 17025 and ISO 9001; when both of these standards speak of the need for corrective action, they urge that the risks and consequences of the occurrence be taken into account in determining what corrective action is needed.

Correction = action to eliminate a detected nonconformity (or fixing the problem)
Corrective action = action to eliminate the causes(s) of the detected nonconformity (or fixing the system that caused the problem)
Preventive action = action to eliminate the cause(s) of a potential nonconformity

Corrective action is reactive (stops recurrence), whereas preventive action is pro-active (prevent occurrence)

Steps in a Corrective Action

1. Review nonconformities (Audit, Customer Complaint, Management Review, Internal Failure, Supplier Failure, Improvement Opportunities),
2. Raise and document Corrective & Preventive Action Request,
3. Take action to rectify the problem,
4. Investigate and determine root cause of problem and action needed to ensure nonconformities do not recur,
5. Implement corrective action,
6. Amend documentation, and
7. Review corrective action taken.

If a major change is required to the system, management may wish to review the nonconformance.

Steps in a Preventive Action

1. Evaluate data that indicates potential nonconformity,
2. Raise and document Corrective & Preventive Action Request,
3. Evaluate the need for action to prevent occurrence of nonconformities,
4. Determine and implement preventive action,

5. Amend documentation, and
6. Review preventive action taken.

The lists above have given the “what” and the “how”; now decide who is best placed to undertake the corrective action. When it comes to the question of “who” is responsible for corrective action normally, it's the people closest to the problem. The "ownership" of both the problem and its solutions should reside with the people in the workplace. However, a team approach is usually needed once the problem, its causes or its solutions, extend beyond the boundaries of a single work area. The problem-solving team should include the interested or affected parties as well as the quality manager; often the auditor will be invited to be a part of such a problem-solving team.

The "*Possible-Probable-Inevitable*" Principle

If there is a weakness in the quality management system, it is *possible* that this weakness may lead to a quality problem or a quality system breakdown.

If there is a second weakness in the system, one that can interact with the first, it becomes *probable* that these two weaknesses will lead to a quality problem or a quality system breakdown.

If there is a third weakness in the system, one that can interact with the first two, it is *inevitable* that these three weakness will, sooner or later, combine to create a quality problem or quality system breakdown - almost always totally unexpected and usually very serious.

When investigating any serious or unusual quality problem or quality system breakdown, always look for multiple causes.

Concept of *Direct* and *Contributing* Causes

In simple terms:
A *direct* cause is one that has a direct cause/effect relationship with the quality problem or quality system breakdown.

A *contributing* cause is one that may not have actually caused the problem but could have either prevented it from happening or allowed it to be detected at an earlier stage.

For example:
Supposing, after a customer complaint, a set of tests had to be repeated because the original test were done using an incorrect (out-of-date) edition of the test method:
The *direct* causes would be those that could have lead the technician to use the incorrect method - document control breakdown, document distribution lapse, lack of access to methods manual, relying on memory, misleading instructions, and so on;
The *contributing* causes would be the breakdowns in the laboratory's work monitoring arrangements that allowed the use of an incorrect method to go undetected - inadequate checking of results before transmission to customer, insufficient supervision, inadequate auditing of methods manual, and so on.

Often the investigation of the *contributing* causes can disclose the possibility of a far wider problem than at first realised.

Common Causes of Breakdowns in Quality Management System

When investigating the causes of a noncompliance or a breakdown in a quality management system, six questions to seek answers to are:

1. Is the requirement clearly documented in the quality management system?
2. Has the requirement been effectively communicated?
3. Have the personnel been properly trained?
4. Do they have all the resources they need?
5. Are there any unusual internal circumstances applying?
6. Are there any external interfering factors?

Use the core ideas of these questions as the branches in a Cause & Effect or “fishbone” diagram. These diagrams were the brainchild of Professor Kaoru Ishikawa of Tokyo University who pioneered quality management processes in the Kawasaki Steel Works.

Why Cause & Effect Diagrams are Useful:

1. Focus attention on one specific problem or issue,
2. Focus on the causes, not the symptoms,
3. Display graphically the theories about what may be the Root Causes of the problem or issue,
4. Show the interrelationship of factors influencing the problem or issue,
5. Cause & effect diagrams do not have a statistical basis, but are excellent aids for problem solving, and
6. Show important relationships between variables and possible causes.

What Cause & Effect Diagrams Look Like: