

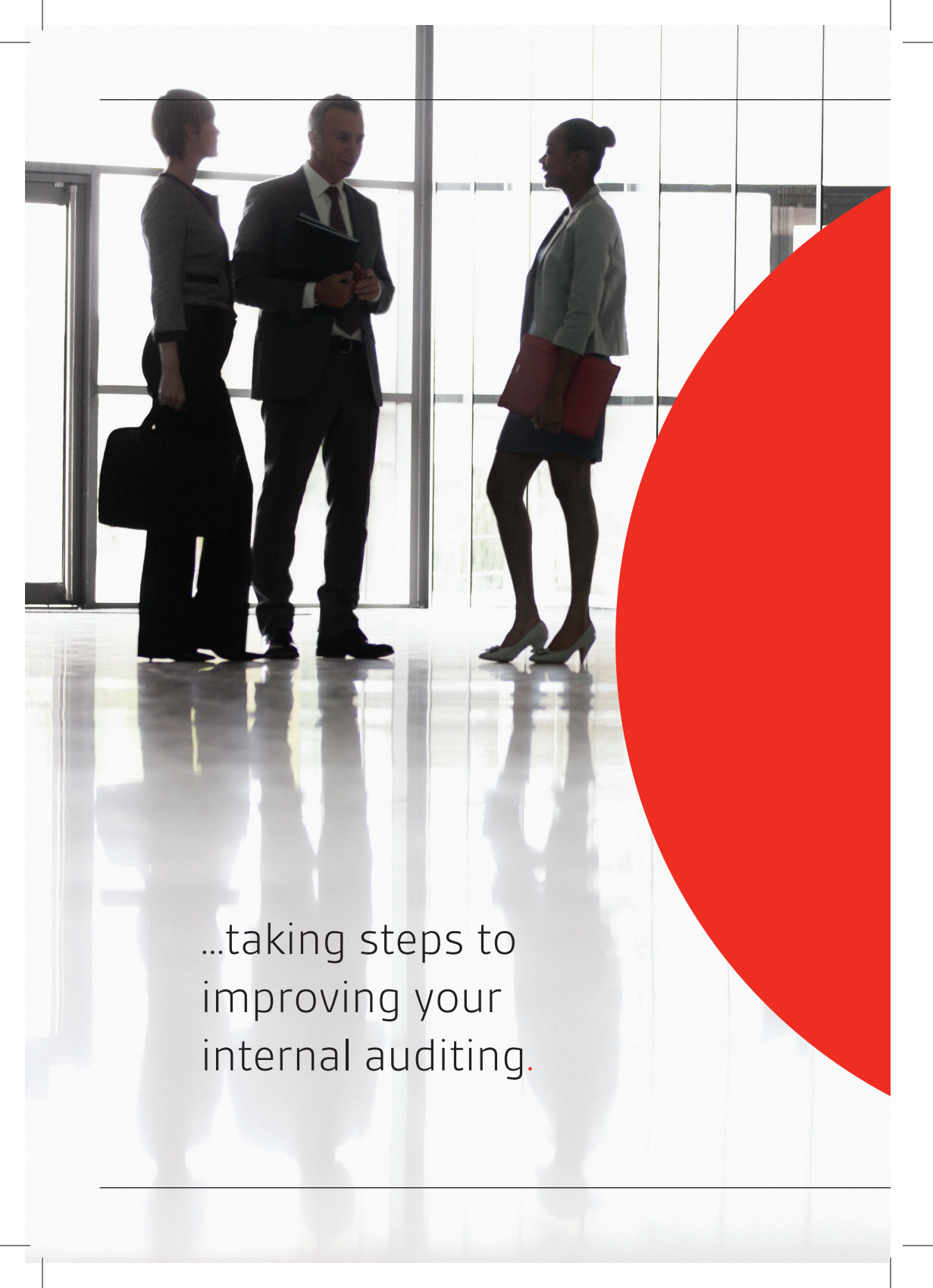


ISO 9001 Quality Management Systems

Tips for Internal Auditing

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...taking steps to
improving your
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ISO 9001 Tips for Internal Auditing

If you are developing or modifying your internal audit programme for ISO 9001, we offer these tips for auditing to the standard. But first, what is an audit and why do them?

According to ISO 9000, the Fundamentals and Vocabulary standard, an audit is:

"A systematic, independent, and documented process, for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled." In other words, making sure that what is going on in practice is in line with policies, processes and procedures.

Audits should be carried out to look for areas for improvement and best practice. They should not be adversarial or confrontational.

Internal audits should be formal, planned, and organized. They are conducted in an impartial and objective manner following an agreed scope and procedures. Audits are used to gather facts and determine the degree to which requirements are being met.

Using the tips in this booklet should help you achieve these audit objectives.

Internal Auditors need to be competent

ISO 19011 defines an auditor as a person with the competence to conduct an audit. Competence is further defined as the demonstrated ability to apply knowledge and skills.

New internal auditors should attend an internal auditor course to learn good practice and how to interpret and apply ISO 9001 requirements.

The internal auditor course explains the concepts and terms of ISO 9001 to ensure consistency in the application of its requirements. (You will need evidence your auditors are qualified, remember to keep records of their training along with their required education, skills, and experience). It is also important to educate all staff about the benefits of internal auditing and about the significant impact it can have on the organization when used in a positive and con-

structive manner. If the organizational culture is correct, and management commitment is given to undertake effective internal auditing, the benefits gained are unlimited. Remember, an auditor must be impartial and objective, and cannot audit their own work.

Review your Internal Audit procedure

ISO 9001 explains what is required for your internal audit procedure.


The standard spells out that the procedure must define responsibilities and requirements for:

- Planning audits • Conducting audits
- Reporting results • Maintaining records

Prior audit results should be considered when planning the audit programme in addition to considering the status and importance of the areas to be audited, ie: some areas may require greater attention than others depending on how important they are to the organization.

As well as meeting the conformity requirements of ISO 9001, much value can be added to an organization by making use of internal audits to gather other valuable information during the audit process. Much can be learned about the overall performance of an organization by simply communicating with people on other issues and ideas. The message is not to simply limit internal audits to conformity issues.

There is a standard for Management Systems Auditing - ISO 19011:2002. Any organization contemplating or conducting audits should obtain this invaluable standard.



...using the 8 Management Principles as a stamp of continual improvement.



Conduct your audits to the eight management principles of ISO 9001

The management principles are the foundation of the ISO 9000 series of standards. As such, they provide a strategic approach to how ISO 9001 is applied.

All the clauses of ISO 9001 can be linked to the principles.

Conducting internal audits using the management principles will give an organization a more top-level approach, this will provide senior management with a better insight into how well their organization is operating and where the more subtle areas for improvement may lie.

The Eight Management Principles are:

- Customer Focus
- Leadership
- Involvement of People
- Process Approach
- Systematic Approach to Management
- Continual Improvement
- Factual Approach to Decision Making
- Mutually Beneficial Supplier Relationships

Adopt a process approach to internal audits

The intent of ISO 9001 is to encourage the adoption of the process approach to manage an organization. As a result, internal audits (of your management systems) need to adopt a similar approach.

An activity that uses resources to transform inputs to outputs can be considered a process. The output from one process may become the input to the next process. To function well, organizations must identify and manage numerous interacting processes.

The Process Approach involves the systematic identification and management of these process interactions within an organization.

For effective audits, you have to understand the process nature of the system and follow the appropriate audit trails.

For example, auditing to the requirements for quality objectives requires considering clause 5.4.1, 'quality objectives', in addition to, related clauses that refer to quality objectives, such as 5.6.1 Management Review and 8.5.1 Continual Improvement.

Therefore, to see if quality objectives have been planned, implemented, monitored, and improved, an audit will need to consider requirements from multiple clauses.



Use of an electronic version of the standard can help identify important cross-references.

ISO 9001 requires your processes to be identified (4.1.a) and their sequence and interaction to be determined (4.1.b). Clause 4.2.2.c states that these process interactions must be described in your quality manual.

Audit planning should identify process interactions and ensure these audit trails are followed for more effective evaluations of your quality management system.



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Evaluate the effectiveness of the system

Auditors often struggle with, or overlook, assessing how well the system has performed.

Every audit situation should be examined from three perspectives:

1. Intent: "Have you said what you do?"

Do the defined or documented processes adequately express your approach?

2. Implementation: "Have you done what you said?"

Do the observed and recorded practices show conformance with the stated intent?

3. Effectiveness: "Have you done it well?"

Do the results of the process indicate the desired outcomes have been achieved? ISO 9000 defines "effectiveness" as the extent to which planned activities are realized and planned results are achieved. In other words, to judge effectiveness you look not only at the conformance of a process, but also at its results compared to its objectives.

...do not be afraid to challenge and probe or follow an audit trail to see where it leads you.



Remind Auditors how to verify conformity

Internal auditors often only rely upon documents and records as evidence of process conformity and don't adequately interview personnel and observe operations.

After determining the audit criteria (requirements), objective evidence should be gathered in four different ways for more complete and effective audits:

1. Interview personnel

Based on your audit planning and checklist questions, ask employees about their jobs. Listen to what they tell you and see if their explanations match the defined process. Use open-ended questions to elicit more complete responses. Do not be afraid to challenge and probe or follow an audit trail to see where it leads you. Talking to people is the best possible way to test their understanding and knowledge about the processes and sub-processes in which they are involved.

2. Observe operations

Aid your own understanding of the process by watching it being performed. See if the observed practices comply with requirements. You will discover the persons being interviewed are more relaxed when you allow them to demonstrate their jobs. In addition, internal audits will be less disruptive since work is actually being completed.

3. Review documents and records

Ask the persons being interviewed what documents and records are used in their work. You may find documents, records and forms beyond those identified in your audit planning. See if the documents are adequately controlled and available for use. Refer to the documents and records to help you follow the work being shown. Verify the records described in the documents are being properly collected and controlled. Also challenge the need for documentation and always try to find better and more effective ways of managing and controlling the processes being audited.

4. Examine records

Auditors cannot interview every person, observe every activity, look at every document, and evaluate every record. You should strive for representative samples that allow you to make informed judgements. Since audits are limited due to sampling, non-conformities may continue to exist in the system beyond those identified and reported. However, with time and well planned audits you can feel confident that you have thoroughly reviewed your system and its performance.

Improve your current Internal Audit practices

Organizations with an existing internal audit programme should review their results to ensure audit objectives are being met and to identify opportunities for improvement.

Ask yourself the following questions:

- Are our internal audit plans and schedules being met?
- Do our plans focus on customer satisfaction?
- How well are departments meeting their requirements?
- Are we identifying the root cause of the problem?
- Are our internal auditors writing good audit reports?
- Are non-conformities written clearly and simply to be easily understood?
- Are we giving compliments for good practices?
- Are we identifying opportunities for improvement?
- How long is it taking to close audit corrective actions?
- What feedback are we receiving about our audits?
- Are we looking at the whole organization as one entity?

Use the update of your internal audit process as an opportunity to take corrective and preventive actions and find the root cause of the problem. Look at past audit reports to see if you are satisfied with current practices and auditor consistency.

Have training sessions with your auditors to go over previously written non-conformity statements and identify what clause references have been used for ISO 9001. Suggest to your auditors that they follow these 6 C's for well written statements:

- **Complete** – include the specified requirement and objective evidence
- **Correct** – take care to accurately and correctly convey the information
- **Concise** – express the statement as briefly and succinctly as possible
- **Clear** – use easy to understand words and terminology
- **Categorized** – if used, identify its severity (major, minor, or concern)
- **Confirmed** – verify the information needed for corrective action is stated

Of course, internal auditors must prepare reports as prescribed by their own audit procedure. Remind them to audit for conformity (not non-conformity) and to share some positive comments in their reports to encourage improved conformance.

Schedule your Internal Audits differently

The purpose of an internal audit programme (schedule) is to plan the type and number of audits, as well as, to identify and provide the necessary resources to conduct them.

The Plan-Do-Check-Act model can be applied to the management of internal audits:

Plan: Define the audit programme

Do: Implement the audit programme

Check: Review the audit programme

Act: Improve the audit programme

The auditors must understand how the clause structure and requirements will affect their audit plans. Instead of auditing by clause, the organization may decide to audit by processes and across the organization.

An earlier tip described the need to look at requirements from multiple clauses to fully assess a particular activity. Organizing audits by clause may limit the evaluation to just a subset of the planning, doing, checking, and acting requirements for a process.

Another method of auditing is to trace customer requirements as an input and the delivery of the product or service as an output, in order to

assess department interfaces. Audits can also be scheduled for a specific contract or project to only assess the involved areas.

Remember that key business processes tend to flow across the organization and hence may touch on many activities and departments. Other processes may flow more vertically within the organization. For this reason alone it is very important to understand the interfaces within your business processes and sub-processes and plan your audits accordingly.

Remember that ISO 9001 requires audits to be planned based on the status, prior audit results, and importance of the areas being audited. Internal audits of critical areas or poorly performing ones may be scheduled more frequently.

If the scope of your system has changed based on permissible exclusions (see clause 1.2) or outsourcing (see clause 4.1), make sure your internal audits are scheduled and planned to provide full coverage of the system.

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