

Auditing the effectiveness of the internal audit

Organizations seeking a suitable, adequate, and effective quality management system (QMS) need to conduct internal audits, to ensure that the QMS functions as intended, and that it identifies weak links in the system as well as potential opportunities for improvement. The internal audit acts as a feedback mechanism for the top management; it can give top management, and other interested parties, assurance that the system meets the requirements of ISO 9001. How the internal audit process is managed is a key factor to ensuring the effectiveness of a QMS.

Requirements and guidance

ISO 9001 clause 8.2.2 states as follows: 'An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits'.

This requirement is intended to focus the internal audit programme on those processes and areas where past history indicates that problems have occurred, or where problems are likely to be ongoing, and/or are likely to occur (because of the nature of the processes themselves). These problems may result from issues such as human factors, process capability, measurement sensitivity, changing customer requirements, changes in the work environment etc.

The processes with high levels of risk of deficiencies or non conformities should have priority in the internal audit programme. Special attention should be given to processes where the high level of risk is influenced by factors such as:

- severe consequences of failure on process capability
- customer dissatisfaction
- non-compliance with product (or process) statutory and regulatory requirements

ISO 9004:2000 clause 8.2.1.3 states: 'Top management should ensure the establishment of an effective and efficient internal audit process to assess the strengths and weaknesses of the quality management system. The internal audit process acts as a management tool for independent assessment of any designated process or activity. The internal audit process provides an independent tool for use in obtaining objective evidence that the existing requirements are fulfilled, since the internal audit evaluates the effectiveness and efficiency of the organization'.

This guidance from ISO 9004 stresses the need for the efficient use of resources when conducting internal audits. (Note, this ISO 9004 guidance is not an auditable requirement for an ISO 9001 assessment).

Audit guidance

When third party auditors examine internal audit processes, they should evaluate issues such as:

- the competences that are needed for and applied to the audit
- the risk analysis performed by the organization (if any) in planning internal audits
- the degree of management involvement in the internal audit process
- the guidance provided by ISO 19011 (but note that ISO 9001 does not require the organization to use ISO 19011)
- the way the outcome of the internal audit process is used by the organization to evaluate the effectiveness of its QMS and to identify opportunities for improvements

A third party auditor needs to:

a) Evaluate the organization's approach to identifying critical areas as well as other parameters. For example, has the organization identified:

- its processes that are critical to product quality,
- its complex processes, or those that need special attention
- its processes that need to be validated
- its processes that need personnel to be qualified
- its processes that need close monitoring of process parameters
- its monitoring and measuring activities that require frequent calibration and/or verification;
- its activities and processes that occur across multiple locations and/or which are labour intensive etc
- Processes where problems have occurred or are in risk
- and established process performance indicators that define effectiveness and efficiency measures, and do these measures align with the organization's overall goals and objectives?

Does the organization use such information when establishing the audit frequency of such processes and activities ?

b) Evaluate the competence of the organization's internal auditors and audit teams. There should be evidence that the organization:

- has identified the competence requirements for its internal auditors
- has provided appropriate training
- has in place a process for monitoring the performance of its internal auditors and audit teams
- includes personnel on its audit teams that have appropriate sector specific knowledge (so that they are able to identify where the likelihood that a deviation in a particular process or activity could lead to a significant consequence for product quality)

An assessment should also be made of whether the internal auditors understand the inherent risk to the reliance that can be placed on the outcome of the audit process, if they:

- fail to consider something which is material to the outcome of the audit
- select an inappropriate sampling regime
- weight the evidence collected inappropriately
- deviate from the audit plan and internal audit procedures

c) Evaluate the planning of audits. The organisation should be able to maximize the use of available resources during the conduct of internal audit activities. This can be facilitated by the adoption of a risk based approach to the planning of internal audits. It should be ascertained whether the organization (through its internal audit process) has considered the use of a risk based approach in developing the internal audit plan, in order to ensure the effective and efficient use of resources, This should also ensure that the inherent risks of audit failure in the audit process, and to audit outcomes, are minimised. The organization should have a process for utilizing past audit results in the planning of future internal audits.

d) Look for evidence that the organization has implemented an effective internal audit programme.

By taking the above factors into account, and by examining whether the internal audit process is leading to any tangible improvements to the QMS, the 3rd party auditor should be able to form a judgement on whether the

organization has implemented an effective internal audit programme and if the outcome of internal audits provides evidence for analysis of the effectiveness of the QMS.

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The ISO 9001 Auditing Practices Group is an informal group of QMS experts, auditors and practitioners drawn from the ISO Technical Committee 176 Quality Management and Quality Assurance (ISO/TC 176) and the IAF. It has developed a number of guidance papers and presentations that contain explanations about the auditing of QMSs. These reflect the process-based approach that is essential for auditing the requirements of ISO 9001.

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