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ISO 9001 Auditing Practices Group

Guidance on:

Internal audit

1. Introduction

Organizations seeking a suitable, adequate, and effective quality management system 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 quality management system.

2. Requirements and Guidance

2.1 ISO 9001 clause 9.2.2 states as follows:

“The organization shall plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits”

By applying risk based thinking, 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, 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 higher levels of risk or nonconformities should have priority in the internal audit programme.

Special attention should be given to processes where risk is influenced by factors such as:

- severe consequences of failure on process capability;
- customer dissatisfaction;
- noncompliance with product (or process) statutory and regulatory requirements.

2.2 ISO 9004:2009 Clause 8.3.3

“Internal auditing is an effective tool for identifying problems, risks and nonconformities, as well as for monitoring progress in closing previously identified nonconformities (which should have been addressed through root cause analysis and the development and implementation of corrective and preventive action plans). Verification that the actions taken have been effective can be determined through an assessment of the improved ability of the organization to fulfill its objectives. Internal auditing can also be focused on the identification of good practices (that can be considered for use in other areas of the organization) as well as on improvement opportunities.”

(Note: this ISO 9004 guidance is not an auditable requirement for an ISO 9001 audit).

3. Audit Guidance

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

- the competencies that are needed for and applied to the audit,
- objectivity and impartiality of the internal audit process
- the risk based thinking performed by the organization 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), and
- 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 uses 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,
- engages auditors with the 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 analysis 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, or
- 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. The results of this risk based approach will enable the organization to define the audit program, the frequency, duration and scope of internal audits, as 9001 does not specify these criteria.

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 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.

It is a good practice in third party audits to audit internal audits processes of the organization toward the end of the third party audit. Auditors will be able to compare the results of internal audit process against their own findings and thereby be able to evaluate effectiveness of this process and the resulting corrective actions.

For further information on the ISO 9001 Auditing Practices Group, please refer to the paper:
Introduction to the ISO 9001 Auditing Practices Group

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