

## Auditing statutory and regulatory requirements

ISO 9001 requires an organization to identify and control the statutory and regulatory requirements applicable to its products (including services). It is up to the organization how to do this within its quality management system (QMS).

The organization should demonstrate that the statutory and regulatory requirements applicable to its products/services have been properly identified, are available and easily retrievable.

Auditors need to be aware of the general and specific statutory and regulatory requirements applicable to the products/services included within the scope of the QMS. During the audit preparation phase, auditors should obtain relevant information from internal or external sources with respect to these statutory and regulatory requirements. This will allow them to make a judgment on the suitability of the QMS to address such requirements. These requirements need to be identified and integrated in the resource management and product realization activities of the organization.

During the audit phase, auditors should:

- ensure that the organization has a methodology in place for identifying, maintaining and updating all applicable statutory and regulatory requirements
- ensure that these statutory and regulatory requirements are utilized as 'process inputs' while monitoring 'process outputs' for compliance with requirements
- ensure that any claimed compliance to standards, statutory and regulatory requirements etc are properly demonstrated by the organization
- if evidence is found during the audit that specific information regarding statutory and regulatory requirements has not been taken into account, the auditors should issue a nonconformity
- auditors should also issue a nonconformity if a non compliance with such requirements is directly identified

Auditors should avoid making statements about what statutory or regulatory requirements are applicable to the products/services of the organization, or about methods of compliance, because of the possibility of liability.

Nonconformities should be issued only in situations where identification has been made of system deficiencies or of direct violations in respect of statutory and regulatory requirements applying to the products/ services of the organization.

However, if non-conformance with other kinds of statutory requirements (eg health and safety, environment etc) is coincidentally, detected during the audit, this fact cannot be ignored by the audits. It should be reported without delay to the auditee and, if required, to the audit client.

If auditors become aware of any deliberate legal non-compliance that could affect the image and credibility of the QMS before, during, or after the audit (including, for example, breach of antitrust law, labour law, health and safety or environmental regulations) then this should be taken into consideration and investigated further, as appropriate. Apart from the regulatory authority's action, it is for the auditors to assess the effectiveness of

the QMS in meeting customer requirements (stated or generally implied) and report this to the certification/registration body management to take appropriate actions.

This article is an edited version of 'Auditing statutory and regulatory requirements' from the website of the ISO 9001 Auditing Practices Group, and is reproduced courtesy of ISO and the IAF. These papers were developed on current best practice and therefore have not been formally endorsed as International Accreditation Forum (IAF) guidance or ISO TC176 interpretations. For further information about the Auditing Practices Group <http://isotc.iso.org/livelink/livelink/fetch/2000/2122/138402/138403/%203541460/customview.html?func=ll&objId=3541460&objAction=browse&sort=name>.

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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