

D 35

ISO 9001 internal audit

Goal

1 Scope

2 Normative references

3 Definitions

4 Principles

- 4.1 Management principles
- 4.2 Audit principles
- 4.3 Performance of the QMS

5 Audit programme

- 5.1 General
- 5.2 Objectives
- 5.3 Responsibilities
- 5.4 Implementation
- 5.5 Records
- 5.6 Audit programme review

6 Auditing

- 6.1 General
- 6.2 Initiating
 - 6.2.1 Objectives, scope and criteria
 - 6.2.2 Situations and feasibility
 - 6.2.3 First contact
- 6.3 Document review
- 6.4 Preparing the audit
- 6.5 Doing the audit
 - 6.5.1 Opening
 - 6.5.2 Audit evidence
 - 6.5.3 Audit conclusions
- 6.6 Audit report

7 Auditor competences

- 7.1 General
- 7.2 Personal attributes
- 7.3 Knowledge and skills
- 7.4 Training
- 7.5 Auditor evaluation

Annexes

Goal of the module: To perform an audit according to ISO 19011 so as to be able to:

- improve the capacity to satisfy stakeholders
- verify the conformity to practices and effectiveness of the processes
- determine the effectiveness of the ISO 9001 quality management system

1 Scope

The word audit comes from Latin "audire" = to listen.

Audit: *systematic and independent survey to determine whether activities and results comply with pre-established measures and are able to achieve the objectives*

Audits are mostly either internal or external.

The internal audits, called also first party audits, are a requirement of the ISO 9001 standard (cf. subclause 8.2.2).

The external, customer (or supplier) and certification audits, called also of second and third parties, are not within the scope of this module.

The internal audit is the most widespread tool to check and evaluate the effectiveness of a quality management system (QMS). Its purpose is in no way to find the weak points in personnel. It has entered a company daily life as an inherent part of the quality management system.

It's only through other people's eyes that one can really see one's weakness. Chinese proverb

An internal audit is of (cf. figure 1-1):

- the quality management system
- a process
- a product (service, project)

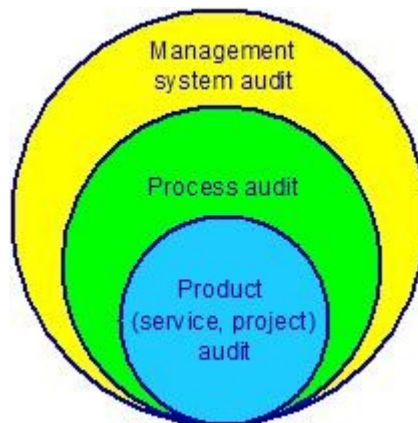


Figure 1-1. Internal audit types

Process: *activities which transform inputs into outputs*

The effectiveness audit is a mixed audit - to check whether the quality management system and its processes are efficient.

The internal audit results are part of the inputs of the management review and allow the identification of fields in which to improve the quality management system as

No system is perfect

As shown in figure 1-2, for the audit process, top management (via the management review) is considered as a customer with needs and expectations, which are themselves related to the processes and various requirements. At the same time top management is often the audit client.



Figure 1-2. Audit process

2 Normative references

The advices given by the ISO 19011 standard can be summarized in the following fields:

- audit principles - clause 4
- audit programme - clause 5
- audit performance - clause 6
- auditor competences - clause 7

A good knowledge of the ISO 9001 standard is required to understand and follow this module.

This module is based on the following generic and international standards:

- **ISO 19011 (2002): Guidelines for quality and/or environmental management systems auditing**
- **ISO 9000 (2005): Quality management systems - Fundamentals and vocabulary**
- **ISO 9001 (2008): Quality management systems - Requirements**
- **ISO 9004 (2009): Managing for the sustained success of an organization - A quality management approach**

All these standards and many others can be ordered on the [ISO](http://www.iso.org) web site, ISO store services.

3 Definitions

The beginning of wisdom is calling things by their right names. Confucius

Some terms and definitions currently used in this module:

Audit criteria: everything against which audit evidence is compared

Audit findings: every deviation from audit criteria

Auditee: everyone who is audited

Auditor: everyone who is trained to carry out audits

Competence: personal skills, knowledge and experiences

Customer: anyone who receives a product

Interested party: person, group or company affected by the impacts from an organization

Nonconformity: non-fulfilment of a specified requirement