

# 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 Establishing
- 5.4 Implementing
- 5.5 Monitoring
- 5.6 Reviewing and improving

### 6 Performing an audit

- 6.1 General
- 6.2 Initiating
  - 6.2.1 First contact
  - 6.2.2 Situations and feasibility
- 6.3 Preparing
  - 6.3.1 Document review
  - 6.3.2 Audit plan
- 6.4 Audit activities
  - 6.4.1 Opening meeting
  - 6.4.2 Audit evidences
  - 6.4.3 Audit conclusions
- 6.5 Audit report
- 6.6 Completing the audit
- 6.7 Audit follow-up

### 7 Competence and evaluation of auditors

- 7.1 General
- 7.2 Auditor competence
- 7.3 Evaluation criteria
- 7.4 Evaluation methods
- 7.5 Auditor evaluation
- 7.6 Improving the competence

### Annexes

**Goal of the module:** To conduct an audit according to ISO 19011 in order to:

- identify improvement opportunities
- increase the satisfaction of interested parties
- evaluate the performance 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 capable of achieving 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. sub-clause 9.2).

The external, customer (or external provider) 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. The internal audit has entered a company daily life as it has become inseparable from:

- any management system
- internal communication
- daily improvement
- corporate culture

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

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

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

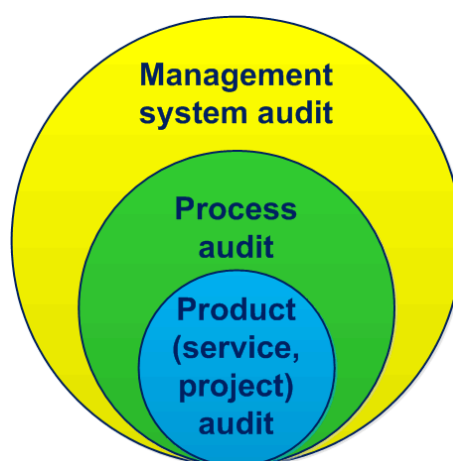


Figure 1-1. Internal audit types

**Process:** *activities which transform inputs into outputs*

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 process “Conduct an audit”, top management (via the management review) is considered as an audit client with needs and expectations, which are themselves related to processes and various requirements.

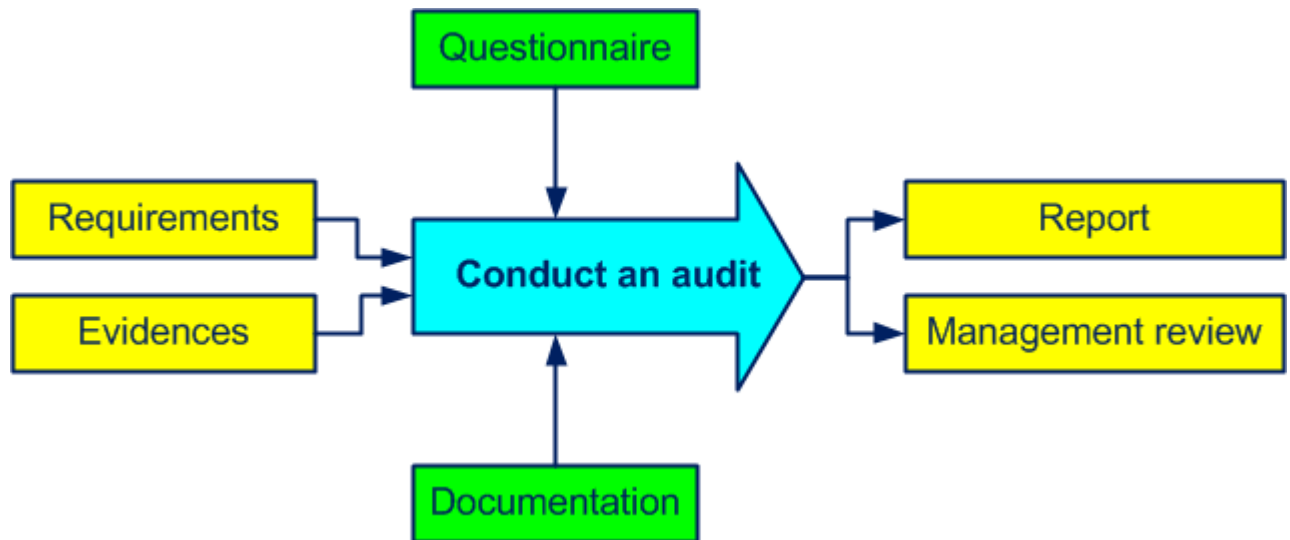


Figure 1-2. Conduct an audit process

## 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 activities - clause 6
- auditor competence - 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 (2011): Guidelines for auditing management systems**
- **ISO 9000 (2015): Quality management systems - Fundamentals and vocabulary**
- **ISO 9001 (2015): Quality management systems - Requirements**
- **ISO 9004 (2009): Managing for the sustained success of an organization - A quality management approach**

All these standards and many more can be ordered in electronic or paper format on the [ISO](#) site. More than 28 000 standards (in English and other languages) are available on the [Public.Resource.Org](#) site.

### 3 Definitions

**The beginning of wisdom is calling things by their proper names. Chinese proverb**

Some terms and definitions currently used in this module:

**Audit client:** everyone requesting an audit

**Audit conclusions:** outcome of an audit

**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

**External provider (supplier):** an entity that provides a product

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

**Nonconformity:** non-fulfilment of a specified requirement

**Organization:** a structure that satisfies a need

**Product (or service):** every result of a process or activity

**Quality objective:** quality related, measurable goal that must be achieved

**Stakeholder:** person, group or organization that can affect or be affected by an organization

Examples of stakeholders: investors, customers, external providers, employees, social or political organizations

In the terminology of quality management systems, do not confuse the following:

- anomaly, defect, dysfunction, failure, nonconformity, reject and waste:
  - anomaly is a deviation from what is expected
  - defect is the non-fulfilment of a requirement related to an intended use
  - dysfunction is a degraded function which can lead to a failure
  - failure is when a function has become unfit
  - nonconformity is the non-fulfilment of a requirement in production
  - reject is a nonconforming product which will be destroyed
  - waste is when there are added costs but not value
- audit and inspect
  - to audit is to improve the QMS
  - to inspect is to verify the conformity of a process or product
- audit, auditee and auditor
  - an audit is a process of improving the QMS
  - an auditee is the one who is audited
  - an auditor is the one who conducts the audit
- audit programme and plan
  - an audit programme is the annual planning of the audits
  - an audit plan is the description of the audit activities
- communicate and inform
  - to communicate is to pass on a message, listen to the reaction and discuss
  - to inform is to give someone meaningful data
- control and optimization
  - control is meeting the objectives
  - optimization is the search for the best possible results
- customer, external provider and subcontractor
  - a customer receives a product

- a external provider provides a product
  - a subcontractor provides a service or a product on which a specific work is done
- effectiveness and efficiency
  - effectiveness is the level of achievement of planned results
  - efficiency is the ratio between results and resources
- follow-up and review
  - follow-up is the verification of the obtained results of an action
  - review is the analysis of the effectiveness in achieving objectives
- indicator and objective
  - an indicator is the information on the difference between the achieved result and the pre-set objective
  - an objective is a sought after commitment
- organization and enterprise, society, company
  - organization is the term used in the standard ISO 9001 as the entity between the external provider and the customer
  - enterprise, society, company are examples of organizations
- organizational chart and process map
  - the organizational chart is the graphic display of departments and their links
  - the process map is the graphic display of processes and their interaction
- process, procedure, product, activity and task
  - a process is how we satisfy the customer using people to achieve the objectives
  - a procedure is the description of how we should conform to the rules
  - a product is the result of a process
  - an activity is a set of tasks
  - a task is a sequence of simple operations

*Remark 1: each time you use the term "improvement opportunity" instead of nonconformity, problem, malfunction or failure, you will gain a little more confidence from the auditee.*

*Remark 2: the use of ISO 19011 and ISO 9000 definitions is recommended. The most important thing is to determine for everyone in the company a common and unequivocal vocabulary.*

For other definitions, comments, explanations and interpretations which you won't find in this module and annex 06 you can consult:

- Quality management system – Indicators and synoptical tables (FD X50 - 171, AFNOR, 2000)
- Information technology -Vocabulary - Part 36: Learning, education and training ([ISO](#)/IEC 2382-36, May 2008)

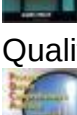
Books for further reading on internal audits:



- Denis Provonost, [Internal Quality Auditing](#), ASQ Quality Press, 2000



- David Hoyle, John Thompson, [ISO 9000 Auditor Questions](#), Transition Support, 2001

-  J. P. Russel, [The Internal Auditing Pocket Guide](#), ASQ Quality Press, 2002
-  Dennis Arter and al, [How to Audit the Process Based QMS](#), Quality Press, 2003
-  Spencer Pickett, [The Essential Handbook of Internal Auditing](#), John Wiley & Sons, 2005
-  Karen Welch, [The Process Approach Audit Checklist for Manufacturing](#), ASQ Quality Press, 2005
-  Paul Palmes, [Process Driven Comprehensive Auditing](#), ASQ Quality Press, 2009
-  Ann Philips, [ISO 9001:2008 Internal Audits Made Easy](#), ASQ Quality Press, 2009
-  J. P. Russel, [The Process Auditing and Techniques Guide](#), ASQ Quality Press, 2010
-  Janet Smith, [Auditing Beyond Compliance](#), ASQ Quality Press, 2012
-  Patrick Ambrose, [ISO 9001:2008: Process Auditing Checklist](#), Amazon Digital Services, 2013

**When I think of all the books still left for me to read, I am certain of further happiness. Jules Renard**

## 4 Principles

### 4.1 Management principles

The seven quality management principles (cf. figure 4-1) will help us achieve sustained success (cf. ISO 9001: 2015, sub-clause 0.2).

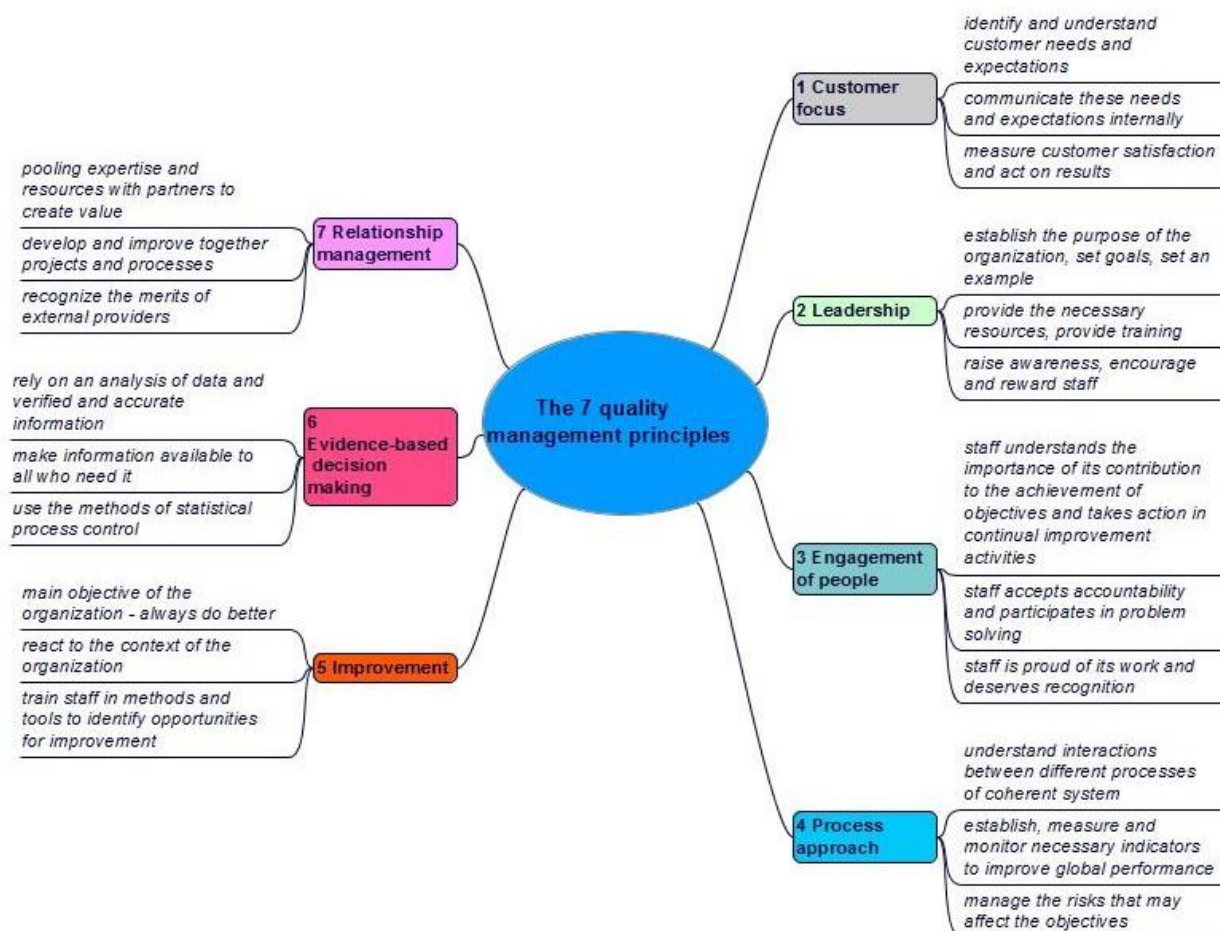


Figure 4-1. The 7 quality management principles

### 4.2 Audit principles

Certain principles must be followed for an audit to be a value added tool.

For the auditor:

- professional ethics, to guarantee:
  - mutual trust
  - compliance with legal requirements
- impartial presentation, to ensure:
  - honest and precise audit conclusions
  - detailed findings and audit report
- professional integrity to guarantee:
  - the importance of the task
  - the given trust
- confidentiality, to treat with care information which is:
  - sensitive
  - confidential

- common sense, it is always the best tool
- curiosity, to learn and succeed
- goodwill to help the auditee identify improvement opportunities
- understandable language
- positive attitude, it is gratifying for the auditee

For the audit:

- independence (the auditor and audited activity do not have conflicts of interest), to guarantee:
  - objective conclusions
  - findings based on objective evidence
- factual approach, to ensure that:
  - audit evidence is verifiable
  - audit conclusions are repeatable

For the auditee:

- remain available
- do not try to hide the truth
- do not be afraid of the answers
- objectively accept the nonconformities found
- be aware of participating in the improvement of the QMS by being:
  - benevolent and
  - cooperative

An auditor cannot audit his own department as

**No-one is a judge in his own case. Latin proverb**



Minute of relaxation. Cf. joke "[The engineer and the shepherd](#)"

#### 4.3 Performance of the QMS

For a quality management system what is of interest is the degree of achievement of objectives or in other words performance. The performance of a QMS is measured by its effectiveness and above all by its efficiency (see figure 4-2).

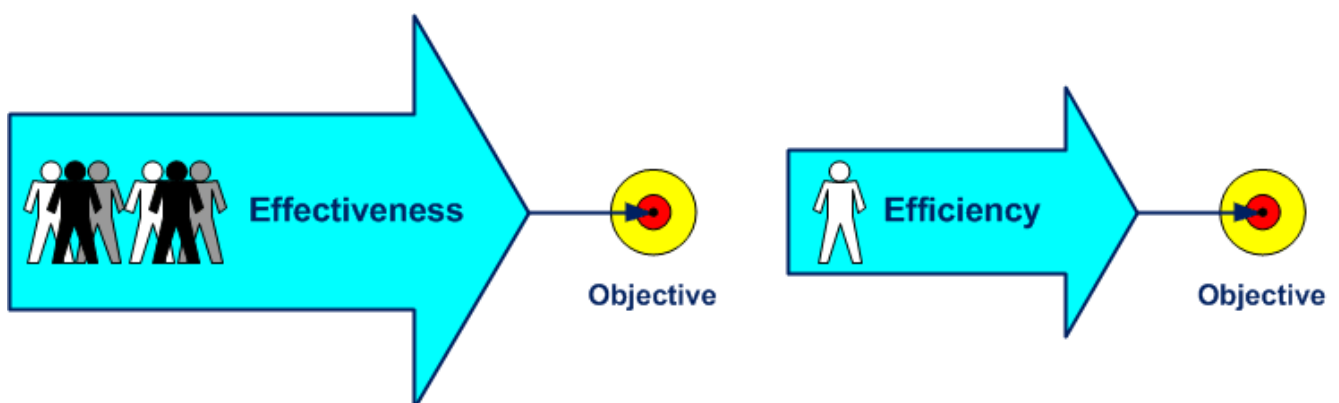


Figure 4-2. Performance of a QMS

**Effectiveness**: capacity to perform planned activities with minimum efforts

**Efficiency**: financial relationship between achieved results and used resources



N.B. We can be effective because we achieved our objective, but not efficient - we used too many resources, we tolerated and produced too much waste!