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ISO 13 485 internal audit

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Annexes

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

- determine the effectiveness of the ISO 13 485 quality management system
- verify the compliance to regulatory and other requirements
- improve the process performance

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 13 485 standard (cf. sub-clause 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. 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 is of (cf. figure 1-1):

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

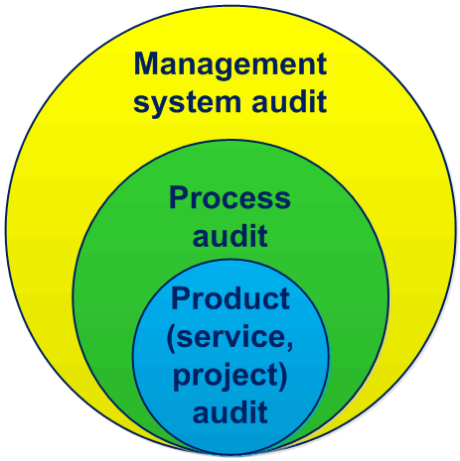


Figure 1-1. Internal audit types

Process: *activities which transform inputs into outputs*

The 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.

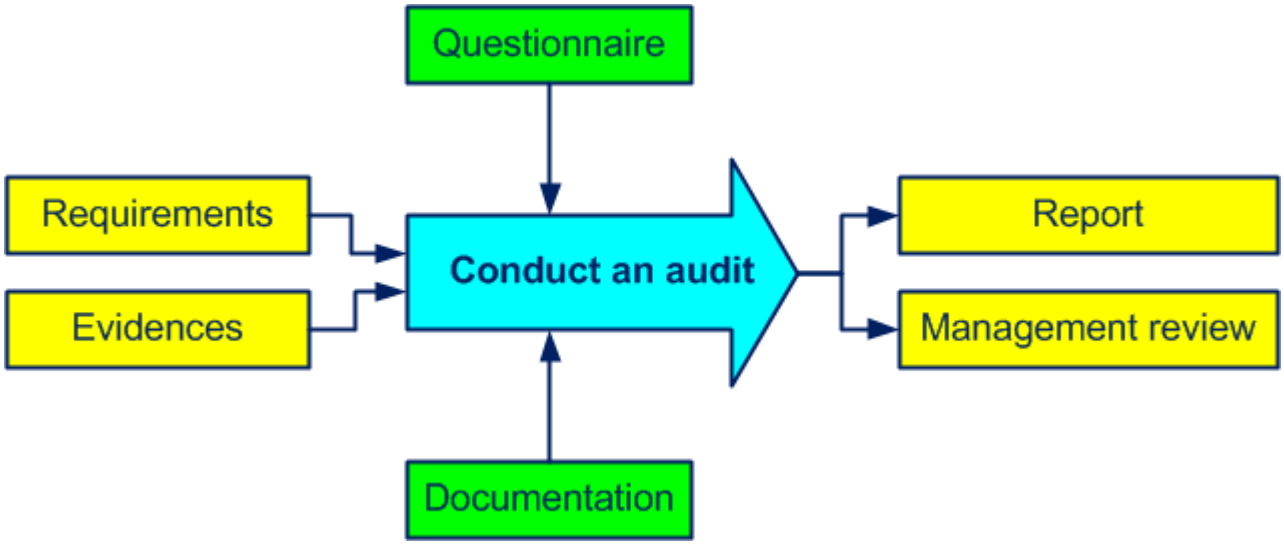


Figure 1-2. Conduct an audit process

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 13 485 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 13 485 (2012): Medical devices - Quality management systems – Requirements for regulatory purposes**
- **ISO 9000 (2005): Quality management systems - Fundamentals and vocabulary**
- **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 web site, ISO store services.

3 Definitions

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

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*
Advisory notice: *notice on the use, modification, return or destruction of a medical device*
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*
Medical device: *product or service to be used for purposes of diagnosis, prevention, monitoring, treatment, alleviation of disease or injury*
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*
Supplier: *an entity that provides a product*

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, supplier and subcontractor
  - a customer receives a product

    - a supplier 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 13 485 as the entity between the supplier 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 non-conformity, malfunction or failure, you will gain a little more confidence from the auditee.

Remark 2: the use of ISO 19 011, ISO 9000 and ISO 13 485 definitions is recommended. The most important thing is to determine for everyone in the company a common and unequivocal vocabulary.

Annexes 07 and 08 specify the frequency of use of certain keywords contained in the standards.

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

- Introduction and support package: Guidance on the Terminology used in ISO 13 485 and ISO 9004 (Document: ISO/TC 176/SC 2/N526 R2, October 2008)
- 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
- Spencer Pickett, The Essential Handbook of Internal Audit, John Wiley & Sons, 2005
- Karen Welch, The Process Approach Audit Checklist for Manufacturing, ASQ Quality Press, 2005

- J. P. Russel, The Internal Auditing Pocket Guide, ASQ Quality Press, 2007
- David Hoyle, John Thompson, ISO 9000 Auditor Questions, Transition Support, 2009
- 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
- Dennis Arter and al, How to Audit the Process Based QMS, Quality Press, 2012
- Patrick Ambrose, ISO 9001:2008: Process Auditing Checklist, Amazon Digital Services, 2013

4 Principles

4.1 Management principles

The eight quality management principles (cf. figure 4-1) will help us achieve sustained success (cf. ISO 9000, sub-clause 0.2 and ISO 9004, Annex B).

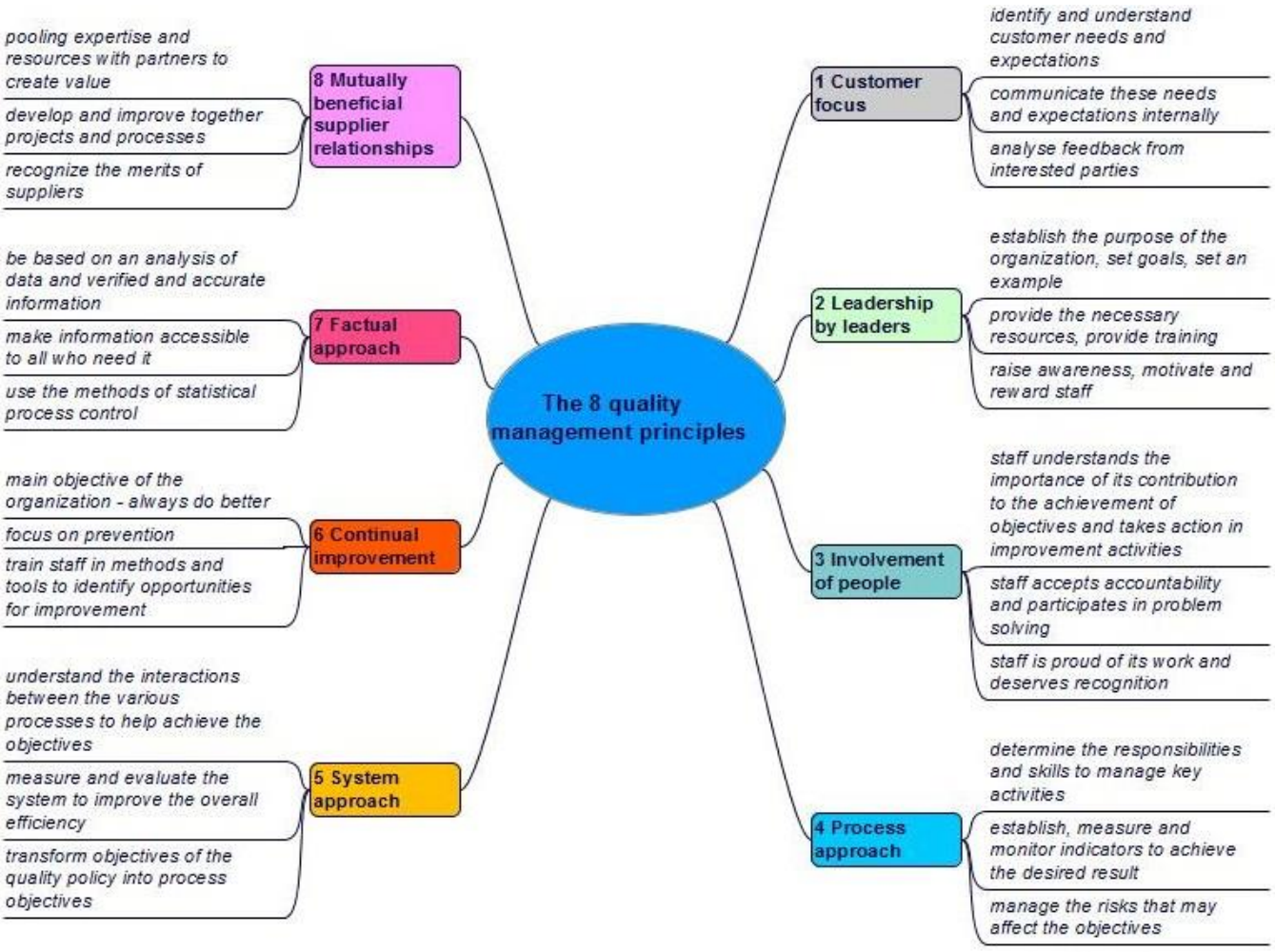


Figure 4-1. The 8 quality management principles

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).

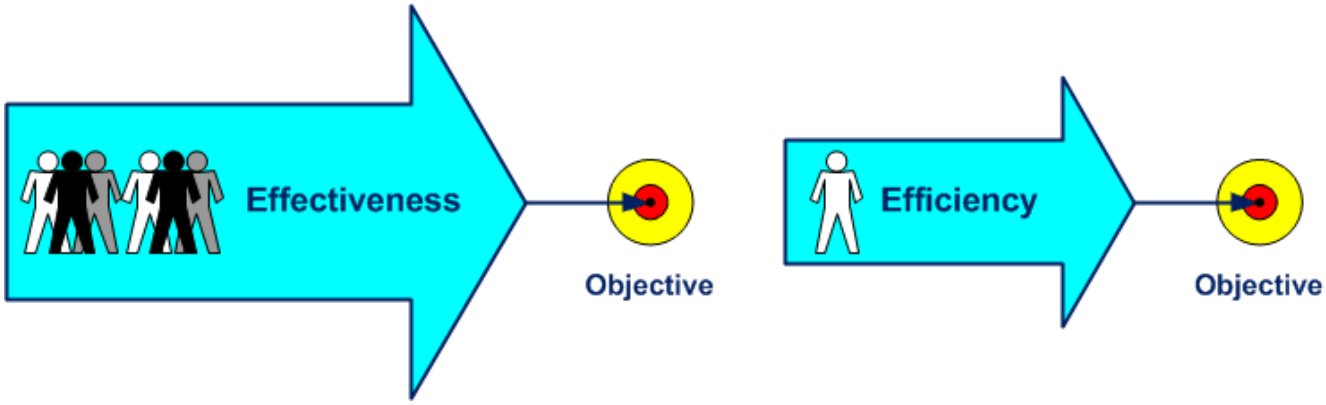


Figure 4-2. Performance of a QMS

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!