D 22v16

ISO 13485 readiness version 2016

Goal

Goal of the module: Readiness for implementation, certification, maintenance and improvement of your quality management system ISO 13485 in order to:

- meet applicable regulatory requirements
- improve public health through safe medical devices
- increase the satisfaction of interested parties

1 Quality approach

1.1 History and references

The technical committee "Management and quality assurance" (ISO/TC 176) within the ISO (International Organization for Standardization) was created in 1980. ISO itself was created in 1947. ISO comes from the Greek "isos" (equal).

The first edition of the ISO 9000 family of standards appeared in 1987.

The first edition of the ISO 13485 standard appeared in 1996. The second edition is from 2003.

The text of ISO 13485 is based on ISO 9001: Quality Management Systems - Version 2008 – Requirements, mainly for the structure and adds specific requirements such as cleanliness of the product, control of contamination, installation activities, sterilization, traceability and complaint handling.

Two notable exceptions are customer satisfaction (sub-clause 8.2.1) and continual improvement (sub-clause 8.5.1). The first point is replaced by "Feedback" (from the customer), which is less subjective and the second point is replaced by maintenance and not continual improvement of the management system, which is more appropriate with the regulation of medical devices.

The ISO 13485 edition of 2012 incorporates the full text of the 2003 edition and adds Annexes ZA, ZB and ZC (informative) for the relationship between ISO 13485 and EU directives 90/385/CEE (active implantable medical devices), 93/42/CEE (medical devices) and 98/79/CEE (in vitro diagnostic medical devices).

The essential performance, safety, health and environmental requirements to which products placed on the market must comply are laid down in the abovementioned European Directives.

The latest version of ISO 13485 ("Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes") was published in March 2016.

This version is based on the standard and the structure of the ISO 9001 version 2008. The new additions include:

- the rise of risk-based thinking. The term risk now appears 20 times
- new terms (such as risk management and life cycle) and new sub-clauses (such as medical device file and complaint handling)
- stronger documentary requirements (more than 20 mandatory procedures)
- the phrase "applicable regulatory requirements" now appears in most sub-clauses (more than 40 times)

A guide to understanding and applying the ISO 13485 standard is available in English. It is the technical report - ISO / TR 14969: 2004 "Medical devices - Quality management systems - Guidance on the application of ISO 13485: 2003" (Medical devices - Quality management systems - ISO 13485: 2003).

In the fifth part of the Health Code "Health Products", Book II: "Medical devices, in vitro diagnostic medical devices and other products and articles regulated in the interest of public

health" are the legal clauses (L5211, L5212) and regulatory requirements (R5211, R5212, R5221 and R5222) for medical devices.

The Decree of 3 March 2003 fixes the lists of medical devices subject to the obligation of maintenance and internal and external quality control.

ISO 14971 (2013): "Medical devices - Application of risk management to medical devices" and NF S99-170 (2013) in French: "Maintenance of medical devices - Quality management system for the maintenance and management of risks associated with the operation of medical devices" will help you identify hazardous situations and evaluate the risks associated with the manufacture of medical devices.

The technical report ISO/TR 24971 (2013) "Medical devices - Guidance on the application of ISO 14971" provides guidance for the development, implementation and maintenance of risk management of medical devices (better understanding the requirements of ISO 14971).

Plenty of useful information and many publications (texts, forms, questions and answers, recommendations) on medical devices can be found on the ANSM (National Agency for the Safety of Medicines and Health Products) website in French.

Guidelines and other information on medical devices are periodically updated on the MEDDEV European Commission's Public Health website "New references of harmonized standards for Medical Devices" (OJ C262 of 30 August 2012).

ISO 15223-1 (2012), "Medical Devices - Symbols for use with labels, labelling and information to provide for Medical Devices - Part 1: General Requirements", identifies requirements for symbols used in the labeling of medical devices, to ensure the correct and safe use of medical devices.

The standard NF EN ISO 13408-1 (2016) "Aseptic treatment of health products - Part 1: General requirements" specifies general requirements and provides guidance on the general scope of aseptic treatment.

IEC 62304 (2006) "Medical Device Software - Software Life Cycle Process" defines life cycle requirements for medical device software.

A free online training program from the University of Lille 2 on CE marking contains a large amount of data (CE marking of medical devices) in French.

The Qualitiso site is rich in information on standards and tools related to medical devices.

The Global Harmonization Task Force (GHTF) website is rich in documents on audit practices, market evaluation and monitoring, quality systems and performance and clinical security of medical devices.

All these references and many others can be ordered (in electronic or paper format) on the AFNOR website www.boutique.afnor.fr (French Association for Standardization) under the standards shop catalogue.

More than 28,000 standards (in English and other languages) are available free of charge at Public.resource.Org.

1.2 Scope

The ISO 13485 standard applies to any company (regardless of size) manufacturing medical devices in the field of design, development, production and servicing activities.

Some examples of medical devices:

- medical gloves
- syringes
- thermometers
- implants and prostheses
- braces
- lumbar belts
- corrective eyewear
- condoms
- diagnostic software

The clothing of hospital care staff is not considered to be a medical device.

Some requirements of clauses 6, 7 or 8 can be excluded. A justification is recorded. This is possible when:

- it does not affect in any way product service conformity related to:
  - meeting customer requirements
  - meeting applicable regulatory requirements
- it does not relieve top management of its responsibilities
- it is justified in the quality manual

The steps to obtain CE marking are:

- describe the product
- determine the classification of the product
- identify associated technical standards
- establish the essential requirements
- identify and evaluate risks
- submit an application for approval to a notified body
- conduct a clinical evaluation, if required
- establish the technical documentation
- make a CE declaration of conformity
- affix the CE marking

CE marking is compulsory for medical devices placed on the market of the European Union.

2 Principles and steps

Quality is anything that can be improved. Masaaki Imai

The quality approach is a state of mind which starts with top management as a priority strategic decision and extends to all employees. Top management develops a quality policy which determines the quality objectives, themselves applicable to all activities. The tool used to achieve the objectives is the quality system. Prevention is a key concept of quality management systems.

Quality is almost free when customers are satisfied: they remain loyal to us. It's only when the customer is not fully satisfied that quality becomes very expensive to us: sooner or later the customer will go to a competitor.

Quality remains long after the price has been forgotten

The seven quality management principles (cf. figure 2-1) will help us achieve sustained success (cf. ISO 9000: 2015, sub-clause 2.3).

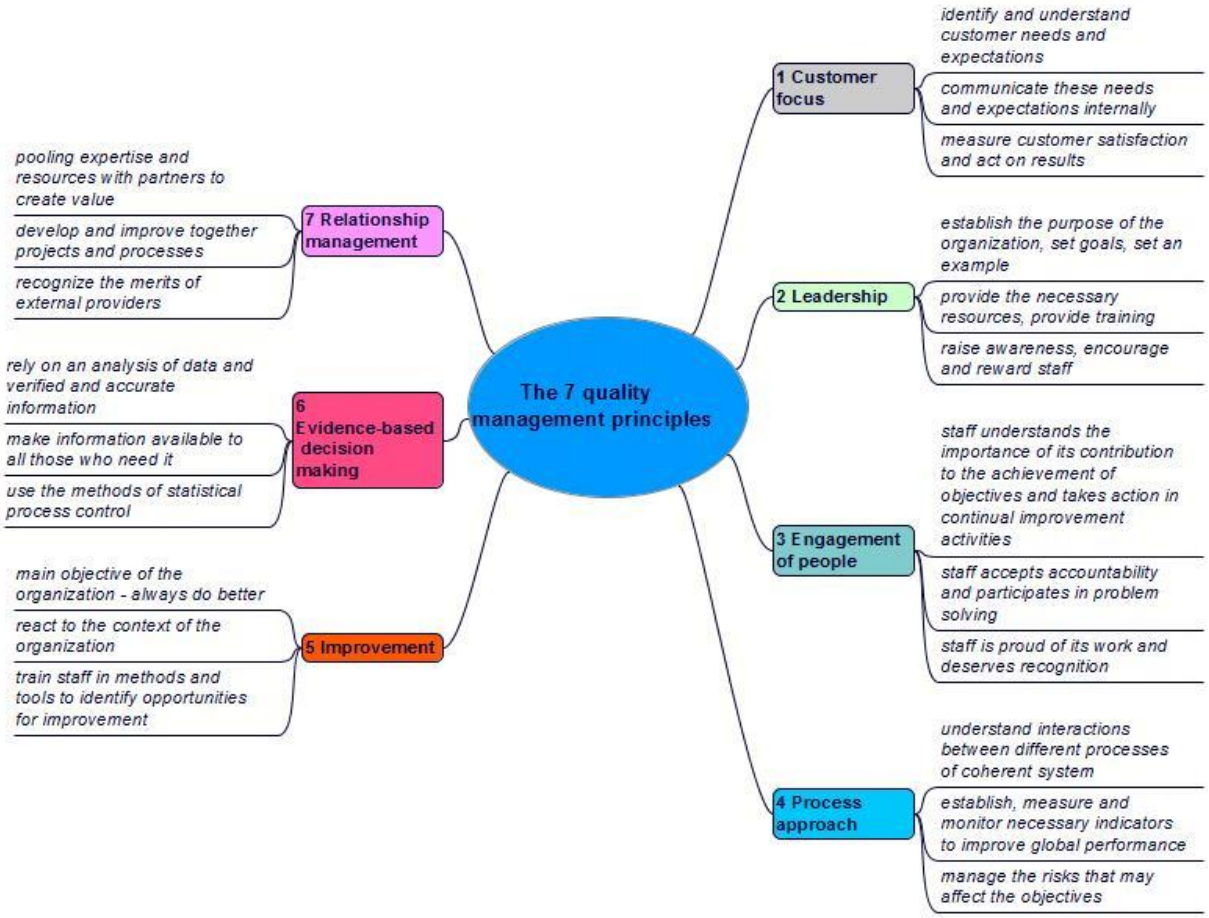


Figure 2-1. The 7 quality management principles

A well-prepared approach is halfway to success

The approach to implementing a quality management system (QMS) starts with preparation. An example is shown in figure 2-2.

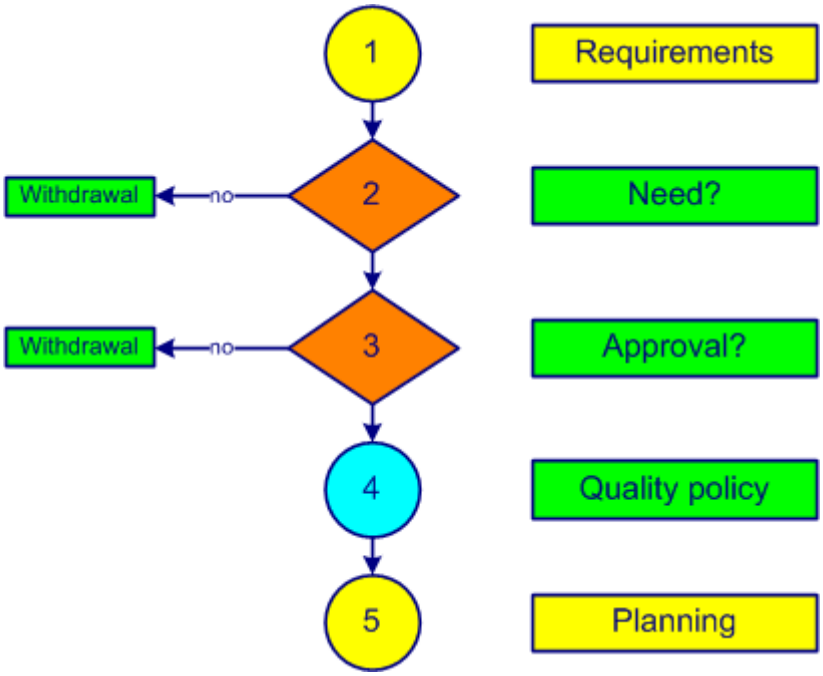


Figure 2-2. QMS preparation

Step 1 involves identifying the needs and expectations (**requirements**) of customers (internal and external). The involvement of top management at its highest level is truly indispensable. The advice of a consultant is often solicited. An external certification body is chosen.

One of the key questions that comes up quickly (**step 2**) is the **need** for this decision. If this is not really necessary or if the estimated costs of the certification approach exceed the available resources, it is better to dismiss the idea immediately.

The ISO 9000 family of standards will stop you making promises you can't fulfill and help you keep those you can. David Hoyle

The benefits of implementing a quality management system are often:

- an improved image of the company
- being one step ahead of the competition
- better economic results
- increased daily effectiveness
- staff who are aware, consulted, motivated and proud
- best practices are valorized
- formalization of knowledge
- process control
- applicable regulatory requirements updated
- reduced production costs
- profitable engagement for all

The benefits of the certification of a quality management system are often:

- new customers
- increased market share
- an increase in sales
- better financial performance

More than one and a half million businesses worldwide cannot be wrong!

The internalization of the spirit of the principles and requirements of an ISO standard significantly improves the overall performance of your business, especially when it is not considered as a constraint.

The **third step** shall determine whether this approach receives the **approval** of the staff. A communication campaign is launched in-house on the objectives of a quality management system (QMS). The staff is aware and understands that, without their participation, the project cannot succeed.

Have confidence; success will come with the involvement and effort of all!

The vision (what we want to be), the mission (why we exist) and the business plan of the company are determined. The **next step** (**4**) includes the addition in the **quality policy** of the specific regulatory requirements of medical devices. If you do not have a copy of the ISO 13485 standard, now is the time to get it.

Planning is the last **step** (**5**) of the project preparation for obtaining ISO 13485 certification. A reasonable period is between 5 to 8 months (each company is unique and specific). The financial resources and staff are confirmed by top management. A management representative (often it is the quality manager) is appointed as project leader. Top management commitment is formalized in a document communicated to all staff.

The establishment and implementation of a QMS are shown in figure 2-3.

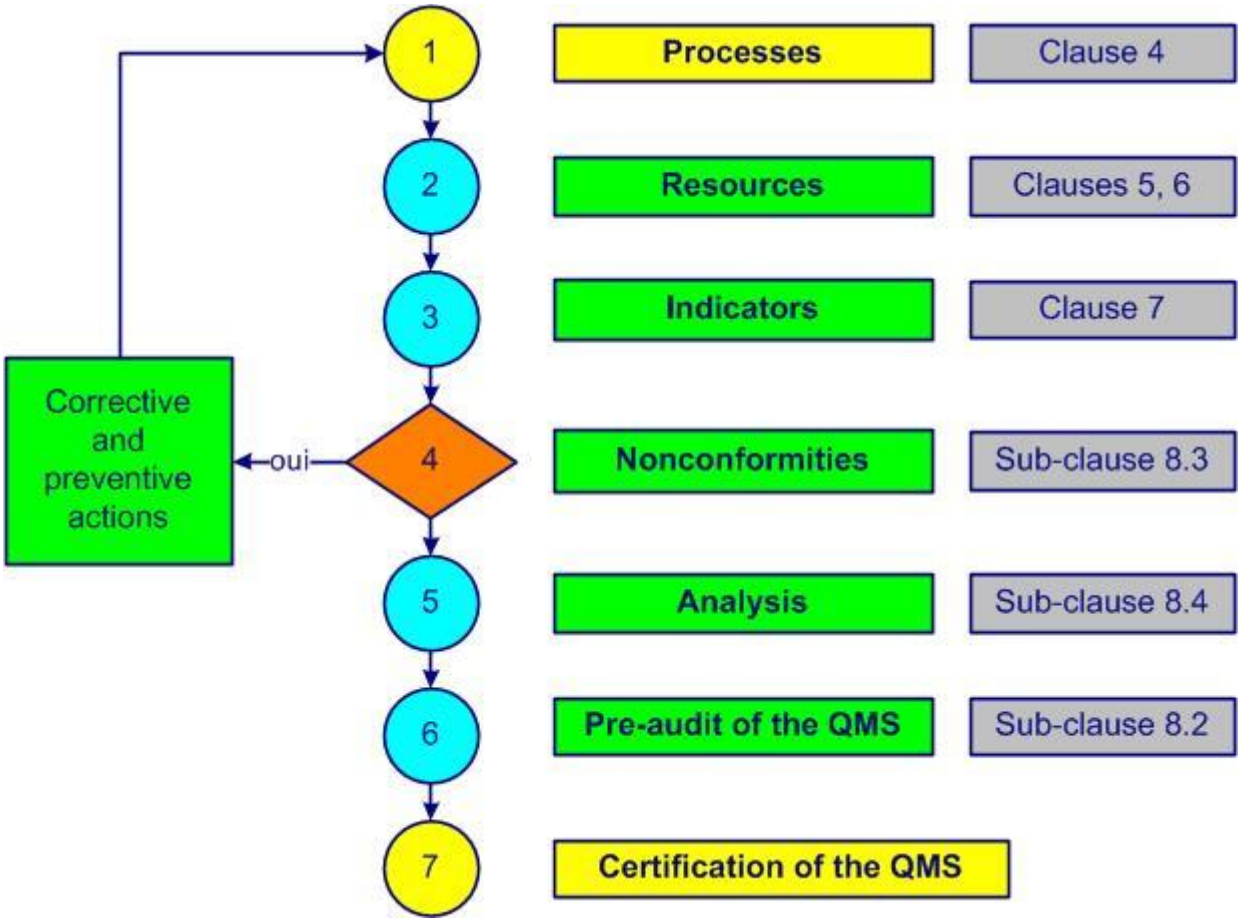


Figure 2-3. QMS implementation

Step 1 aims to identify and determine the **processes** and establish specific requirements in processes and documents. New documents are created. The quality manual is updated.

The new necessary **resources** to achieve the quality objectives are determined in **step 2**. Planning tasks, responsibilities and time frames are established. Training of internal auditors is taken into account.

Step 3 allows you to set and implement methods for measuring the effectiveness and efficiency of each process (**indicators**). Internal audits help to evaluate the degree of implementation of specific requirements.

Nonconformities of all kinds are listed in **step 4**. A first draft for dealing with waste is established. Corrective and preventive actions are implemented and documented. An approach to preventing nonconformities and eliminating causes is established.

A first encounter with **analysis** of data is made in **step 5**. A table with the main costs of obtaining quality (COQ) is filled in by those with the information at hand. Feedback from customers and other data is analyzed to evaluate the adequacy and effectiveness of the QMS.

To conduct the **pre-audit of the QMS** (**step 6**), documentation such as quality manual, procedures and others are checked and approved by the appropriate people. A management review allows evaluation of compliance with applicable regulatory requirements. The quality policy and objectives are finalized. A quality manager from another company or a consultant can provide valuable feedback, suggestions and recommendations.

When the system is accurately implemented and followed, the **certification of the QMS** by an external body is a breeze, a formality (**step 7**).

An example of a certification project plan is shown in annex 01.

An appropriate method for evaluating the performance of your quality management system is the RADAR logic model of excellence EFQM (European Foundation for Quality Management) with its 9 criteria and overall score of 1000 points.

The Deming cycle (figure 2-4) is applied to control any process. The PDCA cycles (Plan, Do, Check, Act) are a universal base for continual improvement.

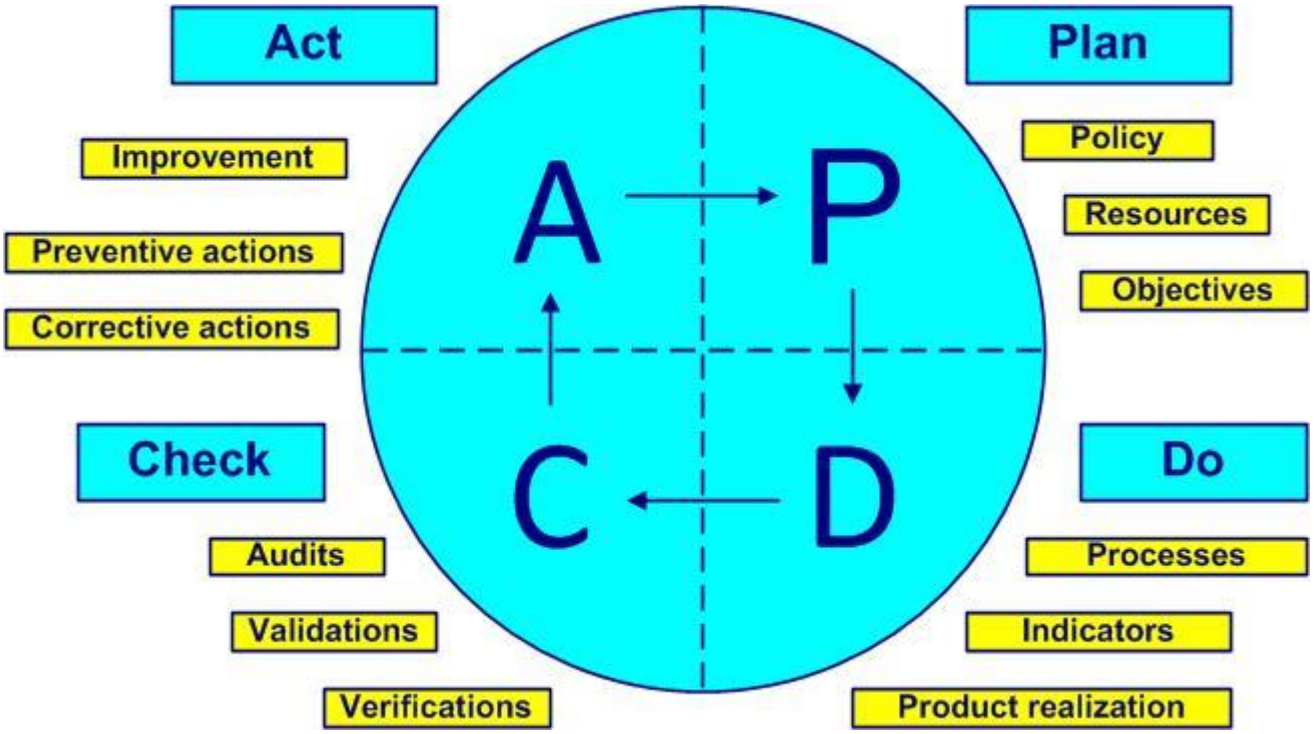


Figure 2-4. The Deming cycle

- Plan – define and establish strategy, customers, policy, resources, objectives, documentation, products, processes, training and deadlines (ISO 13485 clauses 4, 5 and 6)
- Do – implement processes, indicators and product realization (ISO 13485 clause 7)
- Check – inspect, analyze data, verify if objectives are achieved, validate and audit (ISO 13485 clause 8)
- Act – adapt, adjust, improve, react with actions or find new improvements (new PDCA cycle), (ISO 13485 sub-clauses 5.6, 8.3 and 5.5)

For more information on the Deming cycle and its 14 points of management theory, you can consult the classic book "Out of the crisis", W. Edwards Deming, MIT press, 1982.

3 Process approach

3.1 Definitions

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

Certain definitions and acronyms:

Competence: *personal skills, knowledge and experiences*
Conformity: *fulfillment of a specified requirement*
Customer: *anyone who receives a product*
Effectiveness: *capacity to realize planned activities with minimum efforts*
Efficiency: *financial relationship between achieved results and used resources*
FMEA: *failure mode and effects analysis*
Indicator: *value of a parameter*, *associated with an objective, allowing the objective measure of its effectiveness*
Interested party: *person, group or company affected by the impacts of an organization*
Life-cycle: *all phases in the life of a product, from design to disposal*
Management system: *set of processes allowing objectives to be achieved*
Organization (company): *a structure that satisfies a need*
Performance: *measurable and expected results of the management system*
Process: *activities which transform inputs into outputs*
Product (or service): *every result of a process or activity*
QMS: *quality management system*
Quality: *aptitude to fulfill requirements*
Quality management: *activities allowing the control of a company with regard to quality*
Quality management system: *set of processes allowing the achievement of the quality objectives*
Quality objective: *quality related, measurable goal that must be achieved*
Quality policy: *statement by top management allowing the establishment of quality objectives*
Requirement: *explicit or implicit need or expectation*
Risk: *probability of occurrence of a potential hazard*
Supplier: *an entity that provides a product*
System: *set of interacting processes*

Certain terms specific to the medical sector:

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

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

- accident and incident
  - an accident is an unexpected serious event
  - an incident is an event which can lead to an accident
- anomaly, defect, dysfunction, failure, nonconformity, reject and waste:
  - anomaly is a deviation from what is expected
  - defect is the non-fulfillment 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-fulfillment of a requirement in production
  - reject is a nonconforming product which will be destroyed

    - waste is when there are added costs but no value
- audit program and plan
    - an audit program is the annual planning of the audits
    - an audit plan is the description of the audit activities
- audit, inspection, auditee and auditor
    - an audit is the process of obtaining audit evidence
    - an inspection is conformity verification of a process or product
    - an auditee is the one who is audited
    - an auditor is the one who conducts the audit
- control and optimize
    - control is meeting the objectives
    - optimize is searching for the best possible results
- customer, supplier and subcontractor
    - a customer receives a product
    - a supplier provides a product
    - a subcontractor provides service or product on which 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
- inform and communicate
    - to inform is to give someone meaningful data
    - to communicate is to pass on a message, to listen to the reaction and discuss
- objective and indicator
    - an objective is a sought after commitment
    - an indicator is the information on the difference between the pre-set objective and the achieved result
- organization and enterprise, society, company
    - organization is the term used by the ISO 9001 standard as the entity between the supplier and the customer
    - enterprise, society, company are examples of organizations
- 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: the use of ISO 9000 and ISO 13485 definitions is recommended. The most important thing is to determine a common and unequivocal vocabulary for everyone in the company.

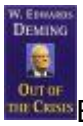
Remark 2: the customer can also be the user, the beneficiary, the trigger, the ordering party or the consumer.

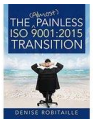
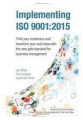
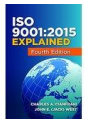
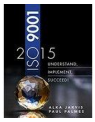
Remark 3: documentation is any information which we must maintain (procedure  *) or retain (record*  *).*

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

- ISO 9000: 2015 - Quality management systems. Fundamentals and vocabulary, (ISO, 2005)
- Study Group 1 Final Document GHTF/SG1/N68, Essential Principles of Safety and Performance of Medical Devices, 2012
- ISO/GUIDE 73 - Risk management - Vocabulary / Management du risque - Vocabulaire, ISO, 2009
- ISO/TS 11139 (2006), Sterilization of health care products - Vocabulary

Books for further reading on quality and medical devices:

-  Philip Crosby, Quality is free; the Art of Making Quality Certain, McGraw-Hill, 1979
-  Kaoru Ishikawa, What is Total Quality Control, The Japanese Way, Prentice-Hall, 1981
-  Edwards Deming, Out of the Crisis, MIT Press, 1982
-  Eliyahu Goldratt, Jeff Cox, The Goal, A Process of Ongoing Improvement, North River Press, 1984
-  Masaaki Imai, KAIZEN, The Key to Japan's Competitive Success, McGraw-Hill, 1986
-  James Harrington, Poor-Quality Cost, Dekker, 1987
-  Dennis Green, Medical Devices: ISO 13485 and ISO 9001, BSI, 2005
-  Larry Webber, Michael Wallace, Quality Control for Dummies, Wiley, 2007
-  Itay Abuhav, ISO 13485: A Complete Guide to Quality Management in the Medical Device Industry, CRC Press, 2011
-  Eric Myhrberg, A Practical Field Guide for Iso 13485 2003, ASQ, 2013
-  Ann Goodall, Implementing an ISO 13485 Quality Management System for Medical Devices, BSI, 2014

-  Denise Robitaille, The (Almost) Painless ISO 9001:2015 Transition, Paton Professional, 2015
-  Jan Gillet, Implementing Iso 9001:2015: Thrill your customers and transform your cost base with the new gold standard for business management, Infinite Ideas, 2015
-  Craig Cochran, ISO 9001:2015 in Plain English, Paton Professional, 2015
-  Charles Cianfrani, John West, ISO 9001:2015 Explained, ASQ Quality Press, 2015
-  Stephanie Skipper, How to Establish a Document Control System for Compliance with ISO 9001:2015, ISO 13485:2016, and FDA Requirements, ASQ Quality Press, 2015
-  Denise Robitaille, ISO 9001:2015 Handbook for Small and Medium-Sized Businesses, Quality Press, 2016
-  Emmet Tobin, ISO 13485 Starter Guide, CreateSpace Independent Publishing Platform, 2016
-  Jeremy Hazel, José Dominguez, Jim Collins, Memory Jogger ISO 9001:2015: What Is It? How Do I Do It? Tools and Techniques to Achieve It, Goal/QPC, 2016
-  Alka Jarvis, Paul Palmes, ISO 9001: 2015: Understand, Implement, Succeed!, Prentice hall, 2016
-  Ray Tricker, ISO 9001:2015 for Small Businesses, Routledge, 2016
-  Emmet Tobin, ISO 13485 Starter Guide, CreateSpace, 2016
-  SEPT, Checklist for ISO 13485:2016, medical devices - quality management systems- requirements for regulatory purposes, Software Engineering Process Technology, 2016

-  Brendan Cooper, ISO 13485 - the Quality Management System for Medical Devices, CreateSpace Independent Publishing Platform, 2017

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

3.2 Processes

The word process comes from the Latin root procedere = go, development, progress (Pro = forward, cedere = go). Each process transforms inputs into outputs creating added value and potential nuisances.

A process has three basic elements: inputs, activities and outputs. 

A process can be very complex (launch a rocket) or relatively simple (audit a product). A process is:

- repeatable
- foreseeable
- measurable
- definable
- dependent on its context
- responsible for its external providers

A process is, among others things, determined by its:

- title and type
- purpose (why?)
- beneficiary (for whom?)
- scope and activities
- initiators
- documents and records
- inputs
- outputs (intentional and not intentional)
- constraints
- occupational health and safety environment
- resources:
  - people
  - material
- objectives and indicators
- person in charge (owner) and actors (participants)
- means of inspection (monitoring, measurement)
- mapping
- interaction with other processes
- risks and potential deviations
- opportunities for improvement

Inspection: *the actions of measuring, testing and examining a process, product, service or material to establish whether requirements are met*

A process review is conducted periodically by the process owner (cf. annex 07).

The components of a process are shown in figure 3-1:

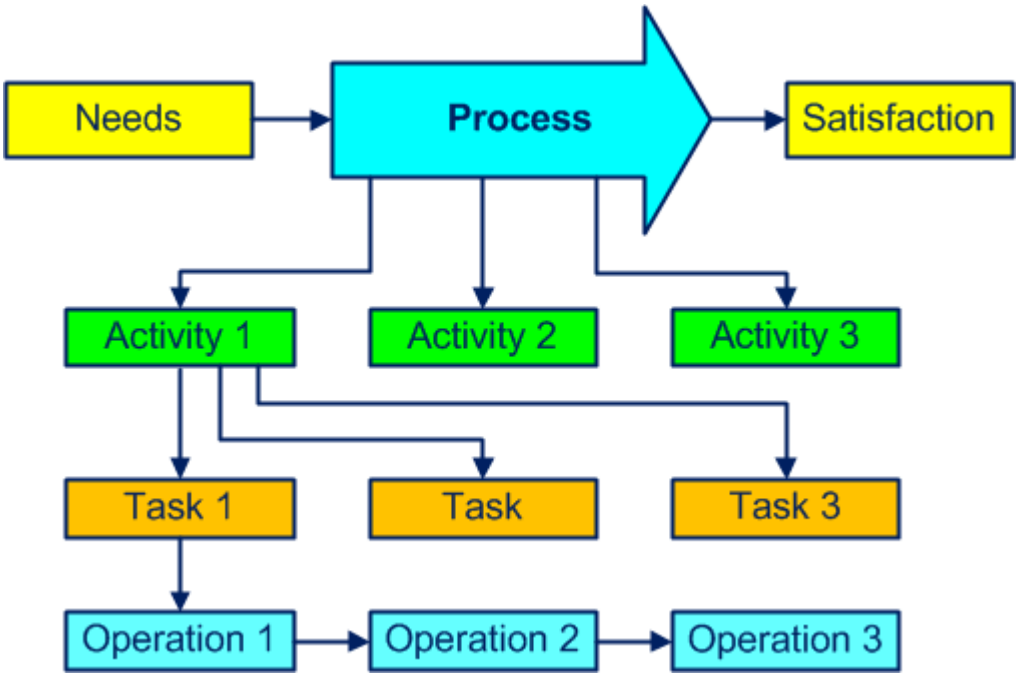


Figure 3-1. Components of a process

Figure 3-2 shows an example that helps to answer some questions:

- which materials, which documents, which tooling? (inputs)
- which title, which activities, requirements, constraints? (process)
- which products, which documents? (outputs)
- how, which inspections? (methods)
- what is the level of performance? (indicators)
- who, with what competence? (people)
- with what, which machines, which equipment? (material resources)

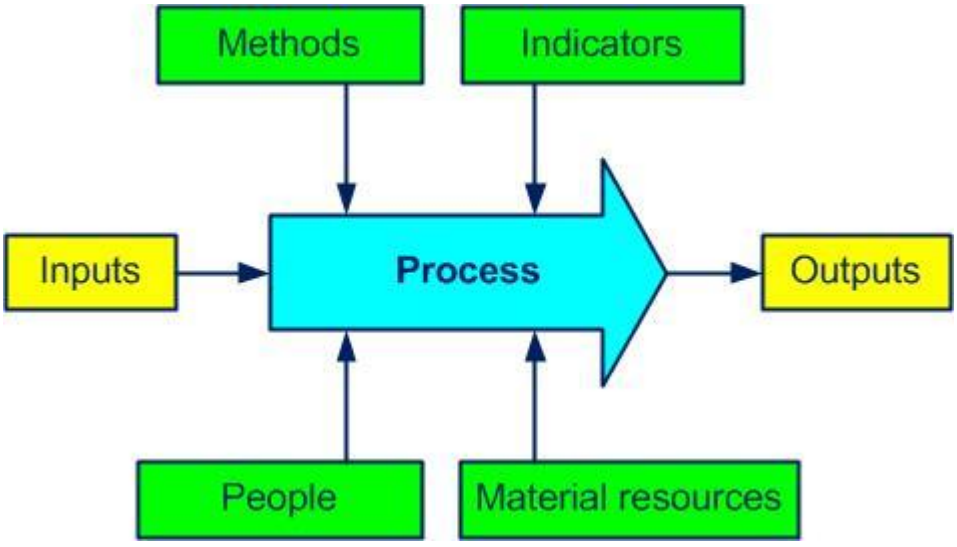


Figure 3-2. Some elements of a process

Often the output of a process is the input of the next process.

You can find some examples of process sheets in the document pack D 02 and a list of processes in annex 04.

Any organization (company) can be considered as a macro process, with its purpose, its inputs (customer needs and expectations) and its outputs (products/services to meet customer requirements).

Our preference is to identify a process using a verb (buy, produce, sell) instead of a noun (purchases, production, sales) to differentiate the process from the company's department or procedure and recall the purpose of the process.

The processes are (as we shall see in the following paragraphs) of management, realization and support types. Do not attach too much importance to process categorizing (sometimes it's very relative) but ensure that all the company's activities at least fall into one process.

3.2.1 Management processes

Management processes are also known as piloting, decision, key or major processes. They take part in the overall organization, elaboration of the policy, deployment of the objectives and all needed checks. They are the glue of all the realization and support processes.

The following processes can be part of this family:

- develop strategy
- establish policy
- address risks
- plan the QMS
- communicate
- conduct management review
- acquire and manage resources
- negotiate contract
- establish process ownership
- analyze feedback
- conduct an audit
- analyze data
- improve

3.2.2 Realization processes

The realization (operational) processes are related to the product and contribute directly to increase the added value.

They are mainly:

- manage outsourced processes
- design and develop new products
- purchase components
- sell products
- produce medical devices
- sterilize components and products
- maintain equipment
- implement traceability
- receive, store and deliver
- inspect production

- control nonconformities
- carry out FMEA
- implement corrective and preventive actions

3.2.3 Support processes

The support processes provide the resources necessary for the proper functioning of all other processes. They are not directly related to a contribution of the product's added value, but are still essential.

The support processes are often:

- control documentation
- provide information
- manage staff
- provide training
- keep accountability
- acquire and maintain infrastructure
- manage inspection means

3.3 Process mapping

Par excellence, process “mapping” is a multidisciplinary work. This is not a formal requirement of either ISO 13485 or ISO 9001 but is always welcome.

The 3 types of processes and some interactions are shown in figure 3-3.

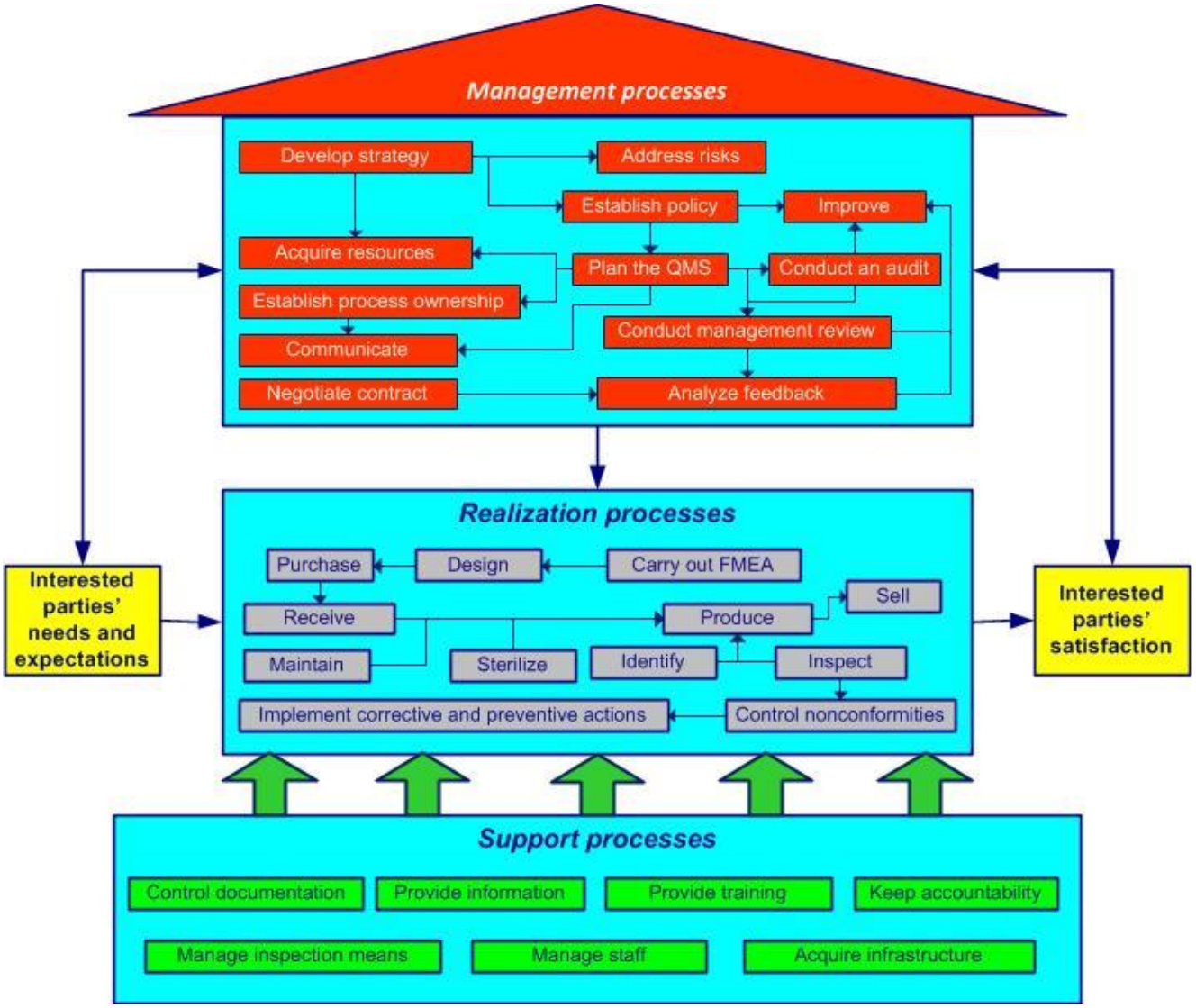


Figure 3-3. The process house

The mapping, among other things, lets you:

- obtain a global vision of the company
- identify the beneficiaries (customers), flows and interactions
- define rules (simple) for communication between processes

To obtain a clearer picture, you can simplify by using a total of about fifteen core processes. A core process can contain several sub-processes: for example, the process "develop the QMS" can involve:

- develop strategy
- establish policy
- address risks
- plan the QMS
- deploy objectives
- acquire resources
- establish process ownership
- improve

Two other process examples (“design”, figure 3-4 and “produce”, figure 3-5) are:

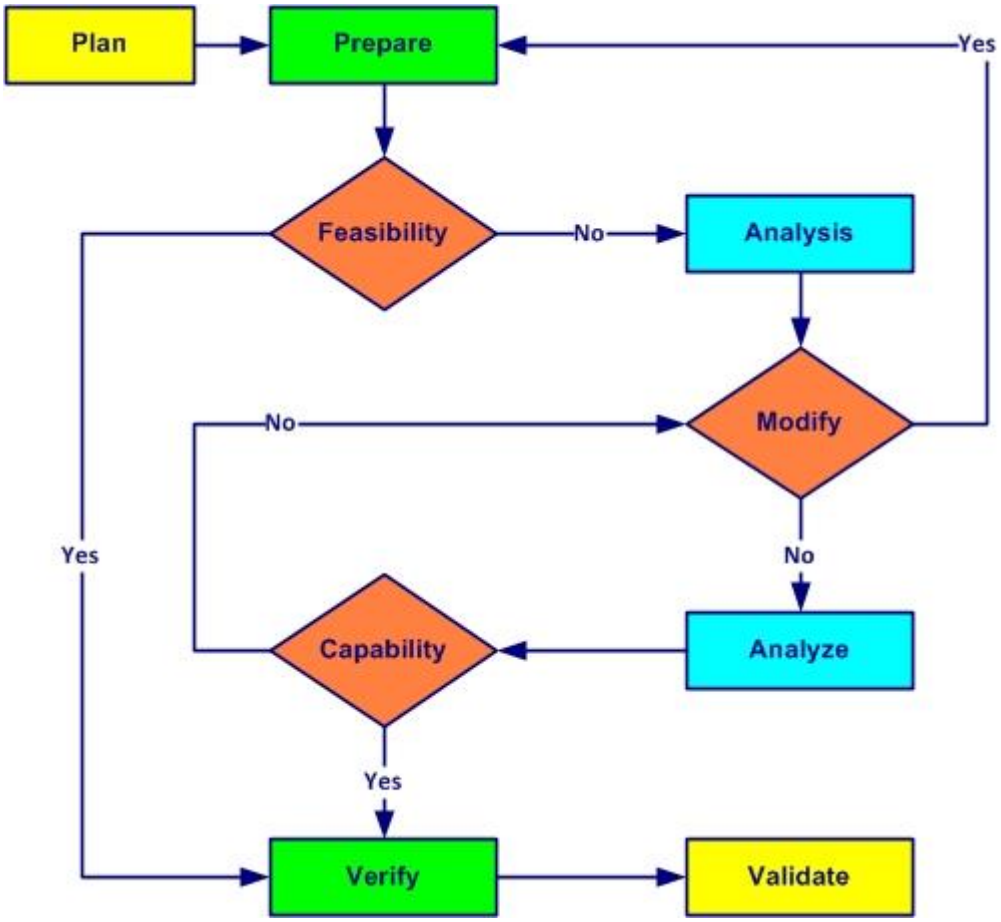


Figure 3-4. "Design" process

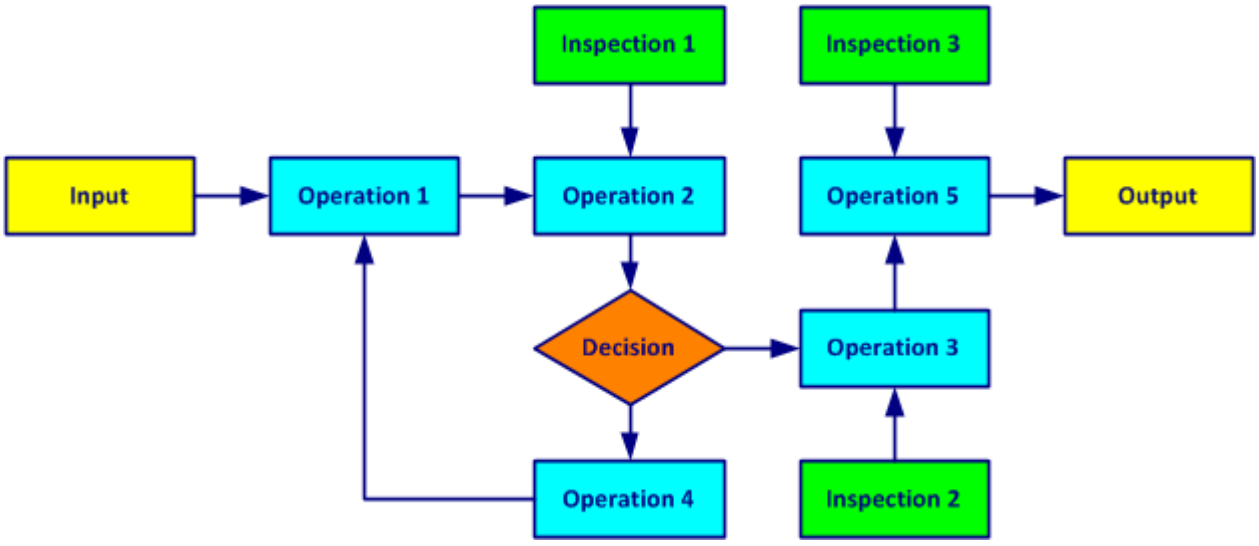


Figure 3-5. "Produce" process

3.4 Process approach

Simple solutions for now, perfection for later

The process approach contributes enormously to the efficient management of the company (cf. annex 13).

Process approach: *management by the processes to better satisfy customers, improve the effectiveness of all processes and increase global efficiency*

When the process approach is integrated during the development, implementation and maintenance of a quality management system, it allows one to achieve objectives that are related to the effectiveness of the QMS, as is shown in figure 3-6.

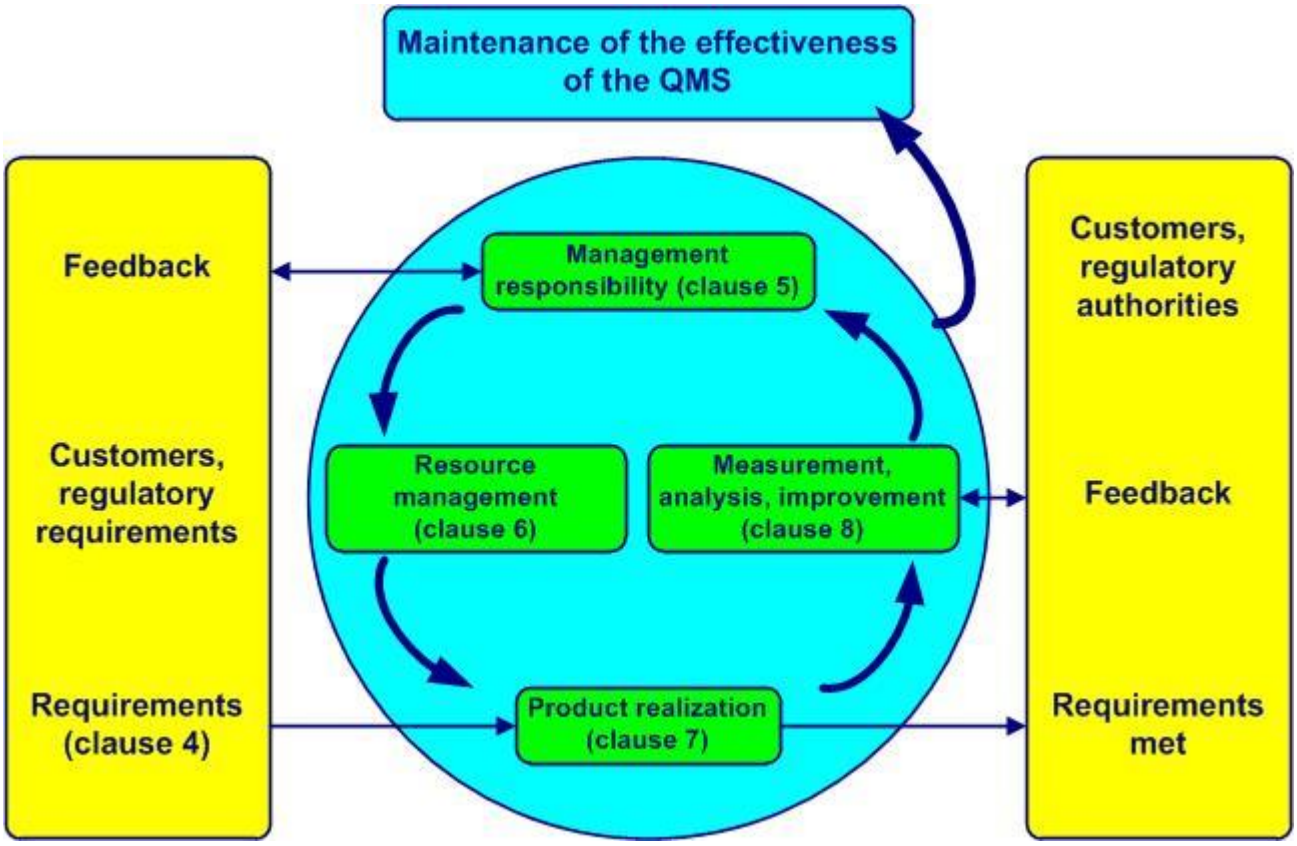


Figure 3-6. Model of a QMS based on process approach and maintenance of the effectiveness

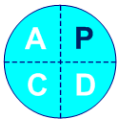
The process approach:

- emphasizes the importance of:
  - understanding and complying with customer requirements
  - prevention so as to react to unwanted elements such as:
    - customer returns
    - waste
  - measuring process performance, effectiveness and efficiency
  - permanently improving objectives based on pertinent measurements
  - process added value
- relies on:
  - methodical identification
  - interactions
  - the sequence and
  - process management which consists of:
    - determining objectives and their indicators
    - piloting related activities
    - analyzing obtained results
- allows one to:
  - better view inputs and outputs and their relationship
  - clarify roles and responsibilities
  - judiciously assign necessary resources
  - break down barriers between departments
  - decrease costs, delays and waste

- and ensures in the long run:
  - control
  - monitoring and
  - improvement of processes

The process approach **is not**:

- crisis management ("You will not solve the problems by addressing the effects")
- blaming people (“Poor quality is the result of poor management." Masaaki Imai)
- priority to investments (“Use your brain, not your money." Taiichi Ohno)



4 QMS

4.1 General requirements *(requirements 1 to 26)*

In the simplified diagram of figure 4-1 we can see the purpose of an ISO 13485 quality management system:

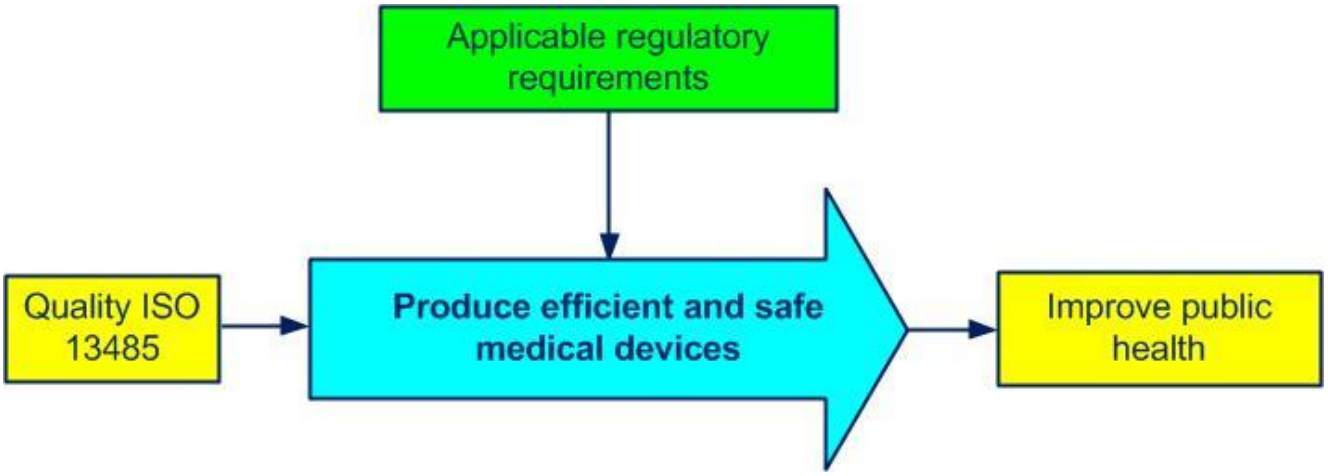


Figure 4-1. Purpose of an ISO 13485 QMS

The requirements of the ISO 13485 standard in clauses 4 to 8 are shown in figures 4-2:

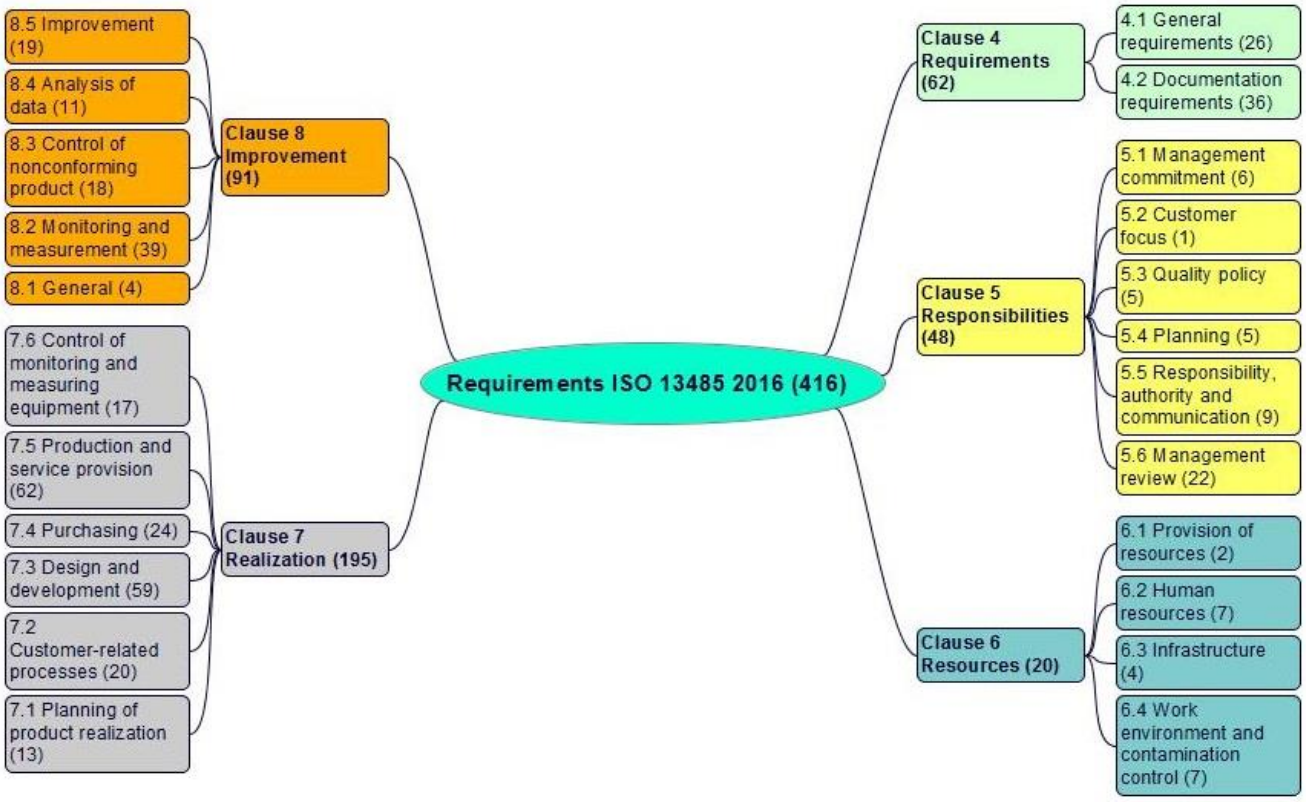


Figure 4-2. Requirements of the ISO 13485 standard

Requirements related to products are specified by the customer, by the company or a regulation.

The requirements of ISO 13485 apply exclusively to the quality management system and its processes:

- customer requirements and applicable regulatory requirements are identified and taken into account
- the quality management system (QMS) is established, documented, implemented and maintained
- the quality policy, objectives, resources and work environment are determined
- the roles of the manufacturer, importer, distributor and authorized representative are documented 
- processes required by the QMS:
  - are identified, measured, monitored
  - records are retained for compliance with requirements:
    - of the ISO 13485 standard
    - applicable regulatory requirements
  - their objectives are established and analyzed
  - their necessary resources are provided
  - their sequence and the interactions are determined
  - their operational criteria are established
  - their information essential for monitoring is ensured
  - their owners are named
- the level of risk of the processes is identified in relation to:
  - impact on safety and performance of medical devices
  - regulatory compliance
- actions to achieve planned results and maintain process efficiency are established and implemented
- staff are involved

In annex 14 are shown the new requirements of the 2016 version of the standard with examples of actions to be undertaken.

Process changes (cf. sub-clause 7.3.9) are:

- evaluated against their impact on:
  - the QMS
  - medical devices
- controlled in accordance with the requirements:
  - of the ISO 13485 standard
  - applicable regulatory requirements

An outsourced process is always controlled and does not relieve the organization of its responsibilities towards customers (cf. sub-clause 7.4). Outsourced processes are identified and their level of risk is proportionate to the ability of the external party to meet the requirements (see annex 12). An element of outsourced process control is the signed supplier quality agreement.

The procedure  software validation includes:

- validation of software applications prior to initial use
- revalidation after software or application change
- a proportionate approach of risk associated with its use
- retaining records

Used software is validated and a list is retained.

Pitfalls to avoid:

- going overboard on quality
- having all procedures written by the quality manager
- forgetting to take into account the specificities related to the corporate culture

Good practices

- *the process map has enough arrows to show who the customer (internal or external) is*
- *reveal the added value of the process during the process review*
- *the list of processes is updated*
- *the analysis of process performance is an example of continual improvement and evidence of the effectiveness of the QMS*
- *the role of the organization is documented in accordance with applicable regulatory requirements*
- *revisions of process changes are evaluated*
- *quality contracts are established for critical outsourced processes*
- *validation records of software applications are coded and retained*

Bad practices

- *some process outputs are not set correctly (customers not considered)*
- *process efficiency criteria are not established*
- *the process list is not updated*
- *the role of the organization is not documented*
- *process owners are not formalized*
- *outsourced processes are not determined*
- *some real activities are not identified in any process*
- *control of outsourced services is not described*
- *sequences and interactions of certain processes are not determined*
- *criteria and methods for ensuring effective processes are not determined*
- *monitoring the effectiveness of certain processes is not established*
- *the impact of process changes is not evaluated*
- *software applications are not validated*

4.2 Documentation *(requirements 27 to 62)*

The right document, at the right place, at the right moment

The documentation of the QMS (cf. figure 4-3) includes:

- the quality manual (QM)
- the quality policy
- the quality objectives
- the process sheets
- the procedures
- the documents needed to control processes
- the documents of external origin (from suppliers, customers, standards)

- the documents required by applicable regulatory requirements
- required records

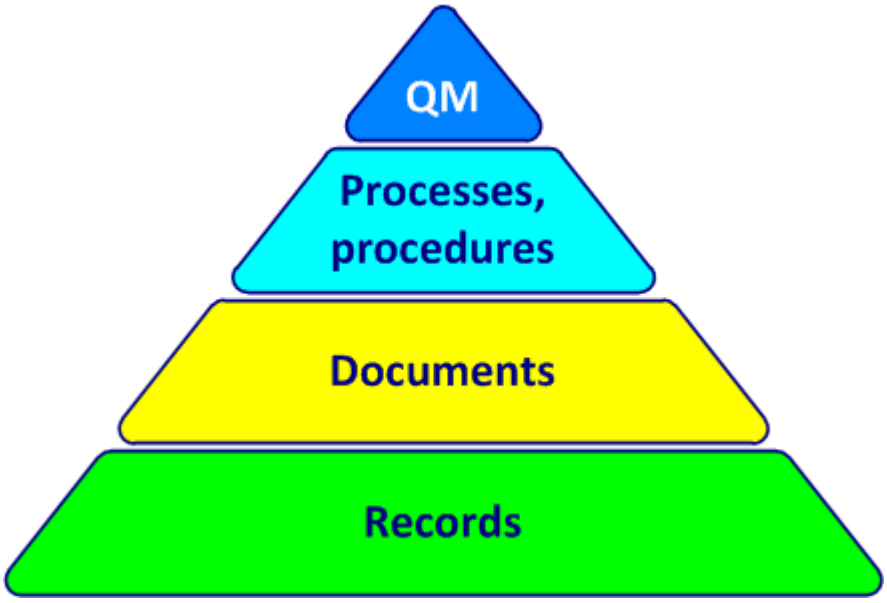


Figure 4-3. Documentation pyramid

The quality manual (cf. annex 02) describes the:

- scope of the QMS
- types of medical devices manufactured
- procedures (cf. annex 03) or a reference to them
- sequence and interactions between processes (process mapping, cf. § 3.3 and annex 04)
- justification of the exclusions from elements of clauses 6, 7 and 8 (cf. § 1.2)

The quality manual is like traffic laws: it is mainly a guide, a tool, but it does not teach you to drive.

The medical device file includes the technical documentation developed and maintained for each model or type of medical device and each servicing activity. This documentation includes:

- product description, intended use, labeling, instructions for use
- bill of materials:
  - assemblies, sub-assemblies
  - components
  - materials
  - labels, instructions for use, advisory notices
  - accessories
  - packaging
- classification of applicable regulatory requirements
- manufacturing, packaging, storage, handling and distribution process (including sterilization methods, inspections, testing and validation)
- flow diagrams, blueprints, drawings, assembly diagrams and working instructions
- measurement and monitoring procedures
- risk analysis

- installation requirements, if appropriate
- servicing activities, if appropriate
- results of verifications, validations, trials, tests, clinical data and declaration of conformity

Customers and authorities have free access to product documentation.

Documents requiring approval of changes by customers or authorities are identified.

A chart summarizing customer requirements, applicable regulatory requirements and processes is a great help in verifying QMS conformity.

Each internal document is verified and approved. Any documented procedure, requirement or activity is implemented and maintained. Outdated (obsolete) documents are identified, retained and their use prohibited in the workshop.

The next-to-last version of a document may become a record.

The technical report ISO/TR 10013 (2006): "Guidelines for quality management system documentation" provides recommendations relative to the documentation of a QMS.

Answers to all 416 requirements (in the text « shall ») of clauses 4 to 8 of the ISO 13485 standard are included in the documentation. ISO 9001 “only” requires 305.

Document: *any support allowing the treatment of information*
Record: *document providing objective evidence of achieved results*
Quality manual: *document specifying the general measures taken by an organization to obtain conforming products or services*
Procedure: *document describing the actions to carry out a process*

The mandatory procedures required by the ISO 13485 standard version 2016 (cf. annex 03) are:

- **Validation of software** (sub-clauses 4.1.6, 7.5.6 and 7.6)
- **Document control** (sub-clause 4.2.4). The procedure ensures:
  - verification (review of content and form)
  - approval (and then issue authorization)
  - updating (verification and approval again)
  - identification of the relevant version in force at the place of use
  - readability
  - availability
  - identification and distribution of documents of external origin
  - prevention of the use of outdated (obsolete) documents and their specific identification
  - prevention of loss or deterioration of documents
  - retention of medical devices outdated documents
- **Record control.** The procedure ensures:
  - identification
  - storage
  - security
  - integrity
  - retrieval

    - availability
    - retention time
    - retrieval
    - disposal
    - readability
    - issue
    - change identification
    - a justification for every requirement which cannot be applied
- **Management review** (sub-clause 5.6)
- **Work environment control** (sub-clause 6.4.1)
- **Design and development** (sub-clause 7.3)
- **Transfer** (sub-clause 7.3.8)
- **Control of changes** (sub-clause 7.3.9)
- **Purchasing** (sub-clause 7.4)
- **Control of production** (sub-clauses 7.5.1 and 8.2.6)
- **Servicing activities** (sub-clause 7.5.4)
- **Process validation** (sub-clauses 7.5.6 and 7.5.7)
- **Identification and traceability** (sub-clauses 7.5.8 and 7.5.9)
- **Preservation of product** (sub-clause 7.5.11)
- **Monitoring and measuring equipment** (sub-clause 7.6)
- **Feedback** (sub-clause 8.2.1)
- **Complaint handling** (sub-clause 8.2.2)
- **Reporting to regulatory authorities** (sub-clause 8.2.3)
- **Internal audit** (sub-clause 8.2.4)
- **Control of nonconforming product** (sub-clause 8.3.1)
- **Advisory notices** (sub-clause 8.3.3)
- **Rework** (sub-clause 8.3.4)
- **Analysis of data** (sub-clause 8.4)
- **Corrective action** (sub-clause 8.5.2)
- **Preventive action** (sub-clause 8.5.3)

You can group several procedures into one. The documentation can be in any form and any type of medium. It contributes, among other things, to providing objective evidence and evaluating the effectiveness and performance of the QMS.

Objective evidence: *demonstrably true factual data*

A procedure may or may not be documented (see ISO 9000: 2015, sub-clause 3.4.5). Our preference is for the documented (written) solution, short, simple and relevant, especially in

cases where the absence of a procedure can lead to deviations from the policy, the quality objectives, the safety or the performance of the medical device.

Changes made are reviewed and approved by the author of the document or by a person with relevant information to make decisions.

Methods of protecting records containing confidential health information are implemented in accordance with applicable regulatory requirements.

A review of the documentation is carried out periodically by the quality manager.

The retention period of at least one copy of the documents is determined (procedures and records). This period complies with applicable regulatory requirements and shall not be less than the lifetime of the medical device and no less than two years from the release of the medical device.

True story

At a third party audit, the auditor asked to see the version history of three procedures and some instructions.

The procedures all had more than 3 versions and the instructions (in our case, audit reports) had on average 2 or 3 versions (actions and one or two follow-ups).

The auditor was comforted because he was afraid he would come across "inactive" documents.

The QMS documentation is related to the size and type of the organization, the complexity of processes and the competence of staff. This documentation is accessible to the personnel concerned and they are informed during evolutions of the documentation. Only the documents that are strictly necessary are required to obtain simplified documentation. Example of documents commonly used include:

- quality manual
- company organization chart
- procedures
- quality plans
- specifications
- work or test instructions
- templates
- records
- FMEA
- documents of external origin
- list of approved suppliers
- test and inspection plans

Specification: *final description of system or product requirements in order to develop or validate it*

The process manage documentation ensures the review, release, changes and implementation of the customer's technical specifications.

Spoken words fly away, written ones stay. Latin proverb

Retained records required by ISO 13485 to prove conformity and effectiveness of the QMS (sub-clauses): 

- role of the organization (4.1.1)
- process control (4.1.3 e and 4.2.1 d)
- software application validation (4.1.6)
- general documentation of the QMS (4.2.1)
- regulatory requirements (4.2.1 e)
- medical device file (4.2.3)
- control of records (4.2.4)
- responsibilities, authorities and independence (5.5.1)
- management review (5.6.1 and 5.6.3)
- staff competence (6.2.e)
- maintenance of infrastructure (6.3)
- work environment (6.4.1)
- contamination control (6.4.2)
- risk management (7.1)
- planning of the production (7.1)
- process and product conformity (7.1 d)
- review of requirements related to product (7.2.2)
- communication with customer (7.2.3)
- design and development inputs (7.3.3)
- design and development outputs (7.3.4)
- design and development review (7.3.5)
- design and development verification (7.3.6)
- design and development validation (7.3.7)
- design and development transfer to manufacturing (7.3.8)
- design and development changes (7.3.9)
- design and development files (7.3.10)
- control of suppliers (7.4.1)
- purchasing information (7.4.2)
- verification of purchased product (7.4.3)
- verification and approval of medical devices before release (7.5.1)
- product cleanliness (7.5.2)
- installation and verification of medical devices (7.5.3)
- servicing activities carried out (7.5.4)
- batch sterilization process parameters (7.5.5)
- process validation (7.5.6)
- sterilization process validation (7.5.7)
- unique identification (7.5.8)
- traceability (7.5.9.1)
- package addressee (7.5.9.2)
- customer property problem (7.5.10)
- product preservation (7.5.11)
- calibration and verification of measuring equipment (7.6)
- results of validation of monitoring and measurement software (7.6)
- feedback (8.2.1)
- complaint handling (8.2.2)
- reporting to regulatory authorities (8.2.3)
- internal audits (8.2.4)
- product monitoring and measurement (8.2.6)
- nonconformities (8.3.1)
- acceptance by concession (8.3.2)
- rework performed (8.3.4)

- analysis of data (8.4)
- corrective actions taken (8.5.2)
- preventive actions taken (8.5.3)

Each record is unique and usually cannot be changed. Any record provides evidence of a task, operation, activity, process or requirement. Records are the essential database for analyzing process efficiency and contributing to the maintenance of the QMS. Examples of other records often used:

- advisory notices
- process capability study
- costs of obtaining quality
- change request
- concession request
- customer complaint
- delivery form
- nonconformity sheet
- conformity certificate

The record retention period is determined and is usually included in the master document list. This period is at least two years, complies with applicable regulatory requirements and cannot be less than the life of the medical device. 

Good practices

- *the quality manual is short and simplified (easy to read by all staff). It contains the scope and justification of the exclusions*
- *document management clearly shows the author and approver of the initial document and subsequent versions*
- *properly managing changes to documents (a line in the middle of the old text, red) can quickly show the history and the identity of the person who has approved the change*
- *a list of the dates of implementation of the changes in production is available in the workshop*
- *the file of each type of medical device is complete*
- *the methods for distributing documents are described in the procedure "Document control"*
- *the hierarchy of documents is logical and clear (manual, processes, procedures, records)*
- *a review of all documentation of the QMS is conducted twice a year, it is very well organized, the actions are completed on schedule*
- *the master list of documents also includes the retention period*
- *documents of external origin (standards, regulations, documents of customers, suppliers and machines) are coded as internal documents and the location is notified in a specific list*

Bad practices

- *the quality manual is not updated*
- *in the quality manual exclusions are neither detailed nor justified*
- *in the quality manual are not justified not applicable processes*
- *some procedures are not updated*
- *the need of some documents is not evaluated*
- *many real activities are not identified in any document*
- *some documents are not codified*

- *files of some medical devices are not complete*
- *documents are not in the place where they are needed*
- *instructions are outdated (version before the last one)*
- *no arrangement to ensure the security of the records*
- *changes to records are difficult to identify*
- *changes are not approved by those with authority*
- *documents are not approved prior to release*
- *during the project launch meeting the list of participants is not recorded*
- *the protection of documents on the network is not defined*
- *documents of external origin (customer, supplier) are not controlled (codified)*
- *the shelf-life and the elimination of rerecords are not established*