D 15 version 2015

ISO 9001 readiness

Goal

Goal of the module: Readiness for implementation, certification, maintenance and improvement of your quality management system (ISO 9001) in order to:

- increase the satisfaction of interested parties
- improve your overall performance
- seize opportunities for continual improvement

1 Quality approach

1.1 Background

The evolution of the quality concept and the standards of quality management systems (Quality Management System = QMS) in industrial countries in the 20th century can be summarized as:

- quality control (till the 1980s) – quality practices, customers are (or seem) satisfied
- quality assurance (the 1990s) – the system is determined and implemented
- quality management (ISO 9000: 2000) – the system is controlled and its efficiency is improved

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 ISO 9000 standards (cf. figure 1-1) have appeared in:

- 1987: first edition
- 1994: first revision, more understandable, customer focus better determined, preventive actions added
- 2000: second revision, simplified structure (8 clauses), priority to process approach and customer satisfaction
- 2008: third revision, clarification of the requirements (no new requirement), better alignment with ISO 14 001
- 2015: fourth revision, new structure (high level), added risk-based thinking, performance becomes a priority, lightweight documentation

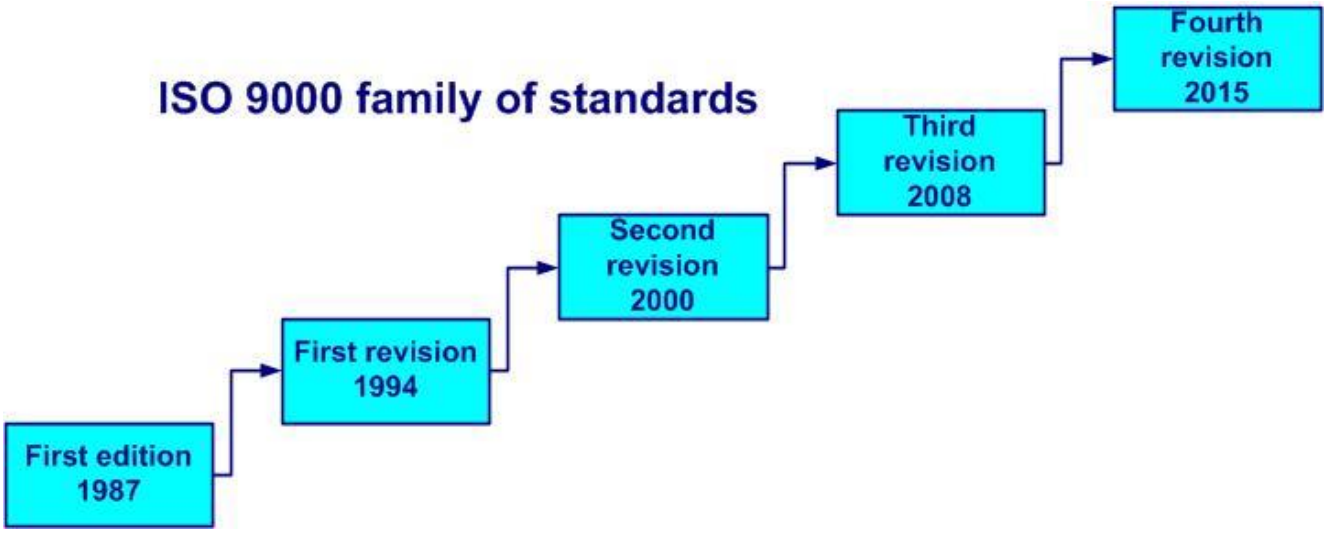


Figure 1-1. Revisions of ISO 9000 family

The new version of the ISO 9001 standard (fourth revision) was published in September 2015.

The ISO standards (more than 18,000) are used in countless fields and are recognized all over the world.

1.2 Scope

The ISO 9001 standard (**Quality management systems - Requirements**) is generic as it can be applied to the management system of any company, without limitations on size, activity or type. It is a voluntary international standard which allows certification by accredited bodies.

Nevertheless, certain requirements cannot be applied in particular cases. This is possible when:

- it does not affect product and service conformity in any way
- it does not relieve top management of its responsibilities
- it is justified in a documented information

1.3 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 management systems include three distinct and interrelated steps:

- the process approach
- risk-based thinking
- continual improvement

The purpose of a quality management system is to increase the satisfaction of customers (both external and internal) by meeting their needs and expectations through continual improvement of the effectiveness of the processes.

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 1-2) will help us achieve sustained success (cf. ISO 9000: 2015, sub-clause 2.3). Previously there were eight principles but now the system approach is integrated into the process approach.

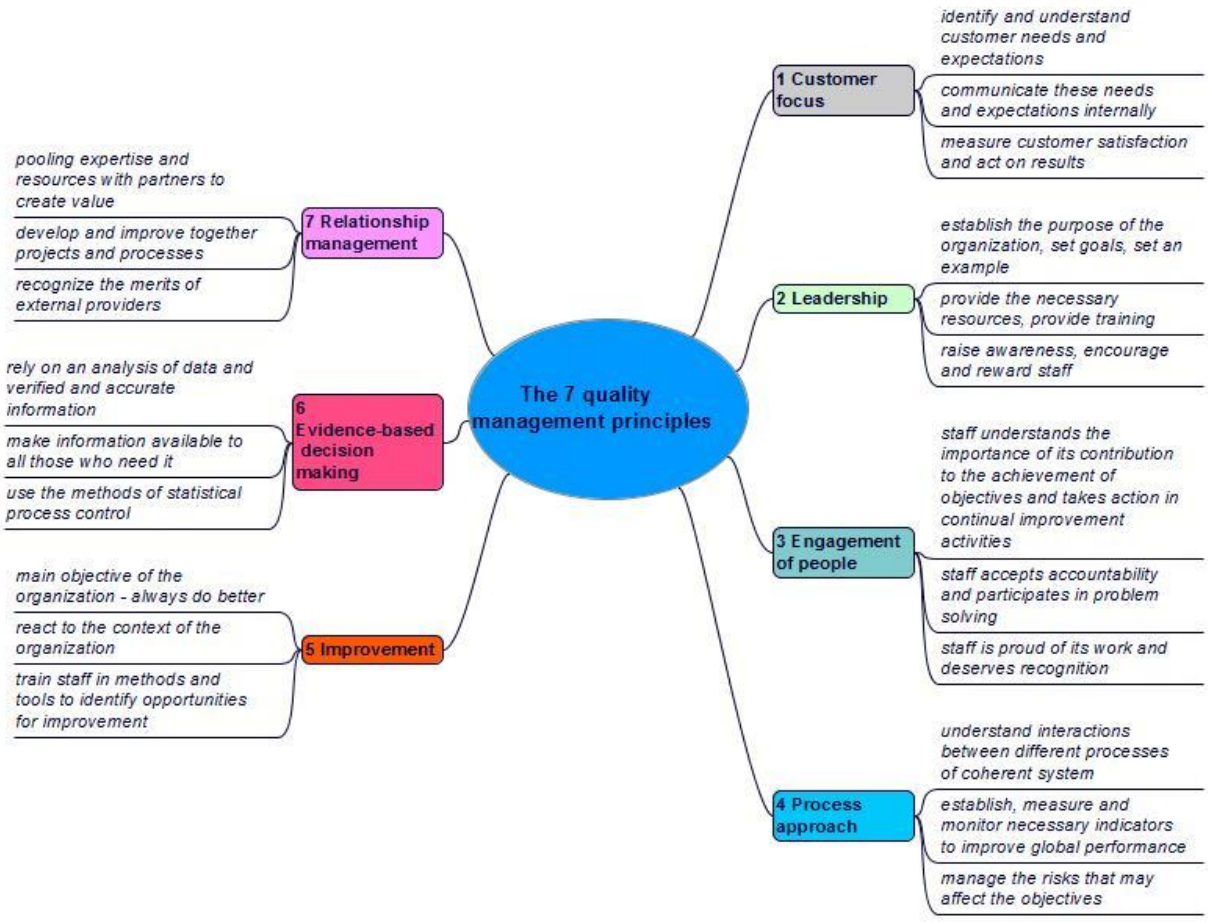


Figure 1-2. The 7 quality management principles

A well-prepared approach is half successful

The approach to implementing a quality management system starts with the preparation. An example is shown in figure 1-3.

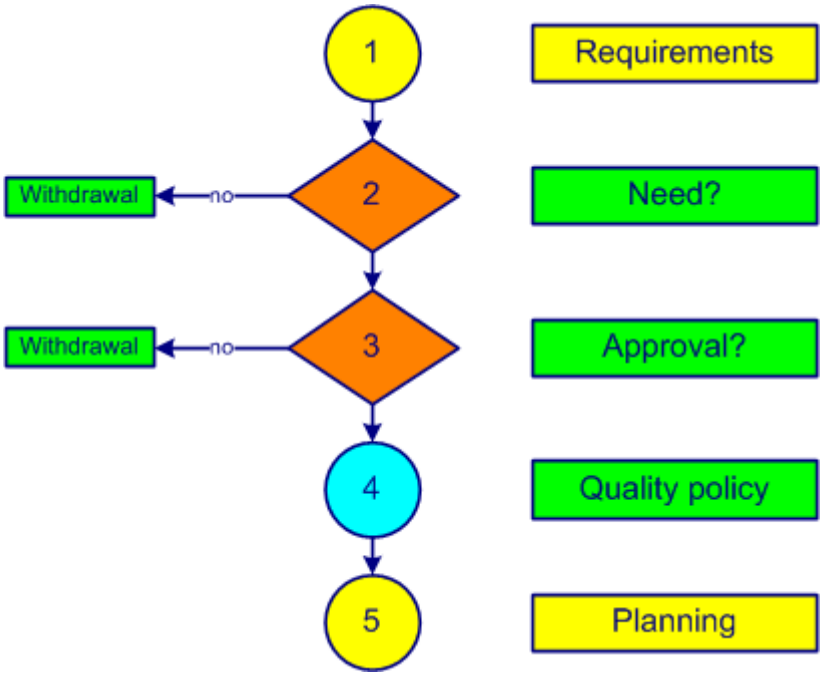


Figure 1-3. QMS preparation

Step 1 involves identifying the needs and expectations (**requirements**) of interested parties:

- staff
- customers, consumers
- competitors
- shareholders, investors
- external providers (suppliers, subcontractors, partners)
- organizations and branch associations
- statutory and regulatory authorities

The involvement of top management at its highest level is truly indispensable. The advice of a consultant is often solicited. A status of the management system (whole or partial) would be welcome at this stage. An external certification body is chosen.

One of the key questions which 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 reject this idea immediately.

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

The benefits of implementing a quality management system are often:

- improved image of the company
- one step ahead of the competition
- enhanced customer satisfaction
- better economic results
- increased daily effectiveness
- staff is aware, consulted, motivated and proud
- high level of risk control
- reduced insurance costs
- profitable engagement for all

- best practices valorized
- formalization of knowledge
- process control
- legal obligations updated

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

- new customers
- increased market share
- 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 **following step** (**4**) includes the establishment of an outline of the **quality policy** and quality objectives. If you do not have a copy of the ISO 9001 standard, now is the time to get it (cf. sub-clause 2.1 of the present course).

Planning is the last **step** (**5**) of the project preparation for obtaining ISO 9001 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 is appointed as project leader. Top management commitment is formalized in a document communicated to all staff. A person is appointed as project leader for obtaining ISO 9001 certification.

The establishment and implementation of an ISO 9001 quality management system are shown in figure 1-4.

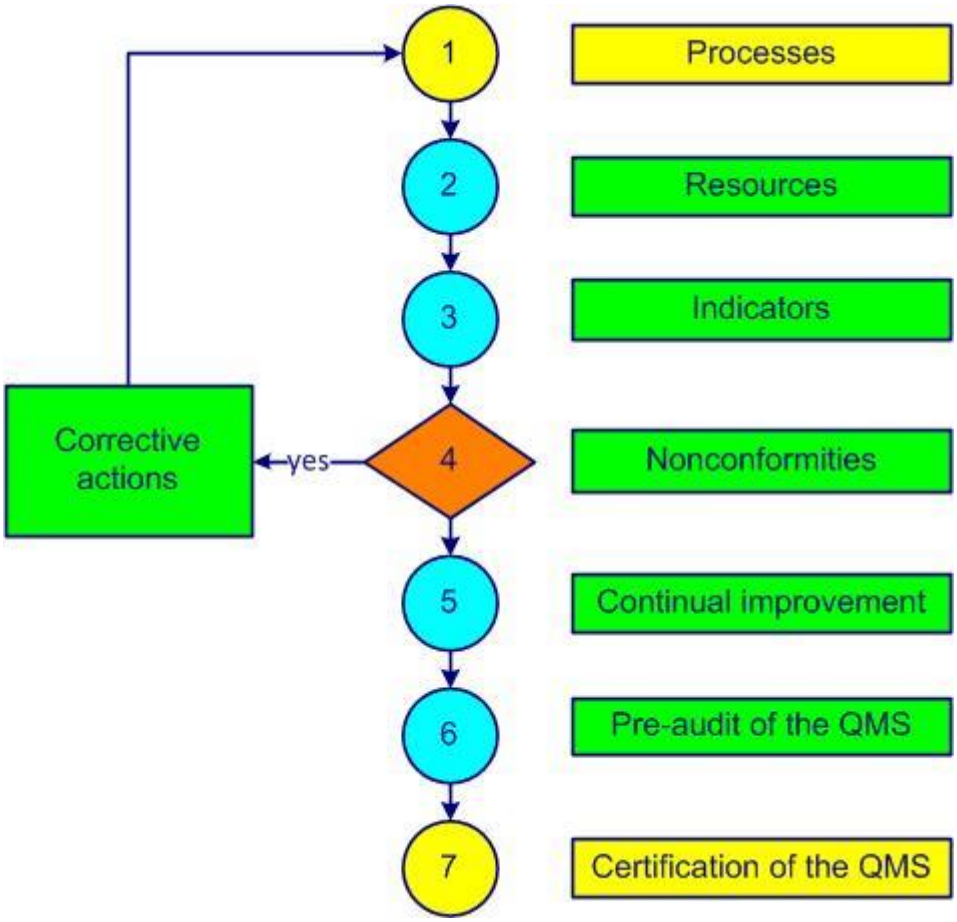


Figure 1-4. QMS implementation

Step 1 aims to identify and determine the **processes**, interactions, owners, responsibilities and drafts of certain documented information. The first versions of process sheets, job descriptions and work instructions are written with the participation of the maximum number of available persons.

The 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 the system.

Nonconformities of all kinds are listed in **step 4**. A first draft for dealing with waste is established. Corrective actions are implemented and documented. A sorting out of corrective actions is introduced.

A first encounter with the tools and application areas of **continual improvement** is made in **step 5**. A table with the main costs of obtaining quality (COQ) is filled by people with the information at hand. Risks are determined, actions are planned and opportunities for improvement are found. An approach to preventing nonconformities and eliminating causes is established. The internal and external communication is established and formalized.

To conduct the **pre-audit of the QMS** (**step 6**) documented information is checked and approved by the appropriate people. A management review allows evaluation of compliance with applicable 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 with 26 steps is shown in annex 14.

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 1-5) is applied to control any process. The PDCA cycles (Plan, Do, Check, Act) are a universal base for continual improvement.

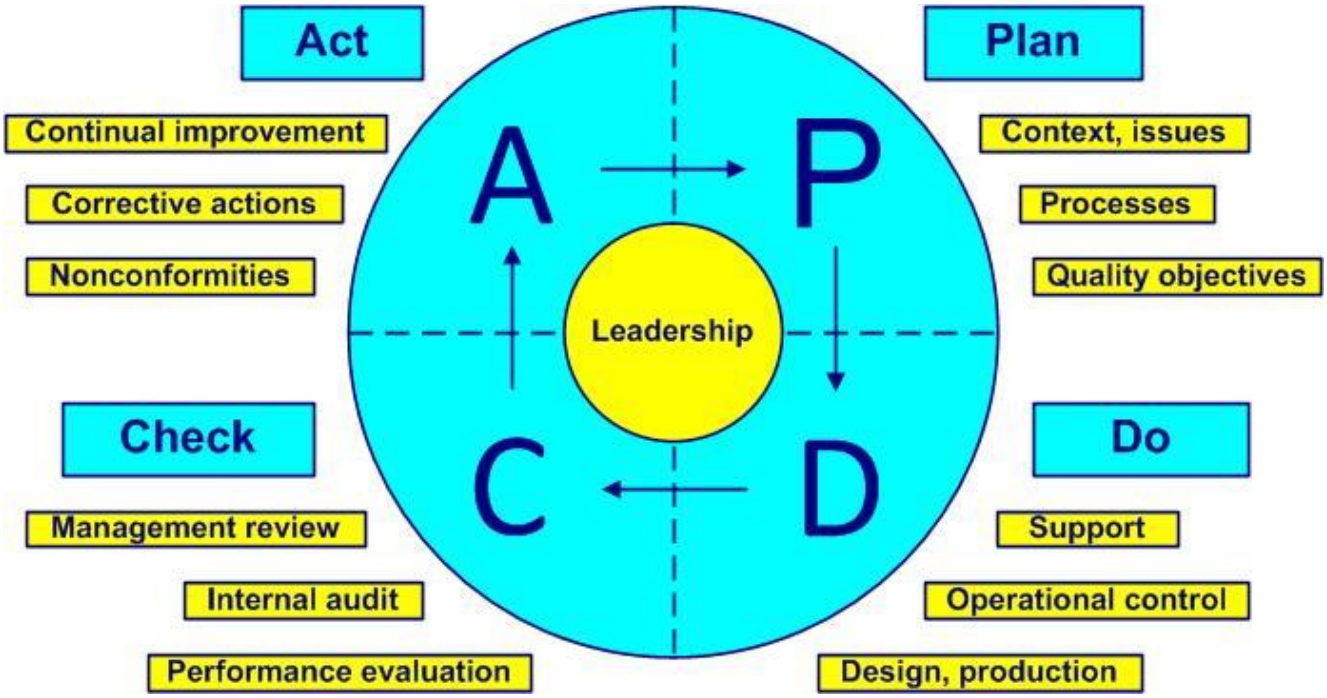


Figure 1-5. The Deming cycle

- Plan – define context, issues and processes, demonstrate leadership, establish quality policy and objectives (clauses 4, 5 and 6)
- Do – realize the product, develop, implement and control processes, demonstrate leadership, bring support (clauses 5, 7 et 8)
- Check – compare, evaluate, inspect, analyze data, conduct audits and management reviews, demonstrate leadership (clauses 5 and 9)
- Act – adapt, demonstrate leadership, treat nonconformities, react with corrective actions and find new improvements (new PDCA cycle), (clauses 5 and 10)

For more information on the Deming cycle and its 14 points of management theory (cf. table 1-1) you can consult the classic book "Out of the crisis" W. Edwards Deming, MIT press, 1982.

Table 1-1. The 14 Deming points

Points	Description
1	Create constancy of purpose for permanent improvement of products and services,

	in order to become competitive, stay in business and provide jobs
2	Adopt the new philosophy in the new economic age. Western management must accept its responsibilities and lead for change
3	Don't be dependent on inspection to achieve quality. Eliminate mass inspection by including quality in the product in the first place
4	Stop buying just on the basis of a low price. Minimize further total costs by cutting down the number of suppliers and build long-term relationships of loyalty and trust with them
5	Improve permanently the production system, improve quality and productivity to obtain costs decrease
6	Establish training for all
7	Establish leadership. The purpose of supervision is to help people, equipment and tooling to do a better job
8	Keep fear out of sight, everybody's work will be more efficient
9	Break down barriers between departments. Teamwork is needed throughout the whole organization to foresee potential problems
10	Eliminate slogans and targets asking for zero defects from the work force. Most of the causes of low quality and productivity belong to the system
11	a. Eliminate work quotas on the shop floor. Substitute leadership b. Eliminate management by objectives. Eliminate management by numerical goals. Substitute leadership
12	a. Remove barriers that rob the worker of the pride of his workmanship b. Remove barriers that rob the people in management of the pride of their workmanship
13	Establish a vigorous training and self-improvement program
14	Put everybody to work to accomplish the transformation. It's everybody's job

2 Standards, definitions, books

2.1 Standards

The ISO 9000 family of standards contains three core booklets (and one guideline):

- **ISO 9000 (2015): Quality management systems - Fundamentals and vocabulary**
- **ISO 9001 (2015): Quality management systems - Requirements**
- **ISO/TS 9002 (2016): Quality management systems - Guidelines for the application of ISO 9001:2015**
- **ISO 9004 (2009): Managing for the sustained success of an organization - A quality management approach**

The new versions of ISO 9001 and ISO 9000 were published in September 2015.

The ISO 9000 standards are compatible with the other management system standards (common vocabulary, process approach, customer satisfaction, continual improvement). An added standard in 2002 (and revised in 2011) is:

ISO 19011: "Guidelines for auditing management systems" (2011).

ISO 14001 (2015 – third edition) is the standard related to the environment: **"Environmental management systems - requirements with guidance for use"**. The new version was published in September 2015.

ISO/TS 16949 (2009 – third edition) is a Technical Specification for automotive manufacturers: **"Quality management systems – Particular requirements for the application of ISO 9001-2008 for automotive production and relevant service part organizations"**.

ISO 31000: 2009 "**Risk management - Principles and Guidelines**" establishes the principles and risk management process, risk assessment and risk treatment.

The standards of the series **ISO 10001** to **ISO 10019** are guidelines for quality management systems and will help you find many answers (cf. ISO 9004:2009, Bibliography).

All of 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.

2.2 Definitions

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

Specific quality terms:

Competence: *personal skills, knowledge and experiences*
Conformity: *fulfilment of a specified requirement*
Corrective action: *action to eliminate the causes of nonconformity or any other undesirable event and to prevent their recurrence*
Customer: *anyone who receives a product*
Customer satisfaction: *top priority objective of every quality management system related to the satisfaction of customer requirements*

Documented information: *any support allowing the treatment of information*
Effectiveness: *capacity to realize planned activities with minimum efforts*
Efficiency: *financial relationship between achieved results and used resources*
External provider (supplier): *an entity that provides a product*
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*
Management system: *set of processes allowing objectives to be achieved*
Nonconformity: *non-fulfilment of a specified requirement*
Organization (company): *a structure that satisfies a need*
Process: *activities which transform inputs into outputs*
Product (or service): *every result of a process or activity*
Quality: *aptitude to fulfil requirements*
Quality management: *activities allowing the control of a company with regard to quality*
Quality objective: *quality related, measurable goal that must be achieved*
Requirement: *explicit or implicit need or expectation*
Risk: *probability of occurrence of a potential hazard*
Top management: *group or persons in charge of the company's control at the highest level*

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-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 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, external provider and subcontractor
  - a customer receives a product
  - an external provider provides a product on which specific work is done
  - 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 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, the consumer.

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

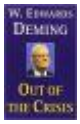
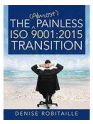
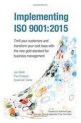
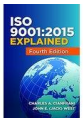
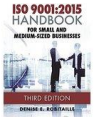
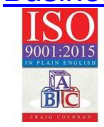
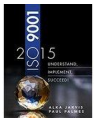
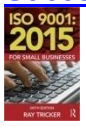
For other definitions, comments, explanations and interpretations which you don't find in this module and in annex 06, you can consult:

- ISO 9000: 2005 - Quality management systems. Fundamentals and vocabulary, (ISO, 2005). New version published in September 2015
- Introduction and support package: Guidance on the Terminology used in ISO 9001 and ISO 9004 (Document ISO/TC 176/SC 2/N 526R2, 2008)
- Quality management system – Indicators and synoptical tables (FD X50 - 171, ISO, 2000)

2.3 Books

Books for further reading on quality:

-  Philip Crosby, Quality is free; the Art of Making Quality Certain, McGraw-Hill, 1979
- Joseph Juran, Management of Quality, McGraw-Hill, 1981
-  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
-  Larry Webber, Michael Wallace, Quality Control for Dummies, Wiley, 2007
-  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
-  Charles Cianfrani, John West, ISO 9001:2015 Explained, ASQ Quality Press, 2015
-  Denise Robitaille, ISO 9001:2015 Handbook for Small and Medium-Sized Businesses, Quality Press, 2016
-  Craig Cochran, ISO 9001:2015 in Plain English, Paton Professional, 2015
-  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

-  Christopher Paris, Surviving ISO 9001: 2015, Oxebridge Quality Press, 2016

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

3 Process approach

3.1 Process

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, 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 determined among others by its:

- title and type
- purpose (why?)
- beneficiary (for whom?)
- scope and activities
- initiators
- documented information
- inputs
- outputs (intentional and not intentional)
- restraints
- people
- material resources
- 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 continual improvement

A process review is conducted periodically by the process owner (cf. annex 01).

Review: *a survey of a file, product, process so as to verify if pre-set objectives are achieved*

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

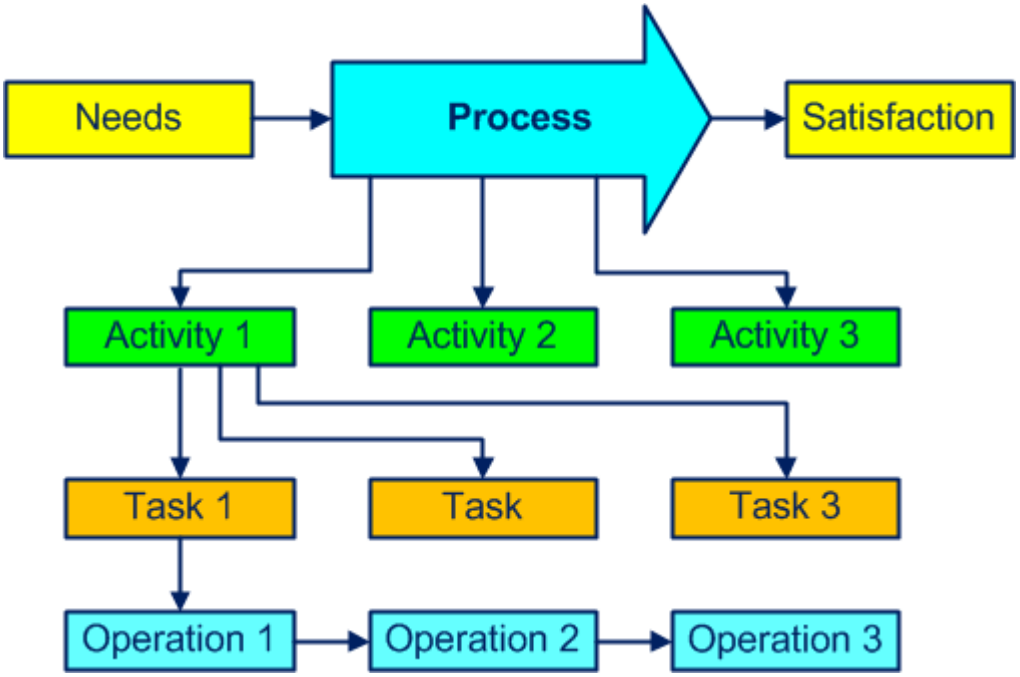


Figure 3-1. Components of a process

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)

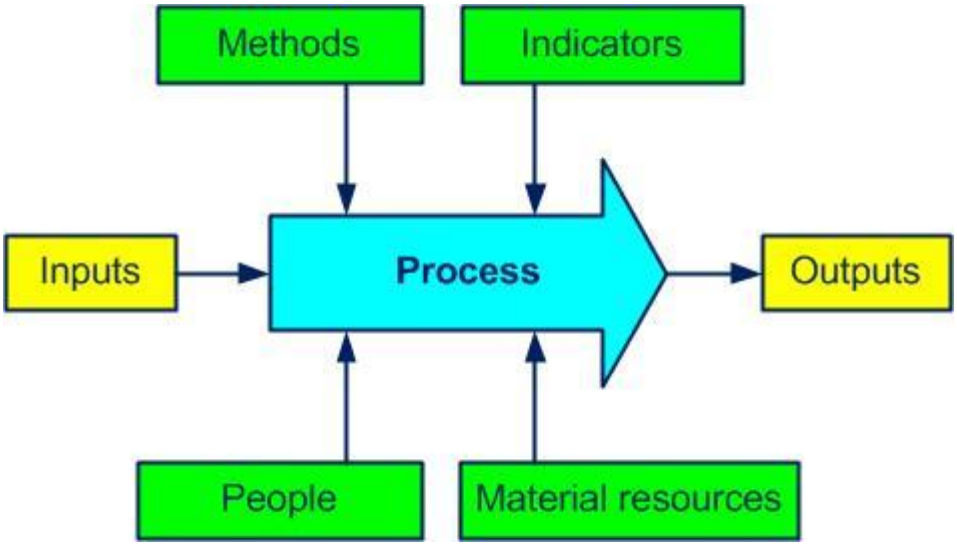


Figure 3-2. Some elements of a process

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 02.

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 documented information to maintain and recall the purpose of the process.

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

3.1.1 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
- develop policy
- deploy objectives
- plan the QMS
- acquire and manage resources
- address risks
- establish process ownership
- conduct an audit
- conduct management review
- communicate
- improve
- measure customer satisfaction
- negotiate contract
- meet requirements
- analyze data

3.1.2 Realization processes

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

They are mainly:

- design and develop
- purchase components
- produce
- maintain equipment
- inspect production
- sell products
- receive, store and deliver
- control nonconformities
- implement corrective actions
- implement traceability

3.1.3 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
- acquire and maintain infrastructure
- provide training
- manage inspection means
- manage staff
- keep accountability

3.2 Process mapping

Par excellence process “mapping” is a multidisciplinary work. This is not a formal requirement of the ISO 9001 standard but is always welcome.

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

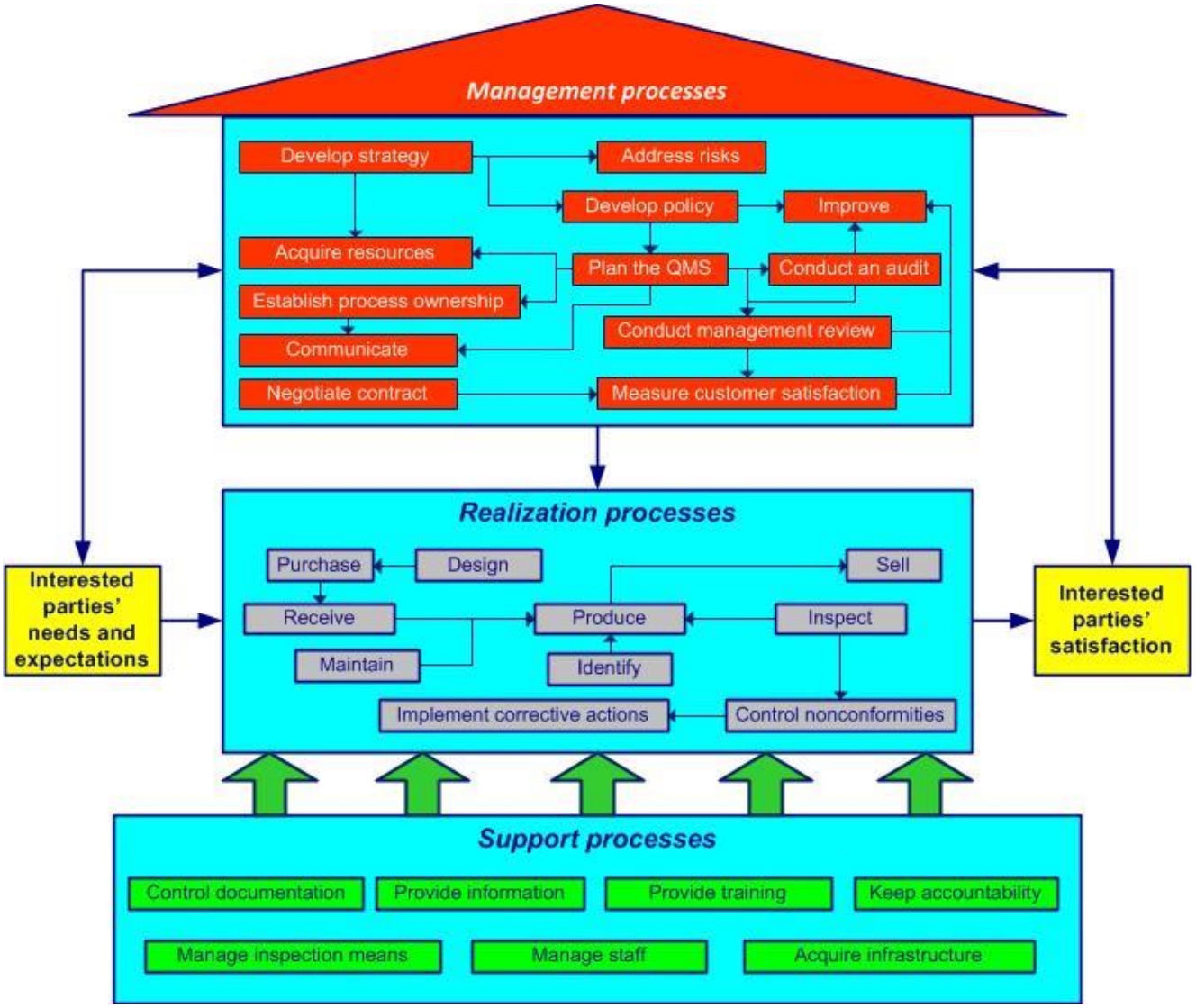


Figure 3-3. The process house

In the outputs, do not underestimate unwanted products such as rubbish, pollution, rejects.

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, a process "develop the QMS" can involve:

- develop strategy
- develop 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):

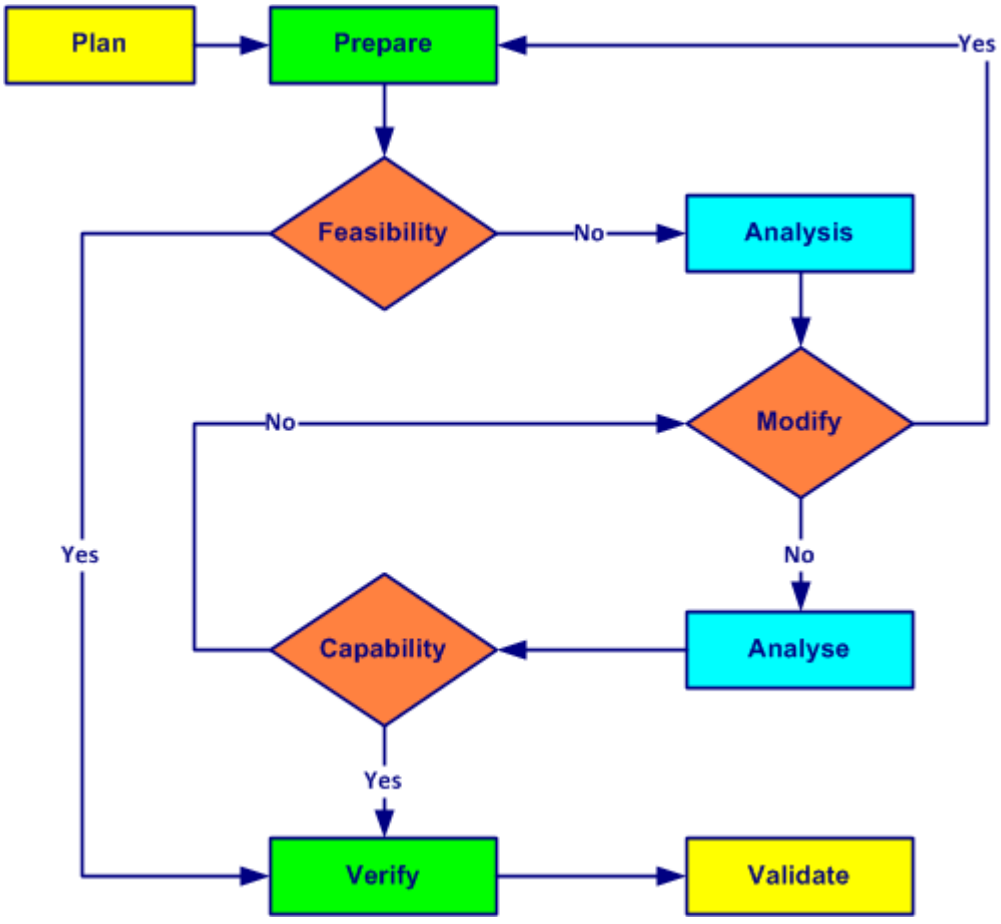


Figure 3-4. Design process

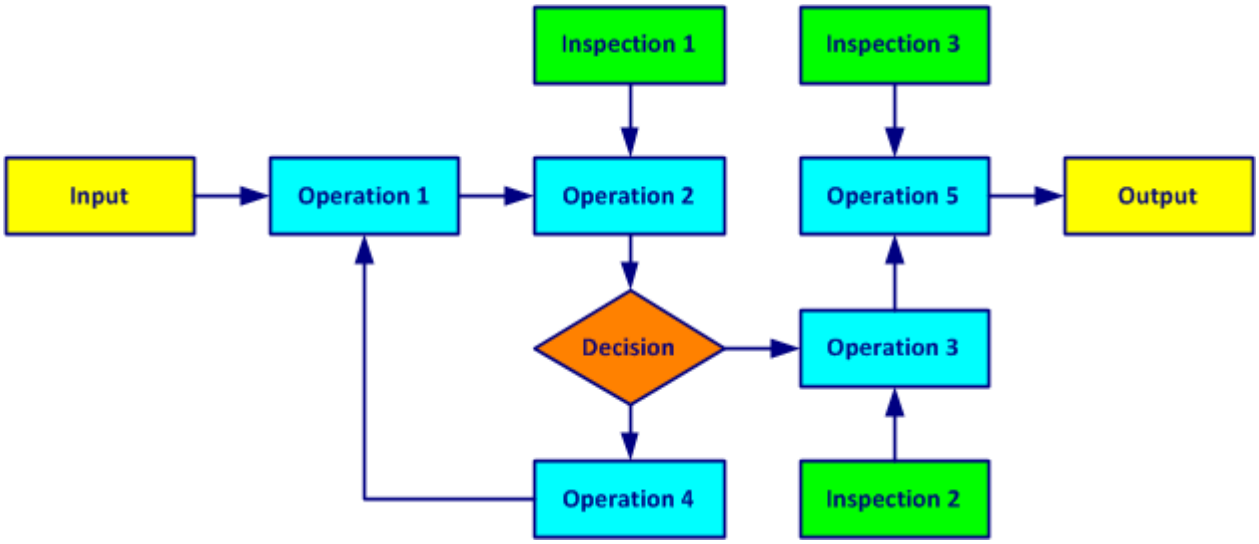


Figure 3-5. Produce process

3.3 Process approach

Simple solutions for now, perfection for later

The process approach contributes enormously to the efficient management of the company (cf. annex 12).

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 continual improvement of a quality management system, it allows one to achieve objectives that are related to customer satisfaction, as is shown in figure 3-6.

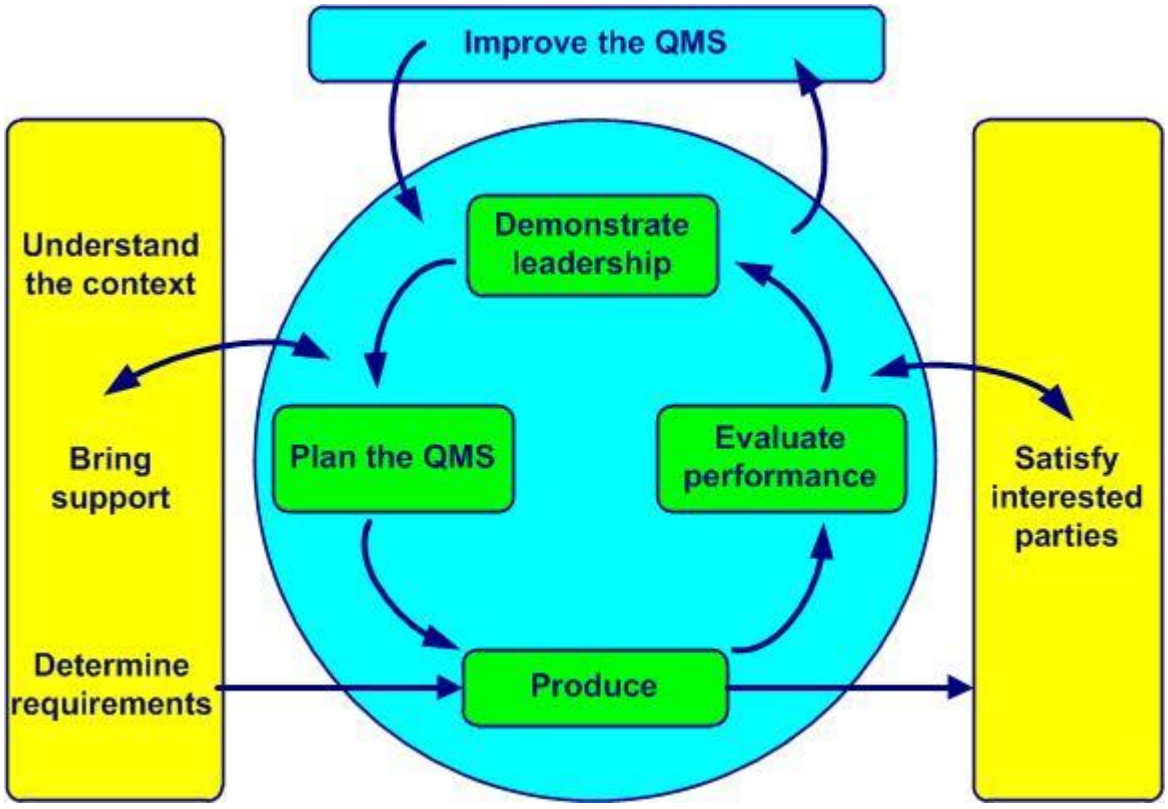


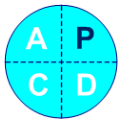
Figure 3-6. Model of a QMS based on process approach and continual improvement

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
    - permanently undertaking improvements
- 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, wastes
- and ensures in the long run:
  - control
  - monitoring and
  - continual 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 Context of the organization

4.1 The organization and its context *(requirements 1 to 2)*

The two most important things do not appear in the company's balance sheet: its reputation and its people. Henry Ford

To successfully implement a quality management system, we must understand and evaluate everything that can influence the reason for being and business performance. You should think carefully about a few key activities:

- develop a thorough diagnosis of the unique context in which your company exists, taking into account these issues:
  - the external environment, such as:
    - social
    - regulatory
    - economic
    - technology
  - the internal environment, such as:
    - specific aspects of the corporate culture:
      - vision
      - rationale, purpose, mission
      - core values
    - staff
    - products and services
    - infrastructure
- monitor and review regularly any information relating to external and internal issues
- analyze the factors that may influence the achievement of business objectives

The SWOT and PESTEL analyses can be useful for relevant analysis of business context (cf. annex 08).

A list of external and internal issues is carried out by a multidisciplinary team. Each issue is identified by its level of influence and control. Priority is given to issues with great influence and poor control.

Good practices

- *diagnosis of the context includes the main external and internal issues*
- *the core values as part of the corporate culture are taken into account in the context of the company*

Bad practices

- *the issues of the context of the company as the competitive environment are not taken into account*
- *in some cases, the corporate culture is not taken into account*

4.2 Needs and expectations of interested parties *(requirements 3 to 5)*

There is only one valid definition of a business purpose: to create a customer. Peter Drucker

To understand the needs and expectations of interested parties, we must begin by determining those who may be affected by the quality management system, such as:

- employees
- customers
- external providers
- owners
- shareholders
- bankers
- distributors
- competitors
- citizens
- neighbors
- social and political organizations

A list of interested parties is carried out by a multidisciplinary team. Every interested party is determined by its level of influence and control. Priority is given to interested parties with great influence and poor control.

True story

The customer is king but we still can fight against rudeness. This example is taken from the restaurant La petite Syrah in Nice and its coffee prices:

"A coffee".....7 €
"A coffee, please".....4,25 €
"Hello, a coffee, please"....1,40 €

Anticipating the reasonable and relevant needs and expectations of interested parties is:

- meeting the requirements of the product or service offered
- preparing to address risks
- finding improvement opportunities

When a requirement is accepted, it becomes an internal requirement of the QMS.

Quality means including the customer's point of view from design to final recycling

A review of product and service requirements (including up to delivery) is conducted to:

- determine the commercial processes

- ensure that these requirements can be met and are:
  - explicit
  - implicit
  - statutory and regulatory
  - specific to:
    - the company
    - the customer and other interested parties
- determine and address gap situations

This review is performed after receipt of the order and prior to acceptance thereof. A feasibility study may be undertaken.

Good practices

- *the list of interested parties is updated*
- *the needs and expectations of interested parties are established through meetings on site, surveys, roundtables and meetings (monthly or frequent)*
- *the application of statutory and regulatory requirements is a prevention approach and not a constraint*

Bad practices

- *statutory and regulatory requirements are not taken into account*
- *the delivery time is not validated by the customer*
- *the expectations of interested parties are not determined*

4.3 Scope of the quality management system *(requirements 6 to 12)*

In many areas, the winner is the one who is best informed. André Muller

The scope (or in other words, the perimeter) of the quality management system is defined. When a requirement cannot be applied, a justification is included in the documented information  that is maintained and is available to any interested party.

The specific context of the company is taken into account to determine the scope of the QMS:

- issues (cf. sub-clause 4.1)
- products and services
- corporate culture
- environment:
  - social
  - financial
  - technology
  - economic
- requirements of interested parties (cf. sub-clause 4.2)
- outsourced processes

Good practices

- *the scope is relevant and available upon request*
- *non applicable requirements are justified in writing*

Bad practices

- *some products are outside the scope of the QMS without justification*
- *the paint shop is not included in the scope of the QMS*
- *the requirements of a customer are not accepted and no justification is present*
- *the scope is obsolete (the new subsidiary is not included)*

4.4 Quality management system and its processes *(requirements 13 to 24)*

If you cannot describe what you are doing as a process, you do not know what you're doing. Edwards Deming

The requirements of the ISO 9001 standard include:

- the management through quality and
- the control of business processes

To do this:

- the quality management system is:
  - established
  - documented (a simple and sufficient documentation system is set up)
  - implemented and
  - continually improved
- the quality policy, objectives, resources and the work environment are determined
- risks are determined and actions to reduce them are established (cf. sub-clause 6.1)
- the core necessary QMS processes are controlled:
  - corresponding resources are ensured
  - the inputs and outputs are determined
  - the necessary information is available
  - owners are appointed (responsibilities and authorities defined)
  - sequences and interactions are determined
  - each process is measured and monitored (established criteria)
  - objectives are set and performance indicators analyzed
  - process performance is evaluated
  - necessary changes are implemented to achieve the expected results
  - actions for continual improvement of processes are established
- audits and reviews of the QMS are performed regularly
- the necessary minimum ("as much as needed") of documented information on the processes is maintained and retained ()

The quality manual is not a requirement of ISO 9001 v 2015, but it is always a possible method to present the company, its QMS and its procedures and processes (cf. annex 13).

 Pitfalls to avoid:

- going overboard on quality
- forgetting to take into account the specificities related to the corporate culture and the context in which the company is located

The requirements of the ISO 9001 standard are shown in figures 4-1:

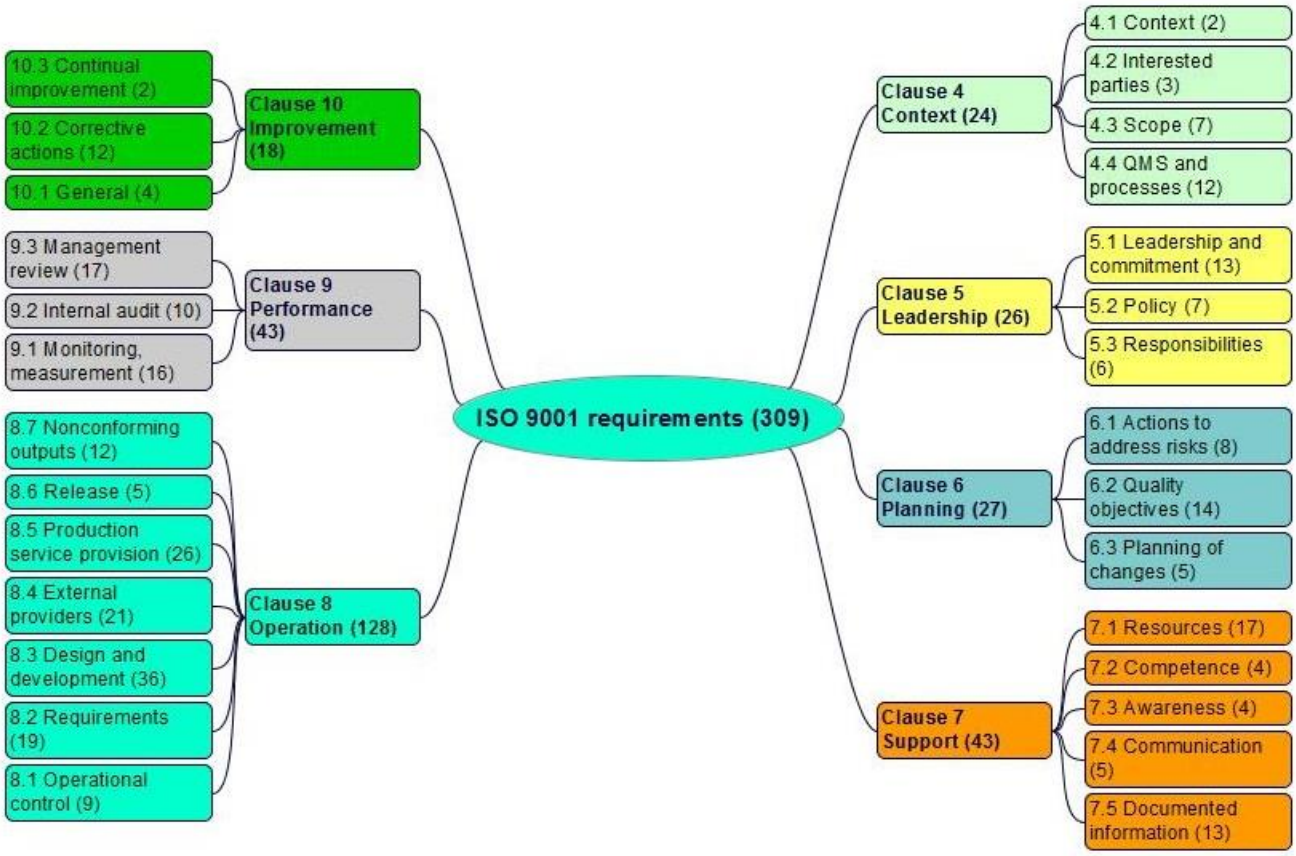


Figure 4-1. The requirements of the ISO 9001:2015 standard

Good practices

- *the process map has enough arrows to show who is the customer (internal or external)*
- *for a process, it is better to use a lot of arrows (several customers) rather than to forget one*
- *reveal the added value of the process during the process review*
- *the analysis of processes performance is an example of continual improvement evidence of the effectiveness of the QMS*
- *top management regularly monitors the objectives and action plans*
- *commitments of top management on continual improvement are widely diffused*

Bad practices

- *some process outputs are not set correctly (customers not considered)*
- *process efficiency criteria are not established*
- *process owners are not formalized*
- *outsourced processes are not determined*
- *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 QMS resources do not allow achievement of quality objectives*
- *the QMS is not updated (new processes are not determined)*