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Lean approach

Objective of the module: Master the Lean approach to be able to:

- contribute to the sustainable development of the company
- increase the added value produced
- make work more attractive for everyone

1 Quality approach

1.1 History

Quality comes from the Latin word qualitas, "way of being", itself derived from the adjective qualis, "as it is".

There are many definitions of the word quality. Some examples:

- state, disposition - Aristotle
- property, attribute - René Descartes
- compliance with requirements - Philip Crosby
- anything that can be improved - Masaaki Imai
- fitness for use - Joseph Juran
- ability to satisfy the customer - Kaoru Ishikawa
- degree to which a set of inherent characteristics of an object fulfils requirements, ISO 9000: 2005, § 3.6.2 (in other words: the ability of a product or service to meet needs)
- absence of defects, Joseph Juran
- seeking the satisfaction of all parties involved in a transaction - Yvon Mougin
- level of excellence
- take pride in your work (work well done)
- do it right the first time and all the time
- it is when the customer likes the product and the employee likes to make the product
- it's when the customer comes back and not the product

The Petit Robert alone gives us six different meanings for the word quality.

Our choice:

Quality: *aptitude to fulfill requirements*

Everyone makes quality, like Monsieur Jourdain made prose.

Everyone has a point of view on quality, often personal and interesting.

No one is against quality and in principle everyone accepts that:

Quality is a journey, not a destination

True story

In the code of King Hammurabi of Babylon (1730 BC), we find one of the oldest written traces of quality requirements:

- *if an architect builds a house and one of the walls falls, this architect will consolidate this wall at his own expense*
- *if an architect builds a house and the house collapses and the master of the house is killed, that architect is liable to death*

For centuries, quality was intrinsic to all craftsmanship (facilitated by direct contact with the customer).

With the advent of industrialization (mass production) appeared the division of labor (design, production and inspection) and the interchangeability of parts (beginning of standardization).

In 1924, for the first time, a "quality assurance" department was created in the Bell Telephone company to better satisfy the end customer. At that time in this company, people who would become world-renowned thought leaders such as Shewhart, Deming and Juran worked on and developed the “statistical quality control” approach.

In the 1930s, excesses were reached. For example, in the same Bell Telephone company, it was noticed at one point that the inspection staff was more numerous than the workers!

Until the early 1940s, the inspection department (often called “control”) had the mission of verifying the conformity of finished products. It was expensive (lots of checks) and not very efficient (defects were discovered at the end of the production cycle).

During the Second World War it was realized that poor quality could be very expensive – a direct link to human lives. Use of inspection at all stages of production began and certain requirements became mandatory (including reception). A finished production with a lot fewer defects was obtained (they were discovered quite early).

The first American military standards for inspection by sampling were put in place.

In 1949, the American Society for Quality Control (ASQC) was created.

The 1960s and 1970s saw the appearance of quality department, continual improvement, prevention, the daily use of statistics in production, the involvement of all personnel and team spirit for quality. Many approaches and various tools emerged (see Chapters 9 and 10 of this module).

The first international standards related to quality (ISO 9000 family) appeared in 1987. We talk about quality assurance, zero defects, prevention, corrective and preventive actions and supplier quality assurance (SQA).

During the 1990s, the quality system encompassed all departments, the notion of total quality and excellence appeared, cf. figure 1-1.

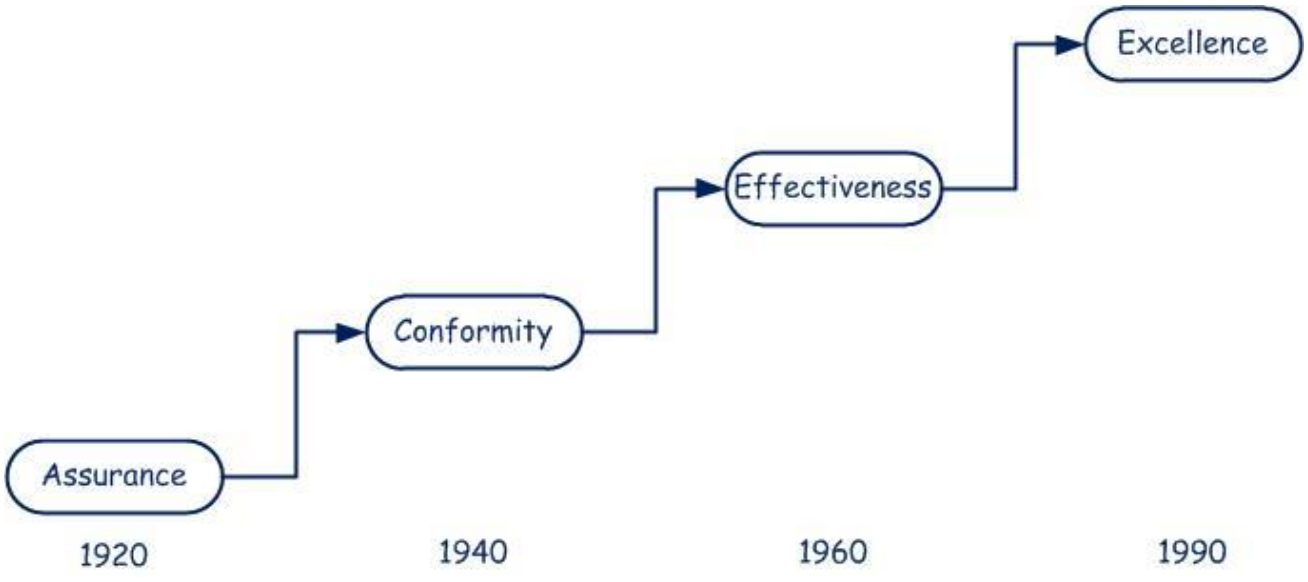

Figure 1-1. History of the quality department

Since the 2000 version of the ISO 9001 standard, quality assurance has been replaced by quality management, the structure has been simplified and the mandatory procedures have reduced. Customer satisfaction, the process approach, efficiency and continual improvement have become priorities.

The future of quality department is summed up in its purpose: to permanently reduce the gap between the expected quality and the quality perceived by the customer or in other words to help create added value for the customer.

1.2 Principles

1.2.1 Management principles

The quality approach is a state of mind that starts with top management as a priority strategic decision and extends to all staff. Top management defines the quality policy, in which the quality objectives are set and applicable to all activities. The tool used to achieve the objectives is the quality management system. The concept of prevention is generalized.

The purpose of a management system (MS) is to increase customer satisfaction (external and internal) by meeting their needs and expectations by continually improving process efficiency.

Quality costs almost nothing when customers are satisfied: they remain loyal to us. It is only when the customer is not completely satisfied that quality becomes very expensive for us: sooner or later the customer goes to a competitor.

Quality remains long after the price has been forgotten

The seven principles of quality management (see figure 1-2) will help us achieve sustainable performance (see ISO 9001: 2015, § 0.2):

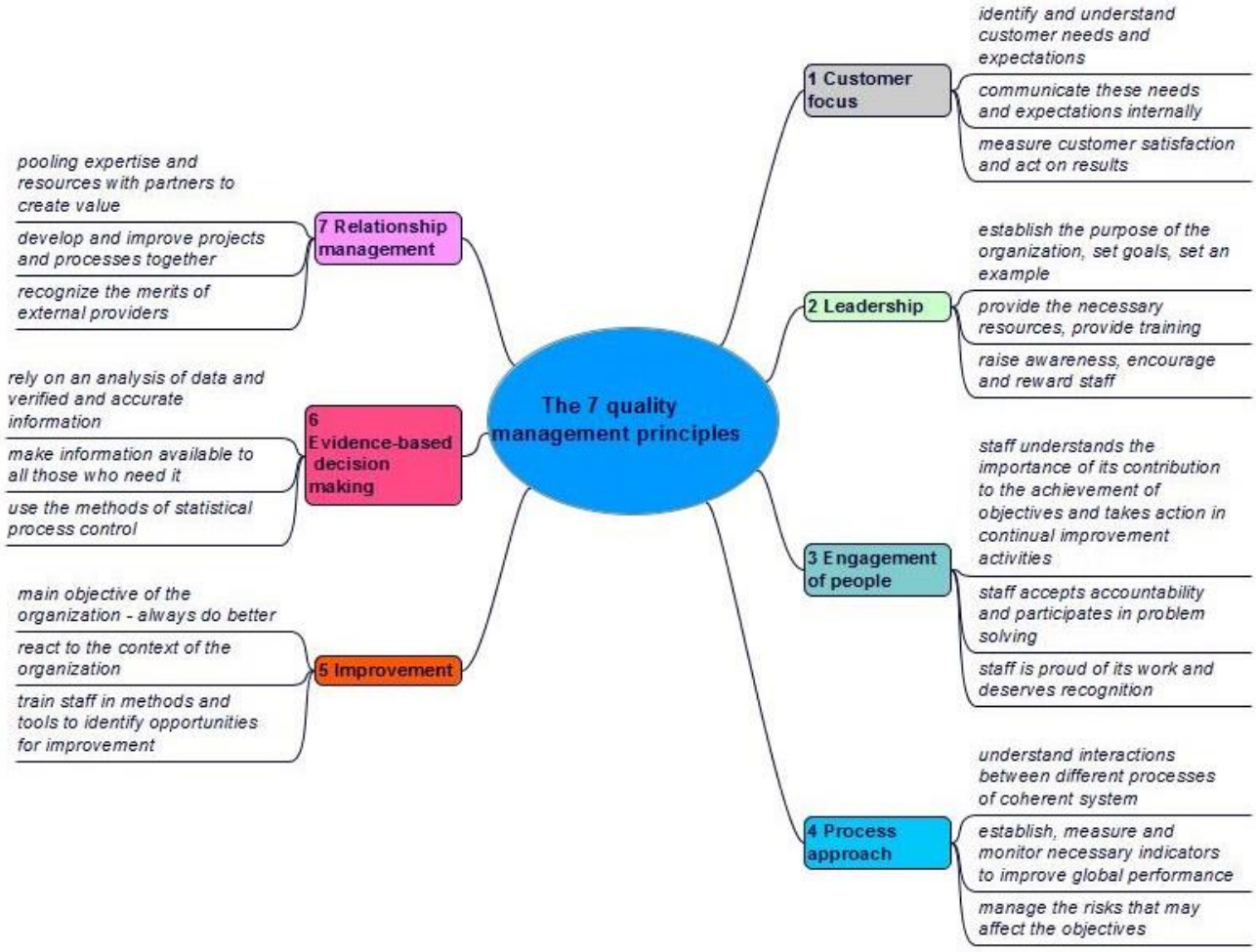

Figure 1-2. The seven principles of quality management

1.2.2 PDCA cycle

The PDCA cycle, also called Deming cycle, applies to the control of any process. PDCA (Plan, Do, Check, Act) cycles are a universal basis for continual improvement (see figure 1-3).

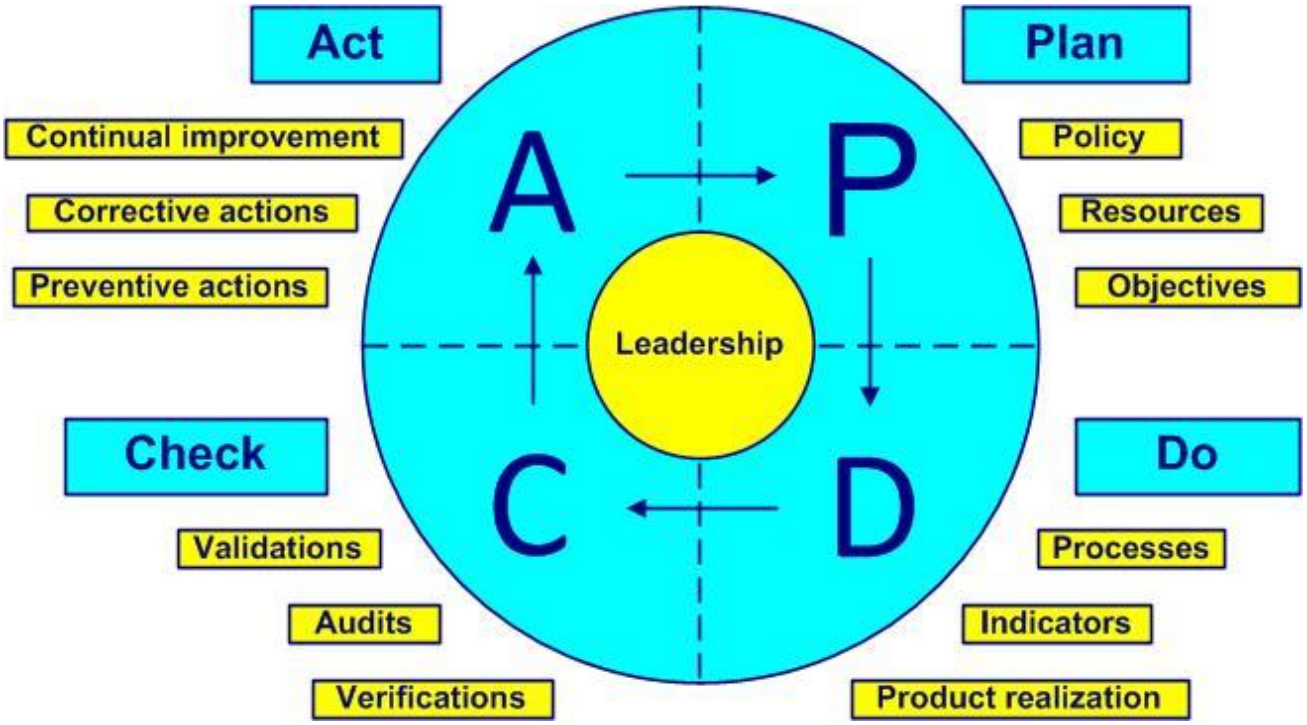

Figure 1-3. Deming cycle

- Plan – define and establish strategy, customers, policy, resources, objectives, documentation, products, processes, training, deadlines
- Do – organize, implement processes, indicators, produce the product
- Check – compare, inspect, analyze data, verify if objectives are met, validate, audit, learn
- Act – improve, react with actions and find new improvements (new PDCA)

2 Definitions, standards and books

2.1 Definitions

The beginning of wisdom is the definition of terms. Socrates

Some definitions and acronyms:

5 M: *Mother nature, Material, Method, Machine and Manpower (also called Ishikawa diagram and fishbone diagram)*
5 S: *from Japanese Seiri = sort, Seiton = set in order, Seiso = shine, Seiketsu = standardize and Shitsuke = sustain*
5 W: *five times Why ?*
8 D: *8 do or 8 actions to carry out. The 8 D tool is mainly used in the automotive industry. Allows a team to identify and eradicate the causes of a problem*
A 3: *report in A 3 visual management format on the essentials of problem solving or project progress*
Agile system: *when waste and cycle time are reduced*
Analysis of material and information flows: *see Value stream mapping*
Andon: *from Japanese light. Signal or light board that indicates the status of the process and alerts in the event of a problem*
Anomaly: *variation compared to what is expected*
AV: *added value*
Benchmarking: *comparative analysis technique against one or more competitors*
Brainstorming: *method allowing the development of ideas from the participants in order to find solutions*
BSC: *Balanced ScoreCard. Management dashboard with strategic indicators on finance, customers, processes and learning capacity*
Chaku-chaku: *from Japanese "charge-charge". Clocked flow working method which allows parts to be moved from one machine to another by loading/unloading*
Conformity: *fulfillment of a specified requirement*
Continual flow: *ideal state in which products move one by one without stopping*
Control chart: *statistical tool with high and low limits. Allows you to easily detect trends and malfunctions*
Control plan*: document describing the specific measures to carry out the control of a product or process*
Control: *see inspection*
COQ: *cost of obtaining quality*
Corrective action: *action to eliminate the causes of nonconformity or any other undesirable event and to prevent their recurrence*
Criticality*: level of a potential risk*
CTQ: *Critical To Quality or determinant for quality. Customer requirements transformed into internal specifications*
Curative action: *action to eliminate a detected nonconformity*
Customer satisfaction: *top priority objective of every quality management system related to the satisfaction of customer requirements*
Customer: *the one who receives a product*
CWQC: *Company Wide Quality Control - quality control throughout the company*
Cycle time: *time between the release of the product from one process and the release of the next product*
Dashboard: *coherent set of indicators to measure performance and facilitate decision support*
Defect: *nonconformity related to a specified use*

DMAIC: *Determine, Measure, Analyze, Improve, Control. Six sigma approach to manage a problem and improve*
Dysfunction: *deviation in the ability of a functional unit to perform a specified function*
Effectiveness: *capacity to perform planned activities with minimum effort*
Efficiency: *financial relationship between achieved results and resources used*
EFQM: *European Foundation for Quality Management. Organization offering a model of excellence ("Sharing effective practices"). EFQM Annual Award*
Fail safe device*: system allowing the prevention of errors by eliminating the human factor, also called Poka-Yoké*
Failure tree analysis (FTA): *tree diagram analysis method (cause - effects) to avoid safety and reliability problems. See also Tree diagram*
Failure: *variation of aptitude of a functional unit to satisfy a specified function*
FIFO: *First In, First Out*
Flow (stream): *the sequential execution of activities (tasks) along the value chain in a process*
Flowchart: *picture of a process that shows the steps performed and their interactions (see also ISO 22 000, 3.6; also called functional diagram and operational diagram)*
FMEA: *Failure Mode and Effects Analysis*
Functional analysis: *studies of the functions of a product or system in relation to its environment (see also NF X50-151)*
Gemba walk: *walk in the field, where it's happening. Favoring analysis in the field rather than in a meeting room*
Gemba: *from Japanese, = real place, in the field*
Genchi genbutsu: *from Japanese, to see how things are done in the field to gain practical experience of the situation*
Goulet: *resource whose average capacity is less than the requirement*
Hansei: *from Japanese, reflection session at the end of each activity. Opportunities for learning and sharing experience. One of the keys to Lean, when we will set new objectives*
Heijunka: *from Japanese smoothing. Organization of the queue to optimize the flow of different products using the same resources*
Hoshin kanri: *from Japanese deployment of politics. Strategic management analysis tool to concentrate efforts and resources on the deployment of priority objectives*
IMS: *integrated management system*
Indicator: *value of a parameter, associated with an objective, allowing the objective measure of its effectiveness*
Interested party: *person, group or organization affected by the impacts from a company*
ISO: *international organization for standardization*
IT flow: *uninterrupted progression of data in the value stream*
Jidoka: *from Japanese, autonomy or automation with a human touch (adding intelligence to a machine). Second pillar of Lean. Automatic detection of the first nonconformity, machine shutdown and problem reporting (Andon)*
JIT: *Just In Time*
Kaizen: *from Japanese, kai = change and zen = good (for the better, better), Kaizen = continual improvement*
Kanban: *from Japanese production order sheet or label. Inventory management by cards or sheets attached to product boxes to operate in pull flow ("takt time" set at the customer's request)*
Kano diagram: *graphical tool to understand customer interest in product specifications*
Key Performance Indicator (KPI): *monitoring a critical aspect of the company's overall performance to make strategic decisions*
Lead time: *total time from order acceptance to product shipping*
Management system: *set of processes allowing objectives to be achieved*
Manager: *someone who gets results through other people*
Material and Information Flow Analysis (MIFA): *see Value Stream Map*

MCT: *multiple choice test*
Monitoring: *set of planned actions to guarantee the effectiveness of control measures*
Muda: *from Japanese, waste. Any activity that consumes resources without adding value to the customer*
Mura: *from Japanese, irregularity. Waste caused by process variability*
Muri: *from Japanese, difficulty. Waste linked to excessive loading*
Non-added value (NAV): *what the customer is not willing to pay (when it is not necessary)*
Nonconformity (NC): *non-fulfillment of a specified requirement*
Non-quality: *gap between expected and perceived quality*
Organization: *a structure that satisfies a need*
Overall Equipment Effectiveness (OEE): *indicator showing the machine utilization rate and hence the effectiveness of a production line*
Pareto chart: *graphical tool for classifying the effects (or causes) of an activity. Called the 80/20 principle: 80% of the effects originate from 20% of the causes*
Poka-Yoké: *from Japanese Poka – unintentional error, Yoké – avoid. See Fail safe device*
Pool stock: *quantity that allows small variations to be absorbed in a smooth environment*
Preventive action: *action to eliminate the potential causes of nonconformity or any other undesirable event and to prevent their appearance*
Problem: *gap that must be reduced to obtain a result*
Process: *activities that transform input into output*
Product (or service): *any result of a process or activity*
Pull flow: *an essential requirement of the Just-in-Time approach. Produce only what the next process needs*
Push flow: *production without taking into account the real needs of the following process*
QCD: *Quality, Cost, Deadline. Classic top management objective. The customer is satisfied and the business is sustainable*
QCDSE: *Quality, Cost, Deadline, Safety, Environment*
QM: *quality manager*
QMS: *quality management system*
QSE: *quality, safety, environment*
Quality Function Deployment (QFD): *approach to identify customer requirements and transform them into internal requirements*
Quality management system (QMS): *everything necessary for the quality management of a company*
Quality management: *activities allowing the control of an organization with regard to quality*
Quality objective: *quality related, measurable goal that must be achieved*
Quality policy: *statement by top management allowing the establishment of quality objectives*
Requirement: *implicit or explicit need or expectation*
Responsibility: *capacity to make a decision alone*
Risk: *likelihood of occurrence of a threat or an opportunity*
Safety: *aptitude to avoid an undesired event*
Scrap: *treatment of an unrecoverable product*
Sensei: *from Japanese meaning "the one who was there before me, who guarantees the knowledge and experience of a technique or know-how", or in other words a master who delivers his teaching to a student*
Shop stock: *part of the stock of finished or semi-finished products which covers process risks: machine stoppages or defects*
SIPOC: *Suppliers, Inputs, Processes, Outputs, Customers. Tool to determine the priorities and scope of the product thanks to the links between the 5 entities*
Six sigma: *statistical approach to improving a process by reducing variability*
SMED: *Single Minute Exchange of Die or change a tool in less than ten minutes. Extremely effective method for reducing series changeover time*

Spaghetti diagram: *map of physical flows (product and labor) to obtain a product in a process*
SPC: *Statistical Process Control*
Stakeholder*: person, group or company that can affect or be affected by an organization*
Statistical Process Control (SPC): *process control approach through the application of statistical techniques*
Strategy: *total approach to achieve objectives*
Supplier: *the one who provides a product*
SWOT: *Strengths, Weaknesses, Opportunities, Threats.Tool for structuring a risk analysis*
System: *set of interacting processes*
Takt time: *from German Takt – rhythm, from English Time – time. Time required to produce a product at the rate of customer demand*
Theory Of Constraints (TOC): *method for identifying and addressing bottlenecks*
Top management (direction): *group or persons responsible for management at the highest level of the company*
Total Productive Maintenance (TPM): *series of preventive measures for treating the causes of stoppages applied to production machines*
Total Quality Control (TQC): *continual improvement activities of all staff, at all levels*
Tree diagram: *graph showing the chain of causes of a problem*
VA*: value analysis*
Value analysis*: method of reducing activities without added value in design with the involvement of industrialization and quality departments*
Value flow: *specific activities to design, develop, produce and deliver a product*
Value Stream Map (VSM): *graphical tool to identify and analyze inventory and information flows, processes, bottlenecks, value added and non-value added to find opportunities for improvement, eliminate waste, solve problems*
Visual management: *displays in the field so that staff can see at a glance priorities, actions and their progress*
VOC: *Voice Of the Customer. Tool to determine what is important to the customer and prioritize their needs*
Waste: *anything that adds cost but not value*
Work standard: *sequences of activities, operations or tasks to be carried out without waste within a given time. Also called operating mode or work instruction*
WWWWHHW: *Who, What, Where, When, How, How much, Why*

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 that can lead to an accident
- anomaly, defect, dysfunction, failure, nonconformity, reject and waste:
  - an anomaly is a deviation from what is expected
  - a defect is the non-fulfillment of a requirement related to an intended use
  - a dysfunction is a degraded function that can lead to a failure
  - a failure is when a function has become unfit
  - a nonconformity is the non-fulfillment of a requirement in production
  - a reject is a nonconforming product that will be destroyed
  - a 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 the 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
    - to control is to meet the objectives
    - to optimize is to search 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 a 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
    - an enterprise, society and 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 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: each time you use the expression "opportunity for improvement" instead of nonconformity, malfunction or failure, you will gain a little more trust from your interlocutor (external or internal customer).

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

- ISO Online Browsing platform (OBP)
- IEC Electropedia
- ISO 9000: 2015 - Quality management systems. Fundamentals and vocabulary, (ISO, 2015)

2.2 Standards

The ISO 9000 family of standards includes three essential booklets:

- ISO 9000 (2015): Quality management systems – Fundamentals and vocabulary
- ISO 9001 (2015): Quality management systems – Requirements
- ISO 9004 (2018): Guidelines for achieving sustained success

A standard added in 2002 and revised in 2018 is:

- ISO 19011: Guidelines for auditing management systems

The standards in the ISO 10001 to ISO 10019 series are guidelines for quality management systems and will help you find many answers (see ISO 9004: 2018, Bibliography).

Standards related to risks:

- ISO 31000: 2018, Risk management – Guidelines
- ISO 31010: 2009, Risk management – Risk assessment techniques
- ISO Guide 73: 2009, Risk management - Vocabulary

FMEA document:

- AIAG & VDA FMEA Handbook, AIAG, 2019

For automobiles:

- IATF 16949 - Quality management system requirements for automotive production and relevant service parts organizations, IATF, 2016

Other standards related to the quality approach:

- CEI 60812: Failure modes and effects analysis (FMEA and FMECA), IEC, 2018
- PAS 99: Specification of common management system requirements as a framework for integration, BSI, 2012
- The EFQM model, EFQM 2019

None of these standards are mandatory, but as Deming said:

It is not necessary to change. Survival is not mandatory

2.3 Books

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


Books for further reading on quality:

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Armand V. Feigenbaum, Total Quality Control, McGraw-Hill, 1951

-  Philip B. Crosby, Cutting the Cost of Quality, The Defect Prevention Workbook for Managers, Industrial Education Institute, 1967
-  Kaoru Ishikawa, Guide to Quality Control, APO, 1971
-  Philip B. Crosby, Quality is Free; the Art of Making Quality Certain, McGraw-Hill, 1979
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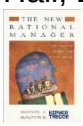
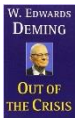
-  Charles Kepner, Benjamin Tregoe, The New Rational Manager, Princeton Research Press, 1981
-  Edwards Deming, Out of the Crisis, MIT Press, 1982
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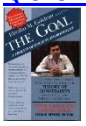
-  Eliyahu Goldratt, Jeff Cox, The Goal, A Process of Ongoing Improvement, North River Press, 1984
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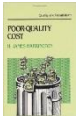
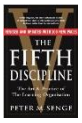
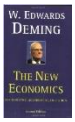
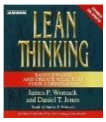
-  James H. Harrington, Poor-Quality Cost, Dekker, 1987
-  Taiichi Ohno, Toyota Production System: Beyond Large-Scale Production, Productivity Press, 1988
-  Peter Senge, The Fifth Discipline, The Art & Practice of The Learning Organization, Doubleday, 1990

-  Edwards Deming, The New Economics, MIT Press, 1993
-  James Womack, Daniel Jones, Lean Thinking, Simon & Schuster, 1996
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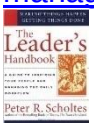
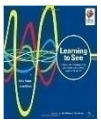
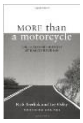
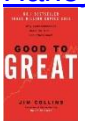
-  Peter Scholtes, The Leader's Handbook, McGraw-Hill, 1997
-  Mike Rother, John Shook, Learning to see, Lean Enterprise Institute, 1999
-  Rich Teerlink, Lee Ozley, More Than a Motorcycle, The Leadership Journey at Harley-Davidson, Harvard Business Scool Press, 2000
-  Jim Collins, Good to Great, Random House, 2001
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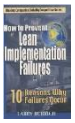
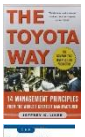
-  Larry Rubrich, How to Prevent Lean Implementation Failures, WCM Associates, 2004
-  Jeffrey Liker, The Toyota Way, McGraw Hill, 2004
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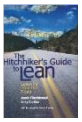
-  Jamie Flinchbaugh, Andy Carlino, The Hitchhiker's Guide to Lean, Lessons from the Road, SME, 2006

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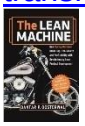
-  Dantar Oosterwal, The Lean Machine, Amacom, 2010
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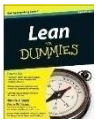
-  Nathalie Sayer, Bruce Williams, Lean for Dummies, Wiley, 2012
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None of these books are mandatory...

3 Process approach

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

3.1 Process types

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 other things, determined by its:

- title and its type
- purpose (why?)
- beneficiary (for whom?)
- scope and activities
- initiators
- documents and records
- inputs
- outputs (intentional and unintentional)
- restrains
- 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 carried out periodically by the process owner (cf. annex 01). 

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

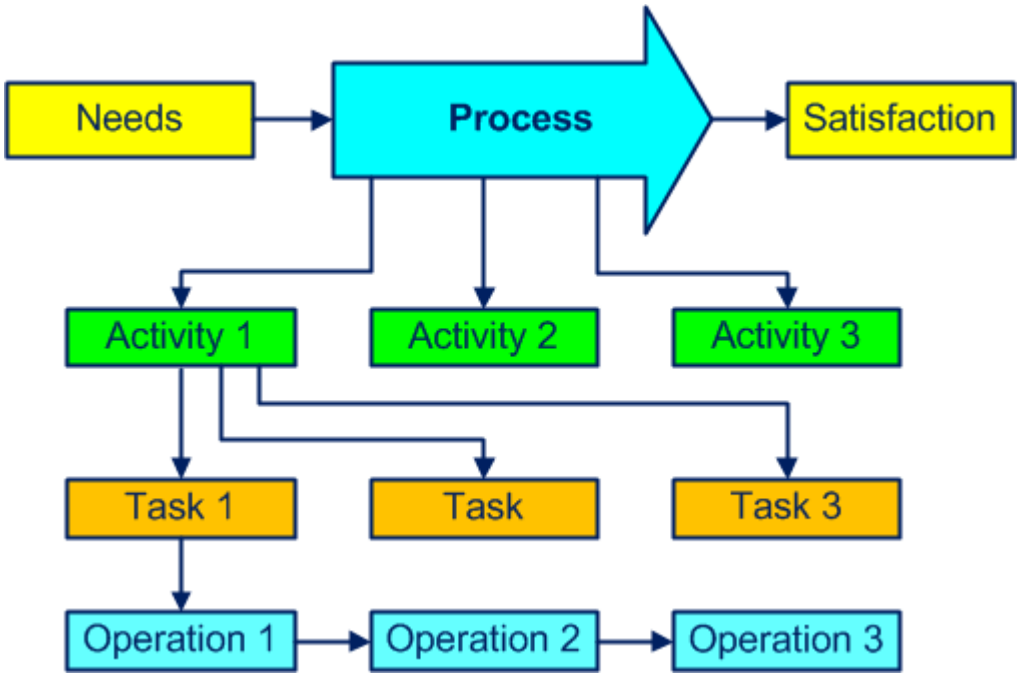

Figure 3-1. Components of a process

Figure 3-2 shows an example that helps answer the 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? (staff)
- with what, which machines, which equipment? (material resources)

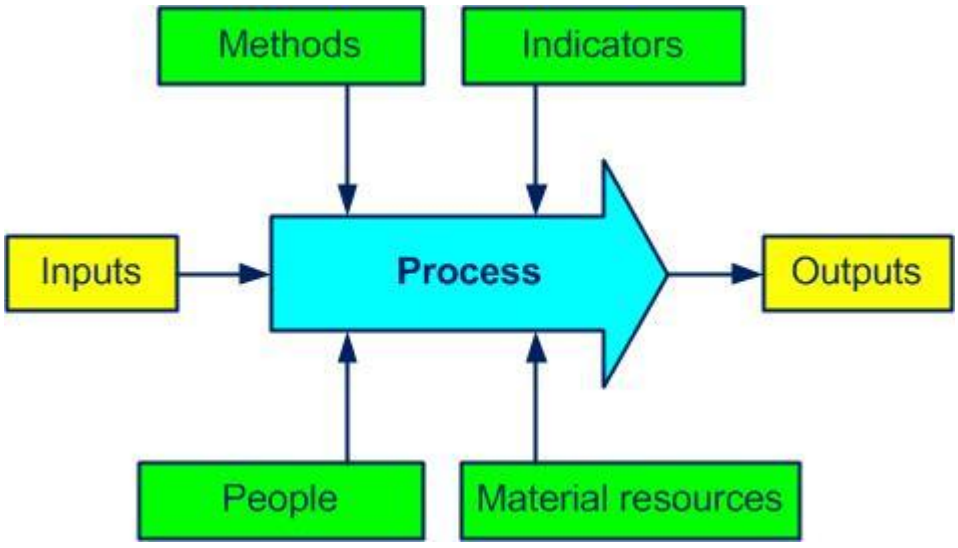

Figure 3-2. Some elements of a process

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

You can find some examples of process forms in the document pack D 02 and 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 satisfy 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 to maintain and recall the purpose of the process.

The processes are (as we will see in the following paragraphs) of management, realization and support types. Do not attach too much importance to process categorizing (sometimes it is very relative) but ensure that all the company's activities at least fall 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 and include development of the policy, deployment of the objectives and all needed checks. They are the glue of all realization and support processes.

The following processes can be part of this family:

- develop strategy
- manage risks
- develop policy
- deploy quality objectives
- establish process ownership
- improve
- audit
- communicate
- plan the QMS
- acquire resources
- carry out management review
- measure customer satisfaction
- negotiate contract
- 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 new products
- purchase components
- produce products
- sell products
- inspect production
- maintain equipment
- implement traceability (identify and keep history)
- receive, store and deliver
- control nonconformities
- implement preventive and corrective actions

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 with the quality manager as the natural owner. This is not a formal requirement of the ISO 9001 standard but is always welcome.

The three types of processes and some interactions are shown in figure 3-3 and annex 02.

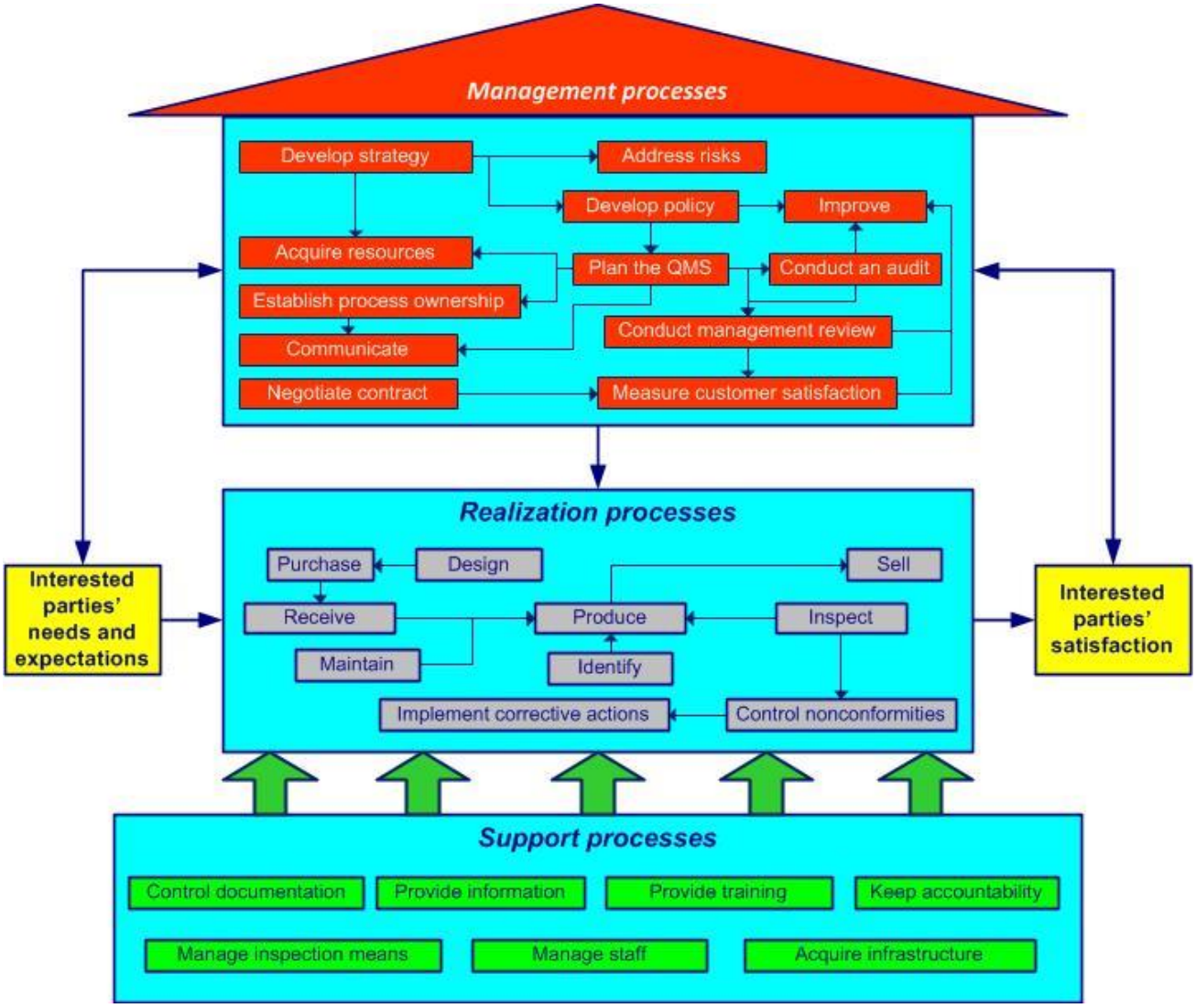

Figure 3-3. Process house

Mapping, among other things, allows you to:

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

To obtain a clearer picture, you can simplify by using a total of about 15 core processes. A core process can contain several sub-processes: for example, the process "develop the QMS" can involve:

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

3.3 Process approach

Simple solutions for now, perfection for later

The fourth principle of quality management is “Process approach” (see § 1.2.1). Some benefits:

- obtain a global vision of the company thanks to the mapping
- identify and manage responsibilities and resources
- achieve effective management of the company based on process indicators
- manage risks that could influence the objectives

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 3-4 (cf. ISO 9001, 0.2).

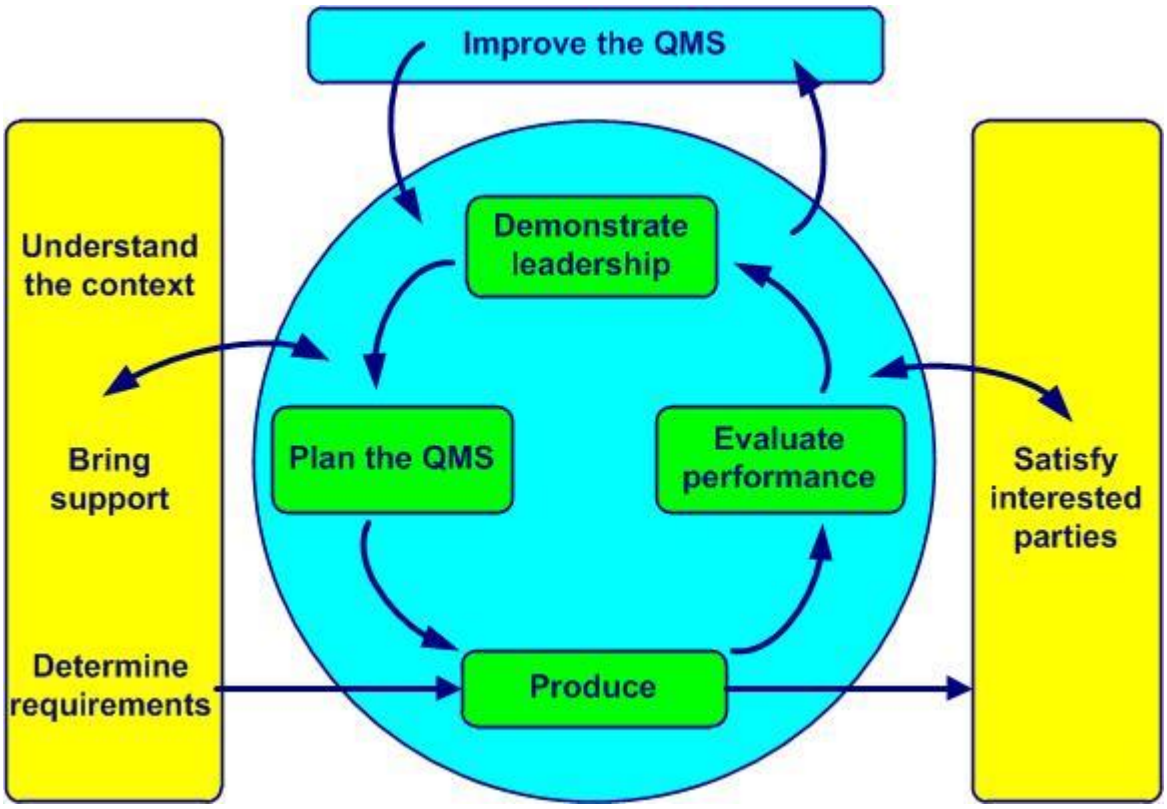

Figure 3-4. Model of a QMS based on the process approach and continual improvement

The process approach (cf. annex 28):

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

For a consulting, support or repair business, identifying and defining processes and mapping may not be very useful. More important is to establish and describe for example:

- job descriptions
- staff competence
- the tools to use
- preferred methods for certain recurring cases

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)
- prioritizing investments (“Use your brain, not your money" - Taiichi Ohno)

4 QMS requirements

4.1 General requirements *(Requirements 1 to 24)*

The requirements of the ISO 9001: 2015 standard in sub-clauses of articles 4 to 10 are shown in figure 4-1:

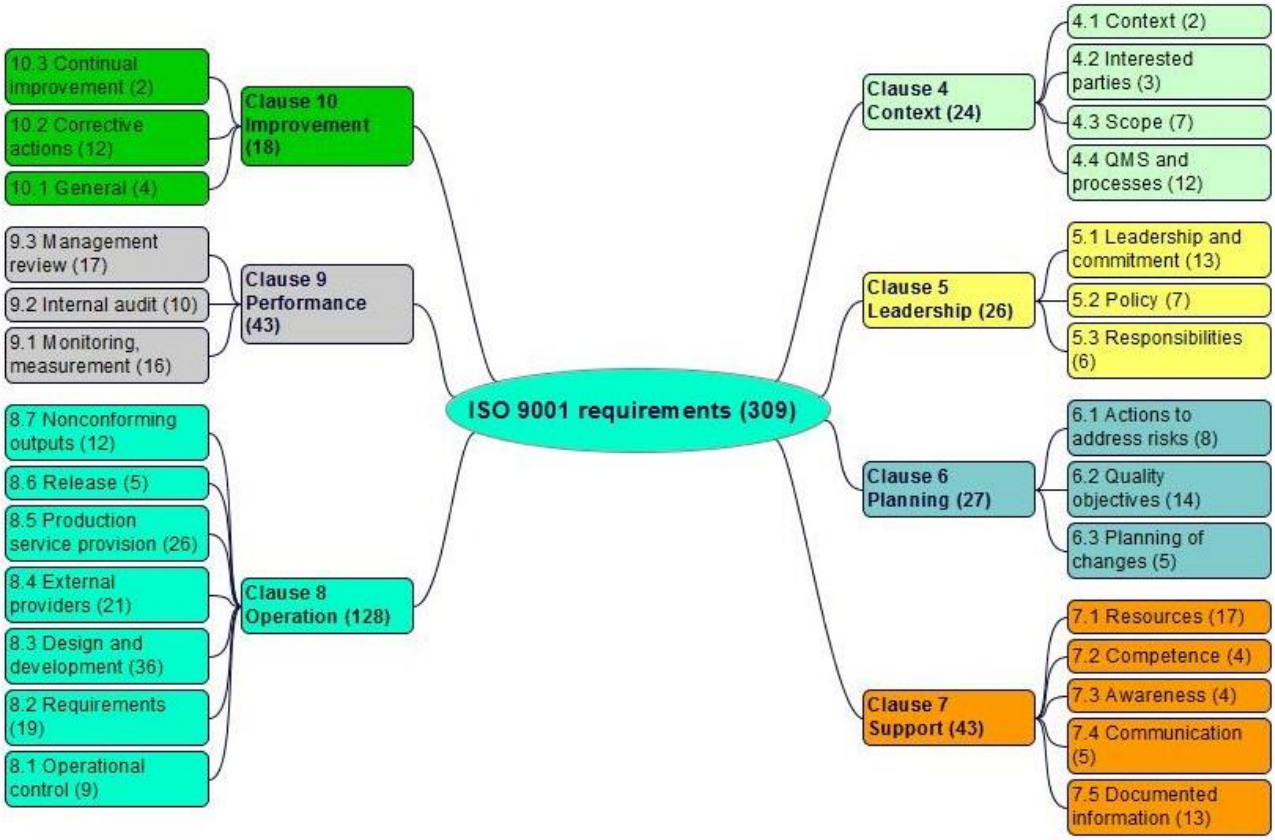

Figure 4-1. Requirements of the ISO 9001 standard

Product requirements are specified by the customer, by the company or by regulation. The requirements of the ISO 9001 standard concern exclusively the quality management system and its processes:

- external and internal issues are determined
- requirements of all interested parties are identified
- the scope of the quality management system (QMS) is established and documented
- the processes necessary for the QMS are identified, the corresponding resources ensured, the owners appointed, the interactions determined
- top management demonstrates leadership (takes responsibility)
- the quality policy, objectives, resources, competence, roles and work environment are determined
- actions to address risks are taken (see annexes 04 and 05)
- each process is measured, monitored, objectives established, followed-up and analyzed
- actions to achieve continual process improvement are established and implemented

Pitfalls to avoid:

- going overboard on quality
- have all procedures written by the quality manager
- forget the specificities linked to the corporate culture

4.2 Top management commitment *(Requirements 25 to 120)*

In a company everyone assumes their responsibilities but responsibility for quality begins with top management because as the Romanian proverb says:

When you sweep the stairs, you start at the top

Top management defines the purpose of the company and ensures the sustainability, quality policy and continual improvement of the QMS (see figure 4-2). Quality objectives are deployed in each department and indicators are put in place to measure process performance.

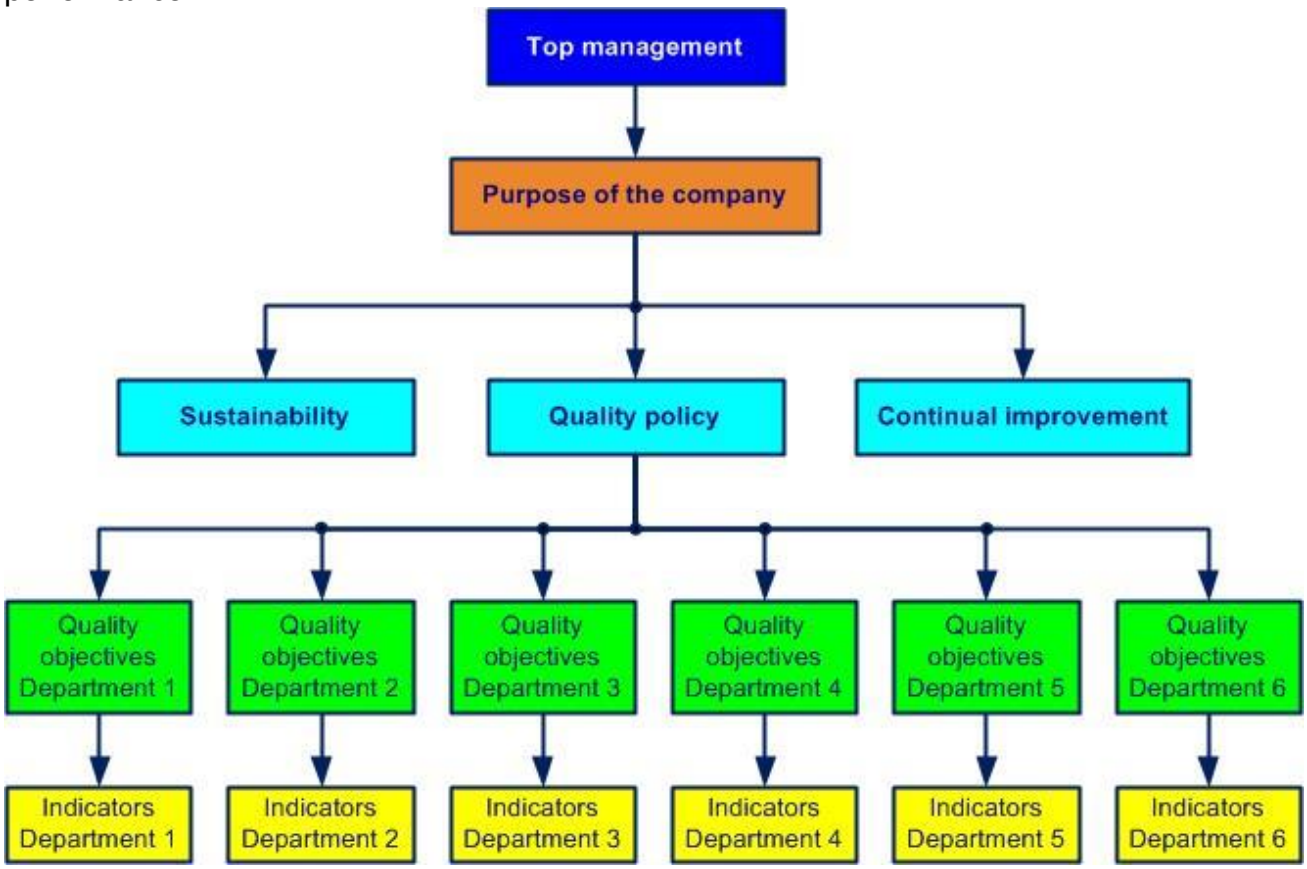

Figure 4-2. Déploiement des objectifs qualité

When policy is ambitious, it stimulates and motivates all staff

To achieve this, top management commits to:

- communicate the importance of customer requirements and regulations
- develop and promote the quality policy (see figure 4-3) which:
  - is adapted to:
    - the purpose of the company
    - the context of the company
    - available resources
  - contributes to:
    - meet customer and regulatory requirements

        - continually improve the effectiveness of the QMS
    - provides the framework for defining quality objectives which are:
        - SMART:
            - Specific
            - Measurable
            - Achievable (and ambitious)
            - Realistic, consistent with policy, (neither unachievable nor too easy to achieve)
            - Temporal (planned over time) and
        - transformed into numerical indicators linked to:
            - customer
            - process
            - product
    - is communicated, understood and applied at all levels by everyone
- conduct management reviews at defined intervals to verify the achievement of quality objectives (see annex 03)
- identify and address risks (threats and opportunities) that could influence:
    - the conformity of products and services
    - the ability to increase customer satisfaction
- ensure the availability of human and technical resources to achieve quality objectives
- determine and respect customer requirements. Explicit or implicit customer requirements are transformed into internal requirements
- plan the QMS with the aim of satisfying general requirements and quality objectives
- maintain the proper functioning of the QMS during the introduction of any modification (internal modifications, new projects, products, processes)
- define and communicate responsibilities and authorities at all levels

Responsibility cannot be shared. Robert Heinlein

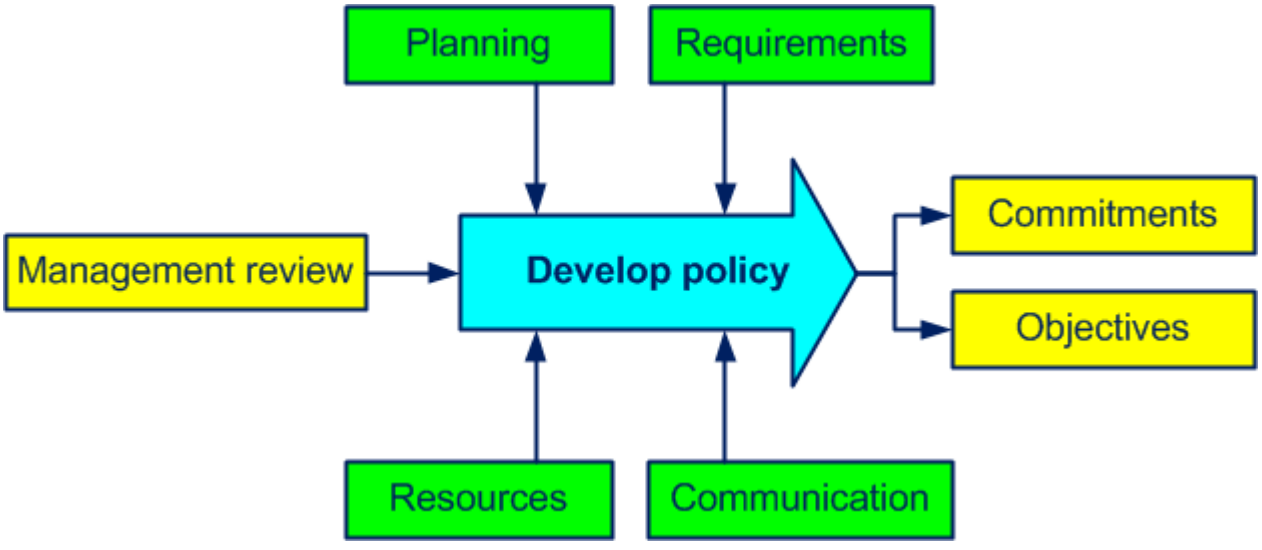

Figure 4-3. The Develop policy process

Top management: *group or persons in charge of the organizational control at the highest level*

Achieving objectives means respecting commitments made in the quality policy

Some examples of objectives:

- growth in turnover
- customer satisfaction
- staff stabilization
- staff competence
- improvement of maintenance

Some examples of indicators:

- evolution of market shares in %
- new customers
- customer return rate
- absenteeism in %
- % of staff trained
- response time in minutes
- machine downtime in minutes

 Minute of relaxation. See the "Gold contract" joke.

Staff are made aware of the:

- importance of respecting the:
  - policy
  - procedures
  - instructions
  - QMS requirements
- impact on quality related to each workstation
- positive effects coming from each person's performance
- role and responsibilities for meeting QMS requirements

4.3 Product realization *(Requirements 121 to 291)*

4.3.1 Planning and customers

The product production processes are planned and developed in accordance with the general requirements of the QMS.

For the operational production of the product, an appropriate documentation (quality plan, project plan, product plan) defines the:

- quality objectives to be achieved
- customer requirements related to the product
- deadlines to respect
- costs not to be exceeded
- production process
- documents (work instructions, product sheets)
- necessary resources (budget)
- activities of:
  - verification
  - validation

  - monitoring
  - inspection
  - test
  - measurement of customer satisfaction (questionnaires)
- acceptance criteria and
- records required

Verification: *periodic inspection survey of compliance of a process, product or material*
Validation: *confirmation that the application of a process, product, service or material allows expected results to be achieved*
Inspection: *actions of measuring, testing and examining a process, product or material to establish whether requirements are met*
Quality plan: *document specifying the methods, means, responsibilities and stages of activities related to quality, applied specifically to a product, project or process*

The only measure of quality is customer satisfaction

A process determines customer, legal and product requirements (see figure 4-4).

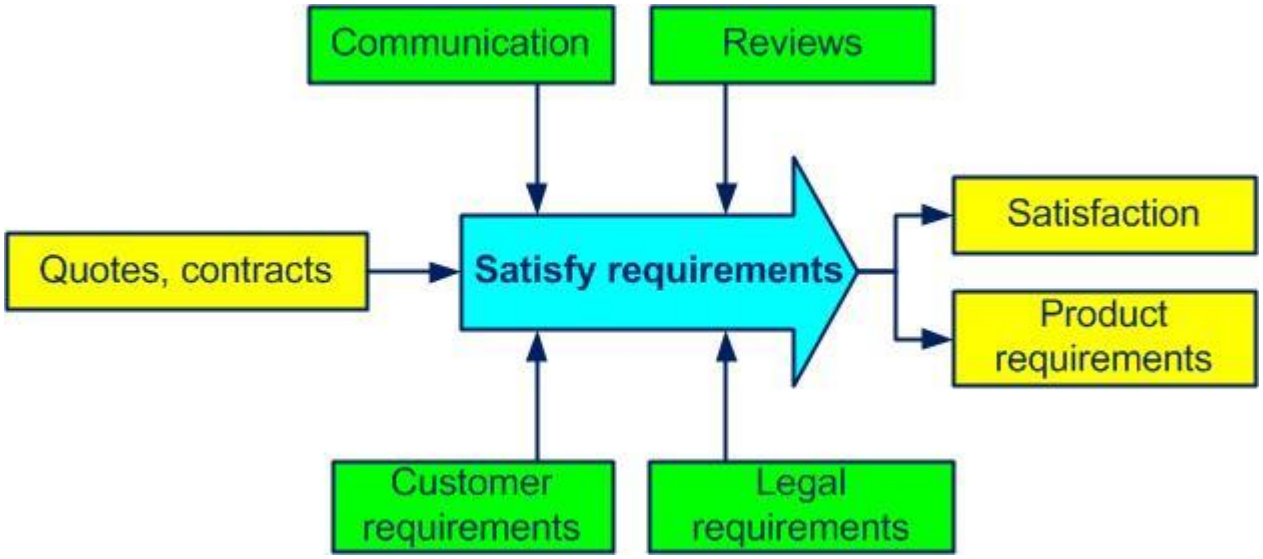

Figure 4-4. The Satisfy requirements process

Transparent communication arrangements with customers (see figure 4-5) are used regarding:

- information about the product (technical specifications, conditions of use and others)
- changes to the product or process
- consultations, contracts, amendments, waivers and orders
- customer information, especially complaints (delays, nonconformities, returns)
- actions put in place to eliminate nonconformities

Good news walks, bad news runs. Swedish proverb

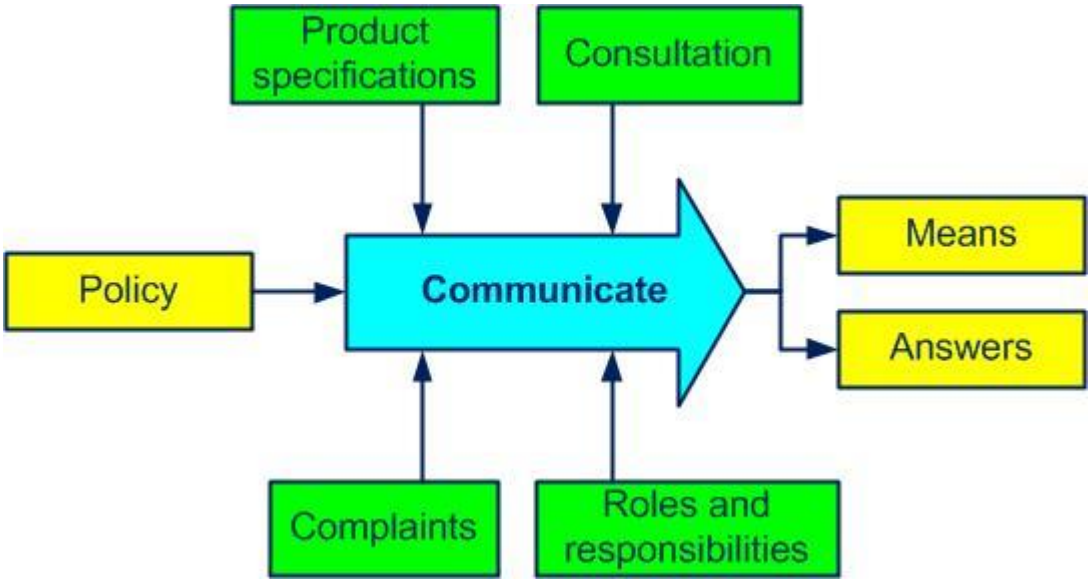

Figure 4-5. The Communicate process


Minute of relaxation. See the "Lack of communication" joke.

4.3.2 Design and development

I did not fail. I just found 10,000 ways that do not work. Thomas Edison

Each stage of the design and development process (we are not talking about research) is planned and controlled (see figure 4-6).

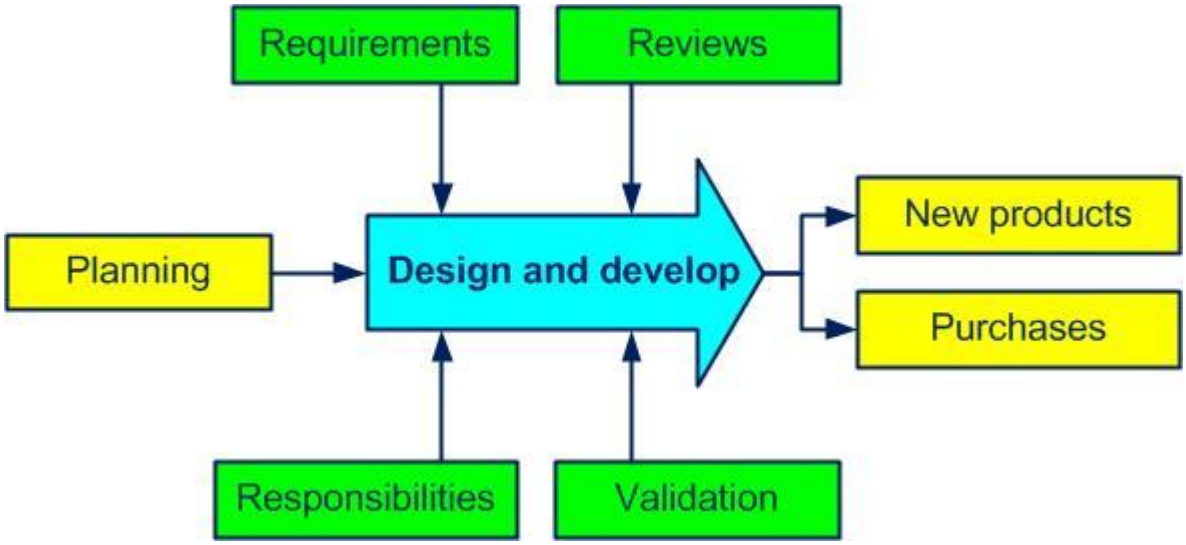

Figure 4-6. The Design and develop process

Responsibilities and authorities are determined and effective communication between all personnel involved is ensured.

The requirements for product design and development inputs are:

- determined and recorded
- complete, unambiguous and non-contradictory

- reviewed regarding their adequacy

Inputs include data related to:

- functional requirements
- market needs
- customer expectations
- regulatory and legal requirements
- similar designs information
- other requirements

Before their use, the outputs of product design and development are:

- verified and
- approved

In addition they are adequate with the inputs and provide the information necessary to:

- purchases
- the production
- product acceptance criteria or a reference thereto
- the functional characteristics of the product
- safety of use of the product

During the design and development process reviews are planned, recorded and carried out at key stages. 

In this way:

- the ability to meet the requirements is assessed and
- problems are identified and solutions proposed

A problem well stated is a problem half solved. Charles Kettering

Verification (technical aspect), validation (functional aspect) and approval of design and development and their modifications are a logical continuation of the reviews; their records are preserved. 

Any modification goes through a thorough review (technical and functional consequences) before being verified, validated and approved by the competent person(s).

4.3.3 Purchases and production

If you buy quality, you only cry once. English proverb

A process ensures that products purchased and services provided by external providers comply with requirements at each delivery.

External providers are evaluated and selected according to defined criteria (compliant product, compliance with cost and deadlines). A reassessment is carried out periodically. Records of assessments, selections, reassessments and related actions are retained. 

Purchasing information is used to describe the purchased product and define requirements:

- for approval of:
  - products
  - procedures
  - processes and
  - equipment
- for staff qualification
- relating to the QMS

The implementation of services linked to the production of the product and preparation of the service is validated in accordance with the specified requirements. Production (see figure 4-7) is carried out under controlled conditions leading to reproducible results.

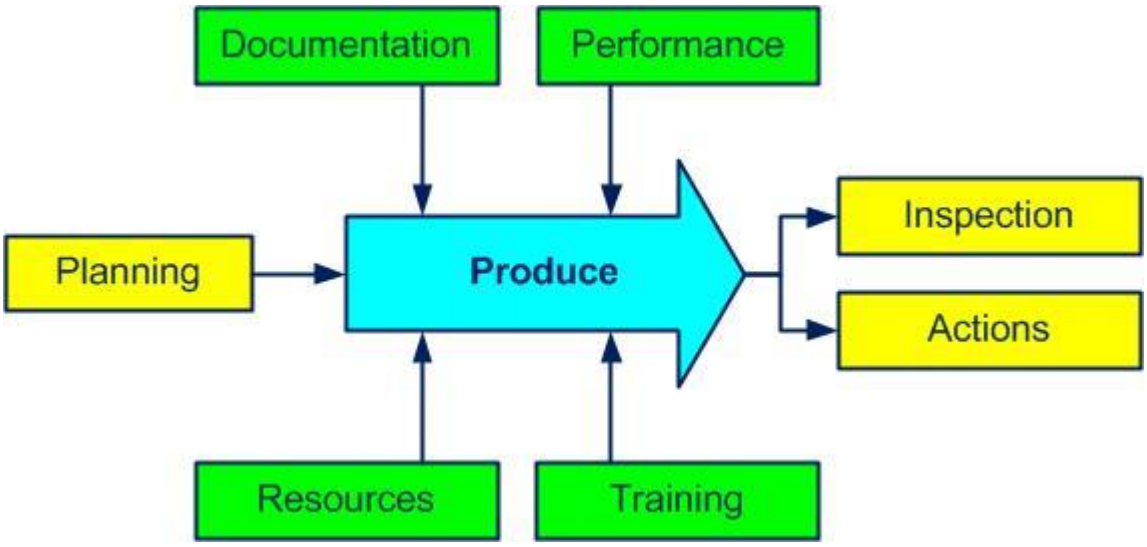

Figure 4-7. The Produce process

These conditions may include means related to:

- product and process characteristics
- acceptance criteria
- work instructions
- appropriate equipment
- operator skills
- monitoring and measurement equipment and activities
- records required
- release, delivery and post-delivery service activities

When appropriate (almost always) the product and its condition, in relation to the inspections carried out, are identified, recorded and the traceability of the product is controlled throughout its production.

Traceability: *aptitude to memorize or restore all or part of a trace of executed functions*

Special care is taken for the customer's property (which may be intellectual property). This property is identified, verified, protected and backed up. For any incident that occurs, the customer is notified immediately and records are kept.

The company insures the completeness of the product and its components with appropriate operations:

- identification
- intermediate storage
- handling
- packaging
- storage
- protection and
- delivery

Product conformity is ensured with processes using appropriate and valid monitoring and measuring equipment. Any measuring instrument is identified and verified (calibrated or verified). The conditions of use, handling and storage of instruments are established and adequate.

True story

How can we reduce the costs of calibrating certain equipment and at the same time reward the best suggestions from staff?

Simple solution: do not calibrate multimeters and other small instruments every year but systematically buy new ones. Each instrument purchased usually has at least one year of warranty (during which neither calibration nor verification is required). Purchasing these instruments costs much less than calibration (by an external company). Old instruments with an expired warranty period (but almost always in perfect condition) are removed from the inventory and then distributed by top management to people who have distinguished themselves recently.

Each user is trained. Records of calibration and verification results are retained. 

When equipment no longer complies, specific actions are taken on both the equipment and the affected product.

4.4 Improvement *(Requirements 292 to 309)*

No system is perfect

Top management plans and carries out a QMS review (at least once a year). The conclusions of the review are recorded (see figure 4-8). 

Its purpose is to review whether the quality management system is:

- relevant
- effective and
- appropriate to the company's vision

Management review: *periodic survey carried out by top management of the management system for its continual improvement*

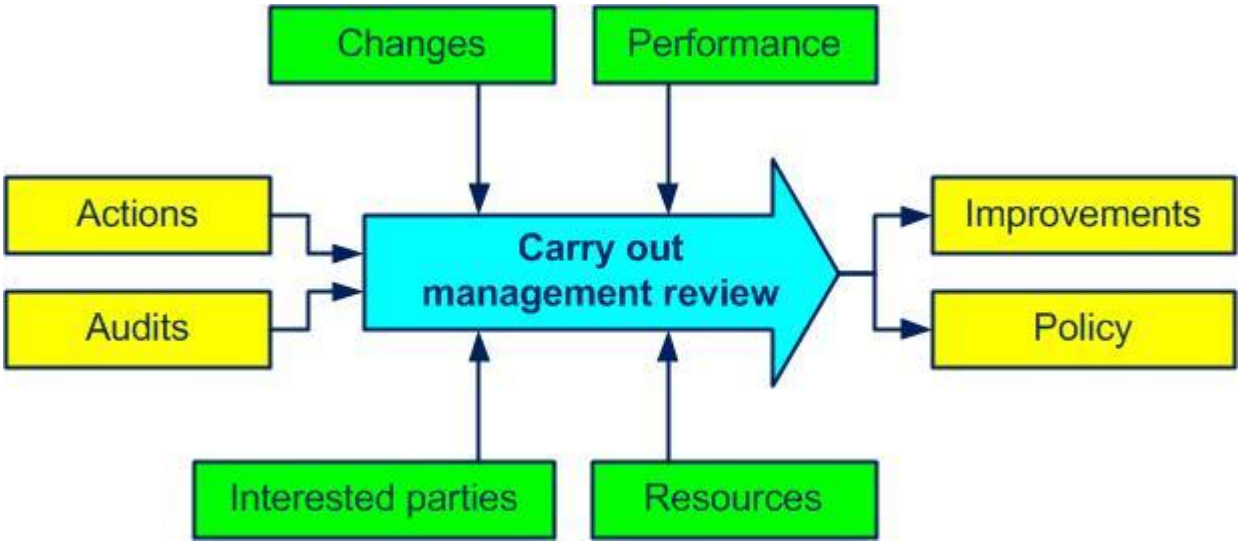

Figure 4-8. The Carry out management review process

Inputs of the review include:

- audit results
- inspection results
- the situation of the necessary resources
- the results of the assessment of compliance with legal and regulatory requirements
- feedback from interested parties (satisfaction and complaints)
- the level of achievement of quality objectives and associated indicators
- monitoring of actions:
  - resulting from decisions from the previous management review
  - handling nonconformities
- information on the performance of:
  - processes, products and services
  - competitors
  - external providers
  - partners
- changes in external and internal issues that may affect the quality management system and the associated threats and opportunities
- inventory of actions implemented in response to improvement risks

Review outputs include decisions related to:

- opportunities for improvement of the:
  - quality management system and its processes
  - product and service
- needs for modification of the quality management system (quality policy, quality objectives)
- resource needs for:
  - maintaining the quality management system and continually improve its effectiveness
  - increase the satisfaction of customers and other interested parties by respecting their requirements

If you can’t measure it, you can’t manage it. Peter Drucker

Processes of:

- monitoring
- measuring
- analysis and
- continual improvement

are planned and implemented to:

- demonstrate product and process conformity
- ensure product and process conformity
- ensure conformity of the QMS
- improve the effectiveness of the QMS

Measures are applied (including statistical techniques) to measure the performance of:

- customer satisfaction
- QMS conformity (internal audits)
- process control
- product control

Performance: *measurable and expected results of the management system*

Monitoring customer perception of their level of satisfaction is an essential indicator of QMS performance.

True story

After a signal from a group manager, a financial analysis of the activities of the quality department of our site was carried out. Receiving inspections were particularly targeted. To everyone's surprise it turned out that the cost was really disproportionate to that of the nonconformities found.

A reduction in activities (and a transfer of staff) was quickly implemented.

The internal audit (see figure 4-9) makes it possible to assess the conformity and effectiveness of the QMS and helps to improve its effectiveness.

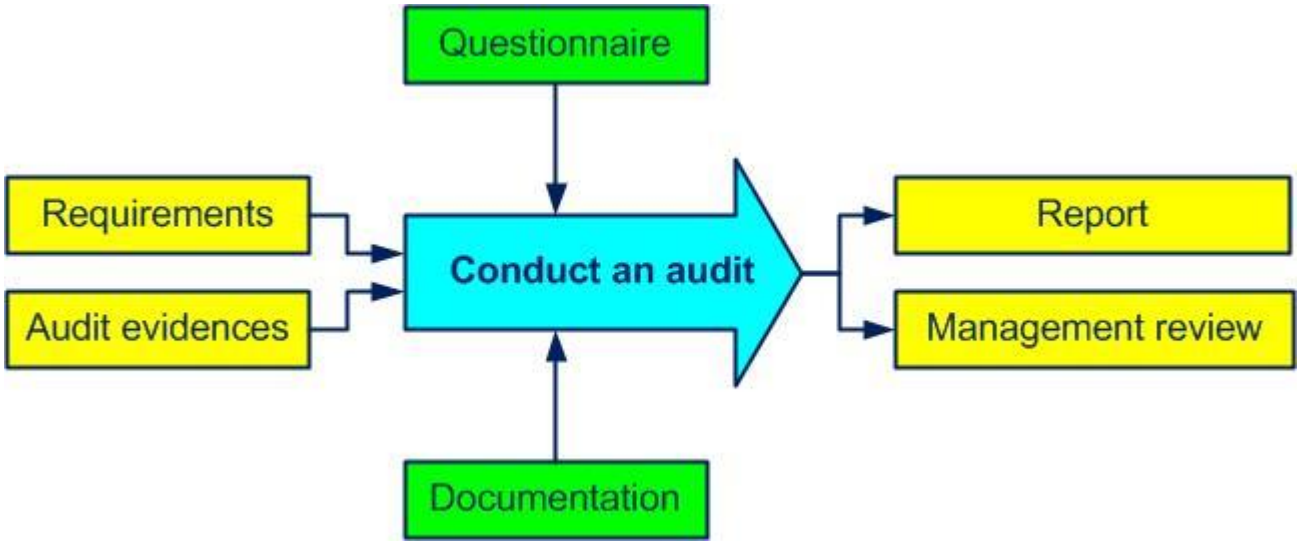

Figure 4-9. The Conduct an audit process

Conformity is determined in relation to:

- the planned arrangements for the production of the product
- meeting the company's QMS requirements
- compliance with legal and regulatory requirements

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

An audit is of:

- the QMS
- a process
- a product

Audit evidence: *demonstrably true data related to audit criteria*

Examples of audit evidence:

- process sheet
- job description
- training attendance sheet
- information on customer returns
- level of indicators

Audit planning (annual audit program) is done based on the state and importance of processes and products, without forgetting the results of previous audits. An auditor cannot audit his department as:

No one should be a judge in his own case. Latin proverb

The audit follow-up (which can be a complementary audit) makes it possible to verify the implementation of the identified improvement opportunities. The results of internal audits are one of the inputs of the management review and make it possible to find areas for improvement of the QMS.

 Minute of relaxation. Cf. the "The quality engineer and the sheperd" joke.

Internal audit activities are carried out using the ISO 19 011 standard as a basis (see T 35v15 Internal audit ISO 9001).

True story

A production manager thought that delivering on time at all costs is a top priority.

He had to deliver parts for an automotive customer. Having not received solder paste within the planned time frame, he gave the order to use expired solder paste. The delivery was made on time. The customer, after a few tests, returned the entire batch as non-compliant. The financial penalty was enormous. This was, a few weeks later, one of the causes of the liquidation of the company.

The production director hid his waiver decision from the customer and his quality manager. Expired solder paste should be destroyed as soon as the expiration date has passed. Two fatal malfunctions.

Qualities shine from afar, defects from up close. Victor Hugo

Continual improvement: *process allowing the improvement of the global performance of the organization*

To improve the efficiency of the QMS, opportunities for improvement must be identified in areas such as:

- customer satisfaction
- customer complaint rates
- working conditions
- on-time delivery
- staff skills
- cost reduction
- net margin

The continual improvement process is based, among other things, on:

- audit results
- necessary resources
- data analysis
- staff suggestions
- setting new improvement targets
- finding and justifying solutions
- implementing solutions and measuring results
- formalizing changes when objectives are reached

Best practices

- *regular updating of quality plans*
- *for inspection activities, all acceptance criteria are defined*

Bad practices

- *missing acceptance criteria for certain products*
- *certain legal and regulatory requirements are not taken into account*

More examples of good practices and bad practices can be found in annexes 07 and 08.

To find out more about QMS requirements, go to module T 15v15 "ISO 9001 readiness version 2015".