

D 19v18

QSE IMS readiness version 2018

Goal

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Goal of the module: Readiness for implementation, certification, maintenance and improvement of your integrated management system Quality, Safety and Environment in order to:

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

1 Integrated system approach

1.1 Background

In most cases, an integrated management system has its origins in the management systems related to:

- quality
- occupational health and safety
- environment

The targets are different (product, personnel, environment), but complementary, as no company can do without one of the three elements.

Quality (Q)

Quality is anything that can be improved. Masaaki Imai

The evolution of the quality concept and the standards of quality management systems 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) appeared in:

- 1987: first edition, based on the US military standard MIL-Q-9858 of 1959
- 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

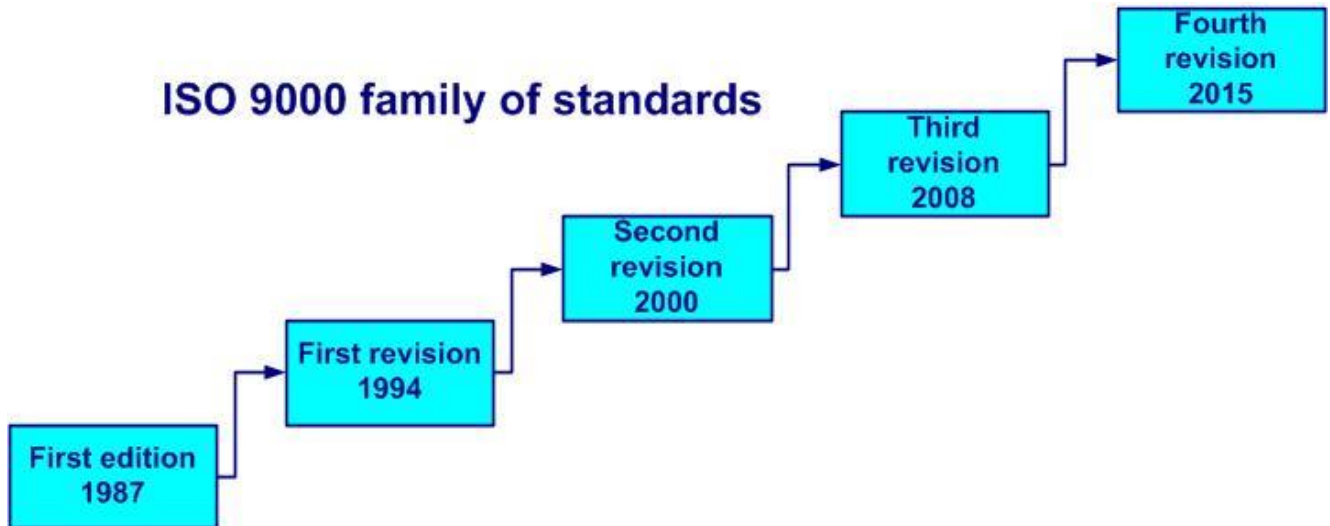


Figure 1-1. Revisions of ISO 9000 family

The three pillars of the ISO 9001 standard are:

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

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

Health and safety (S)

The first laws relating to safety in France appeared in the late 19th century.

In France the integration of occupational risk assessment (related to health and safety of workers) in the management of each company has been an obligation of the Labor Code (R4121-1) since 2001.

The standard BS OHSAS 18001: 2007 is neither French nor an ISO standard but was most commonly used for certifying health and safety worldwide. It is now replaced by the ISO 45001 standard released in 2018.

Environment (E)

The first laws on environmental protection emerged in the 1970s.

The 2015 edition of ISO 14001 standard is distinguished by:

- the new structure (higher level)
- adding the risk-based thinking
- compatibility between environmental policy and strategic direction
- management fully assumes its responsibility (leadership) for the performance of the EMS

The three pillars of sustainable development rest on the balance between:

- society
- environment and

- economy

The ISO 14001 environmental management system as the environmental pillar of sustainable development requires:

- compliance with regulations
- prevention of pollution
- a capacity to respond to emergencies

The prevention of pollution is a must for every responsible company.

1.2 Common concepts

The three quality, safety and environment (QSE) management systems (cf. figure 1-2) share the following concepts:

- PDCA approach
- process approach
- context
- interested parties:
 - needs
 - expectations
 - requirements
 - risks
 - satisfaction
- leadership of management
- commitments of management:
 - policy
 - objectives
 - planning
 - implementation
 - communication and awareness
 - resources
 - management review
- control of documented information
- planning
- operational control
- performance evaluation:
 - monitoring and measurement (inspection)
 - internal audits
- prevention of:
 - nonconformities
 - accidents
 - pollution
- continual improvement

During production, a product may present risks to the health and safety of workers (QS) but also industrial risks of environmental pollution (SE).

When the product cycle reaches the end of its life, it becomes waste and can present a risk and have an impact on the environment (EQ).

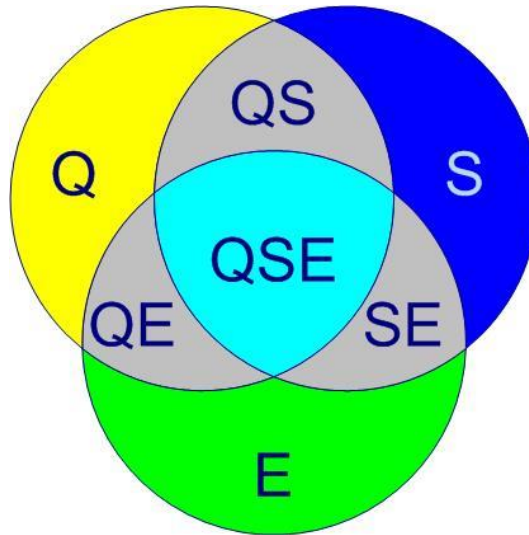


Figure 1-2. Common concepts QSE

Some similarities are specific to two management systems (QS, QE and SE) and strengthen the integration of the QSE system.

1.3 Principles, benefits, approach

The seven quality management principles (cf. figure 1-3) 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.

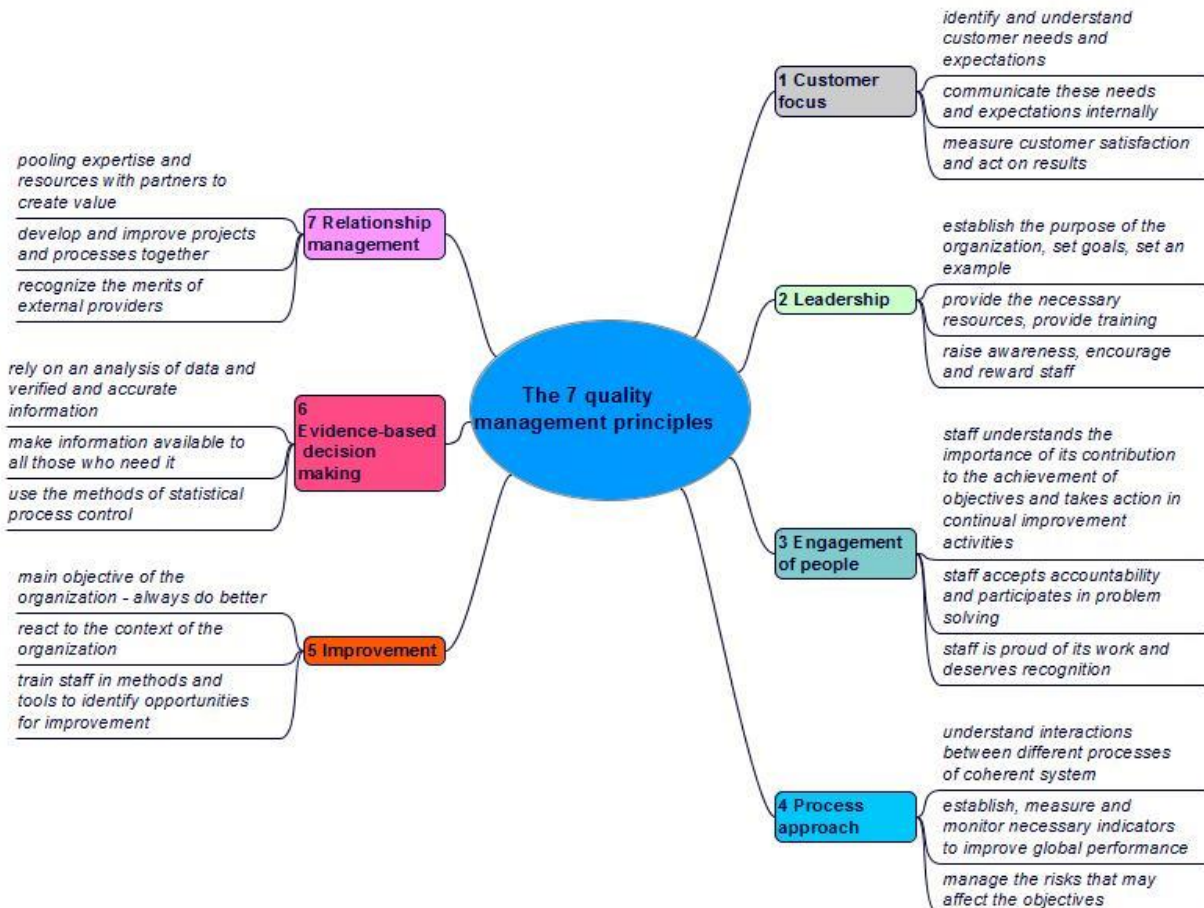


Figure 1-3. The 7 quality management principles

The benefits of a QSE integrated management system include:

- the system is consistent
- management is optimized
- the documentation is without redundancies
- resources are common
- costs are reduced
- prevention is widespread
- process performance is improved
- risks are better set and controlled
- improved image of the company
- confidence in the company is increased
- the satisfaction of all interested parties is better ensured
- commitment to sustainable development is real

A well-prepared approach is halfway to success

The approach to implementing an integrated QSE management system starts with preparation. An example is shown in figure 1-4.

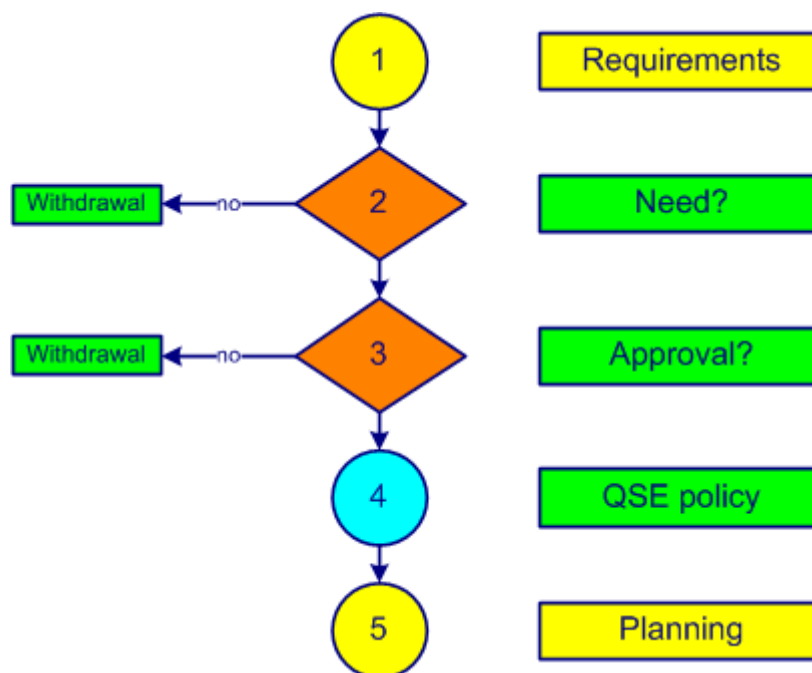


Figure 1-4. IMS preparation

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. Determining the current 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 that comes up quickly (**step 2**) is the **need** for this decision. If this is not really necessary or if the estimated costs of the certification approach exceed the available resources, it is better to 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 an integrated management system are often:

- an improved image of the company
- being one step ahead of the competition
- environmental protection reinforced
- environmental performance evaluated and communicated
- increased safety of staff
- reduction of production costs
- reducing or eliminating incidents
- better preparation for emergencies
- anticipating sustainable development
- increased confidence and satisfaction of interested parties
- the prevention of pollution, hazards and risks becoming routine
- better economic results
- reduced energy consumption
- increased daily effectiveness
- staff who are aware, consulted, motivated and proud
- high level of risk control
- reduced insurance costs
- commitment profitable for all
- good practices are valorized
- standardization of know how
- control of processes
- updated legal obligations

The benefits of the certification of an integrated management system are often:

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

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

True story

Motorola used ISO 9001 to reduce production costs and improve the efficiency of its processes. Streamlining operations has eliminated waste and reduced cycle times.

Motorola has recorded substantial savings, demonstrating the positive impact of ISO 9001 on financial performance. This certification allowed the company to stand out from the competition and access new markets.

True story

IBM, one of the world leaders in information technology, has implemented ISO 45001 to improve the management of stress and psychosocial risks at work. Implementing prevention and support measures for employees has helped reduce stress and improve well-being at work.

IBM has recorded a significant improvement in the mental health of its employees, demonstrating the importance of addressing psychosocial risks and the company's commitment to the well-being of its employees.

True story

Coca-Cola implemented ISO 14001 to reduce its water consumption and improve its environmental efficiency. The implementation of water-saving technologies and employee awareness programs has significantly reduced water consumption.

Coca-Cola has recorded substantial savings, demonstrating the positive impact of ISO 14001 on financial performance and its commitment to sustainability.

The internalization of the spirit of the principles and requirements of QSE standards 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 an integrated management system (IMS). 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 **QSE policy** and QSE objectives. If you do not have a copy of the ISO 9001, ISO 45001 and ISO 14001 standards, now is the time to get them (cf. sub-clause 2.1 of the present course).

Planning is the last **step (5)** of the project preparation for obtaining QSE certification. A reasonable period is between 6 to 12 months (each company is unique and specific). 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 certification.

The establishment and implementation of an integrated management system are shown in figure 1-5.

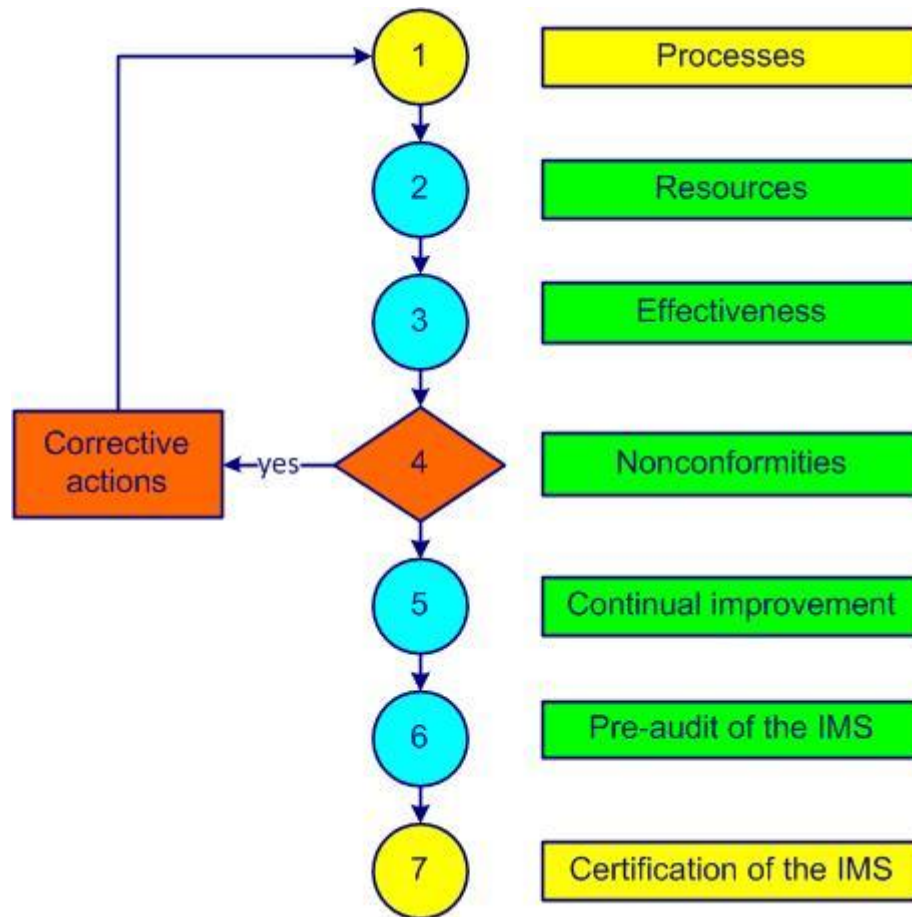


Figure 1-5. IMS implementation

Step 1 aims to determine the **processes**, interactions, owners, responsibilities. Drafts of certain documented information are established. Needs, expectations and requirements of all interested parties are analyzed. The first versions of different documented information (job descriptions, documented information to maintain, work instructions, process sheets) are written with the participation of the maximum number of available persons.

In **step 2** the necessary **resources** to achieve the QSE objectives are set. Planning tasks, responsibilities and time frames are established. Internal staff and subcontractors are aware of potential hazards and environmental impacts. 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 (customer requirements, hazard identification, risk assessment, identification of environmental aspects and impacts, legal and other requirements).

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. Emergencies with potential impacts on health, safety and environment are listed. The responses (action and reaction) to emergencies are put in place and documented.

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 in by those with the information at hand. Risks are determined, actions are planned and improvement

opportunities are taken. An approach to preventing nonconformities and eliminating causes is established. The activities associated with determined hazards and significant environmental aspects, are planned and implemented. A legal watch is undertaken. The risk assessment document is developed. Communication is established and formalized internally and externally.

To conduct the **pre-audit of the IMS (step 6)**, documented information is checked and approved by the appropriate people. A management review allows evaluating whether applicable requirements are met. The QSE policy and objectives are finalized. A QSE 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 IMS** by an external body is a breeze, a formality (**step 7**).

An example of a certification project plan with 28 steps is shown in [annex 01](#).

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

The Deming cycle (figure 1-6) is applied to control any process. The PDCA cycles (Plan, Do, Check, Act) are a universal base for continual improvement.

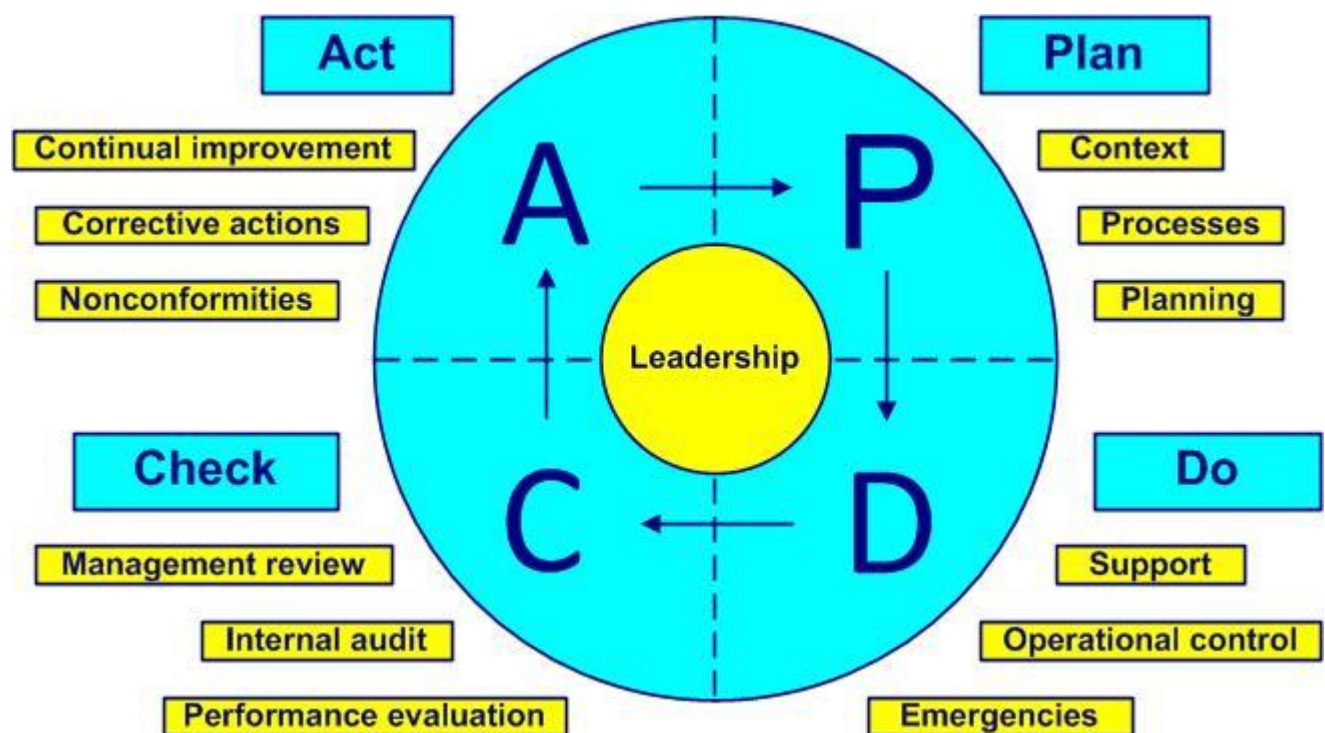


Figure 1-6. The Deming cycle

- Plan – prepare, define context, issues and processes, establish policy and objectives, and demonstrate leadership (clauses 4, 5 and 6)
- Do – develop and implement processes, demonstrate leadership, control life cycle, bring support and respond to emergencies (clauses 5, 7 and 8)
- Check – understand, inspect, analyze data, evaluate, demonstrate leadership, conduct audits and management reviews (clauses 5 and 9)
- Act – adapt, decide, demonstrate leadership, treat nonconformities, react with corrective actions or find new improvements (new PDCA cycle), (clauses 5 and 10)

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


2 Standards, definitions, books

2.1 Standards



The most commonly used standards for integrated management system are:

- ISO 9001 (2015): Quality management systems – Requirements
- ISO/TS 9002 (2016): Quality management systems - Guidelines for the application of ISO 9001:2015
- ISO 45001 (2018): Occupational health and safety management systems – Requirements with guidance for use
- ISO 14001 (2015): Environmental management systems - Requirements with guidance for use

The three standards are generic because they apply to any business, without any constraint on the size, activity or type. The scope of the integrated QSE management system is determined and documented information is maintained. 

Similarities and differences in the purpose of the three standards are shown in figure 2-1:

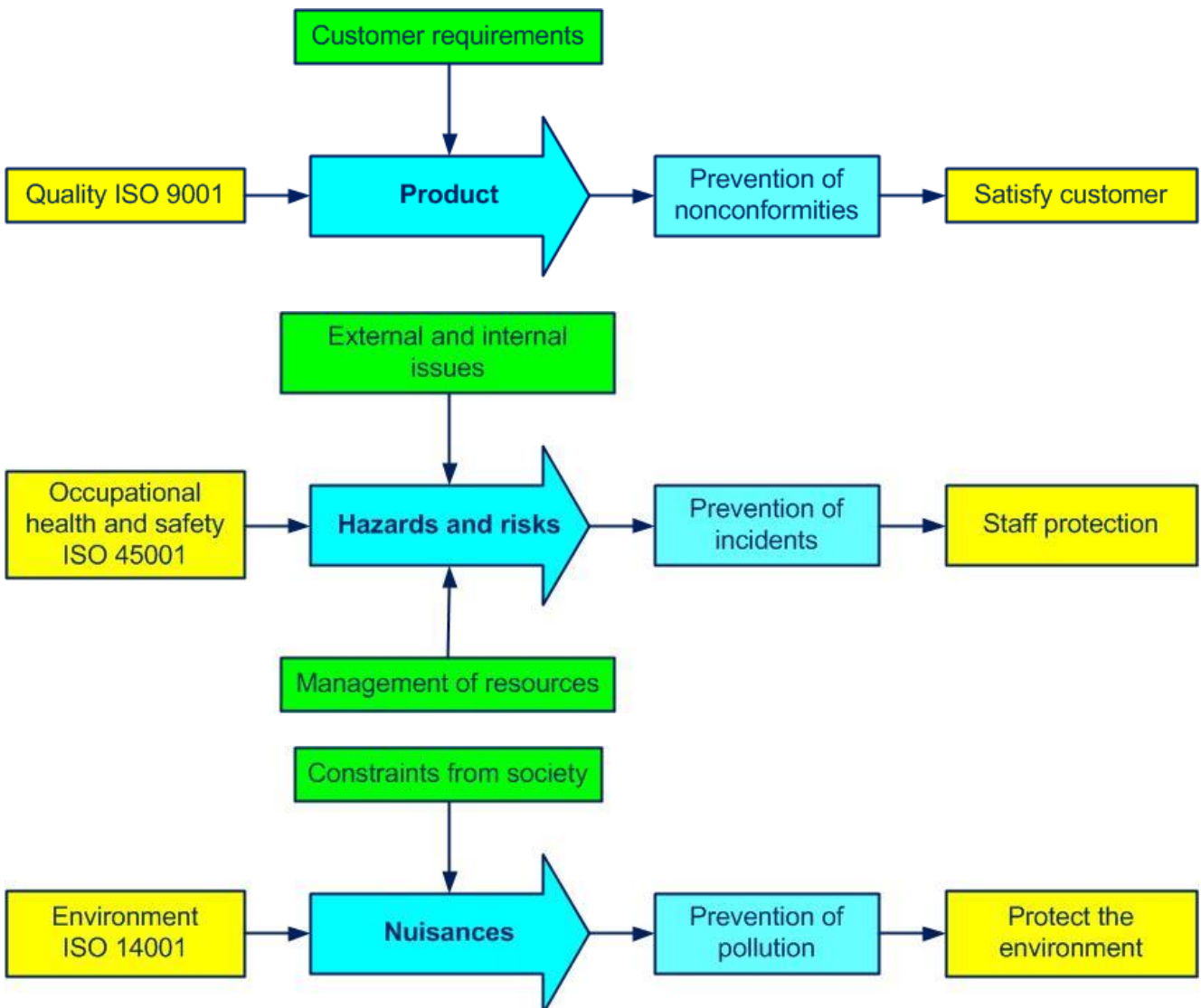


Figure 2-1. Purpose of QSE standards

Another demonstration of the close relationship between the QSE standards is the common standard ISO 19011 (2018 – third edition): Guidelines for auditing management systems.

A British PAS (publicly available specification) is dedicated to the integration of management systems:

- PAS 99: 2012 Specification of common management system requirements as a framework for integration

The ISO 14004: 2016 standard "Environmental management systems - General guidelines on principles, systems and technical implementation" contains many explanations, practical tips and examples.

ISO 14031: 2021 "Environmental Management - Environmental performance evaluation - Guidelines" shows how to set up and use the environmental performance evaluation (EPE) and the analysis of the life cycle to find improvement points. Its commitment to compliance with legal and regulatory requirements, pollution prevention and continuous improvement can be evaluated with the help of indicators.

ISO 14005: 2019 "Environmental management systems - Guidelines for the phased implementation of an environmental management system, including the use of environmental performance evaluation" shows how to implement an environmental management system in 3 phases, 19 clauses and 72 steps.

ISO 14044: 2006 "Environmental management - Life cycle assessment - Requirements and Guidelines" specifies requirements and provides guidelines for conducting life cycle assessments.

ISO 14063: 2020 "Environmental Communication" provides guidance on general principles, policy, strategy and activities relating to internal and external environmental communication.

ISO 14050: 2020 "Environmental management - Vocabulary" provides definitions of basic concepts, directly related to environmental management.

ISO 31000 (2018) "Risk management - Guidelines" establishes the principles and risk management process, risk assessment and risk treatment.

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 for free on the [Public.Resource.Org](#) site.

The [Oxebridge Q001](#) is a user-friendly, open source remix of ISO 9001:2015.

2.2 Definitions

The beginning of wisdom is the definition of terms. Socrates

Most of the terms and definitions of the QSE standards are identical. A small part of terms has slightly different definitions.

Specific quality terms:

Customer: *anyone who receives a product*

Customer satisfaction: top priority objective of every quality management system related to the satisfaction of customer requirements

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

Nonconformity: non-fulfillment of a specified requirement

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

Quality: aptitude to fulfill requirements

Quality management: activities allowing the control of a company with regard to quality

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

Specific health and safety terms:

Acceptable risk: risk reduced to a tolerable level

Accident: undesired event causing death or health and environmental damages

Emergency situation: event that poses a serious threat to life, health, property or the environment

Hazard: situation that could lead to an incident

Incident: undesired event that could lead to health damages

Occupational health and safety (OH&S): everything that can influence the wellbeing of the personnel in a company

Safety: absence of unacceptable risk

Specific environmental terms:

Environment: space in which any organization functions

Environmental aspect: every element of an organization that interacts with the environment

Environmental impact: every change in the environment caused by an organization

Environmental objective: environment related, measurable goal that must be achieved

Environmental performance: measurable results of the environmental management system

Certain common terms:

Competence: personal skills, knowledge and experiences

Conformity: fulfillment of a specified requirement

Corrective action: action to eliminate the causes of nonconformity or any other undesirable event and to prevent their recurrence

Documented information: any support allowing the treatment of information

Effectiveness: capacity to realize planned activities with minimum effort

Efficiency: financial relationship between achieved results and used resources

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

Organization (company): a structure that satisfies a need

Process: activities that transform inputs into outputs

Risk: likelihood of occurrence of a threat or an opportunity

Top management: group or persons in charge of the company's control at the highest level



In the terminology of integrated 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:
 - anomaly is a deviation from what is expected

- defect is the non-fulfillment of a requirement related to an intended use
- dysfunction is a degraded function that can lead to a failure
- failure is when a function has become unfit
- nonconformity is the non-fulfillment of a requirement in production
- reject is a nonconforming product that 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 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
 - control is meeting the objectives
 - optimize is searching for the best possible results
- customer, external provider (supplier) and subcontractor
 - a customer receives a product
 - an external provider provides a product or a service
 - a subcontractor provides a service or a product on which a specific work is done
- effectiveness and efficiency
 - effectiveness is the level of achievement of planned results
 - efficiency is the ratio between results and resources
- follow-up and review
 - follow-up is the verification of the obtained results of an action
 - review is the analysis of the effectiveness in achieving objectives
- 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 use of ISO 9000, ISO 45001 and ISO 14001 definitions is recommended. The most important thing is to determine a common and unequivocal vocabulary for everyone in the company.

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

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


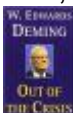






For other definitions, comments, explanations and interpretations that you don't find in this module and in [annex 06](#), you can consult: 


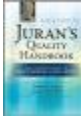

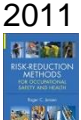

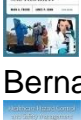







- ISO [Online Browsing platform](#) (OBP)
- IEC [Electropedia](#)
- [ISO 9000: 2015](#) - Quality management systems. Fundamentals and vocabulary


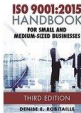








2.3 Books



Books for further QSE reading:

-  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
-  W. 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
-  Thomas Anton, [Occupational Safety and Health Management](#), McGraw Hill, 1989
-  Thomas Lee et al, [Integrated Management Systems: A Practical Approach to Transforming Organizations](#), Wiley, 1999
-  Larry Webber, Michael Wallace, [Quality Control for Dummies](#), Wiley, 2007

- 
David Hoyle, [ISO 9000 Quality Systems Handbook](#), Elsevier, 2009
- 
Joseph M. Juran, [Juran's Quality Handbook](#), McGraw Hill, 2010
- 
CCPS, [Guidelines for Auditing Process Safety Management Systems](#), Wiley, 2011
- 
Joger Jensen, [Risk-Reduction Methods for Occupational Safety and Health](#), Wiley, 2012
- 
Mark Friend, James Kohn, [Fundamentals of Occupational Safety and Health](#), Bernan Press, 2014
- 
James Tweedy, [Healthcare Hazard Control and Safety Management](#), CRC Press, 2014
- 
Terry Bush, [ISO 14001 154 Success Secrets](#) - 154 Most Asked Questions On ISO 14001 - What You Need To Know, Emereo Publishing, 2014
- 
Marek Bugdol, Piotr Jedynek, [Integrated Management Systems](#), Springer, 2014
- 
Denise Robitaille, [The \(Almost\) Painless ISO 9001:2015 Transition](#), Paton Professional, 2015
- 
Jan Gillet, [Implementing Iso 9001:2015](#): Thrill your customers and transform your cost base with the new gold standard for business management, Infinite Ideas, 2015
- 
Charles Cianfrani, John West, [ISO 9001:2015 Explained](#), ASQ Quality Press, 2015
- 
Craig Cochran, [ISO 9001:2015 in Plain English](#), Paton Professional, 2015
- 
Chad Kymal and al, [Integrated Management Systems](#): QMS, EMS, OHSMS, FSMS including Aerospace, Service, Semiconductor/Electronics, Automotive, and Food, ASQ, 2015

- 
 • Milton Dentch, [The ISO 14001:2015 Implementation Handbook](#), ASQ, 2016
- 
 • Denise Robitaille, [ISO 9001:2015 Handbook for Small and Medium-Sized Businesses](#), Quality Press, 2016
- 
 • Jeremy Hazel, José Dominguez, Jim Collins, [Memory Jogger ISO 9001:2015: What Is It? How Do I Do It? Tools and Techniques to Achieve It](#), Goal/QPC, 2016
- 
 • Alka Jarvis, Paul Palmes, [ISO 9001: 2015: Understand, Implement, Succeed!](#), Prentice hall, 2016
- 
 • Ray Tricker, [ISO 9001:2015 for Small Businesses](#), Routledge, 2016
- 
 • Christopher Paris, [Surviving ISO 9001: 2015](#), Oxebridge Quality Press, 2016
- 
 • Charles Reese, [Occupational Health and Safety Management: A Practical Approach](#), CRC Press, 2017
- 
 • Milton Dentch, [The ISO 45001:2018 Implementation Handbook: Guidance on Building an Occupational Health and Safety Management System](#), ASQ Quality Press, 2018
- 
 • Chris Ward, [ISO 45001 Occupational Health and Safety Management System. Guide to Requirements: Non Technical Interpretation of ISO 45001 Requirements](#), Chris J Ward, 2018
- 
 • Ramesh Lakhe, Kranti Dharkar, [ISO 45001:2018 OCCUPATIONAL HEALTH & SAFETY MANAGEMENT SYSTEM](#) (RRL), Independently published, 2018

**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 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 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 02](#)).

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

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



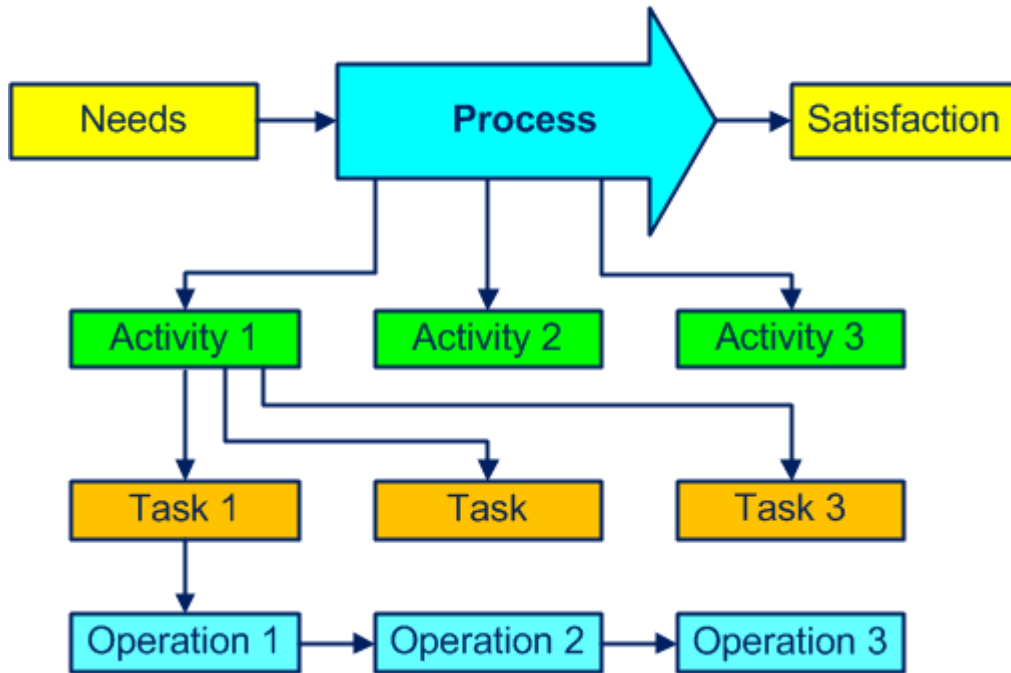


Figure 3-1. Components of a process

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

- which materials, which documents, which tooling? (inputs)
- which title, what objective, which activities, requirements, constraints? (process)
- which products, which unintended results? (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)

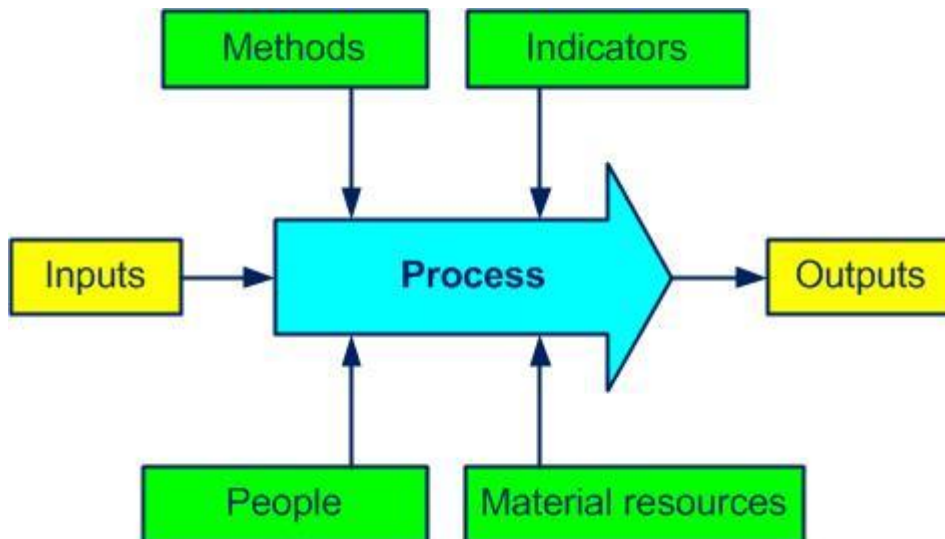


Figure 3-2. Some elements of a process

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 03](#).

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 types. Do not attach too much importance to process categorizing (sometimes it's very relative) but ensure that all the company's activities at least fall into one process.

3.1.1 Management processes

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

The following processes can be part of this family:

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

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
- receive, store and deliver
- inspect production
- control nonconformities
- anticipate emergencies
- implement corrective actions
- implement traceability
- sell

- investigate incident
- manage waste

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
- realize environmental analyses
- study hazards
- acquire and maintain infrastructure
- provide training
- manage inspection means
- provide information
- keep the legal watch updated
- keep accountability
- manage staff

3.2 Process mapping

Par excellence process “mapping” is a multidisciplinary work. This is not a formal requirement of either ISO 9001 (or ISO 45001 or ISO 14001) but is always welcome.

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

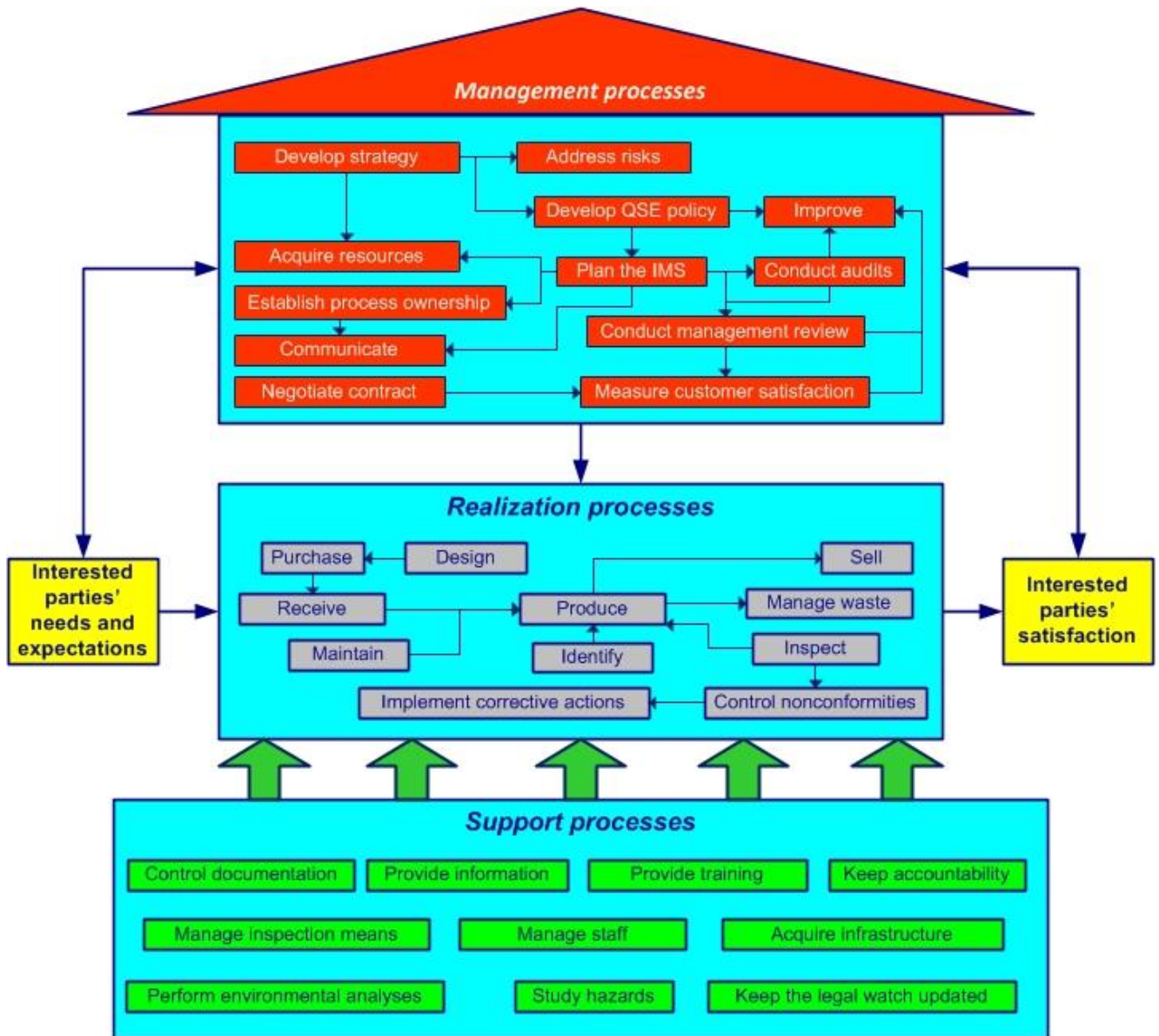


Figure 3-3. The process house

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

Mapping, among other things, allows you to:

- 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 15 core processes. A core process can contain several sub-processes: for example, the process "develop the IMS"

can involve: 

- develop strategy
- develop policy
- address risks
- plan the IMS
- deploy objectives

- acquire resources
- establish process ownership
- improve

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

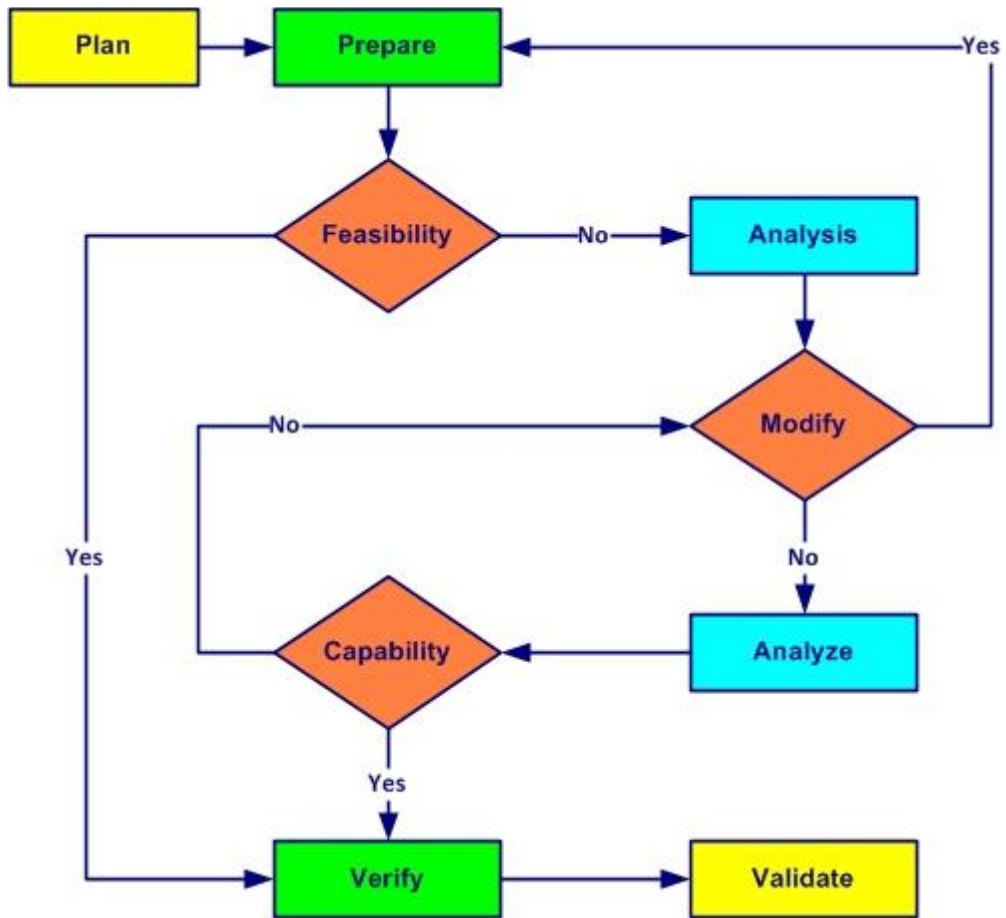


Figure 3-4. Design process

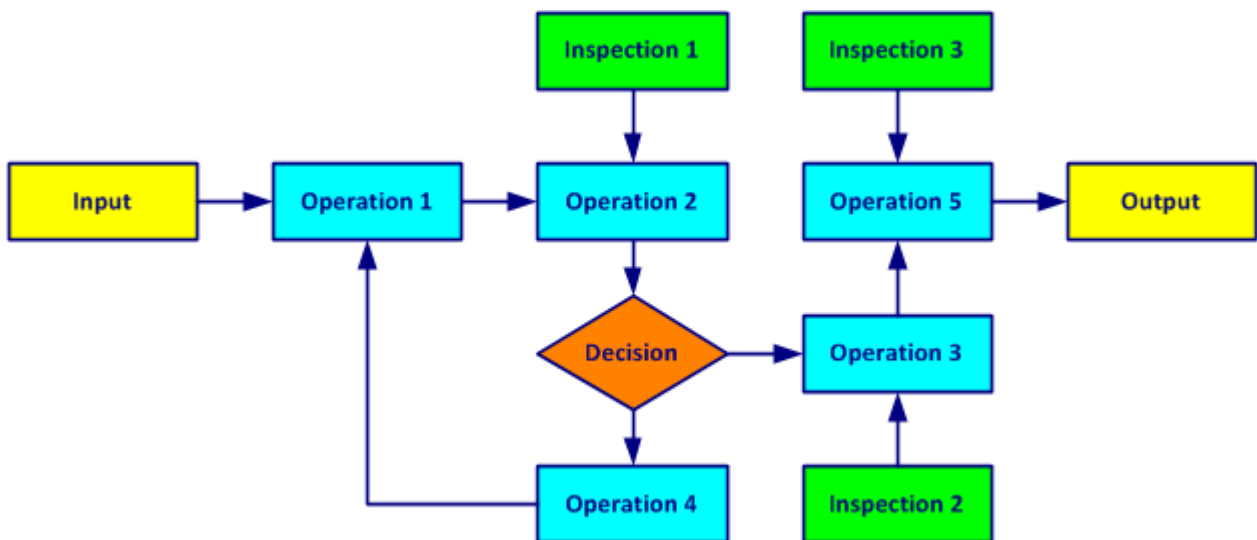


Figure 3-5. Produce process

3.3 Process approach

Simple solutions for now, perfection for later

The process approach contributes enormously to the efficient management of the company (cf. [annex 04](#)).

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 an integrated management system, it allows one to achieve objectives that are related to customer satisfaction, as is shown in figure 3-6.

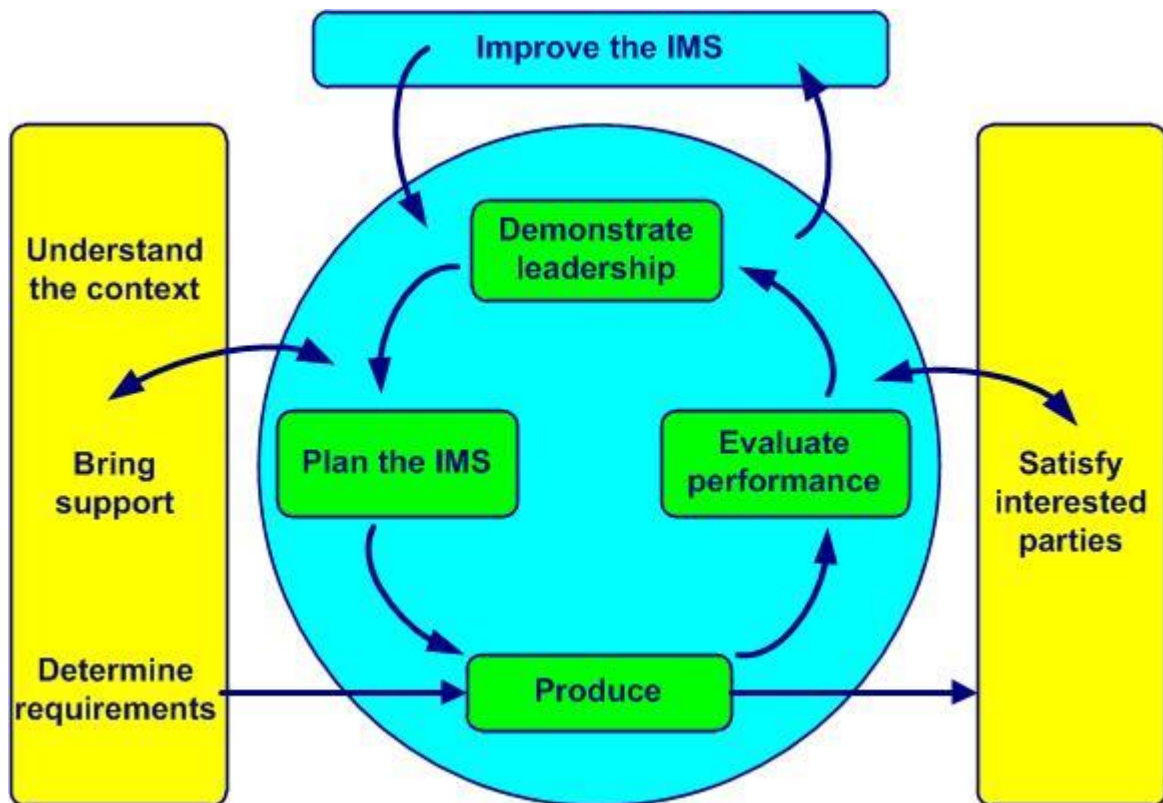


Figure 3-6. Model of an IMS based on process approach and continual improvement

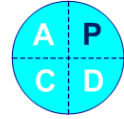
The process approach:

- emphasizes the importance of:
 - understanding and complying with customer requirements
 - prevention so as to react to unwanted elements such as:
 - incidents
 - accidents
 - nuisances
 - rejects
 - 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

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 Context of the organization

4.1 The organization and its context (*requirements [Q](#), [S](#), [E](#)*)

The two most important in a company do not appear in its balance sheet: its reputation and its people. Henry Ford

To successfully implement an integrated QSE 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
 - competitive
 - the internal environment, such as:
 - specific aspects of the corporate culture:
 - vision
 - rationale, purpose and mission
 - core values
 - needs and expectations of
 - workers
 - interested parties
 - products and services
 - infrastructure
 - work conditions
 - work organization
- analyze the factors that may influence the achievement of business objectives
- determine occupational health and safety hazards, perform an initial risk assessment
- establish the significant environmental impacts that could affect or be affected by the company

The SWOT and PESTEL analyses can be useful for relevant analysis of business context (cf. [annex 05](#)).

A list of external and internal issues is created 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*
- *the results of the context analysis are widely diffused*
- *the SWOT analysis includes many relevant examples*
- *the SWOT analysis is a powerful tool for identifying the main threats and opportunities*
- *the list of environmental aspects and impacts is regularly updated*

- *the list of occupational health and safety hazards is regularly updated*

Bad practices

- *certain issues of the context of the company, such as the competitive environment, are not taken into account*
- *environmental impacts are not prioritized*
- *hazard identification is not exhaustive (some hazards were forgotten)*
- *in some cases, the corporate culture is not taken into account*
- *no clear link between the SWOT analysis and the actions undertaken*
- *risk analysis does not take into account strategic issues*
- *some environmental impacts are not taken into account*

4.2 Needs and expectations of interested parties (requirements [Q](#), [S](#), [E](#))

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 integrated management system, such as:

- employees
- customers
- external providers
- owners
- shareholders
- bankers
- distributors
- competitors
- citizens
- neighbors
- social and political organizations
- legal authorities
- OH&S organizations
- occupational physicians

A list of interested parties is carried out by a multidisciplinary team. Every interested party is identified 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 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 involves:

- meeting the requirements of the product and service offered
- meeting the requirements of occupational health and safety
- meeting the requirements of protection of the environment
- preparing to address risks
- finding improvement opportunities

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

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

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*
- *Municipal wastewater regulation defining the discharge conditions to the network is not determined as a compliance obligation*
- *the expectations of interested parties are not determined*
- *the list of interested parties does not contain their area of activity*

4.3 Scope of the integrated management system (requirements [Q](#), [S](#), [E](#))

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

The scope (or in other words, the perimeter) of the integrated 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 IMS including:

- issues (cf. sub-clause 4.1)
- dangerousness of products and services in a life cycle perspective
- 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*
- *the scope takes into account the entire life cycle of products*

Bad practices

- *some products are outside the scope of the IMS without justification*
- *the paint shop is not included in the scope of the IMS*
- *the requirements of a customer are not accepted and no justification is present*
- *the scope is obsolete (a new subsidiary is not included)*
- *an environmental aspect is not taken into account*



4.4 Integrated management system and its processes (requirements [Q](#), [S](#), [E](#))

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 QSE standards cover:

- management by quality
- personnel protection
- protection of the environment and
- the control of business processes

To do this:

- the integrated management system is:
 - established
 - documented (a simple and sufficient documentation system is set up)
 - implemented and
 - continually improved
- the QSE policy, objectives, resources and the work environment are determined
- risks are determined and actions to reduce them are established
- the core necessary IMS 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
 - environmental requirements are integrated into business processes
 - necessary changes are implemented to achieve the expected results
 - actions for continual improvement of processes are established
- the necessary minimum ("as much as needed") of documented information on the processes is maintained and retained ( )
- hazards to occupational health and safety are determined, risks are evaluated and the means of control are in place




- an environmental diagnosis is made, the environmental aspects are determined and significant environmental impacts are determined
- an action plan allows applying the QSE policy, to achieve the objectives and improve QSE performance of the company
-
- reviews and audits of the IMS are carried out regularly
- the history of emergencies, incidents and nonconformities are evaluated, potential emergencies are determined, evaluated and methods are in place to react

The QSE manual is not a requirement of QSE standards, but it is always an opportunity to present the company, its IMS and its procedures and processes (cf. [annex 07](#)).

The ISO guide "[The integrated use of management system standards](#)" of 2018, contains relevant recommendations on the integration of management systems.



Pitfalls to avoid:

- going overboard on quality: 
 - a useless operation is performed without adding value and without the customer asking for it - it is a waste, cf. quality tools [D 12](#)
- having all procedures written by the QSE manager: 
 - quality is everybody's business, "the staff is conscious of the relevance and importance of each to the contribution to quality objectives", which is even more true for department heads and process pilots
- forgetting to take into account the specificities related to the corporate culture: 
 - innovation, luxury, secrecy, authoritarian management (Apple)
 - strong culture related to ecology, action and struggle, while cultivating secrecy (Greenpeace)
 - fun and quirky corporate culture (Michel & Augustin)
 - liberated company, the man is good, love your customer, shared dream (Favi)

The requirements of the three standards ISO 9001, ISO 45001 and ISO 14001 are shown in figures 4-1, 4-2 and 4-3:

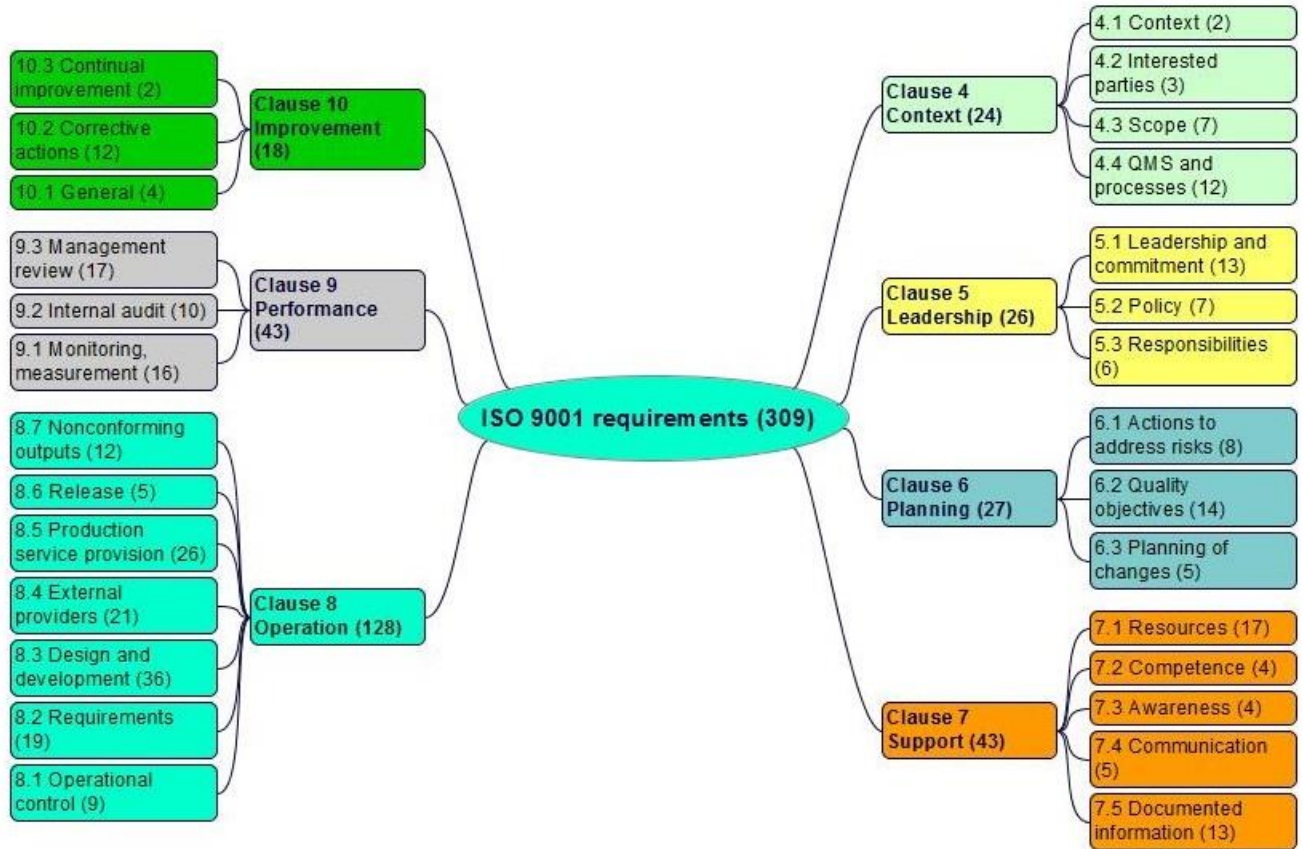


Figure 4-1. The requirements of the ISO 9001: 2015 standard

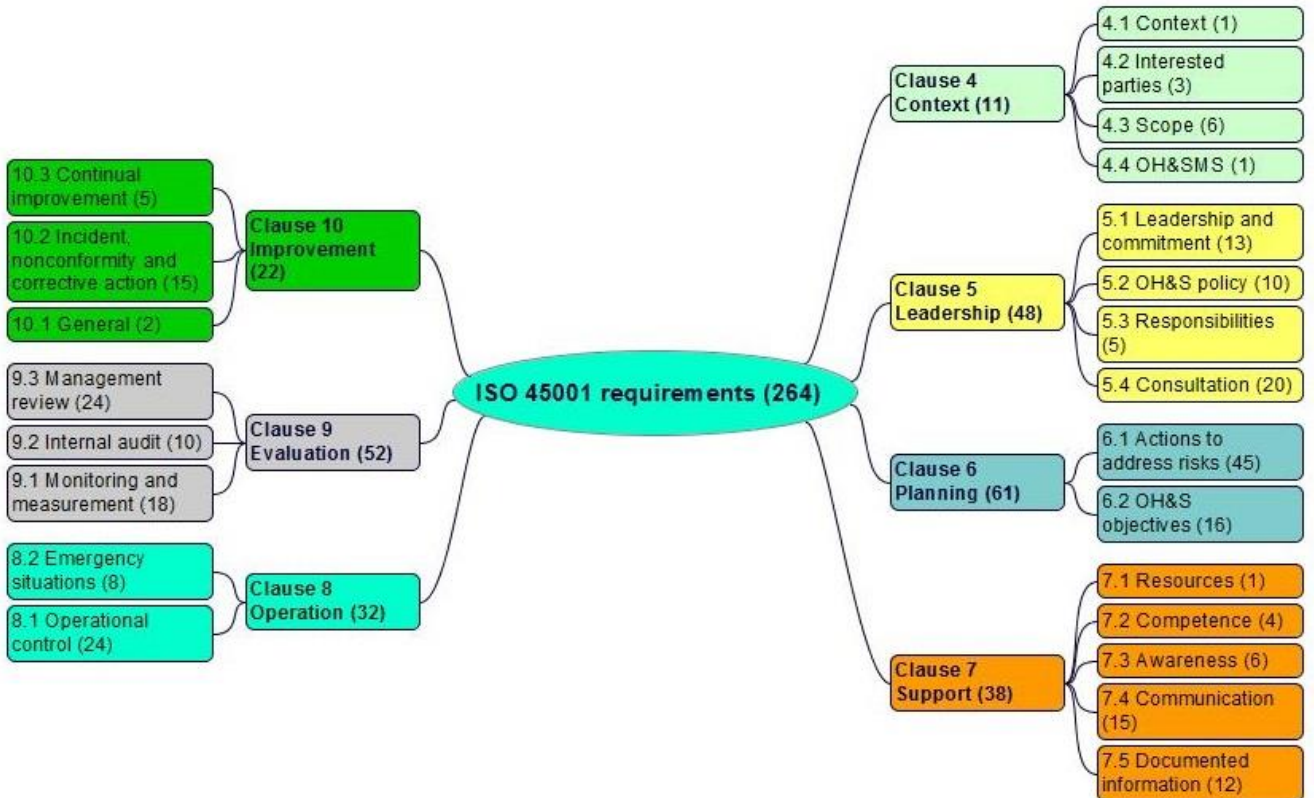


Figure 4-2. The requirements of the ISO 45001: 2018 standard

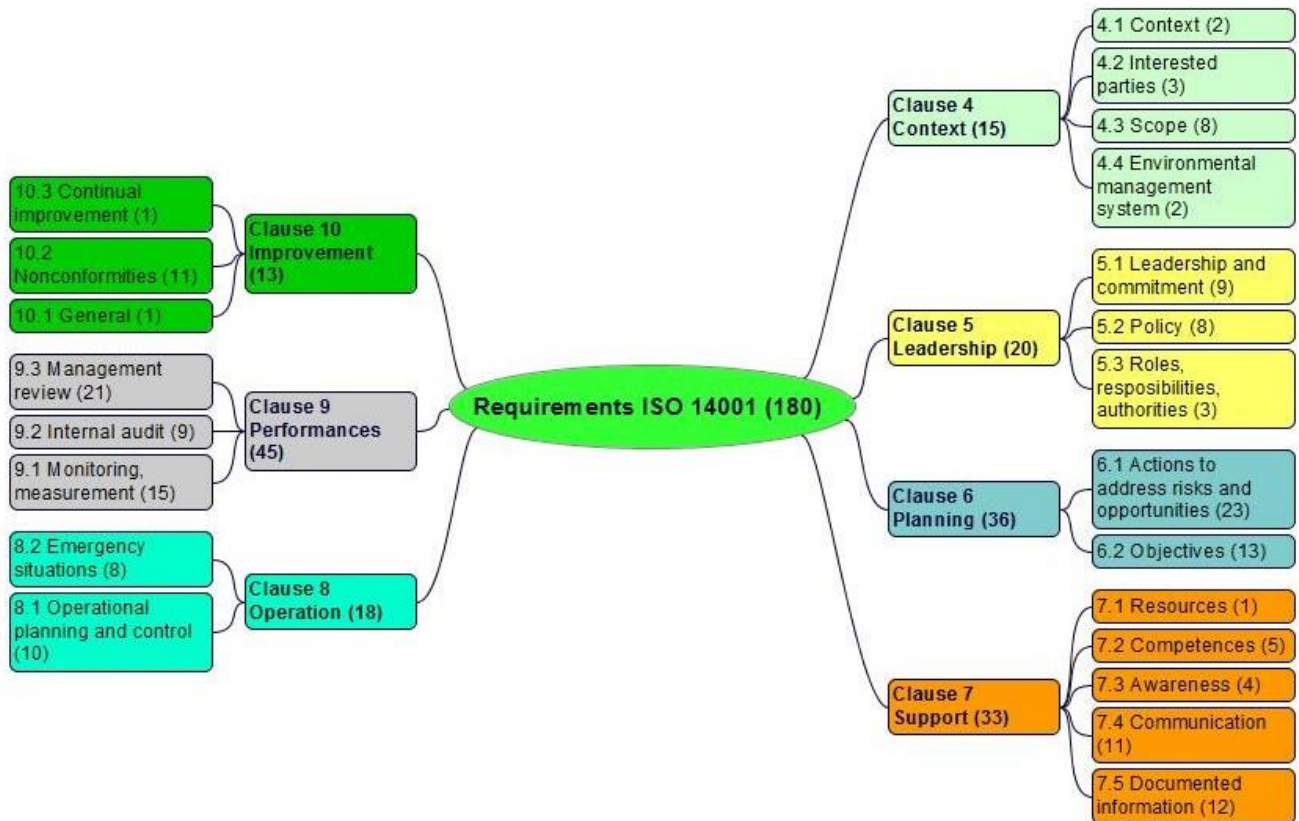


Figure 4-3. The requirements of the ISO 14001: 2015 standard

The requirements of the standards ISO 9001, ISO 45001 and ISO 14001 are complementary when they are not identical (cf. [annex 08](#)).

Good practices

- *the process map has enough arrows to show who the customer (internal or external) is*
- *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 process performance is an example of continual improvement and evidence of the effectiveness of the IMS*
- *top management regularly monitors QSE objectives and action plans*
- *the purpose of each process is clearly defined*

Bad practices

- *some process outputs are not set correctly (customers not considered)*
- *process efficiency criteria are not established*
- *the process owners are not formalized*
- *outsourced processes are not determined*
- *control of outsourced services is not described*
- *very real activities are not determined in any process*
- *control of outsourced services is not described*
- *sequences and interactions of certain processes are not determined*
- *methods to ensure the performance of certain processes are not defined*
- *monitoring the performance of certain processes is not established*
- *the IMS resources do not allow achievement of objectives*

- *the IMS is not updated (new processes not determined)*
- *the threats and weaknesses identified in the SWOT analysis remain without actions*