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**ISO 19443 readiness** **version 2018**

Goal

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| --- | --- |
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**Goal of the module**: Readiness for implementation, certification, maintenance and improvement of your nuclear safety quality and safety management system (ISO 19443) in order to:

* reinforce nuclear safety
* prevent accidents and mitigate consequences
* establish and foster a strong safety culture

**1 Quality approach**

**1.1 Background**

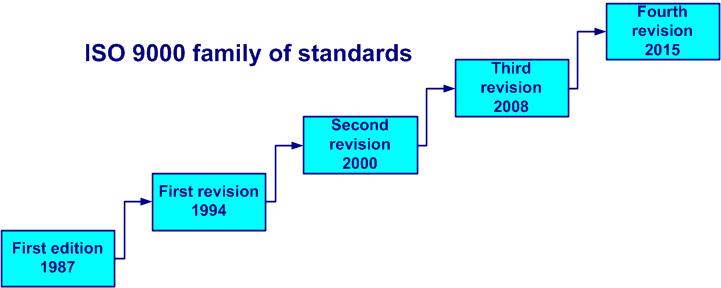
The evolution of the quality concept and the standards of quality management systems (Quality Management System = QMS) in industrial countries in the 20th century can be summarized as:

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

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

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

* 1987: first edition, 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

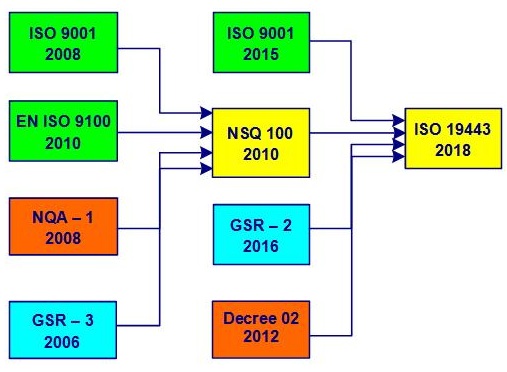


*Figure 1-1. Revisions of ISO 9000 family*

The fourth edition (revision, version) of ISO 9001 was published in 2015.

The standard “[ISO 19443](https://www.iso.org/standard/64908.html) - Quality management systems — Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)” was published in 2018.

Some historical points (standards and references) related with the creation of the ISO 19443 standard, of French initiative, are shown in figure 1-2:



*Figure 1-2. History of ISO 19443*

[Atomic Energy Act](https://en.wikipedia.org/wiki/Atomic_Energy_Act_of_1946), US Congress, 1946

[N45.2](https://www.document-center.com/standards/show/ANSI-N45.2/history/1971%20EDITION) Quality Assurance Program Requirements for Nuclear Facilities, ANSI, 1971

[GS-R-3 IAEA](https://site.ieee.org/npec-sc2/files/2017/06/SC-2Mtg11-1_Att4c_IAEA-GS-R-3.pdf), The management system for facilities and activities, Safety requirements, IAEA, 2006

[NQA – 1](https://www.asme.org/codes-standards/find-codes-standards/quality-assurance-requirements-for-nuclear-facility-applications/2024/print-book), Nuclear Quality Assurance - Quality Assurance Requirements for Nuclear Facility Applications, ASME, 2008

[NSQ-100](https://webstore.ansi.org/standards/asme/asmestpnu0612015?srsltid=AfmBOooEcn676AfZA5yW7ykTqnz5fmRYUkccq6cP5nFwhQGzdHa5rqgv)**,** Nuclear Safety and Quality Management System Requirements, NQSA, 2010

[DOE O 450.2](https://www.directives.doe.gov/directives-documents/400-series/0450.2-BOrder), Integrated Safety Management, US Department of Energy, 2011

[Decree of 7 February 2012](https://www.legifrance.gouv.fr/loda/id/JORFTEXT000025338573), Order of February 7, 2012 establishing the general rules relating to basic nuclear installations (BNI), French laws, 2012

[GSR Part 2](https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1750web.pdf), General Safety Requirements for Leadership and Management for Safety, IAEA, 2016

[AS9100](https://iaqg.org/standard/9100-qms-requirements-for-aviation-space-and-defense-organizations/) - Quality Management Systems – Requirements for Aviation, Space and Defense Organizations, IAQG, 2016

The requirements of ISO 19443 are not intended to replace customer, statutory and regulatory requirements, but are complementary.

In addition to ISO 9001, the ISO 19443 requirements mainly focus on:

* issues that include nuclear safety considerations
* nuclear safety is taken into account in decision making
* nuclear safety culture
* ITNS items and activities break down
* graded approach to the application of quality requirements
* changes to the QMS are managed so nuclear safety is not compromised
* resources are provided so nuclear safety is not compromised
* competence of persons also address specific qualification
* provisions for counterfeit, fraudulent or suspect items (CFSI)
* project and configuration management
* independence of verification and validation of design and development
* design and development verification and validation testing
* evaluation whether external providers meet the requirements of ISO 19443
* ITNS purchasing requirements to all levels of the supply chain
* enhanced traceability
* control of production equipment
* monitoring and measurement activities
* preservation of important to nuclear safety (ITNS) products
* statement of conformity at delivery
* root cause analysis of nonconformities
* analysis and evaluation of nuclear safety culture aspects
* relations with nuclear safety authorities
* nuclear safety culture is included in continual improvement opportunities

**1.2 Scope**

The [ISO 9001](https://www.iso.org/standard/62085.html) standard (Quality management systems - Requirements) is generic as it can be applied to the management system of any company, without limitations on size, activity or type. It is a voluntary international standard which allows certification by accredited bodies.

The scope of ISO 19443 applies to any organization supplying ITNS (important to nuclear safety) products or services.

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

* it does not affect product or service conformity and nuclear safety in any way
* it does not relieve top management of its responsibilities
* it is justified in a document

**1.3 Principles and steps**

**Quality is anything that can be improved. Masaaki Imai**

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

Quality management systems include three distinct and interrelated steps:

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

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

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

**Quality remains long after the price has been forgotten**

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

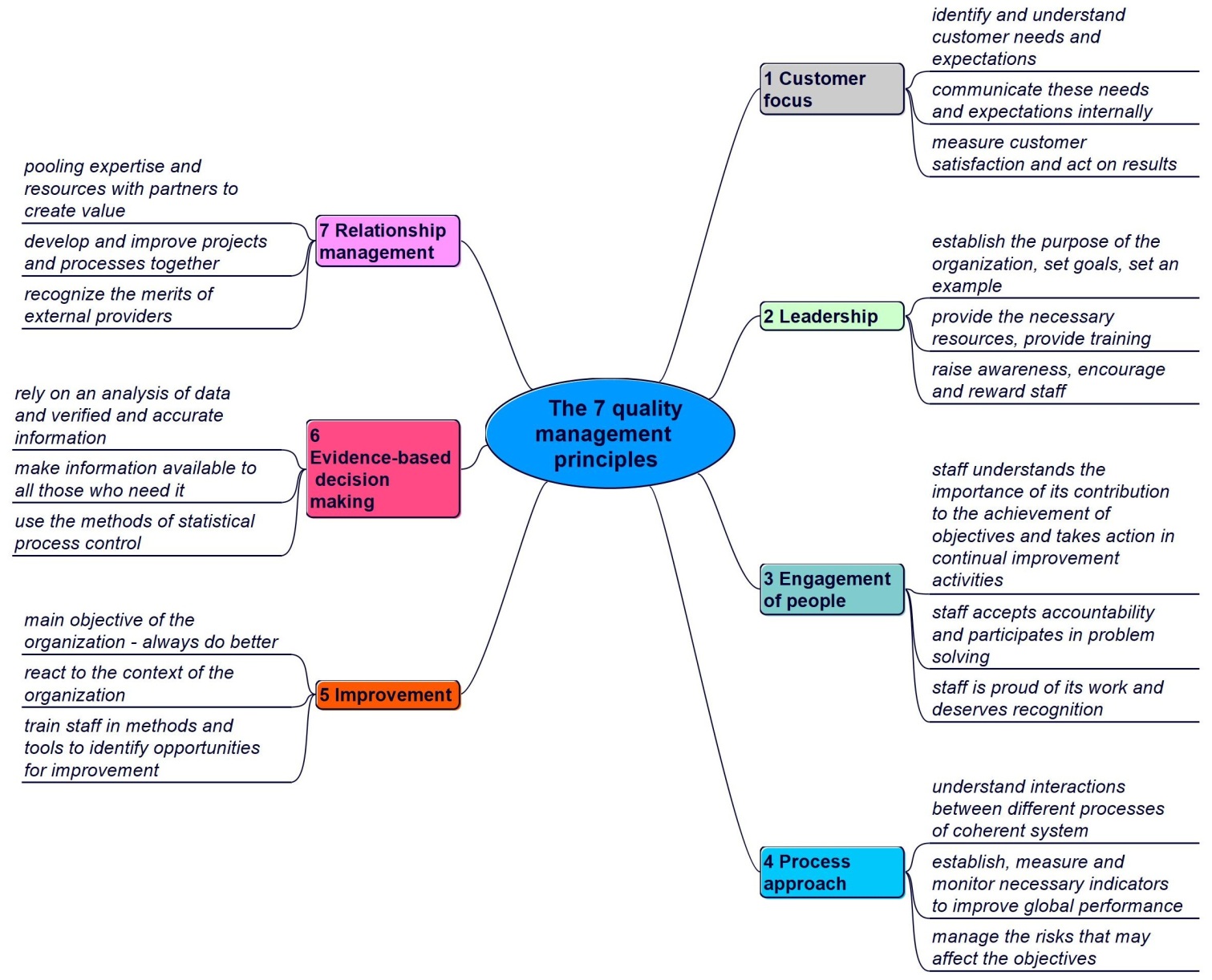
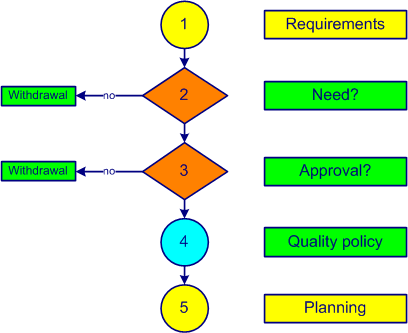


Figure 1-2. The 7 quality management principles

### A well-prepared approach is halfway to success

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



*Figure 1-3. QSMS preparation*

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

* 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 a quality and safety management system are often:

* an improved image of the company
* being one step ahead of the competition
* enhanced customer satisfaction
* better economic results
* increased daily effectiveness
* staff who are aware, consulted, motivated and proud
* high level of risk control
* reduced insurance costs
* profitable engagement for all
* best practices are valorized
* formalization of knowledge
* process control
* updated legal obligations

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

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

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

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

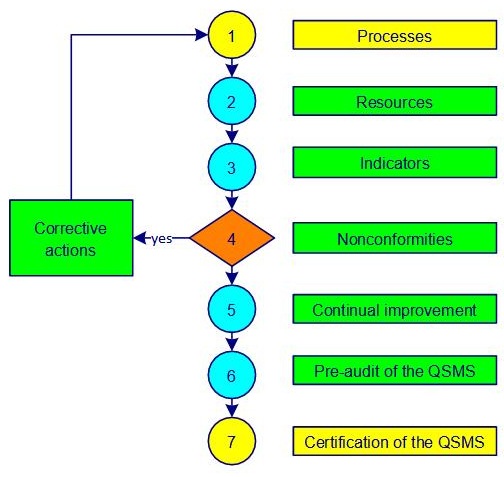
The **third step** shall determine whether this approach receives the **approval** of the staff. A communication campaign is launched in-house on the objectives of a quality and safety management system (QSMS). The staff is aware and understands that, without their participation, the project cannot succeed.

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

The vision (what we want to be), the mission (why we exist) and the business plan of the company are determined. The **following step** (**4**) includes the establishment of an outline of the **quality policy** and quality objectives. If you do not have a copy of the ISO 9001 standard, now is the time to get it (cf. sub-clause 2.1 of the present course).

**Planning** is the last **step** (**5**) of the project preparation for obtaining ISO 9001 certification. A reasonable period is between 5 to 8 months (each company is unique and specific). The financial resources and staff are confirmed by top management. A management representative is appointed as project leader. Top management commitment is formalized in a document communicated to all staff. A person is appointed as project leader for obtaining ISO 19443 certification.

The establishment and implementation of an ISO 19443 quality and safety management system are shown in figure 1-4.



*Figure 1-4. QSMS implementation*

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

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

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

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

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

To conduct the **pre-audit of the QSMS** (**step 6**), the documentation is checked and approved by the appropriate people. A management review allows evaluation of compliance with applicable requirements. The quality policy and objectives are finalized. A quality and safety 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 QSMS** by an external body is a breeze, a formality (**step 7**).

An example of a certification project plan with 26 steps is shown in [annex 01](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php). G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif

An appropriate method for evaluating the performance of your quality and safety management system is the RADAR logic model of excellence [EFQM](http://www.efqm.org/) (European Foundation for Quality Management) with its nine criteria and overall score of 1000 points.

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

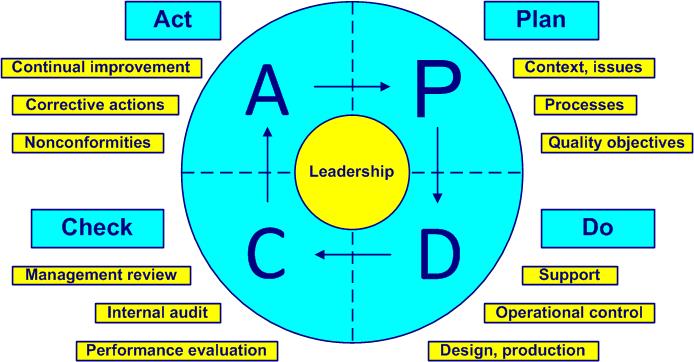


Figure 1-5. The Deming cycle

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

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

**2 Standards, definitions, books**

**2.1 Standards**

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

* [ISO 9000](https://www.iso.org/standard/45481.html) (2015): Quality management systems - Fundamentals and vocabulary
* [ISO 9001](https://www.iso.org/standard/62085.html) (2015): Quality management systems - Requirements
* [ISO/TS 9002](https://www.iso.org/standard/66204.html) (2016): Quality management systems - Guidelines for the application of ISO 9001:2015
* [ISO 9004](https://www.iso.org/standard/70397.html) (2018): Quality management - Quality of an organization - Guidance to achieve sustained success

In addition to [ISO 19443](https://www.iso.org/standard/64908.html) in 2020 was published the guide for application:

[ISO TR 4450](https://www.iso.org/standard/79983.html) - Quality management systems — Guidance for the application of ISO 19443:2018

Safety standards, Nuclear Security series, Nuclear Energy series, Technical documents, Booklets, Reports, Treaties, Conventions and many others are available on the [IAEA](https://www.iaea.org/) web site.

[IAEA](https://www.iaea.org/) requirements are included in numerous codes and standards in technical fields like Mechanical, Electrical, Civil Engineering, fuel design, etc…

Some other standards and documents related to nuclear safety:

[21 FR 355](https://archives.federalregister.gov/issue_slice/1956/1/19/353-355.pdf#page=3), Atomic Energy Commission, Federal Register, 1956

[IAEI-50-C-QA](https://gnssn.iaea.org/Superseded%20Safety%20Standards/Safety_Series_050-C-QA_1978.pdf), Quality Assurance for Safety in Nuclear Power Plants, A code of Practice, IAEI, 1978

[MIL-P-1629A](https://www.dsiintl.com/wp-content/uploads/2017/04/mil_std_1629a.pdf), Procedures for Performing a Failure Mode Effect and Critical Analysis, US DoD, 1980

[Decree of 10 August 1984](https://www.legifrance.gouv.fr/loda/id/JORFTEXT000000321244), Order of 10 August 1984 relating to the quality of the design, construction and operation of basic nuclear installations, French laws, 1984

[75-INSAG-4](https://www-pub.iaea.org/MTCD/Publications/PDF/Pub882_web.pdf), Safety culture - safety series - A report by the International Nuclear Safety Advisory Group, IAEA, 1991

[TECDOC-1169](https://www-pub.iaea.org/MTCD/Publications/PDF/te_1169_prn.pdf), Managing suspect and counterfeit items in the nuclear industry, IAEA, 2000

[GS-R-3 IAEA](https://site.ieee.org/npec-sc2/files/2017/06/SC-2Mtg11-1_Att4c_IAEA-GS-R-3.pdf), The management system for facilities and activities, Safety requirements, IAEA, 2006

[SF-1](https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1273_web.pdf), Fundamental safety principles, IAEA, 2006

[NQA – 1](https://www.asme.org/codes-standards/find-codes-standards/quality-assurance-requirements-for-nuclear-facility-applications/2024/print-book), Nuclear Quality Assurance - Quality Assurance Requirements for Nuclear Facility Applications, ASME, 2008

[S-G-3.5](https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1392_web.pdf), The management system for nuclear installation, IAEA, 2009

[NSQ-100](https://webstore.ansi.org/standards/asme/asmestpnu0612015?srsltid=AfmBOooEcn676AfZA5yW7ykTqnz5fmRYUkccq6cP5nFwhQGzdHa5rqgv), Nuclear Safety and Quality Management System Requirements, NQSA, 2010

[DOE O 450.2](https://www.directives.doe.gov/directives-documents/400-series/0450.2-BOrder), Integrated Safety Management, US Department of Energy, 2011

[DOE P 450.4A](https://www.directives.doe.gov/directives-documents/400-series/0450.4-APolicy-a), Integrated Safety Management Policy, US Department of Energy, 2011

[DOE G 450.4-1C](https://www.directives.doe.gov/directives-documents/400-series/0450.4-EGuide-1c), Integrated Safety Management System Guide, US Department of Energy, 2011

[Guidance for commercial grade dedication](https://www.energy.gov/sites/prod/files/em/CommercialGradeDedicationGuidance.pdf), US Department of energy, 2011

[GSR-3](https://gnssn.iaea.org/CSN/Relevant%20Documents/Safety%20Requirements/French/GSR%20Part%203.pdf), Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA, 2011

[INSAG-25](https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1499_web.pdf), A Framework for an Integrated Risk Informed Decision Making Process, IAEA, 2011

[Decree of 7 February 2012](https://www.legifrance.gouv.fr/loda/id/JORFTEXT000025338573), Order of February 7, 2012 establishing the general rules relating to basic nuclear installations (BNI), French laws, 2012

[DOE G 440.1-1B](https://www.directives.doe.gov/directives-documents/400-series/0440.1-EGuide-1B-admchg1), Chg 1 (Admin Chg) - Worker Safety and Health Program for DOE (Including the National Nuclear Security Administration) Federal and Contractor Employees, US Department of Energy, 2013

[Report](https://www.wenra.eu/sites/default/files/publications/rhwg_safety_of_new_npp_designs.pdf), Safety of new NPP designs, WENRA, 2013

[DOE G 414.1-2B](https://www.directives.doe.gov/directives-documents/400-series/0414.1-EGuide-2b-admchg2), Chg 2 (Admin Chg) - Quality Assurance Program Guide, US Department of Energy, 2013

[Principles PL | 2013-1](https://www.wano.info/wp-content/uploads/2024/07/WANO-PL-2013-1-Pocketbook-English.pdf), Traits of a Healthy Nuclear Safety Culture, WANO, 2013

[TECDOC-1756](https://www-pub.iaea.org/MTCD/Publications/PDF/TE-1756_web.pdf), Root Cause Analysis Following an Event at a Nuclear Installation: Reference Manual, IAEA, 2015

[DOE G 413.3-2](https://www.directives.doe.gov/directives-documents/400-series/0413.3-EGuide-02-admchg1), Chg 1 (Admin Chg) - Quality Assurance Guide for Project Management, US Department of Energy, 2015

[ASME STP-NU-061-1](https://shop.standards.ie/en-ie/standards/asme-stp-nu-061-1-2015-138735_saig_asme_asme_297549/), Comprehensive evaluation of the nsq-100 nuclear safety and quality management system requirements, ASME, 2015

[ISO 14001](https://www.iso.org/standard/60857.html), Environmental management systems - requirements with guidance for use, ISO, 2015

[DOE M 441.1-1](https://www.directives.doe.gov/directives-documents/400-series/0441.1-DManual-1_chg1-admchg), Chg 1 (Admin Chg) - Nuclear Material Packaging, US Department of Energy, 2016

[SSR-2/1 Safety of nuclear power plants](https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1715web-46541668.pdf), Design – Specific safety requirements, IAEA, 2016.

[GSR Part 2](https://gnssn.iaea.org/CSN/Relevant%20Documents/Safety%20Requirements/English/GSR%20Part%202.pdf), General safety requirements – Leadership and management for safety, IAEA, 2016

[DOE-STD-1189-2016](https://www.standards.doe.gov/standards-documents/1100/1189-astd-2016), Integration of Safety into the Design Process, US Department of Energy, 2016

[IATF 16949](https://www.aiag.org/expertise-areas/quality/iatf-16949-2016), Quality management system requirements for automotive production and relevant service parts organizations, AIAG, 2016

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[AS9100](https://iaqg.org/standard/9100-qms-requirements-for-aviation-space-and-defense-organizations/), Quality Management Systems – Requirements for Aviation, Space and Defense Organizations, IAQG, 2016

[NP-T-3.21](https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1725_web.pdf), Procurement engineering and supply chain guidelines in support of operation and maintenance of nuclear facilities, IAEA, 2016

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[REGULATORY GUIDE 1.164](https://www.nrc.gov/docs/ML1704/ML17041A206.pdf), Dedication of Commercial-Grade Items for Use in Nuclear Power Plants, U.S. Nuclear regulatory commission, 2017

[SSG-50](https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1805_web.pdf), Operating Experience Feedback for Nuclear Installations, Specific Safety Guide, IAEA, 2018

[ISO 31000](https://www.iso.org/standard/65694.html), Risk management – Guidelines, ISO, 2018

[ISO 19011](https://www.iso.org/standard/70017.html), Guidelines for auditing management systems, ISO, 2018

[Def Stan 05-135 Part 2](https://edstar.eda.europa.eu/Standards/Details/b573f523-ebc7-4019-83be-b73122828e89), Avoidance of Counterfeit Materiel, UK Defence Standardization, 2019

[NP-T-3.26](https://www-pub.iaea.org/MTCD/Publications/PDF/P1817_web.pdf), Managing Counterfeit and Fraudulent Items in the Nuclear Industry, IAEA, 2019

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[NG‑T‑1.6](https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1868E_web.pdf), Management of nuclear power plant projects, IAEA, 2020

[TECDOC-1910](https://www-pub.iaea.org/MTCD/Publications/PDF/TE-1910_web.pdf), Quality assurance and quality control in nuclear facilities and activities good practices and lessons learned, IAEA, 2020

[Guide de l'ASN n°34](https://www.asn.fr/reglementation/guides-de-l-asnr/guide-de-l-asn-n-34-mise-en-oeuvre-des-exigences-reglementaires-applicables-aux-operations-de-transport-interne), Implementation of regulatory requirements applicable to internal transport operations, ASN, 2021

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[DOE M 435.1-1](https://www.directives.doe.gov/directives-documents/400-series/0435.1-DManual-1-chg3-ltdchg-1), Chg 3 (LtdChg) - Radioactive Waste Management Manual, US Department of Energy, 2021

[MIL-STD-882E](https://safety.army.mil/Portals/0/Documents/ON-DUTY/SYSTEMSAFETY/Standard/MIL-STD-882E-change-1.pdf), System Safety, Standard Practice, US DoD, 2023

[DOE O 426.2A](https://www.directives.doe.gov/directives-documents/400-series/0426-2-border-a-chg1-admchg), Chg 1 (AdminChg), Personnel Selection, Training, Qualification, and Certification Requirements for DOE Nuclear Facilities, US Department of Energy, 2024

[DOE O 205.1D](https://www.directives.doe.gov/directives-documents/200-series/0205-1d-border), Department of Energy Cybersecurity Program, US Department of Energy, 2024

[NRC Regulations Title 10](https://www.nrc.gov/reading-rm/doc-collections/cfr/index.html), Code of Federal Regulations, USNRC, 2025

[TE-1740](https://www-pub.iaea.org/MTCD/Publications/PDF/TE-2082web.pdf), Use of a Graded Approach in the Application of Systematic Approach to Training for Facilities and Activities, IAEA, 2025

Many [ISO](https://www.iso.org/home.html) standards are created in dozens of subjects such as:

Nuclear energy, nuclear technologies, radiation protection, reactor technology, radioactivity measurements, protection against ionizing radiation, nuclear installations, processes and technologies, measurement of radioactivity in the environment, radiation protection in medical environments.

The standards of the series ISO 10001 to ISO 10019 are guidelines for quality management systems and will help you find many answers (cf. ISO 9001:2015, annex B).

More than 28,000 standards (in English and other languages) are available on the [Public.Resource.Org](https://law.resource.org/pub/in/manifest.in.html) site.

The [Oxebridge Q001](https://www.pqbweb.eu/page-oxebridge-q001-standard.php) is a user-friendly, open sources remix of ISO 9001:2015.

Some nuclear-related web sites:

[AFCEN](https://www.afcen.com/en/) - Association Française pour les règles de Conception, de Construction et de surveillance en Exploitation des chaudières électroNucléaires (French Association for the Rules of Design, Construction and Monitoring in Operation of Electro-Nuclear Boilers)

[ANSI](https://webstore.ansi.org/) – American National Standards Institute

[ASNR](https://www.french-nuclear-safety.fr/) - **Autorité de sûreté nucléaire et de radioprotection (The Nuclear Safety and Radiation Protection Authority), France**

[ASME](https://www.asme.org/) - American Society of Mechanical Engineers

[BSI](https://www.bsigroup.com/en-GB/) – British Standards Institute

[CQI](https://www.quality.org/) – Chartered Quality Institute

[EDSTAR](https://edstar.eda.europa.eu/) - European Defence Standards Reference System

[ENSREG](https://www.ensreg.eu/) - European Nuclear Safety Regulators Group

[EPRI](https://www.epri.com/) - Electric Power Research Institute

[EURATOM](https://ue.delegfrance.org/la-communaute-europeenne-de-l#:~:text=Le%2025%20mars%201957%2C%20le,ont%20adh%C3%A9r%C3%A9%20au%20Trait%C3%A9%20Euratom.) - European Atomic Energy Community

[FAA](https://www.faa.gov/) - Federal Aviation Administration

[IAEA](https://www.iaea.org/) - International Atomic Energy Agency

[IAQG](https://iaqg.org/) - International Aerospace Quality Group

[ICSI](https://www.icsi-eu.org/en) – Institute for an Industrial Safety Culture

[INPO](https://www.inpo.info/) - Institute of Nuclear Power Operations

[NEA](https://www.oecd-nea.org/) – Nuclear Energy Agency

[NEI](https://www.nei.org/home) - Nuclear Energy Institute

[NI](https://nuclearinst.com/homepage) – Nuclear Institute

[NIA](https://www.niauk.org/) - Nuclear Industries Association

[NQSA](https://www.nqsa.org/) - Nuclear Quality Standard Association

[NUCLEAREUROPE](https://www.nucleareurope.eu/) – Nuclear Europe

[ONR](https://www.onr.org.uk/) – Office for Nuclear Regulation

[USDOE](https://www.energy.gov/) - US Department of Energy

[USNRC](https://www.nrc.gov/) – United States Nuclear Regulatory Commission

[WANO](https://www.wano.info/) - World Association of Nuclear Operators

[WENRA](https://www.wenra.eu/) - Western European Nuclear Regulators Association

[WINS](https://www.wins.org/) - World Institute for Nuclear Safety

[WNA](https://world-nuclear.org/) – World Nuclear Association

**2.2 Definitions**

**The beginning of wisdom is the definition of terms. Socrates**

Specific quality and nuclear safety terms:

CFS: *counterfeit, fraudulent or suspect (item)*

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*

Customer: *anyone who receives a product*

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

Documented information: *any support allowing the treatment of information*

Effectiveness: *capacity to realize planned activities with minimum effort*

Efficiency: *financial relationship between achieved results and used resources*

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

Graded approach: *activities employed to ensure that the application of requirements is commensurate with nuclear safety significance*

ITNS: *important to nuclear safety*

Indicator: *value of a parameter*, *associated with an objective, allowing the objective measure of its effectiveness*

Management system: *set of processes allowing objectives to be achieved*

Nonconformity: *non-fulfillment of a specified requirement*

Nuclear safety: *achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation risks (IAEA Safety glossary)*

Organization (company): *a structure that satisfies a need*

Process: *activities that transform inputs into outputs*

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*

QSMS: *quality and safety management system*

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

Requirement: *explicit or implicit* *need or expectation*

**Risk**: likelihood of occurrence of a threat or an opportunity

Root cause analysis (RCA): *method of problem solving used for identifying the root causes of faults or problems*

Safety culture: *protection and safety issues receive the attention warranted by their significance as an overriding priority*

Stakeholder: *person, group or company affected by the impacts of an organization*

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

In the terminology of quality and safety 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 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 use of ISO 9000, ISO 19443 and IAEA Safety glossary 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.*

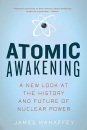
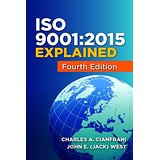
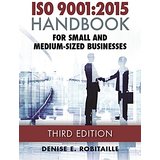
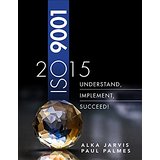
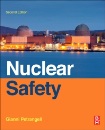
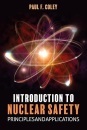
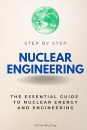
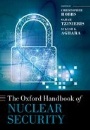
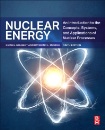
*Remark 3: documented information is any information that we must maintain (procedure*procédure*) or retain (record*G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif*).*

For other definitions, comments, explanations and interpretations that you don’t find in this module and in [annex 06](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php), you can consult: G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif

* IAEA [Safety glossary](https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1830_web.pdf) (2018)
* ISO [Online Browsing platform](https://www.iso.org/obp/ui#home) (OBP)
* IEC [Electropedia](http://www.electropedia.org/)
* [ISO 9000](https://www.iso.org/standard/45481.html): 2015 - Quality management systems. Fundamentals and vocabulary, (ISO, 2015)

**2.3 Books**

Books for further reading on quality and nuclear safety:

* [](http://www.amazon.com/Quality-Is-Free-Certain-Business/dp/0070145121) Philip Crosby, [Quality is free; the Art of Making Quality Certain](http://www.amazon.com/Quality-Is-Free-Certain-Business/dp/0070145121), McGraw-Hill, 1979
* Joseph Juran, Management of Quality, McGraw-Hill, 1981
* [](http://www.amazon.com/What-Total-Quality-Control-Management/dp/013952441X) Kaoru Ishikawa, [What is Total Quality Control, The Japanese Way](http://www.amazon.com/What-Total-Quality-Control-Management/dp/013952441X), Prentice-Hall, 1981
* [](http://www.amazon.com/Out-Crisis-W-Edwards-Deming/dp/0262541157) Edwards Deming, [Out of the Crisis](http://www.amazon.com/Out-Crisis-W-Edwards-Deming/dp/0262541157), MIT Press, 1982
* [](http://www.amazon.com/The-Goal-Process-Ongoing-Improvement/dp/0884270610) Eliyahu Goldratt, Jeff Cox, [The Goal, A Process of Ongoing Improvement](http://www.amazon.com/The-Goal-Process-Ongoing-Improvement/dp/0884270610), North River Press, 1984
* [](http://www.amazon.com/Kaizen-The-Japans-Competitive-Success/dp/007554332X) Masaaki Imai, [KAIZEN, The Key to Japan’s Competitive Success](http://www.amazon.com/Kaizen-The-Japans-Competitive-Success/dp/007554332X), McGraw-Hill, 1986
* [](http://www.amazon.com/Poor-Quality-Cost-Implementing-Understanding-Reliability/dp/0824777433/ref=sr_1_1?s=books&ie=UTF8&qid=1411381319&sr=1-1&keywords=Poor-Quality+Cost) James Harrington, [Poor-Quality Cost](http://www.amazon.com/Poor-Quality-Cost-Implementing-Understanding-Reliability/dp/0824777433/ref=sr_1_1?s=books&ie=UTF8&qid=1411381319&sr=1-1&keywords=Poor-Quality+Cost), Dekker, 1987
* [](http://www.amazon.com/Quality-Control-Dummies-Larry-Webber/dp/0470069090) Larry Webber, Michael Wallace, [Quality Control for Dummies](http://www.amazon.com/Quality-Control-Dummies-Larry-Webber/dp/0470069090), Wiley, 2007
*  James Mahaffey, [Atomic Awakening](https://www.amazon.com/Atomic-Awakening-History-Future-Nuclear/dp/1605981273/ref=pd_bxgy_d_sccl_1/137-1660198-4865827?pd_rd_w=kT2xh&content-id=amzn1.sym.dcf559c6-d374-405e-a13e-133e852d81e1&pf_rd_p=dcf559c6-d374-405e-a13e-133e852d81e1&pf_rd_r=5X13P76WMSWDEDQKH9C3&pd_rd_wg=1i1Ru&pd_rd_r=46094093-2140-477b-b72f-8062a9579697&pd_rd_i=1605981273&psc=1): A New Look At The History And Future Of Nuclear Power,
* Jan Gillet, [Implementing Iso 9001:2015](https://www.amazon.com/Implementing-Iso-9001-customers-management/dp/1908984503/ref=sr_1_2?ie=UTF8&qid=1468668018&sr=8-2&keywords=iso+9001+2015): Thrill your customers and transform your cost base with the new gold standard for business management, Infinite Ideas, 2015
* Craig Cochran, [ISO 9001:2015 in Plain English](https://www.amazon.com/ISO-9001-2015-Plain-English/dp/1932828729/ref=sr_1_1?ie=UTF8&qid=1468668018&sr=8-1&keywords=iso+9001+2015), Paton Professional, 2015
* Charles Cianfrani, John West, [ISO 9001:2015 Explained](https://www.amazon.com/ISO-9001-2015-Explained-Fourth/dp/0873899016/ref=tmm_hrd_swatch_0?_encoding=UTF8&qid=1468668018&sr=8-7), ASQ Quality Press, 2015
* Denise Robitaille, [ISO 9001:2015 Handbook for Small and Medium-Sized Businesses](https://www.amazon.com/ISO-9001-Handbook-Medium-Sized-Businesses/dp/0873899059/ref=sr_1_9?ie=UTF8&qid=1468668018&sr=8-9&keywords=iso+9001+2015), Quality Press, 2016
*  Alka Jarvis, Paul Palmes,[ISO 9001: 2015: Understand, Implement, Succeed!](https://www.amazon.com/ISO-9001-Understand-Implement-Succeed-ebook/dp/B019PFBM34/ref=sr_1_14?ie=UTF8&qid=1468668018&sr=8-14&keywords=iso+9001+2015), Prentice hall, 2016
*  Christopher Paris, [Surviving ISO 9001: 2015](https://www.oxebridge.com/emma/surviving-iso-90012015-published/), Oxebridge Quality Press, 2016
*  Gianni Petrangeli, [Nuclear Safety](https://shop.elsevier.com/books/nuclear-safety/petrangeli/978-0-12-818326-7), Elsevier, 2019
*  Colin Tucker, [How to Drive a Nuclear Reactor](https://www.amazon.com/dp/3030338754/ref=sspa_dk_detail_0?psc=1&pd_rd_i=3030338754&pd_rd_w=LF8rM&content-id=amzn1.sym.7446a9d1-25fe-4460-b135-a60336bad2c9&pf_rd_p=7446a9d1-25fe-4460-b135-a60336bad2c9&pf_rd_r=2S29NTHBVMXBZRZ9XT8G&pd_rd_wg=2j877&pd_rd_r=373e3a7b-a1da-4749-afab-6ee704d0e765&s=books&sp_csd=d2lkZ2V0TmFtZT1zcF9kZXRhaWw), Popular Science, 2020
* Jean Couturier, [Éléments de sûreté nucléaire](chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https:/www.irsn.fr/sites/default/files/documents/larecherche/publications-documentation/collection-ouvrages-irsn/livre-libman_PDF%20web%20couleur.pdf) - Les réacteurs à eau sous pression, (Nuclear Safety Elements - Pressurized Water Reactors), Collection sciences et techniques, 2020 (only in French)
*  Paul Coley, [Introduction to Nuclear Safety](https://www.amazon.com/Introduction-Nuclear-Safety-author/dp/1849955387), Whittles Publishing, 2024
*  John Murray, [Nuclear Engineering Step by Step](https://www.amazon.com/Nuclear-Engineering-Step-Essential-Subject/dp/B0DL682RGJ/ref=tmm_hrd_swatch_0): The Essential Guide to Nuclear Energy and Engineering, Step By Step Subject Guides, 2024
*  Christopher Hobbs et al, [The Oxford Handbook of Nuclear Security](https://academic.oup.com/edited-volume/46401), Oxford University Press, 2024
*  Patrick Delahaye, [ISO 19443 : Le renouveau du nucléaire français](https://www.amazon.fr/ISO-19443-renouveau-nucl%C3%A9aire-fran%C3%A7ais/dp/2124658808) (ISO 19443: The revival of French nuclear power), AFNOR, 2024 (only in French)
*  Malcolm Joyce, [Nuclear Engineering](https://shop.elsevier.com/books/nuclear-engineering/joyce/978-0-443-31400-1): A Conceptual Introduction to Nuclear Power, Elsevier, 2025
*  Raymond Murray, Keith Holbert, [Nuclear Energy](https://shop.elsevier.com/books/nuclear-energy/murray/978-0-443-19031-5): An Introduction to the Concepts, Systems, and Applications of Nuclear Processes, Elsevier, 2025

**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

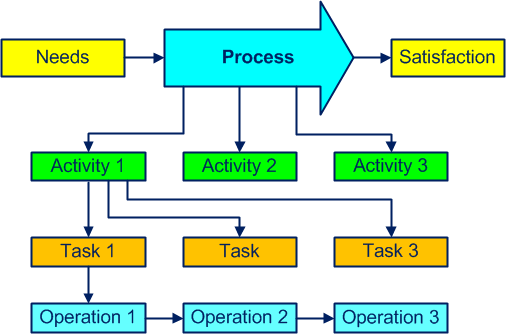
A process is, among other things, determined by its:

* title and type
* purpose (why?)
* beneficiary (for whom?)
* scope and activities
* initiators
* documentation
* 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](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php)). G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif

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

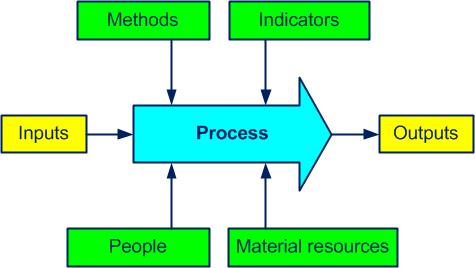
The components of a process are shown in figure 3-1: 



*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 documents? (outputs)
* how, which inspections? (methods)
* what is the level of performance? (indicators)
* who, with what competence? (people)
* with what, which machines, which equipment? (material resources)



*Figure 3-2. Some elements of a process*

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

You can find some examples of process sheets in the document pack [D 02](https://www.pqbweb.eu/document-d-02-processes-for-your-operational-management-system-set-of-documents.php) and a list of processes in [annex 03](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php). G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif

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

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

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

**3.1.1 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 of all the realization and support processes.

The following processes can be part of this family:

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

**3.1.2 Realization processes**

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

They are mainly:

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

**3.1.3 Support processes**

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

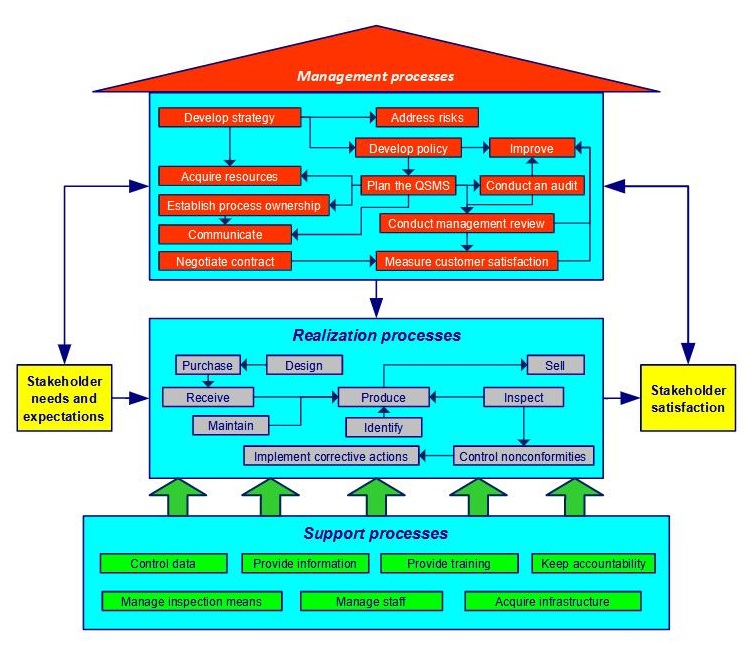
The support processes are often:

* control data
* provide information
* acquire and maintain infrastructure
* provide training
* manage inspection means
* manage staff
* keep accountability

**3.2 Process mapping**

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

The 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.

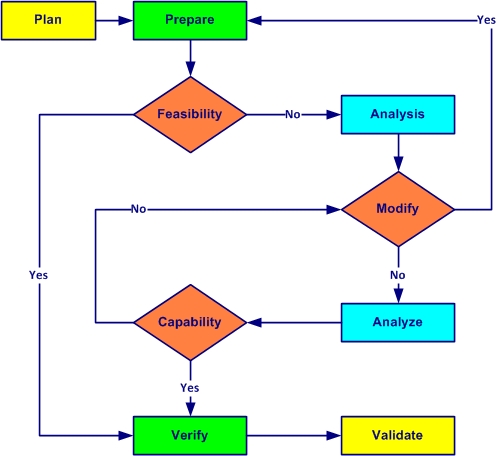
Mapping, among other things, allows you to:

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

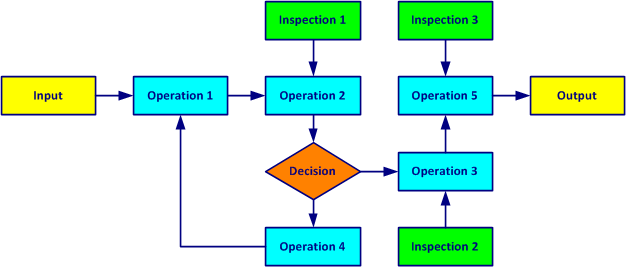
To obtain a clearer picture, you can simplify by using a total of about 15 core processes. A core process can contain several sub-processes: for example, the process "develop the QSMS" can involve: 

* develop strategy
* develop policy
* address risks
* plan the QSMS
* 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](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php)). G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif

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



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

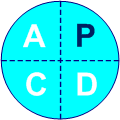
The process approach:

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

The SIPOC tool helps describe any process, cf. [annex 05](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php). G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif

**4 Context of the organization **

**4.1 The organization and its context** *(requirements* [*1 to 4*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#4.1)*)*

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

To successfully implement a quality and safety 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:
  + external issues such as the environment like:
    - social
    - regulatory
    - economic
    - technology
  + internal issues like:
    - specific aspects of the corporate culture:
      * vision
      * rationale, purpose and mission
      * core values
    - staff
    - products and services
    - infrastructure
    - nuclear safety risks and impacts on its activities
* monitor and review regularly any information relating to external and internal issues
* analyze the factors that may influence the achievement of business objectives
* determine whether climate change is a relevant issue

The SWOT and PESTEL analyses can be useful for relevant analysis of business context (cf. [annex 07](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php)). G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif

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

***Good practices***

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

***Bad practices***

* *the issues of the context of the company, such as the competitive environment, are not taken into account*
* *in some cases, the corporate culture is not taken into account*
* *risk analysis does not take into account strategic issues*
* *no clear link between the SWOT analysis and the actions undertaken*

**4.2 Needs and expectations of stakeholders** *(requirements* [*5 to 7*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#4.2)*)*

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

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

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

A list of stakeholders is created by a multidisciplinary team. Every stakeholder is determined by its level of influence and control. Priority is given to stakeholders with great influence and poor control.

Take into account that relevant stakeholders can have requirements related to climate change.

***True story***

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

**

*“A coffee”............................7 €*

*“A coffee, please”.............4,25 €*

*“Hello, a coffee, please”....1,40 €*

Anticipating the reasonable and relevant needs and expectations of stakeholders involves:

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

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

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

***Good practices***

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

***Bad practices***

* *statutory and regulatory requirements are not taken into account*
* *the delivery time is not validated by the customer*
* *the expectations of stakeholders are not determined*
* *the list of stakeholders does not contain their area of activity*

**4.3 Scope of the quality and safety management system** *(requirements* [*8 to 14*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#4.3)*)*

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

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

The specific context of the company is taken into account to determine the scope of the QSMS, including:

* issues (cf. sub-clause 4.1)
* ITNS products and services
* nuclear safety culture
* environment:
  + social
  + financial
  + technology
  + economic
* requirements of stakeholders (cf. sub-clause 4.2)
* entire supply chain
* outsourced processes

***Good practices***

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

***Bad practices***

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

**4.4 Quality and safety management system and its processes** *(requirements* [*15 to 27*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#4.4)*)*

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

The requirements of the ISO 19443 standard include:

* management through quality and
* the control of business processes

To do this:

* the quality and safety management system is:
  + established
  + documented (a simple and sufficient documentation system is set up)
  + implemented and
  + continually improved
* the quality policy, objectives, resources and the work environment are determined
* risks are determined and actions to reduce them are established (cf. sub-clause 6.1)
* the core necessary QSMS processes are controlled:
  + corresponding resources are ensured
  + the inputs and outputs are determined
  + the necessary information is available
  + owners are appointed (responsibilities and authorities defined)
  + sequences and interactions are determined
  + each process is measured and monitored (established criteria)
  + objectives are set and performance indicators analyzed
  + process performance is evaluated
  + necessary changes are implemented to achieve the expected results
  + actions to obtain the continual improvement of processes are established
* audits and reviews of the QSMS are performed regularly
* the necessary minimum ("as much as needed") of documentation on the processes is maintained and retained (procédureG:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif)

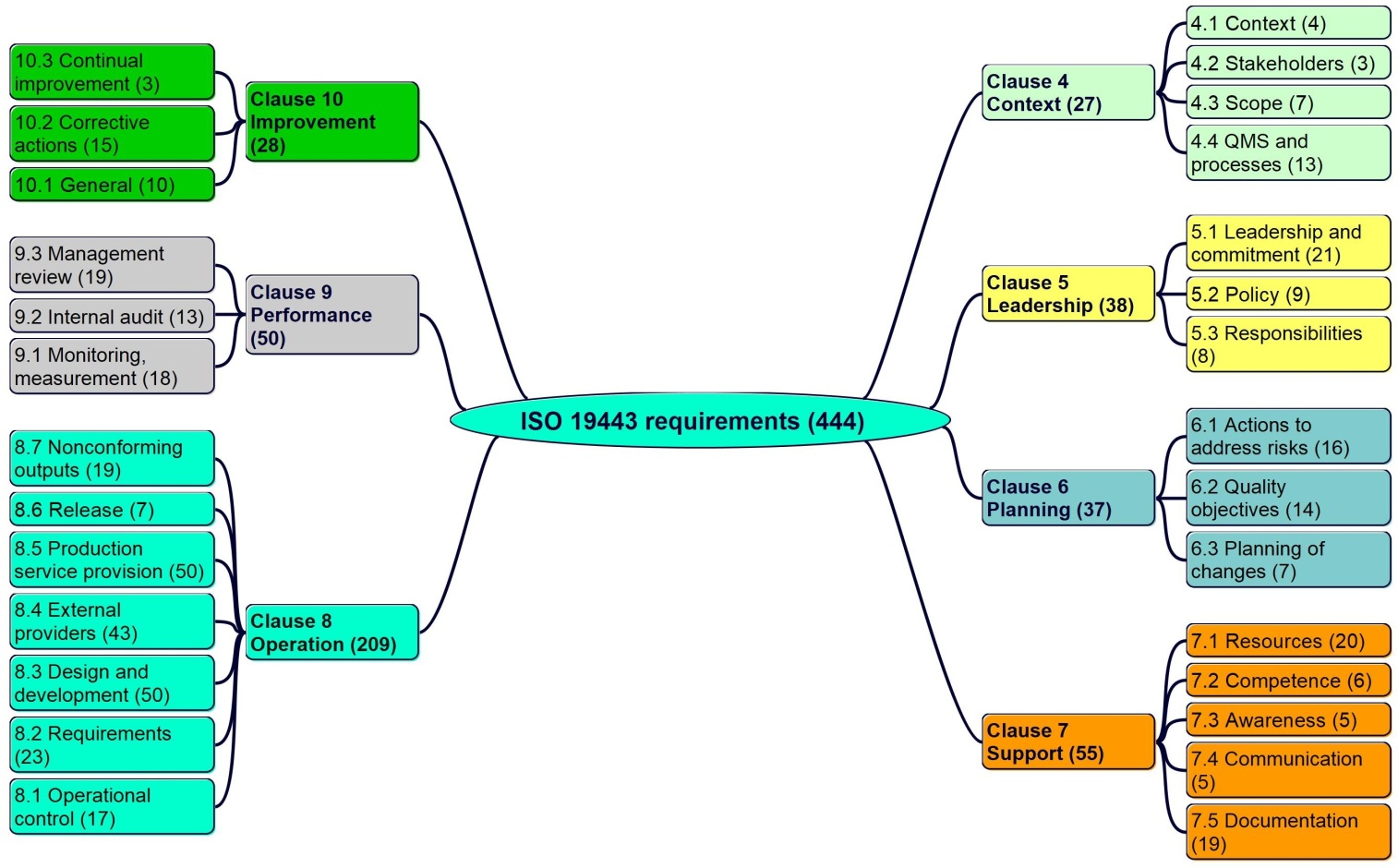
The quality and safety manual (or a quality plan) is a requirement of ISO 19443 version 2018 (cf. [sub-clause 4.4.3](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#4.4)). It is a possible method to present the company, its QSMS, its procedures and processes (cf. [annex 08](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php)) and a description of how the requirements of the standard ISO 19443 are met. G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif

The ISO guide “[The integrated use of management system standards](https://www.iso.org/publication/PUB100435.html)” 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](https://www.pqbweb.eu/document-d-12-quality-tools-for-your-operational-management-system-set-of-documents.php)
* having all procedures written by the quality and safety 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 owners
* 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 ISO 19443 standard are shown in figures 4-1:



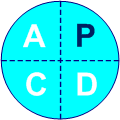
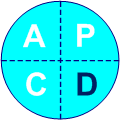
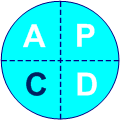
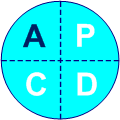
*Figure 4-1. The requirements of the ISO 19443 version 2018 standard*

***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 QSMS*
* *top management regularly monitors the objectives and action plans*
* *the purpose of each process is clearly defined*
* *process owners are members of the management team*

***Bad practices***

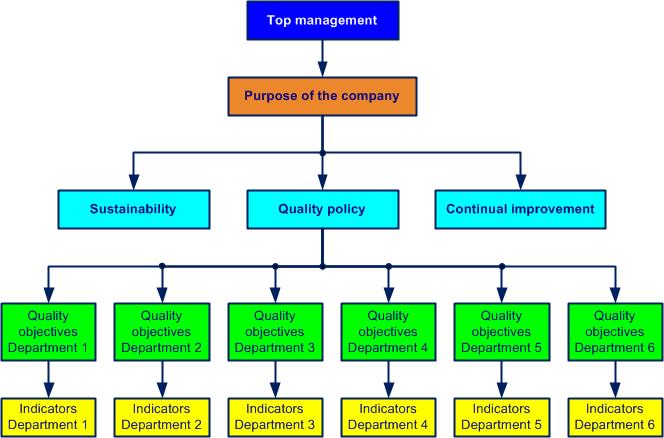
* *some process outputs are not set correctly (customers not considered)*
* *process efficiency criteria are not established*
* *the process owners are not formalized*
* *outsourced processes are not determined*
* *control of outsourced services is not described*
* *sequences and interactions of certain processes are not determined*
* *criteria and methods for ensuring effective processes are not determined*
* *monitoring the effectiveness of certain processes is not established*
* *the QSMS resources do not allow achievement of quality objectives*
* *the QSMS is not updated (new processes are not determined)*
* *the threats and weaknesses identified in the SWOT analysis remain without actions*

**5 Leadership    **

**5.1 Leadership and commitment** *(requirements* [*28 to 48*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#5.1)*)*

### When you sweep the stairs, you start at the top. Romanian proverb

Top management demonstrates leadership (fully assuming its responsibility for the performance of the QSMS) by defining the purpose (the reason to exist) of the company and ensuring the sustainability, quality policy and continual improvement of the quality and safety management system (cf. figure 5-1). Quality objectives are deployed in each department and indicators are implemented to measure process performance.



*Figure 5-1. Deployment of objectives*

**Tell me and I’ll remember for an hour; show me and I’ll remember for a day; but let me do it and I’ll remember forever. Chinese Proverb**

Leadership: *ability to inspire and lead a team to achieve set goals*

Top management at its highest level commits to:

* define and promote the quality policy, which follows from the purpose, strategic direction and context of the company
* communicate the importance of:
  + integrating within internal processes the requirements of:
    - the QSMS
    - customers
    - other stakeholders
    - regulations
  + having a performing quality and safety management system (QSMS)
  + meeting the requirements of the quality and safety management system
* ensure the availability of manpower and technical resources to achieve the objectives
* do everything so that the established objectives are met (lead by example on the field)
* involve staff to achieve expected results
* fully support the process approach and continual improvement
* define, communicate and support the responsibilities and authorities at all levels
* ensure that nuclear safety is:
  + taken into account in decision making
  + not compromised by any decision taken

By applying the principle "customer focus" (ISO 9000: 2015, sub-clause 2.3) top management is committed to:

* determining and ensuring that:
* customer and
* applicable statutory and regulatory requirements are met
* determining and treating upstream risks and opportunities that can have an influence on:
* conformity of products and services
* the ability to improve customer satisfaction
* providing the customer, at each delivery, with conforming products and services
* continually increasing the level of customer satisfaction

**Safety culture is how people behave when no one is watching. Patrick Delahaye**

There are some unanimously accepted principles of a strong nuclear safety culture:

* everyone is personally accountable for nuclear safety (sub-clause 5.1)
* leaders demonstrate a commitment to safety (sub-clause 5.1)
* decision-making reflects safety first (sub-clause 5.1)
* a high level of trust permeates the organization (sub-clause 5.1)
* responsibilities and authorities are fully assumed (sub-clause 5.3)
* professional knowledge and skills are highly valued (sub-clause 7.2)
* a questioning and learning attitude is cultivated (sub-clause 7.3)
* open communication conveys the importance of safety (sub-clause 7.4)
* personnel feel free to raise safety concerns (sub-clause 7.4)
* use of suitable documentation (sub-clause 7.5)
* work planning includes activities such that safety is maintained (sub-clause 8.1)
* nuclear technology is recognized as special and unique (sub-clause 8.2)
* lessons learned (sub-clause 10.1)
* problem identification and evaluation are promptly resolved (sub-clause 10.2)
* nuclear safety undergoes constant examination (sub-clause 10.3)

More details are present in the IAEA report [75-INSAG-4](https://www-pub.iaea.org/MTCD/Publications/PDF/Pub882_web.pdf), “Safety culture - safety series - A report by the International Nuclear Safety Advisory Group”, including list of questions to qualify the effectiveness of the deployment of safety culture.

***True story***

*"In a typical company, if you have a meeting, no matter how important, there is always a part that is not represented: the customer. It is very easy within the company to forget the customer." Jeff Bezos.*

*To address this concern, it became customary to place an empty chair at every meeting.*

***Good practices***

* *top management assumes its responsibility in communicating the importance of having an effective quality and safety management system to sustain the company*
* *the director’s declaration of commitment is shown in a few key locations*
* *the commitments of top management on continual improvement are widely diffused*
* *nuclear safety is taken into account in every decision making*
* *every event, even minor, is deeply scrutinized*
* *criticism is accepted by top management*

***Bad practices***

* *top management commitment does not include objectives*
* *communication of customer requirements is not ensured in the workshop*
* *some indicators are difficult to interpret*
* *some indicators are not consistent with the objectives*
* *overconfident based on past performance*
* *refusal to react to minor events*
* *criticism is hardly accepted*
* *lessons learned are not part of the nuclear safety culture*

**5.2 Policy** *(requirements* [*49 to 57*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#5.2)*)*

**The worst policy is the lack of policy**

The quality policy is written and signed by the director. It:

* is adapted to the purpose, culture and context of the company
* provides the framework for defining and reviewing quality objectives
* is adequate to the nature and extent of risks in the company
* includes a commitment to:
  + continual improvement of performance
  + meet statutory and other requirements
  + ensure that nuclear safety is not compromised by other priorities
* is communicated, understood and applied at all levels
* is reviewed in the context of continual improvement (cf. management review, sub-clause 9.3)
* includes appropriate nuclear safety objectives
* is available to stakeholders

The proof of top management's commitment to a high-performance QSMS is the availability of the quality policy in the form of a document posted in a few key places. enregistrement

The quality policy is maintained as a procedure. procédure (politique)

The quality policy is often accompanied by a charter of values, such as respect, honesty, benevolence, transparency and innovation.

***Good practices***

* *the quality policy matches the available resources and associated objectives*
* *methods of internal and external communication are presented in the quality and manual*
* *the quality policy is shown at a few key locations*
* *nuclear safety considerations are included in the quality policy*
* *the quality policy is communicated to external providers*
* *the quality policy includes the commitment to continual improvement*
* *the quality policy takes into account all the specifics related to the corporate culture*

***Bad practices***

* *the quality policy is not up-to-date*
* *the quality policy is undated*
* *the quality policy is not signed by the director*
* *the quality policy lacks ways to increase customer satisfaction*
* *the quality policy is not posted outside the office of the director*
* *communication of the quality policy to stakeholders is not defined*

**5.3 Roles, responsibilities and authorities** *(requirements* [*58 to 65*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#5.3)*)*

##### **Responsibility cannot be shared. Robert Heinlein**

Top management defines the responsibilities and authorities for the implementation and improvement of the quality and safety management system. Information on these different roles is freely available internally (organizational chart).

The person in charge of that job is appointed to:

* ensure that the quality and safety management system is established, implemented and maintained in accordance with the requirements of the ISO 19443 standard
* involve staff so that process quality objectives are met
* report regularly on the performance of the QSMS to top management
* promote the needs and expectations of customers to all staff
* channeling proposed improvements
* encourage innovations
* monitor change control

This person is part of the organization’s management and:

* has responsibilities and authorities clearly defined (job description, organizational chart)
* has boundaries clearly established
* has skills and knowledge related to the position demonstrated
* addresses impartially and directly to top management on relevant topics
* update job descriptions over time
* is responsible for managing issues relating to nuclear safety and quality

ISO/TS 9002 reminds that “The overall responsibility and accountability for the quality and safety management system remains with top management.”

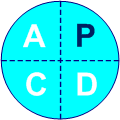
 Minute of relaxation. Cf. joke “[Is Hell exothermic or endothermic?](http://www.pqbweb.eu/admin/pages.php?act=see&id=31#hell)”.

***Good practices***

* *job descriptions for all positions (including management) are available on the intranet*
* *QSMS animation, coordination and training missions are explicitly defined*
* *a culture of self-questioning is present at all levels*

***Bad practices***

* *managers’ roles and missions are not well known or understood in the workshop*
* *the quality and safety manager job description is not updated*
* *responsibilities and authorities of the quality and safety manager are not recorded*
* *the authority to stop production is not included in the quality and safety manager job description*
* *self-questioning is not used at all*

**6. Planning** 

**6.1 Actions to address risks and opportunities** *(requirements* [*66 to 81*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#6.1)*)*

### There is no decision that does not involve risk. Peter Barge

### A risk can have negative impacts (known as threats) or positive impacts (known as opportunities).

### Often the risk is assimilated to a hazard and commonly used in the place of threat.

### To properly plan its quality and safety management system, top management takes into account the:

### list of external and internal issues (cf. sub-clause 4.1)

### determined requirements of stakeholders (cf. sub-clause 4.2)

* scope of the quality and safety management system (cf. sub-clause 4.3)
* processes needed for the quality and safety management system (cf. sub-clause 4.4)
* roles, responsibilities and authorities within the company (cf. sub-clause 5.3)
* improvement opportunities (cf. sub-clause 10.3)

Any risk that can disrupt the normal activities of the company is:

* determined
* analyzed
* evaluated and
* appropriate actions are applied to prevent or reduce undesirable effects

Risk-based thinking allows us to prepare the action to take if an output element of the process does not meet a requirement. In other words, we can be ready in case something goes wrong.

Any opportunity that may increase desirable effects on the quality and safety management system is backed with actions for continual improvement.

The nature of the action is proportionate to the potential impact of risks and opportunities. Several examples of risks are listed in [annex 09](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php). G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif

##### **Actions speak louder than words. English proverb**

An example of the risk classification level of a process is shown in [annex 10](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php). Each risk is classified in a table with impact and likelihood of occurrence ratings. The level of risk may be acceptable, minor non-acceptable or major non-acceptable. Our goal is not to have zero risk (it does not exist) but to create conditions for working with an acceptable level of risk. G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif

Action planning to reduce negative impacts and enhance beneficial impacts often includes setting up:

* quality objectives and indicators
* inputs:
  + support (cf. clause 7)
  + operation (cf. clause 8)
  + performance evaluation (cf. clause 9)
  + improvement (cf. clause 10)
* a method for evaluating the effectiveness of actions (periodical reviews)

An appropriate methodology is chosen to:

* anticipate and evaluate potential risks:
  + estimate the consequences
  + predict the frequency
* classify risks:
  + into acceptable or not acceptable
  + that can be eliminated or controlled (turning them into acceptable)
* ensure consistency between the risk assessment and the objectives of the quality policy

More details of a risk analysis are present in Annex B, [ISO/TR 4450](https://www.iso.org/standard/79983.html).

ITNS (important to nuclear safety) products and services are broken down into items and activities.

Items and activities, whose potential failure may threaten safety functions specified by the customer, are determined.

ITMS items and activities are retained as records and described in a procedure, cf. [annex 11](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php). G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif procédure

The application of requirements related to ITNS items and activities is graded and takes into account customer requirements (cf. sub-clause 8.4), their complexity (cf. sub-clause 7.5) and organizational aspects (cf. sub-clause 8.2.2).

More details of how to determine ITNS items and activities and an example are present in Annex C, [ISO/TR 4450](https://www.iso.org/standard/79983.html).

Actions are commensurate with the relative importance to nuclear safety and the magnitude of any risk involved.

The graded approach is recorded and described in a procedure, cf. [annex 12](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php). G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif procédure

More details of the graded approach can be found in the [TE-2082](https://www-pub.iaea.org/MTCD/Publications/PDF/TE-2082web.pdf) “Use of a Graded Approach in the Application of Systematic Approach to Training for Facilities and Activities”, IAEA, 2025.

More details of two examples for graded approach are present in Annexes E and F, [ISO/TR 4450](https://www.iso.org/standard/79983.html).

Risk-based thinking (cf. ISO 31000) is a process with several distinct activities: 

* identification (list)
* analysis (impact)
* evaluation (type and level)
* treatment (options)
* monitoring and review (effectiveness)

The Manage risks process is shown in [annex 13](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php). An example of a Risk management procedure is shown in [annex 14](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php). procédure G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif

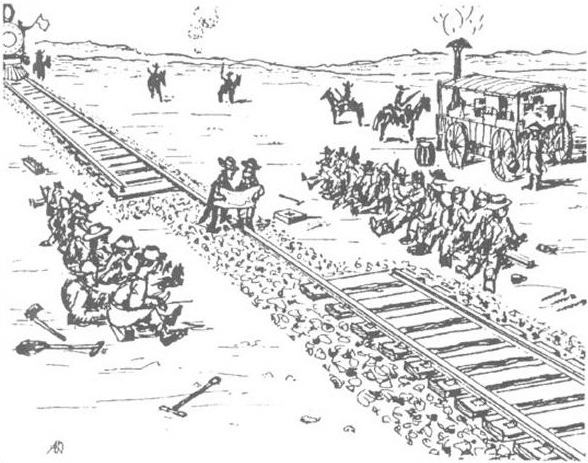
Actions to address risk (cf. [annex 15](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php)) can be summarized as several options: G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif

* avoid the risk (refuse the activity including the risk)
* accept the risk to earn an opportunity
* eliminate the source of risk
* change the likelihood of occurrence of the risk
* react to the consequences of the risk
* share the risk with other stakeholders
* maintain the residual risk (acceptable level)

The actions include, among other things:

* roles and responsibilities at all relevant levels
* the necessary resources (including training needs) and means
* anticipating future changes of a process
* the description of the actions to implement
* the deadline for completion
* the follow-up of actions
* evaluation of results

Example of an unidentified risk:



***Good practices***

* *planned changes are evaluated before they are applied*
* *the list of risks taken into account is exhaustive*
* *actions to reduce certain risks are integrated into key processes*
* *the action plan includes a column used for monitoring the effectiveness of actions*
* *the action plan takes into account the results of internal audits*
* *the list of external and internal issues is exhaustive*
* *when planning actions to address risks, the scope of the QSMS is taken into account*
* *ITNS determination is realized and documented for all products and services*
* *the graded approach is properly used for external providers*

***Bad practices***

* *the list of risks is not updated*
* *risks are not ranked by priority*
* *the risk assessment is not up-to-date*
* *threats and opportunities are not identified for certain processes*
* *some requirements of stakeholders are not taken into account when planning actions to address risks*
* *there is no planning of actions to reduce negative impacts*
* *there is no opportunity to increase the desirable effects*
* *some products are not identified as being ITNS items and activities*
* *excessive requirements due to improper grading*

**6.2 Quality objectives** *(requirements* [*82 to 95*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#6.2)*)*

**He who has no goals will not achieve them. Sun Tzu**

Quality objectives derive directly from the quality policy (cf. sub-clause 5.2). The objectives are shown to all staff through indicators displayed on one or more dashboards. The quality and safety manager (or team leader) monitors the level of indicators daily.

Quality objectives change over time and are a relevant tool for improving customer satisfaction. Quality objectives are SMART:

* Specific (and understandable)
* Measurable (when it is possible)
* Achievable (and comply with the applicable requirements)
* Realistic (adequate with the quality policy)
* Time-bound (planned in time, short and long term)

A procedure on the quality objectives is maintained. procédure

Planning to achieve the quality objectives includes:

* what will be done (what)
* the necessary resources (whom, with what)
* a deadline (until when)
* evaluation of the effectiveness of actions (level obtained)

Some examples of objectives:

* turnover growth
* customer satisfaction
* stabilization of staff
* nuclear protection of people and the environment
* prevention and mitigation of nuclear accidents
* staff competence
* improved maintenance

Some examples of indicators:

* increase in market shares in %
* new customers
* rate of customer returns
* absenteeism in %
* % of staff trained
* time frame for intervention in minutes
* machine breakdown time in minutes

***Good practices***

* *the available resources and associated objectives are in line with the quality policy*
* *quality objectives are realistic and ambitious*
* *indicators are monitored daily*
* *the dashboard is updated weekly*
* *the dashboard with all the indicators allows the daily display of key process performance*

***Bad practices***

* *a dashboard is non-existent*
* *no action is planned to achieve quality objectives*
* *no action is planned to address risks*
* *no risk reduction objectives*
* *resources to achieve certain objectives are not provided*
* *some indicators are difficult to interpret*
* *some indicators are not consistent with the objectives*
* *some objectives are not measurable*
* *some objectives are not monitored regularly*
* *the effectiveness of actions to address risks is not evaluated*
* *the objectives are not broken down into indicators*
* *the responsibility for actions to achieve the objectives is not defined*
* *there are no objectives to improve products*

**6.3 Planning of changes** *(requirements* [*96 to 102*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#6.3)*)*

**The only person who likes change is a wet baby**

Before the introduction of changes, the potential risks are determined. The risks can impact on:

* processes
* products and services
* documentation
* materials and
* parts of the QSMS

The changes in the quality and safety management system are identified and planned.

Every change takes into account the:

* necessity
* goal
* beneficial impact
* risk of potential harm
* availability of people and technical resources
* responsibilities and authorities for its implementation
* communication of changes to the persons concerned

Changes are managed in a way that does not compromise nuclear safety.

Documentation is updated on an ongoing basis.

***True story***

*In 1982, the GM plant in Fremont, California, was closed (5000 layoffs) partly because of the struggles between unions, the combative conservative management and workers who were not at all docile.*

*In 1984, Toyota created a partnership with GM and reopened the plant under the name of Nummi. The contract stipulated that the same amount of cars would be produced with half of the former staff.*

*Japanese officials put in place the "Toyota spirit", the Lean approach, trust, respect, responsibility, freedom to think, act and solve problems, simplification, war on waste, work in small teams, versatility and quality first.*

*The cost of production decreased significantly, absenteeism fell from 20 to 2%, and quality of cars rivaled those produced in Japan.*

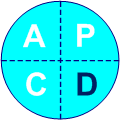
*When change is well prepared and well managed, it can work wonders! Since 2010, the plant has become a Tesla factory (electric cars).*

***Good practices***

* *changes are planned and validated before any application*
* *changes do not compromise nuclear safety*
* *changes are communicated to all persons concerned*

***Bad practices***

* *some changes are applied without planning and risk analysis of potential harm*
* *the person in charge of a change is not known to the persons concerned*
* *change is applied without a clearly established goal*

**7 Support **

**7.1 Resources** *(requirements* [*103 to 122*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#7.1)*)*

**7.1.1 General**

Top management identifies, plans and provides resources to:

* establish, implement, maintain and continually improve the quality and safety management system
* increase the satisfaction of customers and other stakeholders
* confirm its commitment to the effective functioning of the QSMS

Top management takes into account the limits of available internal resources and resorts to external providers when necessary.

Resources include:

* the staff
* infrastructure
* technology of:
  + processes
  + data processing
* natural resources
* financial resources

A review of the adequacy of resources is conducted periodically by top management.

Top management ensures that nuclear safety is not compromised during determination and provision of resources.

**7.1.2 People**

**But in the long run - and I emphasize this - no matter how good or successful you are or how clever or crafty, your business and its future are in the hands of people you hire. Akio Morita**

Top management determines, provides and helps increase the staff competence required for the proper functioning of the QSMS and key processes.

***True story***

*The story of the three stonecutters conveys a great deal. When asked about their work:*

*- the first replied that he is cutting stones for a living*

*- the second that he tries to be the best stonemason in the country*

*- while the third answered that he is building a cathedral*

*Hence the three main types of relationship to work:*

*- livelihood*

*- career*

*- vocation*

 Minute of relaxation. Cf. joke “[Gold contract](http://www.pqbweb.eu/page.php?id=31#gold)”

**7.1.3 Infrastructure**

Top management provides and maintains the infrastructure necessary for the functioning of the QSMS and processes to obtain conformity of products and services. Examples of infrastructure include:

* buildings
* equipment
* related services:
  + computer system
  + software
  + logistics

***True story***

*A piece of equipment was moved to make room for some new, bulky equipment. When scheduled maintenance was to begin on the first piece of equipment, the maintenance guy was unable to perform his activities, as the equipment was too close to the wall. He suggested creating a door in the wall to allow access to the equipment.*

*The only concern was that it was an outside wall!*

**7.1.4 Process environment**

Top management provides the environment necessary for the processes to obtain conformity of products and services. The environment is appropriate and friendly, and includes physical and psychological aspects such as:

* work organization
* happiness at work
* non-blaming approach
* safety rules
* ergonomics
* cleanliness
* temperature
* lighting
* noise

**7.1.5 Inspection resources and traceability**

**The right person, at the right place, at the right moment**

Top management will provide the personnel necessary for the proper functioning of the monitoring and measurement processes (inspection).

Staff inspecting the products and services is trained in the specific activities of the company. This training evolves with each new requirement.

The suitability of the monitoring and measuring resources takes into account the measuring range and measuring accuracy.

Records, demonstrating the suitability for use of staff performing the inspection, are retained. enregistrement

When traceability of the measurement is a requirement, the measuring equipment is:

* identified
* verified (or calibrated) at scheduled intervals
* protected against anything that could invalidate the results of measurements

Records of traceability and actions taken are retained. enregistrement

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

Calibration is checking a value found that is related to a standard, while verification is the positioning of reference points.

Records are retained on the calibration of the measuring equipment when a "house" standard was used. enregistrement

The conditions of use, handling and storage of instruments are established and adequate. Remember that these objects are often fragile, delicate and sensitive.

If a piece of measuring equipment is not conforming during its verification, an analysis is carried out to confirm or cancel the earlier results of the verification. When results are cancelled, a corrective action is implemented, both on the equipment and on the affected product.

***True story***

*How do you reduce the costs of calibration of certain equipment and, at the same time, reward the best suggestions from staff?*

*Simple solution: do not calibrate multi-meters and other small instruments annually, but always buy new ones. Each instrument bought usually has a one year warranty at least (during which time neither calibration nor verification are required).* *The purchase of these instruments is much cheaper than calibration (by an external company). The old instruments with an expired warranty (but almost always in perfect condition) are removed from the inventory and then distributed by top management to people whose work has been outstanding.*

**7.1.6 Organizational knowledge**

The knowledge required for the functioning of the QSMS and processes to achieve conformity of products and services are determined and updated regularly. The acquisition of additional knowledge is facilitated when the need for new knowledge is perceived.

The knowledge is based inter alia on:

* lessons learned
* intellectual property rights
* education received
* good practices

***Good practices***

* *the needed resources are planned and available on time*
* *the resources are in line with the quality policy*
* *the list of equipment, machines and infrastructure is updated regularly*
* *the presentation of the organization on the website is very clear and up-to-date*
* *standards and calibration instructions are codified and archived*
* *provisions of resources do not compromise nuclear safety*

***Bad practices***

* *financial resources are not unblocked on time*
* *unscheduled investment for equipment maintenance and infrastructure renewal*
* *no evidence of compliance with statutory and regulatory requirements of the working environment*
* *cleanliness of the production premises is not adapted to the process requirements*
* *the expectations of staff are not identified*
* *the quality and safety manager does not have a deputy or a substitute*

**7.2 Competence** *(requirements* [*123 to 128*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#7.2)*)*

**If you are planning for a year, sow rice; if you are planning for a decade, plant trees; if you are planning for a lifetime, educate people. Chinese proverb**

The staff and persons working under the control of the company:

* have the appropriate competence (knowledge and skills) and qualification to carry out activities that impact on risks and performance opportunities of the QSMS
* are trained according to needs determined (training program)
* conduct learning actions when it is necessary to acquire new skills. A posteriori, the effectiveness of these actions is evaluated

To determine the competence of a person, the following can be taken into account:

* initial education
* specific trainings (internal auditor)
* on the job training
* professional knowledge:
  + technical
  + use of software
  + organizational
  + foreign language
* specific external certifications and qualifications (welder)
* work experience (years, fields)

The competence of staff with responsibility for improving quality performance mainly concerns those who participate in:

* + determining external and internal issues
  + demonstrating leadership
  + analyzing legal and statutory requirements
  + managing risks
  + seizing opportunities for improvement
  + controlling operational activities
  + evaluating the performance of the QSMS (internal audits)

Records on competence and qualification of staff are retained (skills matrix). Описание: enregistrement

***Good practices***

* *the competence for each activity is determined in a file*
* *the annual training program is updated at least twice a year*
* *during the staff appraisal, an employee may request an addition to the annual training program*
* *the training file of each employee is protected (restricted access)*
* *each course is evaluated at the end of the session and two to three months later*
* *an analysis of the effectiveness of the training is done at year-end*
* *the competence matrix is updated regularly*
* *the list of those requiring regulatory or usage authorizations is up-to-date*

***Bad practices***

* *the necessary skills are not defined for each function*
* *missing skills are not listed*
* *some departments do not determine their training needs*
* *evaluating the effectiveness of training is not practiced*
* *some trainings have not been evaluated, either at the end of the session or later*
* *the annual training program is not updated (training is planned but not provided)*
* *training activities at the workplace are not systematically recorded*
* *persons working on specific missions are not qualified*

**7.3 Awareness** *(requirements* [*129 to 133*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#7.3)*)*

**Nuclear safety is everyone’s responsibility**

The entire staff is aware of the:

* importance of the following:
  + quality policy
  + objectives in each department
  + QSMS requirements
  + legal and statutory requirements
  + work instructions
* positive effects from the performance of everyone
* consequences of potential malfunctions if quality instructions are not followed
* everyone's contribution to the improvement of the QSMS performance
* impact on quality associated with each workstation
* importance of their tasks including potential nuclear safety consequences of errors in their activities
* prevention of counterfeit, fraudulent or suspect items included into the deployment of safety culture

Some questions to help awareness training for persons involved in ITNS products and services:

* what do you think nuclear safety is?
* why nuclear safety is so important?
* what an ITNS product, service, item or activity is?
* what do you think about the importance and impact of individual’s role in achieving nuclear safety?
* how do you know that you are working on ITNS products?
* how can you identify CFS items?

***Good practices***

* *everyone contributes to continual improvement without any constraint*
* *all staff are made aware of the policy and quality objectives*
* *all staff are made aware of the importance of the potential consequences for nuclear safety of errors in their activities*

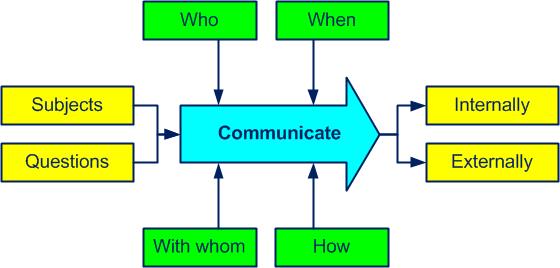
***Bad practices***

* *there is no formal document to raise awareness of new recruits or outside providers’ staff*
* *new hires do not receive formal information on preparing for emergencies*
* *some persons are not made aware of the importance of the potential consequences for nuclear safety of errors in their activities*

**7.4 Communication** *(requirements* [*134 to 138*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#7.4)*)*

#### Good news walks, bad news runs. Swedish proverb

The “communicate” process is shown in figure 7-1. 



*Figure 7-1. The communicate process*

Top management implements communication provisions for appropriate information sharing with staff, customers and other stakeholders (with whom) at appropriate times (when). Try doing this simply because:

**Too much communication kills communication**

Staff is:

* involved (participation)
* consulted
* made aware
* represented
* informed

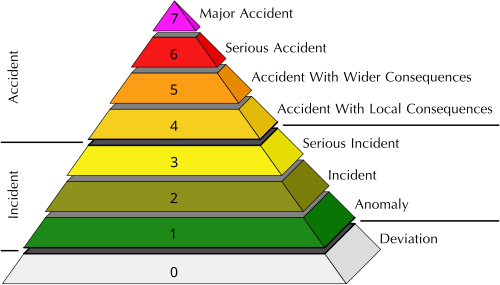
The following activities are defined:

* who is responsible for the communication
* communication methods (how) on the QSMS and their improvement:
  + orientation handbook
  + reports
  + encounters
  + meetings
  + newsletters
  + posters
  + explanatory notes
  + Intranet, Internet
  + dashboards
  + instructions on:
    - evacuation
    - wearing of personal protective equipment
    - access to specific areas
* processing of requests for information, feedback (including complaints) of stakeholders
* communication of externally relevant and mandatory information

Effective communication especially involves:

* explaining
* informing
* making aware

The INES (International Nuclear Event Scale) communication scale is shown in figure 7-2:



*Figure 7-2. The INES pyramid*

***True story***

*The Manhattan military project (the creation of the atomic bomb) was moving too slowly. Secrecy was the rule for security reasons and the nature of the project was hidden from all staff.*

*To move up a gear, the head project leader, Robert Oppenheimer, decided to inform all team members of the nature of the project, its extreme urgency and its critical importance to the end of the war. Unsuspected energy freed itself and work advanced in leaps and bounds.*

*Informing staff about the mission, giving meaning to their work and trusting them is a guarantee of success for any project.*

 Minute of relaxation. Cf. joke “[Lack of communication](http://www.pqbweb.eu/page.php?id=31#lack)”

***Good practices***

* *methods and means of internal and external communication are thoroughly described in the process sheet*
* *communication is transparent and systematic*
* *important issues for staff and stakeholders are consulted on and involved upstream*

***Bad practices***

* *complaints are not taken into account*
* *requests made by stakeholders are not recorded*
* *monitoring of actions in response to complaints is not transmitted to the stakeholder*

**7.5 Documentation** *(requirements* [*139 to 157*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#7.5)*)*

**7.5.1 General**

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

The documentation can be in any form and any medium, but meets the requirements of the ISO 19443 standard.

For an effective quality and safety management system, everyone uses, according to their own judgment, only simplified and strictly necessary documents. To believe that you must at all costs document your competence and skills to conserve and transmit them is a conception of the past.

The term procedure can be replaced by documented information to maintain. procédure

The term record can be replaced by documented information to retain. enregistrement

The documentation is related to:

* the size, type and area of business activity
* the complexity of processes and their interactions
* products and services
* competence of staff

Examples of records commonly used are:

* process sheet
* specification
* work or test instruction
* list of stakeholders
* list of approved external providers
* plan for:
  + quality
  + trial
  + inspection (monitoring and measurement)
  + prevention
  + emergency
* safety protocol
* incident sheet

More details can be found in [ISO 30300:2020](https://www.iso.org/standard/74291.html) “Information and documentation — Records management — Core concepts and vocabulary”.

**7.5.2 Creating and updating**

The QSMS documentation (cf. figure 7-2) includes documentation necessary to processes, one that is maintained (procedures) and one that is retained (records). Documents of external origin (providers, suppliers, customers and standards) are part of the documentation.

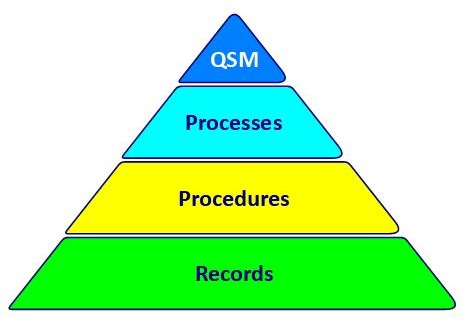


Figure 7-2. Documentation pyramid

All internal documents are codified and approved. Expired (obsolete) documents are identified and their use prohibited.

The technical report [ISO/TR 10013](https://www.iso.org/standard/75736.html) (2021): " Quality management systems — Guidance for documented information" provides recommendations relative to the documentation of a QSMS.

Answers to all 444 requirements (in the text « shall ») of clauses 4 to 10 of the ISO 19443 standard are included in the documentation, cf. sub-clause 4.4.

Every procedure is identified, among other things, by the: procédure

* title
* author (authors)
* coding (reference number)
* format
* creation date
* review
* approval (suitability and adequacy)

Top management ensures the completeness and accuracy of each required translation, including measurement systems considerations and date conventions.

Competent and authorized persons review and approve every document at planned intervals. These persons are always different from the authors.

Whiteout is prohibited for temporary manual corrections.

**7.5.3 Document control**

Document control includes:

* availability:
  + at the right moment
  + at the right place
* suitability for use
* protection
* traceability and authenticity
* confidentiality
* distribution
* storage and preservation
* change management
* retention time
* elimination
* management of documents of external origin

The persons concerned are aware of changes made to the documents prior to release.

The unintended use of obsolete documents is prevented by concrete rules.

The documented procedures procédure required by the ISO 19443 standard version 2018 (cf. [annex 16](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php)) consist of: G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif

* scope of the QSMS (sub-clause 4.3)
* process control (sub-clause 4.4.2 a)
* quality and safety manual (sub-clause 4.4.3)
* quality policy (sub-clause 5.2.2 a)
* risk management (sub-clause 6.1)
* ITNS items and activities (sub-clause 6.1.3)
* graded approach (sub-clause 6.1.4)
* quality objectives (sub-clause 6.2.1)
* operational control (sub-clause 8.1)
* design and development controls (sub-clause 8.3.4)
* external providers (sub-clause 8.4.1)
* nonconforming outputs (sub-clause 8.7.1)

A procedure should be short, simple and relevant, especially in cases where its absence could lead to deviations from the policy or objectives.

The quality policy (sub-clause 5.2.2 a) is similar to a procedure, but is a stand-alone document. politique

Review of the documentary system is conducted periodically with process owners by the quality and safety manager. Each process owner is responsible for the control of activities within its field, including management of its documents.

No one should review their own work.

***True story***

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

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

*The auditor was comforted because he was afraid he would come across “inactive” documents.*

### Spoken words fly away, written ones stay. Latin proverb

All retained documentation is unique and usually cannot be changed, except for error correction. All retained documentation provides proof of a task, an operation, an activity, a process or a requirement. Retained documentation is the data base essential to analyzing process effectiveness and contributing to continual improvement of the QSMS.

The records required to prove conformity to the quality and safety management system are: enregistrement

* process performance (sub-clause 4.4.2 b)
* risk actions (sub-clause 6.1)
* ITNS items and activities (sub-clause 6.1.3)
* graded approach (sub-clause 6.1.4)
* suitability of inspection resources (sub-clause 7.1.5.1)
* calibration (sub-clause 7.1.5.2)
* traceability (sub-clause 7.1.5.2)
* staff competence (sub-clause 7.2)
* effectiveness of the QSMS (sub-clause 7.5.1)
* documents of external origin (sub-clause 7.5.3)
* protection (sub-clause 7.5.3.2)
* process control (sub-clause 8.1)
* conformity of products and services (sub-clause 8.1)
* review of requirements, actions taken (sub-clause 8.2.3.2)
* design and development activities (sub-clause 8.3.1)
* design and development requirements (sub-clause 8.3.2)
* design and development inputs (sub-clause 8.3.3)
* design and development controls (sub-clause 8.3.4)
* design and development testing (sub-clause 8.3.4.1)
* design and development outputs (sub-clause 8.3.5)
* design and development changes, substantiation (sub-clause 8.3.6)
* external providers, activities, actions, control (sub-clause 8.4.1)
* external providers, approval of documentation (sub-clause 8.4.3)
* control of production and service provision (sub-clause 8.5.1)
* monitoring and measurement (sub-clause 8.5.1.2)
* traceability (sub-clause 8.5.2)
* customer’s property (sub-clause 8.5.3)
* control of changes (sub-clause 8.5.6)
* release of products and services (sub-clause 8.6)
* control of nonconforming outputs (sub-clause 8.7.2)
* inspection results (sub-clause 9.1.1)
* audit program and audit results (sub-clause 9.2.2)
* results of management review (sub-clause 9.3.3)
* nonconformities, nature, actions and results (sub-clause 10.2.2)

Examples of other records that are often used:

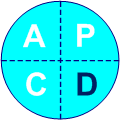
* process capability studies
* costs of obtaining quality
* communications
* change requests
* concession requests
* customer complaints
* list of:
  + issues
  + stakeholders
  + risks
  + legal and statutory requirements
  + processes
  + job descriptions, including top management
  + external documents
  + standards
  + internal auditors
  + monitoring and measurement resources
* training program
* training certificate
* audit report

***Good practices***

* *documents management clearly shows the author and approver of the initial document and subsequent versions*
* *properly managing changes to documents (a line in the middle of the old text, red) can quickly show the history*
* *the hierarchy of documentation is logical and clear (processes, procedures, records)*
* *the master list of documentation also includes the retention period*
* *procedures fulfill their role of controlling situations where their absence could lead to deviations from the legal requirements*
* *external documents (standards, regulations, documents of customers, external providers and machines) are coded as internal documents and the location is noted in a specific list*
* *a review of all documentation of the QSMS is conducted twice a year, it is very well organized and the actions are completed on schedule*
* *records show compliance with statutory and regulatory requirements, the requirements of ISO 19443 and the company's quality policy*
* *a list of dates of implementation of changes into production is available at the workshop*

***Bad practices***

* *the scope of the QSMS is not mentioned in any document*
* *some process sheets are incomplete*
* *many real activities are not identified in any document*
* *some documents are not codified*
* *documents are not approved prior to release*
* *documents are incomprehensible to staff*
* *documents are not located where needed*
* *instructions are outdated (version before the last one)*
* *during the project launch meeting, the list of participants is not recorded*
* *protection of documents on the network is not set*
* *documents of external origin are not under control (codified)*
* *retention period and methods of disposal of documents are not determined*
* *no documentation prohibits the use of dangerous equipment (non-compliance with legal requirements)*
* *documentation is not stored until the date of disposal*
* *quality meeting without retained report*

**8 Operation **

**8.1 Operational planning and control** *(requirements* [*158 to 174*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#8.1)*)*

**Quality control is more than a state of mind. It requires effective tools. Shigeru Mizuno**

The core processes necessary for the quality and safety management system are established, planned, implemented and controlled (cf. sub-clause 4.4). These processes help the company meet the requirements of stakeholders (cf. sub-clause 4.2). The actions to address risks and opportunities are in place (cf. sub-clause 6.1).

To plan and control processes means, above all, to:

* determine requirements related to products and services
* establish criteria for:
  + the acceptance of products and services
  + operation
* provide necessary resources
* meet the criteria in order to prevent a gap related to:
  + quality policy
  + quality objectives
  + statutory and regulatory requirements
* maintain and retain documentation (“to a sufficient extent”) proving that: procédure enregistrement
  + processes were completed as planned
  + products and services are conforming

Examples of performance criteria:

* equipment utilization rule
* work instruction
* qualification requirement
* exposure limit
* storage condition
* requirement for personal protective equipment
* access condition (staff and visitors)

Examples of records:

* prevention plan
* safety protocol
* contingency plan
* job description
* work instruction (techniques to use, monitoring to apply)

The planning process outputs are adapted to the specific operation of the company.

Process changes are made in accordance with sub-clause 6.3. If risks are detected during the upstream analysis, then actions are planned to limit any negative consequence.

More details can be found in [ISO 10006:2017](https://www.iso.org/standard/70376.html) “Quality management — Guidelines for quality management in projects” and [ISO 21500:2021](https://www.iso.org/standard/75704.html) “Project, programme and portfolio management — Context and concepts”.

Top management ensures control of processes performed by external providers in accordance with the requirements of sub-clause 8.4.

Project, schedule, interface and configuration management aspects are taken into account when planning operational processes.

Prevention of counterfeit, fraudulent or suspect items (CFSI) includes:

* rigorous selection of external providers (cf. sub-clause 8.4.1)
* controls applied by the external providers to its supply chain (cf. sub-clauses 8.4.2 & 8.4.3)
* externally provided processes, products and services remain within the control of its QSMS (cf. sub-clause 8.4.2)
* inspection activities performed by competent persons (cf. sub-clause 8.5.1.2)

Each CFSI identified is considered and managed as nonconformity (cf. sub-clause 10.2).

Information on detected CFSIs is disclosed to the parties concerned, including customers.

***True story***

*A supplier was suspicious of an electronic component they had just received. The surface smoothness did not feel right. The customer was notified. The component was segregated and an investigation was carried out and found that the component was counterfeit. The top surface had been sanded down and re-marked. The batch was scrapped and the external provider was red-listed.*

*The supply chain organization adopted an appropriate questioning attitude and took the correct action.*

Examples of actions against counterfeit, fraudulent or suspicious items:

* work with reputable and approved producers, suppliers and distributors
* buy directly from the original manufacturer
* reinforce incoming inspection:
  + verification of proof of conformity
  + external visual check
  + x-ray inspection
  + electrical test
* monitor market prices (low prices = suspicion)
* carry out supplier audits
* learn how to detect false certificates and documents
* specify quality standards in contracts
* test materials
* identify counterfeit brands

The SAE Aerospace Standard [AS6081A](https://www.sae.org/standards/content/as6081a/) (2023) “Counterfeit Electrical, Electronic, and Electromechanical (EEE) Parts: Avoidance, Detection, Mitigation, and Disposition - Independent Distribution” standardizes practices to identify reliable sources, control suspect counterfeit or counterfeit EEE parts, and report incidents.

More details can be found in [NP-T-3.26](https://www-pub.iaea.org/MTCD/Publications/PDF/P1817_web.pdf), Managing Counterfeit and Fraudulent Items in the Nuclear Industry, IAEA, 2019

***Good practices***

* *the acceptance criteria of the products are established, posted and respected*
* *risks identified in production are analyzed, evaluated and treated on a case-by-case basis*
* *the results of the daily check of forklift trucks are recorded in the maintenance file*
* *work instructions, including critical tasks, are updated*
* *the instructions displayed are followed by all staff*
* *the phases of definition and realization of the product or service are included in the project management*
* *a catalog with photos of original components and materials helps staff make visual comparisons in case of doubt*

***Bad practices***

* *the traffic plan is not displayed*
* *some people do not wear personal protective equipment*
* *there are no signs prohibiting unqualified personnel from using certain machines*
* *temporary and permanent changes to processes are not mastered*
* *change consequences are not analyzed*
* *acceptance criteria for products are not clearly defined*
* *records on processes are not retained*
* *the set for the use of personal protective equipment is not displayed*
* *no internal threat awareness program for counterfeit, fraudulent or suspect items*

**8.2 Requirements for products and services** *(requirements* [*175 to 197*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#8.2)*)*

**8.2.1 Customer communication**

### The most important thing in communication is hearing what is not said. Peter Drucker

Communication (see sub-clause 7.4) with customers and other stakeholders covers:

* information on the product and the service (technical specifications, terms of use and others)
* consultations, contracts, amendments, concessions and orders
* the perception of customers, including their claims
* protection and safeguard of customer property
* response requirements following an emergency action
* handle interfaces with external parties

**8.2.2 Determining the requirements related to products and services**

The necessary requirements for products and services that the company is offering are determined and meet applicable statutory and regulatory requirements.

Top management is committed to respond to any complaint relating to the requirements of its products and services.

**8.2.3 Review of requirements related to products and services**

Before committing to providing the products and services, the staff reviews the requirements:

* specified by the customer (including requests about packaging, transportation and post-delivery)
* implicit (necessary for the proper use or intended use by the customer)
* internal
* statutory and regulatory

The review also takes into account the resolution of differences between the expressed requirements and those of the order.

Any oral customer requirement is transcribed in writing and sent to the customer before acceptance.

The review of the requirements for products and services involves all relevant parties in the supply chain, including inspection and test.

The results of the review of requirements, including any new requirement and actions taken as a result of the review, are retained. enregistrement

Once a change of a requirement is known, the change is properly determined and reviewed. Documentation is updated as quickly as possible and the personnel concerned are kept informed without delay.

***Good practices***

* *methods and responsibilities for responding are known to all*
* *any order acceptance is preceded by an analysis of the changes requested by the customer*

***Bad practices***

* *responsibilities for communication with customers are not known to some people*
* *claims remain unanswered or without action*

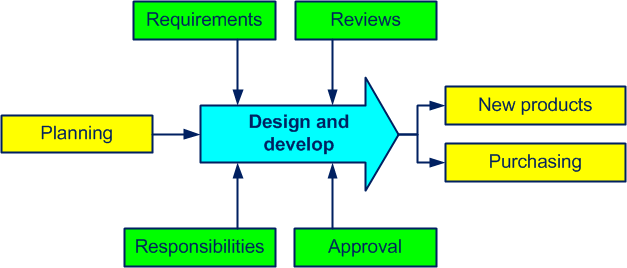
**8.3 Design and development** *(requirements* [*193 to 247*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#8.3)*)*

**8.3.1 General**

I have not failed. I’ve just found 10,000 ways that don’t work. Thomas Edison

The activities “acquire the resources”, “win the quotation” and “validate the contract” are prerequisites for planning the design and development process.

Each stage of the “design and develop” process (cf. figure 8-1) is planned and controlled. 



*Figure 8-1. Design and develop process*

Customers and other stakeholders’ requirements are determined and transformed into internal requirements.

Internal and external design interfaces and associated controls are established in the design and development process.

The level of detail of the design and development activities is documented to avoid ambiguity and to show that the requirements meet the specific intended use.

The FMEA procedure, based on the [AIAG & VDA FMEA Handbook](https://www.aiag.org/training-and-resources/manuals/details/FMEAAV-1), provides a comprehensive and harmonized method for proactive risk management, leading to more robust product designs and manufacturing processes, cf. [annex 17](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php). procédure

Templates of a design FMEA and process FMEA are shown in [annexes 18 and 19](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php). enregistrement

An example of a control plan is present in [annex 20](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php). enregistrement

Where computer-aided design tools are used, proof that these tools are fit for purpose is available.

Any subcontracting of ITNS activities is always entrusted to an ISO 19443 qualified company.

More details of an example of a design and development process are present in Annex K, [ISO/TR 4450](https://www.iso.org/standard/79983.html).

**8.3.2 Design and development planning**

For planning design and development activities, top management takes into account:

* assignment of responsibilities and authorities
* internal and external resource needs
* the expected level of control
* the nature and complexity of the activities
* requirements for each stage, including reviews and authorization before going to the next stage
* effective communication between all personnel involved
* customers and users participation in certain stages
* the requested verifications and validations
* the records on meeting the requirements of the design and development (see sub-clause 8.3.5)
* subsequent requirements of products and services

**8.3.3 Design and development inputs**

The design and development inputs are:

* complete
* without ambiguity
* without conflicts
* without contradictions

Staff takes into account the:

* specific functional and performance requirements
* applicable statutory and regulatory requirements
* previous similar projects information
* internal standards, rules and traditions
* impact of a subsequent inherent product and service failure

Records are retained on the design and development inputs. enregistrement

**8.3.4 Design and development controls**

Controlling the design and development is done so:

* the expected results are formally defined
* the design and development reviews are planned and carried out at key stages and include, when relevant, authorization to go to the next stage
* verifications and validations are carried out as planned by competent independent persons
* action is taken to resolve any problem
* records are retained and the procedure is maintained enregistrement procédure

Verification:  *the periodic inspection survey of compliance of a process, product or material*

Validation: *notice that the application of any process, product or material allows expected results to be achieved*

**8.3.4.1 Design and development verification and validation testing**

Design and development verification and validation testing is planned, performed, controlled, reviewed and documented to guarantee:

* the identification of the correct configuration of the products and services tested and resources used
* the definition of:
  + test objectives
  + conditions
  + parameters to be recorded
  + acceptance criteria
* that the procedure includes the method of operation, the performance of the test and the recording of the results
* requirements of the test plans, specification and procedures are met
* acceptance criteria are met

**8.3.5 Design and development outputs**

Before any production, design and development outputs are:

* verified
* validated
* and records retained enregistrement

The outputs:

* meet the input requirements
* provide information for purchasing and production
* contain the inspection or acceptance criteria or refer to them
* specify the:
  + characteristics for their correct use
  + conditions under which commercial grade items or activities can be used as IRNS items or activities

The functional analysis and analysis of the life cycle can be very useful tools.

**8.3.6 Design and development changes**

The verification (technical viewpoint), the validation (functional viewpoint) and the approval of design and development changes are a logical follow-up to the reviews and allow prevention of any deviation from requirements.

In this way:

* compliance is evaluated
* risks are determined
* solutions are found

The records on the changes, their justification, their reviews, authorizations and actions taken are retained. enregistrement

The person in charge of changes is designated, competent, has sufficient knowledge of the requirements and intent of the original design.

***Good practices***

* *the customer is present at the launch meetings*
* *the new project coordination meetings end with a report signed by the customer including the list of actions to be undertaken*
* *the inputs of the design and development are systematically stripped of any ambiguous, incomplete or contradictory data*
* *a risk approach (identification, analysis, evaluation and treatment) is performed at the beginning of each project*
* *the responsibilities of team members are clearly defined and recorded*
* *any change is communicated to the customer for consultation*
* *verification of the software qualification scope is done in relation to its actual use*

***Bad practices***

* *the stages of the design and development are not planned*
* *the planning of stages is not updated*
* *documentation on some reviews does not exist (or was not kept)*
* *statutory and regulatory requirements are not determined*
* *recycling is not taken into account*
* *verifications and validations are not retained*
* *some changes are not retained*
* *incomplete test instruction (the method is missing)*
* *outputs are not in the form requested by the customer*
* *acceptance criteria are not specified in the outputs*
* *no process is in place for demonstrating the qualification of software for the design of IPSN product or service*
* *the stages requiring authorization before progressing to the next stage are not identified*

**8.4 External providers** *(requirements* [*248 to 290*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#8.4)*)*

**8.4.1 General**

### You can outsource the activity, but you cannot outsource risk. Michael Gallagher

Top management guarantees the conformity of products, services and processes from external providers.

An external provider may be a supplier, a distributor, a partner or a subcontractor.

The control of external providers is ensured in the following situations:

* the external provider's products and services are integrated into the company's products and services
* the external provider's products and services are delivered directly to customers
* a process is performed by the external provider

This control takes into account:

* any level of the supply chain, including the last sub-supplier
* the graded approach outputs (cf. sub-clause 6.1.4)

External providers are evaluated and selected according to defined criteria. Monitoring the performance of external providers is performed regularly. Monitoring is useful, but measuring, calculating or noting is not.

Evaluation and selection includes criteria such as:

﻿

* technical and quality:
  + ability to provide a product or service compliant right first time
  + compliance with codes and standards
* quality and nuclear safety culture:
  + compliance with requirements
  + lessons learnt from previous orders
  + CFS prevention control
  + complaints raised by the organization
  + completeness of quality documentation
  + monitoring results
  + qualification of personnel
* responsiveness:
  + ability to answer rapidly to organization
  + complaint resolution time
* delivery and cost:
  + respect of schedule
  + value for money

The records on evaluation, re-evaluation and actions taken related to the performance of external providers are retained. enregistrement

The evaluation of external providers is valid for a limited period of time and a specific scope.

When an external provider, responsible for ITNS items or activities, cannot demonstrate that its QSMS meets the requirements of ISO 19443, equivalence of provisions is taken.

A procedure related to control of external providers is maintained. procédure

**8.4.2 Type and extent of control of external providers**

The type and extent of control of activities provided by external providers take into account:

* the risks on the ability of the company to meet customer, statutory and other requirements
* the performance level of the external provider, including its supply chain

The implemented verifications ensure that products and services provided by external providers meet customer expectations at every delivery. For this, top management defines the extent of control to be used on the external provider and its outputs.

The verification ensuring that the externally provided processes, products and services meet all requirements takes into account the critical characteristics of commercial grade items and activities.

Commercial grade items or activities are those that are not designed and manufactured in accordance with specific nuclear safety requirements.

Examples of commercial grade activities:

* electrical cables
* seals
* bearings
* sensors

Examples of commercial grade activities:

* standard after-sales service
* metrology
* computer maintenance

External providers can be classified into:

* new
* known
* approved

Inspection will be strengthened for any new external provider. Inspection will be minimal, if it exists at all, for approved external providers.

The responsibilities and authorities for control of externally provided processes, products and services are established by top management.

Outsourced activities (process, product and service) are within the scope of the quality and safety management system (see sub-clause 4.3).

The conformity of externally provided processes, products and services is, in the end, the responsibility of top management.

**8.4.3 Information for external providers**

Communication takes place only after there has been an internal verification of the adequacy of the specified requirements.

Information on the requirements communicated to external providers includes:

* sold products and provided services
* realized processes
* associated QSMS requirements
* technical specifications, including acceptance criteria
* list of relevant documentation, including standards
* documentation that the external provider will submit
* spare parts and ordering data
* approval of:
  + products and services
  + processes
  + methods
  + equipment
  + associated documentation
* release of outputs
* staff competence
* interactions with the quality and safety management system of the company:
  + notification of nonconformities, including CFS items
  + approval for nonconformities disposition
  + notification of changes:
    - in products and services
    - of sub external providers
    - of manufacturing location
  + approval of changes, where required
  + provide access to the relevant areas of all facilities, at any level of the supply chain
* monitoring of the external provider’s performance
* verification or validation activities to be performed at the external provider’s premises

The relevant requirements are communicated to external providers to all levels of its supply chain.

Requirements are reviewed for adequacy before being communicated to external providers.

Procurement changes are managed as the other changes in production requirements.

The records on information for external providers are retained. enregistrement

***Good practices***

* *the list of external providers also includes the history of evaluations*
* *each delivery is evaluated*
* *quarterly update of external provider performance (quality, cost, deadlines)*
* *regular audits at the premises of external providers*
* *partnerships with key external providers (pooling of assets and resources)*
* *critical characteristics of commercial grade items and activities are always verified*
* *controls applied by the external provider include control of its supply chain*
* *requirements are reviewed for adequacy prior to communication to external provider*

***Bad practices***

* *records on evaluation and selection of external providers are not retained*
* *lack of technical specifications in some data sheets*
* *lack of acceptance criteria for certain products*
* *untrained personnel to verify compliance with requirements at product receipt*
* *the results of verification of purchased product are not recorded*
* *delays in delivery are not taken into account*
* *corrective actions are not required from failing suppliers*
* *the performance indicator of some external providers is not monitored*
* *the requirements for adequacy communicated to external provider are not always reviewed before being sent*

**8.5 Production and service provision** *(requirements* [*291 to 341*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#8.5)*)*

**8.5.1 Control of production and service provision**

**Quality control that does not show results is no control. Kaoru Ishikawa**

Top management ensures that production of the product, the provision of the service, the delivery and post-delivery are made in controlled conditions leading to reproducible results.

These conditions include:

* access to documentation relating to products and services specifications enregistrement
* availability of documentation on activities (such as work instructions) and the results to be obtained enregistrement
* resources and the inspection activities
* competent inspection staff
* correct and appropriate use of process equipment
* staff competence
* validation of every process that cannot be checked a posteriori to demonstrate the ability to achieve planned results
* tools to prevent human error (e.g. Poka-Yoke)
* release, delivery and post-delivery activities
* custom and statutory and other requirements related to inspection (cf. sub-clause 8.5.1.2)
* evidence that all inspection activities are completed as planned
* top management involvement to ensure:
  + measurement of product conformity and on-time delivery
  + actions taken when planned results are not achieved
  + nuclear safety is not compromised

The control of these conditions can be obtained with:

* criteria for review and approval of:
  + process and
  + equipment
* specific qualifications of staff
* appropriate documentation

Controlled conditions take into account the graded approach outputs, cf. sub-clause 6.1.4.

***True story***

*A company had a bottleneck in the polishing operation. Top management proposed to acquire a new polishing machine. But Shigeo Shingo was consulted. He observed that milling before polishing removed between 0.6 and 0.9 mm. By having the milling machine remove more material, polishing time could be reduced significantly.*

*The bottleneck was eliminated. You should not use polishing to remove material.*

**8.5.1.1 Control of production equipment**

Computer-aided production equipment is validated prior to production and maintained by competent personnel.

Storage requirements are defined for production equipment and tooling. These storage and preservation requirements are monitored at planned intervals.

**8.5.1.2 Inspection activities**

Inspection (monitoring and measurement) activities (provisions and methods) take into account the graded approach outputs (cf. sub-clause 6.1.4).

Inspection of ITNS items and activities is performed by competent persons, different from those who perform these activities.

Retained records include: enregistrement

* item inspected
* inspection performed
* the date
* the person who performed the inspection
* documents used
* acceptance criteria
* acceptability
* actions taken and follow-up related to nonconformities

**8.5.2 Identification and traceability**

Often the product and its status, in relation to realized inspections, are identified and product traceability is controlled by suitable means throughout its production. In this way the history of the status of the process outputs is identified and saved.

When traceability is a requirement, the unique identification of the status of process outputs is retained. enregistrement

Traceability is a very important aspect in ensuring compliance with nuclear safety requirements. In France, this is a regulatory requirement (decree 07/2012).

It may, for example, take into account the following elements:

* Material, consumables
* Mather nature, location, date, and conditions of implementation
* Methods, procedures
* Machines, equipment, tools
* Manpower, associated skills and qualifications

Particular care is taken to ensure that the identification marks and labels used do not prejudice product conformity.

Where identification of persons is used, such as stamps or electronic signature, appropriate controls are established.

**8.5.3 Property belonging to customers or external providers**

Staff must give particular care to the correct use of the property of the customer or external provider. This property (which may be intellectual property or classified information) is identified (name of owner), verified, protected and safeguarded.

For any incident (loss or damage), information on what happened is communicated immediately to the owner and a record is retained.enregistrement

**8.5.4 Preservation**

Preserving process outputs is carried out with appropriate operations to ensure that requirements are met.

Examples of preservation activities:

* identification
* staging
* handling
* packing
* transport
* storage
* protection and
* delivery

Activities to preserve ITNS product from deterioration can include:

* access limitation
* cleaning
* prevention of foreign objects
* special handling of hazardous materials or sensitive products
* identification, including safety warnings

**8.5.5 Post-delivery activities**

Post-delivery activities (warranty, maintenance, after-sales service) of products and services take into account:

* potential risks
* the life cycle:
  + normal life
  + recycling
  + final disposal
* customer requirements and feedback
* statutory and regulatory requirements
* actions to be taken, including investigation and reporting, when nonconformities are detected

**8.5.6 Control of changes**

The planned changes are discussed in sub-clause 6.3.

The purpose of the control of unplanned changes occurring during the production of products or the provision of services is to maintain compliance with specified requirements.

The results of the review of changes, the determined risks and opportunities, the person authorizing the change and implemented actions are retained. enregistrement

***Good practices***

* *the customer has live access to production data and inspections of their product on the network*
* *traceability of the product contains information on raw materials, machines, personnel and inspections*
* *controlled conditions takes into account the graded approach outputs*
* *monitoring and measurement of ITNS items and activities are performed by competent persons*
* *preservation of ITNS products includes access limitation*

***Bad practices***

* *batch tracking sheet partially filled*
* *inadequate training of the operator on the use of a new machine*
* *unplanned control of spare parts of machines*
* *inventory of products is not done at the planned deadline*
* *the activities of handling, packaging and storage are not described*
* *the documentation for export is not translated*
* *non-compliance with certain traceability requirements*
* *equipment owned by the customer is not identified as such*
* *incidents of equipment owned by the customer are neither retained nor communicated to the customer*
* *pallets are stored outside without protection against rain*

**8.6 Release of products and services** *(requirements* [*341 to 347*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#8.6)*)*

**Inspection does not improve quality, nor guarantee quality. Edwards Deming**

Inspection of finished products and services is performed to verify their conformity.

Delivery is made only after verification of conformity. An exception is possible when a special or customer concession is confirmed in writing.

Concession (after production): *written authorization to deliver a nonconforming product*

More details of an example of scheme for non-conformance information and request for approval along supply chain are present in Annex M, [ISO/TR 4450](https://www.iso.org/standard/79983.html).

Traceability of each delivery (conformity with the criteria for acceptance and the person who has given the authorization) is retained. enregistrement

Each delivery contains all required documents, including a statement of conformity.

***Good practices***

* *inspections are planned on time*
* *the deadline of the inspection arrangements is always met*
* *the traceability of each delivery is easily accessible*

***Bad practices***

* *a nonconforming product is delivered without approved concession*
* *lack of certain information on the traceability of products*
* *not all required documents are present at delivery*

**8.7 Control of nonconforming outputs** *(requirements* [*348 to 366*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#8.7)*)*

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

The nonconforming process outputs are identified and addressed.

Any waste is an internal nonconformity. The 8 wastes most often encountered are:

* overproduction
* excessive stocks
* defects
* unnecessary movement
* unnecessary operations
* waiting
* unnecessary transport
* unused skills

The activities implemented to eliminate waste are a typical example of continual improvement.

The nonconforming product and service, including post-delivery, are treated through:

* analyzing the nonconformity
* eliminating the detected nonconformity (isolation, correction, repair, recovery, retouching, recycling, treatment of scrap)
* allowing its use by written concession issued by a competent authority or by the customer, including a justification approved by the customer
* taking actions to:
  + prevent the intended use (isolation, scrap)
  + contain the effects of the nonconformity on other processes or products
* conducting corrective actions to eliminate the causes
* communicating with the customer, when appropriate (always when it is post-delivery), including information on the nonconformity to be reported

For ITNS items and activities correction is not conceivable.

After treatment of any nonconformity, verification is made to see whether requirements are met to reintegrate the normal flow.

Records are retained on the treatment implemented on nonconformities and include: enregistrement

* the description of the nonconformity
* implemented corrective actions, including justification
* authorized concessions, including justification
* the person who decided treatment

A procedure for the control of nonconforming output is maintained. procédure

***True story***

*A production director thought that delivering on time at all costs was a top priority.*

*He had to deliver parts for an automotive customer. Having received no solder paste in the planned period, he gave the order to use an out-of-date solder paste. The delivery was done on time. The customer, after some testing, returned the entire batch as a nonconforming product. The financial penalty was enormous. A few weeks later, it was one of the causes of the company’s liquidation.*

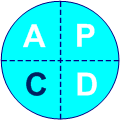
*The production director had hidden his concession decision from the customer and his quality and safety manager. The out-of-date solder paste should have been destroyed as soon as the expiration date was exceeded. Two fatal dysfunctions.*

***Good practices***

* *any problem (internal or external) is retained (nonconformity treatment card, 8 D record)*
* *permission to use concession is always signed by the customer*
* *5 M, Pareto and other tools are used when identifying and analyzing root causes*
* *justification for repair is always approved by the customer*

***Bad practices***

* *send a bill for the recovery or repair to the customer*
* *when awaiting the analysis of a nonconforming product, failure to place it immediately in an isolation area (red, prison)*
* *lack of records on repaired products*
* *concession applied without any signature*

**9 Performance evaluation **

**9.1 Monitoring, measurement, analysis and evaluation** *(requirements* [*367 to 384*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#9.1)*)*

**9.1.1 General**

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

The necessary measurement and monitoring (who, what, how, when) or, in other words, the inspection is carried out:

* at reception (raw materials, semi-finished products)
* into production (critical points of the process, semi-finished products) and
* at the end (finished products)

The process “inspect” (cf. figure 9-1) provides the necessary information for analysis and evaluation of the actions that lead to continual improvement. 

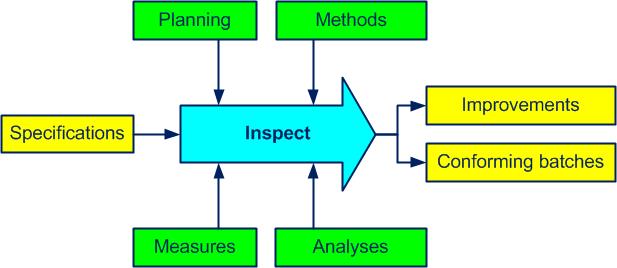


Figure 9-1. Inspect process

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

The inspection and analysis methods are appropriate to the specifics of the company and easily reproducible.

The inspection, analysis and evaluation of the performance of the QSMS demonstrate:

* the ability of the processes to achieve planned results
* the conformity of products and services

Inspection, analysis and evaluation results are retained. enregistrement

The conformity of the product and service to the applicable criteria is ensured with processes regarding the use and maintenance of appropriate inspection equipment and with validity status. Every instrument of measure is identified and verified.

With this data, the performance evaluation of the quality and safety management system is presented at the management review (see sub-clause 9.3).

***True story***

*At the request of a group manager, a financial analysis of the quality department activities of our site was performed. Inspections at reception were particularly targeted. To everyone's surprise, it turned out that the cost was really disproportionate to that of nonconformities found.*

*A reduction of activities (and the transfer of staff) was set up quickly.*

**9.1.2 Customer satisfaction**

##### **The only measure of quality is customer satisfaction**

Arrangements are applied (including statistical techniques) to measure the level of:

* customer satisfaction
* conformity of the QSMS
* process control
* control of products and services

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

The monitoring of customer perception regarding the level of their satisfaction is a key indicator of the performance of the quality and safety management system and helps to find opportunities for improvement.

The methods to obtain data on customer satisfaction are often:

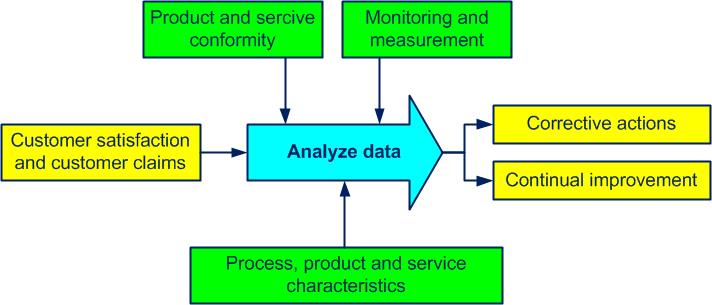
* satisfaction surveys
* direct talks
* visits to the place of use
* feedback
* claims
* recommendations
* congratulations
* market studies

**9.1.3 Analysis and evaluation**

**Get the facts, analyze them and then do what seems right. Robert Waterman**

Applying the principle "evidence-based decision making" (ISO 9000: 2015 sub-clause 2.3), the process “analyze data” (cf. figure 9-2) allows you to take appropriate decisions. 

When the amount of data (information) is very large (often the case), before any analysis, you should start sorting by importance and potential risk.



# Figure 9-2. Analyze data process

The results of the analysis and evaluation of data are used to question the performance of the quality and safety management system and are very useful for the management review. When the amount of data is important, statistical techniques are used.

Data analysis takes into account:

* customer satisfaction and other stakeholders
* customer complaints
* the characteristics of processes, products and services
* nuclear safety culture aspects

These data help to:

* evaluate the:
  + performance of the QSMS
  + need to improve the QSMS
  + conformity of the product produced and service provided
  + effectiveness of change planning
  + performance of:
    - processes
    - external providers
    - nuclear safety culture deployment
* increase customer satisfaction
* confirm the skillful planning of the quality and safety management system
* implement actions to address risks
* find opportunities for continual improvement

When a piece of equipment is no longer compliant, appropriate actions are taken as much on the equipment as on the affected product.

***Good practices***

* *in order to measure the performance of the QSMS, use everything you can get out of the toolbox of the quality and safety manager without restraint*
* *the results of data evaluation lead to many decisions for improvement*
* *customer complaints are answered in writing, if possible, on the same day*
* *each customer has a protected space on the network to follow the progress of their new projects live*
* *inspection results of the key characteristics of activities that could have an impact on quality are used as relevant data to evaluate the conformity of the QSMS*
* *all acceptance criteria for inspections are set*
* *the list of equipment requiring calibration is updated*
* *user manuals of the equipment are easily accessible and in English*
* *the location of each device is established in the master list of equipment*
* *standards and calibration instructions are coded and stored*

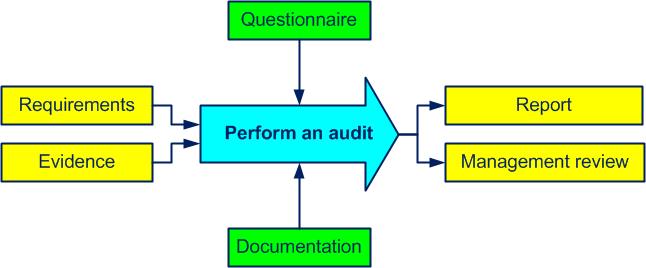
***Bad practices***

* *communication with the customer is slow (response to a request after one week)*
* *monitoring of actions following complaints are not promptly transmitted to the customer*
* *the decisions of the data analysis are not retained*
* *trends that can be discovered in the data are neither sought nor used*
* *QSMS performance measurements are not available*
* *monthly monitoring of activities with impact on quality are not retained*
* *equipment with outdated calibration date*
* *inspection activities are neither defined nor planned*
* *the equipment calibration and verification list is not updated or is incomplete*
* *calibration instruction of an equipment is non-existent*
* *labels to identify the state of calibration are not present on some equipment*
* *verification of an equipment is not retained*
* *appropriate methods of process inspecting do not exist*

**9.2 Internal audit** *(requirements* [*385 to 397*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#9.2)*)*

### The quality control should verify the process, not the product. Edwards Deming

The process “conduct an audit” (cf. figure 9-3) allows the evaluation of the conformity and effectiveness of the quality and safety management system. 



*Figure 9-3. Conduct an audit process*

Internal audits regularly verify whether the quality and safety management system is properly implemented and operational.

Conformity is determined by reference to:

* planned and agreed arrangements
* meeting requirements of:
  + ISO 19443
  + the quality and safety management system of the company
  + customer requirements

Effectiveness is determined in relation to established objectives. The relevance and the level of effectiveness of all processes indicators are checked.

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

An audit can be of:

* the QSMS
* a process
* a product
* a service
* a contract
* a workstation

During a workstation audit, the aim is to audit the operator's operational activities and control of the workstation. Examples of subjects to be audited:

* understanding of work document requirements
* level of self-control
* required qualifications
* conformity of manufacturing documents
* operator’s quality and safety culture
* behavior in the event of a quality problem
* risk awareness
* attitude to questioning approach
* cleanliness of workstation
* validity of measuring equipment

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

Examples of audit evidence are:

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

Audit planning (an annual audit program) is done according to the status and importance of the processes, products and services and their impact on quality.

When planning and implementing the audit program, the following are taken into account:

* the results of previous audits
* quality objectives
* customer feedback
* the changes implemented
* the risks and opportunities related to the processes

An auditor cannot audit his/her own department as

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

The competence and qualification of internal auditors is based on:

* experience in conducting audits (minimum number to maintain qualification)
* training followed
* knowledge of:
  + ISO 19011 recommendations
  + ISO 19443 requirements
* quality management principles
* customer requirements, including ITNS contract clauses
* technological, normative and regulatory watch

The quality and safety manager defines the following for the audits:

* responsibilities
* the selection of auditors
* requirements to:
  + plan
  + conduct audits
  + retain results (audit report)
  + communicate results
* criteria
* the perimeter
* frequency
* the methods

The audit follow-up (which can be an additional audit) allows the verification of the implementation of corrective actions and opportunities for determined improvements.

Records are retained on the implementation of the audit program and the audit results (audit report). enregistrement

The results of internal audits are one of the inputs of the management review and allow opportunities to be found to improve the quality and safety management system.

The activities of the internal audit are performed using as a base the ISO 19011 standard (cf. T 48v18 Internal Audit).

***True story***

*Following a customer complaint, the director asked the quality and safety manager to immediately conduct an unplanned process audit. Later we understood that this audit was the final straw and led to the dismissal of the quality and safety manager because he did not find the time to go to the workshop (he only looked at the documentation).*

*Therefore, audit documentation is important, but within certain limits.*

Description : smileMinute of relaxation. Cf. joke "[The engineer and the shepherd](http://www.pqbweb.eu/page.php?id=31#engineer)"

***Good practices***

* *the crossover audit (of exchange between two companies) is very appropriate and delivers key findings*
* *the audit program covers all key processes of the quality and safety management system*
* *the objectives of the audit program are consistent with the quality policy and the company's specificities*
* *the audit program is communicated to the persons concerned well before the first audit*
* *each audit report contains identified good practices*
* *any opportunity for improvement found during an audit is applied to other departments, processes or products*
* *an audit that is unscheduled but required by a department at a delicate stage often provides added value*

***Bad practices***

* *the audit program is neither followed nor updated*
* *the audit program does not cover all the requirements of the ISO 19443 standard*
* *the list of internal auditors is not updated*
* *the scope of the audit falls within the responsibilities of the auditor*
* *the audit report is not retained*
* *the audit report does not contain any track for improvement or any action*
* *the action requested in the audit report is not implemented in the proposed deadline*
* *the audit was conducted by a student without enough skill and experience (and not part of the list of auditors)*
* *results of audits are not routinely proposed as part of inputs of management review*
* *monitoring at certain stages of the product is not retained*

**9.3 Management review** *(requirements* [*398 to 416*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#9.3)*)*

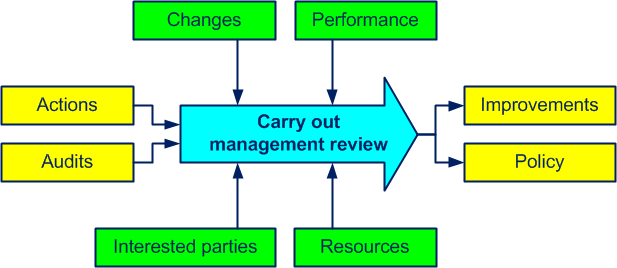
### No system is perfect

Top management plans and implements a review of the QSMS (at least once a year). The conclusions of the process “carry out management review” are retained (cf. figure 9-4 and [annex 21](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php)). enregistrement 

Its purpose is to review whether the quality and safety management system is relevant, effective and appropriate to the company's vision.

Nuclear safety receives attention commensurate with its importance.

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



*Figure 9-4. Carry out management review process*

The inputs of the review include:

* audit results
* inspection results
* nuclear safety in core processes
* the situation of necessary resources
* the results of the evaluation of whether statutory and regulatory requirements are met
* the feedback from stakeholders (satisfaction and complaints)
* the level of deployment of nuclear safety culture
* the level of achievement of quality objectives and associated indicators
* follow-up of actions:
  + from the decisions of the previous management review
  + addressing nonconformities
* performance information of:
  + processes, products and services
  + competitors
  + external providers
  + partners
* changes in external and internal issues that could affect the quality and safety management system and the associated risks and opportunities
* the status of actions implemented to address the risks and improvement opportunities, including lessons learned from global nuclear experience

The outputs of the review include decisions on:

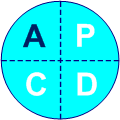
* improvement opportunities:
  + of the quality and safety management system and its processes
  + of products and services
* change needs to the quality and safety management system (quality policy, quality and nuclear objectives)
* resource needs to:
  + maintain the quality and safety management system and continually improve its effectiveness
  + increase customer satisfaction and other stakeholders in accordance with their requirements

***Good practices***

* *process review occurs prior to management review*
* *analysis of process performance is presented by each owner*
* *management review is coupled with the budget*
* *the importance of customer complaints is shared by all*
* *any proposed change is preceded by an impact evaluation*
* *when the opportunity presents itself, do not forget to praise the people who deserve it*
* *decisions are communicated to all*
* *the risks of the processes are analyzed and the effectiveness of the actions evaluated*
* *nuclear safety receives the attention it deserves*

***Bad practices***

* *the monitoring of the actions of the previous review is not presented*
* *performance trends are not in the inputs*
* *audit results are only partially presented*
* *significant changes are not taken into account*
* *the effectiveness of the QSMS is not evaluated*
* *the chosen periodicity is not followed*
* *the management review is incomplete (some key processes are not evaluated and some departments are not represented)*
* *complaints are not properly addressed*
* *the level of achievement of objectives is not analyzed*
* *the status of on-going actions is not commented upon*
* *some inputs of the review are absent (results of the surveys of customer satisfaction)*
* *there is no decision to update indicators*
* *decisions on improving the effectiveness of the QSMS and processes do not exist*
* *no proposal to improve the products is taken*
* *the need for people and material resources is not expressed in numbers or is insufficient to achieve the objectives*
* *lack of resources is not examined*

**10 Improvement **

**10.1 General** *(requirements* [*417 to 426*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#10.1)*)*

### Where there is a problem, there is potential for improvement. Masaaki Imai

The staff seeks, finds and implements improvement opportunities mainly to increase customer satisfaction.

Improvement is made to:

* the processes
* products and services
* undesirable effects
* the quality and safety management system
* lessons learned
* technical advances

Improvement opportunities exist in cases like:

* customer satisfaction and other stakeholders
* the customer complaints rate
* the reduction of nonconformities
* risk reduction
* meeting deadlines
* cost reduction
* methods for identifying good practices
* the implementation of operational control means
* net margin

Adequate resources are provided for improvement plans and activities.

Relevant learning from experience is shared with customers and supply chain organisations.

***True story***

*The paradox of decreased costs by product when the size of the batches decreases.*

*Logically, the bigger the batch size, the lesser the unit cost.*

*But this is not what Taiichi Ohno, known for his anti-common sense solutions, thought. He showed that mass production often has hidden costs (waste) that substantially increase the unit cost.*

*The hidden costs are related to defects that are discovered very late, including activities (and resources) needed in order to sort the products and repair defects, to transport and store a large quantity of products, the size of the storage area required to keep inactive products (and money too); and the need for cut-price sales (due to products having become obsolete in the meantime) and exceptional transportation (to meet the deadline).*

***Good practices***

* *any opportunity for improvement found in a corrective action is applied to other departments, processes or products*
* *each nonconformity is used to improve the process*

***Bad practices***

* *some opportunities for improvement are determined without any action being undertaken*
* *lessons learned from experience are not applied in all departments*

**10.2 Nonconformity and corrective action** *(requirements* [*427 to 441*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#10.2)*)*

**One of the best ways to measure quality is to calculate the price of nonconformities. Philip Crosby**

The responsibilities and authorities necessary to address nonconformities are established.

Every nonconformity is identified, analyzed and processed. The treatment of nonconformities includes activities to:

* identify and analyze nonconformities (customer complaints are part of them)
* include the impact assessment of the nonconformity during the analysis
* isolate nonconformities
* implement curative actions
* determine causes, including root cause analysis, as applicable
* evaluate potential risks
* evaluate the need for corrective actions to prevent the recurrence of nonconformities or greatly reduce their frequency of occurrence
* implement corrective actions
* monitor the effectiveness of actions taken

If needed you may:

* update the list of risks and opportunities
* change the quality and safety management system

Corrective actions are proportional to the consequences of nonconformity (do not go overboard on quality). They are managed and reported without undue delay to top management and, as appropriate, to the customer.

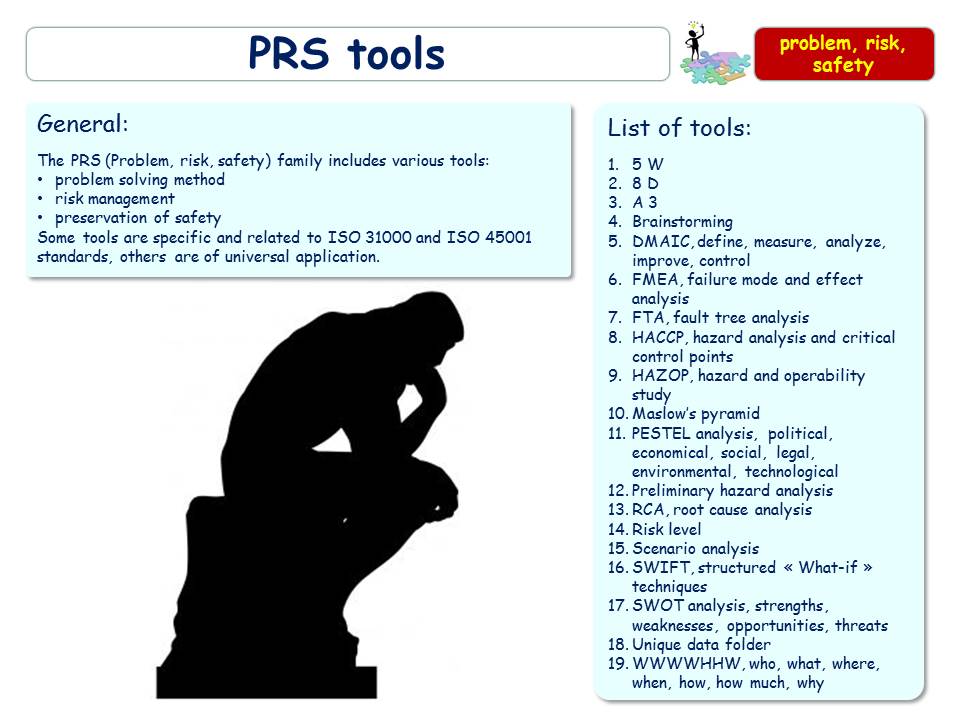
Examples of nonconformities:

* + a legal requirement that is not applied
  + an operational instruction that is not followed
  + a complaint from an stakeholder being untreated
  + a gap found during an audit
  + a quality objective not being achieved
  + a quality performance evaluation that is unrealized
  + an action in response to a risk determined not being implemented
  + suspect item not reported

Records of nonconformities (type, quantity, frequency of occurrence) and actions taken are retained and communicated to those concerned. ../Application%20Data/ISO%2014001/WEB%20ISO%2014001/enregistrement.gif

Actions are justified and their effectiveness is verified.

Some examples of PRS (problem, risk, safety) tools are shown in figure 10-1 and in detailed sheets in [annex 07](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php). G:\19 07\ISO\ISO 14001\Pr à l'ISO 14001\enregistrement.gif



*Figure 10-1. PRS family tools*

The tolls 5 W, 8 D and RCA are very useful for root cause analysis of nonconformities.

Root causes linked to human and organizational factors are mainly:

* lack of:
  + knowledge
  + information
  + autonomy
  + skills
  + know-how
* poor work behavior
* deficiencies in the quality and safety culture

In table 10-1 are shownmost commonly used types of corrective actions.

*Table 10-1 Types of correctives actions*

|  |  |  |
| --- | --- | --- |
| **Action** | **Explanation** | **Example** |
| **Reject** | The nonconforming product, service or process is not fit for the intended use. Such product shall be marked and segregated. Sometimes referred to as “scrap” | When a product is found to be outside of specification with no possibility of rework or repair. The product cannot be considered for concession |
| **Repair** | The nonconforming item, when repaired is capable of functioning in accordance with the design requirements, although it does not fully conform to the original design specification | When a product is found to be outside of specification, but the product could be returned to a conforming state following repair by an approved repair procedure (a component repaired by welding) |
| **Rework** | The item is capable of being fully restored to the original specification requirements | When a product is found to be outside of specification, but the product could be returned to a conforming state following additional work being carried out (a component that may have had a machining operation omitted) |
| **Accept with conditions** | The nonconforming item, service or process will be fit for use under special, specified conditions | When a product is found to be outside of specification, but the product could be accepted the by the design authority on concessions with restrictions (placed on its usage in specific applications or its duration of service) |
| **Accept without modification** | The nonconforming item, service or process deviates marginally from specified requirements but is still declared fit for use. Sometimes referred to as “use-as-is” | When a product is found to be outside of specification, but the product could be accepted the by the design authority on concessions without restrictions (any nonconforming product) |

***Good practices***

* *nonconforming products are systematically identified and separated from other products awaiting analysis and treatment*
* *root cause analysis is performed by default*
* *repaired products are inspected 100% before being returned to the normal flow*
* *monitoring the effectiveness of corrective action is carried out systematically*

***Bad practices***

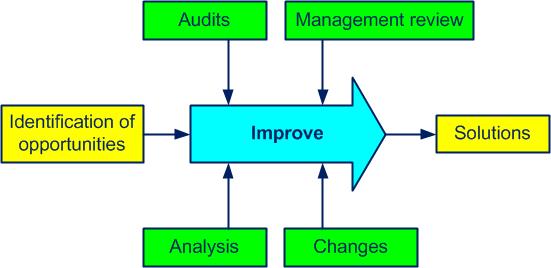
* *responsibility and authority for the control of nonconformities are not defined*
* *after analyzing the causes, no corrective action follows*
* *a customer complaint without any follow-up*
* *lack of analysis of causes of nonconformities*
* *lack of evidence of elimination of causes of nonconformities*

**10.3 Continual improvement** *(requirements* [*442 to 444*](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php#10.3)*)*

**Life is like riding a bicycle. To keep your balance, you must keep moving. Albert Einstein**

The process “improve” (cf. figure 10-2) relies, among other things, on: 

* stable processes
* the results of internal audits
* the decisions of the management review
* data analysis
* nuclear safety culture
* waste elimination
* lessons learned from corrective actions
* good practices among partners and competitors
* establishing new improvement objectives
* search for and justification of solutions
* implementing solutions and measuring results
* standardization of changes when objectives are achieved



## Figure 10-2. Improve process

### If you want to move a mountain, start by removing the small stones. Chinese proverb

The Kaizen method, attitude or event (from Japanese kai = learn, zen = improve) of continual quality improvement is based on the principle of small definite improvements realized by all and all the time. It is a formidable tool for fighting all aspects of waste.

Continual improvement: *permanent process allowing the improvement of the global performance of the company*

***True story***

*One company after, years of growth, saw its sales decline and began to have cash flow problems.*

*The consultant called in to help quickly understood the causes: too many activities and too many people without any added value for the customer.*

*An audit of all processes enabled them to reduce costs by 37% with a single question (If this activity is not realized, will the customer notice?)*

***Good practices***

* *the staff suggestion scheme is well oiled and bears fruit*
* *change management implementation is flawless*

***Bad practices***

* *improvements are applied without being communicated at management review*
* *the nuclear safety culture is not present by default in the continual improvement process*

[**Annexes**](https://www.pqbweb.eu/document-d-28v18-iso-19443-nuclear-safety-management-system-readiness-version-2018-set-of-documents.php)

Annex 01 Certification project plan (PQBD28V18A01)

Annex 02 Process review (PQBD28V18A02)

Annex 03 List of processes (PQBD28V18A03)

Annex 04 Process approach (PQBD28V18A04)

Annex 05 Lean family tools (PQBD28V18A05)

Annex 06 Glossary (PQBD28v18A06)

Annex 07 PRS family tools (PQBD28V18A07)

Annex 08 Quality and safety manual (PQBD28V18A08)

Annex 09 List of risks (PQBD28V18A09)

Annex 10 Risk level (PQBD15V2015A10)

Annex 11 ITNS items and activities (PQBD28V18A11)

Annex 12 Graded approach (PQBD28V18A12)

Annex 13 Manage risks process (PQBD28V18A13)

Annex 14 Risk management procedure (PQBD28V18A14)

Annex 15 Risk reduction action plan (PQBD28V18A15)

Annex 16 List of procedures (PQBD28V18A16)

Annex 17 FMEA procedure (PQBD28V18A17)

Annex 18 Design FMEA (PQBD28V18A18)

Annex 19 Process FMEA (PQBD28V18A19)

Annex 20 Control plan (PQBD28V18A20)

Annex 21 Management review (PQBD28V18A21)

Annex 22 Good practices (PQBD28V18A22)

Annex 23 Bad practices (PQBD28V18A23)

Annex 24 MCT ISO 19443 (PQBD28V18A24)

Annex 25 Quiz requirements ISO 19443 version 2018 (PQBD28V18A25)

Annex 26 Case studies ISO 19443 version 2018 (PQBD28V18A26)