(Template – will be adapted with minimal modifications to suit your specific application)

Some points will be developed, added, cut, or specified (in red)

Quality and safety manual

1. Introduction

1.1 Presentation of the company

1.2 Purpose of the manual

2. Standards and definitions

3. Process approach

3.1 The processes in the company

3.2 Process mapping

4. Context of the company

4.1 Issues

4.2 Stakeholders

4.3 Scope

4.4 Description of the QMS

5. Leadership

5.1 Top management commitment

5.2 Quality policy

5.3 Roles

6. Planning

6.1 Actions to address risks and opportunities

6.2 Quality objectives

6.3 Planning of changes

7. Support

7.1 Resources

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documentation

8. Operation

8.1 Operational control

8.2 Requirements for products and services

8.3 Design and development

8.4 External providers

8.5 Production

8.6 Release

8.7 Nonconforming products

9. Performance

9.1 Monitoring and measurement

9.2 Internal audit

9.3 Management review

10. Improvement

Quality and safety manual revision history

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Page | Change | Revision | Author | Function | Approved | Function | Date |
| all | Creation | 001 |  |  |  |  | 01/01/2025 |
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**1. Introduction**

**1.1** Presentation of the company

**General**

|  |  |
| --- | --- |
| Name | ….. |
| Legal form | ….. |
| Authorized capital | ….. |
| Registered office | ….. |
| Siret | ….. |
| VAT No. | ….. |
| NAF | ….. |
| Phone | ….. |
| Fax | ….. |
| Email | ….. |
| Internet | ….. |
| Director | ….. |
| Sphere of activity | ….. |

**Organization**

Our company includes the following sites: ……

Our company includes the following departments: …… (cf. § 5.3)

**Mission (finality)**

Reinforce nuclear safety

Prevent accidents and mitigate consequences

Establish and foster a strong safety culture

Ensure compliance with legal, regulatory, and other requirements

Achieve and maintain high levels of quality and reliability

…

**Slogans**

"Nuclear Safety, Engineered for Trust"

"Precision for a Safer Nuclear Future"

"Building Nuclear Confidence, Component by Component"

"Your Partner in Nuclear Safety. Guaranteed by ISO 19443"

"Unwavering Quality. Uncompromising Nuclear Safety"

"Beyond Compliance: The ISO 19443 Standard for Nuclear Safety"

…

**Products and services**

Our products are: …

Our ITNS products are: …

Our activities are: …

Our ITNS activies are: …

**History**

History of the company:…..

Now the company: …..

**1.2 Purpose of the manual**

The purpose of this quality and safety manual is to describe the provisions of our quality management system (QMS) to maintain and improve:

* our ability to reinforce nuclear safety
* prevention of accidents
* compliance with applicable legal and regulatory requirements
* a strong safety culture
* our processes

The manual is available internally and externally (on request, the quality and safety manager handles the distribution history).

**2. Standards and definitions**

Our quality management system meets the requirements of the following standard:

* **ISO 19443 (2018): 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)**

For internal audits, our reference is the standard **ISO 19011 (2018): Guidelines for auditing management systems**.

For FMEA, we follow the recommendations of:

* the standard **IEC 60812 (2018): Failure modes and effects analysis (FMEA and FMECA)**

Some terms we use:

QMS:  *quality management system*

Conformity: *fulfillment of a specified requirement*

Customer: *anyone who receives a product*

Customer satisfaction: *top priority objective of every management system*

Documentation: *any support allowing the treatment of information*

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

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

FMEA: *failure mode and effect analysis*

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

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

ITNS*: important to nuclear safety*

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

Nonconformity: *non-fulfillment of a specified requirement*

Nuclear safety: *conditions of protection against undue radiological risks*

Nuclear safety management system: *set of processes allowing achieving nuclear safety objectives*

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

Procedure (documentation to maintain): *document describing the actions to carry out a process*

Process: *activities which 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 an organization with regard to quality*

Quality Management System: *set of processes allowing achieving quality objectives*

Quality and safety manual : *document specifying the general measures taken by an organization to obtain products or services of quality and nuclear safety*

Quality policy: *statement by the top management of an organization related to quality allowing the establishment of quality objectives*

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

Record (documentation to retain): *document providing objective evidence of achieved results*

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

Stakeholder: *person, group or organization that may affect or be affected by an organization*

Supplier (external provider):  *an entity that provides a product*

System: *set of interacting processes*

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

**3. Process approach**

**3.1 The processes in the company**

Top management provides, maintains and improves the resources and staff for the necessary processes. More details are provided in the procedure "Process Control" and in the record "Process List". The processes are classified into 3 types (management, realization and support).

The management processes are:

* develop strategy
* satisfy requirements
* establish process ownership
* establish policy
* plan the QMS
* acquire resources
* communicate
* negotiate the contract
* analyze data
* audit
* carry out management review
* improve
* address risks

The realization processes are:

* maintain equipment
* design and develop
* purchase
* carry out FMEA
* purchase
* control outsources processes
* produce
* inspect
* receive, store and deliver
* implement traceability
* sell
* control nonconformities
* implement corrective actions

The support processes are:

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

**3.2** Process mapping

The process mapping is shown below:

Management processes

Audit

Develop strategy

Plan the QMS

Establish policy

Establish process ownership

Satisfy requirements

Acquire resources

Carry out management review

Communicate

Negotiate the contract

Analyze data

Improve

Address risks

Realization processes

Purchase

Design

Control outsourced processes

Implement traceability

FMEA

Receive

Sell

Inspect

Control nonconformities

Produce

**Needs and expectations of stakeholders**

**Satisfaction of stakeholders**

Maintain

Implement corrective actions

**Support processes**

Provide training

Acquire infrastructure

Control documentation

Manage staff

Provide information

Manage inspection means

Keep accountability

A process review (for key processes) is conducted periodically by the process owner. More details in the process “Establish process ownership”.

**4. Context of the company**

**4.1 Issues**

Our management has made a diagnosis of the context in which our company exists and takes into account the external and internal issues relevant to our strategic direction (see the "Context of the organization" procedure and the documents "External Issues" and "Internal Issues").

We regularly monitor and review information related to the nuclear safety issues and factors that may influence the achievement of our objectives.

**4.2 Stakeholders**

Our management has determined the relevant stakeholders for our company and our QMS (see "List of stakeholders") and their requirements for our company. These requirements relate to product specifications and applicable laws and regulations.

**4.3 Scope**

This quality and safety manual applies to all areas of our business, including production related services, as well as all current and future products. More details in the "Scope of the QMS" procedure.

The scope of our company is: …..

The concerned sites are: …..

The following requirements of ISO 19443 .... are not applicable (§ xx). These requirements do not affect our ability or responsibility to ensure nuclear safety.

The justification is: .....

**4.4 Description of the QMS**

This quality and safety manual describes processes and documentation to be maintained (procedures) and to be retained (records) that are necessary to establish, implement, maintain and continually improve our QMS. The purpose of the manual is described in § 1.2. The QMS takes into account legal, regulatory and customer requirements.

**5. Leadership**

**5.1 Top management commitment**

Top management ensures that nuclear safety is taken into account in decision making and is not compromised by any decisions taken.

Top management determines the quality policy in a written declaration. This declaration is posted in some key places, to be seen by personnel and customers. The quality policy supports our strategic direction and is defined by a commitment from management.

The requirements of our customers and stakeholders are determined and respected by:

* setting up dynamic listening facilities
* their transformation into internal requirements
* measurement of the satisfaction of stakeholders

*Declaration of top management*

The director's personal commitment to improving the effectiveness of the QMS includes the promise to:

* reinforce nuclear safety
* ensure compliance with legal and regulatory requirements
* optimize risk management
* ensure our success imperatively meets the satisfaction of all stakeholders who are expecting a faultless performance in terms of:
  + safety
  + quality
  + time frames
  + costs
* follow the priority rule: make it well the first time
* strive for continual improvement of our performance
* integrate the requirements of the QMS into the internal processes
* define and achieve the objectives set; take appropriate actions when planned results are not achieved
* communicate our results internally and externally

I entrust Mr Martin, our quality and safety manager, any authority necessary to implement our quality policy and to take the required actions. This policy is based on the permanent improvement of our organization, our equipment and our knowledge, thanks to the participation and involvement of all staff. Our quality and safety manual is the engine of this permanent progress and a reflection of the daily management of the organization.

Director Dupond, date

**5.2 Quality policy**

The quality policy is set by top management in its commitment declaration. It is available on request to any stakeholder. More details are given in the "Quality policy" procedure.

The short and medium term strategy plan is determined and updated annually by top management.

The quality management system is the tool of our quality policy.

**5.3 Roles**

The responsibilities and authorities of our company are shown in our organizational chart:

## **Top management**

Quality and safety

Project leaders

Production

Engineering

Commercial

Customers and external providers

Accountability

Maintenance

Administration

Top management appoints Mr Martin, the quality and safety manager, a member of the organization’s management who has independence and authority to manage nuclear safety and quality issues, who has the authority to ensure that the quality management system is determined, implemented and maintained in conformity with the ISO 19443 standard's requirements. He can and must stop production if a nuclear safety or quality requirement is not met. He has free access to top management for the resolution of any problem.

The "Responsibility and Authority" procedure describes how the responsibilities and authorities are applied in our company. The job descriptions of all the posts in the entire staff can be found in the forms attached to the "Training" procedure.

**6. Planning**

**6.1 Actions to address risks and opportunities**

To address risks and to seize opportunities for improvement, we take into account the issues identified. The most important issues are compliance with applicable legal requirements and the working environment. This allows us to achieve the expected results of the QMS, to eliminate or reduce undesirable effects and to increase desirable effects.

The planning of actions to address risks and opportunities allows us to integrate these actions into the QMS and to evaluate their effectiveness. More details are given in the "Risks" procedure.

ITMS products and activities are broken down into items and activities, in order to determine the items and activities, whose potential failure may jeopardize the safety function.

For items and activities, we use a graded approach to the application of quality requirements related to management, documentation, and inspection.

**6.2 Quality objectives**

The quality policy provides the framework for defining quality objectives. The objectives are deployed in each department (and process concerned) and monitored daily by means of indicators. More details in the "Quality objectives" procedure.

**6.3 Planning of changes**

Changes in the QMS and processes are identified and planned. Prior to the introduction of a change, potential risks are identified and evaluated. More details are given in the "Changes" procedure.

**7. Support**

**7.1 Resources**

Resources are planned and provided by top management to:

* implement the quality management system
* improve the efficiency of the quality management system
* increase the satisfaction of customers and other stakeholders

Resources are:

* people who:
  + have specific skills
  + are trained according to identified needs (training programme)
* infrastructure
  + buildings
  + equipment
  + support services (computer system, logistics, metrology, transport)
* technological resources
* financial resources
* working environment:
* human factors:
  + ethical
  + moral
  + risk prevention
* physical:
  + air
  + cleanliness
  + light
  + temperature
  + moisture
  + ESD (electrostatic discharges)

The necessary resources are provided to obtain valid and reliable results throughout monitoring and measurement to determine the acceptability of the product and service. More details are given in the "Monitoring and Measuring" procedure.

A "Monitoring and measuring resource list" is retained and maintained by the metrology manager.

Organizational knowledge helps us to maintain process, product and service compliance over time.

**7.2 Competence**

For each position affecting quality, the necessary competencies are defined and the training needs identified and established. All the operators are followed by a competence matrix, updated at least once a month.

The "Training" procedure shows how to:

* identify training needs
* achieve the required skills
* apply motivation to:
  + achieve quality objectives
  + achieve continual improvement
  + create an environment conducive to innovation

Training is carried out at the workstation for each novelty or change, including for temporary staff.

**7.3 Awareness**

Staff is aware of:

* their contribution to nuclear safety
* its contribution to the achievement of the objectives
* the importance of compliance with the quality policy
* their responsibility for prevention and continual improvement
* consequences of potential malfunctions
* relevant documentation and its changes
* the importance of ethical behaviour

Persons involved in the realization of ITNS products or services are trained on the importance of their tasks, including the potential nuclear safety consequences of errors in their activities.

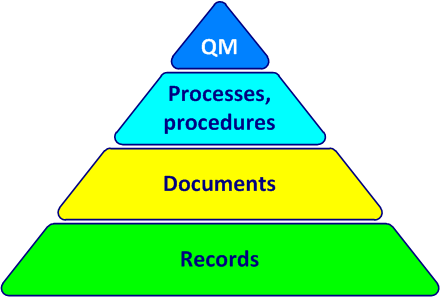
**7.4 Communication**

Internal and external communication is planned and documented (see "Communication" procedure). Top management implements transparent communication arrangements with customers, staff and other stakeholders about:

* product information (technical specifications, conditions of use and others)
* consultations, quotations, contracts and orders
* customer information, especially complaints and actions taken
* the importance for all to respect customer, legal and regulatory requirements
* risk prevention

**7.5 Documentation**

Our company has based its quality management system on documentation at 4 levels, symbolized by the documentary pyramid:



This quality and safety manual (QSM) describes the general dispositions related to the requirements of the quality management system:

* it refers to and relies on procedures and processes
* the procedures themselves refer to and are based on documents (instructions) which are, for example, work instructions to follow at a work station
* finally, documents rely on records to keep a trace (paper or data processing) of an operation of inspection, verification or identification

This manual is written by the quality and safety manager and has been approved by top management.

Any customer or external provider may obtain a copy of the quality and safety manual with the agreement of top management or the QM. The distributed paper copies are in controlled diffusion for one day after printing. The quality and safety manager maintains a list of the distributed copies, the recipients, the version and the date.

The quality and safety manager updates the manual after each change of the quality management system (QMS). The update is carried out in accordance with the procedure "Documentation".

Point by point answers to all of the requirements in articles 4 to 10 of ISO 19443 are present in our documentary system.

The "Documentation" procedure defines how to identify, set up and maintain the control of documents and records. Included are documents of external origin (from external providers, customers, standards or stakeholders). For all documents and records of the QMS, the following details are included or considered:

* the location
* the checking process
* the approval
* the update
* the relevant version in force
* the availability
* the control of documents of external origin
* prevention of the use of obsolete documents (removal, appropriate identification or specific control)
* archiving

For electronically managed documentation, we have implemented a safeguard protection process (automatic daily backup) and provisions against unauthorized intervention.

The "List of procedures" shows the correspondence of the procedures of our QMS with the sub-clauses of the standard ISO 19443.

**8. Operation**

**8.1 Operational control**

The product planning process is developed in line with the requirements of the other processes in the quality management system. The "Operational control" procedure defines the stages of planning and control of operational activities.

The risk approach applied to product realization and service delivery activities is described in the "Risks" procedure.

For any risk identified in one of the processes, a procedure is put in place to reduce this risk. The scope of application of this operational control encompasses all activities associated with each risk identified as:

* workstations
* equipment
* machines
* chemicals
* the materials
* the staff
* external providers
* maintenance
* purchases of:
  + infrastructure:
    - buildings
    - equipment
    - services
  + products
* design of:
  + workstations
  + equipment
  + machines
  + work organization processes

The requirements of certain operational procedures are disclosed to external service providers and subcontractors.

The most commonly used documents are:

* prevention plan
* safety protocol
* emergency plan
* protection device
* work instruction
* accident / accident factsheet

The "Operational Control" procedure defines how to identify, set up and maintain processes related to the production of the product. The aim is to comply with the quality policy and to achieve the objectives. This allows us to:

* maintain control by preventing potential deviations from the quality policy
* establish the roles and responsibilities
* communicate requirements at all levels

We make provisions for counterfeit, fraudulent or suspect (CFS) items at all levels of operations.

**8.2 Requirements for products and services**

The customer process identifies the requirements:

* formulated by the customer and other stakeholders:
  + specification
  + delivery requirements
  + after-sales service
  + others
* not expressed by the customer but necessary for the intended use
* regulatory and statutory relating to the product
* internal

The business process activities are described in the "Contract Review" procedure.

Analysis of the results allows us to:

* identify business processes (product requirements are defined)
* communicate regularly with the customer (quotes, negotiations and contracts)
* ensure that we can meet the requirements identified
* define and resolve situations of deviations
* assess risks (e.g. related to new processes)
* define quality indicators for business processes

**8.3 Design and development**

Each stage of the design and development process is planned and controlled according to the “Design and development” procedure.

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

When design tools (e.g. computation codes or computerized models) are used, we demonstrate that these are fit for purpose.

Requirements for the inputs of product design and development are:

* determined and recorded
* complete, unambiguous and non-contradictory
* reviewed for adequacy

Some examples:

* functional requirements
* regulatory and legal requirements
* similar design information
* other requirements

A risk analysis is conducted using the FMEAs. More details in the "FMEA" procedure.

Before use, the design and development product outputs are:

* verified and
* approved

They must:

* meet the input requirements
* provide information for purchasing and production
* contain the acceptance criteria for the product
* specify the characteristics for their correct use

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

* the capacity to meet requirements is evaluated
* the problems are identified and actions are proposed

The verification (technical viewpoint), the validation (functional viewpoint) and the approval of the design and development and their changes (cf. procedure "Project start") are a logical follow-up of reviews and are performed by competent persons. The records are retained.

**8.4 External providers**

The purchasing process ensures that the purchased products and provided services are in conformity with requirements at each delivery. The external providers are evaluated and selected on the basis of determined criteria in the procedure "External providers". The records of the evaluations, selections and related actions are retained.

**8.5 Production**

We ensure that the activities related to product production and service provision are realized in accordance with specified requirements in controlled conditions leading to reproducible results (cf. procedures "Operational control" and "Maintenance").

These conditions can include means related to:

* product characteristics
* work instructions
* suitable equipment
* qualification of operators
* monitoring and measurement equipment and activities
* activities of release, delivery and after delivery services

If outputs cannot be checked a posteriori, this process will be validated to demonstrate the ability to achieve the planned results, which will be recorded. This can be done through criteria for review and approval of processes and equipment, specific staff qualifications, and specific methods and procedures.

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

We attach special care to customer’s property (which may be intellectual property). This property is identified, verified, protected and safeguarded. The customer is notified immediately and records are retained if any incident occurs.

The conformity of the product and its components is preserved until delivery using operations such as:

* identification
* handling
* packaging
* storage
* protection and
* delivery

The procedure "Reception and storage" describes the rules to follow regarding to management of raw materials, finished and semi-finished products for activities in reception and in the stores.

The procedure "Identification and traceability" contains descriptions of the methods we use to control the aptitude to memorize or restore the history and/or the development of the products.

**8.6 Release**

The release of products and services is always preceded by activities to verify compliance with the requirements for products and services. Product inspections are planned, carried out and their results retained (including the person who authorized the release of the product) to verify that the requirements are met, unless there is a special or customer concession.

The release of products and services is always accompanied by a declaration of conformity.

More details are given in the "Inspection" procedure.

**8.7 Nonconforming products**

The procedure "Nonconformities" determines the responsibilities and necessary inspections to identify and control nonconforming product, including after delivery. Any quality-related dysfunction is identified and analyzed.

This allows us to:

* identify nonconformities
* address nonconformities
* determine and eliminate the causes
* evaluate the need for corrective actions
* implement corrective actions where appropriate
* record results and follow-up
* evaluate the effectiveness of these actions and
* change, if necessary, the documents of the QMS

**9. Performance**

**9.1 Monitoring and measurement**

The conformity of the product is ensured by using appropriate monitoring and measuring equipment with validated status according to the "Monitoring and measuring" procedure.

Every measuring instrument is identified and verified. Every user is trained. The record’s results for the calibration and verification are retained.

We regularly monitor the level of customer satisfaction with their needs and expectations. More details are given in the "Customer satisfaction" procedure.

We perform an analysis and evaluation of monitoring and measuring information. We apply provisions (including statistical techniques) to measure the performance of the:

* satisfaction of customers and other stakeholders
* quality management system
* process control
* control of products and services
* external providers
* actions taken to address risks
* prevention measures (see the "FMEA" procedure)
* continual improvement through seized opportunities
* nuclear safety culture aspects

**9.2 Internal audit**

The internal audit allows us to evaluate the conformity and effectiveness of the quality management system (see "Internal Audit" procedure). Internal audits ensure that the quality management system is properly set up and remains operational. Conformity is determined by reference to:

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

**9.3 Management review**

The management review is planned and its records are kept in accordance with the "Management review" procedure. Its objective is to review whether the quality management system is relevant, adequate and effective.

Nuclear safety receives the attention warranted by its significance.

**10. Improvement**

To improve the effectiveness of the quality management system, our efforts are concentrated to achieve the objectives in cases like:

* customer satisfaction and other stakeholders
* the rate of customer complaints
* meeting deadlines
* the net margin
* reducing costs
* identification of risks
* risk prevention
* the setting up of prevention means

The continual improvement process described in the “Continual improvement” procedure is based on:

* stable processes
* results of audits
* analysis of data
* the establishment of new improvement objectives
* research and evaluation of solutions
* implementation of solutions and measurement of results
* formalizing changes when objectives are met

The Kaizen method of continual improvement in small steps is widely used in all departments. It is a formidable tool for fighting waste in all its forms.

The "Corrective action" procedure defines the requirements for how to:

* conduct a review of nonconformities (customer complaints are included)
* address nonconformities
* identify and eliminate the causes
* evaluate the potential risks
* evaluate the need for corrective actions to prevent the recurrence of non-conformities
* implement curative and corrective actions
* record the results of corrective actions and their follow-up

The corrective action is taken to find and eliminate the cause of the occurrence of nonconformities.

Continual improvement encompasses nuclear safety culture.