# NUCLEAR SAFETY AND QUALITY MANAGEMENT SYSTEM – REQUIREMENTS

**Model for quality management in design & development, manufacturing, erection, commissioning and related services**

CONTENTS

APPENDIX 1: List of modified or added paragraphs to ISO9001:2008 and of ISO9001:2008 notes which shall not be used as they do not meet nuclear safety principles.

# FOREWORD

To enhance nuclear safety in compliance with nuclear quality requirements, nuclear community industrials must develop and continuously improve safe, reliable products that meet or exceed customer and applicable statutory and regulatory requirements.

Organizations have the challenge of purchasing products from suppliers throughout the world and at all levels of the supply chain. Suppliers have the challenge of delivering products to multiple customers having varying quality requirements and expectations.

This document, prepared by the Nuclear Quality Standard Association:

- aims to:
  - develop a high level of nuclear safety and quality culture in all activities,
  - ensure the achievement of the appropriate level of quality in the delivery of products to meet the customer expectations and in compliance with the applicable regulations,
  - contribute to the operational excellence by supporting the continuous improvement initiatives in order to reach the expected quality performances,

  and,

- standardizes quality management system requirements to the greatest extent possible and can be used at all levels of the supply chain by organizations around the world. Its use should result in improved quality, schedule and cost performance by the reduction or elimination of organization-unique requirements and wider application of good practices.

# 0. INTRODUCTION

## 0.1. General

This document specifies additional requirements to ISO 9001:2008 quality management system requirements.

The adoption of these requirements should be a strategic decision of an organization.

These requirements can be used by internal and external parties to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.

Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.

Information “No additional requirements” means that, for the corresponding chapter, the NSQ-100 doesn’t add any requirements to ISO9001:2008 standard.

## 0.2. Process approach

*No additional requirement.*

## 0.3. Relationship with ISO 9004

*No additional requirement.*

## 0.4. Compatibility with other management systems

Correspondence matrix between this document and other international or national standards are provided through NSQ-110 documents series, available on NQSA website (www.nqsa.org).

# 1. SCOPE

## 1.1. General

This document is intended for any organization which supplies product within nuclear industry.

It is emphasized that the requirements specified in this document are complementary (not alternative) to contractual and applicable statutory and regulatory requirements. Should there be a conflict between the requirements of this document and applicable statutory or regulatory requirements, the latter shall take precedence.

NOTE: To be easily usable, the structure of this document has kept the same layout than ISO 9001:2008, except for:

- ISO 9001:2008 “Purchasing information” paragraph 7.4.2 which is divided in three different paragraphs 7.4.2.1 “Content of the procurement documents”, 7.4.2.2 “Procurement document review” and 7.4.2.3 “Procurement document changes”,
- some new paragraphs added to those of ISO9001:2008. Refer to appendix 1 to this document for exhaustive list of added paragraphs.

## 1.2. Application

Where exclusions to the requirements of this document are made, these exclusions are limited to requirements within Chapter 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

This document describes requirements to comply with when establishing and/or implementing a Quality Management System according ISO 9001:2008 in order to ensure that nuclear safety aspects are properly taken into account.

# 2. NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of this document.

ISO 9000:2005, Quality management systems — Fundamentals and vocabulary,

ISO 9001:2008, Quality management systems — Requirements,

IAEA GS-R-3:2006 - The management system for facilities and activities – Safety Requirements.

Note: Wordings from GS-R-3 have been used as it is in order to ensure a better understanding and consistency with GS-R-3 requirements. E.g.: terms and definitions, Safety culture aspects…

# 3. TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in normative references apply.

## 3.1. Activity

Task which directly contributes, during design, development, manufacturing, erection, commissioning and related services, to the quality or performances of the product.

## 3.2. Classification

Classification shall be based upon, at least, nuclear safety aspects, but, depending of contractual requirements, may also consider quality or performances of the product.

## 3.3. Commercial-grade item

A structure, system, or component, or part of thereof, that affects its significance for safety, that was not designed and manufactured in accordance with the requirements of this document. Commercial-grade item do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

## 3.4. Commissioning

The process by means of which structures, systems and components of facilities and activities, having been constructed, are made operational and verified to be in accordance with the design and to have met the required performance criteria.

Commissioning may include both non-nuclear and/or non-radioactive and nuclear and/or radioactive testing.

## 3.5. Critical characteristic

An attribute or feature whose variation has a significant effect on product fit, form, function, performance, nuclear safety and reliability, that requires specific actions for the purpose of controlling variation. This characteristic shall be identifiable and measurable.

## 3.6. Customer

The purchasing organization that puts in an order.

## 3.7. Important For Safety (IFS)

A product, an item or activity whose malfunction or failure could lead to undue radiation hazards.

Items important for safety include:

- those systems, structures and components (SSC) whose malfunction or failure could lead to undue radiation exposure of site personnel or members of the public;
- those systems, structures, and components that prevent anticipated operational occurrences from leading to accident conditions;
- those features that are provided to mitigate the consequences of malfunction or failure of systems, structures, and components.

## 3.8. Item

An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, sub-assembly, sub-system, system or unit, software.

## 3.9. Licensee

The organization legally responsible for the construction and/or operation of a nuclear facility including but not limited to one which has applied for, or which has been granted, a construction permit or operating license by the Regulatory Body having lawful jurisdiction.

## 3.10. Nuclear safety

The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards.

## 3.11. Product

The result of any activity related to design, procurement, manufacturing, inspection, testing, handling, transportation, storage, cleaning, site erection and any operation on SSC. Product can also mean service.

## 3.12. Risk

An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

## 3.13. Safety culture

Overall characteristics and attitudes in organizations and individuals which establish that, as an overriding priority, protection and nuclear safety issues receive the attention warranted by their significance.

## 3.14. Special process

A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

## 3.15. Supplier

Any individual or organization that furnishes products in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor (first rank supplier of the licensee), subcontractor, fabricator, consultant, and their sub tier level.

## 3.16. Surveillance

The act of monitoring or observing which ensures whether an item or activity is in compliance with specified requirements.

# 4. QUALITY MANAGEMENT SYSTEM

## 4.1. General requirements

Assignment of responsibilities shall be clearly defined. For each process which contributes to quality or performances of the product, a designated person, group or function shall be given the authority and responsibility.

NOTE 4: The organization may restrict the application of these requirements to its nuclear business.

### 4.1.1. Nuclear safety culture

The organization shall promote and support a strong safety culture by:

- ensuring a common understanding of the key aspects of safety culture within the organization,
- providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization,
- reinforcing a learning and questioning attitude at all levels of the organization,
- providing the means by which the organization continually seeks to develop and improve its safety culture.

NOTE: According to legal aspects and in order to ensure transparency on product realization, the organization may be required to make available to the licensee all necessary information linked to safety.

### 4.1.2. Classification of items and activities

Taking into account the product complexity, each organization involved in the supply chain shall break down the product classification in order to identify items and activities important for safety (see 3.7) or important for the final quality of the product.

Classification of items or activities important for safety shall be based on analysis of consequences of their potential failure or malfunction on the safety function of the product (see 3.9).

The classification shall be submitted to the customer for acceptance.

NOTE: Customer acceptance doesn't release the supplier concerning its responsibility for the conformity of the product.

The classification procedure shall be documented and records related to classification of an item or activity shall be maintained (see 4.2.4).

### 4.1.3. Grading the application of quality requirements

For classified items or activities, the associated quality management level, inspection & surveillance levels and documentation requirements shall be graded in accordance with the classification of the item or activity.

The organization shall justify and document the method used to define the above relevant requirements.

NOTE: Classified activities could include any manufacturing operation such as heat treatment, welding or other special processes.

## 4.2. Documentation requirements

### 4.2.1. General

The organization shall ensure that personnel have access to, and are aware of, relevant quality management system documentation and changes.

Documentation shall be provided to the personnel in an appropriate language for its understanding.

### 4.2.2. Quality manual

The organization shall specify in a controlled document (quality manual, quality assurance program or plan), subject to evaluation by the customer, the organizational, documentary and technical provisions to meet the requirements of this document and to address the nuclear safety aspects.

If not covered by this document, the quality assurance program or plan shall consider additional quality requirements coming from the contract, the applicable regulations, codes and standards.

### 4.2.3. Control of documents

The preparation, issue and change of documents that specify product quality requirements or prescribe activities affecting product quality such as instructions, procedures, and drawings shall be verified and approved for release by authorized personnel. The individual who performs the verification must be other than those who have prepared, issued or changed the document.

Changes to documents shall be reviewed, recorded and shall be subject to the same level of approval as the documents themselves.

### 4.2.4. Control of records

The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.

Any hand written correction on an already issued record shall be clearly authenticated.

Retention time must be in accordance with legal or customer requirements.

# 5. MANAGEMENT RESPONSIBILITY

## 5.1. Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

f) ensuring a common understanding of the key aspects of safety culture within the organization,

g) providing the means by which the organization continually seeks to develop and improve its safety culture.

## 5.2. Customer focus

Top management shall ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken, if planned results are not, or will not be, achieved, while, at the same time, ensuring that nuclear safety is not compromised.

## 5.3. Quality policy

Top management shall ensure that the quality policy:

f) is appropriate to nuclear safety aspects related to the product.

## 5.4. Planning

### 5.4.1. Quality objectives

*No additional requirement.*

### 5.4.2. Quality management system planning

NOTE: Organizational changes should be evaluated and classified according to their importance to safety and each change should be justified.

The implementation of such changes should be planned, controlled, communicated, monitored and recorded to ensure that nuclear safety is not compromised.

## 5.5. Responsibility, authority and communication

### 5.5.1. Responsibility and authority

The organization shall retain overall responsibility for the management system when an external organization is involved in the work of developing all or part of the management system.

### 5.5.2. Management representative

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

b) reporting directly to top management on the performance of the quality management system and on any need for improvement,

d) the organizational independence to resolve quality management issues.

### 5.5.3. Internal communication

*No additional requirement.*

### 5.5.4. Communication with Regulatory Bodies

With regards to the nuclear safety related product issues, the organization shall ensure that appropriate processes are defined in liaison with the customer to address any communication from nuclear safety Regulatory Bodies.

## 5.6. Management review

### 5.6.1. General

*No additional requirement.*

### 5.6.2. Review input

Lessons learned from other organizations shall be also taken into account.

### 5.6.3. Review output

*No additional requirement.*

# 6. RESOURCE MANAGEMENT

## 6.1. Provision of resources

Information and knowledge of the organization shall be managed as a resource.

## 6.2. Human resources

### 6.2.1. General

Personnel involved in the realization of the product shall be trained on the importance of their tasks and of the eventual consequences on the nuclear safety of any malfunction or error in their activities.

### 6.2.2. Competence, qualification, training and awareness

The organization shall:

b) where applicable, provide training or take other actions, as maintenance of proficiency, to achieve the necessary competence,

f) assess the adequacy of the personnel with the expected or required competence,

The organization shall designate activities that require qualification of personnel and the minimum requirements for such personnel.

Provisions shall be taken to define competent personnel able to elaborate, verify and approve documents issued in foreign languages. A list of these personnel shall be established and maintained.

A documented procedure shall be defined for qualification of such personnel.

## 6.3. Infrastructure

*No additional requirement.*

## 6.4. Work environment

NOTE: The term "work environment" refers to working conditions including radiation safety.

# 7. PRODUCT REALIZATION

## 7.1. Planning of product realization

The organization shall determine, as appropriate:

a) quality objectives and requirements for the product, which may include aspects such as:

- product performances,
- nuclear safety,
- reliability, availability and maintainability,
- producibility and inspectability during and after manufacture,
- health and safety aspects during set-up, operating and maintenance phases,
- when contractually required, environmental aspects of parts and materials used in the product, and
- when contractually required, safety and environmental aspects during retrieval.

e) management of product change,

f) commissioning program, if applicable, and

g) when contractually required, resources to support the operating and maintenance of the product.

NOTE 1: A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a project quality plan.

NOTE 3: Product change means any product change or any modification in production processes which may affect its quality or performances.

### 7.1.1. Project management

As appropriate to the organization and the product, the organization shall plan and manage product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints, complemented, if applicable, with health and safety, environmental, security and economic considerations.

### 7.1.2. Risk management

The organization shall develop a project risk management, related to the achievement of applicable requirements.

This includes, as appropriate to the organization and the product:

a) definition of risk criteria (e.g., likelihood, consequences, risk acceptance),

b) identification, assessment and communication of risks throughout product realization including supply chain,

c) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria.

### 7.1.3. Configuration Management

When applicable, the organization shall establish, implement and maintain a configuration management process that includes, as appropriate to the product:

a) configuration management planning,

b) configuration identification,

c) change control,

d) configuration status accounting, and

e) configuration audit.

NOTE: See ISO 10007 for guidance.

## 7.2. Customer-related processes

### 7.2.1. Determination of requirements related to the product

The organization shall determine:

c) statutory and regulatory requirements, including nuclear safety aspects, applicable to the product.

The supplier has to establish a documented list of items and activities classified as IFS or important for the final quality of the product, and determine the associated quality management level, surveillance level and documentation requirements (see 4.1.2 and 4.1.3).

NOTE 2: Nuclear safety aspects concern the safety culture, the graded approach, IFS items and activities, and the implementation of applicable construction codes and standards.

### 7.2.2. Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:

d) manufacturing feasibility has been investigated and confirmed,

e) all risks are considered for:

- the respect of all safety functions of the product (including mechanical, electrical, instrumentation and command aspects),
- manufacturing, erection, testing and commissioning of the product.

### 7.2.3. Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to:

a) product information, including nuclear safety aspects,

b) when required, management of communication with nuclear Regulatory Bodies.

The organization shall be able to communicate the necessary information, in particular and compulsorily, those related to nuclear safety issues, including data, in a customer-specified language and format (e.g. computer-aided design data, electronic data exchange).

## 7.3. Design and development

### 7.3.1. Design and development planning

During the design and development planning, the organization shall determine and document:

d) the design interfaces.

Where appropriate, the organization shall divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, input and output data and planning constraints.

The different design and development tasks to be carried out shall be based on the nuclear safety and functional objectives of the product in accordance with customer, legal, statutory and regulatory requirements.

Design and development planning shall consider the ability to produce, inspect, install, test and maintain the product.

In case of computation or computerized models, the organization shall demonstrate that those are verified within their scope and validated. Individuals using the above shall be competent (see 6.2.2).

Methods and means used for design verification and their combinations shall be defined prior to design and development realization.

The software design and development stages shall be organized throughout the life cycle including the main four following processes:

- Specification,
- General and detail design,
- Coding,
- Integration and tests.

If tests are used for any design & development purposes, provisions of 7.3.8 shall be respected.

### 7.3.2. Design and development inputs

Inputs relating to product requirements shall be determined, accepted, translated into design documents and records maintained (see 4.2.4). These inputs shall include:

a) functional and performance requirements including nuclear safety requirements (see 4.1.2),

e) risk identified for the product (see 7.2.2).

Design and Development inputs shall include a description of hardware and the specifications addressing interfaces between hardware and software.

### 7.3.3. Design and development outputs

Design and development outputs shall:

d) specify the characteristics of the product that are essential for its safe and proper use (to be included in Instructions of use), and

e) specify, for IFS items or activities, any critical characteristics translated into technical specifications. This shall also be applied to commercial grade items that shall be incorporated in IFS products.

The organization shall define the data required to allow the product to be identified, manufactured, inspected, used and maintained, including at least:

- the drawings, part lists and specifications necessary to define the configuration and the design features of the product,
- the material, process, manufacturing and assembly data needed to ensure conformity of the product, and
- the software configuration management.

NOTE 1: Information for production and service provision shall at least include details for the manufacture, test, installation, operating, maintenance and preservation of product.

NOTE 2: Configuration management shall identify and document characteristics of the software and ensure that consistency is maintained.

### 7.3.4. Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1):

c) to authorize progress to the next stage.

Reviews shall be documented and detailed in such a manner that no ambiguity or misunderstanding may occur.

### 7.3.5. Design and development verification

The methods used for design verification shall be identified and documented.

Design verification shall be performed by any competent person or group, clearly indicated and other than those who performed the original design of the product or participated to related design activities.

### 7.3.6. Design and development validation

NOTE: If required, the design and development validation may involve inspections or reviews from independent parties.

At the completion of design and/or development, the organization shall ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements in the most adverse conditions.

Such demonstration shall be recorded (see 4.2.4).

### 7.3.7. Control of design and development changes

Design and development changes shall be identified, justified, and records maintained.

The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation.

The review of design and development changes shall include evaluation of the effect of the changes on classification, constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

Software changes management shall ensure the integrity, i.e. only validated changes are incorporated.

Software changes verification shall include regression testing.

The personnel or group approving the design and development changes must be authorized, competent in the field of concern and have knowledge of the requirements and the intent of the original design.

### 7.3.8. Design and development verification and validation testing

Where tests are necessary for verification and validation of the design, these tests shall be planned, controlled, reviewed and documented to ensure and prove the following:

a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria,

b) test procedures describe the method of operation, the performance of the test and the recording of the results,

c) the correct configuration of the product is submitted for the test,

d) the requirements of the test plan and the test procedures are observed, and

e) the acceptance criteria are met.

For software, testing methods to be implemented are:

- unit testing, to check software compliance with detailed design inputs,
- integration testing, to check software compliance with general design inputs,
- system testing, to check that overall software complies with specifications.

Any requirement of the software specification shall be validated by a test and testing conditions shall include normal and downgraded conditions.

## 7.4. Purchasing

The hereunder requirements shall be considered for purchasing of products (items or activities) having a direct impact on nuclear safety (IFS) or quality of the final product.

### 7.4.1. Purchasing process

The organization shall be responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer.

Anyone involved in the supply chain shall take the required measures in the purchasing data to ensure that the customer’s requirements are transmitted to the suppliers.

Furthermore, any supplier, at every level of the supply chain, shall verify that requirements have been taken into account and implemented in order to ensure the product acceptance.

The organization shall evaluate and select suppliers, based on their ability to supply product in accordance with the organization's requirements (at least, taking into account technical, quality and safety aspects), and:

a) define the process, responsibilities and authority for:
   - the approval status decision,
   - the change of the approval status.

b) define the necessary actions to implement in case of selection of commercial grade item supplier.

c) periodically review supplier performance; the results of these reviews shall be used as a basis for establishing the monitoring level to be implemented, and

d) maintain a register of approved suppliers.

When a supplier does not meet applicable requirements of this document, partial or complete substitution by the organization quality system to the supplier's one shall be ensured. Information of this substitution shall be made available up to the Contractor.

## 7.4.2. Purchasing information and procurement document control

### 7.4.2.1. Content of the procurement documents

Purchasing information shall describe the product to be purchased and its corresponding scope of work, including, where appropriate:

c) quality management system requirements consistent with nuclear safety classification and/or impact on final quality of the product,

d) technical requirements : identification, revision and, if appropriate, status of specifications, drawings, codes, standards, regulations, process requirements, and other relevant technical data,

e) requirements for design, test, inspection and surveillance (including instructions and acceptance criteria) for determining acceptance of the product and, as applicable, any critical characteristics,

f) identification of the documentation that the supplier has to submit for information, review or approval,

g) requirements to identify spare parts and the related data required for ordering these spare parts,

h) requirements regarding the need for the supplier to:
   - notify the organization of nonconforming product,
   - obtain organization approval for nonconforming product disposition,
   - notify the organization of changes in product and/or process, changes of suppliers, changes of manufacturing facility location and, where required, obtain organization approval, and
   - flow down to the supply chain the relevant requirements including customer requirements,

i) records retention requirements, and

j) right of access by the organization, their customers, third party organizations, Regulatory Bodies, and/ or their respective representatives, to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.

### 7.4.2.2. Procurement document review

The organization shall ensure by a review of the procurement document, the adequacy of specified purchase requirements prior to their communication to the supplier.

Procurement document review shall be performed by competent personnel, other than those who issued the procurement document, and recorded (see 4.2.4).

#### 7.4.2.3. Procurement document changes

Procurement document changes affecting the technical or quality requirements shall be subject to the same process and control as used in the preparation of the original documents (see 7.4.2.1 and 7.4.2.2).

### 7.4.3. Verification of purchased product

Any verification activity shall be planned, documented and recorded (4.2.4).

NOTE: Customer verification activities performed at any level of the supply chain should not be used by the organization or the supplier as evidence of effective monitoring of quality and does not absolve the organization or the supplier of their responsibility to provide acceptable product compliant with all requirements.

Organization, customer, licensee, third party organizations, Regulatory Bodies, and/or their respective representatives, may reserve the right to verify throughout the supply chain that products and quality management system comply with specified purchasing requirements.

## 7.5. Production and service provision

### 7.5.1. Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

c) the use of suitable equipment,

NOTE: Suitable equipment can include product specific tools (e.g., jigs, fixtures, molds) and computer program.

g) evidence that all production, inspection and/or surveillance operations have been completed as planned, or as otherwise documented and authorized.

Planning shall consider, as appropriate:

- establishing, implementing and maintaining appropriate processes to manage IFS items or activities, including process monitoring where critical characteristics have been identified,
- identifying in-process inspection points when adequate verification of conformance cannot be performed at later stages of realization, and
- special processes (see 7.5.2).

#### 7.5.1.1. Control of production process changes

Personnel authorized to approve changes to production processes shall be identified.

The organization shall control and document changes affecting processes, production equipment, tools or computer programs.

The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product conformity.

#### 7.5.1.2. Control of production equipment, tools and computer programs

Production equipment, tools and computer programs used to automate and control/monitor product realization processes, shall be validated prior to release for production and shall be maintained.

Storage requirements, including periodic preservation/condition checks, shall be defined for production equipment or tooling in storage.

#### 7.5.1.3. Inspection and surveillance activities

The organization shall ensure the provisions for inspection and surveillance activities have been taken into account.

The methods used for inspection and surveillance shall be defined. These activities shall be planned and performed by competent personnel other than those who carried out the work.

Appropriate records shall be established, maintained and, as a minimum, identify the following:

- item inspected,
- activity surveyed,
- date of inspection or surveillance,
- identification of personnel who performs the inspection or surveillance,
- statements' details,
- results or acceptability,
- if necessary, follow up actions.

### 7.5.2. Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

NOTE: These processes are often referred to as special processes.

### 7.5.3. Identification and traceability

IFS items or activities are subject to an identification. The associated documentation shall be clearly identified and linked to the products without ambiguity.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish appropriate controls for the media.

### 7.5.4. Customer property

*No additional requirement.*

### 7.5.5. Preservation of product

Preservation of product shall also include, where applicable, in accordance with product specifications and applicable statutory and regulatory requirements, provisions for:

a) limiting the access to the product to avoid undue intervention,

b) cleaning,

c) prevention, detection and removal of foreign objects,

d) special handling for sensitive products or hazardous materials, and

e) marking and labeling including safety warnings.

### 7.5.6. Post-delivery support

As applicable, post-delivery support shall be provided for:

a) collection and analysis of in-service data,

b) actions to be taken, including investigation and reporting, when problems are detected after delivery,

c) control and updating of technical documentation,

d) approval, control and use of repair schemes, and

e) inspection required for off-site work (e.g., organization's work undertaken at the customer's facilities).

## 7.6. Control of monitoring and measuring equipment

The organization shall maintain a register of the monitoring and measuring equipment and define the process employed for their calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

Calibration /verification method shall be based against standards. Where no such standard exists, the basis for calibration/verification shall be defined.

The organization shall ensure that environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out.

Selection of measuring and test equipment shall be based at least on their measuring range and measurement accuracy having regard to the tolerance specified.

In order to avoid use of monitoring and measuring equipment, which are non-conform or requiring calibration/verification, the organization shall:

- Implement and maintain a process for the recall of such equipment,
- Identify and/or segregate or remove from service such equipment.

# 8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

## 8.1. General

*No additional requirement.*

## 8.2. Monitoring and measurement

### 8.2.1. Customer satisfaction

Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product conformity, on-time delivery performance, customer complaints, corrective action requests and implementation of safety culture (see § 4.1.1).

The organization shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

### 8.2.2. Internal audit

Planned arrangements for internal audit shall include specific quality assurance programs or plans.

Audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities including safety culture.

The organization shall qualify auditors according to a documented procedure including qualification criteria.

Auditors shall not audit their own work and shall be appointed by personnel independent of the audited activity.

The organization shall maintain and periodically review auditor qualification.

Records of qualification shall be maintained (see 4.2.4).

### 8.2.3. Monitoring and measurement of processes

In the event of process nonconformity, the organization shall:

a) take appropriate action to correct the nonconforming process,

b) evaluate whether the process nonconformity has resulted in product nonconformity,

c) determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and

d) identify and control any nonconforming product (see 8.3).

### 8.2.4. Monitoring and measurement of product

Measurement requirements for product acceptance shall be documented and shall include:

a) criteria for acceptance and/or rejection,

b) where, in the sequence measurement and testing, operations are to be performed,

c) required records of the measurement results (as a minimum, indication of acceptance or rejection), and

d) any specific measurement instruments required and any specific instructions associated with their use.

When IFS items or activities have been identified, the organization shall ensure that these items or activities are inspected by any clearly indicated competent personnel other than those who performed the activity.

The organization shall ensure that all documents required to accompany the product are present at delivery.

## 8.3. Control of nonconforming product

Products and processes that do not conform to the specified requirements shall be timely identified, segregated, controlled, recorded and reported to an appropriate level of management within the organization.

Nonconformity shall be timely reported in compliance with the customer requirements.

NOTE: The term “nonconforming product” includes nonconforming product returned by a customer.

The following way may be used by the organization to deal with nonconforming product:

e) by taking actions necessary to contain the effect of the nonconformity on other processes or products.

When the characteristics of a product along the supply chain are not conforming with specified requirements, a nonconformity shall be reported.

Where applicable, justifications of use-as-is or provisions for repair shall be submitted to customer for approval.

Product intended for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

## 8.4. Analysis of data

*No additional requirement.*

## 8.5. Improvement

### 8.5.1. Continual improvement

*No additional requirement.*

### 8.5.2. Corrective action

A documented procedure shall be established to define requirements for:

g) flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity,

h) determining specific actions, where timely and/or effective corrective actions are not achieved, and

i) determining if additional nonconforming product exists, based on the causes of the nonconformity and taking further action when required.

Records shall be maintained to demonstrate the completion of any stage of corrective action procedure.

### 8.5.3. Preventive action

A documented procedure shall be established to define requirements for:

f) providing provisions of adequate resources for improvement plans.

The potential nonconformities shall be determined using also:

- feedback from other organizations,
- through the use of technical advance and research,
- sharing of knowledge and experience,
- through the use of techniques that identify best practices.

Bibliography :

[1] ISO 9001:2008 - Quality Management Systems – Requirements
[2] EN 9100:2009 - Quality management systems / Requirements for Aviation, Space and Defense Organizations
[3] IAEA GS-R-3 version 2006 - IAEA Safety Standards /The management system for Facilities and Activities - Safety Requirements n°GS-R-3
[4] IAEA GS-G3-5 version 2009 - The Management System for Nuclear Installations
[5] NQA-1 Part I 2008- Requirements for Quality Assurance Programs for Nuclear Facilities
[6] ASME NQA – 1A - 2009 – Addenda to ASME NQA-1-2008 – Quality Assurance Requirements for Nuclear Facility Applications
[7] KTA 1401 (06/96) General Requirements Regarding Quality Assurance
[8] French regulation: Arrêté et Circulaire du 10 Août 1984 relatif à la qualité de la conception, de la construction et de l'exploitation des installations nucléaires de base
[9] US regulation: 10 CFR 50 Appendix B (Title 10 - Code of Federal Regulations Part 50 - Appendix B) : Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
[10] WENRA - Pilot Study on Harmonization of Reactor Safety in WENRA Countries - March 2003
[11] WENRA - Reactor Safety - Reference Levels - January 2008
[12] FD ISO/TS 16949 - Particular requirements for the application of ISO 9001:2000 for automotive production, and relevant service part organizations (June 2002)

# APPENDIX 1

List of modified or added paragraphs to ISO9001:2008,
and of ISO9001:2008 notes which shall not be used as they do not meet nuclear safety principles

NOTE: *Italic characters* means that the ISO9001:2008 paragraph has not been modified.

| § of NSQ100 | Title | ISO9001:2008 modified § | § added by NSQ100 | ISO9001:2008 notes (*) |
|---|---|---|---|---|
| - | FOREWORD | X | | |
| 0 | INTRODUCTION | | | |
| 0.1 | General | X | | |
| 0.2 | *Process approach* | | | |
| 0.3 | *Relationship with ISO 9004* | | | |
| 0.4 | Compatibility with other management systems | X | | |
| 1 | SCOPE | | | |
| 1.1 | General | X | | NOTE 1 & 2 |
| 1.2 | Application | X | | |
| 2 | NORMATIVE REFERENCES | X | | |
| 3 | TERMS AND DEFINITIONS | X | | |
| 4 | QUALITY MANAGEMENT SYSTEM | | | |
| 4.1 | General requirements | X | | |
| 4.1.1 | Nuclear safety culture | | X | |
| 4.1.2 | Classification of items and activities | | X | |
| 4.1.3 | Grading the application of quality requirements | | X | |
| 4.2 | Documentation requirements | | | |
| 4.2.1 | General | X | | |
| 4.2.2 | Quality manual | X | | |
| 4.2.3 | Control of documents | X | | |
| 4.2.4 | Control of records | X | | |
| 5 | MANAGEMENT RESPONSIBILITY | | | |
| 5.1 | Management commitment | X | | |
| 5.2 | Customer focus | X | | |
| 5.3 | Quality policy | X | | |
| 5.4 | Planning | | | |
| 5.4.1 | *Quality objectives* | | | |
| 5.4.2 | Quality management system planning | X | | |
| 5.5 | Responsibility, authority and communication | | | |
| 5.5.1 | Responsibility and authority | X | | |
| 5.5.2 | Management representative | X | | |
| 5.5.3 | *Internal communication* | | | |
| 5.5.4 | Communication with Regulatory Bodies | | X | |
| 5.6 | Management review | | | |
| 5.6.1 | *General* | | | |
| 5.6.2 | Review input | X | | |
| 5.6.3 | *Review output* | | | |
| 6 | RESOURCE MANAGEMENT | | | |
| 6.1 | Provision of resources | X | | |
| 6.2 | Human resources | | | |
| 6.2.1 | General | X | | |
| 6.2.2 | Competence, qualification, training and awareness | X | | |
| 6.3 | *Infrastructure* | | | |
| 6.4 | Work environment | X | | |
| 7 | PRODUCT REALIZATION | | | |
| 7.1 | Planning of product realization | X | | |
| 7.1.1 | Project management | | X | |
| 7.1.2 | Risk management | | X | |
| 7.1.3 | Configuration management | | X | |
| 7.2 | Customer-related processes | | | |
| 7.2.1 | Determination of requirements related to the product | X | | |
| 7.2.2 | Review of requirements related to the product | X | | NOTE |
| 7.2.3 | Customer communication | X | | |
| 7.3 | Design and development | | | |

| § of NSQ100 | Title | ISO9001:2008 modified § | § added by NSQ100 | ISO9001:2008 notes (*) |
|---|---|---|---|---|
| 7.3.1 | Design and development planning | X | | NOTE |
| 7.3.2 | Design and development inputs | X | | |
| 7.3.3 | Design and development outputs | X | | |
| 7.3.4 | Design and development review | X | | |
| 7.3.5 | Design and development verification | X | | |
| 7.3.6 | Design and development validation | X | | |
| 7.3.7 | Control of design and development changes | X | | |
| 7.3.8 | Design and development verification and validation testing | | X | |
| 7.4 | Purchasing | X | | |
| 7.4.1 | Purchasing process | X | | |
| 7.4.2 | Purchasing information and procurement document control | X (**) | | |
| 7.4.2.1 | Content of the procurement documents | | X | |
| 7.4.2.2 | Procurement document review | | X | |
| 7.4.2.3 | Procurement document changes | | X | |
| 7.4.3 | Verification of purchased product | X | | |
| 7.5 | Production and service provision | | | |
| 7.5.1 | Control of production and service provision | X | | |
| 7.5.1.1 | Control of production process changes | | X | |
| 7.5.1.2 | Control of production equipment, tools and computer programs | | X | |
| 7.5.1.3 | Inspection and surveillance activities | | X | |
| 7.5.2 | Validation of processes for production and service provision | X | | |
| 7.5.3 | Identification and traceability | X | | |
| 7.5.4 | *Customer property* | | | |
| 7.5.5 | Preservation of product | X | | |
| 7.5.6 | Post delivery support | | X | |
| 7.6 | Control of monitoring and measuring equipment | X | | |
| 8 | MEASUREMENT, ANALYSIS AND IMPROVEMENT | | | |
| 8.1 | *General* | | | |
| 8.2 | Monitoring and measurement | | | |
| 8.2.1 | Customer satisfaction | X | | |
| 8.2.2 | Internal audit | X | | NOTE |
| 8.2.3 | Monitoring and measurement of processes | X | | |
| 8.2.4 | Monitoring and measurement of product | X | | |
| 8.3 | Control of nonconforming product | X | | |
| 8.4 | *Analysis of data* | | | |
| 8.5 | Improvement | | | |
| 8.5.1 | *Continual improvement* | | | |
| 8.5.2 | Corrective action | X | | |
| 8.5.3 | Preventive action | X | | |

(*): ISO9001:2008 notes which shall not be used as they don't meet nuclear safety principles.

(**): ISO 9001:2008 "Purchasing information" paragraph 7.4.2 has been divided in three different paragraphs:

- 7.4.2.1 "Content of the procurement documents",
- 7.4.2.2 "Procurement document review",
- 7.4.2.3 "Procurement document changes".