ABSTRACT

This document is the Section D to NSQ-100 Guidelines.

Its objective is to help to the understanding of NSQ-100 requirements through some examples or recommendations and descriptions of industrial good practices.

The Guidelines Section D is related to the planning requirements of NSQ100 (Chapters 7.1 & 7.2).

Summary

- Chapter 1: Purpose of this section
- Chapter 2 : Guidelines

  The following questions are addressed :

  - *How to determine quality objectives and requirements for the product?*
  - *Advices for implementation of commissioning program?*
  - *How to perform a risk analysis for the project?*
  - *What kind of configuration management has to be applied?*

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CHAPTER 1: PURPOSE OF THIS SECTION

The present section refers to NSQ-100 following chapters:

7.1 Planning and product realization

7.2 Customer related process

CHAPTER 2: GUIDELINES

7. PRODUCT REALIZATION

7.1 Planning of product realization

➲ How to determine quality objectives and requirements for the product?

The goal of this determination is to ensure the control of the respect of the requirements applicable to the product:

Product performances: refer to requirements included in the technical specification issued by the purchaser.

Nuclear safety: is a consequence of the declension of the nuclear safety classification to the product parts or activities associated to the construction of the product

Reliability, availability and maintainability: refer to requirements included in the technical specification issued by the purchaser,

Health and safety aspects during set-up, operating and maintenance phases:

Environmental aspects of parts and materials used in the product: refer to French standard NF E01-005 (Mechanical products – Eco-design methodology) or ISO/TR 14062 (Environmental management -- Integrating environmental aspects into product design and development),

Safety and environmental aspects during retrieval:

refer to French standard NF E01-005 (Mechanical products – Eco-design methodology) or ISO/TR 14062 (Environmental management -- Integrating environmental aspects into product design and development).

➲ Advices for implementation of commissioning program?

Procedures and processes should be implemented to ensure that the SSC are installed at the correct location (e.g. by the application of an installation marking system) and to prevent their incorrect use in terms of qualification.

The test and commissioning process should be structured so as to provide a progressive integration both in terms of the hierarchy of the SSC (bottom up approach, starting with parts and single components) as well as in terms of power / loads (bottom up approach starting with minor loads) for SSC and the entire nuclear installation. The commissioning programme should consider specific verification requirements for first of kind SSC.

7.1.1 Project management

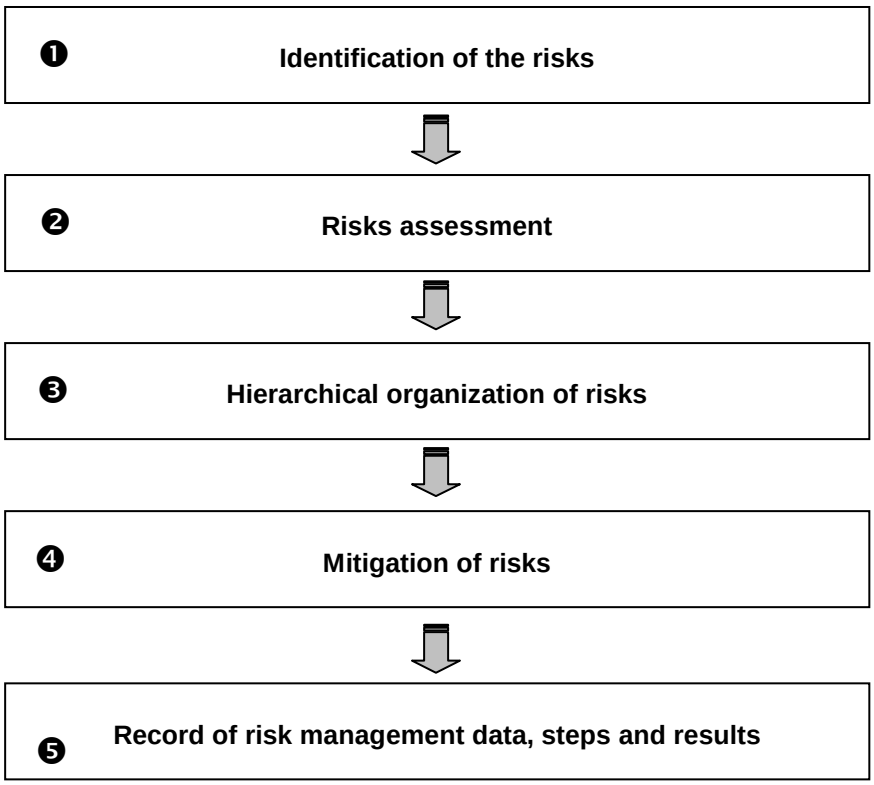
No Guidelines for this Chapter.

7.1.2 Risk management

➲ How to perform a risk analysis for the project?

The following is to be considered as an example, the effective risk analysis must be performed by the manufacturer having regard to its own organization and to the specific aspects of the products he manufactures.

The risk analysis can be performed in 5 consecutive steps:



STEP ❶ : Identification of the risks

LIST OF RISK BY AREA

AREA	Yes	No	Examples
Financial	☐	☐	Unrealistic cost estimates
	☐	☐	Variation of unfavorable exchange rate
	☐	☐	Too low profitability of the project / order
Contractual	☐	☐	Poor understanding of customer needs or specifications
	☐	☐	Difficult to meet contractual obligations in the project or order
	☐	☐	Poor analysis of the impact of changes
	☐	☐	Bad impact of the analysis of requirements traceability
	☐	☐	Bad impact of the analysis of requirements for quality assurance
	☐	☐	Poor analysis of the impact of documentary constraints
	☐	☐	Constraints imposed for unrealistic calendar or without margins
Legal	☐	☐	Poor control aspects and regulatory requirements applicable to the performance of the product
Purchasing	☐	☐	Unavailability of materials / components
	☐	☐	Purchase price of materials / components incompatible with the budget
	☐	☐	Poor transmission of contractual requirements to subcontractors
	☐	☐	Suppliers are imposed or not permitted by the customer
	☐	☐	Unfavorable political developments in the country of the subcontractor
	☐	☐	Supply "single source"
	☐	☐	Misunderstanding of the project needs by subcontractors
	☐	☐	Insufficient ability of the supplier as part of project requirements or order
Project Management **Quality Management System** **Quality Assurance Program**	☐	☐	Industrial Organization unclear or inadequate
	☐	☐	Restructuring, planned or expected
	☐	☐	Do not address correctly one or more of the following: ▪ Organizational functions nonexistent or inadequate, ▪ Organization of organizational and decision interfaces, ▪ Inconsistent schedules of different stakeholders, ▪ Loss of knowledge and know-how, ▪ Safety culture of the company (incl. questioning attitude toward the customer), ▪ Methods and communication tools, ▪ Insufficient or not available human or technical resources, ▪ Imprecision of the evidence to provide for quality assurance aspects, ▪ Methods and communication tools, ▪ Planning management.
Technical & Realization	☐	☐	Inadequate industrial base
	☐	☐	Production logistics difficult to implement
	☐	☐	The technologies considered are immature or poorly controlled
	☐	☐	Principles or concepts proposed are not validated (by the owner, the customer, the Authorities, ...)
	☐	☐	Loss of information on the current configuration of the project or order
	☐	☐	Production process inappropriate against constraints on nuclear safety
	☐	☐	False or incomplete input data
	☐	☐	Not sufficient or inappropriate computing resources
	☐	☐	Non respect of the domain of validity or qualification of codes, standards and software used
	☐	☐	Testing representativeness difficult to obtain
	☐	☐	Test facilities unsuitable or absent
	☐	☐	Compliance evidences difficult or impossible to demonstrate
	☐	☐	Simulation models or tests not validated for conditions of use
HSE	☐	☐	Rules for information protection unclear
	☐	☐	Inadequate level of restriction
	☐	☐	Contractual or regulatory requirements not taken into account (assembly sites)
Human aspects	☐	☐	Cultural differences which may cause misunderstandings
	☐	☐	Poor control of the contractual language
	☐	☐	Poor communication within the company (needs, data, information)
	☐	☐	Objectives or issues inadequately shared (training in safety culture insufficient or absent)
	☐	☐	Training time required for the project or order is too large relative to the constraints of schedule completion
	☐	☐	Poor management of skills and / or qualifications
	☐	☐	Skills and / or qualifications available too remote from the needs required

STEP ❷ : Risks assessment

➲ ***assessment of the risk occurrence***:

OCCURRENCE Level	ASSESSMENT	
	Qualitative	Quantitative (P=likelihood)
1	Low	P < 20%
2	Medium	20 ≤ P < 40 %
3	High	40 ≤ P < 60 %
4	Critical	P > 60%

➲ ***assessment of the severity of the impacts of risks*:**

The highest of the five possible criteria shall be taken into consideration, an impact on safety being unacceptable in all cases and, therefore, considered as critical.

SEVERITY Level	IMPACT on				
	conformity	performance	safety	delivery planning (Id)	costs (Ic)
1	Low	Low		Id < 5%	Ic < 2%
2	Medium	Medium		5 ≤ Id < 10 %	2 ≤ Id < 5 %
3	High	High		10 ≤ Id < 20 %	5 ≤ Ic < 10 %
4	Critical	Critical	Yes	Id > 20%	Id > 10%

STEP ❸: Hierarchical organization of risks ➲ determining the criticality

		SEVERITY Level			
		1	2	3	4
OCCURRENCE Level	1				
	2				
	3				
	4				

STEP ❹: Mitigation of risks

The risks have not to be mitigated but shall be kept in mind.

The risks must be examined again for reduction action (by acting on the occurrence or severity) = moving from orange to yellow or placed under observation in case of impossibility of reduction.

The risks must be addressed and a solution must be found to eliminate them = moving from orange to yellow

STEP ❺: Record of risks management data, steps and results

To ensure traceability of the risk management performed, it's suggested to draft such a table to record all data, steps and results:

Risk identified	Initial risk assessment			Mitigation action			Final risk assessment		
	Occurrence	Severity	Criticality	What	Who	When	Occurrence	Severity	Criticality
#1 : …..									
#2 : …..									

7.1.3 Configuration management

➲ What kind of configuration management has to be applied?

Depending on the context, a graded approach of the **configuration management** may be performed as follows:

Unitarian manufacturing of mechanical or electro mechanic parts:

➲ The list of applicable plans held up to date can be sufficient.

Mass production of mechanical or electro mechanic parts:

➲ It can be desirable to manage the material and software configuration of the equipments of production used for the realization of each of the parts or lots.

Software and equipments of control command:

➲ Management of the configuration following:

- in general: FD ISO 10007 (Quality management systems - Guidelines for configuration management),
- for software: IEEE828 (Standard for Software Configuration Management Plans) and IEEE1042 (Guide to Software Configuration Management).

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

Refer to 4.1.2 and 4.1.3 for identification of IFS items and activities which have to be listed.

The cascading of the process in the supply chain is only mandatory if the sub-suppliers are manufacturing IFS items or performing IFS activities.

When requirements concerning standards and codes are not existing in the contractual requirements, attention of organization all along the supply chain is drafted about:

- Recommended use of Regulator approved standards, or at least,
- Where new or innovative design or features are used, it must be demonstrated that selected codes and standards are fully applicable to the SSC,

In any other case a revised code, standard or specification must be developed and approved.

7.2.2 Review of requirements related to the product

No Guidelines for this Chapter.

7.2.3 Customer communication

An immediate communication to the customer, disregarding any contractual consideration as planning and costs, is compulsory.

Example : *Identification, a posteriori, by the supplier, of design choices, materials, unsuitable processes of manufacturing or inspection, who can question the nuclear safety of products in progress, delivered, even already put in service.*