ABSTRACT

This document is the Section A 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 A is related to the general requirements of NSQ100 (Chapters 0, 1, 4, 5 and 6).

Summary

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

  The following questions are addressed :

  - *What is the general philosophy to be kept in mind for nuclear products or services supply?*
  - *What kind of organizations may be concerned by the NSQ-100 standard?*
  - *How to ensure that personnel are aware of relevant quality management system?*
  - *How to understand: "appropriate language for its understanding"?*
  - *How to made hand written modifications on records?*
  - *Conditions for records storage*
  - *How to define the necessary competence of an individual?*
  - *How to record the adequacy assessment of an individual with the necessary competence?*
  - *Why and how to deliver a qualification to an individual?*

CHAPTER 1: PURPOSE OF THIS SECTION

The present section refers to NSQ100 following chapters:

0	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4.1	General requirements (Notes 4 & 5 only)
4.2	Documentation requirements
5	Management responsibility
6	Resource management (Except 6.2.1)

CHAPTER 2: GUIDELINES

0. INTRODUCTION

0.1 General

The respect of NSQ-100 requirements contributes to reach and maintain a high level of confidence in the capacity of an organization to deliver products or services for the nuclear industry.

The general philosophy to be kept in mind when applying the NSQ-100 requirements and the Guidelines recommendations is:

➲ What is the general philosophy to be kept in mind for nuclear products or services supply ?

SPECIFY	what has to be done
DO	what has been specified
TRACE	what has been done

➲ What kind of organizations may be concerned by the NSQ-100 standard?

CERTIFICATION BY NQSA

Case #1: ISO 9001:2008 certified organization

The possible approach when applying the NSQ-100 is:

❶ Identify the additional requirements coming from the NQS-100 standard which are not already taken into account in the supplier Quality Management System (the organization may already implement practices which address some of the NSQ-100 requirements).

❷ For the implementation of the additional requirements not already addressed in the quality management system, two possibilities may be foreseen:

- ➲ First possibility : to upgrade the existing general quality management system.
- ➲ Second possibility : to issue a specific quality management document usually called "**Quality Assurance Program**" which describes the provisions to be specifically enforced by the organization to meet NSQ-100 requirements. These provisions may only be applied for the nuclear projects for which NSQ-100 is applicable.

Case #2: ISO 9001:2008 not certified organization with a quality management system complying with:
- ISO 9001:2008, or
- any other specific standard (e.g. NQA-1, KTA14-01, …)

The possible approach when applying the NSQ-100 is:

❶ Identify the eventual additional requirements coming both from the ISO9001:2008 and the NQS-100 standards which are not already taken into account in the supplier Quality Management System (the organization may already implement practices which address some of the ISO 9001:2008 or NSQ-100 requirements).

❷ For the implementation of the additional requirements not already addressed in the quality management system, two possibilities may be foreseen:

- ➲ First possibility : to upgrade the existing general quality management system.
- ➲ Second possibility : to issue a specific quality management document usually called "**Quality Assurance Program**" which describes the provisions to be specifically enforced by the organization to meet ISO 9001:2008 and NSQ-100 requirements. These provisions may only be applied for the nuclear projects for which NSQ-100 is applicable.

NO CERTIFICATION BY NQSA

Organization without quality management system

The possible approach, when applying the NSQ-100, within a specific contractual agreement with the customer, is:

❶ Identify the requirements, which are agreed with the entity for which the product or service is supplied, coming both from the ISO9001:2008 and the NSQ-100 standards,

❷ Elaborate a specific quality management document usually called "**Project Quality Plan**" which describes the provisions foreseen to meet the above ISO 9001:2008 and NSQ-100 agreed requirements.

0.2 Process approach

No Guidelines for this Chapter.

0.3 Relationship with ISO 9004

No Guidelines for this Chapter.

0.4 Compatibility with other management systems

When the organization has to comply with other management systems, it is suggested to refer to the following NQSA documents:

NSQ-110: NSQ-100 compliance matrix with I.A.E.A GS-R-3 version 2006 - IAEA Safety Standards /The management system for Facilities and Activities - Safety Requirements n°GS-R-3

NSQ-120: NSQ-100 compliance matrix with NQA-1 Part I 2008- Requirements for Quality Assurance Programs for Nuclear Facilities & ASME NQA – 1A - 2009 – Addenda to ASME NQA-1-2008 – Quality Assurance Requirements for Nuclear Facility Applications

NSQ-130: NSQ-100 compliance matrix with KTA 14-01 (06/96) General Requirements Regarding Quality Assurance

1. SCOPE

1.1 General

No Guidelines for this Chapter.

1.2 Application

Exclusions are limited to requirements within chapter 7, means that the design & development related requirements included this chapter may not be taken into account when applying NSQ-100.

Wording **design & development activities** may be understood as activities where a supplier:

"establish a set of processes that transforms requirements into specified characteristics or into the specification of a product".

NOTE

- *The terms "design" and "development" are sometimes used synonymously and sometimes used to define different stages of the overall design and development process.*
- *A qualifier can be applied to indicate the nature of what is being designed and developed (e.g. product design and development).*

For more information, it may be referred to ISO9000 standard.

2. NORMATIVES REFERENCES

No Guidelines for this Chapter.

3. TERMS AND DEFINITIONS

No Guidelines for this Chapter.

4. QUALITY MANAGEMENT SYSTEM

4.1 General requirements

Refer to above chapter 0.1 – General.

4.2 Documentation requirements

4.2.1 General

The documentation has a great importance in the nuclear industry which requires a "**culture of the proof**", so that the documentation is therefore used as "a proof" to demonstrate:

- the effective performance of an action, and
- that everything has been implemented to ensure the required quality level.

The documentary system shall include and define the provisions to manage the documentation specifically issued to answer to NSQ-100 requirements, if these provisions are different to those of the general quality management system.

➲ How to ensure that personnel are aware of relevant quality management system?

The organization shall:

❶ **define** which specific quality management system documents are applicable:

- Quality Assurance Program or Plan,
- design process,
- manufacturing processes or procedures,
- inspection plan and procedures,
- surveillance plan and procedures,
- provisions for the non Conformances treatment,
- …,

❷ **identify** personnel involved in the project, their scope of responsibilities & activities and the associated documentation (association may be under the form of a matrix),

❸ **elaborate** an action plan in order to ensure that all these personnel will receive an appropriate training commensurate with their responsibilities & activities,

❹ **implement** the action plan and register its performance.

Personnel shall be trained to the:

- safety culture context associated to the order or the project,
- requirements coming from the quality document applicable for their activities,
- specific documentation related to their own activities.

Note:

- *the provisions to ensure that personnel are aware of relevant quality management system can be described in the Quality Assurance Program or Plan,*
- *personnel training shall be recorded.*

➲ How to understand: "appropriate language for its understanding"?

For some contracts or projects, the documentation must be in a language different from the organization language.

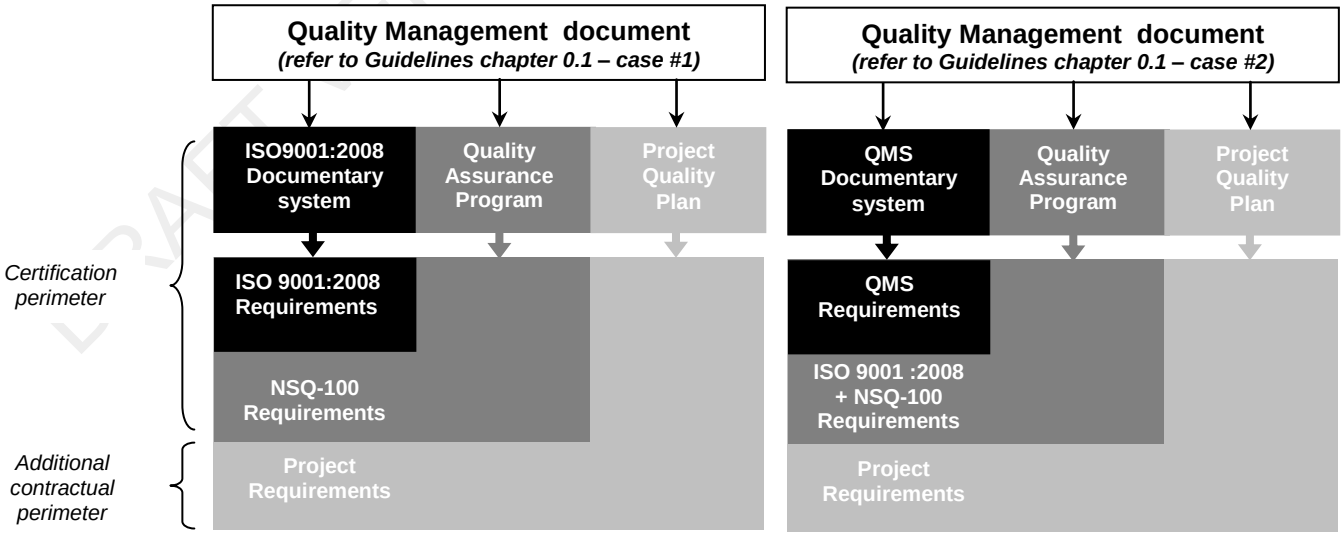
For the working documents used within the organization for the contract or project and submitted to this requirement, it is suggested to identify the cases where the translation in both languages (organization language and contractual or project language) may be necessary to ensure correct implementation of relevant quality requirements and therefore to propose to workers bilingual documents as:

- manufacturing documents (e.g. welding procedures),
- inspection documents and records,
- ….

4.2.2 Quality manual

The "**quality management document**" may be, depending on the scheme chosen by the organization for implementation of NSQ-100 requirements (refer also to Guidelines given at above chapter 0.1):

- the Quality Manual and all associated documents which constitutes the documentary system,
- a Quality Assurance Program,
- a Project Quality Plan.



An example for Quality Assurance Program layout is available on NQSA website: www.nqsa.org

4.2.3 Control of documents

The wording "**same level of approval**" means that, for changes to documents, the same principles than those applied for initial approval of the documents shall be applied.

The wording "**other than those**" doesn't involve hierarchical independence aspects, but only that the individual who is performing the verification must be different than the individual(s) who have issued the document.

This last "**other than those**" requirement can be found in the following NSQ-100 chapters:

7.3.5 Design and development verification *(see specific requirement in this chapter)*
7.4.2.2 Procurement document review
7.5.1.3 Inspection and surveillance activities
8.2.4. Monitoring and measurement of product

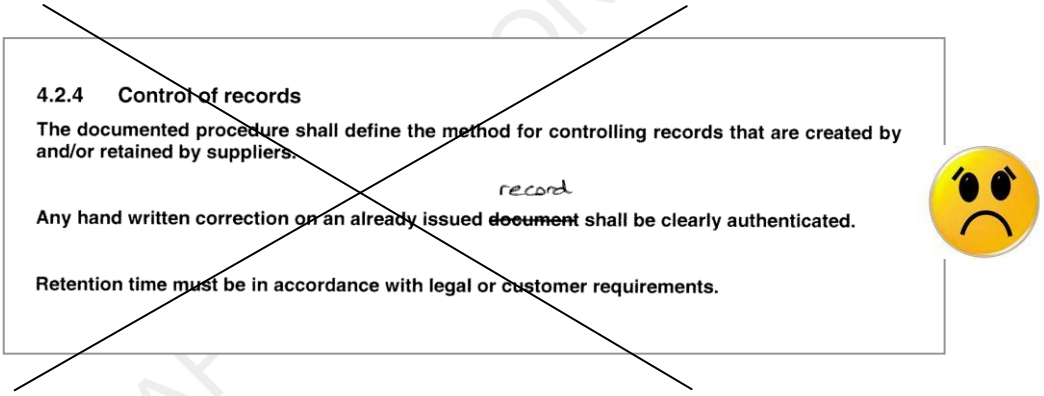
The organization should identify and document the personnel authorized to elaborate, review and approve document, whenever the considered document is an initial issue or a revised one.

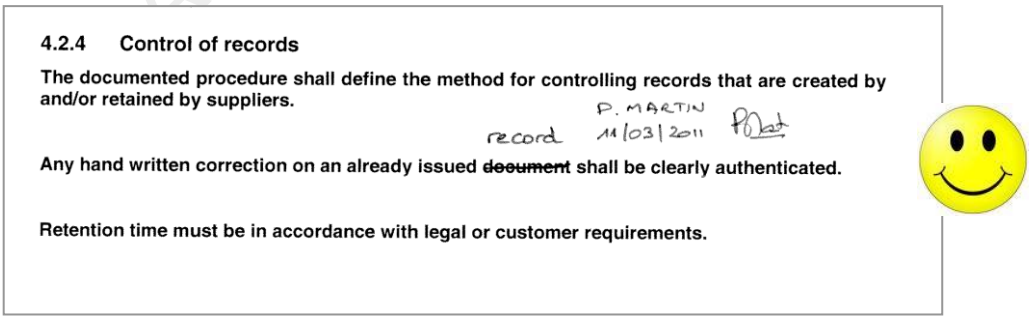
4.2.4 Control of records

➲ How to made hand written modifications on records?

Hand written modification must be authenticated with:

- Name of the person which has modified the document,
- Date of the modification,
- Visa of the individual who has modified the document.





For text modification, it's absolutely **forbidden** to use correcting fluid or tape.

➲ Conditions for records storage

Records shall be stored in facilities constructed and maintained in a manner that minimizes the risk of loss, damage, or destruction from (non exhaustive list):

- free access to the records to avoid undue intervention,
- natural events: wind, water, fire, …
- atmospheric conditions such as high and low temperatures and humidity, dust,
- insects or rodents,
- harmful conditions (e.g. excessive light, stacking, electromagnetic fields, …) as applicable for the specific media utilized for records storage.

In case of digital filing, it will be necessary, having regard to the requested storage duration (whatever will be the origin of the request: internal or contractual), to take into account the risks of obsolescence for:

- the storage support (CR-ROM, USB disks, magnetic tapes, …),
- the software for IT files reading.

5. MANAGEMENT RESPONSIBILITY

5.1. Management commitment

➲ How to demonstrate the Management commitment?

The top management may demonstrate its implication through:

- specific training and qualification of the staffs (e.g. safety culture),
- communication inside the organization to emphasize the specificities of the nuclear environment and the importance of the respect of the applicable requirements and documents,
- implementation of dedicated procedures and processes,
- taking into account of the experience feedback,
- its awareness of safety culture implementation level in the organization (through management reviews, minutes of meeting, …)

5.2. Customer satisfaction

It's expected from the Top management:

- their participation to periodical orders or projects reviews in order to ensure that contractual requirements on product conformity and on-time delivery performance are measured and respected,
- taking of appropriate actions by giving the adequate means to solve any above issue without compromising safety.

5.3. Quality policy

No Guidelines for this Chapter.

5.4. Planning

5.4.1. Quality objectives

No Guidelines for this Chapter.

5.4.2. Quality management system planning

No Guidelines for this Chapter.

5.5. Responsibility, authority and communication

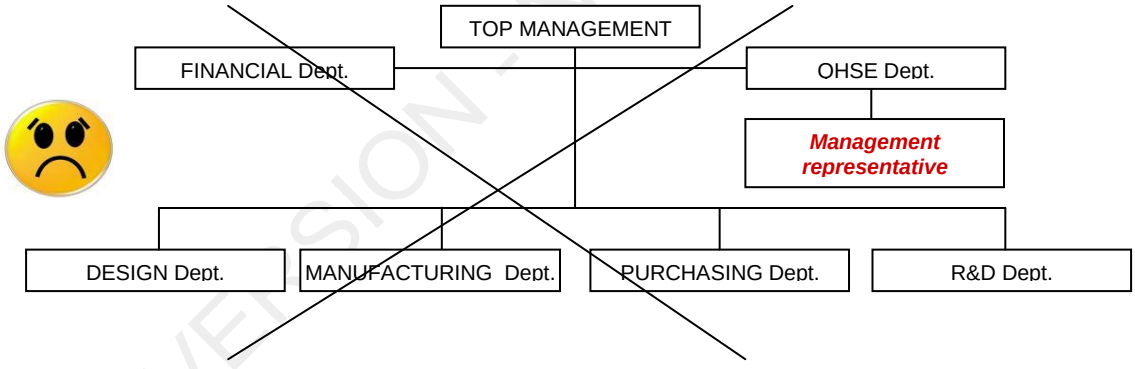
5.5.1. Responsibility and authority

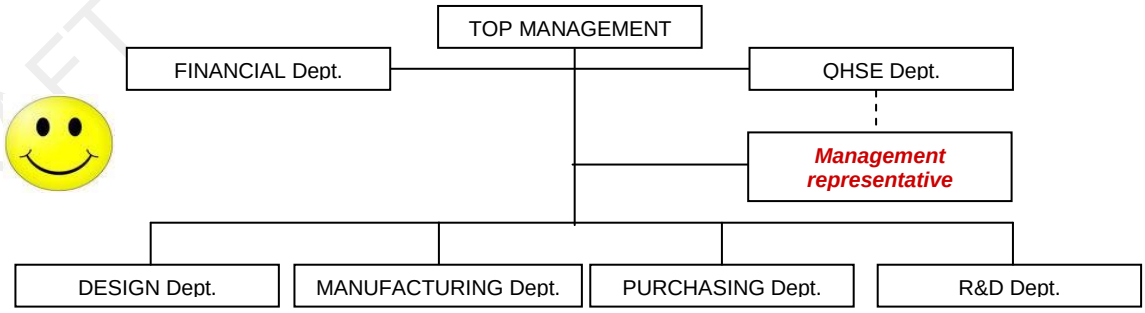
Should the organization calls for consulting services for NSQ-100 management system implementation, the top management shall ensure that the proposed solutions:

- fits to the organization,
- are effectively taken over by the organization personnel.

5.5.2. Management representative

Disregarding the organizational choices made by the organization, the "**management representative**" shall report "**directly**" to Top management, as explained through the following examples:





The wording "organizational independence" to resolve quality management issues must be understood as being in a position to resolve quality management issues avoiding any conflict of interests.

5.5.3. Internal communication

Guidelines must be defined and documented to ensure effective communication and team support allowing individuals to receive the advice, information and support they require, and to provide the necessary feedback wherever it is required.

5.5.4. Communication with Regulatory Bodies

The process to address any communication from any nuclear safety Regulatory Body must:

- be written and communicated inside the organization,
- identify the personnel authorized to answer the requests of the Regulatory Body,
- define the methods of communication towards the customer within answer to Regulatory Body.

5.6. Management review

5.6.1. General

No Guidelines for this Chapter.

5.6.2. Review input

It is recommended as good practice to add, as a review input, the performance results of the “critical” suppliers (refer to Guidelines section F).

5.6.3. Review output

No Guidelines for this Chapter.

6. RESOURCE MANAGEMENT

6.1. Provision of resources

No Guidelines for this Chapter.

6.2. Human resources

6.2.1. General

Refer to Guidelines section B on Safety Culture.

The training must be traced and recorded.

6.2.2. Competence, qualification, training and awareness

➲ How to define the necessary competence of an individual?

The word "**competence**" can be understood as being the demonstrated ability of an individual to apply knowledge and skills. The following knowledge and skills can be taken into account:

- initial education,
- complementary specific training,
- on the job training,
- professional knowledge: technical, use of software, organizational, regulations, foreign language (read / write / speak), …
- personal specific external certifications,
- personal behaviour (may be, depending of the job: communication ability, diplomatic, open-minded, perceptive, observant, self-reliant, organized, decisive, …),
- work experience (duration and fields),
- …

➲ How to record the adequacy assessment of an individual with the necessary competence?

The record of the adequacy "**assessment**" of the individual with the necessary competence may be performed through the establishment of a skills matrix, which have to be updated and reviewed periodically.

The matrix may take into consideration the following:

- different jobs & functions existing in the organization and having an impact on the quality of the product,
- abilities necessary to perform satisfactorily these jobs & functions (e.g. : foreign language knowledge, software knowledge, …).

An example of skills matrix is given hereafter:

	DESIGN ACTIVITIES (1)				MANUFACTURING ACTIVITIES (1) (3)							INSPECTION ACTIVITIES (1) (3)							LANGUAGES SKILLS (1) & (2)			
	Design & risk analysis	Drawings issuance	Design calculations on software #1	Design calculations on software #2	Cutting	Forming	Welding	Heat treatment	Cabling	Assembling	Painting	NDT (DPT)	NDT (MP)	NDT (UT)	Visual inspection of welds	Visual inspection on coating	Dimensional inspections	Dimensional inspections on 3D machine	English	German	Spanish	Chinese
Mr s A	1	x	x																R1 W1 S1	R1 W1		
Mr B	2	x		x			MM/YY MM/YY					MM/YY MM/YY								R2 W2 S2		

Notes: *(1): one or more levels may exist, depending on the job. These levels (L1, L2, L3, …) must be defined together with the correspondence task / required level, when applicable.*

(2): knowledge for Read (R), Write (W) and Speak (S) may be defined, together with the correspondence task (e.g. for document: elaboration, verification, approval) / required level, when applicable.

(3) : for qualifications - here in grey columns - it's suggested to add initial qualifications date and qualification date of validity.

➲ Why and how to deliver a qualification to an individual?

The word "**qualification**" can be understood as the result of the demonstration of the ability of an individual to fulfil specified requirements for a required function (e.g.: welder qualification, inspector qualification, auditor qualification, …).

The delivery of a qualification for an individual can be either:

❶ required by manufacturing code or standard (e.g. NDT inspector qualification according EN473 standard or ASNT system, the delivery being provided by an external organization: for EN473, or by the organization itself: for ASNT),

❷ being the choice of the organization to increase the confidence level which can be given to the actions performed by the individual.

Therefore, for the above situation ❷, it's suggested that the organization identifies what are the activities linked to:

- special processes as defined in chapter 7.5.2 of ISO9001:2008,
- specific activities which may have a critical impact on quality or safety (e.g. inspection activities).

The above demonstration of ability shall be:

- performed against established requirements or ratings, adapted to the corresponding function and defined in a documented procedure, e.g.:

Knowledge or skill	Requirement or Rating
Initial education	Minimum level of education (e.g. bachelor, master, …)
Complementary specific training	Coverage of the training
On the job training	Number or duration of on the job training operations
Professional : technical, use of software, organizational, regulations, foreign language (read / write / speak), …	Evaluation during interviews, written exams or practical tests,
Personal behaviour	Evaluation during interviews
Work experience (duration and fields)	Number of years of experience in an identical or closely related field
…..	…..

- based on one or on a combination of the above knowledges or skills, and
- traced and recorded.

The documented procedure for qualification must take into account:

- maintenance of proficiency,
- withdrawal or renewal of qualification,

6.3. Infrastructure

No Guidelines for this Chapter.

6.4. Work environment

No Guidelines for this Chapter.