

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 E is related to the design requirements of NSQ100 (Chapters 7.3).

Summary

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

The following questions are addressed :

- *What is the meaning of “Design and development planning”?*
- *What are the “design interfaces”?*
- *How to understand the wording “Where appropriate”?*
- *How to understand the wording “translated into design documents”?*
- *What may be the “design and development outputs”?*
- *What are the technical specifications for “IFS associated products”?*
- *What is a “design and development review”?*
- *What is a “design and development verification”?*
- *What is a “design and development validation”?*
- *How to “assess” Design and development changes?*

- Annex 1: Example of design follow-up table for a Pressure Actuator

CHAPTER 1: PURPOSE OF THIS SECTION

The present section refers to NSQ100 following chapters:

7.3 Design and development

CHAPTER 2: GUIDELINES

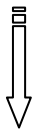
7.3 Design and development

7.3.1 Design and development planning

➡ What is the meaning of “Design and development planning”?

Design and development planning shall integrate at least the following chronological stages:

① Preliminary Design = **analysis of specifications** (contractual & statutory requirements), and **identification of the means** (= design documents”) to answer to the specifications.



➔ *Purchasing (cf. NSQ-100 chapter 7.4) can start. In some particular stages (critical lead time for some components) and when sufficient confidence in the requirements fulfillment is ensured, production phase may also start.*

This phase corresponds to NSQ-100 chapters:

- ➔ 7.3.2 “Design and development inputs”
- ➔ 7.3.3 “Design and development outputs”

During this phase, design reviews shall be performed according NSQ-100 chapter:

- ➔ 7.3.4 “Design and development review”

② Detailed Design = design performance (issuance of design documents).



During this phase, design reviews shall be performed according NSQ-100 chapter:

- ➔ 7.3.4 “Design and development review”

③ Final Design = verification and validation of design (“freezing” of design as all requirements have been fulfilled)

➔ *Production (NSQ-100 chapter 7.5) process can start.*

This phase corresponds to NSQ-100 chapters:

- ➔ 7.3.5 “Design and development verification”
- ➔ 7.3.6 “Design and development validation”

Note: Refer to table 1 in appendix 1 for examples about the above stages.

➡ **What are the “design interfaces”?**

Wording **design interfaces** may be understood as the result of the analysis of the interaction between internal or external design activities which may affect, or may be affected, by the one or more of the other activities performed by the organization.

Other activities may be (non exhaustive list):

- Process and system,
- Layout,
- Transport to site (mode of transport, transport conditions, Inco terms, ...)
- Erection and commissioning,
- Compliance with regulations,
- Safety and radiation protection,
- (*non exhaustive list*)

The result of this analysis shall be materialized and therefore formalized in the technical specifications in order to ensure effectiveness of communication between all these activities and the clarification of respective roles and responsibilities.

As an example, and for a tank, the design interfaces may be characterized as follows:

				Others activities taken into account		
				Layout	Transport to site	Safety and radiation protection
Data resulting from interfaces analysis	➡	Dimensions, weight, supports, handling, ...	➡	Dimensions, weight, handling, mode of transport, access to site, regulations, ...	➡	Drain position, cleanliness, safety classification, ...

➡ **How to understand the wording “Where appropriate”?**

Where appropriate means in adequacy with the product complexity.

When, having regard to the product complexity, it has been decided to manage the design as a project (refer to chapter 7.1.1 of NSQ100), it is recommended to document the following points:

- **distinct design activities,**
- **definition of the tasks,**
- **necessary resources,**
- **responsibilities,**
- **design content,**
- **input and output data,**
- **planning constraints.**

For **design content, input and output data** purposes, it is suggested to draft a follow-up table as per the model given in appendix 1

7.3.2 Design and development inputs

➡ **How to understand the wording “translated into design documents”?**

For each requirement coming from the analysis of specifications (contractual & statutory requirements), the organization shall “**translate**” the input into “**design documents**” which means that a mean of compliance such as (non exhaustive list):

Mean of compliance	Associated Design document(s)
Design	Drawing, Physical description, ...
Analysis	Calculation note, technical data sheet, risk analysis, ...
Test	Test procedure (detailed design) or report (validation), ...
Similarity	Description of similar product already manufactured or tested,

shall be associated to each above requirement.

7.3.3 Design and development outputs

➡ **What may be the “design and development outputs”?**

Design and development outputs may be:

- | | | |
|--|---|---|
| <p>Documents issued for design & development or production purposes (1):</p> | <ul style="list-style-type: none"> - calculations notes (mechanical, flow, thermal, ...), - qualification files, - RAM analysis, - drawings, - part lists, - technical data sheets, - process outlines, - (non exhaustive list) | <p>} <i>when used for product manufacturing</i></p> |
| <p>Documents intended for the final user (2):</p> | <ul style="list-style-type: none"> - operating and maintenance manual, - drawings, - part lists, - list of recommended spare parts, - technical specifications for IFS associated products, - instructions of use, - ... (non exhaustive list) | |

(1): Part of these documents may be required to be supplied by the organization to the customer.

(2): the list of such documents is contractual.

⇒ What are the technical specifications for “IFS associated products”?

IFS associated products are those for which critical characteristics are supporting / ensuring the IFS function of the product.

Taking the example of an oleo-pneumatic actuator, the **IFS associated products** and the contents of **technical specifications** may be as follows:

IFS associated products	Critical characteristics contained in the Technical specifications
Gasket	Lifetime in terms of cycles (e.g. based on qualification tests)
Hydraulic fluid	Physical and chemical properties

7.3.4 Design and development review

⇒ What is a “design and development review”?

The different sequential stages planned by the organization for the Preliminary and Detailed design phases (refer to above Guidelines for NSQ-100 chapter 7.3.1) should be closed by a **“Design and development review”**.

These reviews shall be sized in terms of:

- quantity,
- number and quality of attendants (which may be organization representatives, customer representatives or Contractor representatives, ...),

having regard to the complexity of the product.

Each design stage shall be successfully reviewed, i.e.:

- review without additional actions,
- review with conditions/clarifications to be performed,

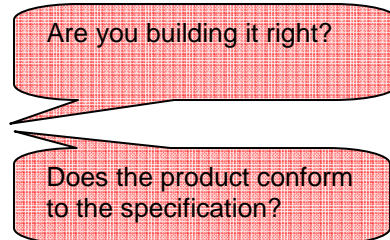
before to progress to the next sequential stage.

7.3.5 Design and development verification

➡ **What is a “design and development verification”?**

Verification is a process. It uses objective evidence to confirm that specified requirements have been met.

Verification meaning can be expressed by the questions:



Whenever specified requirements have been met, a **verified status** is achieved.

The outputs of **Design and development verifications** are objective evidences to confirm that design and development outputs meet specified design input requirements.

There are many means, methods or tools (non exhaustive list) to **verify** that requirements have been met:

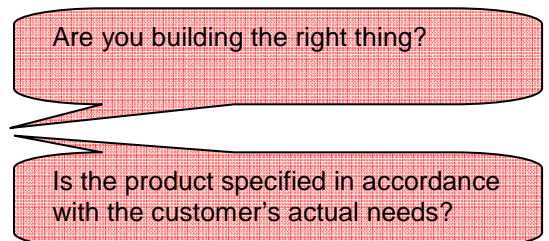
- | | | |
|----------------|---|---|
| <i>means</i> | { | <ul style="list-style-type: none"> - Performance of tests, - Performance of alternative calculations, - Comparison of a new design specification with a proven design specification, |
| <i>methods</i> | { | <ul style="list-style-type: none"> - Review of documents before issuance, - Peer review results, |
| <i>tools</i> | { | <ul style="list-style-type: none"> - Traceability analysis, - tests exhaustiveness, - worst case analysis, |

7.3.6 Design and development validation

➡ **What is a “design and development validation”?**

Validation is a **process** which uses objective evidence to confirm that the requirements which define an intended use or application have been met.

Validation meaning can be expressed by the questions:



Whenever all requirements have been met, a **validated status** is achieved.

The outputs of **validation process** are objective evidences to confirm that products meet the requirements which define their intended use or application within a simulated use environment.

7.3.7 Control of design and development changes

➔ How to “assess” Design and development changes?

The following steps may be used to **assess** the design and development changes:

- Identification of the reason of change,
- Description of the modification,
- Identification of the interfaces : impact on other product(s), data or process(es),
- Assessment of the consequences of the modification (technical, financial, timing, ...).

7.3.8 Design and development verification and validation testing

No Guidelines for this Chapter.

Example of design follow-up table for a Pressure Actuator

Number & content of reviews, participants to reviews are depending of the product complexity and of contractual requirements

Preliminary Design						Detailed Design		Final design			
Design and development input(s) identified after specifications analysis				Design and development output(s) intended		Design performance		Design Vérification		Design Validation	
Document of reference	Document Chapter	Requirement	Requirement Acceptance	Intended Mean(s) of Compliance	Intended type of evidence	Used Mean(s) of Compliance	Issued type of evidence	Status	Reference of Verification report	Design Validation (Yes / No)	Reference of Validation report
Spec_DocNumber_Req_013	1.00	Operating pressure 150 bar	Accepted	Analysis	Offer (confirmation of requirement by preliminary calculation)	Analysis	Calculation note ref . XXXXXX	Comply		OK	Hydraulic pressure test report
Spec_DocNumber_Req_014	1.01	Closing time < 5 seconds	Accepted	Analysis	Offer (actuator technology choice : e.g. pneumatic actuator)	Analysis	Technical data sheet of the actuator + complementary calculation note	Comply		OK	Functional test report
Spec_DocNumber_Req_015	1.02	Butt weld ends	Accepted	Design	Offer (preliminary drawing)	Design	Drawing n° XXXXX	Comply		OK	"As built" drawing
Spec_DocNumber_Req_016	1.03	Leakage rate 10 ⁻⁶ l/s at 5 bar	Denied	Similarity	Current technology available near the supplier						
Spec_DocNumber_Req_017	1.04	Interval between two majors maintenance operations >= 10 years	Partial	Design	Current technology requires intervals of 5 years for some seal gaskets						
Spec_DocNumber_Req_017 rev. 1	1.04	Interval between two majors maintenance operations >= 5 years	Accepted	Design	Offer (maintenance for gasket replacement to be done every 5 years, maintenance for other operations to be done every 10 years)	Design	Gasket technical data sheet	Comply		OK	Gasket technical data sheet & maintenanc operating manual

To be assessed by the organization as:

- Accepted
- Partial
- Denied
- Noted (If it is not a requirement in itself but an information that may be useful for the design (e.g. due to it impacts the applicable specifications to take into account))
- Not applicable (should not be if the document of reference is 100% specific and appropriate)

"Denied" or "partial" acceptance may exist at the stage of preliminary design (refer also to § 7.2.2 of NSQ-100) before issuance of submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders. In this case, the corresponding open points shall be discussed with the customer before to progress to the next design stage.

Means of compliance may be (non exhaustive list):

- Design = Drawing, Physical description, ...
- Analysis = Calculation note, technical data sheet, risk analysis, ...
- Test = test procedure (detailed design) or report (validation), ...
- Similarity = similar product already manufactured or tested.