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REVISION STATUS

Revision	Date	Modifications	Written / Checked
0		Initial issue	

The rules and classification of activities relating to the FCC3 package models defined below are applicable to all activities starting after 30 September 2013.

For activities starting before 30 September 2013, the rules and classification defined in Chapter 7 of the safety analysis report TFX DC 2159 Rev. G are applicable.

This chapter describes general quality assurance provisions applicable to the various activities (design, manufacturing and testing, operation, maintenance and transportation). Quality assurance arrangements specific to manufacturing, operation and transport activities are defined in Chapter 1.7 of this Report, while the provisions specific to maintenance activities are addressed in Chapter 1.8.

1. PRINCIPLES

The transport regulations in force as of the date of this Chapter require the application of quality assurance programmes covering:

- Design,
- Manufacturing and testing,
- Use,
- Maintenance,
- Transport

for packages designed to hold radioactive materials.

These activities are the responsibility of various parties (applicant, owner, prime contractor, constructors, users, transporters, shippers, maintenance companies, etc.) who are all required to draw up their own appropriate quality assurance programmes and to issue and retain supporting documentation (records) relating to their activities.

It should be noted that the owner must have in its possession at all times all relevant records relating to the package, and the shipper must be in possession of all documents relating to transportation of the package.

As of the date of this document, the quality assurance programmes (or management systems depending on the text) may be based on the requirements set forth in one or more of the following documents referenced by way of example and to the extent applicable:

- Code GS-R-3 "The Management System for Facilities and Activities",
- Safety Series TS-G-1.4 "Quality Assurance for the Safe transport of Radioactive Material" published by the IAEA,
- Code 10 CFR 71 Subpart H published by USNRC,
- ISO 9001 - 2008 version "Quality Management Systems".

A management system is a set of interlinked or interacting elements defining a policy and the objectives used to achieve objectives in an efficient manner.

The document versions given in this chapter are those in force at the date of the operations (design, manufacture and testing, operation, maintenance and transport).

This safety analysis report, which contains safety analysis studies validating the design of the FCC3 package model, has been drawn up as part of TN International's Quality Management System which meets the requirements of the GS-R-3 Code and ISO 9001-2008.

This Management System also covers the maintenance and manufacturing activities for which TN International is responsible.

The Quality Safety & Environment Management System (QSE-MS) applied by TN International is described in a Manual supplemented by the set of documents referenced therein. This set of documents is referred to as the Methodological Reference. It covers all TN International processes and provides a basis for continual improvement of the QSE-MS system.

The management system defines the scope of authority and responsibilities of the organisation and departments carrying out activities having an impact on safety, quality, health, security and the environment.

The Management System is supported by Quality Assurance arrangements designed to ensure that the activities, products or services conform to client requirements and/or objectives as well as internal, statutory and regulatory requirements. These arrangements include checks and inspections of the activities, products and services concerned.

2. QUALITY ASSURANCE CLASSES APPLICABLE TO FCC3 PACKAGE MODELS

2.1 Rules

A modulation of the quality assurance requirements is applied due to the unequal safety-related importance of the activities and components relating to the FCC3 package models.

The activities relating to the FCC3 packages are subject to Quality Assurance requirements depending on their safety-related importance. Various classes are defined. The component parts of the package are classified with reference to their importance to safety, reliability and maintainability.

The QA (Quality Assured) class corresponds to the application of a quality assurance programme compliant with the requirements of Code GS-R-3 and ISO 9001-2008.

The QNC (Non Quality Classified) class is applied to standard or catalogue equipment, or simple services for which a certificate of conformity is the only requirement.

The classification is initially determined by the entity requesting package approval, who's activities, particularly those involving design and safety studies, are QA classified.

The other parties involved define, cascade-wise and with the agreement of their respective clients, the applicable classes of Quality Assurance programmes relevant to their various activities, and, where necessary, apply specific monitoring and inspection requirements.

The requirements transmitted may be derived either directly from GS-R-3 or equivalent standards, for example ISO 9001-2008 supplemented as appropriate.

2.2 Classification of activities relating to FCC3 package models.

Activity	Applicable QA Class
Package and components	
Design & Modification	QA
Manufacture	QA
Maintenance	QA
Packages	
Preparation of packages	QA
Loading, unloading and shipping	QA
Transport commissioning	QA
Transport	QAP*

* Quality Assurance Programme adapted to the activity, for example as defined in IAEA Safety Series TS-G-1.4.

2.3 Classification of components for the FCC3 package model

The following table lists the quality assurance classes applicable to the manufacture of the various components.

Components	Applicable QA Class
Resin pouring	QA
Shock absorbing covers	QA
Other components and services	NCQ

Unless otherwise stated, this classification is applicable to finished equipment, ready for use or integration.

The manufacture of this equipment may be broken down into sub-assemblies, components and/or elementary services, which in turn may be classified according to their individual contributions to the quality of the equipment. The level of inspection and testing to be carried out on the components is detailed in Chapter 1.4 of this Report.

3. COMMON QUALITY ASSURANCE PROVISIONS

This section describes general quality assurance arrangements to be applied across all activities (design, manufacture, maintenance, transport, etc.) for the various types of operations associated with compliance with a safety requirement (technical inspection, handling of non-conformities, archiving, etc.).

3.1 Arrangements relating to technical inspections associated with compliance with a safety requirement

All non-documentary inspections are referred to as technical inspections. Technical inspections must be carried out by competent operators on the basis of documents specifying the tests involved and, where appropriate, verification of these tests. The verifications must be carried out by competent operators other than the persons who carried out the tests. The scope of these tests and verifications is adapted according to the safety impact the products and services concerned.

The tests and verifications must be documented (inspection or test reports issued and signed by the operators carrying out the tests and verifications, etc.).

Before carrying out a technical inspection associated with a safety requirement, the operator must:

- Note the identification of the equipment used and check the validity of the calibration date.

- Make sure that the equipment is capable of achieving the required accuracy and reliability and that the ambient conditions are suitable.

3.2 Handling of non-conformities

All non-conformities found must be described and an appropriate resolution process defined through the necessary channels. The implementation and proper application of the decisions taken must be verified before the issue is signed off.

The impact of the non-conformity on safety must be assessed and taken into account in the decision-making process. Any variances between the package model as described in the drawings and requirements of this Report and the actual equipment will only be accepted following an additional analysis demonstrating that the variances do not call into question the conclusions of this Safety Analysis Report.

If the competent authorities of the countries through which or to which the package is to be transported have defined declaration criteria, these authorities must be informed of any non-conformities with respect to their requirements.

3.3 Document control

3.3.1 Production of documents

Documents must be drawn up, checked, and if necessary approved, then distributed appropriately. The author(s) and checker(s) of the documents must be chosen having regard to the skills and competence required.

All documents containing safety-related requirements must be checked.

The person checking the document must be a person other than the author.

The approval signature signifies that a document is fit for use and confirms that the author and checker have the necessary competence to undertake these tasks.

In the case of manufacturing activities, maintenance and operation of the package (depending on the type of documentation not issued by the designer), the entity responsible for these operations (manufacturer, maintenance contractor, operator, etc.) is responsible for ensuring the conformity of documentation issued (operating procedures, etc.) with the requirements of the safety analysis report received either directly or through a third party. This third party will then be required to guarantee the conformity of the documents transmitted with the safety analysis report.

3.3.2 Document archiving

All documents must be archived according to their importance for safety:

– Documents meeting one of the following criteria must be permanently archived (the archiving period must be at least equal to the service life of the equipment concerned):

  - Proof of capability of the equipment to operate safely,

- Periodic inspections, maintenance and, where necessary, repairs and modifications of the equipment,
- Determination of the cause of an accident or equipment failure,
- Regulatory, legal or contractual requirement,

– Other documents must be archived, as the case may be, in accordance with legal, regulatory or contractual requirements.

3.3.3 Traceability

Current document versions must be recorded. These records must be used as a reference by all document users.

3.4 Management of subcontracting

3.4.1 Evaluation

The monitoring of subcontracted services must be carried out by means of inspections and/or audits. Inspections and audits must be carried out by qualified personnel authorised to perform these tasks. Inspections and audits must be formalised and documented in reports.

3.4.2 Subcontracting of manufacturing activities

In the case of manufacturing, the application of Quality Assurance arrangements in relation to the type of subcontracted manufacturing services (production processes and inspection/test procedures) is obligatory.

The requirements must be defined in a set of manufacturing specifications containing general quality-related requirements, construction drawings, production and procurement specifications.

This document set must be checked to ensure conformity with the applicable requirements defined in the Safety Analysis Report and those relating specifically to Quality Assurance.

3.4.3 Design, studies and tests

Where part of the design, calculations or tests are subcontracted, a design specification must be issued for use by the service provider. The specification must properly cover the applicable requirements, in particular those relating to Quality Assurance.

3.4.4 Transport activities

For transportation and related services, the application of Quality Assurance arrangements is required depending on the mode of transport and/or type of content transported.

The requirements must be defined by a set of documentation containing general quality-related requirements, technical requirements relating to the operations to be carried out (tie-down, handling, etc.) and to the modes of transport (road, sea, etc.).

This document set must be checked to ensure conformity with the applicable requirements defined in the Safety Analysis Report and those relating specifically to Quality Assurance.

3.4.5 Maintenance

For maintenance services, the application of Quality Assurance arrangements is required depending on the type of equipment and activities concerned (processes and inspections).

The requirements must be defined in a set of documentation containing general quality-related requirements and the technical requirements relating to the operations to be carried out.

This document set must be checked to ensure conformity with the applicable requirements defined in the Safety Analysis Report and those relating specifically to Quality Assurance.

4. DESIGN & STUDIES QUALITY ASSURANCE

4.1 Engineering

Before starting design work, the basic design data must be validated and all regulatory requirements listed.

4.1.1 Design drawings

These drawings define the essential parameters and functional dimensions of the package used in the calculations supporting this Safety Analysis Report.

The drawings must be checked and verified in accordance with § 3.3.1.

4.1.2 Design output data

The output data from the design work comprises design definition documentation (design drawings, calculations, specifications, operating instructions, etc.) together with documents demonstrating compliance with safety-related requirements (safety analysis report, calculations, etc.).

All of these documents must be checked in accordance with § 3.3.1 prior to use.

4.2 Calculations

This section relates to the performance of calculations requiring the use computer code.

Verification of the calculations must be documented indicating the scope of the checks carried out. Verification of the results must be formalised by a signature. The checker must be a person other than the author.

The use of computer code is subject to the issuance or preparation of a qualification/validation document defining the scope and validity of the code.

4.3 Qualification tests

Qualification tests are carried out on models or systems (possibly at reduced scale). The representative nature of the model must be formally studied. The applicable requirements and criteria must be defined in a test programme.

The models must be constructed in compliance with the procedures applicable to the manufacturing activity as defined in Chapter 1.7 of this Report.

A list of inspections and checks to be carried out during the test must be drawn up. These inspections and checks must be carried out in accordance with § 3.1.

The "measured" results obtained during the tests (dimensional measurements, leakage measurements, acceleration curves, etc.) must be documented in test reports.