QUALITY ASSURANCE APPLICABLE

TO PACKAGE MODEL TN-MTR

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REVISION STATUS

Revision	Date	Modifications	Prepared by / Checked by
Old reference: DOS-16-00173678-800			
0	N/A	Document first issue.	JFM / LCA
New reference: DOS-18-011415-038			
1.0	N/A	New reference due to new document management system software.	JFM / LCA

The rules and classifications for activities related to the TN-MTR package model defined below are applicable for all activities starting after December 31 2010.

For activities starting before December 31 2010, the rules and classification defined in revision 2 of the safety analysis report 4466-Z-8A are applicable.

This chapter gives the general quality assurance measures common to the various activities (design, fabrication and tests, use, maintenance and transport) as well as specific measures for safety studies and design. Quality assurance requirements specific to fabrication and maintenance activities are defined in Chapter 7A in this file, and requirements specific to use and transport are defined in Chapter 6A.

1. PRINCIPLES

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

- design,
- Fabrication and testing,
- use,
- maintenance,
- transport

of packages containing radioactive materials.

These activities are done by different players (designer, client, project management, manufacturers, users, shippers, transporters, maintenance companies, etc.) that must all produce appropriate quality assurance programs, and produce and keep documents (records) substantiating their activity.

It should be noted that at a given moment, the owner must have, in his possession, all records related to the packaging and the shipper must have all records related to shipping of the packaging.

As of the date of this chapter, the quality assurance programs (or management systems – depending on the texts) can be based, for example and when applicable, on the requirements laid out in one or more of the following documents:

- Code GS-R-3 "The Management System for Facilities and Activities".
- Safety Series No.113 "Quality Assurance for Safe Transport of Radioactive Material", published by the International Atomic Energy Agency,
- Code 10 CFR 71 Subpart H published by the USNRC.
- ISO standard 9001 - 2000 or 2008 version 'Quality Management Systems'.

A management system is a set of elements related to each other or interacting with each other that define a policy and objectives and help to achieve these objectives effectively and efficiently.

The document revisions given in this chapter are those in force as of the date of execution of operations (design, manufacturing and proof testing, use, maintenance and transport).

The elements of the TN-MTR package model presented in this document were designed as part of the TN International Quality Management System which meets the requirements of the GS-R-3 Code and ISO standard 9001 2008 version.

This management system also covers maintenance and manufacturing activities for which TN International is responsible.

TN International's Quality Safety and Environment Management System (SMQSE) is described in a Manual, together with the set of documents to which it refers. This set of documents is referred to as the Methodological Baseline. It covers all TN International processes and organises the continuous improvement of the QSEMS.

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 based on Quality Assurance requirements to guarantee that activities, products or services are conforming with customer requirements / objectives, internal, legal or regulatory requirements. These requirements include inspections and checks on activities, products and services.

2. QUALITY ASSURANCE SYSTEM CLASSES APPLICABLE TO THE TN-MTR PACKAGE MODEL

2.1 Rules

Quality Assurance requirements are modulated due to the unequal importance of activities and components for the TN-MTR package model.

Activities related to the TN-MTR package model are subjected to Quality Assurance requirements in accordance with their safety-related importance; different classes are defined. Packaging components are classified as a function of their importance for safety, and their reliability and maintainability.

Class QA (with Quality Assurance) corresponds to the application of a Quality Assurance program in accordance with Code GS-R-3 and ISO standard 9001 - 2000 or 2008 version.

Class QNC (Not classified) is applicable to standard equipment or catalogue equipment, or a very simple service for which all that is required is a certificate of conformity.

The classification is fixed originally by the packaging designer whose activities and particularly the design and safety studies are QA classified.

Other participants work in cascade, with the agreement of their customer, to define applicable classes of Quality Assurance programs adapted to the different activities and, if necessary, apply specific monitoring and inspection requirements.

The requirements can be either code GS-R-3 directly or equivalent requirements, for example ISO standard 9001 2000 or 2008 version with suitable addendums.

2.2 Classification of activities related to the TN-MTR package.

Activity	Applicable QA class
Packaging and components	
Design, tests and modification	QA
Manufacturing	QA
Maintenance	QA
Package (including empty packaging)	
Preparation of packages	QA
Loading, unloading, shipment	QA
Transport commissioning	QA
Transport	Quality Assurance Program (1)

(1) Adapted to the activity, for example, as defined in IAEA Safety Series No. 113.

2.3 Classification of the TN-MTR package model components

The following table details the quality requirement class applicable to the manufacturing of the various elements.

Components	Applicable QA class
Containment (including bolts and orifices), trunnions (including bolts), baskets	QA
Resin	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 construction of this equipment can be broken down into sub-assemblies, components and/or basic services, themselves classified according to their contribution to equipment quality. Moreover, the level of the inspections to be conducted on the components is specified in Appendix 7A-1 in this file.

3. COMMON QUALITY ASSURANCE REQUIREMENTS

This section describes general quality assurance requirements to be applied regardless of the activity (design, manufacturing, maintenance, transport, etc.) for the different types of operations related to compliance with a safety requirement (technical inspection, treatment of nonconformities, archiving, etc.).

3.1 Provisions for technical inspections related to compliance with a safety requirement

All non-documentary tests are known as technical inspections. Technical inspections must be done by competent operators based on documents specifying inspections and their verification, if applicable. Verifications shall be made by competent operators other than those who made the inspections. The extent of these inspections and verifications is adapted depending on the impact of the products or services on safety.

The inspections and checks shall be recorded (inspection or test reports signed by the operators who conducted the inspections and checks).

Before carrying out a technical inspection related to the compliance of a safety requirement, the operator must:

- record the identity of the equipment used, check the validity of the calibration date,
- make sure that the equipment is sufficiently precise and accurate and that environment conditions are satisfactory.

3.2 Treatment of nonconformities

Any observed nonconformity shall be characterised and the appropriate treatment shall be defined based on necessary opinions. Implementation of decisions and their correct application shall be checked before the malfunction is cleared.

The safety impact of the nonconformity shall be evaluated and taken into account in the decisions. Any differences between the package model described through the drawings and requirements in this file and the existing equipment are allowed provided that a further analysis demonstrates that they do not challenge the conclusions of this safety analysis report.

If the competent authorities in the country through which or to which the package is to be transported have defined declaration criteria, they shall be informed about the nonconformities in accordance with their requirements.

3.3 Document control

3.3.1 Producing the documents

The documents shall be prepared, verified and possibly approved and then distributed depending on their type. The document author and verifier(s) shall be determined depending on the necessary skills.

All documents containing a safety requirement shall be verified.

The verifier shall be a person different from the author.

The approval formally states that a document is useable and certifies that the author and verifier of the document have the necessary skills to perform these actions.

The designer is responsible for ensuring the compliance with the safety analysis report requirements of the documents (manufacturing specifications, user's manual, maintenance specification) which he issues to other players.

For the packaging manufacturing, maintenance and usage activities, Project Management (manufacturer, maintenance company, plant operator, etc.) is responsible for the compliance of the issued documents (processes, etc.) with the safety analysis report requirements received via the documents written by the designer.

3.3.2 Archiving the documents

The issued documents shall be archived according to their safety-related importance.

- Documents meeting one of the following criteria must be permanently archived (the period of permanent archiving shall be considered to be at least equal to the lifetime of the relevant equipment):
  - proof of equipment ability to operate safely,
  - periodic inspections, maintenance and if necessary equipment repair or modification,
  - determination of the root cause of an accident or equipment failure,
  - regulatory, legal or contractual requirement,
- other documents must also be archived if necessary, in accordance with legal, regulatory or contractual requirements.

3.3.3 Traceability

Revisions of documents in force shall be recorded. These recordings shall be used as a reference for all document users.

3.4 Control over subcontracting

3.4.1 Evaluation

Subcontracted services shall be monitored by means of inspections and/or audits. Inspections and audits shall be conducted by personnel qualified and authorised to perform these tasks. Inspections and audits shall be formally defined and a report shall be produced for them.

3.4.2 Subcontracted manufacturing

For manufacturing, Quality Assurance provisions shall be applied depending on the type of subcontracted manufacturing (manufacturing and inspection processes).

Requirements shall be defined in a production file containing general requirements dealing with quality, production drawings, production and procurement specifications.

It shall be verified that this document set correctly reproduces the applicable requirements set out in the safety analysis report and Quality Assurance-related requirements.

3.4.3 Design, studies and tests

When a part of a design, calculation or a test is subcontracted, a design specification shall be produced for use by the calculation or test service provider. The specification shall correctly reproduce the applicable requirements, in particular Quality Assurance-related requirements.

3.4.4 Transport activities

Quality Assurance measures shall be applied for transport and associated services, depending on the transport mode and/or the type of transported content.

The requirements shall be defined in a file containing the general requirements on quality, the technical requirements on the operations to be performed (tie-down, handling, etc.) and the modes of transport (road, sea, etc.).

It shall be verified that this document set correctly reproduces the applicable requirements set out in the safety analysis report and Quality Assurance-related requirements.

3.4.5 Maintenance

Quality Assurance measures shall be applied for maintenance services depending on the nature of the equipment used and activities involved (processes and inspections).

Requirements shall be defined in a file containing general quality-related requirements and technical requirements related to operations to be done.

It shall be verified that this document set correctly reproduces the applicable requirements set out in the safety analysis report and Quality Assurance-related requirements.

4. QUALITY ASSURANCE FOR DESIGN AND STUDIES

4.1 Engineering

Basic design data shall be validated before the design is started, making sure that all regulatory requirements have been listed.

4.1.1 Design drawings

These drawings shall define essential parameters and functional dimensions of the packaging used for calculations justifying this file.

Design drawings must be verified in accordance with Section 3.3.1.

4.1.2 Design output data

Design output data are made up of conceptual design documents (conceptual design drawings, calculation notes, specifications, user's manuals, etc.) and documents justifying compliance with the safety requirements (safety analysis report, calculation notes, etc.).

All these documents shall be verified before use in accordance with section 3.3.1.

4.2. Performing the calculations

This section applies to calculations using computer programs.

The calculation verification shall be certified and shall indicate the extent of the verification made. It shall formally be defined by a signature on the results. The verifier shall be someone other than the person who prepared the work.

The use of computer programs is dependent on obtaining or preparing a qualification / validation file, which defines the scope and the validity range of the program.

4.3 Qualification test

The qualification tests are run on mock-ups or systems (if necessary, at a reduced scale). The representative nature of the mock-up must be formally studied. The applicable requirements and criteria must be defined by drawing up a test program.

The models must be manufactured in line with the provisions specific to the manufacturing activity as defined in Chapter 7A in this file.

A list of the inspections and checks to be performed during the test shall be produced. These inspections and checks shall be conducted in accordance with section 3.1.

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