

**Radioactive Material Transport Package Quality Plan**

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**1. PURPOSE**

This Quality Plan describes how the quality assurance requirements for the design, fabrication, assembly, testing, maintenance, repair, modification and use of BWXT radioactive material (RAM) transport packages are achieved. It identifies the activities, responsibilities and actions necessary to ensure that all regulatory, customer and internal QA program requirements are met.

In combination with the systems described in the Quality Manual, QSF-00, and the Transportation of Radioactive Materials Program, this document is the basis for compliance with CNSC, IAEA and USNRC requirements for Quality Assurance/ Management Systems.

**2. SCOPE**

This plan is applicable to all BWXT Radioactive Material (RAM) Type A (returnable and non-returnable) and Type B Transport Packages. RAM transport packaging falls within the scope of BWXT's Quality Management System (QMS). The policies, responsibilities, and procedures comprising the QMS are described in the Quality Manual (QSF-00). This Quality Plan supplements the Quality Manual with specific requirements for transport packages.

This plan also provides specific requirements applicable to third party packages and third party package handlers who fall under this program.

**3. RESPONSIBILITIES**

Senior management responsibilities are described in the Quality Manual. Responsibilities for quality related activities specific to transport packages are described below:

**3.1 Quality Assurance**

- The Director Quality Assurance has overall responsibility for this plan.
- Quality Assurance is responsible for the review of new design plans or design changes for transport packages to ensure compliance with this plan. In consultation with the TDA-P, QA also reviews non-conformances to determine quality impact.
- Quality Assurance oversees the supplier qualification process.
- Quality Assurance is responsible for oversight of this program as it applies to third party package handlers.

**3.2 EHS Compliance**

- EHS Compliance (EHS) is responsible for the identification of regulatory requirements and coordinates the communications with the competent authorities.
- EHS Compliance is responsible for maintaining the USNRC Quality Program Approval, or equivalent.
- In consultations with the TDA-P, EHS reviews non-conformances to determine regulatory impact.
- EHS Compliance will assist QA in assessing compliance of third party package handlers with respect to this program.

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**3.3 Technical Design Authority, Transport Packaging (TDA-P)**

- The TDA-P is responsible for the design, specification, and testing of radioactive material packages.
- The TDA-P is responsible for verifying that all regulatory submissions for RAM transport package certification are accurate and complete and for the assessment of non-conformances against the documented design.
- The TDA-P is responsible for assessing the fitness for use of third party packages in consultation with EHS Compliance.

**3.4 Project Engineer**

The Project Engineer is responsible for design projects from inception to completion, as directed by the TDA-P. This includes:

- preparation or review of design documentation,
- design qualification testing,
- preparation of specifications for manufacturing,
- review of Manufacturing, Inspection and Test Plans (MITP) and fabricator's Special Processes,
- specification of inspection requirements for incoming packages and spare parts,
- approval of collection plans and approved configurations within CBS and
- Approval of any new or revised item masters for transport package components.

**3.5 Procurement**

- Procurement initiates the supplier qualification process for suppliers for transport packages and components
- Procurement ensures that transport package requirements and specifications as defined in the CBS item master are communicated to the supplier through the purchase order.
- Procurement ensures that the supplier is provided with the current versions of the drawings, specifications and other documents as appropriate.
- Upon receipt and delivery of the finished product, Procurement coordinates the ordering and delivery of finished product and requests the supplier Quality records (inspection and test data) as required by the item master and/or specification.

**3.6 Manager, Production**

- The Manager, Production, is responsible for the incoming receipt, inspection, and maintenance of packages in the fleet and the records resulting from these activities.
- The Manager is responsible for the control and inspection of the inventory of components.

**3.7 Quality Control**

- Quality Control is responsible for the incoming inspection of newly fabricated transport packages and the records resulting from these activities.
- Quality Control is responsible for incoming inspection of components for transport packages as specified by the item master or applicable specification.

## 4. PROCEDURE

### 4.1 Contract Review

Proposed uses of transport packaging that may not meet the specified requirements are referred to the TDA-P, for review. Each nonstandard application is reviewed for its capability to meet the standard, code, and regulatory requirements. For Type B packages, regulatory approval is obtained before use of any new packaging configurations.

### 4.2 Design Control

The method used for planning, conducting, reviewing, verifying, and controlling design activities is defined within QSF-00, and 000069.SOP "Requirements and Guidelines for the Control of Design". The following requirements supplement these procedures.

#### 4.2.1 Design Planning and Activity Assignment

At project initiation, written plans are prepared for design and verification activities for each new or modified RAM package design. The project is assigned to qualified personnel equipped with the resources necessary to prepare a fully compliant design. The TDA-P has the responsibility for the extent of planning activities, which depend upon the complexity of the design or design change.

#### 4.2.2 Design Input

The Project Engineer verifies design input requirements for adequate identification and documentation. Design input verification involves, but is not limited to:

[REDACTED]

Incomplete, ambiguous, or conflicting requirements are resolved by the Project Engineer and are documented in accordance with 000069.SOP.

#### 4.2.3 Design Output

Design output is documented and expressed in terms of requirements, calculations, tests, and analysis. Refer to Appendices 1 and 2 for a list of these requirements. The design output shall meet and include the following elements:

[REDACTED]

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[Redacted text block]

The following sections provide additional descriptions for some of these elements:

4.2.3.1 Safety Analysis Report (SAR) (or Engineering Assessment)

A safety analysis report is prepared for Type A and Type B transport packages. The SAR provides the technical basis for the safety assessment of the package. It is an essential part of the regulatory submission for Type B transport packages. For Type A packages, the SAR is subject to audit by Competent Authority. This document is also referred to as an Engineering Assessment.

[Redacted text block]

The SAR for a RAM transport package includes at least the following:

- a) package description detailing radioactive contents, containment system, shielding, and operational features

[Redacted text block]

- b) structural evaluation including but not limited to:
  - i. structural design

[Redacted text block]

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ii. general requirements for packages such as:

[REDACTED]

iii. conditions of transport

- c) thermal evaluation
- d) accident analysis, based on IAEA or national competent authority regulatory requirements
- e) an illustration
- f) test results, and/or engineering justification

[REDACTED]

4.2.3.2 Design, Manufacture and Operating Specification

All Type B packages shall have a Design, Manufacture and Operating Specification (DMOS).

[REDACTED]

The DMOS summarizes regulatory commitments and includes, at least:

- a) the authorized contents, isotope, activity and form
- b) the possible range of external dimensions
- c) safety critical materials used and their dimensions and tolerances
- d) a list of engineering drawings and procedures, without revision levels
- e) reference to an information drawing which identifies the design
- f) marking and labeling
- g) requirements for quality assurance in manufacture typically in the form of applicable standards
- h) requirements for use, including preparation for shipment and inspection and maintenance.

[REDACTED]

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4.2.3.3 Information Drawings Versus Engineering Drawings

[Redacted text block]

4.2.3.4 Illustration

[Redacted text block]

4.2.3.5 Technical Specification

The Technical Specification is an integral part of the design documentation for a Type A returnable or Type B package. It establishes the overall technical requirements for manufacture, assembly, inspection, test and delivery for each model of transport packaging. The technical specification must be reviewed by Quality Assurance and approved by the TDA-P. [Redacted]

[Redacted text block]

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4.2.3.6 Material Specification

Material specifications and/or Item Masters are required for all packaging components, typically associated with Type A packages.

[Redacted]

4.2.3.7 CBS Outputs

Package implementation is controlled by a Common Business System (CBS). Specific design outputs for CBS include:

[Redacted]

4.2.4 Design Verification and Review

Designs and associated documents are verified and/or reviewed to ensure that they meet specified design requirements. Design verification is performed by qualified staff by conducting testing or by comparison to similar designs.

[Redacted]

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4.2.5 Design Changes

All changes to the design of RAM transport packages are managed through the change control system

[Redacted]

4.3 Procurement

Procedure; P-002, "Procedure for Supply Chain Management" and 4808, "Item Master Request" describe the methods and responsibilities to ensure that the purchased RAM transport packaging, components, materials, and services conform to specified requirements.

[Redacted]

4.4 Control of Customer Supplied Product

Transport packaging supplied by customers is used in accordance with design and licensing documentation. As a minimum requirement, the customer is required to provide:

- a) copies of relevant transport certificates, including certification of Special Form Radioactive Material Approval Certificates if applicable
- b) operating procedures (i.e. user instructions, inspection and maintenance procedures).
- c) A listing of critical packaging components and instructions on sourcing, handling and maintenance, if required.
- d) Components are segregated and controlled

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**4.5 Identification and Traceability**

- 4.5.1 Type A non-returnable packages are consumables and are identified and controlled according to 000022.SOP "Identification and Traceability of Controlled Raw Materials, In-Process Product and Final Product".
- 4.5.2 For Type A returnable and Type B packages, traceability requirements are established in the respective technical specification. At a minimum, Type B packages are identified with a model number and a unique serial number.
- 4.5.3 The Inventory of packages is maintained by the business units and is the responsibility of the production manager.

**4.6 Process Control**

The requirements for process control during the manufacture of transport packages are defined in the Technical Specification and are the responsibility of the Supplier. Processes that affect inspection and use of packages are controlled by the relevant procedure.

**4.7 Inspection and Testing**

Inspection Plans are written for tests and inspections performed during the life cycle of RAM transport packaging. These plans outline the type of inspection or testing to be undertaken. For

[REDACTED]

[REDACTED]

**4.7.1 Package Qualification**

New package qualification (first-time inspection) and acceptance requirements for Type A returnable and Type B packages are defined in the Technical Specification

[REDACTED]

**4.7.2 Incoming Inspection**

Incoming inspection for Type A non-returnable packages and other package components is performed as per IS/OP 2717 F000, CO-QC/IT-0025 and 040801.SOP "Raw Materials - Receiving, Testing, Release and Reserve". Purchased material is received into quarantine and held until the completion of testing at which time it is released for use.

Incoming inspection of newly fabricated packages is completed before they are added to inventory.

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**4.7.3 Inspection and Maintenance**

Inspection and Maintenance procedures are used to define the requirements for regular and annual inspection and testing for Type A returnable and Type B Packages. Maintenance requirements are also defined in these procedures.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

For third party packages, inspection and maintenance is performed as per the transport certificate.

**4.8 Handling, Storage, Packaging, Preservation and Delivery**

4.8.1 The Technical Specification identifies the requirements for handling and storing of raw material, off the shelf components and fabricated items by suppliers.

[REDACTED] All RAM transport packages are prepared for shipment in accordance with Preparation for Shipment procedures.

[REDACTED]

[REDACTED]

4.8.3 Third party employees may be used as package handlers and perform preparation for shipment activities. Any third party package handlers that perform work under this Quality Plan must be trained on all relevant procedures. Work performed must follow specified procedures and quality systems.

4.8.4 SE-OP-015 "Receiving Radioactive Material" defines the requirements for receipt of transport packages.

**4.9 Control of Quality Records**

The following quality records are required for RAM transport packaging. They are maintained to provide evidence of conformity to requirements and that the quality system is operating correctly. Normally, Unit History Files are maintained in Corporate Records.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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**4.10 Training**

The BWXT policy on competency, awareness, and training is described in QAP AP-47. Training requirements are defined for all key roles affecting safety of RAM transport. All personnel involved in the design, packaging, and transport of radioactive material receive training in radiation safety and transport regulations.

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**5. REFERENCE DOCUMENTS**

- IAEA Specific Safety Requirements, "Regulations for the Safe Transport of Radioactive Material 2018 Edition", IAEA No. SSR-6
- International Standard, "Quality Systems Management – Requirements", ISO 9001.
- National Standard of Canada, "Quality Assurance Program – Category 2", CSA N299.2
- Packaging and Transport of Nuclear Substances Regulations, 2015
- USNRC, "Packaging and Transportation of Radioactive Material", Regulation 10 CFR 71
- IS/OP 2717 F000, "Inspection Overview Procedure"
- IN/OP 0524 F000, "Transport Package Repairs"
- QAP AP-01, "Quality Assurance Release"
- QAP AP-45, "Change Control Procedure"
- QAP AP-47, "Training Program"
- P-002, "Procedure for Supply Chain Management"
- QSF-00, "Quality Manual"
- 000021.SOP, "Inspection, Measurement and Test Equipment"
- 000038.SOP, "Procedure for Developing Specifications"
- 000069.SOP, "Requirements and Guidelines for Control of Design"
- 040801.SOP "Raw Materials - Receiving, Testing, Release and Reserve"
- SE-OP-036, "Transportation of Radioactive Materials Program"
- 4808, "Item Master Request"

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Appendix 1 – Design Output Requirements/Documentation Requirements for Transportation Packages

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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