Transport of Radioactive Material Code of Practice

Procurement Guide for Transport Packaging

Produced by the Transport Container Standardisation Committee

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This Code of Practice has been prepared by the Transport Container Standardisation Committee. The Committee comprised:

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Special Note

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PREFACE

IAEA Safety Standard Series No. SSR-6, Regulations for the Safe Transport of Radioactive Material, (2012 Edition) require that quality assurance programmes are established to cover all aspects of design, manufacture, testing, documentation, use, maintenance and inspection for all packages.

This Procurement Guide for Transport Packaging provides guidance for the supply of services required to enable the procurement of transport packaging that meet the requirements for the safe transport of radioactive material. It should be noted that these services are considered to include the minimum requirements to enable the user to procure goods and services in a responsible manner and to operate as an Intelligent Customer.

In particular this guidance document provides advice on:

- Specification of functional requirements
- Activities associated with design, manufacture and testing
- Records Management

The aim of this guidance document is to promote good practice in the procurement of goods and services that are used for the safe transport of radioactive material. In particular this document aims to cover supply of approved single use or reusable transport packaging.

This document represents good practice and takes the form of recommendations. It should be noted that the word “shall” denotes a requirement; the word “should” denotes a recommendation; and the word “may” denotes permission, neither a requirement nor a recommendation. Imperative statements also denote requirements. To be in compliance with this document, all requirements shall be met but not necessarily all recommendations.

CONTENTS

1. Definitions

Approval Authority. An organisation or an individual responsible for the approval of package designs.

Certificate of Approval (Approval Certificate). Certificate of Approval means a certificate issued by an Approval Authority signifying that the package design fulfils the requirements of the applicable regulations.

Competent Authority. Competent Authority means any national or international regulatory body or authority designated or otherwise recognised as such for any purpose in connection with the Regulations.

Design Number. A number assigned to a specific packaging design, described in TCSC 1073.

Design Authority. An organisation or an individual responsible for the specification and design of the packaging.

Intelligent Customer. The capability of an organisation to have an appropriate understanding and sufficient knowledge of the product or service being supplied.

Package Design Safety Report. The Package Design Safety Report provides the documentary evidence of the compliance of the package design with all the applicable requirements.

Quality Assurance. Quality Assurance means a systematic programme of controls and inspections, applied by an organisation or body involved in the transport of radioactive material, which is aimed at providing confidence that the standard of safety prescribed in the Regulations is achieved in practice.

Regulations. Used throughout this document are defined as IAEA Safety Standard Series No. SSR-6, Regulations for the Safe Transport of Radioactive Material, (2012 Edition). It should be noted that the requirements of other National and/or modal regulations also may apply and need to be considered.

Supplier. The Organisation contracted to provide the Transport Packaging in accordance with this guide.

User. The Organisation or Client responsible for procurement of the Transport Packaging.

Permanent Records (as-built) Lifetime Records. Records Maintained by or for the responsible organisation for at least the life of the particular packaging whilst it remains in an operational condition.

Permanent records are those which are of significant value to meet one or more of the following objectives.

- Evidence that the manufactured items comply with the approved design
- To demonstrate capability for safe operation
- To enable maintenance, rework, repair, replacement or modification of an item
- To determine the cause of an accident or malfunction of an item
- To provide baseline data for in service inspection
- To facilitate decommissioning

2. Introduction

The purpose of this document is to provide guidance for the supply of services required to enable the procurement of transport packaging that meet the requirements for the safe transport of radioactive material. It should be noted that these services are considered to include the minimum requirements to enable the User to procure goods and services in a responsible manner and to operate as an Intelligent Customer. It is considered that these services could include:

- Design services
- Prototype testing
- Manufacture of packaging
- Supply of propriety components that form packaging and
- Supply of approved packaging

The scope of this guidance document is to promote good practice in the procurement of goods and services that are used for the safe transport of radioactive material. In particular this document aims to cover supply of approved single use or reusable transport packaging and the management and maintenance of the associated Permanent Records (as-built) Lifetime Records.

3. Roles and Responsibilities

3.1 Responsible Designer

The organisation(s) which has a formal responsibility for developing the package design. They should maintain detailed, specialised knowledge of all the systems and components important to safety, and have a core capability in the detailed design process.

The designer should consider the requirements relating to safety, health, the environment, security, quality, economic factors and other design base codes and standards, including elements of the organization's management policy that may go beyond existing regulatory or statutory requirements.

3.2 Design Authority

The person or organisation that is responsible for the design of the package; each package design should have only one package designer. They may or may not also be the *Package Designer*.

The *Design Authority* should also be able to demonstrate that any proposed changes, modifications or deviations from the accepted design have been carefully considered, justified, controlled, documented and implemented, and are in accordance with, or better than, the controls applied to the original design.

3.3 Licence Applicant / Holder

The party that seeks/holds the package transport licence from the Competent Authority. They may or may not also be the *Design Authority*.

3.4 Owner / Operator

The party that owns and operates a licenced package. They may or may not also be the *Licence Holder*.

The Owner and Operator may be separate entities and each would be responsible as the O*wner* of the licenced package and as the O*perator* of the licenced package.

3.5 External parties / Stakeholder interfaces

This includes other associated parties including, but not limited to; the *Competent Authority*, test facility, packaging manufacturer, packaging maintenance facility, consignor/consignee and carriers.

4. Types of Procurement

It is considered useful for the User to define the scope of supply and give due consideration to the type of procurement that may be required to support the use of Transport Packaging.

Due consideration should be given to the extent of ancillary equipment that may be required to support the use of the transport packaging. The User should consider the scope of supply and need for the specification of:

- ancillary equipment such as tie-down system, lifting equipment, packaging rotating stands, supports for use during storage, test equipment and specialist tools
- Specification and availability of spares
- Duration of approval and re-licensing activities
- Notice of design changes, improvements and associated procedures
- Repair procedures, modifications and
- Continuity of after sales service

The following criteria need to be addressed in compiling a Functional Specification for the procurement and supply of Transport Packaging:

- Modes of transport
- Permitted packaging contents
- Dose rate limitations
- Mass limit of packaging
- Mass limit of contents
- External dimensions
- Internal dimensions
- Temperature constraints
- Loading/unloading constraints
- Maintenance requirements
- The packaging shall be supplied as an approved radioactive material transport container, for the countries of operation
- The operating regime and, for re-useable packaging, the frequency of operation and packaging life
- Materials of construction and constraints
- The User should consider the need for acceptance criteria to demonstrate compliance with the functional requirements and agree these with the Supplier. These can form part of the final acceptance checks and
- Storage, packing and delivery requirements
- Final geological disposal

The list below sets out the types of procurement that may be required and further details are in the sections that follow:

- Design / Licencing / Re-Licencing
- Manufacture / Physical assets
- Maintenance Services
- Operation Services
- Decommissioning
- Through Life Support

4.1 Design / Consultancy / Licensing / Re-Licencing

The following should be considered to be important when determining the scope of design activities that are required for the supply of transport packaging;

- Design for a new transport package
- Re-licencing a design for an existing package
- Obtaining a new Licence

The following criteria are considered to be important in the specification of design activities that are required for the supply of transport packaging.

The User should consider the extent to which the supplier shall provide the necessary safety documentation for the packaging. In particular this shall include:

- Certificates of conformity
- Certificate of Approval
- Operating instructions
- Applicable maintenance instructions
- Provision for spares and
- Identity of the Design Authority

It should be noted that, dependent on extent of use and User requirements the following may be necessary:

- Package Design Safety Report
- Package Design Safety Report supporting references
- Manufacturing specification
- Manufacturing drawings
- Build records including manufacturing quality plans and
- Calculations and test reports

It shall be made clear, when procuring transport packaging, whether the design is included or excluded. Further, the role, responsibility and identity of the Design Authority shall be clearly established together with approval routes for procedures for repair, concession and modification approval throughout the lifetime of the transport packaging. Design re-approval shall also be considered if the validity of the Certificate of Approval is time limited.

4.2 Manufacture / Physical assets

The following should be considered to be important when procuring the manufacture, testing and inspection activities that are required for the supply of transport packaging;

- Supplier selection and assessment
- Supplier management, monitoring and performance
- Standards & Technical Specification for manufacture, testing & inspection
- Definition of requirements for Lifetime Records

The User shall assess the competency of the supplier to provide the defined goods and services. The results of this assessment together with risks associated with the packaging will help the user determine the extent of User involvement with manufacture, acceptance tests and inspection activities.

Manufacturing activities should be carried out in accordance with recognised national or international standards. The manufacturer shall prepare a quality plan that identifies the key manufacturing processes and testing requirements for the packaging and associated equipment. This should cover the activities involved in the manufacture, assembly and testing of the packaging.

The User may wish to review quality plans and consider the extent to which involvement is required to verify the compliance of the packaging. The scope includes, but is not necessarily limited to, the following activities:

- Procurement and control of materials, welding consumables and proprietary items
- Material cross contamination control (e.g. chlorides, non-ferrous and ferrous)
- Welding (including welder qualification, weld specification and non-destructive examination: NDE)
- Material testing
- Leak testing
- Load testing of lifting points
- Pressure testing
- Shielding testing
- Specialist processes (typically casting, forging, heat treatment: procedures and qualifications)
- Finishing systems (coatings, bead blasting, plating, polishing)
- Assembly of the packaging
- Functional testing for operation of the packaging
- Confirmation of the mass of packaging and/or components
- Inspection, non-conformance and concession control
- Review of reports, material and test certification and other quality documentation and
- Delivery requirements

The User may choose to review procedures, calibration certification and personnel qualifications.

The User may require access to the Supplier's premises at any reasonable time for the purpose of examining materials, components and records during or on completion of the contract. This may extend to any sub-contractor that the Supplier may employ.

The User should expect the Supplier to be responsible for carrying out inspection to ensure that the items produced comply with the specification.

It is reasonable to expect all equipment necessary for undertaking inspection and testing shall be provided by the Supplier. However, the user may consider the provision of specialised equipment to support specific inspection activities.

The User may choose to consider the use of an independent or third party inspector to undertake inspections at Suppliers works.

4.3 Maintenance Services

The following should be considered to be important when procuring the maintenance and inspection activities that may be required for transport packaging;

- Supplier selection and assessment
- Supplier management, monitoring and performance
- Standards & Technical Specification for manufacture, testing & inspection
- Mandatory Testing / Insurance Inspections.
- Definition of requirements for Lifetime Records

4.4 Operation Services

The following should be considered to be important when procuring the operational services that may be required when using transport packaging;

- Supplier selection and assessment
- Supplier management, monitoring and performance
- Storage and Transport requirements
- Stacking Requirements / Floor Loading
- Lifting methods / Handling Equipment
- Safety Case for Operators / Dose Monitoring
- Conventional Health & Safety requirements
- Definition of requirements for Lifetime Records

4.5 Decommissioning

When selecting the original supplier for manufacture consideration should also be given to their long-term capabilities for;

- Removing Packaging Units from Service
- Recall & Decommissioning
- Disposal Routes / Final Geological Disposal

4.6 Through Life Support

The following should also be considered when procuring transport packaging;

- Licence Holder
- Damage – Refer to Design Authority
- Change of Use / Change of Contents

5. Contractual Models

5.1 Collaborative Working

There is a need to involve multiple parties so consideration should be given to establishing collaborative relationships. Reference should be made to BS11000 Collaborative Business Relationships - Part 1: A Framework Specification.

This British standard specifies requirements for the effective identification, development and management of collaborative business relationships between discrete organisations.

Potential parties who may be involved in these relationships may include, although not be limited to;

- Competent Authority
- Responsible Designer
- Design Authority
- Licence Holder / Applicant
- Owner / Operator
- Design Support / Consultant
- Manufacturer
- Transport Company

As an example, the Design Authority (who may also be the Package Licence Applicant/Holder) for the transport package holds regulatory responsibility (enforced by the Competent Authority) for ensuring the manufactured package meets the design intent and thereby must implement and have oversight of appropriate Quality Assurance Processes in place to meet its regulatory obligation.

It would however not be practical for both parties to pursue these conflicting responsibilities and obligations independently, and this may lead to significant repetition of work and an unnecessary burden on the selected manufacturer. It would therefore be practical for both parties to enter into a collaborative agreement and joint working arrangement with appropriate commercial arrangements that respect all stakeholders' oversight responsibilities.

The Parties involved in the procurement should consider and take note of the requirements of the ONR Technical Assessment Guides relating to procurement activities and in particular NS-TAST-GD-077 "Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items." This guide and the associated NS-TAST-GD-033 "Licensee Management of Records," provide good advice on managing supply chain relationships and on the management and storage of "as-built" lifetime records.

5.2 Commercial Arrangements

- Due to the need to involve multiple parties consideration will be required for types of Collaborative working. (Refer to BS11000)
- Consideration will also be required for how & when any relationship may end.

5.3 Control of Intellectual Property Rights (IPR)

- It is expected that the control of IPR will remain with the Design Authority
- Arrangements need to be considered with regard to the ownership of background IPR for each transport package being developed and, any developed foreground IPR ownership needs to be considered to allow ongoing IPR development between all Parties

5.4 Insurances

- Given the need for Collaborative Arrangements greater consideration should be given to ensure the appropriate insurances are put in place to address the particular liability relevant to the type of procurement and parties involved.

5.5 Risks and long term requirements

- Consideration must be made to ensure that appropriate measures are in place for both the short & long term security and Storage of Records (see section 7)
- This includes the Issue & Allocation of Serial Numbers.
- Also the management of Serial Number recording for each package.

6. Export Control

When procuring the design, manufacture and supply of transport packaging using suppliers and/or End Users from outside the UK, due consideration should be given to the requirements set out by the UK Export Control Organisation and regulations relating to the export and controls of dual-use technology, goods and services from the UK.

In particular, due account should be taken of activities undertaken relating to shielding and criticality data which may fall under the UK Strategic Export Control List.

Guidance on obtaining export control licences and on what items are controlled can be found on the UK Export Control Organisation website (SPIRE). www.spire.bis.gov.uk
Helpline : eco.help@bis.gsi.gov.uk

The main legislation to be aware of is the Export Control Act 2002 and export Control Order 2008.

The EU dual list is also incorporated into the UK's consolidated listing of controlled goods which is published as the UK Strategic Export Control List.

7. Records Management

The following criteria are considered to be important in the specification and management of Permanent Records (as-built) Lifetime Records that are required for the supply of transport packaging.

The specification for the management of Permanent records shall cover the requirements to ensure that the records are duly archived, accessible and retrievable.

7.1 Responsibilities for record generation and retention

The Design Authority shall maintain full indexed files for each end user packaging and have oversight. These files shall be used to store permanent documents generated during the life of the packaging.

Records covering design activities shall be categorised as Quality Records and shall be maintained accordingly. Design documentation shall permit assessment of the design by suitably qualified and experienced personnel.

A file, or a series of files, shall be opened for each package design, and as the design proceeds, all relevant documents including reports, calculations and test results shall be kept in the file.

The end user should also store and maintain (electronically/hard copy) copies of as built package manufacture lifetime records for each package.

Permanent Records (see definitions) shall be kept for the periods as specified in Section 7.5, examples are:

- Permanent Records
- Design specification
- Design documentation
- As-built lifetime documentation
- Quality plans
- Modification documentation
- Non-permanent Records
- Purchase orders
- Calibration records;
- Audit reports;
- Movement documentation.

7.2 Prototype Records

Package Prototype design records are considered to be a pre-requisite requirement for generation and retention. The following documentation is considered important depending on package specification:

- Design review Records
- Package Design Safety Report
- Package Design Safety Report supporting references
- Manufacturing specification
- Manufacturing drawings
- Support substantiation documentation may also include:
    - Thermal barrier tests
    - Full fire test
    - Thermal FE (if appropriate to full fire test)
    - Impact testing – Full, Scale, Impact limiter,& FE (if based on similar design) and simulated contents inclusion and records

- Containment assurance test - Pre, post and during impact
- Critically Report (if deemed required)
- Manufacturability studies and reports.

It is important that for any analysis undertaken using computer codes that the input and output files are retained.

7.3 Manufacturing Records

On completion of manufacture (Prototype or approved package) an “as-built lifetime record” shall be supplied for each individual package. The “as-built lifetime record” shall be held in an indexed binder.

Depending upon the responsibilities within the contract and the purchasing specification of the packaging, the following criteria are considered to be important in the specification of build records that are required for the supply of transport packaging

- Contents Index
- Completed Quality Assurance Plan/Quality Control Plan
- Procurement & control of materials, welding consumables & proprietary items
- Drawing list
- As-built drawings, including schematics and layout
- Design Change Requests and decisions
- Non-Conformance Reports
- Concession Reports
- Material certificates giving mechanical properties and chemical analysis
- Certificates of conformity for bought-in items
- Inspectors’ qualifications
- Inspection procedures
- Welder Qualifications
- Welding Procedure Qualification
- Weld Maps and schedules
- NDE operator qualifications
- Non-Destructive Testing Reports
- Inspection Reports/Certificates
- Casting and or forging records (where appropriate
- Heat treatment procedures and certificates
- Information on proprietary parts supplied by the manufacturer
- Qualifications of contractor’s NDT personnel
- Operations and Maintenance Manuals
- Certificates of Conformance to Specification
- Material cross contamination control (e.g. chlorides, non-ferrous and ferrous)
- Welding (including welder qualification, weld specification and non-destructive examination: NDE)
- List of key processes used, along with issue status
- Dimensional inspection report for key components
- Material testing
- Leak testing procedures and reports
- Proof load test certificates
- Pressure testing
- Shielding testing
- Specialist processes (typically casting, forging, heat treatment: procedures and qualifications)

- Finishing systems (coatings, bead blasting, plating, polishing)
- Assembly of the packaging
- Shielding test procedure and report
- Functional test procedure and report
- Reports of all mechanical testing
- Functional testing for operation of the packaging
- Weight record of packaging
- Certificates of conformity for bought-in items
- Correspondence regarding requests for concessions and
- An overall certificate of conformity
- Modification Records
- Review of reports, material and test certification and other quality documentation

7.4 Usage Maintenance Records

The end user is responsible for ensuring that periodic inspection and associated maintenance is carried out within the specified time limit before the packaging is used again. Inspection and maintenance shall follow the "Maintenance Schedule" approved at the design stage. If the end user sets up a sub-contract for another organisation to undertake this work, a copy of the schedule shall be provided to the sub-contractor.

Records of all results and the completed schedule shall be retained by the end user as part of the individual container maintenance file.

Detailed schedules of turn-around and periodic inspection and maintenance shall be supplied with any application for design approval of packages.

The end user is responsible for each consignment and for ensuring that only maintained packaging are consigned.

Reusable packaging shall be maintained in accordance with the manufacturer's instructions. Records of maintenance shall be recorded as part of the permanent record of the container.

When the need for a repair is identified, proposals shall be agreed with the Design Authority before any repair is carried out. Where the repair would result in a change to the approved design, the appropriate Modification Approval shall be raised to re-instate the package approval before re-use as a RAM Package.

The responsibility for ensuring that repairs/modifications are correctly documented rests with the Design Authority* who shall ensure that approvals are modified as appropriate.

* NB : For certain Package Types the ultimate responsibility may rest with the Competent Authority.

7.5 Retention and Protection of records

The collection, storage and preservation of records is a legal requirement for RAM packaging. All stages of design, procurement, manufacture, maintenance and operation shall be recorded. Legible, complete and easily identifiable records shall be generated as the work proceeds, and maintained to furnish proper evidence of activities affecting safety and quality. In particular, records shall be kept of all inspections, maintenance and repairs undertaken during the lifetime of each reusable packaging.

Build Records need to be kept for 2 years after last use and it shall be made clear who has responsibility to retain these records for each packaging and for informing all Parties when a package has been scrapped.

If the user consigns from a site licensed under the Nuclear Installations Act, then all records shall be kept for 30 years after last use of the packaging. If a package is lost, jettisoned, stolen, or abandoned then this period shall be extended to 50 years.

8. Licencing Records (incl. Export control records)

Licencing Records generated between the Design Authority and the package approver shall be maintained and may include as applicable:

a) Detailed Design Drawings
b) Design Safety Report and associated design substantiation reports
c) Design Review Minutes and clearance actions records
d) Receipt Inspection and Unloading Schedule
e) Turnaround Inspection Schedule
f) Routine Maintenance Schedule
g) Loading and Despatch Inspection Schedule

9. References

IAEA Safety Standard Series No. SSR-6, Regulations for the Safe Transport of Radioactive Material, (2012 Edition)

UK Export Control Organisation website (SPIRE): www.spire.bis.gov.uk

Export Control Act 2002 and the Export Control Order 2008.

BS11000-1:2010 Collaborative business relationships – Part 1: A framework specification

ONR Technical Assessment Guide – NS-TAST-GD-077 Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services

ONR Technical Assessment Guide – NS-TAST-GD-033 Licensee Management of Records

10. Appendices

Appendix A:

Checklist to ensure that Transport Packaging is procured in accordance with this Code of Practice.

APPENDIX A

Checklist to ensure that Transport Packaging is procured in accordance with this Code of Practice.

	Roles and responsibilities	Initial
1	Has the Owner and Operator been identified?	
2	Has the Responsible Engineer been appointed and notified?	
3	Has the role of the Licence Applicant / Holder been identified and agreed?	
4	Have the interested External Parties / Stakeholders been identified and notified?	
5	Have the interested External Parties / Stakeholders been notified of packaging modification and scope of manufacture?	
6	Has the Design Authority been appointed and/or advised of any change to packaging under his responsibility?	

Types of Procurement

	General	Initial
7	Has the Procurement Scope been clearly identified and agreed?	
8	Has a Technical Specification been prepared and issued?	
9	Have the Parties considered and agreed the Type of Procurement required for this package procurement?	

	Design	Initial
10	Is this is a Design for a new Transport Package?	
11	Does this transport package procurement require the Re Licencing of a Design for an existing Package?	
12	Does this supply of transport packaging require a new Licence?	
13	Has the User identified the extent of the safety & design documentation for the package procurement or modification?	
14	Does the specification clearly identify the responsibility and involvement of the Design Authority?	
15	Have all the requirements for Design Lifetime Records been defined and agreed?	

	Manufacture	Initial
16	Are processes in place for appropriate supplier selection and assessment?	
17	Are processes in place for the management of suppliers, monitoring and performance?	
18	Have the necessary Quality Assurance requirements for the manufacture, testing and inspection of transport packages been agreed with the supplier?	
19	Has the supplier been provided with the appropriate Standards and Technical Specifications for the manufacture?	
20	Have the necessary Quality Assurance arrangements and Quality Plans been put in place with the Interested Parties / Stakeholders and Design Authority to ensure appropriate oversight?	
21	Have Quality Control Plans been specified and put in place which include Interested Parties/ Stakeholders and Design Authority involvement?	
22	Have full requirements for Manufacturing Lifetime Records been defined and agreed by all Parties?	

	Contractual models	Initial
23	Have all the Parties been identified?	
24	Have the responsibilities for each Party been clearly stated and agreed?	
25	Have collaborative agreements been put in place and agreed?	
26	Do all Parties know how and when the contractual relationship will end?	
27	Are arrangements for the ownership of IPR clearly known and understood?	
28	Are the necessary insurances to cover all Parties involved in the procurement of the packages been put in place?	
29	Are the package traceability requirements sated and agreed?	

	Export control	Initial
30	Will any of the Parties be contracting with and/or sending information to other parties outside the UK?	
31	Have the Parties checked the requirements with the export control organisation control list to determine the requirements for an export control licence?	
32	Has an export control licence been issued?	

Records management		Initial
33	Has the identification of permanent records been established both for design and procurement packages?	
34	Have design record indexes been established and accepted by the Parties for both prototype and approved packages?	
35	Have manufacture LTQR indexes been established and approved by the Parties for both prototype and package procurement?	
36	Have usage and maintenance records schedules been agreed and put in place for the package?	
37	Have Licencing records (between DA and Package Approver) and maintenance arrangements been put in place for the package?	
38	Have arrangements been put in place for the maintenance and retention of permanent quality records including prototype and package design?	
39	Have permanent records retention periods been established and agreed by and for all stakeholders?	
40	Have protection arrangements for permanent records been reviewed and deemed acceptable?	

Licensing records		Initial
41	Have arrangements been put in place between the Parties for the maintenance of Licencing Records (incl. Export Control)?	

Signed to confirm packages bought in accordance with TCSC 1094		
Signature	Print Name	Date