
INSPECTION PROCEDURE 86001

DESIGN, FABRICATION, TESTING, AND MAINTENANCE OF TRANSPORTATION PACKAGINGS

Effective Date: 08/17/2023

PROGRAM APPLICABILITY: IMC 2690

86001-01 INSPECTION OBJECTIVE

- 01.01 For use when conducting performance-based safety inspections of organizations that hold Certificates of Compliance (CoCs) for transportation packagings. The organization is typically the primary holder of a CoC and may be responsible for design, modification, fabrication, assembly, testing, procurement, repair, and maintenance activities. The primary CoC holder is responsible for maintaining all permanent records required by 10 CFR Part 71, Subpart H.
- 01.02 To verify the adequacy of activities related to design, modification, fabrication, assembly, testing, procurement, repair, and maintenance of transportation packagings. Establish that these activities are in accordance with commitments and requirements specified in the CoC, Safety Analysis Report for Packagings (SARP), U.S. Nuclear Regulatory Commission (NRC) approved Quality Assurance Program (QAP) for Transportation of Radioactive Materials, and 10 CFR Part 71. Determine that the transportation packaging is safe to use based on observation of activities, and examination of permanent quality records and other supporting documentation.

86001-02 INSPECTION REQUIREMENTS

- 02.01 Prior to onsite activities, review the following information:
- a. SARP and CoC for the transportation packagings that will be inspected.
 - b. Docket file of the QAP holder where the inspection is to be performed.
- 02.02 Verify that the CoC holder's activities related to transportation packagings are being conducted in accordance with the CoC, as well as the NRC-approved QAP (reference Regulatory Guide 7.10), and that implementing procedures are in place and effective.
- 02.03 Verify that provisions are in place for reporting defects which could cause a substantial safety hazard, as required by 10 CFR Part 21.
- 02.04 Interview selected personnel and review selected design documentation to determine that adequate design controls are implemented.

- 02.05 Review selected drawings, procedures and records, and observe selected activities being performed to determine **whether** the fabrication, test, and maintenance activities meet SARP design commitments and requirements documented in the CoC.
- 02.06 Observe activities affecting safety aspects of the packaging (such as fabrication, assembly, and testing) to verify that they are performed in accordance with approved methods, procedures, and specifications.
- 02.07 Review selected drawings and records, and interview selected personnel, to verify that the procurement specifications for materials, equipment, and services received by the QAP holder meet the design requirements.
- 02.08 Review selected records and interview selected personnel to verify that a nonconformance control program is effectively implemented, and that corrective actions for identified deficiencies are technically sound and completed in a timely manner.
- 02.09 Review selected records and procedures, interview selected personnel, and observe selected activities affecting the safety aspects of the packaging to verify that individuals performing activities affecting quality are properly trained and qualified, and to verify that management and quality assurance (QA) staff are cognizant and provide appropriate oversight.
- 02.10 Verify that audits of the QAP and activities affecting the safety aspects of the packaging are scheduled, have been performed as scheduled, and that identified deficiencies have been satisfactorily resolved in a timely manner.

86001-03 INSPECTION GUIDANCE

03.01 General Guidance

The focus of this inspection procedure is to determine whether the CoC holder is designing, fabricating, testing, and maintaining transportation packaging in accordance with the SARP, CoC, and NRC-approved QAP. The purpose of the inspection is to verify that transportation packaging are safe to use.

03.02 Specific Guidance

- a. Inspection Requirement 02.01 The SARP describes design, fabrication, test, and maintenance commitments and functions for a given transportation packaging. The CoC is a document issued by NRC to specify acceptable transportation package requirements. A listing of transportation packaging that are registered to QAP holders is maintained by the **Office of Nuclear Materials Safety and Safeguards, Division of Fuel Management (NMSS/DFM)**. This listing identifies the packaging for which the QAP holder is registered as the primary and secondary CoC holder. The primary CoC holder is responsible for maintaining a data package containing all records related to certification, design, design changes, and fabrication for that transportation packaging. A secondary CoC holder is normally a user-only of that packaging.

The QAP specifies commitments made by an organization to meet the requirements of 10 CFR Part 71. The QAP Approval is the document issued by NRC to identify the conditions of QAP applicability to the requirements of 10 CFR Part 71, Subpart H.

- b. Inspection Requirement 02.02. The NRC-approved QAP is implemented effectively, and procedures are in place to provide adequate controls for management oversight and design, fabrication, testing, and maintenance activities (reference NUREG/CR-6314).
- c. Inspection Requirement 02.03. An appropriate document identifying the provisions of Part 21 is posted in a conspicuous location. A Part 21 implementing procedure is in place, and responsible personnel are familiar with it. A statement in accordance with the provisions of Part 21 is on purchase orders for basic components.
- d. Inspection Requirement 02.04. The design control process is clear and well-documented. Documentation to be permanently maintained includes: design review meeting minutes, design change information (e.g., Engineering Change Notices, drawing revisions, dimensional or material changes), test results, calculations, and any other applicable analyses. Internal and external design interface controls are established. SARP design commitments and CoC design requirements are reviewed to determine that design characteristics can be controlled, inspected and tested, and that inspection and test criteria are identified.

Proper selection and accomplishment of design verification processes such as by design reviews, alternate calculations, or qualification testing are performed. When a test program is used to verify the adequacy of a design, sufficient documentation to describe the qualification test of the prototype unit under adverse design conditions is maintained.

- e. Inspection Requirement 02.05. Fabrication travelers, test procedures, and maintenance activities reflect the design specifications identified in the SARP and CoC. Design characteristics defined as important-to-safety (reference NUREG/CR-6407) by the CoC holder are adequately addressed and verified during the fabrication, testing, and maintenance of the packaging.
- f. Inspection Requirement 02.06. Equipment used in activities affecting safety aspects of the packagings is appropriate for the task, calibrated, and used within the sensitivity range of the equipment. Personnel are trained in the use of equipment that they are using to perform these activities.

Adequate instructions, procedures, and drawings are in place and implemented properly by the personnel using them. Personnel know how to obtain a copy of the latest revision of the procedure that they are using to perform an activity. Applicable instructions, procedures, and drawings are available at the locations where the activities are being performed. Revisions to instructions, procedures and drawings are reviewed and approved appropriately by the CoC holder to ensure that CoC requirements are met, and that adequate document controls are implemented.

- g. Inspection Requirement 02.07. Procedures are adequate to ensure that procured material, services, and equipment meet the design specifications. Materials that are identified as important-to-safety (reference NUREG/CR-6407) have complete documented traceability: from the chemical composition of the batch of bulk material from which it was made, to the serial number of the transportation packaging in which it is used. This documentation is required to be maintained for 3 years after the last use of the packaging. Audits of vendors for items important-to-safety are sufficiently comprehensive and are performed on a scheduled basis.

- h. Inspection Requirement 02.08. Nonconforming items are identified and segregated, and a system is in place to control and disposition these items, **including counterfeit, fraudulent or suspect items (CFSI), to preclude inadvertent use. CFSI is defined as items that are intentionally manufactured or altered to imitate a legitimate product with the legal right to do so (Counterfeit); intentionally misrepresented with the intent to deceive (Fraudulent); or reasonably suspected of being Counterfeit or Fraudulent (Suspect).** Packagings that are not in accordance with the CoC are identified as nonconforming items and are dispositioned to prevent inadvertent use. A corrective action system is in place to resolve deficiencies in a timely manner.
- i. Inspection Requirement 02.09. Personnel performing activities affecting safety aspects of the packaging (e.g., fabrication personnel, welders, QA personnel, Quality Control inspectors, nondestructive examination personnel, test technicians, and maintenance personnel) are trained for the activity for which they are responsible. Management oversight and involvement in the implementation of the QAP is apparent. The QA organization is sufficiently independent from cost and schedule constraints. QA oversight is performed at key steps in activities affecting the safety aspects of the packaging.
- j. Inspection Requirement 02.10. QA audits are scheduled to be performed on a periodic basis as specified in the implementing procedure. Audits are sufficiently comprehensive to assess all applicable eighteen criteria identified in Subpart H of 10 CFR Part 71. Audits are performed by appropriately trained personnel not having direct responsibility in the areas being audited.

86001-04 INSPECTION RESOURCES

The number of inspectors, as well as the resources required for the inspection, depends on the scope of the activities performed by the CoC holder for the transportation packaging (e.g., complexity of design, specialized fabrication techniques, number of units, number of models).

The time required to prepare for these inspections will vary depending on the amount of activity at the CoC holder's facility during the time of the inspection. Inspection activities at the CoC holder's facility will require approximately 90 hours for three inspectors. Inspection preparation and report writing is estimated at approximately 48 hours for three inspectors. Inspection activities will be performed primarily by NMSS inspection staff, with occasional assistance from other NRC Offices and Regions.

Inspection results shall be documented in accordance with the guidance provided in IMC 2690.

86001-05 REFERENCES

Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material"

IMC 2690, "Inspection Program for Storage of Spent Reactor Fuel and Reactor-Related Greater-Than-Class C Waste at Independent Spent Fuel Storage Installations and for 10 CFR Part 71 Transportation Packagings," January 2021

NUREG/CR-6314, "Quality Assurance Inspection for Shipping and Storage Containers"

NUREG/CR-6407, "Quality Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety"

END

Attachment 1: Revision History for IP 86001

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
N/A	ML073370352 01/16/08 CN 08-003	This document has been revised to change SFPO to SFST and some minor editorial changes. No other changes are proposed by 11/28/2007.	N/A	N/A
	ML23216A053 08/17/23 CN 23-024	Revised to incorporate CFSI guidance and minor editorial changes.	Yes, Verbal discussion of changes during next ISFSI inspector counterpart call. Due date is 10/31/2023.	