DESIGN, FABRICATION, TESTING, AND MAINTENANCE OF TRANSPORTATION PACKAGINGS

PROGRAM APPLICABILITY: 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), NRC-approved Quality Assurance (QA) Program 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 on-site activities, review the following information:

a. SARP and CoC for the transportation packagings that will be inspected.

b. Docket file of the QA Program 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 QA Program (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 that 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 QA Program 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 QA staff are cognizant and provide appropriate oversight.

02.10 Verify that audits of the QA Program 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

General Guidance

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

Specific Guidance

03.01 Comprehensive files of correspondence regarding NRC-approved QA Program holders are maintained in the NRC docket room for review and reproduction purposes. QA Program information is maintained under the docket number of the entity to which it is issued (reference NUREG-0383, Volume 3). SARP and CoC information is maintained under the docket number of the transportation packaging to which it is issued (reference NUREG-0383, Volume 2).

a. 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 packagings that are registered to QA Program holders is maintained by NMSS/SFPO. This listing identifies the packagings for which the QA Program 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. SARPs and CoCs are available in the NRC Docket Room, and additional information may be found with the cognizant Project Manager, NMSS/SFPO.

b. The QA Program specifies commitments made by an organization to meet the requirements of 10 CFR Part 71. The QA Program Approval is the document issued by NRC to identify the conditions of QA Program applicability to the requirements of 10 CFR Part 71, Subpart H. QA Programs, QA Program Approvals, and past inspection reports are available in the NRC Docket Room.

03.02 The NRC-approved QA program 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).

03.03 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.

03.04 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.

03.05 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.

03.06 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.

03.07 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 three 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.

03.08 Nonconforming items are identified and segregated, and a system is in place to control and disposition these items. 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.

03.09 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 QA Program 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.

03.10 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 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 Manual Chapter 2690.

86001-05 REFERENCES

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

NUREG-0383, Volumes 1-3, "Directory of Certificates of Compliance for Radioactive Materials Packages."

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."

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