Los Alamos National Laboratory

Managing Transportation Quality

The Whole Quality Program, Not Just Type B Packaging…

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Abstract

There has been a long-standing quality program described in 10 CFR Part 71, for Type B packaging. In addition, Title 49 CFR Parts 173.474 and .475 define quality controls for packaging and pre-shipment examination. However, at many facilities, this is the extent of the quality program. The purpose of this paper is to discuss other components of an effective quality program and their role in regulatory compliance.

Introduction

At the onset of the nuclear age, experts realized that the perils presented by radioactive materials called for a standard for construction, operation, and qualification of personnel for nuclear facilities that was more rigorous than anything previously used. NQA-1 became the standard. While the rigor of NQA-1 needs to be graded, as a standard, it describes the infrastructure that should be the basis of an effective quality program for the packaging and transportation of hazardous materials. Unfortunately, NQA-1 has been relegated to the world of Type B packaging and nuclear facilities.

The Department of Energy (DOE) promulgated regulations in 10 CFR Part 830 that require a quality program for all nuclear activities, including packaging and transportation of radioactive materials. Virtually the same requirements have been in place for all activities that affect safety since 1982 (DOE Order 5700.6). Using the NQA-1 standard at least as a reference can provide *guidance* in identifying issues that need to be addressed.

Packaging Program

It is generally agreed upon that the first "safety system" for transportation is the packaging. The bottom line is that if the package doesn't leak, then the physical risk of any hazardous material has been contained.

The DOT has made it clear that packaging is the responsibility of the shipper; therefore the shipper (or offeror) must ensure that the packaging quality program is implemented and that records are maintained in support of each packaging configuration. Direction from DOT's enforcement team indicates that regardless of the manufacturer's markings on a packaging system or component, the shipper must have records to validate its use in the tested configuration. For packagings that do not *require* testing, such as those used for limited quantities, the shipper must still be able to demonstrate that the packaging will meet the conditions normally incident to transportation even though those conditions are no where defined.

Safety Analysis Reports for Packaging (SARPs) are used to document the integrity of Type B packages however no such direction is available to define documentation requirements for packages used for less than Type B quantities or for other hazardous materials. However, quality assurance and DOT requirements demand that the shipper be able to provide evidence that any packaging configuration in use has been tested or otherwise evaluated against criteria representative of the normal conditions of transportation.

Type A Packages

Los Alamos National Laboratory has developed a standard for documentation of Type A packages. Required content of the data package for each packaging configuration includes:

Design Specification

The design specification contains clear and complete specifications for the packaging as a whole and for each component of the packaging. It also includes material requirements, drawings for each component and the whole, and assembly drawings and instructions. Evidence of design review by personnel with the expertise to evaluate the design, other than those who have been directly associated with the design, are also included in the design specification package.

Procurement Specification

A whole-package procurement specification must be developed, including quality or other special requirements applicable to the packaging, such as marking, testing data, accompanying documentation, etc. If any parts or components of the packaging may require replacement or maintenance, the procurement specification shall include the specification for each part/component. Maintenance requirements should be specified to ensure that if a Statement of Work for maintenance activities is generated, it completely describes the maintenance activities to be performed.

Test Requirements

The test requirements shall be identified and described. The equipment used and the environment where testing is to be conducted should also be described. For example, the physical configuration of a "hard, unyielding surface" for drop tests should be included. Drawings, pictures or videotapes should also be included if available.

Written Summary of the Qualifications of the Individuals/Organization Performing Testing

The summary shall include the basis for qualification of the personnel managing and performing the tests, results of a review of the test procedures, and verification that the tests were performed under the control of a documented quality program. A description of the test procedures, pass/fail criteria, the records to be maintained following testing, and a description of the methodology used to document pre- or post-test modifications to the packaging shall also be included.

Description of the Package and its Contents as Tested

The configuration and content, including physical form of the test media, shall be described. Details, such as loading, internal packaging, cushioning, blocking and bracing, or absorbent materials, closure mechanism, and drawings shall be included.

Results of Testing

A written description of the results of testing shall be completed. Any defects or potential failure points shall be identified. Any modifications to the packaging or the test process made during testing or test preparation shall be included. Pictures, video tapes, etc. should be included, when available, to provide visual evidence of the test results.

Written Evaluation of How the Packaging Meets Regulatory Requirements

A written description, item by item, shall be prepared describing how the tested packaging configuration meets each of the package's performance requirements. The description shall be prepared by a person qualified to evaluate test results and shall be signed and dated.

Pre-use Inspection Checklist

A pre-use inspection checklist identifying all the salient characteristics that, if not in the same condition as tested, could cause package failure. Items, such as nuts or bolts, that could be inadvertently replaced or switched and that could be replaced with counterfeit materials, shall be clearly described so that the user can verify that all parts are as tested. The checklist should identify any parts or components of the packaging that may be subject to degradation during storage or after repeated use, criteria for accepting or rejecting surface damage, and parts or components that need

frequent inspection to determine maintenance status. Components that could easily be damaged during the packaging's assembly or loading should also be identified.

Specification for the Allowable Contents for the Packaging

Although this information may be prescribed in the Certificate, this is a separate document that clearly describes the content, physical form, chemical form, quantity limits, and configuration of the package as tested. The only allowable content and configuration is based solely upon the test configuration.

Configuration, Loading, and Closure Instructions for the Packaging

All instructions necessary to ensure that the package contents are limited to the tested physical form, loaded and cushioned or braced, internally packaged, and closed as tested shall be included. Torque values for fasteners shall also be identified.

Maintenance Requirements and Instructions

Requirements for maintenance and any instructions for maintaining or replacing components shall be described. A requirement for a written verification by the user that maintenance has been successfully completed and that the container has been returned to service as originally tested shall be included. The user shall maintain this written verification in his/her container records.

Any Additional Information or Instructions

Any additional instructions or requirements of which the user or a procurement officer should be aware shall be included.

Certificate of Conformance

A Certificate of Conformance, similar to that generated by regulatory agencies, that certifies the packaging's conformance to requirements is the final document in the data package. Test requirements that have been met, description of content, special conditions, communications requirements, etc. should be included in the Certificate. The Certificate shall be signed by the Transportation Program Manager, or designee, only after verification that the data package's content is complete and that all regulatory requirements have been met.

Limited Quantity Packages

Limited quantity packages do not require testing, however they must meet the basic packaging requirements of 49 CFR 173.24 and 172.24a. The shipper must be able to demonstrate that the package will meet the normal conditions of transportation.

One way in which that may be done is through historical data. If the shipper maintains comprehensive records regarding the packaging configuration of each limited quantity package that has been shipped or transported, these records can support the shipper's claim. For example, if the shipper can provide evidence that of

200(?) shipments of a specific package configuration, there has been no evidence of leakage, then the assumption can be made that the package has met conditions of normal transportation. However, if there is no objective evidence available that clearly describes the configuration of packages used and their record of usage, then the packaging should be tested and documented. Test criteria should include any conditions that might be encountered in transportation. For example, if it is a package that is being transported within a limited area…maybe within a facility's boundaries, the testing should include conditions that simulate the environment, normal modes of shipment, potential drops from a dock or the bed of a truck, and normal handling. If the packaging configuration is to be used for cross-country shipments, then the criteria for testing should include any conditions that might be encountered during transport, including weather, climatic conditions, and any other factors that could reasonably be anticipated. Part of the data package for a limited quantity package should also include records from the review performed to determine the conditions to which the package might be subjected.

In either case, through historical records or through evaluation and testing, records shall be maintained on the integrity of even packagings for limited quantities of radioactive materials.

Performance test requirements found in 49 CFR Part 178, Subpart M provides some general guidance on testing that might be performed to evaluate packagings for limited quantities.

Test requirements for small quantity exceptions for non-radioactive materials are described in 49CFR Part 173.4. These might also provide a basis for testing of packagings for limited quantities of radioactive materials.

Other Quality Requirements for a Transportation Program

In addition to the controls on packaging, a Transportation Quality Program must include training. DOT requirements for training are clear and very basic, however additional training should be provided regarding specific procedures and quality assurance program requirements. Workers performing packaging activities must be trained to procedures developed for each specific packaging configuration. Training of all kinds must be documented and any recurrent training requirements must be completed.

Transportation Quality Programs must also address other issues that may not be as straightforward as packaging and training. Process reviews to evaluate and improve procedures/processes are important and provide a methodology to identify and implement corrective actions where needed. Using personnel who have no real understanding of the process gives the opportunity to view it through fresh eyes. The DOE's Integrated Safety Management (ISM) process requires evaluation of the results of performing processes, as required by quality criteria.

Maintenance of records provides the objective evidence needed to demonstrate compliance with requirements. Indexing and verifying/validating records completes the records maintenance program and enables the user to track and substantiate important data. Records must be controlled to ensure their completeness and credibility.

The use of a controlled document system to prepare, review, distribute, and modify documents ensures that each document is prepared in a consistent manner and that each user is in possession of the most recent version of the document. Reviewers have the opportunity to provide input to improve the quality of the document and the process.

Work procedures that affect safety should be prepared to identify hazards, hazard mitigation processes, and conditions for operations. A walk-down of each procedure should be performed to verify the process and find opportunities for improvement or to identify deficiencies.

In the design and development of any packaging system, whether Type B or less than Type B, designs must be developed, verified, reviewed, and controlled. Design changes should also be verified and reviewed and the design documentation for packaging systems in use must be clearly modified and validated.

Procurement actions for packaging systems and components should only include vendors who have been qualified for the item(s) being procured and whose qualification status is current. The provision of accurate and complete specifications, including any quality, documentation, testing, or certification requirements, is absolutely essential. Vendor qualification procedures should be developed to allow flexibility in qualifying vendors based on the rigor required for the items being procured.

Upon receipt, packaging systems and components must be inspected to a rigor commensurate with the system's intended use, welds verified, and an inventory taken to ensure that all required components have been received. Fasteners or other parts that are subject to counterfeiting must be inspected. Qualified workers must perform inspections and documentation must be maintained to provide objective evidence that inspection and acceptance has been accomplished. Instrumentation used to inspect packaging systems, either upon receipt, prior to use, or prior to shipment must be calibrated and documented.

Finally, Transportation and/or Line Managers must maintain an active internal assessment program to ensure that all requirements continue to be met.

Conclusion

While packaging is the key component to the management of quality within a transportation program, it is not the only factor. An effective transportation program must include all the necessary controls and records to ensure that work is performed by qualified workers, designs are clear, complete, and controlled, and that items are procured from qualified vendors according to established specifications and inspected and documented upon receipt in order to track vendor performance. With these components in place, the quality of a transportation program can be objectively evaluated with an end result of transportation excellence.