10 CFR 71.95 REPORT EVALUATION FORM

Docket No.: 71-6613

Package Model No.: 702

Report Submitted By: Lori Podolak, Manager, Regulatory Affairs/Quality Assurance

Report Date: October 15, 2014.

Report ADAMS Accession No.: ML14289A447

Review the incoming report to determine if additional Commission or staff action is warranted. The review should consider whether the report identifies a generic defect or problem with the package design and the safety significance of the issue. Note that a high safety significance represents a potential for significant radiation exposure, medium safety significance represents a potential for some moderate radiation exposure, and low safety significance represents little or no potential for radiation exposure.

1. The report identifies:

__ Significant reduction in the effectiveness of a package during use;
__ Defect with a safety significance;
✓ Shipment in which conditions of the approval were not observed.

2. What is the safety significance? ___ High __ Medium ✓ Low

3. Summary of the report:

The Model No. 702 is a package used for transporting special form sources. This report is being submitted to identify instances where the manufacturing and handling of the package did not conform to the licensing drawings and operating procedures referenced in the certificate of compliance (CoC). Specifically, the report mentioned two deviations from the CoC for the Model No. 702 package (Docket No. 71-6613):

A. Process deviation when applying the torque as specified in Drawing No. R70290, Revision X, page 1.
B. Fabrication and design variations:
1. Addition of pads to the shield cask plate (serial Nos. 6 and 7)
2. Oversized base plate (serial Nos. 8 and 9)
3. Two small threaded holes on the lid top plate (serial Nos. 8 and 9)

The staff determined that these deviations are of low safety significance. The information below contains a summary of the circumstances related to these deviations.

A. Deviation from Process and Drawing No. R70290, Revision X, Page 1

In 2002, QSA established a process for dispatching the Model No. 702 package for shipment. Two main steps of the process were as follows:

3. Summary of the report (Continue):

A. Deviation from Process and Drawing No. R70290, Revision X, Page 1 (Continue)

1. ***Radioisotope Laboratory (RL) staff*** - transfers the package to Distribution staff for final processing before shipment, after applying the torque to the cage bolts specified in Drawing No. R70290, Revision X, page 1.
2. ***Distribution staff*** - performs the physical radiation surveys, label the package, and prepare the transportation documentation for the shipment, without removing the 702 transport cage or altering the torques applied to the package by the RL staff.

In September 2014, QSA Regulatory Affairs staff became aware of a deviation from the process, approved in 2002, for loading and preparing the Model No. 702 package for shipment. Deviations from the approved process were as follows:

1. ***RL staff stopped applying the torque to the cage bolts prior to sending the Model No. 702 packages to Distribution staff.*** Moreover, RL staff did not verify if the torque applied to the bolts were in compliance with the approved operating procedures for the package.
2. ***Distribution staff was removing the cage, after receiving the package from the RL staff, to access information inside the cage enclosure.*** Moreover, they did not have a wrench with the torque required (i.e., 370 ± 5 in-lbs.) for tightening the bolts of the Model No. 702 (corresponding to Drawing No. R70290, Revision X, page 1).

These changes were in violation with QSA's procedure approved in 2002. QSA's internal investigation found that their staff did not understand the significance of the changes they initiated and their relationship with regulatory compliance of the Model No. 702. QSA mentioned in its 71.95 Report that 138 Type B shipments made by QSA Global, Inc., Burlington, MA, from 2011 to September 2014 may not be in compliance with the required torques for the cage bolts and this deviation did not result in any incident.

B. Fabrication and Design Variations

1. ***Addition of Pads to the Shield Package Plate (Serial Nos. 6 and 7)***

In September 2014, a customer informed QSA about a deviation related to the design of Model Nos. 702 packages, serial No. 6, consisting on the addition of pads to the shield package plate. Production staff was aware of this condition on serial No. 6 as well as No. 7, since both serial Nos. contained these welded pads. (The CoC holder accepted these two packages for shipment, since 1991, based on the container radiation profiles.)

QSA believed that their staff added these pads at the time of the original manufacturing to compensate for a curvature and prevent the package from rocking on the skid. At the time, the CoC holder added the welded pads without obtaining an amendment to reflect deviation from the drawings referenced in the CoC. Also, since QSA used serial Nos. 6 and 7 for more than 20 years, RL staff thought that these packages were acceptable for shipment.

3. Summary of the report (Continue):

2. **Oversized Shield Package and Addition of Threaded Holes on Lid Assembly**

From September to October 2014, QSA identified two discrepancies between the description of drawing requirements and serial Nos. 8 and 9. These discrepancies included:

a. oversized shield package (approximately 1/32- to 1/16-inch).
b. two small (approximately ¼-inch diameter) threaded holes on the lid assembly.

The CoC holder accepted these two packages for shipment, since 1992, based on the container radiation profiles.

4. Corrective actions taken by the licensee:

A. Process Deviation – Preparing Model No. 702 for Shipment - Corrective actions taken included the following:

1. Return the non-compliant packages for processing to comply with the requirements of the Type B certificate.
2. Re-train appropriate staff on all applicable specifications required to ensure compliance with the CoC. The CoC holder planned to re-train this staff by October 7, 2014.
3. Share a training presentation with the staff about the importance of document and process control requirements. The target date for completing this action was January 2015.

B. Fabrication and Design Variations- Corrective actions taken included the following:

1. ***Addition of Pads to the Shield Package Plate (Serial Nos. 6 and 7)***
   a. Tagged serial Nos. 6 and 7 as rejected and removed them from service.
   b. Identified all shield casks with this modification.
   c. Suspended shipments of the Model No. 702 packages pending inspection by QSA's Quality Control staff of active packages against Drawing No. R70290, Revision X. (As October 2014, QSA identified two other packages with discrepancies from the approved drawings.)

2. **Oversized Shield Package and Addition of Threaded Holes on Lid Assembly (Serial Nos. 8 and 9)**
   a. Tagged serial Nos. 8 and 9 components as rejected and removed them from service.
   b. Evaluated discrepancies in the QSA Issues Management System.
   c. Evaluate the adequacy of other QSA property (active Type B packages) manufactured more than 10 years ago to ensure this property remains in compliance with applicable regulatory requirements. The target date for completing this action was October 31, 2014.
      Note: Additional package designs affected by this non-compliance are Model Nos. 650L, 770, and 976. On December 1, 2014, the CoC for Model No. 770 was terminated per the CoC holder request (ADAMS No. ML14343A238).
   d. Review existing procedures (e.g., design change) to ensure current practices are adequate to address the "history" of the package. The target date for completing this action was November 28, 2014.

5. Staff comments:
This report was submitted by the CoC Holder. Currently, regulations under 10 CFR 71.95 specify that package users are to submit 10 CFR 71.95 Reports.

6. Staff conclusion:

_✓_ The report does NOT identify generic design or license/certificate issues that warrant additional Commission or staff action. This report is considered closed.

__ There is a need to take additional action. Provide a summary of the bases and recommended actions:

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