10 CFR 71.95 REPORT EVALUATION FORM

Docket No.: 71-9269
Package Model No.: 650L

Report Submitted By: QSA Global, Inc.

Report Date: October 27, 2022 [ML23004A027]

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 pac	kage d	uring ı	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:

On September 9, 2022, a Czech Republic facility contacted QSA Global, Inc. (QSA) after identifying a 650L container lid with significantly worn holes on the bottom plates and another lid with washers welded to the top of the bottom plate holes. The Czech Republic facility questioned if these Model 650L container lids were acceptable for use in shipments. QSA advised that any lids with welded washers were not usable under the Type B approval and that any lids with the amount of wear identified by the Czech facility were also not usable for shipment under the Type B approval as the material no longer fell within the allowed material thickness range on the descriptive drawing.

4. Corrective actions taken by the licensee:

Of the 261 Model 650L packages in active circulation for radioactive shipments, QSA inspected seventy lids located in the Burlington, MA facility and found four additional lid assemblies with washers welded to the top of the bottom plate holes. Inspections performed at the remaining facilities in the United States and the Czech Republic sites found no additional lids with welded washers. The five lids with washers welded to the bottom plate identified at the Burlington, MA and the Czech Republic facilities were removed from further use. QSA also directed staff at the USA facilities to remove any lids identified with welded washers from service.

QSA required internally approved manufacturing instructions for modifications or repairs to shipping containers beginning in September 2005. Since then, no manufacturing instruction has been approved to include welding washers to the 650L lid assemblies. QSA also determined that welding washers onto the Model 650L lids was never documented on any production or descriptive drawings. Therefore, QSA could not determine exactly when these modifications occurred, but based on the age of the container design, it is likely to have happened 30 or more years ago when other Quality Assurance control lapses associated with the fabrication and modification of Type B container were also noted.

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Inspection of Model 650L lids at the Burlington, MA facility, and other QSA facilities also demonstrated that all 650L lids had varying levels of wear around the bottom plate holes. The amount of wear observed varied from minor/superficial to significant thinning (i.e., 1/16 inches of plate material remaining). After performing these inspections, the Czech Republic facility identified another three lids with questionable wear. The three lids at the Czech Republic facility with questionable wear were returned to Burlington, MA for evaluation, and the one lid with significant thinning was removed from further use because the bottom lid plate no longer met the minimum plate thickness identified on the descriptive drawing.

QSA could not accurately estimate the number of shipments made involving these lids or when these shipments occurred for the following reasons. First, any 650L lid can be used with any 650L base unit to make a Type B shipment. Second, the 650L lids modified with washers have been used for over 30 years. Nevertheless, QSA is unaware of any 650L shipment which involved the loss of package integrity, or failure to retain the lid to the container base during transport.

After the Czech facility notified QSA of the welded washer and lid thinning issues, QSA thoroughly compared the descriptive drawings versus the fabrication drawings. QSA subsequently identified tolerance issues associated with the components used to fabricate both the inner shells as well as both the lid top and the bottom plate. As a result, QSA submitted an amendment request to correct these discrepancies as well as to both provide fabrication flexibility and improve clarity. In addition to submitting the amendment request, QSA committed to enhance staff training on inspection acceptance criteria for Type B containers. QSA also committed to enhance methods of regulatory review and detection of issues beyond the standard inspection and acceptance criteria currently used by production staff for these packages.

5. Staff comments:

None.

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: