

# 10 CFR 71.95 REPORT EVALUATION FORM

**Docket No.:** 71-9314

**Package Model No.:** 976 Series

**Report Submitted By:** Lori Podolak

**Report Date:** July 29, 2015

**Report ADAMS Accession No.:** ML15216A367

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:

This report is regarding shipments made using the Model No. 976 Series transportation package for which shipments were made in a package that did not meet the drawings referenced in the certificate of compliance. There were several items that either didn't meet the drawings or it isn't clear that, based on the production drawings, the materials of construction meet the drawings in the certificate. In particular items that are out of compliance include:

- Packages were built with a 2 mm groove weld instead of the 1/8<sup>th</sup> inch fillet weld on the 3056 Shield Unit Top Hat.
- The 3056 Top Plate was constructed of a single machined piece instead of a two-piece construction connected with a 1/8<sup>th</sup> inch fillet weld.
- The 3056 Strap thread block and Handle Weldment is shown as welding in three places but were actually welded in four places.
- Drawing No. 1911, Rev. No. F required the stainless steel for the jacket body and 300 series stainless steel for the jacket top from June 2005 to July 2009. In July 2009, the drawings were changed to require ASTM 304 stainless steel. Earlier versions of the production drawings for these parts did not comply with the new material requirement. Records review for all parts identified that the inspection records used for product acceptance from 2005 to 2007 did not require a material check or certification for the, jacket parts used in production units. Therefore the actual grade of stainless steel was not confirmed.
- The weld specification for an eyebolt on the 855 shield, as shown on Drawing No. R85590 Sheet 2, includes identification of a 3/16<sup>th</sup> inch fillet weld on the eyebolt below the cover plate. Due to the presence of the steel nut welded to underside of the cover assembly, it is not possible to weld the eyebolt below the plate once it is threaded-into the steel nut.

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The issues identified for the 976 Series package are similar in nature and cause as the ones identified for other QSA packages, including the Model Nos. 650L, 770, 702, 680-OP and 741-OP packages. QSA stated that the root cause is that the package design was not adequately implemented across the descriptive drawings referenced in the certificate and the production drawings, i.e., changes were made to the production drawings that were never carried through to the descriptive drawings referenced in the certificate of compliance.

QSA stated that the discrepancies were caused for the following reasons:

- In some cases, the translation of manufacturing requirements present on all versions of the grandfathered drawings and pre-existing shield units failed to fully reflect all applicable transport configuration details in the drawings referenced in the certificate of compliance.
- In other cases, material specification requirements were added to the descriptive drawings with implementation dates, but then were not translated as necessary to the affected production drawings impacted.
- In some cases no phase-in date was used and the descriptive drawing changes did not fully incorporate pre-existing components still in use. These errors are attributed to failures to accurately review historical inspection records prior to implementing changes without an implementation date, and failure to implement production drawing changes after changes had been accepted on descriptive drawings by the NRC.

QSA stated that subsequent failure to adequately define material specifications for some of the 976 Series package components was a combination of:

- lack of guidance documentation,
- human error,
- a large volume of drawing revisions processed within a small time period, and
- drawing revisions processed by a small group of individuals in Engineering and Regulatory.

#### **4. Corrective actions taken by the licensee:**

QSA submitted an amendment to correct these deficiencies which was approved under Rev. No. 6 of the certificate of compliance. QSA stated that continued compliance will be verified as part of its routing quality assurance internal audits.

In addition QSA stated that it is

- Issuing enhanced inspection guidance procedures to identify standard inspection requirements for certain types of inspections and/or quality classifications for product acceptance,
- Revise Procedure WI-R-3 127 "Preparation and Approval of Submissions to Regulatory Authorities" to add a section specific to review, and if necessary initiate changes to production drawings, for changes accepted under a descriptive assembly drawing tied to an active product approval.

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- Revise Procedure WI-B-1303 to more clearly identify that descriptive drawing changes, without phase in dates, must require removal from use of any non-compliant product as part of the phase-in level.

**5. Staff comments:**

The staff has reviewed the certificate holder's report, and its evaluation of the incident, and it agrees that the safety significance of the event is minor. The staff finds that the certificate holder's corrective actions should be sufficient to prevent future occurrences.

QSA Global, Inc. is certificate holder of the package. The regulations specify in 10 CFR Part 71.95(a) that the licensee, after requesting the certificate holder's input, shall submit the written report. To date the U.S. Nuclear Regulatory Commission has not received any reports pursuant to 10 CFR 71.95 from its licensees rather the certificate holder submitted the written report.

**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:

- By its own admission, QSA has had the same systemic issues for essentially all of its package designs. In its report pursuant to 10 CFR 71.95, QSA stated that "The issues identified for the SENTRY Series packages are similar in nature and cause to the issues identified for the 650L, 770, 702, 680-OP and 741-OP packages..."

Recommend performing an inspection at QSA in the first quarter of FY18 to determine whether QSA has corrected and adequately implemented its proposed changes.

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