Incident Investigation

Incident Date: 4/13/2017 – Dose Rate Levels in Excess of allowable on-contact and TI limits

Lead Investigator: Travis Snowder (President/CEO)

Incident Review Team: RSC

Investigation Team: Travis Snowder/ Bryce Rich (RSC Chair)/ Michael Albanese (RSO)

On April 13, at approximately 9:04 am, it was reported that Qal-Tek Associates (QTA) had received a shipment showing elevated dose readings. The shipment was shipped by a QTA authorized shipper, after performing a demonstration in NYC on April 11th. The shipment was inspected and it was determined that the cause of the elevated readings was the failure of the source holder shields through a lack of positive closure of the lid from retaining the sources during shipment. Specifically, three sources (2-Cs-137 and 1 Co-60) had escaped the source holder shield but were contained in the outer package, the result was that radiation levels on-contact and at 1 meter exceeded allowable limits and warranted immediate NRC notification.

In accordance with QTA Procedure, OP-PRO-145, immediately upon incident notification, an incident report was generated and the investigation team was formed. The QTA promptly called an RSC meeting within 1 business day of the incident notification from QTA Radiation Safety officer. The RSC, upon request from the QTA CEO, formed the investigation team and the incident review team comprised of the CEO, RSC chairman and RSO. It was determined upon request from the CEO and in accordance with QP-PRO-145, that Travis Snowder (President/CEO/QA Manager) would lead the Investigation Team. The RSC required that it perform a review of the final incident investigation report and the determined Corrective and Preventative Action's (CAPA's).

The investigation strategy included the following criteria;

- Complete timeline review.
- Identification of all involved parties.
- Verbal and written testimonies from all directly involved parties.
- Pictorial and testimonial review of shipment packaging.
- Review of relevant QTA procedures and processes.

This investigation intends to evaluate and determine the proper CAPA to resolve the root cause of this specific incident as well as identify any related or relevant CAPA's which would improve the quality and compliance of QTA's shipping practices.

Root Cause Analysis Chain

START------ The elevated dose reading of the package on receipt at QTA ID is directly related to the sources coming out of the designated shielded internal containment (pig).

- Why did the sources come out of the pig?
  - The internal packaging allowed the pig to rotate, and the lid to come off enough to allow the sources to escape.
- Why did the pig not have some security or closure control on the lid.
  - The RSC had previously reviewed a shipping cask with a positive closure mechanism as designed by QTA experienced shipping staff. However, the RSO and un-trained RT (both not experienced in performing this task) took the lead once the initial package design was found to be overweight of the Common Carrier overnight limits.
- Why did the QTA shipper in NY, not identify the packaging difference in the return shipment?
  - The QTA shipping in NY was also limited in their experience with this type of shipment and was not aware of the previous pig design approved by the RSC.
- Why were inexperienced staff allowed to package the pig?
  - The RSO's (ID and NY shipper) were authorized to ship as they had met regulatory training requirements (DOT and IATA requirements), but had not been trained on proper packaging nor were they experienced in the performance of any packaging.
- Why were they not trained or experienced in packaging.
  - The external and internal packaging curriculum did not include function specific training for packaging. The RSO was pulled out of his oversight role and assumed operational duties (i.e. packaging) due to personnel changes and competing priorities of more experienced staff in the time window available to ensure the package was delivered on time. The NY shipper was a new shipper for QTA and had only shipped one package via ground prior to this air shipment about a year earlier.
- Why does external and internal DOT and IATA trainings not include function specific packaging training or emphasize the need to have packaging instructions for each specification package?.
  - The packaging used for each shipment is unique to companies packaging needs and therefore it is assumed each employer provides additional function specific training in order to comply with the intent of the regulations and therefore have packaging instructions to meet the packaging requirements and provide didactic training.
- Why were the QTA shippers not trained to QTA's packaging instructions?
  - Qal-Tek's packaging instructions were not specific enough to train to any specific requirements and are primarily related to gauges/ devices or specific waste disposal shipments. Packaging instructions for source shipments do not have robust packaging instructions.

- Why did QTA not have well established packaging instructions?
  - QTA has relied on shipper experience from gauge and waste shipments of which neither shipper had while working at QTA.
- Why were the shippers allowed to ship without proper OJT and experience in packaging shipments?
  - In addition to prior work experience and cross-training experience at QTA employee training matrices identify and track what training is required for each job role. The procedures and special regulatory and operational training sessions provide the work guidance for each employee and OJT training ensures it's understood before staff are allowed to work independently. Since the external and internal DOT/IATA training only provided types of packages and performance requirements and did provide packaging instructions there was no source packaging instructions in the shipping procedure to OJT to.

Root Cause Determination

QTA has not provided adequate function specific packaging training for their shippers prior to working independently.
QTA shipping procedures did not contain packaging instructions or standards and rely on experienced shippers to prevent improper packaging.

Proposed CAPA

- QTA must develop and provide function specific packaging instructions and OJT train each shipper to prove packaging conformance with the packaging instructions.
- QTA must develop specific packaging instructions which will eliminate experience as the only precaution to proper and safe packaging. These packaging instructions must account for the following component flaws identified in the root cause analysis chain.
  - Specific packaging materials which prevent voids or shifting of contents during shipment.
  - Shipping Pigs with positive closure devices which allow for adequate shielding, size and source shape configurations.
  - Simple and standard packaging instructions to reduce packaging errors and prevent loss of source containment.

QTA Shipping Program Audit

During the review of this incident, an audit of QTA's shipping practices were performed to determine actual shipping practices demonstrated as related to both the initial and return shipment of the package related to this incident. The sequence of events and related facts were evaluated through review of the incident report, testimonials, pictorial evidence and documented accounts from the directly involved parties. This information was evaluated against QTA shipping procedures, relevant DOT shipping regulations.

The following observations and findings were identified.

Observations

1- The Skolnik drum used in the packaging was tested in accordance with Type A certification and the contents of QTA's package were within specification of the test criteria identified in Skolnik Test report ID# 10-069 (Solids, Heavy Bulk Materials (e.g. lead bricks and steel plates). However, the test criteria of Skolniks report did not have to account for an inner primary container without a positive closure device. Therefore, QTA's packaging instructions must include control mechanisms to ensure such inner containers have a robust positive closure device.

2- Even though the original shipping package did not fail upon arrival at NYC, despite the evidence of rough handling in transit per the dent on the drum when received in NY, the shipper did not notify the QTA RSO of potential internal packaging failure. Had a notification to the RSO been made at this time, a more secure packaging plan may have been developed.

3- The Drum was dented during shipment from ID to NY. The NY QTA shipper did notify the RSO to determine if this damage would prevent the drum from being allowed to be return shipped. The NY QTA shipper at this time did not notify the ID RSO of the potential internal packaging failure (lid not secured on pig). QTA packaging instructions need to more clearly identify when a packaging should be identified as "failed" or "near-miss" failure.

4- The receiver in ID (QTA) was not able to perform a dose survey *prior to the removal of the package* from the Common Carrier Truck. This is a violation of QTA procedures. Had this survey occurred prior to the removal of the drum from the delivery vehicle, it would have provided additional information as to when the sources may have become dislodged from the pig. However, more importantly, the habits displayed by common carrier deliveries to QTA could pose serious risks to QTA's staff, facilities and property in the event of a significant package failure. Additional effort need to be made to prevent common carriers from unloading deliveries prior to radiological evaluation.

Findings

1- The chemical “form” for several sources were improperly identified as “solid metal” on the Declaration for Dangerous Goods.
2- Source packing instructions were not part of the shipping procedures that could have prevented improper pig selection and packaging.
3- QTA shipping staff was not function specific trained to all QTA packaging situations.
4- Clear package failure or near-miss notification requirements are not incorporated into QTA shipping procedures

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