

April 16, 2018

MEMORANDUM TO FILE: License No. 21-04073-01; Docket No. 030-02037
License No. 34-29200-01MD; Docket No. 030-36973

FROM: Kevin Null, Health Physicist
Materials Inspection Branch

THRU: Aaron T. McCraw, Chief
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SUBJECT: FOLLOWUP INFORMATION TO EVENT NUMBER (EN) 53320,
DATED APRIL 8, 2018: SURFACE CONTAMINATION ON THE
OUTSIDE OF A PACKAGE EXCEEDING NRC REPORTING
REQUIREMENTS

The purpose of this memorandum is to provide additional detail concerning the information described in EN 53320. Both the recipient (McLaren Greater Lansing Hospital (McLaren)) and the shipper (Cardinal Health – Jenison, Michigan facility (radiopharmacy)) of a package containing radioactive material were contacted to gather the information provided below.

In summary, it appears that the package was contaminated at the radiopharmacy as a result of an incident involving a broken vial containing technetium-99m (Tc-99m). The incident occurred before the package was shipped to McLaren, but after the package had already been surveyed and wiped by radiopharmacy staff. Further, it appears that even though McLaren identified the contamination by conducting smears for contamination, they appear to have missed an opportunity to identify the contamination while conducting radiation level surveys.

Information from the licensee:

- At about 4:30 a.m. on April 8, 2018, the licensee received eight (8) unit doses containing Tc-99m for cardiac imaging from a local radiopharmacy. Total activity was 326 millicuries (mCi), about 40 mCi per unit dose.
- The nuclear medicine technologist (NMT) arrived at 7:00 a.m. and surveyed the package at about 7:30 a.m. The surveys included radiation level surveys at 1 meter and at the surface, and smears for removable contamination.
- Radiation levels were essentially background, i.e., 0.02 millirem per hour at the surface. A smear of the entire package identified 8,427 disintegration per minute (dpm). More detailed smears identified contamination on the top (11,490 dpm/300 cm²) and right side (15,750 dpm/300 cm²) of the shipping container.
- According to the radiation safety officer (RSO) for McLaren, there was no evidence indicating that the contamination occurred at their facility. Through followup discussions with radiopharmacy staff, the RSO became aware that the radiopharmacy had broken a multi-dose vial containing Tc-99m at the radiopharmacy prior to shipment of the unit doses. The multi-dose vial was supposed to be shipped to McLaren as well, but was delayed due to the incident.

- The RSO could not explain why their radiation level surveys were at background levels even though the package was clearly contaminated. The NMT was not immediately available for a discussion; however, the RSO was going to ask the NMT to demonstrate the survey technique and instrumentation that she/he used to conduct the survey.
- On April 10, 2018, the RSO followed up with me on the package survey technique that was used by the NMT. The RSO confirmed that the NMT conducted the package surveys in accordance with their procedure, using a portable survey meter coupled to a pancake probe.

Information from the radiopharmacy:

- The corporate RSO conducted an investigation and determined that radiopharmacy staff were preparing two shipping containers for McLaren: one contained the eight unit doses, and the other contained a single, multi-dose vial containing Tc-99m.
- Both containers had been surveyed by radiopharmacy staff for radiation levels and removable contamination. Results were within acceptable limits.
- After the surveys were conducted, the container holding the multi-dose vial fell off the counter onto the floor and the vial inside the lead pig broke.
- Radiopharmacy staff cleaned up the contamination from the broken vial and proceeded to ship the container with the eight unit doses to McLaren.
- The corporate RSO speculated that, during the clean-up process, radiopharmacy staff cross-contaminated the other container that was shipped to McLaren. Because the container had already been surveyed, it was shipped shortly after the incident without being resurveyed after the incident.
- The corporate RSO confirmed that radiopharmacy staff wore appropriate protective clothing, including lab coats and disposable gloves, during the spill clean up. It is believed that staff members' gloves became contaminated when she/he cleaned up the broken vial, and that the contamination was spread when she/he handled the other package. In accordance with standard procedure, the gloves were treated a radioactive waste.
- The corporate RSO stated that there was no contamination identified in the radiopharmacy lab after clean up of the incident. In addition, the car and driver were surveyed with no contamination identified.
- There were only two shipments that were prepared on the day of the accident, which was on Sunday, April 8, 2018. Both packages were for McLaren. No other shipments were made on April 8, 2018.