

November 2016 – March 2017 RAM NMED Events and Medical Reportable Events

8 total events

2 medical events

1. On December 20, 2016, the Department received notification of a medical event. During an administration of yttrium-90 (Y-90) TheraSpheres, a leak occurred while connecting the infusion line from the source vial to the microcatheter through which the spheres are administered to the patient. The leak occurred because the physician administering the spheres simultaneously unclamped the administration line while trying to connect it to the microcatheter. The physician then incorrectly assumed that the leaking fluid only contained clean saline from priming the infusion line and proceeded with the administration. This resulted in approximately 8.99 millicurie of Y-90 activity being administered; or 35% of the prescribed 25.95 mCi activity. The prescribed dose was 174.7 gray (Gy), with the leak resulting in a dose to the patient's liver of about 60.1 Gy. The leak also caused contamination of the treatment area, which was immediately and successfully decontaminated. No harmful effect to the patient resulted from the event. The referring physician and patient were made aware of the event during the procedure. The licensee will retrain physicians on the correct Y-90 administration procedures and also on proper leak and spill clean-up procedures before any further treatments occur.

2. On January 19, 2017, a therapeutic dosage of yttrium-90 (Y-90) TheraSpheres was administered to a patient, apparently without incident. Measurements of the radioactive waste following administration determined that 29% of the prescribed activity was administered to the patient (13.91 mCi vs. 47.88 mCi). This resulted in a dose to the liver of 34.8 Gy vs. the 120 Gy dose that would have been received if the prescribed activity had been administered. The cause of the event appears to be a partial obstruction in the catheter or the line connecting the TheraSpheres vial to the catheter. This was supported by this particular patient's vasculature being complicated, which may have resulted in the micro catheter moving slightly following initial placement and also a greater than usual amount of saline collected in the overflow vial. This is consistent with greater resistance than usual in the line and catheter. No adverse effect to the patient was noted and the patient returned for an additional dose administration to the same portion of the liver on February 8, 2017. A reactive inspection occurred and upon review it was determined that no corrective actions were needed as all procedures were properly followed.

2 leaking source events

1. On May 25, 2016, the Department received notice that a cesium-137 reference standard vial was leaking. The source was an Eckert & Ziegler Model SRV-137-200U with an activity of 0.205 millicuries. The source was immediately removed from service, replaced in the original lead container, and placed in a sealed bag. All equipment associated with the source was wipe tested for contamination with none found. The source container was wipe tested and found to be free of contamination. The source was returned to the manufacturer on July 11, 2016.

2.	On October 20, 2016, the Department received notice of a leaking cesium-137 vial on a mobile PET/CT unit. The source was a NAS Model MED3550 with an activity of 0.134 millicuries. The physicist confirmed proper and secure storage of the vial, and proper wrapping to prevent the spread of contamination. Upon inspecting the vial, a small area of possible degradation was observed that was presumed to be the source of the leak. The physicist then performed a wipe test of the pig holding the vial, and found contamination. The pig was also wrapped and secured to prevent any spread. The entire hot lab was surveyed and wipe tested and no other contamination was found except for a minor finding in the dose calibrator dipper, which was pulled from service and promptly decontaminated. The source was returned to the manufacturer on November 9, 2016.
2 lost or stolen events	
1.	On November 17, 2016, the Department received a notification from a general licensee that during a routing inventory check in September 2016, it was discovered that a static eliminator gauge had gone missing. Its last known use was during the first six months of the year 2011. The general licensee was unaware of its reporting responsibility. The gauge, an NRD Inc. Model P-2021-5000 contained approximately 10 millicuries of polonium-210. The licensee believes the gauge was lost when the company reconfigured its machinery at some point during 2012. The gauge has not been located. Given that over 13 half-lives have transpired since the gauge was lost, there is no current public health and safety hazard.
2.	While attempting to obtain information to renew a general license on February 16, 2017, the Department discovered the licensee was no longer in possession of their RMD Instruments Model LPA-1B XRF device. The device contained a 12 mCi cobalt-57 source as assayed on August 18, 2011. The licensee has filed an incident report (# 2017-06686) with the City of Chester Police Department for the recovery of the device but has no knowledge of when the device went missing. The Department has begun proceedings for a notice of violation and penalty with the licensee. The licensee has elected to terminate their general license and not pursue obtaining another gauge. The XRF gauge would have a current activity of approximately 0.06 millicuries and would not now pose a public health and safety hazard.
1 Overexposure (false)	
1.	On November 2, 2016, the Department received a notification from a medical licensee that the September 2016 exposure readings for an authorized user's (AU) body and ring badges exceeded the regulatory limits. The body badge result was 7,165 mrem and the ring badge reading was 6,490 mrem. The licensee contacted Landauer and was informed that these exposures were considered irregular, meaning: "The exposures were not typical and do not follow the basic rules of radiation absorption." An investigation concluded that the AU's work habits and job duties remained unchanged for 2016. His average historical exposure for the first 10 months of 2016 was 20 mrem body and 93 mrem ring, and the average exposure received by his coworkers in the same time frame was 35 mrem body. These values, coupled with the fact that he does not work at a facility where an exposure of this magnitude in a single month is a reasonable assumption, led all involved to conclude that the reading was the result of an unusual event or damage to the badge. The AU was assigned the average dose of 25 mrem body and 100 mrem ring for this reporting period.

1 gauge event	
1.	On January 13, 2017, the Department was notified by a licensee that a malfunction of a roll pin on the shutter handle of a Berthold Model 8010 density gauge containing 20 millicuries of cesium-137 occurred. The roll pin, which holds the shutter handle to the shutter shaft on one of their in-line density gauges became sheared off during an attempt to move the shutter to the open position, rendering the gauge unusable. The shutter is in the closed position and out of service awaiting repair from a service provider. No overexposures occurred.

November 2016 – March 2017 Therapeutic and Diagnostic Machine Medical Reportable Events	
2 total events	
1.	On November 18, 2016, a patient was being treated on an Elekta Infinity linac unit for 2 different treatment sites. The first site was successfully treated. The patient was then repositioned for the second treatment. All treatment parameters were confirmed before treatment began. While the patient was being assisted from the treatment table, a staff member noticed that the cone used for the treatment was not the cone used in the treatment planning. The correct treatment dose was delivered but the total area was smaller than intended. Additional treatment was delivered to the missed target area. No adverse effect is expected to the patient. The facility reported to the equipment manufacturer that the unit did not provide an error message when the cone did not match the targeted field size.
2.	On December 26, 2016, it was discovered that a patient was prescribed Stereotactic Body Radiation Therapy for 3 fractions at 1 fraction per week for 3 weeks. The patient received all 3 fractions in 1 week. The correct site was treated. The correct total dose and correct dose per fraction were given. However, the weekly administered dose to the intended site differed from the weekly prescribed dose by more than 60%. The patient's treatments were scheduled incorrectly. There is no expected risk to the patient.