

**October 2018 – August 2019 RAM NMED Events**

**17 total events**

**1 - Unplanned mechanical failure**

1. In November 2018, the DEP was notified by the licensee that part of their access control system to their irradiator is currently inoperable. Specifically, “detection of entry while the sources are exposed must activate a visible and audible alarm to make the individual entering the room aware of the hazard” (§36.23(b)), and “the alarm must also alert at least one other individual who is onsite of the entry” (§36.23(b)). Non-compliance with these two items also renders them in non-compliance with “attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in paragraph (b) of this section” §36.23(c). The alarm system was taken off-line since it is not operating as intended or required and was resulting in nuisance alarms and a corrective action was put in place to handle this temporary malfunction. The licensee notified all staff members that a member of the radiation safety staff will need to accompany anyone doing any irradiations and will use trained staff to substitute for these and act as the alarms until a resolution can be found. In addition to the initial two malfunctions, a third issue regarding the irradiator was discovered. While investigating the auto alarm, they also identified yesterday afternoon that a visible and audible alarm was not “activated” if the door is opened while the source is exposed. The licensee stressed that while the source is out, there are systems (interlocks) that are completely functional. These systems will not allow anyone to open the door to the irradiator while the source is out. The licensee performed a root cause analysis alongside the security system vendor, and the state performed a reactive inspection. All issues were repaired as of January 11, 2019.

**1 - Inability to retract radiography source**

1. In November 2018, a licensee reported while using a Sentinel Model 880 Delta containing a 39.2 curie source of iridium-192, the guide tube had come unbound from the strapping used to hold the collimator and guide tube to the weld being inspected and fell approximately the full length of the guide tube. This left the guide tube hanging at a 90-degree angle from the exposure camera which proved too great to let the source be retracted into a shielded position inside the exposure device and left the source inside the collimator. The technicians secured the area by adjusting their 2 millirem/hour boundaries to an unshielded source distance and immediately contacted their Operations Manager. Once on scene, the Operations Manager utilized various tools to straighten the guide tube enough for the source to be fully retracted into a shielded position. The device was taken back to the licensee’s storage vault for inspection and possible repair or disposal by the manufacturer. Direct read dosimetry showed exposures of 18 millirem for the Operations Manager, 18 millirem for the radiographer and 5 millirem for the radiography assistant, thus no overexposures have occurred because of this event. Corrective actions include retraining on suspended exposure procedures and future discussion of this event at monthly staff meetings.

<b>3 - Gauge events (Stuck Shutter)</b>	
1.	In October 2018, a licensee reported an IRMS Model TG-2 gauge containing 3000 millicuries of americium-241 did not properly perform following scheduled maintenance. Specifically, the shutter failed to open completely and then would not open at all. The gauge was taken out of service and a service provider was contacted, responded, and corrected the problem. The licensee contacted the same service provider in November 2018 to transfer the device for proper disposal. Licensee and service provider survey results indicated no abnormal amounts of radiation in the area before, during or after the event or removal of the device. There were no overexposures related to this event.
2.	In March 2019, while at a temporary job site, a DEP inspector found a Troxler model 3411 with the shutter stuck open. The gauge contained 40 millicuries of americium-beryllium source and 8 millicuries of cesium-137. The technician did not know how long the shutter had been open and was only able to get the tungsten sliding block closed by tapping on the gauge. After it was closed, the technician was unable to get the sliding block open again. Corrective actions included returning the gauge to the manufacturer for repair and licensee personnel received additional training.
3.	In March 2019, a licensee reported that a fixed gauge, a Berthold Technologies model LB-7410 containing a 300 millicurie americium-241 source was not able to operate as designed. It was determined on 3/21/2019 that the shutter locking mechanism cylinder was able to be pulled out of the gauge. The gauge was being removed from the east side of the #3 Blast Furnace to the storage area at the Blast Furnace Spares Building. A service provider was already scheduled to be on site to observe removal and transport of the gauge. The cylinder was never fully removed; but if it was, that would allow the shutter to be manually opened or closed. The cylinder locking device was depressed by the service provider and it is currently in that condition. The shutter can't be moved with the cylinder depressed. The gauge is currently locked in a storage area. Berthold Technologies has repaired the gauge.
<b>2 - Lost, stolen, or missing licensed material</b>	
1.	In March 2019, a manufacturer technician notified the department of a missing 0.5 millicurie californium-252 source from a Sabia model XL-5000 fixed nuclear gauge analyzer. The manufacturer was performing replenishment of two of seven sources. It was discovered that the analyzer only contained six sources. The analyzer was removed and disassembled, destroying the unit, in efforts to locate the missing source but it was not located. The manufacturer technician surveyed the unit and the area multiple times and did not find the source. The remaining sources have been packaged in a drum for safe storage until shipping can be arranged. The company that serviced the unit, can't account for when the source went missing but is confident that it had been in its proper place previously.

2.	<p>In April 2019, DEP received a report that a metal recycler discovered a cesium-137 source in a load of scrap metal. A radiation portal monitor alarmed at the metal recycling facility in Slippery Rock, Pennsylvania. The load was reading approximately 4 millirem/hour at a distance of four feet through the scrap metal. The load was transferred back to its origin point, where it was off-loaded and sorted. DEP representatives oversaw the off-loading. An intact nuclear gauge, a Nuclear Chicago model 5193, was found bolted to a plate. The gauge contained a cesium-137 source with a current activity of 70.7 millicuries. A representative noted bolts for another gauge, but no gauge was found. The found gauge was secured in a building on site. The remaining site was cleared, except for a few remaining buildings. The licensee had a general license with DEP but did not notify of intent to terminate their license or to vacate their licensed location. Upon later review of their license, it was noted that they possessed another gauge (serial #220) of the same model. The location of gauge #220 is unknown. DEP located former employees to discuss the site and conducted several walkthrough surveys. The cause of the incident was management deficiency; failure to notify DEP and properly dispose/transfer their gauges. The old licensee is out of business with no assets. The current owner took responsibility and paid for disposal. The second gauge was never located.</p>
<b>4 – Medical Events</b>	
1.	<p>In February 2019, a patient was administered 171 millicuries of liquid Iodine-131 (I-131) through a feeding tube inserted into the patient’s gastric tube as he was unable to swallow the I-131 in pill form. While flushing the feeding tube with saline, a technologist noticed a pool of liquid next to the patient on a disposable drape, on the patient, and on the imaging table, that was determined to be radioactive. The feeding tube was removed from the gastric tube, and flushed, without any further leaking. All non-essential personnel were cleared from the room and the nuclear medicine staff contained the spill, decontaminated the patient and the site. All radioactive trash was contained in a lead-lined storage drum and secured. No hospital personnel were contaminated during this event. The licensee reported that given the I-131 dose was diluted with saline, the total amount of I-131 that was spilled could not be determined at the time of the event. In an effort to determine the activity and dose the licensee surveyed all contaminated items in their storage drum. Using this data and conservative decay calculations the licensee estimates 97.2 millicuries was spilled. This resulted in an under-dose of 56.8%. The patient was scheduled for another administration to complete the therapy. No harm is expected to the patient.</p>
2.	<p>In July 2019 it was reported that a patient received less dose than prescribed during a Y-90 microsphere SIR-Sphere treatment. The total dosage of 9.58 millicuries was split into two equal dosages of 4.79 millicuries to be administered to segments 5 and 8 of the liver. The first vial, segment 5, was successfully administered but only 75.7% or 3.6 millicuries of the second vial was administered to segment 8. The referring physician and the patient were verbally informed. No harm is expected to the patient. The DEP is awaiting further information on the cause of this event.</p>

3.	In February 2019, while reviewing a patient treatment plan, it was discovered that the patient had received a dose from a high dose rate remote afterloader containing iridium-192 that was less than the prescribed dose in the written directive. The original treatment plan was prescribed for 7.0 gray per fraction, however at the beginning of the 3rd fraction it was noticed that the total dose delivered was 4.67 gray instead of the prescribed 14 gray they should have received for the same 2 fractions. The physician has informed the patient and will amend the written directive to add additional fractions at different doses to achieve the original prescribed dose to the treatment area.
4.	In February 2019 a patient was prescribed 31.3 millicuries of yttrium-90 Sir-Spheres for metastatic colorectal cancer and 31.69 millicuries was delivered at time of treatment. From the post Y-90 bremsstrahlung scan, performed on the day of treatment, it was discovered by the nuclear medicine physician, that some of the Y-90 microspheres also traveled to the stomach and left lobe of liver. The doctor has informed the patient and the patient is being monitored for potential complications. The doctor is working to determine the percentage of the Y-90 that went to stomach and left lobe of liver. The licensee has determined that the cause of the event was undetected movement of the catheter tip from the intended location in the right hepatic artery to the proper hepatic artery. This may have been caused by movement of the patient, possibly exacerbated by reduced slack in the catheter after pulling it back to correct its initial position. It was reported that the patient had begun to experience nausea and vomiting, and an endoscopy was performed on March 7th. The scope revealed mild to moderate erythema in the gastric antrum. The attending physician who performed the endoscopy believes that the patient's symptoms should resolve in 1-2 weeks with continued treatment. Corrective actions included updating their procedures and providing retraining to personnel.
<b>1 - Doses in excess of the occupational dose limits</b>	
1.	In February 2019 it was discovered that an Interventional Radiologist exceeded the annual occupational limit of 50 rem. He received 53.34 rem for the 2018 calendar year. This was discovered during the RSO's monthly occupational exposure report review on 2/1/2019. His occupational exposures occurred in the Interventional Radiology department where he performs both fluoroscopically guided interventions and yttrium-90 Sir-Sphere cases. A reactive inspection was performed. No harm is expected to the employee. The licensee determined that the cause of the event was human error. Corrective actions included updating their procedures and providing retraining to personnel.
<b>5 - Equipment failed to function as designed</b>	
1.	In March 2019, a licensee reported a fixed nuclear gauge, a Berthold Technologies model LB-300-ML became disabled during routine source movement on 3/19/2019. The incident involved a cobalt-60 source, model P-2608-100 with an activity of approximately 5.3 millicuries. During the process of installing the cobalt-60 source rod and moving it from a transfer shield to the gauge and industrial process mold, they experienced difficulty in getting the source rod to insert into the mold. It was suspected that the rod was slightly bent. The rod was retracted into the fully shielded position in a spare transfer shield. That transfer shield was then taken to a designated storage area and secured from unauthorized access. A service provider was contacted for possible repair or replacement. No radiation exposure over regulatory limits occurred. Repairs to the gauge were conducted.

2.	<p>In June 2019, a licensee reported an equipment failure during a cardiovascular brachytherapy treatment (CVBT), where the source train failed to retract from the patient at the end of the treatment time. The catheter was manually removed from the patient after two attempts, approximately 30 seconds, and placed in the emergency container and secured. No harm is expected to the patient and no radiation overexposures occurred. The transfer device (Best Vascular/Novoste model A1767) contained a strontium-90 source train (Best Vascular/AEA Technologies model SICW.2, serial #AB863) with an activity of 79.73 millicuries. Best Vascular was immediately notified and responded to the site on 6/17/2019 to retrieve the source train and repair the device. The service engineer was able to drive the source train into the catheter and retract it into the device several times without incident. The licensee believes the CVBT catheter was not fully seated into the device, causing a small leak and a subsequent pressure differential, which does not allow the source train to fully retract into the device. The cause of the event was determined to be operator error.</p>
3.	<p>In July 2019 a Troxler gauge, model 4640-B, was hit by a roller while on a job site at the Philadelphia Airport. The gauge contained a cesium-137 source with an activity of 8 millicuries. The area was secured, and the PA DEP responded to the site. The gauge was not found to be leaking and was secured for shipment back to the operators' office in New Jersey. Preliminary investigation indicates the gauge operator is not licensed to operate within Pennsylvania. There was no exposure to workers or the public. This event is currently ongoing.</p>
4.	<p>In July 2019, the licensee called to report an equipment failure event where during a cardiovascular brachytherapy treatment the source failed to retract at the end of the treatment time, due to a kink in the catheter line. The unit being used was a Best Vascular, Inc., A1000 Series using the Novoste Beta-Cath 3.5 Delivery System and a strontium-90 source with a source strength of 79.3 millicuries. A service engineer for Best Vascular was present during the time of treatment and was able to unkink the catheter line allowing the source to fully retract into the unit. There was no harm to the patient and no overexposure occurred. This event was forwarded to the NRC for information as to the possibility of a generic issue.</p>
5.	<p>In August 2019, as a result of a Departmental inspection, the licensee reported an equipment failure event that occurred in February of 2019. The equipment was a Varian Gammamed Plus, containing 6.518 curies of iridium-192. A patient was receiving her last of three fractions of treatment with total treatment time for this fraction being 222.6 seconds divided through a total of eight positions. Twenty-five seconds into treatment the unit issued an inactive source error and retracted the source. The physicist entered the room to confirm that the source was retracted. The manufacturer was called. At the manufacturers recommendation the console key was powered off then back on and the remaining treatment was initiated to continue with the untreated area. This time at 25.8 seconds into the treatment the same error occurred. The remaining treatment plan was saved into the planning computer, and the patient had the applicator removed and was sent home. Varian sent a field service representative who successfully replaced the Geiger Muller board and functionality was verified. The patient was then rescheduled. The continued treatment on 2/25/2019 accurately reflected the partial treatment and was appropriately scaled to reflect the source decay from the previous treatment. The final portion of the treatment was delivered without incident. There was no harm or over exposure to the patient. The patient was informed at the time. The attending physician has yet to be notified.</p>

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