## April 2016 - November 2016 RAM NMED Events

#### 14 total events

#### 3 medical events

- 1. This medical event was discovered during a routine review of the written directives (WD) from the previous year. A patient was to receive their sixth and final radium-223 (Ra-223) "Xofigo" injection on April 13, 2015. Their weight was recorded as 72.5 kilograms. The authorized user (AU) prescribed 0.98 millicuries (mCi) and signed the WD on April 9, 2015. The correct amount should have been 0.098 mCi. This error was not noticed by either the pharmacy, who dispensed 0.099 mCi, or the Nuclear Medicine Technologist, who measured 0.099 mCi in the dose calibrator. The patient did receive the correct dosage; however, the WD was never altered to show the correct amount, resulting in a medical event. If the Technologist had noticed the actual amount prescribed in the WD, the percent error would have been -89.9%. The hospital has revised all Xofigo WD's to be stated in microcuries and re-trained all AU's on proper WD procedures.
- 2. On July 13, 2016, a patient was scheduled to receive two separate yttrium-90 (Y-90) TheraSphere administrations within the same treatment to two different liver segments. Upon delivery of the first microsphere administration an occlusion occurred within the delivery system preventing the procedure from being completed. The same occlusion was noted during the second procedure. The pre and post administration radiation survey measurements of the dosage vials and administration materials indicated 25.3% of the intended activity was delivered in the first administration and 25.1% of the intended activity was delivered for the second administration. This results in a medical event. No harm is expected to the patient and they were rescheduled for re-treatment the following month. The manufacturer was informed and noted their desire to perform analyses on the administration materials. The cause is still as yet undetermined, and as such, corrective actions are still undetermined. Both administrations came from the same TheraSphere lot and both administration kit lot. The manufacturer was not informed of any other sites having a similar problem with that lot. The licensee will continue to follow accepted procedure until any defect is noted.
- 3. On September 12, 2016, a licensee notified the Department of a dose to a patient's skin estimated to be greater than 50 rem. A patient was to receive a 29 millicurie (mCi) technetium-99 (Tc-99) injection for a bone scan. While injecting the dose the technologist noticed leakage at the injection site and immediately stopped the injection. The patient's arm was wiped and cleaned with gauze several times. The hospital estimates the contamination from the residual activity to be approximately 15.8 mCi, resulting in a dose greater than 50 rem. Licensee calculations show a total dose to the epidermal layer to range from approximately 32 centigray (cGy) to 620 cGy. The broad range results from utilizing initial exposure time of 1 minute, followed by chronic exposure with no further remediation for up to 24 hours (after which it is assumed the residual activity was removed by routine bathing/showering by the patient at home). It was noted that the lack of prompt erythema or delayed (20 days) radiogenic events suggests the dose was less than the approximate threshold of 200-300 rem for the development of radiation dermatitis. Corrective actions included; revision of existing spill / contamination procedures, revision of the decontamination procedure, and new policies on intravenous administrations.

## 2 radiography events

- 1. On July 13, 2016, a licensee was using a QSA Model 880 delta radiographic exposure device containing 32.9 curies of iridium-192 (Ir-192). Upon retracting the source into the safe position the radiographer noticed the locking mechanism did not engage. He was able to crank out the source and retract it again, noting this time the locking mechanism did engage. The radiation safety officer (RSO) was notified. The camera was taken out of service and returned to the manufacturer for evaluation. No over exposures occurred as a result of this event.
- On September 30, 2016, the Department received a notification of an overexposure reading of 5,088 millirem (mR) for the second quarter of the year on a dosimetry badge from a radiographer. After completing an investigation, it was determined that the dose was probably false. The radiographer has stated that he leaves his dosimetry in his backpack and that the backpack stays in the truck he normally works out of. This truck was used by other radiographers during this time, possibly exposing his dosimetry without his knowledge. Also, his daily dosimetry reports note a total of 150 mR during this time period and his assistant received a total dose of 92 mR for the same timeframe. Corrective actions include better control of dosimetry.

#### 1 radium event

1. On May 5, 2016, an NRC Equipment Corporation Model 530 Alphatron vacuum gauge was discovered in a wooded area in Blair County. The gauge contained approximately 100 microcuries of radium-226 (Ra-226). The Department retrieved the gauge and it was collected in the annual "Radium Roundup" in September. No known exposures occurred with this discovery and no removable contamination was present on the device.

## 1 suspicious activity

1. On August 1, 2016, a radiography licensee observed a suspicious black Dodge pick-up truck driving in front of their facility holding a cell phone out of the driver's window. The individual appeared to be videotaping the facility. The Local Law Enforcement Agency (LLEA), was contacted, took statements, and reviewed a copy of the surveillance video. The Department also performed a reactive inspection, but found no evidence of activity related to possible theft, sabotage, or diversion of category 1 or 2 quantities of radioactive material. The LLEA also gathered video surveillance from another business on the street. Neither videotape provided any identities or any proof of wrongdoing. The complaint was marked as closed. No further action was taken.

## 2 shipping / transportation events

- On May 18, 2016, a Pharmacy courier mistakenly picked up a pig from a licensee which he 1. assumed to be empty because it was located near other PET containers he was scheduled to return to the pharmacy. The pig actually contained two germanium / gallium calibration rods containing 2.16 millicuries each. As he loaded the pig into his vehicle the two rods fell onto the ground. Without realizing they were radioactive he picked them up using his bare hands and placed them into the trunk of his vehicle, unshielded. He then returned to the pharmacy. He placed the pig and two rods on top of the other empty pigs in the pharmacy's loading area. The pharmacy's radiation safety officer (RSO) noticed the rods and surveyed them, noting the dose rate on contact at greater than 200 mR/hr and 1.4 mR/hr at one meter. The rods were immediately shielded and secured. Surveys and swipes of the rods, the area they were discovered, the courier's hands, and the transport vehicle were then taken. No removable contamination was found. A survey calculation by the RSO determined the dose to the hands to be below regulatory limits and that the other pigs within the transport vehicle provided enough shielding to reduce his exposure below regulatory limits. The courier's body badge was evaluated and noted that he received a typical result for the period. No ring badge was worn. The rods were properly packaged and returned to the licensee.
- 2. On August 25, 2016, the Department was notified by a licensee that an undamaged package containing a vial of 5 millicuries of iodine-123 (I-123) in liquid form was received in which 5 of the 6 sides of the package exceeded the removable contamination limits in 10 CFR 71.47. The highest side showed over 10,000 dpm. After completing wipe testing, the technologist performed an area survey. The area background was found to be 0.04 mR/hr. At 1 meter, the package was found to be 0.05 mR/hr. At the package surface the reading was found to be 0.4 mR/hr. The contamination was identified as technetium-99m. Given this finding, the package was opened and verified to contain I-123. The contamination is believed to have been transferred from somewhere else. Upon return to the originator pharmacy, a survey of the delivery driver's hands, vehicle, and all packages in the vehicle was performed. None showed contamination. All hospital personnel involved and surrounding areas were surveyed and found to be contamination free. No one received a dose above regulatory limits. No cause of the contamination has been determined.

## 5 gauge events

On August 1, 2016, during a routine maintenance check, a licensee became aware of a Ronan Engineering Model SA-1 gauge containing 40 millicuries of cesium-137 (Cs-137) with an inoperable shutter. The gauge was located in a remote area with high vibration and the handle to the shutter seemed to have dislodged due to the vibration, making it unusable, and stuck in the closed position. The gauge was placed out of service until repairs were completed by a licensed contractor. No over exposures occurred. The gauge will be monitored more frequently in the future to prevent this occurrence.

- 2. On August 8, 2016, a technician stepped away from a Humboldt nuclear density gauge containing 11 millicuries of cesium-137 (Cs-137) and 44 millicuries of americium-241 (Am-241). During that time a compacting roller impacted the gauge with its rear tire, damaging the gauge and making it unusable. The area was controlled and both the roller and the gauge were surveyed, neither showing contamination. The gauge was then visually inspected to confirm that the source was in the shielded position, secured in the transport container, and returned to the approved licensee storage facility. A leak test was completed with negative results. No over exposures occurred as a result of this event. The gauge was sent for repair and refresher training was provided to all gauge users.
- 3. On August 25, 2016, the Department was notified that a licensee had a 3.8 millicurie cobalt-60 (Co-60) source rod that became bent and unusable during the process of moving it from a transfer shield to a gauge. During the process the licensee observed difficulty in getting the source rod to insert into the gauge mold. The licensee, using a remote handling device, partially removed the Co-60 source from the transfer shield and briefly (about 30 seconds) inspected it. It was noted that the rod was partially bent. The rod was immediately retracted into the fully shielded position in the transfer shield. The transfer shield containing the Co-60 source was then taken to a designated storage area where it was secured from unauthorized access. The calculated dose to the worker(s) was estimated to be 0.44 millirem. The source was leak tested with negative results. No exposures over regulatory limits occurred. The manufacturer was contacted, arrived at the facility, and straightened the source rod, leak tested it again with negative results, and installed it into the gauge mold normally. It was determined that the bending was most likely due to misalignment of the transfer shield and gauge mold. Licensee workers now will receive new gauge training. This training shall include revisions to the source handling procedure.
- 4. On September 21, 2016, a licensee notified the Department that a Troxler moisture density gauge containing 9 millicuries (mCi) of cesium -137 (Cs-137) and 44 mCi of americium-241 (Am-241) was damaged when it was run over by a drum compactor. The gauge was visually inspected by the licensee and leak tested on site. It was noted that radioactive sources were not compromised by the event. The leak test results were negative. The gauge was transported to the licensee's headquarters and returned to Troxler for repairs. No over exposures occurred from this event. The licensee has revised its job site policies to include more stringent safety controls to prevent a reoccurrence.
- 5. On October 15, 2016, a licensee reported that an Ohmart / Vega Model SHLG density gauge containing 800 millicuries of cesium-137 (Cs-137) was discovered to have a non-responsive shutter stuck in the open position. The gauge area was roped off and no over exposures occurred. The manufacturer was contacted and repairs were made on site. Surveys of the gauge revealed 0.3 mR/hr at one foot and 1.4 mR/hr on contact. Leak test results were negative. The manufacturer relieved a vacuum that had developed in the base of the gauge to close the shutter. It was suggested that this gauge be replaced. The Department's inspector was present for the repair.

# April 2016 - November 2016 Therapeutic and Diagnostic Machine Medical Reportable Events

## 5 total events

- 1. A written prescription for accelerator therapy was written to administer two fractions per day for the first five days of treatment. Only one fraction was administered resulting in a weekly under dose by 50%.
- 2. On August 19, 2016, 10 fractions were administered, however, fluid in the lung was not accounted for resulting in greater than 30% of the weekly prescribed dose to the wrong area.
- 3. During a cardiac catheterization procedure, which occurred on three separate days in September 2016, a patient received a total dose of 19 Gy to a single area on the patient's back. Suspected acute damage was a possibility and thus reported to the Department. Follow-up observations on skin integrity revealed no reaction to the dose.
- 4. On October 3, 2016, a patient received four field treatments each day instead of the prescribed two treatments resulting in 100% excess of the prescribed dose. The reason the discrepancy occurred was due to an initial treatment plan for four treatments but later changed.
- In April 2016, 14 accelerator therapy fractions were delivered to a field size larger than prescribed resulting in 40% of the dose received outside the treatment volume.