

March 2017 – October 2017 RAM NMED Events	
7 total events	
2 medical events	
1.	<p>A patient was prescribed 12.16 millicuries of yttrium-90 (Y-90) SirSpheres® for a treatment of left lobe metastasis of the liver. As the authorized user was pushing on the syringe to deliver the dose of microspheres he noticed a strong resistance, as did the interventional radiologist who was simultaneously infusing a contrasting agent. Staff tried several times to adjust the catheter, the 3-way stopcock, and other tubing, without improvement. The administration was aborted to prevent any further safety issues. The microcatheter was pulled from the patient and the SirSpheres® vial with the microcatheter and other radioactive waste were put in the collection jar for measurement with an ion chamber. As the microcatheter was pulled from the patient, a very small defect was observed. The interventional radiologist described it as a kink. The licensee believes as the microspheres were administered they clumped at the kink and that is what caused the resistance and blockage. The activity administered was 5.64 millicuries, which is 53.6% less than the prescribed dosage. The outer wrapping of the catheter was kept for reporting purposes. The authorized user was notified of the final dose to the patient and he made a note on the written directive describing why the administration was stopped. After an investigation of this event, including conversations with the interventional radiologist and the authorized user, the licensee is confident that the cause of the blockage was the result of a manufacturing defect in the microcatheter. Therefore, the product information was reported to the manufacturer and a voluntary MedWatch FDA Adverse Event reporting form (FDA 3500) was completed and submitted to the licensee Risk Management Office.</p>
2.	<p>A patient was scheduled to be treated with 11.87 millicuries of yttrium-90 (Y-90) microspheres (TheraSphere®). During the treatment, the attending interventional radiologist noticed liquid leaking from the connection between the administration "e-line" and the catheter that had been placed into the patient. The treatment was immediately stopped and decontamination efforts immediately began. Contamination was found to be present on the patient's thigh and groin, but was immediately and successfully decontaminated. The resultant skin dose was calculated to be 0.11 millirem and no adverse effects are expected. All contaminated items were collected and used for the post treatment 4-sided measurements. There was no resulting contamination of attending personnel, and personal protective equipment worked as intended. The interventional lab was released by Radiation Safety without any delays to patient care. No overexposure is believed to have occurred. The patient and referring physician were notified the day of the procedure. The initial measurements indicated that only 43% of the intended dose was delivered to the patient. However, after consulting with BTG Nordion regarding accounting for geometrical variations of the waste containers, the dose delivered to the patient was subsequently determined to be 70.3% of the intended dose. The event occurred due to the poor connection from the "e-line" to the microcatheter. This was most likely due to human error (not sufficiently tightening the connection).</p>

1 lost or stolen events	
1.	On March 8, 2017, a licensee conducted an inventory of the iodine-125 (I-125) seeds used for breast seed localization. During the course of this audit it was found that one of the vials contained a metal marker rather than the I-125 seed. The treatment related to this marker was completed on January 19, 2017, and the activity of the seed was 169 microcuries. The lead pathology assistant and the pathology assistant were then interviewed by the radiation safety officer and the specimen images from the procedure were reviewed. The seed and the marker were both present on the images. The pathology report stated that the seed and the marker were removed from the specimen. The licensee believes the pathology assistant mistakenly put the marker in the vial to be stored and placed the seed in the sharps container which goes out to biohazard waste. All waste from this date has already been disposed of. As a result, the licensee has retrained all staff, modified the procedure to place both the marker and seed in the vial to be stored, and to survey all trash and vials before disposal.
1 Unplanned fire or explosion	
1.	At about 0700 on March 17, 2017, the Department received notification of a vehicle fire near mile marker 286 on I-76 (PA Turnpike). The vehicle was carrying approximately 2 curies (74 GBq) of Tc-99m and 1 curie (37 GBq) of fluorine-18 (F-18) for a PA radiopharmacy licensee. Department emergency response and radiological health physics staff responded to the scene. The vehicle was entirely engulfed in flames due to a mechanical issue within the engine and allowed to burn itself out. There were no reports of injuries and no overexposures occurred. A representative from the licensee was on scene and collected contaminated debris and ash which was returned to their facility for decay. The vehicle was then transported to an isolated storage area, allowed to decay to background, and released on Friday, March 24, 2017. The entire area was surveyed and no residual contamination was discovered. The licensee reported the incident to US DOT, DOT incident report #1173754.
2 gauge events	
1.	The radiation safety officer reported via telephone that on May 8, 2017, the indicator light on an Accu-Ray Model U-3 gauge containing 1 curie of americium-241 would not change from red (open) to green (closed). The area around the shutter was surveyed and it was found to be closed. It was then determined that the shutter piston had malfunctioned, not allowing the shutter to open. The area was roped off and a service provider was notified. They responded and replaced the shutter piston. It was finally determined that the piston had hydraulically seized. A back up cylinder has been ordered.
2.	On August 25, 2017, a licensee identified a failure of the collimator block attached to the shutter assembly on one of its Thermo Measure Tech Model 5204 gauges containing 4 curies of cesium-137. The gauge was immediately removed from service. A licensed service provider was contacted and the broken shutter mechanism was removed and replaced with a spare. The shutter mechanism was then tested and confirmed as operating properly. Survey results indicated no abnormal amounts of radiation in the area before or after the repair work. All regulatory precautions were taken and no overexposures occurred.

1 overexposure

1. A cyclotron engineer was working on multiple components within two separate cyclotrons during the week of July 17 (exact date is unknown) when he received an extremity exposure of 79,251 millirem to his left hand and 94,517 millirem to his right hand, as noted on the dosimetry report from his ring badges. His whole-body dosimetry result for the entire month of July was 680 millirem. No unusual work was noted for the event week, and he has recorded normal exposures for all weeks up to this event thus far. The licensee investigated and the Department performed a reactive inspection on August 17, 2017. In both cyclotron maintenance and chemistry module rebuild tasks, there is the potential of contact with up to several hundred millicuries of residual F-18 in the systems. The tasks involved in both areas can consume a person for hours. As no specific event was identified, and based on the vast difference in the whole-body badge results and the ring dosimeter results, it is probable there was undetected contamination on gloves, rings or the skin of the hands. Since the whole-body dosimeter and the electronic dosimeter data for the engineer do not indicate levels as high as his rings, a large area source has been ruled out. Others working in the lab had no comparable exposures during the week or month, ruling out the possibility of a general spill or unshielded source as the cause of the ring exposures to the engineer. Since the cause appears to be failure to conduct contamination surveys in a timely manner while working with significant F-18 activity, the primary corrective action was to provide information on how a relatively small activity in rather short periods of time can result in high exposures to employees. A training module will be developed and disseminated for mandatory viewing with a test to affirm that the information has been acquired. In addition, a review of the adequacy of gloves and the materials that they are made of that are being used by the licensee will be undertaken. If inadequacies are determined, or if better gloves are identified, a change in the PPE program will be instituted.