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Nuclear Material Events Database

Review of Medical Events For Inadequate Training (Fiscal Year 2017-2018)

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Review of Medical Events For Inadequate Training (Fiscal Year 2017-2018)

Introduction

At the request of NRC, Idaho National Laboratory (INL) staff performed a review of medical event records contained in the Nuclear Material Events Database (NMED). The objective was to determine the number of medical events caused by inadequate training of medical staff.

The review was limited to reportable medical events that occurred in Fiscal Years 2017 and 2018 (86 events total). INL performed a detailed review of each record including every reference document (publicly available) used to create the records.

INL determined that the records/references do not contain enough detailed information to identify how many medical events are caused by inadequate training of medical staff.

Background

The NMED contains records of events involving nuclear material reported to the NRC by NRC licensees, Agreement States, and non-licensees. The database is maintained by INL and contains over 25,000 records of material events submitted to the NRC from January 1990 to present. The events are classified into the following categories based on event reporting requirements defined by Title 10 of the Code of Federal Regulations (10 CFR):

- Equipment
- Leaking Sealed Source
- Lost/Abandoned/Stolen Material
- Medical
- Radiation Overexposure
- Release of Licensed Material or Contamination
- Transportation
- Other

Each record is a summary of the event, developed from publicly available reference documents. Note that the level of detail contained in the reference documents received by INL varies greatly between NRC and Agreement State-regulated events. NRC-regulated event references may include: licensee event notifications to the NRC Operations Center, licensee written reports, NRC inspection reports, NRC Notices of Violation, etc. However, for an Agreement State-regulated event, those detailed reports are provided to the Agreement State regulatory agency; NMED typically receives just a summary of those reports.

Most material licensees do not perform formal root cause determinations following an event. Thus, NMED does not attempt to record root cause information. Rather, NMED captures the direct cause of an event; the cause that most directly resulted in the event (closest cause to the event). For example, if a gauge is stolen from a vehicle, the direct cause is “theft”, regardless of whether appropriate security controls were in place or the gauge user was maintaining control of the gauge.

Data

This review was limited to medical events that occurred between October 1, 2016, and September 30, 2018 (Fiscal Years 2017 and 2018). Even though many events were reported and entered into the NMED for operational experience purposes, only those events required to be reported by 10 CFR are addressed in this report (86 events total). The records were downloaded from the NMED on February 5, 2019. Note that because the NMED is a dynamic database that is updated daily, variations in data may be encountered over time.

Observations

Appendix A contains a listing of the 86 events included in this study.

Of the 86 events, 14 were regulated by NRC and 72 by Agreement States.

Of the 86 events, 18 were categorized as Abnormal Occurrences (AO) or Potential AOs. Note these events are considered Potential AOs until they complete NRC's formal AO determination process and are reported in NUREG-0090, *Report to Congress on Abnormal Occurrences*.

Each NMED record contains a cause field, which captures a single, direct cause of the event. The list of possible causes is divided into six general cause categories, each with sub-categories (see Appendix B for detailed cause definitions). When creating or updating an event record, if the reference document does not contain enough detailed information to select a specific sub-category cause, the overall category is used.

The Human Error cause category contains five sub-category causes:

- Inattention to Detail
- Failure to Follow Procedure or Wrong Procedure Used
- Communication Problem
- Inadequate Training
- Management Deficiency

The Inadequate Training sub-category is defined as "inadequate training (or no training) to enable a person to perform a desired task." None of the 86 event records listed Inadequate Training in the cause field.

It is difficult to identify a specific cause of inadequate training from the reference documents. The references clearly identify that events result from human error, but are usually limited to identifying the direct cause/error, such as a failure to enter the correct activity in the physics calculations, bringing the wrong dosage to the procedure room, etc. The references do not identify why the human error occurred. Thus, a reader cannot typically determine the difference between a momentary lapse in attention, inadequate training for the task, etc.

Of the 86 events, 38 records listed some type of human error as the cause: 32 were listed under the Human Error category and 6 listed a more specific sub-category [Failure to Follow Procedure or Wrong Procedure Used (4) and Management Deficiency (2)].

Medical procedures typically involve a defense-in-depth process that should identify and correct errors before any patient administration.

Each NMED record contains a corrective actions field, which can capture several actions taken to prevent recurrence. It is common for the corrective actions to include procedural modifications and additional

training. However, this additional training does not necessarily indicate a previous condition of inadequate training of medical staff. Rather, it appears to focus on lessons learned and procedures/processes improved following the event.

Single event that identified inadequate training (see Appendix C for event summary)

Event 170294 - This was an Abnormal Occurrence event involving a patient that was administered a dose of Y-90 microspheres that was greater than prescribed. The licensee's response to NRC's Notice of Violation identified that staff did not have the required training. "Specifically, the nuclear medicine technician that was ordering the sources was not trained in the ordering, measuring, and preparation process for Y-90 microspheres." However, other errors occurred in the process that otherwise should have identified and corrected the technician's error. For example, the Authorized User did not verify the activity of the Y-90 and a written directive was not completed prior to the administration. The NMED record listed Human Error, Management Deficiency in the cause field.

Other events that may infer inadequate training (see Appendix C for event summary)

Event 170134 - This was an Abnormal Occurrence event involving a prostate seed implant procedure where dose was delivered to an unintended site. Although the placement of the needles was correct, the technique used to "drop" the seeds from the needles may have caused a 1-cm shift in placement. Corrective actions included restricting the urologist's participation in brachytherapy cases pending additional mentoring and training in this technique.

Event 180136 - In this event, a patient received less dose than prescribed during a high dose rate brachytherapy skin treatment. A contributing cause was that an authorized medical physicist was inexperienced in using a custom immobilization device. One of the corrective actions is that a therapist will be present at the first treatment and any time a physicist is treating a patient for the first time.

Event 180281 - This is a Potential Abnormal Occurrence event involving a prostate seed implant procedure where dose was delivered to an unintended site. A post-implant CT scan showed that 32 seeds were implanted outside of the prostate. The event resulted from a poorly placed Foley catheter. As one of the corrective actions, the licensee implemented specific training for physicians and participating staff on how to prevent and/or recognize when a Foley catheter balloon is inflated in the urethra.

Conclusion

INL determined that the records/references do not contain enough detailed information to identify how many medical events are caused by inadequate training of medical staff. Although this review identified a few possible events, this should not be considered definitive.

Appendix A

This following is a list of the 86 reportable medical events included in this review. The table displays whether the event was regulated by an Agreement State (AS) or NRC, if the event was an Abnormal Occurrence (AO), and the cause and corrective actions.

EVENT	AS or NRC	AO	CAUSE	CORRECTIVE ACTIONS
160434	AS		Equipment Failure	Procedure Modified
160529	AS		Patient Other	Procedure Modified
170003	AS		Equipment Failure	New Equipment Obtained
				Personnel Received Additional Training
				Procedure Modified
170006	AS		Human Error	Increased Monitoring To Ensure Compliance
170008	AS		Human Error	Personnel Receive Improved Supervision
				Personnel Received Additional Training
170019	AS		Procedure Problem	New Procedure Written
				Procedure Modified
170034	AS	AO	Human Error	Improve Radioactive Material Labeling And Handling
				Personnel Received Additional Training
				Procedure Modified
170035	AS		Equipment Failure	No Corrective Action Taken
170056	AS		Equipment Failure	Personnel Received Additional Training
170083	NRC	AO	Patient Other	No Corrective Action Taken
170128	AS	AO	Human Error	Procedure Modified
170134	AS	AO	Human Error	Personnel Receive Improved Supervision
				Personnel Received Additional Training
170148	AS		Human Error	Personnel Received Additional Training
170153	NRC	AO	Human Error	Personnel Received Additional Training
				Procedure Modified
170154	AS		Defective Or Failed Part	Procedure Modified
170168	AS		Patient Other	No Corrective Action Taken
170183	AS		Failure To Follow Procedure Or Wrong Procedure Used	Procedure Modified
170190	AS		Not Reported	Personnel Received Additional Training
170196	AS		Defective Or Failed Part	Equipment Returned To Manufacturer For Repair Or Disposal
170211	AS		Failure To Follow Procedure Or Wrong Procedure Used	Procedure Modified
170212	AS		Equipment Failure	New Procedure Written
170216	AS		Human Error	Procedure Modified
170217	AS	AO	Human Error	Personnel Received Additional Training
				Procedure Modified

170270	AS		Defective Or Inadequate Procedure	Procedure Modified
170284	NRC		Defective Or Failed Part	Repairs Made Without Engineering Change To System
170290	AS		Defective Or Failed Part	No Corrective Action Taken
170292	AS		Equipment Failure	No Corrective Action Taken
170294	NRC	AO	Management Deficiency	New Personnel Hired
				Personnel Receive Improved Supervision
				Personnel Received Additional Training
				Procedure Modified
170312	AS		Human Error	Personnel Received Additional Training
				Procedure Modified
170335	AS		Defective Or Inadequate Procedure	Procedure Modified
170352	AS		Defective Or Inadequate Procedure	Equipment Returned To Manufacturer For Repair Or Disposal
				Procedure Modified
170357	AS	AO	Management Deficiency	Personnel Received Additional Training
				Procedure Modified
170361	AS		Equipment Failure	Equipment Returned To Manufacturer For Repair Or Disposal
170369	AS		Defective Or Failed Part	No Corrective Action Taken
170372	AS		Equipment Failure	Equipment Returned To Manufacturer For Repair Or Disposal
				Procedure Modified
170399	NRC	AO	Human Error	Personnel Received Additional Training
				Procedure Modified
170404	AS	Potential	Design, Manufacturing, Or Installation Error	Procedure Modified
170407	AS		Human Error	Procedure Modified
170427	NRC		Equipment Failure	Procedure Modified
170453	NRC		Human Error	Personnel Received Additional Training
				Procedure Modified
170481	AS		Human Error	No Corrective Action Taken
170484	AS		Equipment Failure	Equipment Returned To Manufacturer For Repair Or Disposal
170505	AS		Equipment Failure	Not Reported
170527	NRC		Defective Or Inadequate Procedure	Procedure Modified
170544	AS		Human Error	Procedure Modified
170546	AS		Human Error	New Quality Management Plan
				Procedure Modified
170552	AS		Human Error	Personnel Received Additional Training
170554	AS		Not Reported	Not Reported
170569	AS		Equipment Failure	Manufacturer Will Notify Customers Of Defect
180001	AS		Not Reported	Not Reported
180002	AS		Not Reported	Not Reported

180014	AS		Human Error	Procedure Modified
180027	AS		Not Reported	Not Reported
180039	AS		Not Reported	Not Reported
180043	AS		Equipment Failure	New Quality Management Plan
180045	AS		Other	Procedure Modified
180058	AS		Human Error	Personnel Received Additional Training
				Procedure Modified
180063	NRC	Potential	Human Error	New Quality Management Plan
				Personnel Received Additional Training
				Procedure Modified
180074	NRC	Potential	Failure To Follow Procedure Or Wrong Procedure Used	New Equipment Obtained
				Personnel Received Additional Training
180088	AS		Not Reported	No Corrective Action Taken
180093	AS	Potential	Human Error	New Quality Management Plan
				Procedure Modified
180104	AS		Human Error	New Equipment Obtained
				Procedure Modified
180136	NRC		Human Error	New Procedure Written
				Personnel Receive Improved Supervision
180159	AS		Human Error	New Procedure Written
180174	AS		Human Error	Personnel Received Additional Training
180175	AS		Equipment Failure	No Corrective Action Taken
180183	AS		Human Error	Procedure Modified
180184	AS		Equipment Failure	New Equipment Obtained
				Personnel Received Additional Training
				Procedure Modified
180190	AS		Equipment Failure	New Equipment Obtained
				Procedure Modified
180192	NRC		Human Error	Personnel Received Additional Training
				Procedure Modified
180252	AS	Potential	Human Error	New Procedure Written
				New Quality Management Plan
				Personnel Received Additional Training
				Procedure Modified
180257	AS		Human Error	Personnel Received Additional Training
180265	AS		Equipment Failure	Repairs Made Without Engineering Change To System
180268	AS	Potential	Human Error	Procedure Modified
180270	AS		Not Reported	Not Reported
180281	AS	Potential	Human Error	New Quality Management Plan
				Personnel Received Additional Training

				Procedure Modified
180282	AS		Not Reported	Procedure Modified
180313	AS		Not Reported	Not Reported
180334	AS	Potential	Human Error	New Quality Management Plan
				Personnel Received Additional Training
				Procedure Modified
180344	AS		Patient Other	New Equipment Obtained
				Procedure Modified
180377	AS	Potential	Failure To Follow Procedure Or Wrong Procedure Used	Procedure Modified
180378	NRC		Not Reported	Not Reported
180402	AS		Equipment Failure	Equipment Returned To Manufacturer For Repair Or Disposal
				Procedure Modified
180415	NRC		Equipment Failure	Procedure Modified
180436	AS		Equipment Failure	Equipment Returned To Manufacturer For Repair Or Disposal
				Procedure Modified
180455	AS		Equipment Failure	Equipment Returned To Manufacturer For Repair Or Disposal

Appendix B

The following is a list of the direct causes contained in the NMED cause field. When creating or updating an event record, if the reference document does not contain enough detailed information to select a specific sub-category cause, the overall category is used.

1. Equipment Failure. A condition resulting from the failure, malfunction, or deterioration of equipment, parts, or material.

    1A Defective or Failed Part. Equipment that experienced a general failure including age-related failures.
    1B Design, Manufacturing, or Installation Error. Equipment failure resulting from a defect in design, manufacturing, or installation.
    1C Maintenance Problem. Equipment failure resulting from inadequate or improper maintenance. For example, use of the wrong lubricant, failure to perform preventive maintenance, or incorrect reassembly.
    1D Mechanical Impact. Equipment failure resulting from an impact other than from a vehicle accident.
    1E Equipment Misuse. Equipment failure resulting from the incorrect selection of equipment or from the use of equipment in a fashion other than what it was designed for. For example, the inability to retract a radiography source due to the use of an incompatible guide tube.

2. Procedure Problem. A condition resulting from the lack of a procedure or an inadequate procedure.

    2A Defective or Inadequate Procedure. A procedure that either contains an error or lacks something essential to ensure the successful performance of the activity.
    2B Lack of Procedure. No written procedure was in place to perform the activity.

3. Human Error. A condition resulting from a human error, mistake, or oversight.

    3A Inattention to Detail. Inadequate attention to the specific details of the task. For example, a technician properly followed patient identification procedures but inadvertently selected the wrong syringe and injected the wrong radiopharmaceutical.
    3B Failure to Follow Procedure or Wrong Procedure Used. The failure to use or the inappropriate use of written instructions, procedures, or other documentation. For example, a technician failed to follow patient identification procedures and injected the wrong patient.
    3C Communication Problem. Inadequate presentation or exchange of information. For example, H-3 fire control devices were inadvertently included in a shipment of non-radioactive material because of a lack of communication between the radiation safety officer and the shipping department.
    3D Inadequate Training. Inadequate training (or no training) to enable a person to perform a desired task. For example, a moisture density gauge was lost when it fell from a truck because the technician was not properly trained in the requirements for securing the gauge.
    3E Management Deficiency. Deficient managerial policies, administrative controls, work planning, resource allocation, or supervision. For example, a hospital does not have adequate controls in place to prevent janitorial staff from disposing of radioactive material in the non-radioactive trash.

4. External. A condition resulting from factors that are not under the control of the reporting organization or the suppliers of the failed equipment or service.

   4A Weather or Ambient Condition. Unusual weather or ambient conditions, such as hurricanes, tornadoes, flooding, earthquake, and lightning.
   4B Power Failure or Transient. Power loss attributed to outside supplied power.
   4C External Fire or Explosion. A fire or explosion external to the device in question; not necessarily external to the facility. For example, a fire at a manufacturing facility that damaged a fixed gauge.
   4D Theft, Sabotage, or Vandalism.
   4E Patient Intervention. Actions by a patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.
   4F Patient Provided Inadequate Information. Although not patient intervention, this cause specifically addresses situations where a patient does not provide needed information. For example, a woman that refuses a pregnancy test before a nuclear medical procedure and later discovers that she is pregnant.
   4G Patient Other. This cause refers to medical events that are not caused by patient intervention and are beyond the control of the licensee (not cause 4E or 4F). For example, an intravascular brachytherapy procedure that could not be performed due to a patient's restrictive vasculature.
   4H Vehicle Accident or Device Struck by Vehicle. This cause typically refers to accidents involving vehicles carrying radioactive material and gauges that have been run over by vehicles.
   4I Intentional Violation. The case where an individual is well aware of particular requirements regarding radioactive material and deliberately disregards those requirements, possibly for malevolent purposes.

5. Other. The cause does not fit into any of the above categories. When the Other category is used, a description of the cause shall be provided in the event narrative.

   5A Contaminated or Potentially Contaminated Worker Transported to an Offsite Medical Facility.
   5B Well Logging Source Abandoned Down Hole.
   5C Residential Patient Waste. Radioactive medical waste found in residential trash. In such a case, it is assumed that the waste came from a patient discharged in accordance with applicable regulatory requirements.

6. Not Reported. The cause was not provided or could not be determined.

Appendix C

Single event that identified inadequate training

Event 170294 - A patient was administered 8.55 GBq (231.08 mCi) of Y-90 microspheres for a dose of 54,000 cGy (rad) to the right lobe of the liver, instead of the intended 1.71 GBq (46.22 mCi) for a dose of 11,000 cGy (rad) on 6/14/2017. This event was caused by using the wrong calibration date (6/11/2017 instead of 6/4/2017) when ordering the microspheres, resulting in a much higher activity than intended. The microspheres were surveyed with a dose calibrator prior to administration, but the abnormal results were not questioned. Also, the written directive was not prepared and signed by an authorized user prior to the administration. The patient's lung dose from lung shunting for this treatment was 2,576 cGy (rad), rather than the intended 524 cGy (rad). The prescribing physician discussed the error with the patient. As of March 2018, the patient had no clinically significant symptomatic complications related to this event. This event was caused by inadequate training, inadequate procedures, and human error. An NRC inspection identified programmatic deficiencies that contributed to this event. Corrective actions included personnel training, procedure modification, staff changes, and additional oversight.

Other events that may infer inadequate training

Event 170134 - A patient only received 2,760 cGy (rad) instead of the prescribed 11,000 cGy (rad) during brachytherapy seed implant into the patient's prostate gland on 3/2/2017. The incident involved 90 I-125 seeds with a total activity of 999 MBq (27 mCi). The authorized user placed the seeds from the first three needles and the urologist placed the seeds from the last 21 needles under ultrasound guidance, which showed that the needle placement was correct. However, post CT scans on 3/3/2017 revealed that the seeds from the last 21 needles were placed approximately 1 cm inferior to the intended locations. The seeds did not end up in the rectum or bladder, but in the most inferior aspect of the prostate extending down to the penile bulb. The medical physicist calculated the D90 dose received by the urethra at 2,602 cGy (rad), the rectum at 861 cGy (rad), and the penile bulb at 8,689 cGy (rad). There were no acute effects to the patient or side effects to the areas outside of the treatment site. The cause of the event was human error. Although the needles were placed correctly, the technique used to "drop" the seeds from the needles caused them to miss the treatment site. Corrective actions included restricting the urologist's participation in brachytherapy cases pending additional mentoring and training.

Event 180136 - A patient received less dose than prescribed during Ir-192 high dose rate high dose rate (HDR) skin brachytherapy to the temple area due to an incorrect setup (missing immobilization device). The incident involved a 303.76 GBq (8.2096 Ci) Ir-192 source. The patient was prescribed eight fractions of 500 cGy (rad) each, for a total dose of 4,000 cGy (rad). The patient was treated with the incorrect setup on 3/8 and 3/12/2018 by the same physicist. The patient was then treated with the correct setup on 3/15/2018 by a different physicist. Following the 3/15/2018 treatment, the patient's setup was still on the treatment table when the first physicist noticed the immobilization device in the setup. The patient's next treatment was scheduled for 3/19/2018. The incident was discussed with the physician and the decision was made to perform another CT simulation without the immobilization device prior to the next treatment. The plan was recreated, using the same dwell weights and positions as the original plan. At that point, they discovered that the patient had been underdosed by 65%; the total administered dose after the first two fractions was 350 cGy (rad), rather than the intended 1,000 cGy (rad). The prescribing physician was notified. The direct cause of the incident was failure to properly recreate the initial patient setup. The exclusion of the immobilization device caused the patient's head to be in the wrong position, leaving a gap between the treatment device and the patient's skin. Contributing factors included the lack of a specific policy regarding custom immobilization devices in HDR skin brachytherapy procedures (this was only the second brachytherapy patient using custom immobilization), the pictures from the simulation did not completely show the immobilization device, and it is generally a therapist (not a physicist) who reproduces the daily setup using custom immobilization. At the time of the incident, there was not a verification system in place to track the items needed for each custom setup. Corrective actions included

creating a policy for this type of treatment. The new policy ensures that a therapist will be present at the first treatment and any time a physicist is treating the patient for the first time. In the CT simulation, any custom immobilization used in brachytherapy will be photographed with and without the patient. This will ensure that each piece of the custom immobilization device can be clearly visualized. The IT Department installed a computer monitor, keyboard, and mouse in the HDR treatment vault. A ninth treatment fraction was added to make up for the missing dose in the first two fractions.

Event 180281 - Brachytherapy seeds were incorrectly placed during a prostate implant procedure on 6/14/2018. Prior to the procedure, doctors inserted a Foley catheter into the patient. The catheter balloon was inflated in the prostatic-urethra, instead of the bladder as intended. Using the catheter balloon as a guide, the patient was implanted under ultrasound guidance with 54 Pd-103 seeds that contained a total activity of 4 GBq (108.167 mCi). The ultrasound guidance was compromised because it defaulted to a magnified view of the surrounding area. The patient returned on 6/15/2018 for a CT scan to verify seed placement. The CT scan revealed that 32 of the seeds had been implanted outside of the prostate. In addition, only 51 of the seeds were located. The three missing seeds are believed to have been passed via stool prior to the patient's follow up CT scan. An additional seed is believed to have also been passed as a result of an enema during the follow up exam post CT scan. The patient was prescribed a dose of 12,500 cGy (rad) to the entire prostate gland volume (18.3 cm3), but the treatment only delivered 1,000 cGy (rad) to the prostate volume. The NRC Event Notification stated that the rectal tissue received 18,677 cGy (rad) and that no rectum dose was anticipated. However, a follow-up report stated that the rectum was intended to receive no more than 18,000 cGy (rad). The hospital determined that there is a risk of radiation damage to the rectum and surrounding tissues. The patient and authorized user were notified on the day of discovery and a special investigation was performed by the hospital. The Utah Department of Environmental Quality performed a special onsite inspection. The event was caused by a poorly placed Foley catheter, staff failing to properly locate the Foley catheter, and proper anatomy for guidance within a magnified ultrasound image. The hospital implemented specific training for physicians and other participating staff to prevent recurrence. The ultrasound manufacturer was contacted and the default magnification of the ultrasound unit was changed to a value that allows for initial visualization of the relevant prostate anatomy in its entirety. The hospital also implemented policy changes. Prior to the insertion of the seed needle, using the widest field of view possible, both the sagittal and axial ultrasound images will be obtained to validate Foley catheter placement. Both the authorized user and the medical physicist will audibly concur that image quality is sufficient for proceeding with the implant and the medical physicist will document that in their operative reports or treatment records. After the first seed is implanted in the patient, a fluoroscopic image will be obtained to validate that the relative position of the seed and the Foley catheter are as anticipated.