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United States Nuclear Regulatory Commission
Protecting People and the Environment

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Volume 42

Report to Congress on Abnormal Occurrences

Fiscal Year 2019

Office of Nuclear Regulatory Research

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ABSTRACT

Section 208 of the Energy Reorganization Act of 1974, as amended (Public Law 93-438), defines an abnormal occurrence (AO) as an unscheduled incident or event that the U.S. Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66) changed the AO reporting frequency from quarterly to annually.

This report describes nine events in Agreement States and no events involving NRC licensees that were identified as AOs during fiscal year (FY) 2019. These events are based on the criteria defined in the NRC Policy Statement on "Abnormal Occurrence Reports," issued on October 2, 2017 (82 FR 45907). Seven AOs were medical events as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material." The eighth AO was a human exposure event and the ninth AO involved the theft and recovery of Category 2 sources, as defined in 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." The NRC did not identify any events at commercial nuclear power plants as AOs.

Agreement States are those States that have entered into formal agreements with the NRC, in accordance with Section 274 of the Atomic Energy Act of 1954, as amended (AEA) (Public Law 83-703), to regulate certain quantities of AEA material at facilities within the States' borders. Currently, there are 39 Agreement States.

Appendix A, "Abnormal Occurrence Criteria," to this report presents the NRC's criteria for identifying AOs. The NRC identified one event during FY 2019 that meets the guidelines for inclusion in Appendix B, "Other Events of Interest." The event received significant media coverage due to extensive contamination of personnel and building structures due to the breaching of a sealed cesium-137 source. No events meet the guidelines for inclusion in Appendix C, "Updates of Previously Reported Abnormal Occurrences." Appendix D, "Glossary," defines terms used throughout this report. Appendix E, "Conversion Table," presents conversions commonly used when calculating doses.

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EXECUTIVE SUMMARY

INTRODUCTION

Section 208 of the Energy Reorganization Act of 1974, as amended (Public Law 93-438), defines an "abnormal occurrence" (AO) as an unscheduled incident or event that the U.S. Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66) modified the AO reporting frequency from quarterly to annually.

This report describes events that Agreement States identified as AOs in fiscal year (FY) 2019, based on the criteria defined in the NRC policy statement, "Abnormal Occurrence Reports" (Volume 82 of the Federal Register (FR), page 45907 (82 FR 45907)). Agreement States are those States that have entered into formal agreements with the NRC, in accordance with Section 274 of the Atomic Energy Act of 1954, as amended (AEA) (Public Law 83-703), to regulate certain quantities of AEA material at facilities within the States' borders. The NRC has determined that, of the incidents and events reviewed for this reporting period, only those that are described in this report meet the criteria for reporting as AOs. For each AO, this report documents the date and place, nature and probable consequences, cause or causes, and actions taken to prevent recurrence.

Appendix A, "Abnormal Occurrence Criteria," to this report presents the NRC's criteria for identifying AOs. The NRC identified one event during FY 2019 that met the guidelines for inclusion in Appendix B, "Other Events of Interest." During this reporting period, no events met the guidelines for inclusion in Appendix C, "Updates of Previously Reported Abnormal Occurrences." Appendix D, "Glossary," defines terms used throughout this report. Appendix E, "Conversion Table," presents conversions commonly used when calculating doses.

THE LICENSING AND REGULATORY SYSTEM

The system of licensing and regulation used by the NRC to carry out its responsibilities is implemented through the regulations in Title 10 of the *Code of Federal Regulations*. The NRC regularly conducts licensing reviews, inspections, enforcement, investigations, operating experience evaluations, incident response, and confirmatory research. The agency informs and involves stakeholders and the public to ensure openness and transparency in its regulatory process.

The NRC adheres to the philosophy that multiple levels of protection best ensure public health and safety. The agency achieves and maintains these levels of protection through regulations specifying requirements that ensure the safe use of radioactive materials. Those regulations contain design, operation, and quality assurance criteria appropriate for the various activities regulated by the NRC. Licensing, inspection, investigations, and enforcement programs offer a regulatory framework to ensure compliance with the regulations. In addition, the NRC is striving to make the regulatory system more risk-informed and performance-based, where appropriate. Agreement States conduct regulatory programs that are adequate to protect public health and safety and are compatible with the NRC's program.

REPORTABLE EVENTS

The NRC initially issued the AO criteria in a Commission policy statement published on February 24, 1977 (42 FR 10950), followed by several revisions. The agency published the most recent revision to the AO criteria in the FR on October 2, 2017 (82 FR 45907); the revised criteria became effective on that date. The NRC staff used these criteria to define AOs for this FY 2019 report.

Reviews of and responses to operating experience are essential to ensure that licensees conduct their activities safely. To that end, NRC regulations require licensees to report certain incidents or events to the NRC. Such reporting helps to identify deficiencies and ensure that corrective actions are taken to prevent recurrence.

The NRC and its licensees review and evaluate operating experience to identify safety concerns. The NRC responds to risk-significant issues through licensing reviews, inspections, enforcement, and enhancements to regulations. In addition, the agency maintains operational data in computer-based data files for more effective collection, storage, retrieval, and evaluation of events.

The NRC routinely makes information and records on reportable events at licensed facilities available to the public. The agency also disseminates information through public announcements and special notifications to licensees and other stakeholders. The NRC issues an FR notice describing AOs that occurred in the previous FY at facilities licensed or otherwise regulated by the NRC or Agreement State. In addition, the NRC routinely informs Congress of significant events, including AOs that occur at licensed or regulated facilities.

AGREEMENT STATES

Agreement States are those States that have entered into formal agreements with the NRC, in accordance with Section 274 of the AEA, to regulate certain quantities of AEA material at facilities within the States' borders. Agreement States must maintain programs that are adequate to protect public health and safety and are compatible with the NRC's program for such materials. Currently, there are 39 Agreement States. All Agreement States report event information in accordance with the compatibility criteria the NRC established in its "Agreement State Program Policy Statement" (82 FR 46840; October 6, 2017). The NRC also has procedures for evaluating materials events and identifying those that meet the AO criteria. The NRC uniformly applies the AO criteria (see Appendix A) to events at licensee facilities or activities involving the use of radioactive material regulated by either the NRC or the Agreement State. In 1977, the Commission determined that the annual report to Congress should also include events that meet the criteria for AOs at licensees regulated by the Agreement State. The FR notice that the NRC issues to disseminate AO-related information to the public includes these events as well.

INTERNATIONAL INFORMATION

The NRC exchanges information with various foreign governments that regulate nuclear facilities and materials. The agency reviews and considers this international information in its research and regulatory activities, as well as in its assessment of operating experience.

Although the NRC may occasionally refer to such information in its AO reports to Congress, the agency reports only domestic AOs.

OTHER EVENTS OF INTEREST

The NRC offers information about events that do not meet the criteria for AOs but are of interest based on the criteria in Appendix B to this report. The NRC identified one event that occurred during FY 2019 that met these criteria.

UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

Appendix C typically includes updates on previously reported AOs that remain open during the fiscal year addressed in the report or for which significant new information becomes available. However, there are no such updates for this reporting period.

ABBREVIATIONS

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
AO	abnormal occurrence
AU	authorized user
CFR	*Code of Federal Regulations*
Ci	curie(s)
CNMT	certified nuclear medicine technologist
CT	computerized tomography
DOE	U.S. Department of Energy
FR	*Federal Register*
FY	fiscal year
GBq	gigabecquerel(s)
Gy	gray(s)
HEPA	high-efficiency particulate air
I	iodine
IN	information notice
MBq	megabecquerel(s)
mCi	millicurie(s)
MD	management directive
mrem	millirem
mSv	millisievert(s)
NRC	U.S. Nuclear Regulatory Commission
Pd	palladium
Rb	rubidium
Sr	strontium
Sv	sievert(s)
TBq	terabecquerel(s)
TEDE	total effective dose equivalent
Y	yttrium

ABNORMAL OCCURRENCES IN FISCAL YEAR 2019

Appendix A, "Abnormal Occurrence Criteria," supplies the specific criteria for determining whether an event is an abnormal occurrence (AO). Appendix A contains criteria for three major categories:

I. All Licensees
II. Commercial Nuclear Power Plant Licensees
III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events

This section of the report includes only the specific events in Categories I, II, and III for which an AO was reported. The identification number for the events, which were all reported by Agreement State(s) start with "AS."

I. ALL LICENSEES

During this reporting period, two events were identified as AOs based on Criterion I, "All Licensees," in Appendix A.

AS19-01 Human Exposure Event at NRD-Advanced Static Control, Grand Island, New York

Criterion I.A.1(b) of Appendix A to this report provides, in part, that a human exposure event shall be considered for reporting as an AO if any unintended radiation exposure to an adult (any individual 18 years of age or older) resulted in an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ other than the lens of the eye, the bone marrow, and the gonads of 2,500 millisieverts (mSv) (250 rem) or more.

Date and Place — April 1, 2019, Grand Island, NY

Nature and Probable Consequences—On April 1, 2019, NRD-Advanced Static Control reported an internal radiation overexposure to one employee that meets this criterion. The employee attempted to clean up a small area of rust in a nonradioactive area of the licensee's facilities. The employee inappropriately used a high-efficiency particulate air (HEPA) vacuum from a different area of the facility that had previously been used to clean up americium-241 metal. When the employee turned it on, the vacuum blew out debris and the area radiation alarms activated, indicating that the discharged debris was radioactive. The employee immediately turned off the vacuum and shut the doors to the area. The radiation safety officer (RSO) was then notified. The RSO sealed the location to prevent further entry. The RSO determined that the employee was in the contaminated area for approximately 20 minutes. The RSO contacted the Department of Energy's (DOE) Oak Ridge Radiation Emergency Assistance Center/Training Site and bioassay samples were collected and sent out for processing. The results showed that the employee received 2,990 mSv (299 rem) to the maximally exposed organ (bone). The licensee is following the health of the employee and does not anticipate any adverse health effects from this incident.

Cause(s) — The primary root cause was determined to be failures related to a HEPA vacuum. Additional factors contributing to this event were the improper use of a HEPA vacuum in an area for which it was not designed, inadequate procedures, and poor emergency training.

Actions Taken To Prevent Recurrence

Licensee — The licensee revised its radiation protection procedures to prohibit the use of potentially contaminated equipment in areas where contamination is not expected and to clearly define the procedures to follow during an emergency. After the revisions to the procedures were complete, the licensee staff received training on the revisions.

State — The New York Department of Health, Bureau of Environmental Radiation Protection, conducted an onsite reactive inspection of the licensee. Based on the inspection, the State identified several violations. The State will review the licensee's corrective actions during the next inspection.

This event is closed for the purpose of this report.

AS19-02 Stolen Industrial Radiography Cameras from Western Technologies, Inc., Phoenix, Arizona

Criterion I.C.1, of Appendix A to this report provides, in part, that any stolen, diverted, abandoned, or unrecovered lost radioactive material that meets or exceeds the thresholds listed in Appendix A, "Category 1 and Category 2 Radioactive Materials," to 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," shall be considered for reporting as an AO.

Date and Place — April 28, 2019, Phoenix, AZ

Nature and Probable Consequences — On April 28, 2019, Western Technologies, Inc. reported the theft and recovery of three industrial radiography cameras, each containing an activity that exceeded the threshold for a Category 2 quantity of radioactive material. An employee, who had been authorized for unescorted access to radioactive material, stole three industrial radiography cameras from the licensee's secure storage area after normal working hours. Law enforcement was notified, and the cameras were recovered and returned to secure storage on the day of the theft.

Cause(s) — This event remains under law enforcement investigation.

Actions Taken To Prevent Recurrence

Licensee — The licensee upgraded its access security measures for after normal business hours to prevent a single individual with unescorted access from removing Category 2 quantities of radioactive materials.

NRC — The NRC is monitoring the progress of the licensee's response to this event.

State – The Arizona Agreement State regulator is monitoring the licensee's response to this event.

This event is closed for the purpose of this report.

II. COMMERCIAL NUCLEAR POWER PLANT LICENSEES

During this reporting period, no events at commercial nuclear power plants in the United States met the criteria for AOs described in Appendix A.

III. EVENTS AT FACILITIES OTHER THAN NUCLEAR POWER PLANTS AND ALL TRANSPORTATION EVENTS

During this reporting period, seven events at Agreement State licensee facilities were identified as AOs based on Appendix A, Criterion III, "Events at Facilities Other Than Nuclear Power Plants and All Transportation Events."

AS19-03 Medical Events at Swedish Medical Center, Englewood, Colorado

Criteria III.C.1(a) and III.C.2(b)(iii) of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose that is equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow and is a prescribed dose or dosage that was delivered to the wrong treatment site.

Date and Place — December 15, 2018, Englewood, CO

Nature and Probable Consequences — Swedish Medical Center reported that a rubidium-82 (Rb-82) generator was flushed with the incorrect saline solution, resulting in levels of strontium (Sr)-82 and Sr-85 in the eluate (solution) that exceeded manufacturer-specified limits. Although the licensee performed the required breakthrough tests, it failed to identify the increased Sr breakthrough amount and used the doses in patient procedures. Eight patients were affected, with calculated doses to the red bone marrow ranging from 1.007 to 2.569 Gy (100.7 to 256.9 rad). The licensee's primary concern for the patients was the development of bone marrow suppression, which can result in anemia, nausea, and vomiting in the near-term and a decrease in blood cell counts during the first 6 weeks after exposure. The licensee followed the patients for 10 weeks after the event; the medical director of hematology/oncology evaluated the patients routinely. Based on clinical results and observations, the licensee reported that the patients did not exhibit signs of bone marrow suppression.

Cause(s) — The primary root cause of the event was a programmatic failure to properly interpret the results of the Sr breakthrough test. The secondary root cause of the event was the use of the improper saline solution when flushing the Rb-82 generator. This type of saline solution should not be used with these generators because it will cause increased levels of Sr breakthrough.

Actions Taken To Prevent Recurrence

Licensee — To address the primary root cause, the licensee ceased use of this model of Rb-82 generator once the event was identified until retraining could take place. The licensee performed retraining on quality control procedures, including how to properly interpret results from the dose calibrator. The licensee also performed retraining on how to conduct the breakthrough tests for Rb-82 generators. The licensee submitted a license amendment request to replace the currently authorized Rb-82 generator with a different product. The licensee determined that the automated quality control steps of the alternate product may help prevent

recurrence of the event. To address the secondary root cause, the licensee performed retraining on the use of the proper saline, including the ordering and verification of the correct saline solution before administration to patients.

State — The Colorado Department of Public Health and Environment investigated the event. The State has received the licensee's corrective actions and will review them during the next inspection.

NRC — On December 23, 2019, the NRC issued Information Notice (IN) 2019-11, "Strontium-82/Rubidium-82 Generator Elution Events and Issues." (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19281A220). The purpose of IN 2019-11 was to communicate operating experience and to inform other medical licensees of the potential for significant Sr breakthrough if the incorrect saline solution is used.

This event is closed for the purpose of this report.

AS19-04 Medical Event at Midwestern Regional Medical Center, Zion, Illinois

Criteria III.C.1(b) and III.C.2(b)(iii) of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose that exceeds, by 10 Gray (Gy) (1,000 rad), the expected dose to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) from the administration defined in the written directive and is a prescribed dose or dosage that was delivered to the wrong treatment site.

Date and Place — February 1, 2019, Zion, IL

Nature and Probable Consequences — On February 1, 2019, Midwestern Regional Medical Center reported that a patient undergoing treatment for liver cancer with yttrium-90 (Y-90) microspheres received a dose that was at least 10 Gy (1,000 rad) more than expected to the wrong treatment site. The written directive prescribed 779.2 megabecquerels (MBq) (21.06 millicuries (mCi)) of Y-90 microspheres to the liver. After the treatment, a single photon emission computerized tomography (CT) scan revealed that 259 MBq (7 mCi) of Y-90 microspheres were delivered to the spleen, the wrong treatment site. The licensee determined that the spleen received a dose of 106.5 Gy (10,650 rad). The dose to the spleen should have been minimal. The licensee notified the referring physician and patient of the event, and the licensee reported that no adverse health effects are expected from the additional dose.

Cause(s) — During administration of the treatment, the licensee's authorized user (AU) began to feel pressure in the syringe. The AU switched to a smaller gauge syringe but that did not make a difference, so the treatment was aborted. The root cause is believed to be clumping at the tip of the microcatheter, which was then released into the bloodstream because of the pressure within the tubing as the microcatheter was retracted. Correct placement of the microcatheter in the right lobe of the patient's liver was verified before administration and no issues were found with the delivery system and the three-way valve. Post treatment, the licensee did not locate any physical obstruction in the delivery tubing.

Actions Taken To Prevent Recurrence

Licensee — The licensee conducted an in-depth review of the medical event and found no apparent cause aside from clumping at the tip of the microcatheter. The licensee implemented changes to its procedures to include "pulsing" of the dose to further ensure adequate agitation to separate the Y-90 microspheres and prevent clumping, paying attention to uniform aliquot size, and returning to the use of a previously employed microcatheter system.

State — The Illinois Emergency Management Agency performed a reactive inspection on February 5, 2019. A review of the incident did not provide any evidence of departures from regulations, the manufacturer's recommendations, or the licensee procedures. The State considers the licensee's corrective actions to be adequate.

NRC — On December 31, 2019, the NRC issued IN 2019-12, “Recent Report Medical Events Involving the Administration of Yttrium-90 Microspheres for Therapeutic Medical Procedures” (ADAMS Accession No. ML19262G231) to communicate operating experience and to inform other medical licensees of recently reported medical events involving the administration of Y-90 microspheres.

This event is closed for the purpose of this report.

AS19-05 Medical Event at Albert Einstein Healthcare, Philadelphia, Pennsylvania

Criteria III.C.1(b) and III.C.2(b)(iii) of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose that exceeds, by 10 Gy (1,000 rad), the expected dose to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) from the administration defined in the written directive and is a prescribed dose or dosage that was delivered to the wrong treatment site.

Date and Place — February 13, 2019, Philadelphia, PA

Nature and Probable Consequences — On February 13, 2019, Albert Einstein Healthcare reported that a patient undergoing treatment for liver cancer with Y-90 microspheres received a dose that was at least 10 Gy (1,000 rad) more than expected to the wrong treatment site. The written directive prescribed 1.16 gigabecquerel (GBq) (31.3 mCi) to the right lobe of the liver for metastatic colorectal cancer. After treatment, a single photon emission CT scan revealed that 392 MBq (10.6 mCi) and 38.9 MBq (1.05 mCi) of Y-90 microspheres were delivered to the wrong treatment sites: the stomach and left lobe of the liver, respectively. The licensee determined that the stomach received a dose of 91.9 Gy (9,190 rad) and the left lobe received a dose of 21.7 Gy (2,170 rad). The dose to the stomach and left lobe of the liver should have been minimal. The referring physician and patient were notified of the event. The patient was given preventive treatment to avert ulcers and gastritis that could potentially result from the additional dose. Following these precautions, the licensee reported that no adverse health effects are anticipated.

Cause(s) — The cause was determined to be undetected movement of the catheter tip from the intended location in the right hepatic artery to the left hepatic artery. This may have been caused by movement of the patient and possibly exacerbated by reduced slack in the catheter after pulling it back to correct its initial position.

Actions Taken To Prevent Recurrence

Licensee — The licensee committed to having the instructing physician complete refresher training before the first proctored case for each type of microsphere, the physician who performs the arterial mapping also perform the treatment, and creating and implementing a checklist for the treatment room that includes a step requiring the physician to look for vessels that may cause stomach shunting (or shifting) to occur.

State — The Pennsylvania Department of Environmental Protection performed reactive inspections on February 28 and March 7, 2019. The State considers the licensee's corrective actions to be adequate.

NRC — On December 31, 2019, the NRC issued IN 2019-12 to communicate operating experience and to inform other medical licensees of recently reported medical events involving the administration of Y-90 microspheres.

This event is closed for the purpose of this report.

AS19-06 Medical Event at Holmes Regional Medical Center, Melbourne, Florida

Criteria III.C.1(b) and III.C.2(a) of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose that exceeds, by 10 Gy (1,000 rad), the expected dose to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) from the administration defined in the written directive and represents a dose or dosage that is at least 50 percent greater than that prescribed.

Date and Place — June 11, 2019, Melbourne, FL

Nature and Probable Consequences — On June 11, 2019, Holmes Regional Medical Center reported that a patient undergoing treatment for liver cancer with Y-90 microspheres received a dose that was at least 10 Gy (1,000 rad) more than expected and was at least 50 percent greater than the prescribed dose. The written directive prescribed a dose of 120 Gy (12,000 rad) to the right lobe of the liver. After the treatment, the licensee determined that the patient was administered a dose of 698 Gy (69,800 rad) to the right lobe of the liver. The referring physician and patient were notified of the event. The licensee reported that no adverse health effects are anticipated from the additional dose but will follow the patient closely.

Causes — The licensee determined that the cause was the staff's failure to properly assay and reconcile the dose on two different occasions—once before the start of the procedure and a second time a few hours later when the dose was ready for administration. A time-out was performed when the staff entered the interventional laboratory with the dose; however, the administering radiologist did not confirm the dose before administration. The licensee's process was to use a patient identifier when ordering the dose and when verifying receipt of the dose to administer. However, the licensee determined that the staff was not aware of this process and did not verify that this patient identifier matched the patient undergoing treatment when assaying the dose.

Actions Taken To Prevent Recurrence

Licensee — The licensee changed its procedures, instituting and providing documented training for the following: a formal time-out in the interventional laboratory to reconcile the prescribed dose with the assayed dose, and a peer process for assaying doses that requires two nuclear medicine technologists to independently assay and sign off on the measured activity.

State — The Florida Bureau of Radiation Control performed a reactive inspection on July 1, 2019. The State considers the licensee's corrective actions to be adequate to prevent a recurrence of a similar medical event.

NRC — On December 31, 2019, the NRC issued IN 2019-12 to communicate operating experience and to inform other medical licensees of recently reported medical events involving the administration of Y-90 microspheres.

This event is closed for the purpose of this report.

AS19-07 Medical Event at Physicians Surgical Center of Fort Worth, Fort Worth, Texas

Criteria III.C.1(b) and III.C.2(b)(iii) of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose that exceeds, by 10 Gy (1,000 rad), the expected dose to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) from the administration defined in the written directive and is a prescribed dose or dosage that was delivered to the wrong treatment site.

Date and Place — August 1, 2019, Fort Worth, TX

Nature and Probable Consequences — On August 1, 2019, Physicians Surgical Center reported that a patient undergoing treatment for prostate cancer with palladium (Pd)-103 brachytherapy seeds received a dose that was at least 10 Gy (1,000 rad) more than expected to the wrong treatment site. The written directive prescribed 100 Gy (10,000 rad) to be administered to the prostate using 52 Pd-103 seeds with 47.8 MBq (1.29 mCi each) or 2.49 GBq (67.2 mCi) total. Instead, the licensee determined post-treatment that all 52 of the Pd-103 seeds were placed 4 centimeters short of the prostate, resulting in 2.49 GBq (67.2 mCi) going to the penile bulb. The dose to the penile bulb should have been minimal; however, the estimated dose was 73 Gy (7,300 rad). The estimated dose to the prostate was minimal. The patient and the referring physician were both informed of the event. The licensee believes that no adverse effects are expected from the misplaced seeds.

Cause(s) — The physician performing the implanting procedure used ultrasound imaging to locate the prostate and misidentified the penile bulb as the prostate. The licensee believes this occurred because the penile bulb was very similar in size to the prostate (10.8 cubic centimeters versus 12 cubic centimeters for the prostate) and they were very close to each other.

Actions Taken To Prevent Recurrence

Licensee — The licensee's medical physicist, radiation oncologist, and the nurse assistant involved in the event have reviewed their imaging planning and implantation process. These individuals received additional instruction about the need to confirm that the probe is in the appropriate treatment site before the first needle insertion.

State — The Texas Department of State Health Services investigated and determined that the licensee's corrective actions are adequate.

This item is closed for the purpose of this report.

AS19-08 Medical Event at Duke University Medical Center, Durham, North Carolina

Criteria III.C.1(b) and III.C.2(a) of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose that exceeds, by 10 Gy (1,000 rad), the expected dose to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) from the administration defined in the written directive and represents a dose or dosage that is at least 50 percent greater than that prescribed.

Date and Place — September 16, 2019, Durham, NC

Nature and Probable Consequences — On September 16, 2019, Duke University Medical Center reported that a patient undergoing Y-90 microsphere brachytherapy for liver volume ablation received an overdose to one of the two intended treatment sites. Specifically, a segment of the right lobe of the liver was prescribed to receive 43.2 mCi for a total dose of 251 Gy (25,100 rad). Instead, this segment received 3.32 GBq (89.6 mCi) for a total dose of 562 Gy (56,200 rad). The patient and the referring physician were both informed of the event. The licensee reports that no adverse health effects are anticipated because of very low pulmonary and gastrointestinal shunting and the small volume of the liver treated compared to the volume of untreated liver.

Causes — The primary cause for this event was determined to be human error. Specifically, the licensee's AU failed to properly follow the licensee's procedures for administering this type of therapeutic treatment. The AU stated that it was not evident during the final time-out procedure that the dosage was twice the prescribed amount and intended for another patient being treated later. Additionally, the licensee determined that the practice of using a single transport box from the radiopharmacy to the Interventional Radiology suite for multiple patient Y-90 microsphere doses was a contributing factor.

Actions Taken To Prevent Recurrence

Licensee — The licensee conducted an internal review of the event on September 18, 2019, and the AU was retrained on appropriate medication handoff and administration procedures. The licensee also identified other process-related factors that could be improved to reduce the probability of a recurrence. Such measures included, but are not limited to, (1) clearly indicating on the written directive that the dosage is part of a multi-segment treatment, (2) using a separate box to transport the dose(s) for each patient, (3) conducting person-to-person handoffs of transport boxes and dosages at key transfer points, (4) reviewing all forms used in the treatment process to identify opportunities to improve clarity and ease of use, and (5) considering incorporating the written directive process for Y-90 microsphere treatments into the institutional electronic system used for protocoling and delivering other drug treatments.

State — The North Carolina Radioactive Materials Branch conducted an onsite reactive investigation for this event. The State has received the licensee's corrective actions and will review them during the next inspection.

NRC — On December 31, 2019, the NRC issued IN 2019-12 to communicate operating experience and to inform other medical licensees of recently reported medical events involving the administration of Y-90 microspheres.

This event is closed for the purpose of this report.

AS19-09 Medical Event at Vanderbilt University Medical Center, Nashville, Tennessee

Criteria III.C.1(b) and III.C.2(a) of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose that exceeds, by 10 Gy (1,000 rad), the expected dose to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) from the administration defined in the written directive and represents a dose or dosage that is at least 50 percent greater than that prescribed.

Date and Place — July 16, 2019, Nashville, TN

Nature and Probable Consequences — On July 16, 2019, Vanderbilt University Medical Center reported that a patient undergoing treatment with iodine-131 (I-131) for thyroid cancer received a dose that was at least 10 Gy (1,000 rad) more than expected and at least 50 percent greater than that prescribed. The written directive prescribed 0.518 GBq (14 mCi) of I-131 to deliver a thyroid dose of 400 Gy (40,000 rad). Post treatment, the licensee determined that the patient was administered 1.221 GBq (33 mCi), resulting in a thyroid dose of 965 Gy (96,500 rad). The patient and the referring physician were both informed of the event. The licensee reports that no adverse health effects are anticipated for the patient.

Cause(s) — The licensee determined that the root cause for this event was human error. The licensee's certified nuclear medicine technologist (CNMT) did not follow procedures and thus did not verify that the correct dose was being given to the patient. The CNMT performed a time-out procedure, which included reviewing the written directive, verifying it with the attending physician, and having the CNMTs perform a dose assay on the 0.518 GBq (14 mCi) NaI therapy capsule. After performing adequate patient identification procedures, the CNMT went to the nuclear medicine laboratory and collected a 1.2 GBq (33 mCi) therapy capsule instead of the 0.518 GBq (14 mCi) capsule. The CNMT did not look at the label to ensure it was for the intended patient and administered the 1.2 GBq (33 mCi) capsule.

Actions Taken To Prevent Recurrence

Licensee — All CNMTs have been retrained on the importance of following established policies and procedures for administration of therapeutic radiopharmaceuticals, including checking the label to ensure that the medication is for the correct patient. The CNMTs are now required to use a workstation on wheels to confirm the dose again before administration. In addition, all therapeutic radiopharmaceuticals will be stored in the licensee's radiopharmacy until the patient is present and the staff is ready to conduct the time-out. Multiple therapy doses will not be stored in the nuclear medicine laboratory.

State — The State of Tennessee performed a reactive inspection on July 24, 2019. The State considers the licensee's corrective actions to be adequate.

This event is closed for the purpose of this report.

APPENDIX A
ABNORMAL OCCURRENCE CRITERIA

ABNORMAL OCCURRENCE GENERAL STATEMENT OF POLICY

The Commission will apply the following policy in determining whether an incident or event at a facility or involving an activity that is licensed or otherwise regulated by the Commission or an Agreement State is an abnormal occurrence (AO).[1]

An incident or event is considered an AO if it involves a major reduction in the protection of public health or safety. The incident or event has a moderate or severe impact on public health or safety and could include, but need not be limited to, the following:

(1) Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission or Agreement State;

(2) Major degradation of essential safety-related equipment;

(3) Major deficiencies in design, construction, use of, or management controls for, facilities or radioactive material licensed by or otherwise regulated by the Commission or Agreement State; or

(4) Substantiated case of actual loss, theft, or diversion of risk-significant radioactive material licensed by or otherwise regulated by the Commission or Agreement State.

The NRC identified the following criteria for determining an AO and the guidelines for "other events of interest" in a policy statement published in the *Federal Register* on October 2, 2017 (82 FR 45907).

Abnormal Occurrence Criteria

The following presents the criteria, by types of events, used to determine which events will be considered for reporting as AOs.

I. All Licensees[2]

A. Human Exposure to Radiation from Licensed Material

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[1] Events reported to the NRC by Agreement States that reach the threshold for reporting as AOs will be reported as such by the Commission.

[2] Medical patients and human research subjects are excluded from consideration under these criteria, and these criteria do not apply to medical events defined in § 35.3045 of Title 10 of the Code of *Federal Regulations* (10 CFR), "Report and notification of a medical event," which are considered in AO Criteria III.C.

1. Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in:

    a. An annual total effective dose equivalent (TEDE) of 250 millisieverts (mSv) (25 rem) or more;

    b. An annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ other than the lens of the eye, the bone marrow, and the gonads of 2,500 mSv (250 rem) or more;

    c. An annual dose equivalent to the lens of the eye of 1 Sievert (Sv) (100 rem) or more;

    d. An annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow of 1 Sv (100 rem) or more;

    e. A committed dose equivalent to the gonads of 2,500 mSv (250 rem) or more; or

    f. An annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more.

2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.

3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by an independent physician[3] deemed qualified by the NRC or Agreement State.

B. Discharge or Dispersal of Radioactive Material from Its Intended Place of Confinement

The release of radioactive material to an unrestricted area in concentrations that, if averaged over a period of 24 hours, exceed 5,000 times the values specified in Table 2 of Appendix B, “Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage,” to 10 CFR part 20, “Standards for protection against radiation,” unless the licensee has demonstrated compliance with § 20.1301, “Dose limits for individual members of the public,” using § 20.1302(b)(1) or § 20.1302(b)(2)(ii). This criterion does not apply to transportation events.

[3] “Independent physician” is defined as a physician not on the licensee's staff and who was not involved in the care of the patient involved.

C. Theft, Diversion, or Loss of Licensed Material; Sabotage; or Security Breach[4, 5, 6]

1. Any stolen, diverted, abandoned, or unrecovered lost radioactive material that meets or exceeds the thresholds listed in Appendix A, "Category 1 and Category 2 Radioactive Materials," to 10 CFR part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Excluded from reporting under this criterion are those events involving sources that are lost or abandoned under the following conditions: sources that have been lost and for which a reasonable attempt at recovery has been made without success, or irretrievable well logging sources as defined in § 39.2, "Definitions." These sources are only excluded if there is reasonable assurance that the doses from these sources have not exceeded, and will not exceed, the reporting thresholds specified in AO Criteria I.A.1 and I.A.2 and the agency has determined that the risk of theft or diversion is acceptably low.

2. An act that results in radiological sabotage as defined in § 73.2.

3. Any substantiated[7] case of actual theft, diversion, or loss of a formula quantity of special nuclear material,[8] or an inventory discrepancy of a formula quantity of special nuclear material that is judged to be caused by theft or diversion.

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[4] Information pertaining to certain incidents may either be classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Executive Order 13526, "Classified National Security Information," as amended (75 FR 707; January 5, 2010), or any predecessor or successor order to require protection against unauthorized disclosures. Any classified details about these incidents would be available to Congress upon request, under appropriate security arrangements.

[5] Information pertaining to certain incidents may be Safeguards Information as defined in § 73.2 because of safety and security implications. The AO report would withhold specific Safeguards Information in accordance with Section 147 of the Atomic Energy Act of 1954, as amended. Any safeguards details regarding these incidents would be available to Congress upon request, under appropriate security arrangements.

[6] Reporting lost or stolen material is based on the activity of the source at the time the radioactive material was known to be lost or stolen. If, by the time the AO report is due to Congress, the radioactive material has decayed below the thresholds listed in Appendix A to 10 CFR part 37, the report will clarify that the radioactive material has decayed below the thresholds.

[7] "Substantiated" means a situation in which there is an indication of loss, theft, or unlawful diversion, such as an allegation of diversion, report of lost or stolen material, or other indication of loss of material control or accountability that cannot be refuted following an investigation, and requires further action on the part of the agency or other proper authorities.

[8] "Formula quantity of special nuclear material" is defined in § 70.4, "Definitions."

4. Any substantial breakdown[9] of physical security, cyber security, or material control and accountability programs that significantly weakens the protection against loss, theft, diversion, or sabotage.

5. Any significant unauthorized disclosures (loss, theft, and/or deliberate disclosure) of classified information that harms national security or of Safeguards Information that threatens public health or safety.

D. Initiation of High-Level NRC Team Inspection[10]

II. Commercial Nuclear Power Plant Licensees

A. Malfunction of Facility, Structures, or Equipment

1. Exceeding a safety limit of a license technical specification (TS) (§ § 50.36(c)).

2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials that could result in exceeding the dose limits of 10 CFR part 100, "Reactor site criteria," or five times the dose limits of General Design Criteria (GDC) 19, "Control Room," in Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR part 50, "Domestic licensing of production and utilization facilities," could occur from a postulated transient or accident (*e.g.,* loss of emergency core cooling system, loss of control rod system).

B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy

1. Discovery of a major condition not specifically considered in the safety analysis report or TS that requires immediate remedial action.

2. Personnel error or procedural deficiencies that result in the loss of plant capability to perform essential safety functions such that a release of radioactive materials exceeding the dose limits of 10 CFR part 100 or five times the dose limits of GDC 19 in Appendix A to 10 CFR part 50, could

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[9] A substantial breakdown is defined as a red finding under the Reactor Oversight Process (ROP) in the physical security inspection program or any plant or facility determined to have overall unacceptable performance.

[10] This item addresses the initiation of any incident investigation teams, as described in NRC Management Directive (MD) 8.3, "NRC Incident Investigation Program" (ADAMS Accession No. ML13175A294), or initiation of any accident review groups, as described in MD 8.9, "Accident Investigation" (ADAMS Accession No. ML13319A133).

occur from a postulated transient or accident (*e.g.,* loss of emergency core cooling system, loss of control rod drive mechanism).

C. Any operating reactor events or conditions evaluated by the NRC ROP to be the result of or associated with licensee performance issues of high safety significance.[11]

D. Any operating reactor events or conditions evaluated by the NRC Accident Sequence Precursor (ASP) program to have a conditional core damage probability (CCDP) or change in core damage probability (ΔCDP) of greater than or equal to 1×10^{-3}.[12]

E. Any operating reactor plants that are determined to have overall unacceptable performance or are in a shutdown condition as a result of significant performance problems and/or operational event(s).[13]

III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events

A. Events Involving Design, Analysis, Construction, Testing, Operation, Transport, Use, or Disposal

1. An accidental criticality.

2. A major deficiency in design, construction, control, or operation having significant safety implications that require immediate remedial action.

3. A serious safety-significant deficiency in management or procedural controls.

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[11] The NRC ROP uses four colors to describe the safety significance of licensee performance. As defined in NRC MD 8.13, "Reactor Oversight Process" (ADAMS Accession No. ML17347B670), green is used for very low safety significance, white is used for low to moderate safety significance, yellow is used for substantial safety significance, and red is used for high safety significance. Reactor conditions or performance indicators evaluated to be red are considered AOs.

[12] Results from the NRC ASP program are used to monitor agency performance against the agency's strategic safety goal (e.g., ensure the safe use of radioactive materials) and objectives (e.g., prevent and mitigate accidents and ensure radiation safety). A precursor event with a CCDP or ΔCDP of greater than or equal to 1×10^{-3} is used as a performance indicator for the strategic safety goal by determining that there have been no significant precursors of a nuclear reactor accident and that there have been no more than one significant adverse trend in industry safety performance.

[13] Any plants assessed by the ROP to be in the unacceptable performance column, as described in NRC Inspection Manual Chapter (IMC) 0305, "Operating Reactor Assessment Program" (ADAMS Accession No. ML19256A191), or under NRC IMC 0350, "Oversight of Reactor Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns" (ADAMS Accession No. ML17116A273). This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

4. A series of events (in which the individual events are not of major importance), recurring incidents, or incidents with implications for similar facilities (generic incidents) that raise a major safety concern.

B. Fuel Cycle Facilities[14]

1. Absence or failure of all safety controls (engineered and human) such that conditions were present for the occurrence of a high-consequence event involving an NRC-regulated hazard (radiological or chemical).[15]

2. An NRC-ordered safety-related or security-related immediate remedial action.

C. Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects[16]

1. A medical event, as defined in § 35.3045, which results in a dose that:

a. Is equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal to or greater than 2.5 Gy (250 rad) to the gonads; or

b. Exceeds, by 10 Gy (1,000 rad), the expected dose to any other organ or tissue from the administration defined in the written directive; and

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[14] Criterion III.A also applies to fuel cycle facilities.

[15] High-consequence events for facilities licensed under 10 CFR part 70, "Domestic licensing of special nuclear material," are those that could seriously harm the worker or a member of the public in accordance with § 70.61, "Performance requirements." The integrated safety analysis conducted and maintained by the licensee or applicant of 10 CFR part 70 fuel cycle facilities identifies such hazards and the safety controls (§ 70.62(c)) applied to meet the performance requirements in accordance with § 70.61(b) through (d).

Fuel cycle facilities licensed under 10 CFR part 40, "Domestic licensing of source material," or certified under 10 CFR part 76, "Certification of gaseous diffusion plants," have licensing basis documents that describe facility specific hazards, consequences, and those controls used to prevent or mitigate the consequences of such accidents. For these facilities, a high-consequence event would be a release that has the potential to cause acute radiological or chemical exposures to a worker or a member of the public similar to that defined in Appendix A to Chapter 3, Section A.2, of NUREG 1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications—Final Report," issued June 2015, under "Consequence Category 3 (High Consequences)" (ADAMS Accession No. ML15176A258).

[16] Criteria III.A.2, III.A.3, and III.A.4 also apply to medical licensees.

2. A medical event, as defined in § 35.3045, which involves:

   a. A dose or dosage that is at least 50 percent greater than that prescribed, or

   b. A prescribed dose or dosage that:

      (i) Uses the wrong radiopharmaceutical or unsealed byproduct material; or

      (ii) Is delivered by the wrong route of administration; or

      (iii) Is delivered to the wrong treatment site; or

      (iv) Is delivered by the wrong treatment mode; or

      (v) Is from a leaking source or sources; or

      (vi) Is delivered to the wrong individual or human research subject.

APPENDIX B
OTHER EVENTS OF INTEREST

This appendix discusses other events of interest that do not meet the criteria for abnormal occurrences (AOs) in Appendix A to this report. The Commission may determine that events other than AOs may be of interest to Congress and the public and should be included in an appendix to the AO report as "Other Events of Interest." Such events may include, but are not necessarily limited to, events that do not meet the AO criteria but that have been perceived by Congress or the public to be of high health or safety significance, have received significant media coverage, or have caused the U.S. Nuclear Regulatory Commission (NRC) to increase its attention to or oversight of a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.

OEI 19-01 Washington Harborview Contamination Event

Date and Place — May 2, 2019, Seattle, WA

On May 2, 2019, International Isotopes Inc. (INIS), a subcontractor to Triad National Security (Management and Operations contractor for Los Alamos National Laboratory) inadvertently breached a sealed cesium-137 source at the University of Washington, Harborview Medical Center, Research and Training Building in downtown Seattle. INIS is an NRC licensee that was working in the State of Washington, an Agreement State, under reciprocity. INIS was attempting to recover the source for the Department of Energy National Nuclear Security Administration (DOE/NNSA) Off-Site Source Recovery Program. The source breach resulted in contamination of personnel and the building, and a release of material to the environment. The licensee determined from subsequent bioassay procedures that seven individuals received internal radiation exposure from the event. The licensee estimated that the highest internal dose to one of the individuals was 0.7 mSv (70 mrem) and all doses were below regulatory limits. No health effects are expected.

NRC, DOE/NNSA, and the State of Washington coordinated on identifying causes and lessons learned from the event. Cleanup efforts are underway and will result in eliminating the contamination and releasing the facility for use.

APPENDIX C
UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During this reporting period, there were no updates to previously reported abnormal occurrences.

APPENDIX D
GLOSSARY

Ablation[1]—removal or excision. Ablation is usually carried out surgically. For example, surgical removal of the thyroid gland (a total thyroidectomy) is ablation of the thyroid.

Act—the Atomic Energy Act of 1954 (Public Law 83-703), including any amendments.

Authorized user—as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) 35.2, "Definitions," a physician, dentist, or podiatrist who (1) meets the requirements in 10 CFR 35.59, "Recentness of Training," and 10 CFR 35.190(a), 10 CFR 35.290(a), 10 CFR 35.390(a), 10 CFR 35.392(a), 10 CFR 35.394(a), 10 CFR 35.490(a), 10 CFR 35.590(a), or 10 CFR 35.690(a), or (2) is identified as an authorized user on (i) a Commission or Agreement State license that authorizes the medical use of byproduct material, (ii) a permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material, (iii) a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material, or (iv) a permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

Bioassay[1]—determination of kinds, quantities, or concentrations and, in some cases, locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed (in vitro) from the human body.

Brachytherapy—as defined in 10 CFR 35.2, a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

Brachytherapy seed implantation for prostate cancer[1]—Radioactive seed implants are a form of radiation therapy for prostate cancer. The radioactive seeds are loaded into the designated number of needles in a specific order, and each needle is inserted through the skin in the perineum and into the prostate using continuous ultrasound guidance. Once accurate needle placement is confirmed, the seeds in that needle are released. This process is continued until all of the radioactive seeds have been implanted.

Brachytherapy source—as defined in 10 CFR 35.2, a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Breakthrough—partial elution of the parent isotope with the desired daughter eluate from the generator (i.e., Sr and Rb or Mo and Tc).

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[1] These terms are not defined in Title 10 of the *Code of Federal Regulations* or an NRC management directive, inspection procedure, or policy statement. Rather, these definitions are based on those in Merriam-Webster's "MedlinePlus Online Medical Dictionary." (see https://www.merriam-webster.com/medical).

Catheter [1]—a tubular medical device for insertion into canals, vessels, passageways, or body cavities for diagnostic or therapeutic purposes to permit injection or withdrawal of fluids or to keep a passage open.

Deep dose equivalent—the external whole-body exposure dose equivalent at a tissue depth of 1 centimeter (cm) (1,000 milligram (mg)/(cm^2).

Dose equivalent (H_T)—as defined in 10 CFR 20.1003, "Definitions," the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest; the units of dose equivalent are the rem and sievert (Sv).

Effective dose equivalent (H_E)—as defined in 10 CFR 20.1003, the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated.

Eluate [1]—the washings obtained by removing absorbed material from an absorbent by means of solvent.

Exposure—as defined in 10 CFR 20.1003, being exposed to ionizing radiation or to radioactive material.

External dose—as defined in 10 CFR 20.1003, that portion of the dose equivalent received from radiation sources outside the body.

Gray (Gy)—as defined in 10 CFR 20.1004, "Units of Radiation Dose," the international system's unit of absorbed dose; 1 Gy is equal to an absorbed dose of 1 joule per kilogram (100 rad).

Interstitial[1]—situated within, but not restricted to or characteristic of, a particular organ or tissue; used especially of fibrous tissue.

Manual brachytherapy—as defined in 10 CFR 35.2, a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are close to a treatment site or directly into the tissue volume.

Medical event—as defined in 10 CFR 35.2, an event that meets the criteria in 10 CFR 35.3045(a) or (b). Regulations in 10 CFR 35.3045(a) state that a licensee shall report any event as a medical event, except for an event that results from patient intervention, in which:

1. The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in:

    i. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin and (A) the total dose delivered differs from the prescribed dose by 20 percent or more; (B) the total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage

range; or (C) the fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more.

ii. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following: (A) an administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure; (B) an administration of a radioactive drug containing byproduct material by the wrong route of administration; (C) an administration of a dose or dosage to the wrong individual or human research subject; (D) an administration of a dose or dosage delivered by the wrong mode of treatment; or (E) a leaking sealed source.

iii. A dose to the skin or an organ or tissue other than the treatment site that exceeds by (A) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and (B) 50 percent or more the expected dose to that site from to the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

2. For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

i. The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

ii. The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

iii. An administration that includes any of the following: (A) the wrong radionuclide; (B) the wrong individual or human research subject; (C) sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or (D) a leading sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

Regulations in 10 CFR 35.3045(b) state that “A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.”

Prescribed dosage—as defined in 10 CFR 35.2, the specified activity or range of activity of unsealed byproduct material as documented (1) in a written directive or (2) in accordance with the directions of the authorized user for procedures performed pursuant to 10 CFR 35.100, "Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required," and 10 CFR 35.200, "Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive Is Not Required."

Prescribed dose—as defined in 10 CFR 35.2, (1) for gamma stereotactic radiosurgery, the total dose as documented in the written directive, (2) for teletherapy, the total dose and dose per fraction as documented in the written directive, (3) for manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive, or (4) for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

rad—as defined in 10 CFR 20.1004, the special unit of absorbed dose; 1 rad is equal to an absorbed dose of 100 ergs/g or 0.01 joule/kilogram (0.01 Gy).

Radiation (ionizing radiation)—as defined in 10 CFR 20.1003, alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in 10 CFR Part 20, "Standards for Protection against Radiation," does not include nonionizing radiation, such as radio waves or microwaves, or visible, infrared, or ultraviolet light.

Radiation therapy (radiotherapy)[1]—the treatment of disease with radiation (such as X-rays).

Reactive inspection— as defined in NRC Inspection Manual Chapter 2800, "Materials Inspection Program," and Management Directive 8.10, "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility," an inspection performed for the purpose of obtaining additional information in response to an event.

rem—as defined in 10 CFR 20.1004, the special unit of any of the quantities expressed as dose equivalent; the dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

Shallow dose equivalent (H_S)—as defined in 10 CFR 20.1003, which applies to the external exposure of the skin of the whole body or the skin of an extremity, the dose equivalent at a tissue depth of 0.007 centimeters (7 milligrams/square centimeter).

Sievert (Sv)—as defined in 10 CFR 20.1004, the international system's unit of any of the quantities expressed as dose equivalent; the dose equivalent in Sv is equal to the absorbed dose in Gy multiplied by the quality factor (1 Sv = 100 rems).

Source material—as defined in 10 CFR 40.4, "Definitions," (1) uranium or thorium, or any combination thereof, in any physical or chemical form, or (2) ores that contain by weight 1/20th of 1 percent (0.05 percent) or more of (i) uranium, (ii) thorium, or (iii) any combination thereof. Source material does not include special nuclear material.

Special nuclear material—as defined in 10 CFR 70.4, "Definitions," (1) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material

that the Commission, pursuant to the provisions of Section 51, “Special Nuclear Material,” of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but not including source material, or (2) any material artificially enriched by any of the foregoing but not including source material.

Stereotactic radiosurgery—as defined in 10 CFR 35.2, the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

Therapeutic dose—as defined in 10 CFR 35.2, a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.

Treatment site—as defined in 10 CFR 35.2, the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Written directive—as defined in 10 CFR 35.2, an authorized user’s written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in 10 CFR 35.40, “Written Directives.”

APPENDIX E
CONVERSION TABLE

Radioactivity and Dose

QUANTITY	FROM METRIC UNITS	TO NON-INTERNATIONAL SYSTEM UNITS	DIVIDE BY
Radioactivity	megabecquerel (MBq)	curie (Ci)	37,000
	gigabecquerel (GBq)	Ci	37
	terabecquerel (TBq)	Ci	0.037
Absorbed dose	gray (Gy)	rad	0.01
Dose equivalent	sievert (Sv)	rem	0.01
	millisievert (mSv)	rem	10
	mSv	millirem (mrem)	0.01
	microsievert (μSv)	mrem	10

NRC FORM 335 (12-2010) NRCMD 3.7

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10. SUPPLEMENTARY NOTES
NRC Project Manager Minh-Thuy Nguyen

11. ABSTRACT (200 words or less)
Section 208 of the Energy Reorganization Act of 1974 identifies and abnormal occurrence (AO) an an unscheduled incident or event that the Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Report Elimination and Sunset Act of 1995 requires that the AOs be reported to Congress on an annual basis. This report includes those events that the NRC has determined to be AOs during fiscal year 2019.

This report describes nine events at Agreement State-licensed facilities and no events involving NRC licensees that meet the criteria to be classified as AOs. The NRC also identified one event during FY 2019 that meets the guidelines for inclusion in Appendix B, "Other Events ofInterest.11

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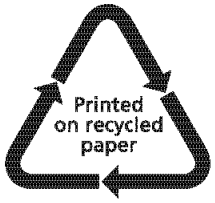

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