POLICY ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Annette L. Vietti-Cook, Secretary

FROM: Commissioner Caputo

SUBJECT: SECY-20-0018: Report to Congress on Abnormal Occurrences: Fiscal Year 2019

Approved XX **Disapproved** ____ **Abstain** ____ **Not Participating** ____

COMMENTS: **Below** XX **Attached** XX **None** ____

Approved, subject to the attached edits.

Annie Caputo Digitally signed by Annie Caputo Date: 2020.03.27 12:33:55 -04'00'

Signature

DATE

Entered in STARS

Yes X

No ____

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

CHAIRMAN

AC Edits

The Honorable Nancy Pelosi
Speaker of the House of Representatives
Washington, DC 20515

Dear Madam Speaker:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am forwarding the enclosed "Report to Congress on Abnormal Occurrences: Fiscal Year 2019." This submission is in accordance with Section 208 of the Energy Reorganization Act of 1974, as amended (Public Law 93-438), and the Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66), which require the NRC to identify and report abnormal occurrences (AOs) to Congress annually. An AO is an unscheduled incident or event that the Commission determines to be significant from the standpoint of public health or safety.

The enclosed AO report for fiscal year 2019 describes nine events involving Agreement State licensees. Seven AOs were medical events, as defined in NRC regulations, one AO ~~event~~ was a human exposure event, and one AO ~~event~~ involved the theft and recovery of three industrial radiography cameras containing Category 2 quantities of radioactive material.

If you have any questions or need additional information, p~~P~~lease ~~feel free to~~ contact me or have your staff contact Eugen Dacus, Director of the Office of Congressional Affairs, at 301-415-1776~~, if you have any questions or need more information~~.

Sincerely,

Kristine L. Svinicki

Enclosure:
As stated

Identical letter sent to:

The Honorable Nancy Pelosi
Speaker of the House of Representatives
Washington, DC 20515

The Honorable Michael Pence
President of the United States Senate
Washington, DC 20510

The Honorable John A. Barrasso
Chairman, Committee on Environment and Public Works
United States Senate
Washington, DC 20510
cc: Senator Thomas R. Carper

The Honorable Mike Braun
Chairman, Subcommittee on Clean Air and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510
cc: Senator Sheldon Whitehouse

The Honorable Frank Pallone, Jr.
Chairman, Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515
cc: Representative Greg Walden

The Honorable Bobby L. Rush
Chairman, Subcommittee on Energy
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515
cc: Representative Fred Upton

The Honorable Paul Tonko
Chairman, Subcommittee on Environment
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515
cc: Representative John Shimkus

The Honorable Marcy Kaptur
Chairman, Subcommittee on Energy and Water Development
Committee on Appropriations
United States House of Representatives
Washington, DC 20515
cc: Representative Mike Simpson

The Honorable Lamar Alexander
Chairman, Subcommittee on Energy and Water Development
Committee on Appropriations
United States Senate
Washington, DC 20510
cc: Senator Dianne Feinstein

AC Edits

Report to Congress on Abnormal Occurrences

Fiscal Year 2019

United States Nuclear Regulatory Commission
Washington, DC 20555-0001

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 that occurred in Agreement State (AS) and no events involving NRC licensees that the agency identified as AOs during fiscal year (FY) 2019. These events are based on the criteria defined in the NRC Policy Statement on "Reporting Abnormal Occurrence Reports," issued on October 2, 2017 (82 FR 45907). ~~; Appendix A, "Abnormal Occurrence Criteria."~~ 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 a Category 2 source, as defined in 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." The agency did not identify any events at commercial nuclear power plants as AOs.

AS 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 AS.

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." The event received significant media coverage due to extensive contamination of personnel and building structure 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.

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 the NRC or an Agreement State (AS) identified as AOs in fiscal year (FY) 2019, based on the criteria defined in the NRC Policy Statement on "Reporting Abnormal Occurrence Reports," issued on October 2, 2017 (82 FR 45907). ~~in this report's Appendix A, "Abnormal Occurrence Criteria," that became effective in FY 2018~~. AS 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 rules and 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. AS conduct regulatory programs that are adequate to protect public health and safety and are compatible with the NRC's program.

ABBREVIATIONS

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
AO	abnormal occurrence
AS	Agreement State(s)
AU	authorized user
CFR	*Code of Federal Regulations*
~~cGy~~	~~centigray(s)~~
Ci	curie(s)
CNMT	certified nuclear medicine technologist
CT	computerized tomography
DOE	U.S. Department of Energy
~~DOH~~	~~Department of Health~~
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
~~rad~~	~~radiation absorbed dose~~
Rb	rubidium
~~rem~~	~~roentgen equivalent man~~
Sr	strontium
Sv	sievert(s)
TBq	terabecquerel(s)
TEDE	total effective dose equivalent
Y	yttrium

Commented [AC1]: cGy is not an official SI unit of dose, and it is also not defined in the AO criteria. Use of Gy and multiples thereof are corrected throughout.

Commented [AC2]: Not used in this AO report.

Commented [AC3]: rem is not an acronym, but a unit of special dose, see the NCRP glossary. While it was derived originally from the phrase "roentgen equivalent mammal" and later "**roentgen equivalent, man," Refs: Health Phys. 82(3):373–386; 2002, and** https://www.remm.nlm.gov/dictionary.htm#r, is It is not an acronym for rem.

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. Aall lLicensees
II. cCommercial nNuclear pPower pPlant lLicensees
III. eEvents at fFacilities other tThan nNuclear pPower pPlants and aAll tTransportation eEvents

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 all Agreement State(s) AO reports start with "AS." Similarly, the identification number for all U.S. Nuclear Regulatory Commission (NRC) AO reports start with "NRC."

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 resulted in an annual sum of the deep dose equivalent (external and internal 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 roentgen equivalent man (rem)) or more. The employee attempted to clean up a small area of rusty contamination in a nonradioactive area of the licensee's facilities. The employee inappropriately used a high-efficiency particulate air (HEPA) vacuum from another the Silver Recovery area of the facility. This vacuum had previously been used to clean up americium-241 metal. The employee turned on the vacuum and noticed it was blowing out debris. The employee immediately turned off the vacuum and shut the doors because the area radiation alarms had activated, indicating that the vacuum debris being discharged was radioactive. After the doors were shut, the radiation safety officer (RSO) was notified. The RSO sealed the location from 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's Radiation Emergency Assistance Center/Training Site and bioassay samples were collected and sent out for processing. Bioassay results

Commented [AC4]: rem is not an acronym, but a unit of special dose see the NCRP glossary; While it was derived from the phrase "**roentgen equivalent, man" ref:** https://www.remm.nlm.gov/dictionary.htm#r, is It is not an acronym for rem.

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

Criterion I.C.1, "Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach" of Appendix A to this report provides, in part, that any stolen, diverted, abandoned, or unrecovered 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. A licensee 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 without approval from the licensee. Law enforcement was notified, and the cameras were recovered and returned to secure storage on the day of the theft.

Cause(s) — The disposition of the event is pending law enforcement investigation.

Actions Taken to Prevent Recurrence

Licensee — The licensee upgraded their access security measures 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 licensees' response to this event.

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

This event is closed ~~open~~ 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 AS 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 ~~radiation absorbed dose (~~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 strontium (Sr) breakthrough occurred in a Bracco rubidium-82 (Rb-82) generator, resulting in levels of Sr-82/Sr-85 exceeding manufacturer-specified limits. Although the licensee did perform the required breakthrough tests, it failed to identify the increased Sr breakthrough amount which was ~~and~~ used in ~~the~~ doses to ~~in~~ patients ~~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 resulting in anemia, nausea, and vomiting in the acute phase and a decrease in blood cell counts during the first 6 weeks postexposure. 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 bone marrow suppression.

Commented [AC5]: Forced hyphen to prevent Sr-82 from breaking on two lines.

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 improper use of ~~l~~Lactated Ringer's saline solution when flushing the generator. This type of saline should not be used with Rb-82 generators because it will cause increased Sr breakthrough.

Actions Taken ~~t~~To Prevent Recurrence

Licensee — To address the primary root cause, the licensee ceased use of the Bracco Rb-82 generator once the event was identified. 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 competitor's product. The licensee determined that the automated quality control steps of the competitor's product may help prevent recurrence of the event. To address

the secondary root cause, the licensee performed retraining on the use of normal saline, including the ordering and verification of the correct saline 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, t~~T~~he NRC issued ~~a generic communication in the form of an~~ 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 ~~the~~ IN 2019-11 ~~i~~was to alert ~~provide operating experience and to inform~~ other medical licensees of these events that resulted in patients receiving greater doses than expected and for the potential for significant Sr breakthrough if the incorrect eluent is used.

Commented [AC6]: The IN purpose does not state that it provides OpE experience.

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 more than expected to the wrong treatment site. The written directive prescribed 779.2~~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 106.48 Gy (10,648 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.

Commented [AC7]: Four significant digits for both MBq nd mCi amounts.

Cause(s) — During administration, the authorized user (AU) began to feel pressure in the syringe. The licensee 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 positive pressure in the tubing as the microcatheter was retracted into a curved catheter~~the Shepard's hook~~. Correct placement of the catheter in the right lobe of the patient's liver had been verified before administration and the delivery system and three-way valve were evaluated with no issues. Post treatment, the licensee did not locate any physical obstruction in the delivery tubing.

Commented [AC8]: The Shepherd's hook is a curved catheter. Alternately, you could state "… a curved catheter (called a Shepherd's hook)," but it is not necessary to delineate the specific model of catheter in this writeup.

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 of the microspheres. The licensee implemented changes to its procedures to include "pulsing" of the dose to further ensure adequate agitation, 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 23, 2019, t~~T~~he NRC issued ~~a generic communication in the form of an~~ IN 2019-11 (ADAMS Accession No. ML19262G231). The purpose of ~~the~~ IN 2019-11 was to alert and ~~is to provide operating experience and to~~ inform other medical licensees of recently reported medical events involving the administration of Y-90 microspheres.

Commented [AC9]: The IN purpose does not state that it provides OpE experience…

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 stomach and left lobe of the liver, respectively, which were the wrong treatment sites. The licensee determined that the stomach received a dose of 91.9 Gy (9,190 ~~cGy (~~rad) and the left lobe received a dose of 21.7 Gy (2,170 ~~cGy (~~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. The licensee reported that no adverse health effects are expected.

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 physician complete training before the first proctored case for each type of microsphere, having the physician who performs the arterial mapping also perform the treatment, and creating and implementing a checklist to be followed in the treatment room that will include a step requiring the physician to look for vessels that may cause stomach shunting 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, t~~T~~he NRC issued ~~a generic communication in the form of an~~ IN 2019-12, "Recent Reported Medical Events Involving the Administration of Yttrium-90 Microspheres for Therapeutic Medical Procedures (ADAMS Accession No. ML19262G231). The purpose of ~~the~~ IN 2019-12 wa~~i~~s to alert and ~~provide operating experience and to~~ inform other medical licensees of recently reported medical events involving the administration of Y-90 microspheres.

Commented [AC10]: The IN purpose does not state that it provides OpE experience.

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 ~~cGy (~~rad) to the right lobe of the liver. After the treatment, the licensee determined that the patient was administered a dose of 69.8 Gy (69,800 ~~cGy (~~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 expected from the additional dose but plans to 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 is to use a patient identifier when ordering the dose and when verifying receipt. 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 has changed its procedures, instituting and providing documented training for the following: a formal time-out in the interventional laboratory to reconcile the prescribe 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, ~~T~~the NRC issued ~~a generic communication in the form of an~~ IN 2019-12 (ADAMS Accession No. ML19262G231). The purpose of ~~the~~ IN 2019-12 ~~is to provide operating experience and~~ was to alert 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 (1.292 mCi) each or 2.49 GBq (67.2 mCi) total). Instead, post treatment the licensee determined that all 52 of the Pd–103 seeds were placed 4 centimeters inferior to the prostate, resulting in 2.49 GBq (67.2 mCi) distributed to going to the penile bulb. The dose to the penile bulb should have been minimal; however, the estimated dose to the penile bulb 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.

Commented [AC11]: Three significant digits for both MBq and mCi.

Commented [AC12]: Forced hyphen to prevent Pd-103 from breaking on two lines.

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 (cc) versus 12 cc 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. The individuals involved received additional instruction about the need to confirm that the probe is in the base position 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, segment 5 of the right lobe of the liver was prescribed to receive 1.59 GBq (43.2 mCi) for a total dose of 251 Gy (25,100 rad). Instead, segment 5 of the right lobe 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 liver treated compared to the volume of untreated liver.

Causes — The primary cause for this event was determined to be human error. Specifically, the AU failed to properly follow the licensee's procedures for administering this type of therapeutic treatment. The AU stated that it was not evident to him during the final time-out procedure that the dosage he read was twice the dosage prescribed and that it was the dosage 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 multisegment 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, tThe NRC issued ~~a generic communication in the form of an~~ IN 2019-12 (ADAMS Accession No. ML19262G231). The purpose of ~~the~~ IN 2019-12 ~~is~~was to

alert and ~~provide 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 ~~T~~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 1.2~~21~~ ~~T~~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 verify the correct dose was being given to the patient. The CNMT performed a time-out procedure, which included reviewing the written directive, verifying the written directive 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 hot 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 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 the ~~"WOW" (~~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 time-out is ready to be performed. Multiple therapy doses will not be stored in the nuclear medicine hot 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 States (AS) 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 AS;

(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 AS; or

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

~~Appendix A to this policy statement sets forth the criteria for determining whether an incident or event is as an AO.~~

~~Abnormal Occurrence Criteria~~

~~An incident or event is considered an AO if it involves a major reduction in the degree of protection of public health or safety. This type of 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 AS;~~

~~(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 AS; or~~

~~(4) substantiated case of actual loss, theft, or diversion of risk-significant radioactive material licensed by or otherwise regulated by the Commission or AS.~~

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

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 (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 (UW), Harborview Medical Center, Research and Training Building (HRT) in downtown Seattle. INIS 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 (OSRP). 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 m~~ill~~rem) 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 E
CONVERSION TABLE

Radioactivity and Ionizing Radiation

QUANTITY	FROM METRIC UNITS	TO NON-INTERNATIONAL SYSTEM UNITS	DIVIDE BY
(Radionuclide) Activity	megabecquerel (MBq)	curie (Ci)	37,000
	terabecquerel (TBq)	Ci	0.037
	gigabecquerel (GBq)	Ci	37
Absorbed dose	gray (Gy)	rad	0.01
	~~centigray (cGy)~~	~~rad~~	~~1.0~~
Dose equivalent	sievert (Sv)	~~roentgen equivalent in man (~~rem~~)~~	0.01
	~~centisievert (cSv)~~	~~rem~~	~~1.0~~
	millisievert (mSv)	rem	10
	mSv	millirem (mrem)	0.01
	microsievert (μSv)	mrem	10