POLICY ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Hanson

SUBJECT: SECY-21-0023: Report to Congress on Abnormal Occurrences: Fiscal Year 2020

Approved X **Disapproved** ____ **Abstain** ____ **Not Participating** ____

COMMENTS: **Below** X **Attached** X **None** ____

I approve issuance of the Fiscal Year 2020 Report to Congress on Abnormal Occurrences and the accompanying cover letter, subject to the attached edits.

Entered in STARS
Yes ✓
No ____

Christopher T. Hanson

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Date: 2021.03.19 11:55:32 -04'00'

Signature
Christopher T. Hanson
Date: March 19, 2021

CTH edits

Report to Congress on Abnormal Occurrences

Fiscal Year 2020

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 seven events in Agreement States and two events involving NRC licensees that were identified as AOs during fiscal year 2020. These events are based on the criteria defined in the NRC Policy Statement on "Abnormal Occurrence Reports," issued in Volume 82 of the *Federal Register (FR)*, page 45907 (82 FR 45907; October 2, 2017). Eight AOs were medical events as defined in Title 10 of the *Code of Federal Regulations* Part 35, "Medical use of byproduct material." There was one AO that was a human exposure event.

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. In addition, the NRC identified four events during fiscal year 2020 that meet the guidelines for inclusion in Appendix B, "Other Events of Interest." The first of these events was a human exposure event with possible internal contamination. The second event involved a gauge failure that resulted in unintended exposure to seven individuals, three of whom were classified as radiation workers who received occupational radiation exposure below regulatory limits. The third event was a stuck source event that resulted in an exposure above the regulatory annual limit to an individual involved in recovering the source. The fourth event concerned an extended loss of offsite power event at a commercial nuclear power plant. 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 the NRC and the Agreement States identified as AOs in fiscal year (FY) 2020, based on the criteria defined in the NRC Policy Statement, "Abnormal Occurrence Reports" (Volume 82 of the *Federal Register*, page 45907 (82 FR 45907; October 2, 2017)). 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, those that are described in this report meet the criteria for reporting as AOs with respect to their significance for public health and safety. 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. In addition, the NRC identified four events during FY 2020 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 strives to become a modern, risk-informed regulator.

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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 2020 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 also 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 promptly informs Congress of significant events, including AOs, should they occur.

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 whether regulated by either the NRC or an Agreement State.

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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 four events that occurred during FY 2020 that met these criteria.

UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

Appendix C typically includes updates on previously reported AOs that remain open during the FY 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
ASP	Accident Sequence Precursor
Bq	becquerel(s)
CCDP	conditional core damage probability
ΔCDP	change in core damage probability
CFR	*Code of Federal Regulations*
Ci	curie(s)
CT	computerized tomography
DOE	U.S. Department of Energy
EDG	emergency diesel generator
ESW	essential service water
FR	*Federal Register*
FY	fiscal year
GBq	gigabecquerel(s)
Gy	gray(s)
HDR	high dose rate
I	iodine
Ir	iridium
LOOP	loss of offsite power
MBq	megabecquerel(s)
mCi	millicurie(s)
MD	management directive
mm	millimeter(s)
mph	miles per hour
mrem	millirem
MRI	magnetic resonance imaging
mSv	millisievert(s)
NRC	U.S. Nuclear Regulatory Commission
RSO	Radiation Safety Officer
REAC/TS	Radiation Emergency Assistance Center/Training Site
SBO	station blackout
Sv	sievert(s)
TEDE	total effective dose equivalent
Y	yttrium

ABNORMAL OCCURRENCES IN FISCAL YEAR 2020

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), starts with "AS." Similarly, the identification number for all U.S. Nuclear Regulatory Commission (NRC) licensee AO reports starts with "NRC."

I. ALL LICENSEES

During this reporting period, one event was identified as an AO based on Criterion I, "All Licensees," in Appendix A.

NRC20-01 Human Exposure Event at Christiana Care Health Services, Newark, Delaware

Criterion I.A.2 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 any minor (an individual less than 18 years of age) results in an annual total effective dose equivalent (TEDE) of 50 millisieverts (mSv) (5 rem) or more, or if any unintended radiation exposure to an embryo/fetus results in a dose equivalent of 50 mSv (5 rem) or more.

Date and Place—January 9, 2020, Newark, DE

Nature and Probable Consequences—On January 29, 2020, Christiana Care Health Services reported that an embryo/fetus received an unintended radiation dose when a patient who was unknowingly pregnant received the first of four doses of lutetium (Lu-177) dotatate for treatment of a neuro-endocrine tumor. On January 9, 2020, immediately before administration, the patient documented "No" to the question "Is there any chance that you are pregnant?" and was administered the prescribed dose of 7.53 gigabecquerel (GBq) (203.5 millicuries (mCi)) of Lu-177 dotatate and counseled to use contraception for several months following the therapy. On January 28, 2020, the patient notified her medical oncologist that she was pregnant. The treating physician was notified on the same day. The licensee stated that the patient had a negative serum pregnancy test on January 3, 2020. It is believed the patient became pregnant after the test, with a possible conception date of between January 3 and January 5, 2020.

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The licensee calculated the dose to the embryo/fetus to be 143 mSv (14.3 rem). The treating physician reviewed the radiation effects with the patient and stated that there was no expected increased risk of fetal death or anatomical malformations at delivery. An independent medical consultant concurred with the licensee's evaluation of the event, including the dose calculation. Subsequently, the patient chose to terminate the pregnancy and continue the treatment. The patient was then scheduled for her next treatment in March 2020.

Cause(s)—The cause of the event was determined to be a weakness in the pregnancy policy to address pregnancy limitations and contraceptive measures between collecting the pregnancy test and therapy dosage administration. The policy in place during the event required a negative pregnancy test 7 days before the administration and relied on a negative declaration of pregnancy immediately before the administration. Patients were counseled to refrain from becoming pregnant following an administration but were not specifically counseled to refrain from becoming pregnant between the pregnancy test and the administration.

Actions Taken To Prevent Recurrence

Licensee—The licensee took measures to provide additional assurance of a negative pregnancy status, out of an abundance of caution. Specifically, the licensee revised its pregnancy policy to require a negative serum pregnancy test within 48 hours before treatment instead of 7 days, and to require a nuclear medicine physician to reemphasize with each therapy patient the need to avoid pregnancy and to use contraception, particularly between the pregnancy test and the therapy date.

NRC—The NRC performed a special inspection on February 5, 2020, to review the event and concluded that the licensee met regulatory requirements, took measures to provide added assurance, reported the medical event as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.3047, "Report and notification of a dose to an embryo/fetus or a nursing child."

This event is closed for the purpose of this report.

II. COMMERCIAL NUCLEAR POWER PLANT LICENSEES

During this reporting period, no events at a commercial nuclear power plant 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 and one event at an NRC licensee facility were identified as AOs based on Appendix A, Criterion III, "Events at Facilities Other Than Nuclear Power Plants and All Transportation Events."

AS20-01 Medical Event at West Penn Allegheny Health System, Pittsburgh, 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 gray (Gy) (1,000 rad), the expected dose to any organ or tissue (other than a major portion of the bone marrow, or 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—November 8, 2019, Pittsburgh, PA

Nature and Probable Consequences—On November 8, 2019, the West Penn Allegheny Health System reported that a patient received a dose that was at least 10 Gy (1,000 rad) more than expected to the wrong treatment site while undergoing an eye plaque radiotherapy procedure. The eye plaque contained 13 iodine (I)-125 seeds, with each seed containing approximately 137.94 megabecquerel (MBq) (3.73 mCi), for a total activity of 1.79 GBq (48.46 mCi). The prescribed dose was 85 Gy (8,500 rad) for treatment of an ocular melanoma that required a total treatment time of 101 hours.

On the morning of November 8, 2019, the eye plaque was implanted and covered with bandages. Thirty minutes after the eye plaque was implanted, the patient complained of excessive pain, and the nursing staff contacted the ophthalmologist about the management of the patient's pain. The position of the eye plaque was not known at this time because it was covered by bandages. Several hours later when the pain did not subside, the ophthalmologist instructed the ophthalmology fellow to remove the bandages and check the eye and position of the eye plaque. It was at this time that the ophthalmology fellow noticed that the plaque had become dislodged. An operating room was booked, and the ophthalmologist removed the eye plaque. The licensee believes the plaque became dislodged when the patient first complained of pain and that the plaque was in the incorrect position for approximately 8.5 hours. The licensee calculated the maximum unintended dose to the normal sclera and cornea to be 18.99 Gy (1,899 rad) at a depth of 1 millimeter (mm). The ophthalmologist reexamined the patient after the eye plaque was removed on November 8, 2019, and on November 20, 2019. No damage to the eye was found as a result of the eye plaque becoming dislodged. The patient and referring physician were notified of the event on November 8, 2019. The patient was successfully retreated on November 22, 2019.

Cause(s)—The licensee believes the event occurred due to the lack of a second intact suture. Although the procedure does not state the number of sutures to use, typically, the ophthalmologist uses two sutures to keep the eye plaque in place. When the ophthalmologist went to remove the eye plaque, the ophthalmologist discovered that only one suture was intact. The second suture was not found. Possible reasons for the missing suture include (1) it broke away from the eye plaque eyelets, (2) the suture pulled through the tissue on the inside of the eye, or (3) the suture was accidentally cut while tying.

Actions Taken To Prevent Recurrence

Licensee—The licensee has implemented the following corrective actions to prevent future occurrence: (1) The surgeon will affix three sutures to the eye plaque to better ensure proper placement, and (2) the referring physician agreed to notify radiation oncology immediately upon learning of any concerns with the eye plaque or the patient.

State—The Pennsylvania Department of Environmental Protection performed a reactive inspection on November 14, 2019, and verified that timely notification had been made to the referring physician and the patient in accordance with 10 CFR 35.3045, “Report and notification of a medical event.” The Pennsylvania Department of Environmental Protection considers the licensee’s corrective actions to be adequate.

This event is closed for the purpose of this report.

AS20-02 Medical Event at Mount Nittany Medical Center, State College, 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, or 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—December 13, 2019, State College, PA

Nature and Probable Consequences—On December 13, 2019, Mount Nittany Medical Center reported that a high dose rate (HDR) remote afterloader brachytherapy Tandem and Ovoid applicator dislodged during treatment. The patient was prescribed five fractionated doses of 6 Gy (600 rad) each over a period of 2.5 weeks for a total dose to the cervix of 30 Gy (3,000 rad). Fractions 1, 2, 3, and 5 were delivered without incident. However, at the end of the fourth fraction, which was delivered on December 13, 2019, the applicator was found dislodged and laying between the patient's legs. The patient was seen for follow-up appointments on December 27, 2019; December 30, 2019; and January 6, 2020. Observed effects were described as "moist desquamation" on both upper legs due to the applicator being dislodged from the vaginal canal. Mount Nittany Medical Center is unsure how long the applicator was dislodged; however, based on the effects observed, a dose to the skin of both thighs in the range of 10–30 Gy (1,000–3,000 rad) is assumed to have occurred. The patient and the authorized user were notified at the time of the event on December 13, 2019, and the referring physician was notified on December 16, 2019. Both the Wound Clinic physician and the authorized user noted that the wounds on the patient's legs healed, and no further complications were seen.

Cause(s)—The exact cause of the event is unknown; however, the licensee believes that the patient may have changed positions during treatment. The movement may have allowed the applicator to slip out of position. The patient would have been unaware that the device shifted since it could not be felt due to a spinal block.

Actions Taken To Prevent Recurrence

Licensee—The licensee has updated its operating procedures and policies for the HDR remote afterloader brachytherapy and has provided related training.

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State—The Pennsylvania Department of Environmental Protection performed a reactive inspection on December 23, 2019, and determined the licensee implemented corrective actions to prevent reoccurrence.

This event is closed for the purpose of this report.

AS20-03 Medical Event at Prisma Health Baptist Hospital, Columbia, South Carolina

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, or 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—January 29, 2020, Columbia, SC

Nature and Probable Consequences—On February 3, 2020, Prisma Health Baptist Hospital reported that during a prostate brachytherapy procedure, all I-125 brachytherapy seeds were inadvertently implanted into the patient's bladder instead of the prostate. The written directive prescribed 145 Gy (14,500 rad) to be administered to the prostrate using 76 I-125 seeds with an activity of 12.95 MBq (0.35 mCi) each or 984.2 MBq (26.6 mCi) total. A computerized tomography scan performed on January 31, 2020, identified that 41 of the I-125 seeds were in the bladder wall and surrounding fatty tissue. Additionally, the licensee further assumed that the patient urinated out the remaining 35 I-125 seeds into his septic tank system at home. The planned dose to the bladder was 75 Gy (7,500 rad); however, the licensee's calculations indicate the postimplant dose to be approximately 180 Gy (18,000 rad). The patient, referring urologist, and oncologist were notified of the event on February 3, 2020. The patient is experiencing frequent urination both during the day and at night and urgency. The licensee indicates the patient's potential long-term effect is for inflammation of the bladder (also known as hemorrhagic cystitis) defined by lower urinary tract symptoms that include painful urination and blood in the urine.

Cause(s)—The licensee has identified some aspects of its procedure that may have led to this medical event including the following:

- The prostate base location coordinates may have inadvertently shifted or were misidentified (or both) before the implant procedure started.
- Fluoroscopy was not used to compare with the transrectal ultrasound image, so the incorrect location would not have been identified.

Actions Taken To Prevent Recurrence

Licensee—The licensee temporarily suspended its prostate seed implant program and performed an internal review, which was completed on April 30, 2020. Corrective actions included updating the prostate implant program and performing appropriate training. Additionally, the licensee revised its prostate seed implant policy and provided vendor refresher training to authorized users and physicists involved with prostate seed implant procedures. The licensee resumed its prostate seed implant program effective June 22, 2020.

State—The South Carolina Department of Health and Environmental Control performed a reactive onsite inspection on February 11, 2020, reviewed the incident causes and considers the licensee's planned corrective actions to be adequate.

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This event is closed for the purpose of this report.

AS20-04 Medical Event at Rhode Island Hospital, Providence, Rhode Island

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, or 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—March 3, 2020, Providence, RI

Nature and Probable Consequences—On March 3, 2020, Rhode Island Hospital reported that the stereotactic frame holding a patient in treatment position had disengaged during a gamma knife treatment of a left vestibular schwannoma (a rare tumor that forms in the nervous system). As a result of the improper positioning of the patient, the estimated dose to the treatment site was 4 Gy (400 rad), and an unintended dose of 13.6 Gy (1,360 rad) was estimated to a region of the left temporal lobe within the brain. The attending neurosurgeon notified the patient of the estimated dose right after treatment. The results of a follow-up magnetic resonance imaging (MRI) on June 22, 2020, revealed a stable vestibular schwannoma without any evidence of acute changes, and no changes were seen to the left temporal lobe. Additionally, the attending neurosurgeon conducted follow-up meetings with the patient on June 24, 2020 (televisit), and on July 23, 2020 (phone call), during which the patient stated that they continued to have no neurological complaints from the treatment. A second follow-up MRI was performed 4 months later, and the results were normal.

Causes—The cause of the event is believed to be improper positioning of the patient. Additionally, it is unknown what contributed to the frame movement and how the screws securing the patient in the treatment position had shifted from the initial position. The licensee arranged for a service call from the manufacturer, and the manufacturer's field service engineers could not identify any system issue that may have contributed to the event.

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Actions Taken To Prevent Recurrence

Licensee—The licensee took a number of corrective actions, including requiring that the radiation therapist to ensure that the patient understands that any movement of the head within the headframe is not anticipated and should be communicated immediately.

State—The Rhode Island Department of Health is tracking the event and has remained in contact with the licensee's medical physics team about the event. Additionally, the Rhode Island Department of Health determined an onsite inspection was not necessary for this event and that the licensee took all appropriate actions immediately upon discovery of the event.

This event is closed for the purpose of this report.

AS20-05 Medical Event at Regents of the University of California (UCLA Medical Center), Los Angeles, California

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, or 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—July 8, 2020, Los Angeles, CA

Nature and Probable Consequences—On July 10, 2020, University of California Los Angeles Medical Center reported that during an ovarian cancer treatment involving an HDR remote afterloader on July 8, 2020, a patient received a dose that was at least 10 Gy (1,000 rad) more than expected and administered to the wrong treatment site. The written directive prescribed 24 Gy (2,400 rad) be administered to the treatment site; however, post-treatment, it was determined that 1.1 cubic centimeters of the treatment site received only 1.9 Gy (190 rad), while 1 cubic centimeter of the large bowel received an unintended dose of 17.1 Gy (1,710 rad).

The treatment staff performed a routine pretreatment manual measurement with a wire, determining that the HDR remote afterloader catheter length was 203 mm. This catheter length was entered into the HDR remote afterloader. During the HDR treatment process, the HDR remote afterloader dummy source did not travel all the way out to the 203 mm treatment distance. The staff had to manually abrade the plastic catheter entrance, which allowed the dummy source to travel the 203 mm treatment distance, but the treatment staff didn't evaluate whether the restricted catheter entrance had impacted the initial catheter measurement of 203 mm. After the treatment, the lead physicist was notified of the need to abrade the catheter entrance. Concerned that the catheter entrance obstruction may have impacted the initial catheter measurement, the lead physicist had the removed catheter remeasured. Upon remeasurement, it was determined that the treatment length should have been 241 mm, a 38 mm difference. The erroneous measurement occurred because a weld on the dummy wire caught on the catheter entrance during the initial manual measurement. The patient and referring physician were notified. The licensee reported that while no short-term adverse health effects were noted, there is a longer-term potential of colonic perforation necessitating surgical correction or colostomy.

Cause(s)—The incorrect catheter length entry into the HDR remote afterloader treatment delivery system was due to a defective catheter entrance that was not detected in the manual process of determining treatment catheter length. Additionally, the licensee determined that no explicit procedural check was in place to verify that the treatment distance was consistent with the nominal catheter length and that training was not sufficient to compensate for the lack of an explicit procedure.

Actions Taken To Prevent Recurrence

Licensee—The licensee revised the HDR remote afterloader procedures and forms to add specific provisions to verify that the measured catheter length is consistent with the nominal catheter length, including discrepancy thresholds that require an investigation before treatment planning and treatment can commence. All therapists, dosimetrists, and physicists were trained

on the updated procedures and forms. The catheter vendor was notified of the event and was asked to address the quality control/design of the catheter entry dimensions.

State—The California Department of Public Health reviewed the university's investigation and took enforcement action against the licensee for the lack of written procedures to provide high confidence that HDR remote afterloader treatments are conducted in accordance with the treatment plan. Future inspections are planned to verify the effectiveness of the licensee's corrective actions.

This event is closed for the purpose of this report.

AS20-06 Medical Event at Mayo Clinic Hospital, Phoenix, Arizona

Criterion III.C.1(a) of Appendix A to this report provides, 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 Gy (100 rad) to a major portion of the bone marrow or to the lens of the eye.

Date and Place—June 09, 2020, Phoenix, AZ

Nature and Probable Consequences—On June 11, 2020, Mayo Clinic Hospital in Phoenix reported that a patient received a dose that was greater than 1 Gy (100 rad) to the lens of the eye while undergoing an eye plaque radiotherapy procedure. The eye plaque contained 21 I-125 seeds, with each seed containing approximately 111.89 MBq (3.02 mCi), for a total activity of 2.35 GBq (63.47 mCi). The patient was prescribed 85 Gy (8,500 rad) from I-125 seeds that were to be removed after 5 days (120 hours).

On June 4, 2020, at 10 a.m., the eye plaque was successfully affixed to the patient's eye, with removal scheduled for June 9, 2020, at approximately 8 a.m. On the evening of June 8, 2020, the patient experienced a life-threatening medical event and was transported by ambulance and helicopter to St. Joseph's Hospital in Phoenix, where the patient underwent an emergency procedure. After consultation with the St. Joseph's Hospital care team, it was determined that the risk of transporting the patient immediately to Mayo Clinic Hospital was too high. When the patient regained consciousness and was stabilized, the risks were explained, and the patient was transported back to Mayo Clinic Hospital on the evening of June 9, 2020. The Mayo Clinic Hospital care team informed the patient of the potential risks of the I-125 eye plaque removal procedure in someone who had recently experienced a cerebrovascular event requiring thrombolysis, and the I-125 eye plaque was removed on June 11, 2020 (2 days later than prescribed, and 7 days (174 hours) total). All 21 I-125 seeds were recovered, and the patient received an estimated 123.5 Gy (123,500 rad) to the treatment target (the eye). The lens of the eye was prescribed to receive 24.8 Gy, but instead received an estimated 35.5 Gy. The patient is expected to either lose vision or have severely compromised vision in the affected eye.

Causes—The cause of the incident was the unexpected hospitalization to treat a life-threatening medical event that the patient experienced 5 days into a 7-day eye plaque radiotherapy treatment.

Actions Taken To Prevent Recurrence

Licensee—Because the overexposure was the result of an informed medical decision made for the patient's greater safety, this was a unique situation not requiring formal procedures to prevent recurrence.

State—The State was in constant contact with both licensees (St. Joseph's Medical Center and Mayo Clinic Hospital) throughout the event.

This event is closed for the purpose of this report.

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NRC20-02 Medical Event at Veterans Administration Boston Healthcare System, Boston, Massachusetts

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, or 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 5, 2020, Boston, MA

Nature and Probable Consequences—On August 6, 2020, the Department of Veterans Affairs reported that a patient undergoing treatment for liver cancer with yttrium (Y)-90 microspheres received a dose that was at least 10 Gy (1,000 rad) more than expected to the wrong treatment site. On August 5, 2020, the patient was prescribed a dose of 225 Gy (22,500 rad) to the right lobe of the liver through the administration of 2.47 GBq (66.7 mCi) of Y-90 microspheres. Postimplant imaging indicated that approximately 2.0 GBq (54.4 mCi) was unintentionally delivered to a segment of the left lobe of the liver, resulting in a dose of approximately 160 Gy (16,000 rad) to that segment. The patient and referring physician were notified. At 10 weeks post-treatment, liver function was stable, and there was no clinically significant hepatotoxicity. Follow-up of the patient is continuing.

Cause(s)—The cause was likely placement of the tip of the intra-arterial catheter into the wrong branch of the hepatic arterial system. A contributing factor was the patient's extremely distorted hepatic anatomy, caused by previous treatments for the same cancer.

Actions Taken To Prevent Recurrence

Licensee— The licensee stated that it would perform additional imaging when clinically indicated (e.g., providing treatment to a patient with distorted hepatic anatomy).

NRC—The Department of Veterans Affairs National Health Physics Program reviewed the medical event under its Master Materials License with the NRC and conducted a reactive inspection. A Veterans Affair physician review group also independently reviewed the medical event. From this the Department of Veterans Affairs National Health Physics Program concluded that there were no violations.

This event is closed for the purpose of this report.

AS20-07 Medical Event at University Hospitals of Cleveland, Cleveland, Ohio

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, or 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 27, 2020, Cleveland, OH

Nature and Probable Consequences—On September 2, 2020, University Hospitals of Cleveland reported that a patient undergoing liver cancer treatment using split dose Y-90 microspheres received a dose that was at least 10 Gy (1,000 rad) more than expected to the wrong treatment site. The patient's anterior right and posterior right liver lobe sites were each prescribed a dose of approximately 124 Gy (12,400 rad) using 2.22 GBq (60 mCi) of Y-90 microspheres. The posterior site was treated first and then the catheter was moved to the anterior position. Post-treatment survey results of the acrylic beta shield waste containers indicated that 99 percent of the 4.44 GBq (120 mCi) activity was delivered to the patient. Routine post therapy Bremsstrahlung imaging indicated that the posterior site received 0.74 GBq (20 mCi) and 35 Gy (3,500 rad), while the anterior site received 3.7 GBq (100 mCi) and between 170 and 180 Gy (17,000 and 18,000 rad). Additionally, the surrounding liver tissue received a dosage between approximately 80 and 85 Gy (8,000 and 8,500 rad), which was greater than the expected dosage of less than 50 Gy (5,000 rad). There was no evidence of activity outside of the liver on the routine post therapy Bremsstrahlung imaging and no adverse health effects are expected. The patient and referring physician were notified on September 3, 2020 and the patient was monitored to determine if additional treatment is needed.

Causes—The cause could not be determined as the licensee had used a guide sheath to position the catheter to each target site and the position was confirmed by using fluoroscopy. The positioning of the catheter was documented on immediate pre-therapy time stamped images to be acceptable and in appropriate position prior to administration.

Actions Taken To Prevent Recurrence

Licensee—The licensee will no longer conduct split dose procedures.

State—The Ohio Department of Health conducted a reactive inspection on September 16, 2020, and confirmed that the licensee followed required regulations, guidance, policies and procedures.

This event is closed for the purpose of this report.

APPENDIX A
ABNORMAL OCCURRENCE CRITERIA

ABNORMAL OCCURRENCE GENERAL STATEMENT OF POLICY

The U.S. Nuclear Regulatory Commission (NRC) 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 criteria below for determining an AO and the guidelines for "other events of interest" in a policy statement published in Volume 82 of the *Federal Register*, page 45907 (82 FR 45907; October 2, 2017).

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 (§ § 50.36(c)).

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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 technical specification that requires immediate remedial action.

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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 Accident Sequence Precursor 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

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:

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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.

(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, "Abnormal Occurrence Criteria," to this report. The U.S. Nuclear Regulatory Commission (NRC) 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 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 20-01 Spectratek, Services

The NRC included this event in this report because of the unusual human exposure and the significant attention and oversight from both the NRC and the Agreement State.

Date and Place—October 22, 2019, Albuquerque, New Mexico

On June 23, 2020, NRC received notification from the Agreement State describing a potential individual overexposure occurring on October 22, 2019, at Spectratek, Services (licensee). This licensee manufactures and distributes tracer materials used in well logging operations.

The exposure occurred when a welded container containing approximately 40.11 GBq (1,080 mCi) of iridium (Ir)-192 ceramic beads was improperly opened. On October 22, 2019, the licensee's Radiation Safety Officer (RSO) sent the individual into the facility's hot room to retrieve a quantity of iridium ceramic beads from a sealed container for shipment to a customer. Under normal conditions, these containers are opened in a sealed glove box inside the hot room using manipulator arms, but at the time of the event the manipulator arms failed to function as intended. The individual attempted to open the container outside of the glove box. The individual hand drilled into the top of the container to open and relieve the internal pressure. When the container's wall was breached, some of the contents sprayed onto the individual's upper torso, face, and eyes.

Approximately 1000 mCi activity of radioactive material was recovered from the container. Approximately 2 mCi activity was collected during decontamination of areas outside the hot room, indicating that approximately 78 mCi activity was released inside the hot room and was not recovered. For estimating the individual's internal radiation dose, the licensee assumed that the individual had ingested or inhaled the entire 78 mCi unrecovered quantity and estimated that the individual had received a whole-body dose of approximately 6.5 mSv (650 mrem). The licensee did not conduct any bioassay measurements on the individual. The licensee also did not report the event to the Agreement State since the individual's estimated dose was below the regulatory threshold for reporting.

On May 23, 2020, the individual became ill and was transported to a local hospital where the family informed the physician that he may have been "radiation poisoned" months earlier and

described that earlier event. This information was conveyed to the Regional Program Manager of the U. S. Department of Energy Region 4 Radiological Assistance Program who in turn notified the Agreement State.

On June 23, 2020, the Agreement State consulted with NRC on how to further proceed with determining the individual's dose. The Agreement State also consulted with the U.S. Department of Energy (DOE) Radiation Emergency Assistance Center/Training Site (REAC/TS) personnel and several other DOE health physicists. On July 17, 2020, the individual received a whole-body count at the Carlsbad Environmental Monitoring & Research Center, Carlsbad, NM, to determine if any residual Ir-192 remained in his body. The results showed internal activity of 160.58 becquerel (Bq) (4.34 nanocurie (nCi)) of Ir-192 and 25.09 Bq (0.677 nCi) of cesium (Cs)-134. On August 13, 2020, a second whole-body count and lung scan was performed at Los Alamos National Laboratory which resulted in no detectable counts. The Agreement State then performed a dose calculation based on the information obtained from the Carlsbad Environmental whole-body count and calculated a whole-body dose of 0.055 mSv (5.5 mrem) to the exposed individual and requested NRC assistance to complete the dose reconstruction for the incident.

During the licensee's internal investigation, the licensee terminated the RSO. The Agreement State continues to investigate this incident and gather information for potential regulatory action. The Agreement State has also spoken with the licensee concerning the safety significance of their investigation observations. The Agreement State will continue to update NRC as new information develops. Coordination between the two agencies on dose reconstruction is continuing.

OEI 20-02 INEOS Oligomers Chocolate Bayou Works

The NRC included this event in this report because the event received significant attention and oversight from both the NRC and the Agreement State.

Date and Place—June 30, 2020, Alvin, Texas

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On June 30, 2020, INEOS Oligomers Chocolate Bayou Works reported a gauge failure that resulted in unintended exposure of seven individuals, three of whom were classified as radiation workers. The gauge's rotary element and source tube separated from the gauge body as a result of what appeared to have been a significant force of yet unknown origin being applied to the rotary element. Upon discovery, workers attempted to reinstall two loose pieces, later identified as the 3.5 GBq (95 mCi) Cs-137 source and the source cover plate. Initially, six of the seven individuals were believed to have received radiation exposure that potentially exceeded regulatory limits. It was determined that three of the workers had handled the source and one of these three had placed the source in his shirt pocket for an estimated 34 minutes.

In order to assess the exposure received by these workers, a physician working under the guidance and direction of the DOE REAC/TS monitored the affected workers. No adverse health effects were observed in any of the individuals. The Agreement State preliminarily estimated the whole-body dose to the maximally exposed individual at greater than 250 mSv (25 rem). DOE REAC/TS estimated the whole-body dose to that individual at less than 750 mSv (75 rem). A radiation professional, working for the licensee's technical consultant, performed dose reconstructions for all the exposed individuals using test exposures simulating the conditions of the event, a cost-free on-line radiation calculator, and guidance contained in Regulatory Guide (RG) 8.40, "Methods for Measuring Effective Dose Equivalent from External Exposure," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML100610534). Using this methodology, the maximally exposed individual was assigned an estimated whole-body dose that exceeded the AO threshold. That same individual was assigned an estimated skin dose to the chest that was just below the AO threshold. Assigned estimated doses to the other individuals were well below AO thresholds. Two non-radiation workers did exceed the regulatory limit of 2 mrem in any 1 hour.

The NRC performed dose modeling using an Electric Power Research Institute (EPRI) effective dose equivalent (EDE) calculation program developed for exposure to hot particles and a computer code designed to estimate dose to the skin from a hot particle (VARSKIN 6.2.1). Using these methods, the NRC calculated the EDE (whole-body) dose was 4.9 mSv (490 mrem), and the calculated aggregate skin dose was 0.29 Sv (29 rem), both values below AO thresholds. The NRC and the Agreement State agreed that the actual exposure to the maximally exposed individual was closer to the values utilizing the EPRI and VARSKIN dose modeling approach. This conclusion was also informed by the lack of any observed health effects to the individual. The NRC and Agreement State agreed that the individual's exposure did not exceed any AO thresholds.

Following the discovery of the failed gauge, INEOS staff removed the gauge from service and contracted with a technical consultant who transferred the source to a source broker for disposal. The gauge body (without the source) was returned to the distributor/manufacturer (Endress+Hauser, Inc.) for a failure analysis. Because Endress+Hauser, Inc. holds an NRC license for the receipt, storage, and distribution of this gauge design, the NRC conducted a

follow-up inspection and review of the licensee's failure analysis in order to determine whether the gauge failure was a potentially generic issue due to a quality control or design deficiency, and to determine whether an immediate safety concern existed with the continued use of this design of gauge. Although the NRC's inspection of this gauge failure has not yet been completed, there was enough evidence to conclude that the failure did not present an immediate safety concern with the continued use of this design of gauge.

OEI 20-03 Applied Technical Services, Inc.

The NRC included this event in this report because the event received significant attention and oversight from both the NRC and the Agreement State.

Date and Place—August 3, 2020, Mugla, Alabama

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On November 30, 2020, Applied Technical Services, Inc. reported that a stuck source event, which occurred on August 3, 2020, resulted in an exposure above the regulatory annual limit to an individual involved in the source recovery. The licensee reported that while using a 4.1 terabecquerel (TBq) (111 Ci) Ir-192 radiography source at an asphalt plant, a magnetic stand broke free from the side of a tank and crushed part of the radiography source guide tube. Multiple efforts by the radiographer to return the source into the shield housing were unsuccessful. The radiographer contacted the RSO, who instructed the radiographer and his two assistants to move their whole-body dosimeters to their wrists to get an accurate extremity exposure reading. Additional shielding was also used by the radiographer and the assistants to reduce the radiation exposure to allow them to get closer to the crushed guide tube and exposed source. The radiographer attempted to return the crushed guide tube to a rounded shape with pliers and a hammer but was unsuccessful. The guide tube was then cut, which freed up enough space to allow the source to be successfully retracted.

All radiography personnel working at the asphalt plant were badged and no un-badged personnel received any exposure during the event. The dosimeters worn by the radiography workers involved in the event were immediately sent off for processing. One individual received a dose to the extremities of 635.8 mSv (63.58 rem), which is over the allowable annual limit of 500 mSv (50 rem) for radiation workers. The other two employees received assigned extremity doses of 104.4 mSv (10.44 rem) and 26.1 mSv (2.61 rem), respectively. These three employees were removed from radiography operations for the remainder of the calendar year. Additionally, the licensee returned the radiography exposure device back to the manufacturer for investigation.

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Since the RSO had directed the individuals to move the whole-body dosimeters to the wrist, the licensee used the doses captured by the direct reading dosimeters worn at the chest to calculate the individual's whole-body doses. Each individual recorded their dosage after each attempt at recovery. The State regulators directed the licensee to reflect a whole-body dose calculated from the direct reading dosimeters as opposed to the dose captured by the dosimeter worn at the wrist. The adjusted whole-body doses to the three affected workers are 25.19 mSv (2.519 rem), 21.78 mSv (2.178 rem), and 7.981 mSv (0.7981 rem). The Agreement State performed an investigation of the event and both the Agreement State and the NRC agreed that the individuals' exposure did not exceed any AO thresholds.

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OEI-04 NextEra Energy

The NRC included this event in this report because the event received significant oversight from the NRC and attention from members of the public.

Date and Place—August 10, 2020, Palo, Iowa

On September 11, 2020, NextEra Energy reported an unusual event and unit trip due to loss of offsite power had occurred on August 10, 2020, at the Duane Arnold Energy Center. Extremely severe thunderstorms with heavy rain and high winds damaged all offsite power sources resulting in a reactor protective system automatic shutdown or trip. An automatic reactor shutdown is expected for a loss of offsite power (LOOP) event. Reactor inventory control was maintained by reactor core isolation cooling and the safety relief valves were used to remove decay heat. Operators restored offsite power to the safety-related buses approximately 25 hours after the LOOP occurred and brought the plant to cold shutdown conditions on August 11, 2020.

The NRC performed an ASP analysis that resulted in a mean conditional core damage probability of 8×10^{-4}, which is below the AO threshold of 1×10^{-3}. That report is available at ADAMS with Accession No. ML21056A382. Throughout the review of this event, the analysis assumptions and results were systematically reviewed to identify necessary standardized plant analysis risk model changes to realistically represent the event and expected plant response. The high winds experienced were not a beyond design basis event. The systems and components responded as designed and the overall peak wind speeds were within limits of a design basis tornado.

The NRC Senior Resident Inspector for Duane Arnold reported to the site and monitored the licensee actions throughout the event and recovery. The NRC remained in the normal response mode since the plant shutdown safely and mitigating systems responded as expected. Region III sent additional inspectors to perform an event response follow-up and inspection under the baseline inspection program. The inspectors determined that the licensee effectively implemented the site's emergency plan to protect public health and safety during the event. No findings or violations of more than minor significance were identified and the NRC inspectors verified that there were no radiological impacts from this event.

Duane Arnold Energy Center was planning to be permanently shut down in October 2020; however, storm damage to the non-safety related structures resulted in the plant permanently shutting down after the event. The plant is currently undergoing decommissioning activities

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APPENDIX C
UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

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

APPENDIX D
GLOSSARY

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.

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.

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.

ΔCDP—increase in core damage probability for the time period during which a component or multiple components were deemed unavailable or degraded.

Conditional Core Damage Probability—conditional probability that a core damage state is reached given the occurrence of the observed initiating event (and any subsequent equipment failure or degradation).

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[1] These terms are not defined in Title 10 of the *Code of Federal Regulations* or a U.S. Nuclear Regulatory Commission (NRC) management directive, inspection procedure, or policy statement. Rather, these definitions are based on those on the National Institutes of Health–National Cancer Institute Web site (see https://www.cancer.gov/about-cancer).

Deep dose equivalent—the external whole-body exposure dose equivalent at a tissue depth of 1 centimeter (1,000 milligram per square centimeter).

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.

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.

Eye plaque radiotherapy[1]—a type of radiation therapy used to treat eye tumors. A thin piece of metal (usually gold) with radioactive seeds placed on one side is sewn onto the outside wall of the eye with the seeds aimed at the tumor. It is removed at the end of treatment, which usually lasts for several days.

Gamma knife—a type of radiosurgery (radiation therapy) machine that acts by focusing low-dosage gamma radiation from many sources on a precise target. Areas adjacent to the target receive only slight doses of radiation, while the target gets the full intensity.

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/gram 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).

Deleted:

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.

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.

Vestibular schwannoma (also known as acoustic neuroma, acoustic neurinoma, or acoustic neurilemoma)[2]—is a benign, usually slow-growing tumor that develops from the balance and hearing nerves supplying the inner ear. The tumor comes from an overproduction of Schwann cells—the cells that normally wrap around nerve fibers like onion skin to help support and insulate nerves.

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
Absorbed dose	gray (Gy)	rad	0.01
Dose equivalent	sievert (Sv)	rem	0.01
	millisievert (mSv)	rem	10
	mSv	millirem (mrem)	0.01