Report to Congress on Abnormal Occurrences

Fiscal Year 2018

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) modified the AO reporting frequency from quarterly to annually.

This report describes three events involving NRC licensees that the agency identified as AOs in fiscal year (FY) 2018 based on the criteria defined in Appendix A, "Abnormal Occurrence Criteria and Guidelines for Other Events of Interest," to this report. Two 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 third AO event involved a category 2 source, as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." During this reporting period, the NRC did not identify any events as AOs at commercial nuclear power plants in the United States.

This report also describes eight AOs that occurred in Agreement States (AS) and that were identified as AOs during FY 2018 based on the criteria defined in Appendix A. Seven were medical events, as defined in 10 CFR Part 35, and one event involved radiography operations. 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 located within the States' borders. Currently, there are 38 AS.

Appendix A to this report presents the NRC's criteria for identifying AOs. No events were identified for inclusion in Appendix B, "Other Events of Interest," for this reporting period. Appendix C, "Updates of Previously Reported Abnormal Occurrences," provides updated information for one event that was identified in "Report to Congress on Abnormal Occurrences: Fiscal Year 2017" (NUREG-0090, Volume 40), issued May 2018. 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 or an Agreement State (AS) identified as AOs in fiscal year (FY) 2018, based on the criteria defined in this report's Appendix A, "Abnormal Occurrence Criteria." One event included in this report occurred in FY 2017 and therefore was evaluated against the AO criteria published in the *Federal Register* on October 12, 2006 (71 FR 60198). 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.

Of the 11 AOs discussed, one occurred in FY 2017 but is included in this report because the NRC completed its evaluation of the event once the information was available in FY 2018. Information on AOs must be complete to permit an adequate evaluation. Occasionally, all the required information is not available in time to evaluate and report on an AO in the FY of its occurrence.

Appendix A to this report presents the NRC's criteria for identifying AOs. The NRC did not identify any events during FY 2018 that met the guidelines for inclusion in Appendix B, "Other Events of Interest."

Appendix C, "Updates of Previously Reported Abnormal Occurrences," provides updated information for one event identified in "Report to Congress on Abnormal Occurrences: Fiscal Year 2017," (NUREG-0090, Volume 40). 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 in its regulatory process, consistent with the NRC's "Strategic Plan: Fiscal Years 2018–2022," (NUREG-1614, Volume 7), issued February 2018.

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. As a regulator, AS ensure compliance with requirements for the safe and secure use of radioactive material in their states.

REPORTABLE EVENTS

The NRC initially issued the AO criteria in a Commission policy statement published in Volume 42 of the *Federal Register* (FR), page 10950 (42 FR 10950), on February 24, 1977, followed by several revisions over subsequent years. The agency published the most recent revision to the AO criteria in the *Federal Register* on October 2, 2017 (82 FR 45907); the revised criteria became effective on that date. This revision establishes the criteria that the NRC staff has used to define AOs for this FY 2018 report. Event AS18-02, included in this report, occurred in FY 2017 and therefore was evaluated against the AO criteria published in the *Federal Register* on October 12, 2006 (71 FR 60198).

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

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

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

AGREEMENT STATES

AS 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. AS 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 38 AS. Vermont has submitted an application to become the 39th AS.

AS report event information in accordance with compatibility criteria the NRC established in its "Agreement State Program Policy Statement" (82 FR 46840; October 6, 2017). The NRC also has procedures for evaluating materials events and identifying those that meet the AO criteria. The NRC uniformly applies the AO criteria (see Appendix A) to events at licensee facilities or activities involving the use of radioactive material regulated by either the NRC or the AS. In 1977, the Commission determined that the annual report to Congress should also include events that meet the criteria for AOs at licensees regulated by AS. The *Federal Register*

notice that the NRC issues to disseminate AO-related information to the public includes these events as well.

INTERNATIONAL INFORMATION

The NRC exchanges information with various foreign governments that regulate nuclear facilities and materials. The agency reviews and considers this international information in its research and regulatory activities, as well as in its assessment of operating experience. Although the NRC may occasionally refer to such information in its AO reports to Congress, the agency reports only domestic AOs.

OTHER EVENTS OF INTEREST

The NRC offers information about events that do not meet the criteria for identification as AOs but are of interest based on the criteria in Appendix B of this report. The NRC did not identify events that occurred during FY 2018 that met these criteria.

UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

In Appendix C, this report includes an update on a previously reported AO that was first reported in FY 2017. This AO involved a medical event at Providence Alaska Medical Center, Anchorage, AK.

ABBREVIATIONS

AEA	Atomic Energy Act of 1954, as amended
AO	abnormal occurrence
AS	Agreement States
ASP	NRC Accident Sequence Precursor program
AU	authorized user
CCDP	conditional core damage probability
CFR	*Code of Federal Regulations*
cGy	centigray(s)
Ci	Curie(s)
CT	computerized tomography
ΔCDP	change in core damage probability
FR	*Federal Register*
FY	fiscal year
GBq	gigabecquerel(s)
Gy	gray(s)
HDR	high dose rate
I	iodine
Ir	iridium
IR	interventional radiologist
MBq	megabecquerel(s)
mCi	millicurie(s)
MD	management directive
MIBG	meta-iodobenzylguanidine
mrem	millirem
mSv	millisievert(s)
NRC	U.S. Nuclear Regulatory Commission
rad	radiation absorbed dose
REAC/TS	Radiation Emergency Assistance Center/Training Site
rem	roentgen equivalent man
RSO	radiation safety officer
SI	International System of Units
Sv	sievert(s)
TBq	terabecquerel(s)
TEDE	total effective dose equivalent
TPS	treatment planning software
TS	technical specification
Y	yttrium

ABNORMAL OCCURRENCES IN FISCAL YEAR 2018

Appendix A, “Abnormal Occurrence Criteria and Guidelines for Other Events of Interest,” to this report supplies the specific criteria for determining whether an event is an abnormal occurrence (AO). Appendix A contains criteria for the following four major categories:

I. All Licensees
II. Commercial Nuclear Power Plant Licensees
III. Events at Facilities other than Nuclear Power Plants and All Transportation Events
IV. Other Events of Interest

This section discusses events in Categories I, II, and III. Appendix B, “Other Events of Interest,” addresses Category IV events.

I. ALL LICENSEES

During this reporting period, two events, one involving an AS licensee and one involving an NRC licensee, were significant enough to be reported as an AO based on Criterion 1, “All Licensees.”

AS18-01 Human Exposure Event at Intertek Asset Integrity Management, Longview, Texas

Criterion I.A.1 (a), “For All Licensees,” 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 total effective dose equivalent (TEDE) of 250 millisieverts (mSv) (25 rem) or more.

Date and Place — July 20, 2018, Longview, TX

Nature and Probable Consequences — Intertek Asset Integrity Management reported a radiation overexposure to a radiographer resulting from operations conducted in June 2018. The licensee’s dosimetry processor stated that the radiographer's dosimeter read 375 mSv (37.5 rem) deep dose equivalent for the month of June 2018. The Radiation Safety Officer (RSO) stated that the dosimeter report indicated that the exposure was irregular, meaning the assessed dose exceeded normal bounds. The dosimeter was reprocessed, and the second reading was consistent with the initial reading. After consulting with the Radiation Emergency Assistance Center/Training Site (REAC/TS), the RSO received analysis results on August 14, 2018 for blood samples sent to REAC/TS which were consistent with the dosimetry readings that an overexposure occurred. The RSO initially thought the exposure was due to a misplaced dosimetry badge. The corporate RSO travelled to the location where the radiographer worked to interview personnel. The radiographer stated that the badge had not been misplaced but was left in the radiography truck a few times on days off. The radiographer reported that his pocket dosimeter did read off-scale high following one work assignment; however, he documented a false reading on his exposure record. The radiographer was removed from all duties that would give any additional exposure to ionizing radiation. The radiographer's co-worker's dosimeter indicated normal results. The licensee does not expect any adverse health effects to the radiographer from this event.

Cause(s) —The radiographer did not follow company operating and safety procedures. He did not complete the required post exposure surveys, and he did not report his pocket dosimeter

off-scale reading upon occurrence. He could not recall any time he had equipment issues or malfunctions.

Actions Taken To Prevent Recurrence

Licensee — The RSO sent out an alert to remind personnel to be safety-conscious.

The licensee held meetings with all employees to restate that all readings on pocket dosimeters must be recorded as read on the device. Any unusual readings are to be reported immediately.

State —The Texas Department of State Health Services investigated the incident and concurred with the exposure results for the radiographer. The licensee and radiographer were cited for failure to perform surveys, failure to control exposure, failure to cease work, and failure to report dosimeter off-scale readings and inaccurate dosimetry recording. The department has completed its investigation of the event.

This event is closed for the purpose of this report.

NRC18-01 Stolen Industrial Radiography Camera from Prime NDT Services, Inc., Ripley, West Virginia

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 — September 1, 2018, Ripley, WV

Nature and Probable Consequences — Prime NDT Services, Inc. reported the theft and recovery of an industrial radiography camera containing 3.996 terabecquerel (TBq) (108 Curie (Ci)) of iridium-192, which exceeds the threshold for a Category 2 quantity of radioactive material.

On September 1, 2018, two employees were transporting an industrial radiography camera in Ripley, West Virginia. During a stop at a convenience store, the two employees left their vehicle, which contained the radiography camera, unattended. The keys to the vehicle were inside and the vehicle was left unlocked. While the employees were inside the store, the truck was stolen. Immediately upon realizing the vehicle was missing, the employees told the convenience store clerk, who called the police. The vehicle was found by police less than three hours later. The licensee responded to the location of the truck and recovered the vehicle. The licensee determined that the camera was still locked within the back of the truck and had not been tampered with. There was no radiological impact to the public or employees.

Cause(s) — Licensee failed to properly secure the truck while it was unattended.

Actions Taken to Prevent Recurrence

Licensee — Prime NDT Services retrained all radiographers within 30 days of the incident and provided them with more specific procedures associated with truck locking and alarms.

NRC — The NRC conducted a reactive inspection on September 10, 2018, to assess the facts and circumstances of the event. The inspection report was issued on November 15, 2018. An inspection to review the effectiveness of the licensee's corrective actions is scheduled to take place in the first calendar quarter of 2019.

This event is 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, Criterion II, “Commercial Nuclear Power Plant Licensees.”

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

During this reporting period, two events at NRC licensee facilities and 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."

AS18-02 Medical Events at University of Mississippi in Jackson, Mississippi

This case occurred in FY 2017 prior to the publication of the updated AO criteria in the *Federal Register* on October 2, 2017. Therefore, the previous criteria language applies to this event. More specifically, the 2006 AO Criteria III.C.1(b) and III.C.2(b)(iii) stated, in part, that a medical event shall be considered for reporting as an AO if it results in a dose equal to or greater than 10 Grays (Gy) (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site. While the event occurred in FY17, the NRC staff completed its evaluation of the event in FY18.

Date and Place — November 8, 2016, through August 15, 2017, Jackson, MS

Nature and Probable Consequences — On August 23, 2017, the University of Mississippi reported that four patients were treated between November 8, 2016, and August 15, 2017, for cervical cancer with an iridium (Ir)-192 source in an Elekta Nucletron Model microSelectron®-high dose rate (HDR) remote afterloader brachytherapy unit. The written directives prescribed doses of 28 Gy (2,800 rad) for three patients and 27 Gy (2,700 rad) for one patient to be delivered in four separate fractions to the base of the uterus using a tandem and ring applicator. Each dose fraction was to be delivered with a source step size of 5 millimeters (mm) for the tandem and 2.5 mm for the ring. However, during a post treatment plan review of the four patients, the licensee determined that the administered source step size was 5 mm for both the ring and tandem in at least one fraction for each patient. The difference in the source step size caused the source to dwell at incorrect positions as the source stepped through the ring applicator, compounding the difference in each step. As a result, the later dwell positions shifted into the shaft of the ring applicator and proximal to the vaginal surface (wrong treatment site), resulting in a doses greater than 10 Gy in at least one fraction per patient to the patients' vaginal canals.

The following table provides the calculated dose based on isodose lines that each patient received in the vaginal canal because of the incorrect source step size. The dose to the vaginal canal was higher than the prescribed dose to the treatment site, the base of the uterus, because of the difference in geometry and volumes.

Patient	Number of Fractions with Incorrect Source Step Size	Dose to Vaginal Canal (wrong treatment site) per Affected Fraction
A	3	>10 Gy per fraction
B	3	>10 Gy per fraction
C	2	>10 Gy per fraction
D	1	>14 Gy per fraction

The referring physician and patients were notified and the patients were scheduled for individual appointments to discuss their cases. The licensee does not expect any adverse health effects from these events to the patients.

Cause(s) — The licensee used Oncentra® Brachy treatment planning software (TPS) with the microSelectron® HDR remote afterloader to treat these four patients. During the affected fractions, the licensee used a default applicator module in the software, which incorrectly set the source set size for the ring to 5 mm instead of the intended 2.5 mm.

Actions Taken To Prevent Recurrence

Licensee — The licensee informed Elekta, the manufacturer of the afterloader and TPS, of the software issue on August 17, 2017. In addition, the licensee suspended use of the tandem and ring applicator model within the TPS and will perform calculations for all catheters used for the tandem and ring applicator manually until notified of Elekta's software correction.

Manufacturer — In July 2017, Elekta was informed that, while performing quality assurance testing, three other users found that the TPS changed the default setting to 5 mm instead of the intended 2.5 mm. Elekta was in the process of writing a field safety notice to send to all of its users when it learned of the University of Mississippi event on August 17, 2017. Elekta sent the field safety notice on August 18, 2017, to its users. The field safety notice recommended use of only the default source step size with microSelectron® afterloaders until an upgrade to the software is available. Elekta strongly advised users to perform proper quality assurance for all treatment plans before delivering the first fraction to the patient. Additionally, Elekta issued a statement to all of its customers on August 22, 2017, that they will temporarily stop the delivery of applicator modeling software. Elekta issued an update to the Oncentra Brachy TPS which contained a patch to prevent recurrence.

State — On August 17, 2018, the Mississippi State Department of Health, Division of Radiological Health, forwarded the Elekta field safety notice to all Mississippi radioactive material licensees that possess a microSelectron® HDR. The Mississippi State Department of Health, Division of Radiological Health, conducted a reactive inspection of the licensee on September 1, 2017.

NRC — The NRC was notified by another AS licensee that this software issue caused 5 similar medical events at its institution between March 6, 2017, and June 13, 2017. This licensee discovered these events after they received the notification from Elekta on August 22, 2017. While these events were medical events as the patients received dose to areas other than the treatment site, the doses from these events did not meet the AO criteria. To ensure all applicable licensees were notified of the software issue, the NRC mailed the Elekta field safety notice to its medical licensees and ensured all NRC licensees who have the microSelectron® HDR remote afterloader were sent the notifications from Elekta. The NRC also informed all AS.

This event is closed for the purpose of this report.

NRC18-02 Medical Event at Centro De Radioterapia at Hospital Auxilio Mutuo, Hato Rey, Puerto Rico

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 to the wrong treatment site.

Date and Place — January 24, 2018, Hato Rey, PR

Nature and Probable Consequences — On February 8, 2018, Centro De Radioterapia at Hospital Auxilio Mutuo reported that a patient undergoing a gynecological HDR remote afterloader treatment with Ir-192 received a dose that was at least 10 Gy (1,000 rad) more than expected to the wrong treatment site. The written directive prescribed three fractions of 400 centigrays (cGy) (rad) each for a total of 1,200 cGy (rad) to a depth of 5 centimeters (cm) to the vaginal cuff. On January 24, 2018, before administration of the third fraction, the attending nurse noticed a skin reaction on the patient's inner thighs. At that time, the radiation oncologist did not suspect a radiation burn and administered the third treatment fraction. On February 6, 2018, the patient's referring physician noted that the affected area on the patient's thighs had progressed to moist desquamation, which is indicative of radiation injury. The licensee determined that, based on the area of the skin involved, one entire treatment fraction was delivered to the thigh and not to the vaginal cuff as prescribed. The dose estimate for the patient's skin on the thigh directly in contact with the surface of the catheter is between 5154 cGy (rad) and 8555 cGy (rad), where the dose should have been minimal according to the treatment plan. The patient and referring physician were notified of the event. The licensee, referring physician, and consulting physician do not expect any adverse health effects to the patient from this event.

Cause(s) — The licensee believes that the catheter slid out of the segmented cylinder applicator and ended up between the thighs of the patient during the treatment. When the applicator and catheter are properly assembled, the catheter is fixed in place by a pressure coupling and a locking nut. During its investigation of the event, the licensee determined that the locking nut likely became loose, possibly due to inadequate catheter set up, which allowed the catheter to slide out of the applicator and irradiate the thigh instead of the vaginal cuff. A contributing factor to the cause of the event was the method the licensee used to position the patient for treatment after verifying the proper placement of the cylinder applicator. The licensee believes that the process of lowering the legs to the table and securing the feet together could have resulted in displacement of the catheter, the applicator, or both.

Actions Taken To Prevent Recurrence

Licensee — The licensee implemented the following corrective actions:

- revised its procedures for HDR treatments using the cylinder applicator and specified that only the authorized user (AU) was to assemble and place the cylinders into the patient until further notice
- trained all HDR personnel in its commitment to patient safety and discrepancy recognition during procedures

- established a safety monitoring committee that met weekly to review and track patient conditions and treatments
- retrained all HDR personnel on the use of the segmented cylinder set
- trained all HDR personnel on the use of the revised protocol for HDR cylinder treatments, including a revised checklist to require personnel to initial as tasks were performed during treatments

NRC — The NRC conducted reactive inspections on February 13–14 and June 21, 2018. In addition, the NRC contracted the services of a medical consultant to perform an independent review of the medical event. The medical consultant concluded that the acute skin reaction (i.e. moist desquamation) was resolved by May 1, 2018. Small cosmetic changes to the skin are likely, but the risk for functional effects or tissue necrosis is low. The NRC's medical consultant agreed with the licensee's assessment of (1) cause, (2) effect on the patient, (3) the appropriateness of the licensee's immediate action on discovery, and (4) corrective actions to prevent recurrence. The NRC found the licensee's response to be adequate.

This event is closed for the purpose of this report.

NRC18-03 Medical Event at Missouri Baptist Medical Center in St. Louis, Missouri

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

Date and Place — January 29, 2018, St. Louis, MO

Nature and Probable Consequences — On January 29, 2018, the Missouri Baptist Medical Center reported that a patient undergoing treatment to the left breast using a Varian Medical Systems, Inc., Model GammaMed Plus *ix* HDR remote afterloader with Ir-192 received a dose that was at least 10 Gy (1,000 rad) more than expected to a volume of skin following the first of ten planned fractionated treatments. The intended maximum dose to the skin, in accordance with the written directive, should not have exceeded 425 cGy (rad) in one treatment. After treatment, the licensee determined that a small volume of breast skin received a dose between 1,542 cGy (rad) and 1,899 cGy (rad). The licensee used a Strut-Adjusted Volume Implant applicator for the treatment. After the treatment, it was noted that the dwell times in one catheter appeared unusual. Upon further review of the treatment, the licensee determined that the catheters were labeled incorrectly during the digitization of the applicator, which occurred during the initial treatment planning process. This caused the physical orientation of the catheter within the patient to differ from the digital orientation of the catheter in the TPS. As a result, the higher dwell times that were intended for the treatment site were shifted outward, resulting in a higher-than-intended dose to the skin. The physician cancelled the patient's remaining fractions. The patient and referring physician were notified of the event. The licensee determined that there is a small risk for late skin toxicity (e.g., subcutaneous fibrosis and scarring).

Cause(s) — The licensee determined that the cause of the medical event was operator error in labeling the catheters during treatment planning. After review of the event, the licensee determined that their written procedures did not include adequate, independent verifications to provide high confidence to prevent errors during the treatment planning process.

Actions Taken To Prevent Recurrence

Licensee — As a corrective action to prevent recurrence, the licensee (1) updated its HDR procedures to require a second medical physicist or physician to independently check and verify the identification of the catheter in the TPS, (2) designed and added an HDR plan review checklist to include the second independent review of the HDR treatment plan, including the digitization of the catheter(s) , (3) added the HDR plan review to the departmental quality monitoring program audit, and (4) trained the physicists and radiation oncology physicians on the revised procedures.

NRC — The NRC performed a reactive inspection and found the licensee’s response to be adequate. In addition, the NRC contracted the services of a medical consultant to perform an independent review of the medical event. The medical consultant concluded that there have been no deterministic effects observed as of two months following the incident and that there is a small risk for late toxicity (e.g., subcutaneous fibrosis and scarring). The NRC’s medical consultant agreed with the licensee's assessment of (1) cause, (2) effect on the patient, (3) the

appropriateness of the licensee's immediate action on discovery, and (4) corrective actions to prevent recurrence.

This event is closed for the purpose of this report.

AS18-03 Medical Event at Texas Oncology Professional Association, Austin, 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 to the wrong treatment site.

Date and Place — February 19, 2018, Austin, TX

Nature and Probable Consequences — The Texas Oncology Professional Association reported that a patient undergoing a treatment fraction with an Ir-192 source in a Nucletron Model MicroSelectron-HDR remote afterloader received a dose that was at least 10 Gy (1,000 rad) more than expected to the wrong treatment site. The written directive prescribed 500 cGy (rad) per fraction for five fractions to the vaginal cuff. During digitization of the applicator's 13 channels, channel 12 was digitized twice as the digitization of channel 13 was inadvertently included in channel 12, which caused there to be no dwell positions in channel 13. Despite the mistake, the dose distribution to the critical organs and treatment site and the dose-volume histogram in the TPS appeared as expected to the licensee. The TPS showed the extended length of channel 12 and no dwell positions in channel 13 in the software's planning screen which displays dwell positions. However, the physician approved the plan, and it was transferred from the planning computer to the treatment console computer. The plan, as viewed on the treatment console, showed the length of channel 12 extending 5.5 cm past the treatment site and no dwell positions in channel 13. When the patient returned on February 21, 2018, to receive the second fraction, the medical physicist checked the treatment plan, calculation, and delivery before delivering the fraction, in accordance with the licensee's procedures, and identified that an error had occurred during the first fraction. The licensee's medical physicist and prescribing physician reviewed the treatment plan. The licensee determined that two areas along the vaginal wall (wrong treatment site), a combined volume of approximately 0.5 cc, received 1,000 cGy (rad) or more than the intended dose, which should have been minimal. The patient and referring physician were notified of the event. The licensee does not expect any adverse health effects to the patient from this event.

Cause(s) —The event occurred as a result of the medical physicist rushing to complete the plan and export it to the treatment console to treat a patient who was experiencing discomfort (full bladder). The radiation team was assembled, and the patient was taken to the radiation vault for treatment before plan preparations were completed. The second review of the plan was done in a hurried manner and the digitization error was overlooked.

Actions Taken To Prevent Recurrence

Licensee — The licensee reviewed the event with its clinical staff and physics group. To prevent recurrence, Texas Oncology will make every effort to provide a thorough second check of treatment plans by a medical physicist who has not worked on the plan. The licensee will carefully review each channel in an applicator. The patient will not be brought to the treatment area until the plan is checked and exported to the treatment control computer and treatment data are verified against the planned data. If any doubt arises, the treatment will be delayed until the problem, if any, is resolved,

State — The State of Texas conducted an onsite investigation. It has reviewed the corrective actions the licensee submitted and considers them to be adequate.

This event is closed for the purpose of this report.

AS18-04 Medical Event at University of Pennsylvania, 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 to the wrong treatment site.

Date and Place — May 25, 2018, Philadelphia, PA

Nature and Probable Consequences — On May 25, 2018, the University of Pennsylvania reported that a 17-year-old patient undergoing treatment for neuroblastoma with iodine (I)-131 meta-iodobenzylguanidine (MIBG) received a dose that was at least 10 Gy (1,000 rad) more than expected to the wrong treatment site. The written directive prescribed 30.23 gigabecquerels (GBq) (817 millicuries (mCi)) of I-131. The dosage administered measured 30.86 GBq (834 mCi) and was delivered over the course of 90 minutes in a 50-ml syringe through an automatic pump. The nuclear medicine technologist saw a small amount of blood on the patient's blanket and blood in the port line down to the Spiros connector. At the conclusion of the infusion, the patient indicated that his pants were wet. The licensee staff removed the blanket and pants from the room and surveyed them separately. The survey indicated that the items were contaminated. No decontamination of the patient's skin was performed at that time. Two days after the treatment, the patient reported discomfort and slight reddening on the skin of his upper right thigh. The third day after the treatment, the red patch developed into an open wound. The licensee determined that the patient's skin had been contaminated for approximately 24–48 hours. The licensee stated that because of the large dosage of I-131 infused into the patient, the staff were unable to detect the contamination on the patient's skin separately from the internal activity until erythema developed. The estimated activity delivered to the correct treatment site was determined to be 22.98 GBq (621 mCi). The licensee calculated that approximately 7.77 GBq (210 mCi) had leaked onto the linens and the patient's clothing during the treatment. Based on survey measurements, nuclear medicine imaging, and the patient's clinical symptoms, the dose to the skin was estimated to be between 50,000 cGy (rad) and 120,000 cGy (rad) to a 15-cm^2 area. The licensee's radiation safety staff consulted with Oak Ridge National Laboratory REAC/TS to verify and validate the dose calculations. The AU and the referring physician were informed, and the referring physician notified the patient's mother.

Cause(s) — The cause of the incident is believed to be a faulty connection between the port line and the pressure tubing. The patient was disconnected from the infusion pump to use the bathroom part way through the procedure. This is not typical for this procedure, and the licensee believes that the disconnection and subsequent reconnection of the pump to the patient at the connector was a contributing factor. The manufacturer evaluated the connector and determined there were no manufacturing defects.

Actions Taken To Prevent Recurrence

Licensee — The licensee conducted a full root-cause analysis and developed and implemented the following corrective actions:

- A multidisciplinary I-131 MIBG team with representatives from Nuclear Medicine, Environmental Health & Radiation Safety, Nursing and Oncology has been established. The team will meet regularly to review and update policies and procedures for I-131 MIBG therapies. Some immediate steps taken include the following:

  - use of absorbent chux under the administration line over the patient's body
  - change to the administration procedure to require that the infusion not be stopped unless medically necessary and determined by the AU
  - implementation of continuous patient observation during administration including evaluation of the use of portable video monitoring
  - implementation of a new procedure to address patient fluid management before and during infusion
  - review of the infusion system with a focus on the Spiros connector, including additional training on its use

- Patient-specific decontamination procedures have been developed for each MIBG treatment. Since decontamination procedures must consider the patient's age and medical condition, the medical staff has had significant input into the procedures for these patients. The licensee will use the knowledge gained from the patient-specific decontamination procedures to refine the decontamination standard operating procedure.

- Testing has begun to find a system that can accurately detect contamination when contamination is suspected during therapeutic treatment in which an activity on the skin that would result in desquamation with as little as 0.002 percent of the dose.

- Radiation safety incident response procedures have been revised to include a time out and immediate involvement of additional health physics staff during incidents, including during possible medical events. The revision is aimed at ensuring physicists focus on all aspects of the incident response and to prevent the medical event reporting requirements from taking attention away from patient care.

State — The Pennsylvania Department of Environmental Protection performed a reactive inspection on June 6 and June 13, 2018. The State reviewed the licensee's corrective actions and will evaluate their implementation at the next routine inspection. The State is supporting the NRC in the development of a generic communication to inform other licensees of the potential contamination risks associated with this treatment.

This event is closed for the purpose of this report.

AS18-05 Medical Event at Southwestern Regional Medical Center (doing business as Cancer Treatment Centers of America), Tulsa, Oklahoma

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 to the wrong treatment site.

Date and Place — June 6, 2018, Tulsa, OK

Nature and Probable Consequences — On June 6, 2018, Southwestern Regional Medical Center (doing business as Cancer Treatment Centers of America) reported that a patient undergoing treatment for liver cancer with yttrium (Y)-90 microspheres (Sirtex Medical model SIR-Spheres) received a dose that was at least 10 Gy more than expected to the wrong treatment site. The written directive prescribed 1.35 GBq (36.38 mCi) of Y-90 microspheres to the right lobe of the liver. Following the treatment, a subsequent single photon emission computerized tomography scan revealed that the microspheres were delivered to the left lobe of the liver. The licensee determined that the left lobe received a dose of 11,080 cGy (rad). The dose to the left lobe should have been minimal. The referring physician and patient were notified of the event. The licensee reported that no adverse health effects are expected from the additional dose.

Cause(s) — The cause was human error. The interventional radiologist (IR) who performed the arterial mapping for catheter placement and subsequent administration of the Y-90 noted that the patient's hepatic arterial anatomy was atypical, in that the left and right hepatic arteries appeared identical in fluoroscopic images. A different IR who administered the dose was not aware of this fact. A partial hepatic angiogram did not adequately distinguish between the two arteries. The IR accidentally placed the catheter in the left hepatic artery instead of the right hepatic artery.

Actions Taken To Prevent Recurrence

Licensee — The licensee has changed its procedures to require that the same IR perform the arterial mapping and administer the dose within the same week. When possible, the IR will also perform a full hepatic angiogram before administration.

State —The State of Oklahoma Department of Environmental Quality performed a reactive inspection of this event. The State considers the licensee's corrective actions to be adequate.

This event is closed for the purpose of this report.

AS18-06 Medical Event at Central Texas Medical Specialists, Austin, Texas

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

Date and Place — July 10, 2018, Austin, TX

Nature and Probable Consequences — On July 10, 2018, Central Texas Medical Specialists reported that a patient undergoing treatment for vaginal cancer using an HDR remote afterloader using Ir-192 received a dose that was at least 10 Gy (1,000 rad) more than expected to a volume of the vagina during one of the fractionated treatments. The written directive prescribed a six-fraction dose of 350 cGy (rad) per fraction. After treatment, the licensee determined that the patient received 2,100 cGy (rad) during the first fraction. The medical physicist noticed that the total treatment value (2,100 cGy (rad)) was incorrectly entered into the TPS. The radiation oncologist was notified, who then notified the referring physician and patient. The overall brachytherapy plan was modified, and the volume treated in the first fraction was considered complete. The patient will not receive further treatment. The licensee reported that no adverse health effects are expected because of the event, but the radiation oncologist plans to follow the patient closely.

Cause(s) — The licensee indicated that human error and poor decision making caused the medical event. A busy work schedule that day led to starting the first fraction after normal working hours. Despite the unavailability of a second medical physicist to independently review the dose-per-fraction data entered into the TPS, the medical physicist decided to develop the treatment plan, transfer the plan to the treatment console, and conduct the procedure without ensuring a second check of the plan parameters, including the dose, in accordance with the licensee's procedures.

Actions Taken To Prevent Recurrence

Licensee — The licensee has modified its procedures to make three significant changes. First, a medical physicist, different than the one who planned the case, will conduct an enhanced independent review of the treatment plan parameters at the treatment planning console. Second, the treatment team will conduct an enhanced "time out" at the treatment console to check the patient name, dose and prescription, source activity, and prescription number. Finally, a medical physicist will verify that the exported treatment plan from the planning console matches the plan at the treatment console. In addition to these changes, the Radiation Safety Committee and Root Cause Analysis Team met in late August 2018 to continue an ongoing comprehensive review and discussion of the policies and procedures and to look for additional opportunities for improvement.

State — The Texas Department of State Health Services conducted an onsite investigation in early August 2018. The department completed its investigation, citing one violation.

This event is closed for the purpose of this report.

AS18-07 Medical Event at Oregon Health & Science University, Portland, Oregon

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

Date and Place — August 9, 2018, Portland, OR

Nature and Probable Consequences — On August 9, 2018, the Oregon Health & Science University reported that a patient undergoing treatment for liver cancer using Y-90 microspheres (Nordion model TheraSphere) 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 13,600 cGy (rad) of Y-90 to the liver. After treatment, the licensee determined that the patient received an activity of 3.841 GBq (103.8 mCi), resulting in a dose of 29,400 cGy (rad) of Y-90 to the liver.

On August 8, 2018, the nurse manager verified that the nuclear medicine staff had received the patient's intended Y-90 microsphere dose. However, the nuclear medicine staff received a second Y-90 dose on August 9, 2018, that was to be used for a different patient the following week. The nuclear medicine technician took that second dose, opened it, and measured it without checking the printed code on the shipping box, which included the patient's initials. The RSO performed the dose calibrator reading and a decay calculation based on the manufacturer's calibration data sheet associated with the second dose. Both agreed within 10 percent. However, the results were not compared with the written directive before administration. The licensee performed post-delivery calculations that showed the wrong dose had been delivered to the patient, confirming it as a medical event. The patient then received a post administration scan, which indicated that the dose had stayed within the liver. The referring physician and patient were notified of the incident. As of November 11, 2018, the patient has responded well to the initial treatment and has shown no adverse effects.

Cause(s) — The licensee indicated that several factors contributed to the medical event. First, the staff failed to follow procedures by not comparing the dose calibrator activity to the prescribed activity on the written directive. Second, the staff failed to follow procedures for verifying which dose was for which patient by not checking the patient initials on the dose shipping box before selecting the dose.

Actions Taken To Prevent Recurrence

Licensee — The licensee's corrective actions include updating its procedures for Y-90 microsphere administration and training the staff on the updated procedures. The new procedures require the nuclear medicine technologist to write the calibrator data on the written directive form and compare the data with the "Required Activity" value on the form. The nuclear medicine technologist also will use an online calculator and manufacturer calibration data sheet to determine actual activity. Having one individual perform the steps to ensure the correct dosage is being delivered to the IR staff (i.e. the activity comparison, calculation of decay, and bringing the dose to the IR staff) will provide an additional assurance to prevent recurrence.

In addition, the individual who delivers the dose for administration will verbally confirm the pre-procedure readings on the written directive with the nurse who sets up the delivery box.

State — Oregon Radiation Protection Services met with the licensee to discuss root causes and revisions to the program. Oregon Radiation Protection Services recommended the procedure updates and training, with an emphasis on double checking patient identity and dose at every stage of the procedure. The State issued violations. The licensee's corrective actions were found to be acceptable to Oregon Radiation Protection Services

This event is closed for the purpose of this report.

AS18-08 Medical Event at University of Utah, Salt Lake City, Utah

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 to the wrong treatment site.

Date and Place — June 14, 2018, Salt Lake City, UT

Nature and Probable Consequences — On June 14, 2018, the University of Utah reported that a patient undergoing treatment for prostate cancer with palladium (Pd)-103 seeds received a dose that was at least 10 Gy (1,000 rad) more than expected and was administered to the wrong treatment site. The written directive prescribed the implantation of 54 Pd-103 seeds, containing a total activity of 4 GBq (108.167 mCi). The prescribed dose was 125 Gy (12,500 rad) to the entire prostate volume. The AU implanted the seeds using a Foley catheter under guided ultrasound. The patient returned on June 15, 2018, for a post treatment computer tomography (CT) scan to verify the placement of the seeds. The CT scan revealed that 32 of the seeds had been implanted outside of the prostate. The licensee determined that 186.77 Gy (18,677 rad) was delivered to 3 cc of rectal tissue (wrong treatment site). This rectal tissue should have received a minimal dose. The licensee determined that there is a risk of radiation damage in the rectum and surrounding tissue from this dose. The patient and referring physician were notified of the event.

Cause(s) — The licensee determined that the dose to the wrong treatment site was caused by a poorly placed Foley catheter. The catheter balloon was inflated in the prostatic-urethra instead of the bladder, as intended. The licensee determined that the ultrasound guidance was compromised because the ultrasound unit defaulted to a magnified view of the surrounding area.

Actions Taken To Prevent Recurrence

Licensee — The licensee has implemented specific training for its physicians and other participating staff on how to prevent and recognize when a Foley catheter balloon is inflated in the urethra, especially in the presence of unusual urethral/bladder anatomy. The licensee contacted the ultrasound manufacturer, which changed the default magnification of the ultrasound unit to a value that allows for initial visualization of the relevant prostate anatomy in its entirety. In addition to employee training and equipment changes, the licensee has also implemented policy changes. Before insertion of the seed needle, using the widest field of view as possible, both sagittal and axial ultrasound images will be obtained to validate Foley catheter balloon placement. Both the AU and the medical physicist will audibly concur that the image quality is sufficient for proceeding with the implant, and the medical physicist will document this in the operative reports or treatment records. After the first radioactive seed is implanted in the patient, a fluoroscopic image will be obtained to validate that the relative position of the seed and the Foley catheter is as anticipated in the treatment plan.

State — The State of Utah performed a followup inspection that concentrated on review of the licensee's training provided to the AUs and medical physicists. The State had no further concerns about the licensee's corrective actions.

This event is closed for the purpose of this report.

APPENDIX A
ABNORMAL OCCURRENCE CRITERIA

ABNORMAL OCCURRENCE GENERAL STATEMENT OF POLICY

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

COMMISSION DISSEMINATION OF ABNORMAL OCCURRENCE INFORMATION

The Commission widely disseminates AO reports to the public. The Commission submits an annual report to Congress on AOs at or associated with any facility or activity that is licensed or otherwise regulated by the NRC. This report provides the date, place, nature, and probable consequences of each AO; the cause or causes of each AO; and any action taken by the licensee to prevent recurrence.

Abnormal Occurrence Criteria

An incident or event is considered an abnormal occurrence (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;

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

(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.

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

Abnormal Occurrence Criteria

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

I. For All Licensees[2]

A. Human Exposure to Radiation from Licensed Material.

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,

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[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.

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 U.S. Nuclear Regulatory Commission (NRC) or AS.

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.

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

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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.

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.

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[8] that is judged to be caused by theft or diversion.

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 Safeguards Information that harms the public health and safety.

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

II. Commercial Nuclear Power Plant Licensees

A. Malfunction of Facility, Structures, or Equipment

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

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

3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials that could result in exceeding the dose limits of 10 CFR part 100, “Reactor site criteria,” or five times the dose limits of General Design Criteria (GDC) 19, “Control Room,” in Appendix A, “General Design Criteria for Nuclear Power Plants,” to

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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.”

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).

10 CFR part 50, “Domestic licensing of production and utilization facilities,” could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

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

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

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

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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. ML101400045), green is used for very low safety significance, white is used for low to moderate safety significance, yellow is used for substantial safety significance, and red is used for high safety significance. Reactor conditions or performance indicators evaluated to be red are considered AOs.

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

[13] Any plants assessed by the ROP to be in the unacceptable performance column, as described in NRC Inspection Manual Chapter (IMC) 0305, “Operating Reactor Assessment Program” (ADAMS Accession No. ML15317A147), or under NRC IMC 0350, “Oversight of Reactor Facilities in a Shutdown Condition Due to Significant Performance and/or Operational Concerns” (ADAMS Accession No. ML063400076). This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

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.

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. For 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

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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.

(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:

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

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

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

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

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

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

APPENDIX B
OTHER EVENTS OF INTEREST

This appendix discusses other events of interest that do not meet the criteria for abnormal occurrences (AOs) in Appendix A to this policy statement. 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 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. During this reporting period, no events met the guidelines for inclusion in Appendix B, "Other Events of Interest."

APPENDIX C
UPDATES OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During this reporting period, updated information became available for one abnormal occurrence (AO) event that the U.S. Nuclear Regulatory Commission (NRC) had reported in NUREG-0090, Volume 40, "Report to Congress on Abnormal Occurrences: Fiscal Year 2017," issued May 2018 (FY 2017 AO report). This AO involved a medical event at Providence Alaska Medical Center in Anchorage, AK.

Medical Event at Providence Alaska Medical Center, Anchorage, Alaska (previously reported as NRC17-04 in NUREG-0090, Volume 40, issued May 2018)

Date and Place – June 14, 2017, Providence Alaska Medical Center, Anchorage, AK

Background – On June 14, 2017, a medical event occurred at the Providence Alaska Medical Center (the licensee) involving a patient who underwent yttrium (Y)-90 microsphere brachytherapy treatment of the liver. Based on the treatment plan, the authorized user (AU) intended to administer Y-90 to deliver a dose of 11,000 centigrays (cGy) (rad) to the right lobe of the liver. After the administration of Y-90 to the patient, the licensee determined that the patient had received a total of 54,000 cGy (rad) to the right lobe of the liver. As a result, the radiation dose to the right lobe of the liver was approximately 491 percent of the intended radiation dose from the treatment plan. The NRC conducted an onsite special inspection and performed an independent review of the causal factors that led to the medical event. The FY 2017 AO report discusses the details of the event under Event NRC17-04.

Update on Actions Taken To Prevent Recurrence

Licensee – The licensee's corrective actions included (1) performing a series of audits to identify deficiencies in the licensee's overall radiation safety program, (2) implementing process changes for the preparation and review of written directives, the ordering of Y-90, and the verification of Y-90 activity against the written directive, (3) making staffing changes, (4) retraining staff involved with Y-90 procedures, (5) providing additional oversight to the Y-90 program, (6) engaging the Y-90 vendor to incorporate feedback on the ordering process, and (7) revising its written procedures for administering Y-90.

NRC – On June 25–26, 2018, the NRC performed a follow-up inspection at the licensee facility to review activities since the resumption of the licensee's Y-90 program and to review the licensee's implementation of corrective actions in response to the medical event and the NRC enforcement action. The NRC determined that the licensee had adequately implemented corrective actions for its Y-90 program and that there had been no additional medical events at the facility.

The NRC's physician and medical physicist consultants were unable to predict the potential adverse effects expected to the patient based on the available dosimetric and imaging information, but recommended the patient be medically followed by the licensee. The NRC followed up with the licensee to determine if the patient experienced any adverse effects as a result of the medical event. On April 3, 2018, the licensee stated the patient was being medically followed and had not experienced any significant symptomatic complications as a result of the medical event.

This event is closed for the purpose of this report.

APPENDIX D
GLOSSARY

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

Angiogram[1] — a radiograph made by the radiographic visualization of the blood vessels after injection of a radiopaque substance.

Arterial mapping — mapping of the blood vessels

Authorized user (AU) — 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 (AS) 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 AS 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 Dwell Time – The time a brachytherapy source stays at a single treatment location.

Brachytherapy seed implantation for prostate cancer—a form of radiation therapy for prostate cancer. 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.

Digitization of Brachytherapy Applicator - the process of converting the brachytherapy applicator into digital form for treatment planning.

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

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

Desquamation – Peeling off of skin.

Dose equivalent— 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 roentgen equivalent man (rem) and sievert (Sv).

Effective dose equivalent— as defined in 10 CFR 20.1003, the sum of the products of the dose equivalent to the organ or tissue and the weighting factors 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.

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

High dose-rate remote afterloader — as defined in 10 CFR 35.2, a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1,200 rads) per hour at the point or surface where the dose is prescribed. Remote afterloaders deliver the therapeutic dose to a limited volume by sending a radioactive source to multiple points in an array of implanted catheters or channels of the intracavitary applicator.

Hepatic artery[1] — the main artery that supplies blood to the liver

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

Interventional radiologist[1] — an individual who practices a medical specialty that provides minimally invasive image-guided diagnosis and treatment of disease.

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 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, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in one of the following:

(1) 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 (i) the total dose delivered differs from the prescribed dose by 20 percent or more; (ii) the total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or (iii) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) 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: (i) an administration of a wrong radioactive drug containing byproduct material; (ii) an administration of a radioactive drug containing byproduct material by the wrong route of administration; (iii) an administration of a dose or dosage to the wrong individual or human research subject; (iv) an administration of a dose or dosage delivered by the wrong mode of treatment; or (v) a leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

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.

Neuroblastoma[1] — cancer that forms in nerve cells

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 AU 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 per gram or 0.01 joule per kilogram (0.01 gray).

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- or microwaves, or visible, infrared, or ultraviolet light.

Radiation therapy (radiotherapy)[1] — the treatment of disease with radiation

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," dated March 28, 2014 (ADAMS Accession No. ML18073A209), 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 Sievert).

Shallow dose equivalent— 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 cm (7 mg/cm^2).

Sievert (Sv) — as defined in 10 CFR 20.1004, the unit (expressed in the International System of Units) of any of the quantities expressed as dose equivalent; the dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rem).

Subcutaneous fibrosis[1] — development of excess fibrous connective tissue in an organ under the dermis layer of skin

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

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

Written directive — as defined in 10 CFR 35.2, an AU'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 Ionizing Radiation

QUANTITY	FROM METRIC UNITS	TO NON-SI 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 man (rem)	0.01
	centisievert (cSv)	rem	1.0
	millisievert (mSv)	rem	10
	mSv	millirem (mrem)	0.01
	microsievert (μSv)	mrem	10