

Event Detail - Abnormal Occurrence

ITEM #: 950291 **AO #:** NRC 95-04 **EVENT DATE:** 03/14/1995
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT THE UNIVERSITY OF VIRGINIA, IN CHARLOTTESVILLE, VIRGINIA
NAME: University of Virginia Medical Center **CITY:** Charlottesville **STATE:** VA

Nature and Probable Consequences:

A patient was prescribed a manual brachytherapy procedure using cesium-137 (Cs-137) sources loaded in an applicator, for a total gynecological treatment dose of 3000 centigray (cGy) (3000 rad).

During insertion of the applicator into the patient, one of the sources fell onto the patient's bed and was unnoticed by the license staff involved in performing the procedure. A nurse found the source in the bed on March 15 and removed it. The source was reloaded into the applicator and the physician revised the prescribed dose to 2500 cGy (2500 rad). The licensee estimated that source remained at approximately 10 centimeters (4 inches) from the patient's foot for 18 hours and delivered a dose of about 1 cGy (13 rad) to the foot.

The licensee notified the referring physician and the patient of the misadministration. An NRC medical consultant was obtained who concluded that the patient was receiving appropriate follow-up care. In addition, the licensee and the medical consultant concluded that the patient will not experience any adverse health effects as a result of the misadministration.

Cause:

The licensee's staff involved in the brachytherapy procedure were not familiar with handling of the applicator that contained the Cs-137 sources. Also, because of anatomic characteristics of the patient, the physician had difficulty inserting the source carrier into the applicator. The design of the afterloading device allows the source to slide out of the carrier if any unusual manipulation of source carrier is required. The difficulty experienced by the physician in inserting the source in the applicator and the design of source carrier resulted in the source falling out of the carrier during the insertion process.

Licensee Action:

The licensee provided training for its staff, involved in brachytherapy procedures, concerning the precautions which must be taken when handling an applicator such as the one used in the subject procedure. Also, emphasis was placed on the need to be more attentive during the source insertion process in order to account for all prescribed sources.

NRC Action:

NRC conducted a special inspection on March 23-24, 1995, to review the circumstances surrounding the misadministration. The inspection report was issued on May 2, 1995. Enforcement action will be taken as appropriate.

This event is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported in the Federal Register. Appendix A (see Event Type 3 Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

ITEM #: 950645 AO #: NRC 95-05 EVENT DATE: 05/09/1995
TITLE: MEDICAL THERAPEUTIC RADIOPHARMACEUTICAL MISADMINISTRATION OF IODINE-131 AT MASSACHUSETTS GENERAL HOSPITAL IN BOSTON, MASSACHUSETTS
NAME: Massachusetts General Hospital CITY: Boston STATE: MA

Nature and Probable Consequences:

A patient was prescribed a 296 megabecquerel (MBq) (8 millicurie [mCi]) dosage of iodine-131 (I-131) for hyperthyroidism; however, a dosage of 1106.3 MBq (29.9 mCi) was administered.

Representatives of the hospital informed the referring physician and the patient of the misadministration. An NRC medical consultant was obtained to evaluate the event and stated that the higher dosage given to the patient will result in a more likely achievement of the intended therapeutic goal to eliminate the patient's hyperthyroidism. Additionally, the consultant determined it is unlikely that the patient is at significant risk of experiencing long-term consequences from receiving the higher dosage beyond the risk associated with the prescribed dosage. Therefore, the impact on the patient's health is expected to be negligible with no expected long-term disability. (The intent of the prescribed dose was to ablate the portion of the thyroid remaining after surgery then support the patient with thyroid supplement the rest of her life. This did not change with the administered dose.)

Cause:

The licensee stated that this event occurred because of a human error. The technologist involved in this procedure inadvertently switched the labeled lids on the vial shields containing the I-131 dosages prescribed for different patients. Additionally, the technician failed to check for the correct dosage on the vial label, and the wrong dose was administered to the intended patient.

Licensee Action:

The licensee instituted a procedure for checking the vial label before giving a dose. In addition, the licensee is obtaining a second dose calibrator which will be used in the out-patient dosing room of the Thyroid Clinic. Each dose will be re-assayed immediately before the I-131 is administered to the patient, rather than relying on the assay which was performed in the Thyroid Lab before the dose was transported to the outpatient dosing room.

NRC Action:

NRC performed an inspection on May 12, 1995, to learn about the event and determined that it constituted a misadministration as defined in 10 CFR 35.2. NRC determined that this was an isolated violation of the licensee's Quality Management Program and issued a Notice of Violation at the Severity Level IV on June 26, 1995. This event is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5 [a] in Table A-1) of this report notes that administering a therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent and the actual dose is greater than 1.5 times the prescribed dose can be considered a AO.

ITEM #: 950755 AO #: NRC 95-06 EVENT DATE: 05/09/1995
TITLE: MULTIPLE MEDICAL BRACHYTHERAPY MISADMINISTRATIONS AT MADIGAN ARMY MEDICAL CENTER IN FORT LEWIS, WASHINGTON
NAME: Madigan Army Medical Center CITY: Fort Lewis STATE: WA

Nature and Probable Consequences:

Four patients were prescribed brachytherapy procedures, using iridium-192 seeds of different source strengths, and received doses other than those prescribed because of the same computer input error. (The same computer input error could cause either underdoses or overdoses because the algorithm used was dose dependent.) Details of the misadministration are as follows:

Patient A: The patient was prescribed a dose of 2800 centigray (cGy) (2800 rad) for a gynecological brachytherapy treatment, but received a dose of about 1680 cGy (1680 rad) instead. (Event Date 05/09/95)

Patient B: Event 1 - The patient was prescribed a dose of 1600 cGy (1600 rad) for lung treatment, but received a dose of about 2128 cGy (2128 rad) instead. (Event Date 02/09/94)

Event 2 - On another day, the same patient was prescribed a dose of 1500 cGy (1500 rad) for lung treatment, but received a dose of about 2350 cGy (2350 rad) instead. (Event Date 01/11/95)

Patient C: The patient was prescribed a dose of 3000 cGy (3000 rad) for gynecological treatment, but received a dose of about 5142 cGy (5142 rad) instead. (Event Date 08/23/94)

Patient D: The patient was prescribed a dose of 1500 cGy (1500 rad) for a biliary tract treatment, but received a dose of about 2050 cGy (2050 rad) instead. (Event Date 02/03/95)

The licensee does not expect the patients to experience any adverse health effects as a result of the misadministrations.

Cause:

Based upon NRC's initial review of the misadministrations, it appears that the probable causes of the treatment errors were failure to: (1) independently review or check the data input to the computerized treatment planning system, and (2) perform an independent check of dose rate calculations generated by the treatment planning system.

Licensee Action:

The physics staff at MAMC promptly corrected the data entered into the computer treatment planning computer, recalculated the doses received by the patients, and took steps to ensure that appropriate data will be used for future treatment plans.

NRC Action:

NRC initiated an inspection on June 6, 1995, to review the circumstances associated with the misadministrations and to review the licensee's corrective actions. (As of the date of this report, the inspection is ongoing.) An NRC medical consultant will review each case in order to provide an independent assessment of the potential consequences of the overdoses.

This event is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5[d] in Table A-1) of this report notes that administering a therapeutic dose from a sealed source such that the treatment dose differs from the prescribed dose by more than 10 percent and the event (regardless of health effects) affects two more patients at the same facility can be considered an AO.

ITEM #: 950290 AO #: AS 95-02 EVENT DATE: 03/14/1995

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION BY MOBILE TECHNOLOGY, INC., AT IRVINE MEDICAL CENTER IN IRVINE, CALIFORNIA

NAME: Irvine Medical Center CITY: Irvine STATE: CA

Nature and Probable Consequences:

A patient was prescribed a brachytherapy treatment to the left lung using a high dose rate (HDR) remote afterloading unit. However, because of an error the patient received 800 centigray (800 rad) to the right lung.

The patient and the referring physician were informed of the misadministration. The patient's physician stated that based on a five year survival rate the change of clinically noticeable complications would be extremely low, and no significant change in lung function could be measured with the dose given to the right lung. a dose of this type may eventually cause a drying out of the luminal mucosal cells in that region, resulting in a "dry cough."

Cause:

A chest x-ray showing that the HDR remote afterloading unit's positioning catheter was erroneously placed in the right lung was reviewed by either the pulmonologist or the radiation oncologist.

Licensee Action:

The licensee took the following actions to prevent recurrence: (1) real-time fluoroscopy will be used at the time of the bronchoscopy; (2) a guide wire will be utilized within all bronchial catheters at the time of the bronchoscopy; (3) a chest x-ray will be obtained and reviewed by the participating physicians immediately following the bronchoscopy and catheter insertion, and prior to patient transport to the brachytherapy unit; and (4) confirmation of the intended treatment site will be obtained from the patient consent form and through verbal communication with the pulmonologist, radiation oncologist, patient, and unit staff members.

NRC Action:

Other Agency Action:

The State Agency requested that the licensee take the above corrective actions.

This event is considered closed for the purpose of this report.

Criteria:

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

ITEM #: 950451 AO #: AS 95-03 EVENT DATE: 04/06/1995
TITLE: OVEREXPOSURE OF PERSONNEL AT GWINNETT MEDICAL CENTER IN LAWRENCEVILLE, GEORGIA
NAME: Gwinnett Medical Center CITY: Lawrenceville STATE: GA

Nature and Probable Consequences:

Licensee personnel involved in a brachytherapy treatment using iridium-192 seeds received exposures above minimum as a result of handling what they assumed was a dummy source. The personnel included physicists, physicians, technologists and nursing staff. One of the physicists was pregnant (estimated at 11 weeks), but did not receive any significant overexposure. The most significant case was an overexposure to Physicist A who received 8.83 millisievert (mSv) (883 millirem [mrem]) effective dose equivalent and 12,560 mSv (1256 rem) to the hands. Exposures for other involved individuals were as follows:

Physicist B: 1.15 mSv (115 mrem) effective dose equivalent and 433 mSv (43.3 rem) to the hands

Physician A: 1.08 mSv (108 mrem) effective dose equivalent and 54 mSv (5.4 rem) to the hands

Physician B: 0.31 mSv (31 mrem) effective dose equivalent and 108 mSv (10.8 rem) to the hands

Technologist: 1.55 mSv (155 mrem) effective dose equivalent

It should be noted that physicist A has not shown any signs of erythema.

Cause:

The licensee stated that the overexposures occurred because: (1) the hospital procedures were not followed when ordering the radioactive material; (2) the personnel handling the iridium-192 seeds assumed that they were dummy sources; (3) the physicist who primarily handled the sources did not have proper training and experience, or adequate supervision during the performance of the treatment; (4) a survey meter was not used while opening the shipping container; (5) film badges were not worn or were worn improperly; (6) there was confusion among the physicists as to whether a dummy source was ordered; (7) there were problems identifying the dummy source from the radioactive seeds, and (8) the source was left unshielded after being returned to the shipping container.

Licensee Action:

The licensee addressed the issues involving the incident, and either has or will implement corrective actions to prevent recurrence. Exposure dose calculations have been made by a certified health physicist. The personnel training and accreditation program has been modified. Physicist A and Physicist B have received inservice training and were advised not to handle any radioactive material until May 1996.

NRC Action:

Other Agency Action:

The Department of Natural Resources of the State of Georgia investigated the incident. The corrective and preventative actions submitted by the licensee will be reviewed during the next inspection by the Department. Enforcement action will be taken as appropriate.

The event is considered closed for the purpose of this report.

Criteria:

Appendix A (see For All Licensees, Criterion No. 1) of this report notes that exposure of the feet, ankles, hands or forearms of an individual to 375 rem or more of radiation can be considered an AO.

ITEM #: 950065 AO #: AS 95-04 EVENT DATE: 07/28/1994

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT SOUTHWEST TEXAS METHODIST HOSPITAL IN SAN ANTONIO, TEXAS

NAME: Southwest Texas Methodist Hospital CITY: San Antonio STATE: TX

Nature and Probable Consequences:

Two patients were prescribed brachytherapy procedures using manual loading for prostate treatment. One prescribed to receive dose of 160 gray (Gy) (16,000 rad) of iodine-125 and the other was prescribed a dose of 115 Gy (11,500 rad) of palladium-103. However, because of an error the implant sources of the two patients were switched.

The patients and their referring physician were notified of the misadministration. The licensee staff indicated that the two doses were biologically equivalent and stated that the only effects expected are those that would result if the prescribed doses were administered to the correct patients.

Cause:

The licensee was unable to determine how the misidentification occurred.

Licensee Action:

The Radiation Safety Committee immediately implemented new procedures for ordering, receiving, loading, sterilizing, and implanting prostate implants.

NRC Action:

Other Agency Action:

The State Agency investigated the incident and reviewed the new procedures of prostate implants. No violations were cited.

This event is considered closed for the purpose of this report.

Criteria:

Appendix A (see Event Type 5[d] in Table A-1) of this report notes that administering a therapeutic dose from a sealed source so that the treatment dose differs from the prescribed dose by more than 10 percent and the event (regardless of health effects) affects two or more patients at the same facility can be considered an AO.

ITEM #: 960191 AO #: AS 95-01 EVENT DATE: 05/23/1993
TITLE: MEDICAL TELETHERAPY MISADMINISTRATION AT AN "UNSPECIFIED LICENSEE" IN NEW YORK, NEW YORK
NAME: Unspecified Licensee CITY: New York STATE: NY

Nature and Probable Consequences:

A patient was prescribed a total dose to the right superclavicular area and spine of 2400 centigray (cGy) (2400 rad) using cobalt teletherapy equipment. During simulation, the technologist erroneously placed the preparatory tattoo marking the treatment area on the wrong side of the patient. The patient consequently received a dose of 900 cGy (900 rad) to the left superclavicular area which was the wrong treatment site. The patient was then resimulated and the treatment to the correct site was administered as prescribed.

The licensee informed referring physician of the misadministration, and the referring physician chose not to inform the patient. The licensee also stated that no adverse health effects resulted from the misadministration.

Cause:

The misadministration occurred because the licensee staff marked the wrong treatment area on the patient during a simulation preparation for treatment.

Licensee Action:

The licensee issued a notice to all of its personnel concerning the importance of accurate marking of treatment areas. Also, residents, physicists, technologists, and attending staff were reminded that the treatment remarks in patient charts should accurately reflect the original prescription. In-service training was held concerning the issues, and the applicable procedures covering treatment prescriptions and field markings were revised.

NRC Action:

Other Agency Action:

Acting under authority granted by the State Agency, the New York City Bureau of Radiological Health investigated the misadministration and submitted its investigative reports to NRC. The reports contained information about the licensee's actions to prevent recurrence.

This event is considered closed for the purpose of this report.

Criteria:

Appendix A (see Event Type in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

ITEM #: 900051 AO #: NRC 90-02 EVENT DATE: 01/17/1990
TITLE: MEDICAL THERAPY MISADMINISTRATION
NAME: Monongahela Valley Hospital CITY: Monongahela STATE: PA

Nature and Probable Consequences:

On January 17, 1990, the licensee notified NRC Region I by telephone that earlier that day a cesium-137 brachytherapy source become dislodged from its applicator while a patient was undergoing treatment for uterine cancer.

During the treatment, a malfunction of a remote afterloading brachytherapy irradiator occurred. The device, a Curietron 2E1000 was manufactured by CIS-U.S., a French-owned company. The malfunction resulted in the disconnection of the tube used to transfer the sources (in this instance, cesium-137) from the shielded storage unit to the patient. The disconnect resulted in one the cesium-137 sources being located for an undetermined time near the upper part of the patient's leg, rather than in the patient. The licensee initially estimated a range of potential unintended dose to the patient's leg from 23 rem to 23,700 rem, depending on the length of the exposure and the proximity of the source to the patient's leg. Three physical examinations of the patient have indicated no visible signs of radiation damage to date, which would indicate that the actual exposure was at the lower end of the range. Additional future examinations of the patient will be performed.

The licensee subsequently reported two additional equipment problems with this device on January 18, but neither incident resulted in further unintended radiation exposures.

Cause:

Based upon visual examination of the failed equipment by Region I inspectors dispatched to the site on January 19, 1990, the failure appeared to be faulty material used in the retaining ring of the connector which attached to the applicator, or inadequate equipment design.

Licensee Action:

The device was removed from service for evaluation by the manufacturer. The faulty connectors have been replaced by a proven design.

NRC Action:

Region I performed a special inspection (Ref. 3). An NRC medical consultant evaluated the exposure and concluded that the licensee's follow-up actions were appropriate.

The manufacturer informed Region I that it has distributed only one other similar device in the United States. Region I staff notified the licensee having the similar device of the problem that occurred at Monongahela Valley Hospital. That licensee has also replaced the connectors.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence:

ITEM #: 900085 AO #: NRC 90-03 EVENT DATE: 02/02/1990
TITLE: MEDICAL THERAPY MISADMINISTRATION
NAME: Ball Memorial Hospital CITY: Muncie STATE: IN

Nature and Probable Consequences:

On February 2, 1990, the licensee reported that a therapeutic misadministration was discovered earlier that day in the treatment of a patient for lung cancer. A therapy dose had been administered to an area of the body other than the intended treatment area. The intended procedure called for 1,500 rem to the right lung area over a 25 hour period. A ribbon holding seven seeds (small sealed radiation sources) containing a total of 14.3 millicuries of iridium-192 was inserted into the patient's lung. Between the time the catheter was inserted and the time the iridium-192 seeds were placed in the catheter, a kink developed in the catheter. Because of the kink, the seeds were not inserted into the intended location in the lung, but rather remained in the pharynx area about 25 centimeters (about 10 inches) from the intended treatment area.

The licensee reported that no complications resulted from the misadministration. A medical consultant retained by the NRC concluded that the misadministration would not be of clinical significance because of the localized nature of the radiation dose to the area affected.

The procedure was repeated on the following day, and the intended lung area was successfully exposed.

Cause:

The misadministration was caused when a kink developed in the catheter inserted into the patient's bronchial tubes. The kink prevented the ribbon containing iridium-192 seeds from being fully inserted, and licensee personnel failed to detect that the ribbon was not properly placed.

Licensee Action:

The licensee has revised its treatment procedure for patients with iridium-192 implants. After the ribbon containing the seeds is placed in a patient, its location will be verified using portable x-ray equipment.

NRC Action:

A special inspection was conducted to review the circumstances surrounding this misadministration (Ref. 4). No violations of NRC regulations were identified. The NRC's medical consultant concluded that appropriate procedures had been instituted to minimize the likelihood of a recurrence of a similar misadministration.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 900100 AO #: NRC 90-04 EVENT DATE: 02/07/1990
TITLE: MEDICAL THERAPY MISADMINISTRATIONS
NAME: University of Wisconsin CITY: Madison STATE: WI

Nature and Probable Consequences:

The licensee notified NRC Region III on February 8 and March 16, 1990 of two therapy misadministrations that occurred on February 7, and March 15, 1990, respectively, due to a common cause (i.e., erroneous information being entered into a computer controlling the treatment location). The second event resulted in the wrong part of a patient's body receiving a therapy dose.

The treatments were performed using an afterloading device that inserts a high intensity radiation source (nominally 10 curies of iridium-192) into a previously placed tube in the treatment area. The device permits high doses of radiation to the very localized area in a short time period. The placement and movement of the radiation source are controlled by a computer, allowing precise placement and timing.

In the first instance, a 42 year-old patient was undergoing treatment for vaginal cancer. The intended treatment schedule called a total of four treatments of 1,620 rem each, two each to the left and right sides of the vagina, for a total of 3,240 rem per side. The first dose to the right side was correctly administered, but erroneous information was entered into the control computer for the second dose on February 7, 1990, resulting in a single dose of 2,500 rem to the right side treatment area; therefore, the total dosage to the right side was 4,120 rem - 27 percent higher than prescribed. The error was detected and a revised prescription was administered to the left side.

The second misadministration involved a 66 year-old patient being treated for a bronchial tumor. Incorrect information was entered into the computer for the first of four 400 rem treatments, resulting in the incorrect placement of the iridium-192 source. The treated area was about 9 centimeters (about 3.5 inches) from the intended treatment point. When the error was discovered, the licensee repeated the procedure to provide the intended dose to the intended treatment area. The remainder of the treatments were performed without incident.

In both misadministrations, the licensee does not expect any adverse medical effects.

Cause:

Both misadministrations were caused by the entry of incorrect data into the treatment planning computer. The data from the planning computer was then transferred to a computerized treatment device. Because of the nature of the treatment procedure, dose calculations must be quickly made after the treatment tube has been inserted.

Licensee Action:

The licensee prepared an extensive quality control/quality assurance program, including verification of key steps and calculation by a second qualified individual. More extensive training is to be provided to certain personnel involved in the treatment procedure and the adequacy of training will be verified through examinations. The licensee is also formalizing the treatment procedures and better defining the responsibilities of the various personnel involved in the treatments.

NRC Action:

A special inspection was conducted by NRC Region III on March 26-28, 1990 (Ref 5). As a result of the inspection findings, the licensee has modified its quality control/quality assurance program and undertaken other corrective actions. The changes have been incorporated into the facility's NRC license.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 900098 AO #: NRC 90-05 EVENT DATE: 02/08/1990
TITLE: MEDICAL THERAPY MISADMINISTRATION
NAME: Cleveland Clinic Foundation CITY: Cleveland STATE: OH

Nature and Probable Consequences:

On February 15, 1990, the licensee notified NRC Region III of a potential misadministration, involving cobalt-60 teletherapy, that occurred on February 8, 1990. The patient received a dose 50% greater than the physician's prescribed dose. On February 6, 1990, a physician prescribed nine treatment of cobalt-60 radiation for a 62 year-old patient suffering from cervical spine cancer. The patient was to receive 278 rem of radiation each day for nine consecutive days, beginning February 6. Following the first two treatments on February 6 and 7, the physician decided to stop the treatments to reevaluate the cervical spine area diagnosis. On the evening of February 7, the physician wrote a "stop prescription" on the first page of the patient's treatment chart. On February 8, the technologist did not see the stop treatment order listed on the first page of the chart, but instead turned to the second page where no change was listed. The patient subsequently received an additional 278 rem of radiation to the cervical spine. The technologist, supervising technologist, and chief technologist became aware of the stop treatment order later that day.

The attending physician stated that he did not believe the additional treatment of 278 rem would be clinically harmful to the patient. He based his evaluation on the fact that, among other things, the dose rate was far below a dose rate that would be "deleterious" to spinal cord tissue, and because he still has the option of resuming treatments. The patient's symptoms have improved since the treatments have been halted. The physician plans to withhold further treatments if improvements continue.

Cause:

The licensee did not have a clear mechanism for documenting changes in prescriptions prior to subsequent treatment.

Licensee Action:

The licensee's corrective actions included: (1) establishing a clear mechanism for documenting changes in prescriptions prior to subsequent treatment; and (2) conducting annual in-service training regarding misadministration reporting and review.

NRC Action:

An NRC Region III inspector was sent to the hospital March 7-9, 1990 to review circumstances surrounding the misadministrative (Ref. 6). An Enforcement Conference was held with the licensee on May 2, 1990, to review the findings of the inspection and possible enforcement actions. The licensee's corrective actions are considered satisfactory.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 900048 AO #: NRC 90-06 EVENT DATE: 02/16/1990
TITLE: MEDICAL THERAPY MISADMINISTRATION
NAME: Washington Hospital Center CITY: Washington STATE: DC

Nature and Probable Consequences:

On February 16, 1990, the licensee notified Region I by telephone that a therapeutic misadministration involving a teletherapy unit had occurred earlier that day. This was followed by a written report of the incident, dated February 23, 1990, and received by Region I on March 1, 1990.

The misadministration occurred when the wrong patient was administered 45 rem to the lung. The radiation therapy technologist called patient A's name, however, the wrong patient (patient B) responded. The technologist did not confirm the patient's identity with patient B's wrist band or the name on his hospital chart. The technologist questioned patient B when she could not find the lung treatment positioning marks. Patient B responded that the marks had been washed off. This same technologist also commented to patient B that he looked different from the Oncology Department treatment chart picture. (At the time, the technologist was actually looking at patient A's treatment chart.) Patient B responded that his appearance had changed since he lost his hair. The technologist positioned the patient and, together with a second technologist, who had returned from lunch, proceeded with the treatment. While patient B was undergoing treatment to the lung, the second technologist noticed that the name on patient B's hospital chart did not match the name on the department treatment chart and terminated the treatment. The patient was then identified as patient B who was at the hospital for radiation therapy to the brain.

The licensee has advised the NRC that no adverse effects are anticipated as a result of the misadministration.

Cause:

The cause was attributed to human error on the part of the radiation therapy technologist. The technologist did not verify the patient's identity with the available wrist band and patient's hospital chart.

Licensee Action:

The licensee's corrective actions included counseling of the technologist, re-instruction of all the therapy technologists on the proper method for patient identification, and discussion of the incident at a department staff meeting for additional emphasis on patient identification techniques.

NRC Action:

Region I reviewed the circumstances surrounding this incident. The licensee's corrective actions are considered satisfactory.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:	900164	AO #:	NRC 90-07	EVENT DATE:	03/08/1990
TITLE:	RECEIPT OF AN UNSHIELDED RADIOACTIVE SOURCE AT AMERSHAM CORPORATION IN BURLINGTON, MASSACHUSETTS				
NAME:	Amersham Corporation	CITY:	Burlington	STATE:	MA

Nature and Probable Consequences:

On March 8, 1990, Amersham Corporation informed NRC Region I that a shipment of 14 Model 500-SU source changers (reportedly empty) received from its customer, NDI Corporation, Seoul, Korea, contained an unshielded radioactive source. The wooden crate containing the source changers was not labelled as containing radioactive material. Shipping documentation indicated that the source changers were empty. However, routine surveys of the crate on its receipt at Amersham's Burlington, Massachusetts facility revealed a radiation level of about 100 millirem per hour near the back of the truck that delivered the pack to Amersham and about 10 rem per hour near the package. Subsequent surveys revealed levels of about 150 rem/hr, a significant radiation level, at contact with the source changer (approximately 4" to 6" from source). The licensee subsequently retrieved the radiography source from an interior, unshielded part of the source changer.

Inquiries made by NRC and Amersham indicated that the package left Pusan, Korea by ship on January 29, 1990. The ship arrived in Los Angeles, California on February 11, 1990; the crate remained on the ship until February 13, when it was off-loaded and picked up by a local trucker and taken to a repackaging facility. The crate was subsequently transported to a Nova Transportation Services Company container Freight Station in Compton, California on February 14, where it stayed until February 16, 1990, when it was transported by Covenant Transport, Inc. to the Patriot Trucking Co. warehouse in Boston, Massachusetts. The truck transporting the package made three stops enroute to Boston, two in Pennsylvania and one in Maryland, arriving at the Patriot warehouse on February 22, 1990. The crate remained there until delivery to Amersham on March 8, 1990. The shipper from Los Angeles to Boston was made in-bond, such that the crate cleared U.S. Customs in Boston. No radioactive contaminant was found in the source changer. The other source changers were found not to contain any radioactive material. The licensee stated that the source had been cut from its pigtail connector.

Based on the nature and potential consequences of the event, and the generic questions generated by the event, an NRC Incident Investigation Team (IIT) was organized on March 9, 1990. The IIT was charged to: (a) quickly resolve questions of radiation exposure; (b) determine what happened; (c) identify the probable causes as to why it happened; and (d) make appropriate findings and conclusions which would form the basis for any necessary follow-up actions.

One part of the Team began work on March 10, 1990 at the Amersham facility in Burlington. The other part of the Team began work on March 12, 1990, in Los Angeles, where the wooden crate containing the source changers had arrived.

The Team completed its investigation of the event in April 1990. The Team report was issued in May 1990 as NUREG-1405, "Inadvertent Shipment of a Radiographic Source from Korea to Amersham Corporation, in Burlington, Massachusetts" (Ref. 7). The principal findings and conclusions of the Team are as follows:

1. The cause of the incident was that a stored source was inadvertently left in a source changer when the device was returned from the end-user to Amersham's Korean distributor for shipment. Neither the end-user, Korea Industrial Testing Company, Ltd. (KIT) nor the distributor (shipper) NDI Corporation (NDI), used effective methods to ensure that there was no source in the changer. Inability of the two parties to detect the source was exacerbated by the fact that the connecting cable, or pigtail, had been removed that is, cropped from the source. Events leading to the inclusion of the iridium-192 source in the shipment are also being investigated by the Ministry of Science and Technology, and the Korean Institute of Nuclear Safety, the responsible regulatory authorities in Korea.
2. The Team was able to identify the radiographic source as a 56 curie, iridium-192 source manufactured on April 13, 1989, by Industrial Nuclear Company, San Leandro, California. Using the manufacturer's decay curve for the iridium-192 source, the Team determined the source's activity at the time when potential exposures to individuals might have occurred. Corporation facility measurements consistent with the values derived from the manufacturer's decay curve for the source.
3. While potential radiation exposure to the general public was possible, the number of individuals that could have been exposed was limited because the shipment was maintained "in-bond" from its arrival in Los Angeles on February 11, 1990, to the time it cleared U.S. Customs Service in Boston on March 7, 1990. The transport vehicle carrying the shipment from Los Angeles to Boston was driven across country with infrequent stops of mostly short duration.
4. Although the maximum estimated potential whole-body radiation exposures range from 27 to 35 rem for the two long-distance drivers, and 0.5 to 5.6 rem for other individuals that may have been in close proximity to the source for extended periods of time these estimates are not supported by cytogenetic studies done on the five individuals that had the highest potential for exposure. The cytogenetic data suggest that the source may have remained shielded so that no actual exposures occurred until the shipment was transferred from storage in Boston to Amersham's facility in Burlington, Massachusetts.
5. The safe handling and transportation of radioactive materials imported to the United States are highly dependent on the actions of foreign shippers and their agents to properly prepare packages for shipment, properly identify the contents, and accurately describe the contents in shipping documents. There are no DOT or NRC requirements for carriers or shipping agents to monitor or survey shipments during transit.

6. Carriers, freight forwarders, or shipping agents do not independently verify the accuracy of shipping documents for import shipments at the U.S. place of entry. Misclassified or mislabeled shipments are usually discovered by the receiving organization. There are no clear-cut requirements for a receiver to report to DOT or NRC instances where packages are not properly prepared for shipment or where the contents are not accurately identified. Current DOT regulations require carriers to report incidents when there is death, serious injury, or substantial property damage, breakage, spillage, or suspected radioactive contamination. NRC regulations require that licensees report any instance in which there is significant reduction in the effectiveness of any NRC-authorized packaging during use (10 CFR 71.95), if there is a high radiation level or contamination on packages when received (10 CFR 20.205), and for incidents in which there is the potential for significant exposure (10 CFR 20.403). The Team could not determine whether NRC regulations would have required Amersham to report previous instances where cropped sources had been inadvertently shipped from the Republic of Korea. Although the shipment was mislabeled and misidentified in these instances, the sources arrived within the shielded source tubes of the source changers. The Team could find no evidence that the instances were reported to either the NRC or DOT. The incident being investigated, where the source was received in an unshielded position, was reported pursuant to NRC requirement, 10 CFR 20.403.

7. As an importer, Amersham was required to provide the shipper and the forwarding agent, at the place of entry into the United States, complete information on how to comply with DOT regulations. The instructions provided to the shipper by Amersham for classifying and preparing the source changers for shipment were incomplete. While instructions were included for preparing the shipment of the source changers as an "excepted" package, no specific directions were provided for the case where the empty source changers did not meet the requirements for an "excepted" package. In spite of the inadvertent inclusion of an iridium-192 source, the shipment of empty source changers was improperly prepared for transport. Because the surface radiation level of the shipment exceeded 0.5 mrem/hr, it was required to be shipped within the United States as a Type A package. Lack of instruction for preparing a Type A package may have contributed to the misclassification of the package as an excepted package. However, proper classification of the shipment as Type A would probably not have prevented the incident.

8. Amersham's instructions for returning an empty Model 500-SU source changer were made available to NDI and KIT and were adequate for determining whether a source changer contained an authorized (i.e., uncropped) source, since a visual examination would detect the presence of a pigtail. However, in view of previous incidents involving the receipt by Amersham of cropped sources from the Republic of Korea, the instructions were deficient in that they did not anticipate that sources without pigtails might be stored in the source changer and not removed before shipment. Specific instructions requiring both radiation survey and a probe of the source tubes, if implemented by the end-user, would have prevented this incident.

9. Amersham did not provide "shipper" instructions to the freight forwarder at the place of entry into the United States (Los Angeles), as required, but rather to its Customs broker in Boston. In this case, Amersham provided an erroneous instruction to transport the package as an "excepted" package.

10. The Team found no violation of NRC regulations with respect to the receipt of the source changer shipment to Amersham. NRC's regulations do not apply to the shipment of these source changers across the United States, other than 10 CFR Part 110.27, which specifies requirements for importing by-product material. Shipment of the source changers within the United States was subject to DOT transportation regulations.

11. DOT regulations permit the use of an NRC-certified Type B package (a Type B package is required to transport iridium-192 in encapsulated sources exceeding 20 curies), such as the Model 500-SU source changer, for shipment of Type A (a Type A quantity for iridium-192 in encapsulated sources is less than 20 curies) quantity, for example, either as empty (with the DU shielding) or as a source totaling less than 20 curies. However, DOT regulations are ambiguous as to whether an NRC-certified Type B package must be used in strict accordance with the NRC-certificate for shipment of Type A quantities or whether the package need only comply with the general requirements for Type A packages in the DOT regulations. Thus, the Team could not determine whether the source involved in this incident could have been shipped in the Model 500-SU source changer as a Type A quantity, because the source (with or without the pigtail) is not authorized in the NRC certificate.

12. The 14 source changers involved in the incident did not conform to the drawings referenced in NRC Certificate of Compliance 9006, Revision No. 9, in that all of these source changers were constructed without a source cable locking assembly. In addition, some of the 14 source changers were not constructed according to the dimensions specified in the drawings referenced in the Certificate of Compliance. However, the Team determined that these discrepancies did not contribute to the cause of this incident.

Cause:

The cause of the incident is described above in Item 1 of the Team's findings and conclusions.

Licensee Action:

NRC Action:

Based on the findings and conclusions of the IIT, the NRC Executive Director for operations has assigned staff responsibilities for generic and facility specific actions to be taken. It is planned to include the resolution or disposition of each IIT finding and conclusion in the Office for Analysis and Evaluation of Operation Data (AEOD) Annual Reports (NUREG-1272 series).

This item is considered closed for the purposes of these quarterly abnormal occurrence reports.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence. In addition, Example 2 (i.e., exposure to an individual in an unrestricted area such that the whole body dose received exceeds 0.5 rem in one calendar year) of Appendix A is applicable to this event.

ITEM #: 900190 AO #: NRC 90-08 EVENT DATE: 03/16/1990
TITLE: MEDICAL THERAPY MISADMINISTRATION
NAME: Riverside Regional Medical Center CITY: Newport News STATE: VA

Nature and Probable Consequences:

On March 16, 1990, the licensee notified NRC Region II that a therapy misadministration had occurred earlier that day when the wrong patient was administered 296 rads (from a teletherapy unit) to the midline of the brain. The radiation therapy technologist had gone to the waiting room and called for the patient by surname only. However, the technologist did not properly identify the patient prior to treatment by comparing the patient to the photograph which is affixed to the medical chart. The patients in quest had the same last name and first initial, were of the same race and gender, were of approximately the same age, had approximately the same treatment region, same treatment technologist, and approximately the same appointment time. The patient for whom treatment was intended was late for his appointment and was not present when called for in the waiting area. The wrong patient who was in for follow-up examination only, responded to the call.

The licensee has advised the NRC that no adverse effects are anticipated as a result of the misadministration.

Cause:

The cause is attributed to human error by the licensee's radiation therapy staff. The technologists did not confirm the identity of patient by comparing the patient to the photograph affixed to the medical chart.

Licensee Action:

The licensee's corrective actions included strengthening of their patient identification policies to add a photograph to the therapy setup sheet for the patient, and use of skin marks to identify the treatment area, where appropriate. The entire radiation therapy staff was trained in the revised procedures for patient identification.

NRC Action:

Region II conducted a special inspection on March 19, 1990, to review the circumstances associated with the misadministration and to review the licensee's immediate corrective actions (Ref. 8). Region II conducted an Enforcement Conference with the licensee on April 12, 1990, to discuss the event, and agreed with the corrective actions to prevent recurrence. One violation of NRC requirements was identified (Ref. 9).

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 900189 AO #: NRC 90-09 EVENT DATE: 03/16/1990
TITLE: MEDICAL THERAPY MISADMINISTRATION
NAME: John F. Kennedy Memorial Hospital CITY: Edison STATE: NJ

Nature and Probable Consequences:

On March 16, 1990, the licensee notified NRC Region I that earlier that day a patient, receiving an endobronchial iridium-192 treatment, received an unintended therapy dose to the face. The misadministration was estimated to have occurred from as early as 10:30 p.m. March 15, to midnight when it was first observed, and continued to approximately 4:45 a.m. on March 16 when the iridium was removed to a lead shielded container.

The misadministration occurred when a ribbon containing 25 seeds with 3.5 millicuries each of iridium-192, inserted into a previously placed endotracheal catheter, became dislodged. The catheter, inserted in the patient's bronchi, remained in place. However, the ribbon containing the iridium seeds became completely dislodged from the catheter outside the lung and ultimately came to rest beside the patient's face. The duty nurse noticed the dislodged source about midnight, but took no action at the time. The ribbon remained unsecured until 2:00 a.m. when the duty nurse taped the unsecured end, which contained the iridium seed to the left side of the patient's face where it remained for approximately 3 hours. To tape the ribbon to the patient's face, the nurse handled the active part of the ribbon with unshielded fingers.

At about 4:15 a.m., the Charge Nurse attended the patient and noticed the dislodged source. The Charge Nurse called the Radiation Safety Officer who directed removal of the ribbon from the patient, using a remote handling tool, and placed the source in a shielded container.

The licensee made preliminary dose estimates of 1,032 rem to the left side of the patient's face, 282 rem to the eyes, and 357 rem to the scalp since the patient at one point folded the ribbon in her hair. The duty nurse who handled the ribbon received an estimated 17.6 rem to the fingers.

At 7:30 a.m. on March 16, the radiation oncologist rethreaded the iridium ribbon through the catheter and the patient's endobronchial treatment was continued, ending at 9:30 p.m. the same day. The patient was discharged from the hospital on March 20, 1990. The licensee advised the NRC that no adverse effects were anticipated as a result of the misadministration.

However, at 1:00 a.m. on March 22, 1990, the patient was readmitted to the hospital through the Emergency Room complaining burning eyeballs and sensitivity to light. The patient's eyes were medicated and bandaged. Later that day, the patient was seen by an ophthalmologist who diagnosed the condition as keratoconjunctivitis; the doctor said that this condition could be viral-related but did not rule out the possibility of radiation-induced conjunctivitis. The patient was discharged from the hospital the following day.

An NRC medical consultant reviewed the event and concluded that the patient should not have any long term adverse effects except for the remote possibility of change in the lens of the eye.

Cause:

The cause of the event was due to the source becoming completely dislodged outside the catheter, and the inappropriate response of the duty nurse to the dislodged source. The nurse's response resulted in a significant, unnecessary radiation dose to the patient as well as an unnecessary dose to the nurse's fingers.

The nurse had received training in the equipment and procedures in March 1988, two years prior to assignment to this, the nurse's first case, in March 1990. Refresher training given in December 1989 did not include visuals or handling of simulated brachytherapy seeds. Therefore, the nurse did not recognize the configuration of the ribbon containing the radioactive seeds. The licensee's procedure for brachytherapy implants requires that the shift nurses be briefed on radiation safety precautions related to the specific case. The procedure requires that initially, this briefing be given by the Radiation Safety Officer to the nurses on duty at the time of the implant. They then pass this information on to the succeeding shifts, etc. In this event, the briefing was not done for the shifts subsequent to the initial shift.

Licensee Action:

The licensee's corrective actions included: (1) review of the content of the training course; (2) provision during training of visuals of each type of brachytherapy configuration and handling; (3) a Post Test with a minimal score of 80% - this includes retraining and retesting, if necessary, to obtain 80%; (4) a picture or sketch on each patient's chart and/or each patient's door of the configuration of the brachytherapy implant; (5) exploration of means to make sources more secure in the implant site; (6) deferring the nurse from working with brachytherapy patients until retraining takes place; and, (7) formulation of a subcommittee of the Radiation Safety Committee to investigate this incident and render a full report to the Radiation Safety Committee.

NRC Action:

NRC Region I performed an inspection to review the circumstances associated with the event. The licensee's corrective actions were considered to be satisfactory. However, two violations of NRC requirements were identified, i.e., (1) the duty nurse had not been adequately briefed concerning radiation safety precautions associated with care of the patient, and (2) the Radiation Safety Officer had not established a procedure for performing a radiation survey or evaluation prior to and upon entry into the room of a brachytherapy implant patient. On May 21, 1990, the NRC issued to the licensee a notice of violation and proposed civil penalty.

the amount of \$1,250 (Ref. 10). The licensee paid the civil penalty.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 900194 AO #: NRC 90-10 EVENT DATE: 03/19/1990
TITLE: MEDICAL THERAPY MISADMINISTRATION
NAME: St. Mary's Medical Center CITY: Saginaw STATE: MI

Nature and Probable Consequences:

On March 19, 1990, the licensee reported to NRC Region III that earlier that day a 46-year-old patient received a therapeutic radiation dose of 250 rem to the thoracic portion of the spine rather than to the intended treatment area (i.e., the lumbar portion, which is a lower portion of the spine).

The patient had previously received a total radiation dose of about 4,500 rem to the thoracic portion of the spine during treatment in April 1986 and December 1987. In March 1990, a prescription for further treatment, this time to the lumbar portion of the spine was prepared. The treatment plan was prepared and an X-ray of the treatment area was taken. The treatment plan called for a series of 31 treatments, of 250 rem each, administered with a cobalt-60 teletherapy unit. On March 19, 1990, the patient received the first treatment of the series, but the radiation technologist mistakenly administered the 250 rem dose to the thoracic spine rather than the intended lumbar portion of the spine. The technologist then reviewed the patient's chart and immediately realized the error.

The unintended treatment of the thoracic area brought the total radiation dose to that area to approximately 4,800 rem. The licensee stated that there is a low probability of radiation damage to the spinal cord from a total radiation dose of this magnitude. The patient will be monitored for possible future conditions, but no medical treatment is required for the additional radiation dose.

Cause:

The cause was due to human error in failing to follow procedures. The radiation technologist, in preparing the first treatment procedure, asked the patient to identify the treatment area. The patient indicated an area of the thoracic spine which contained a tattoo from the earlier treatments.

The technologist failed to follow normal treatment procedures that require technologists to review the patient's chart, examine the X-ray film showing the treatment area, and obtain verification of the treatment setup by a second technologist, prior to initiating treatment. The patient's chart and X-ray film clearly showed the correct treatment area.

Licensee Action:

The licensee provided training to the technologist involved, and other staff technologists, on the correct treatment procedures and quality assurance measures, including verification of treatment setups by a second qualified individual. The licensee also submitted its quality assurance procedures to be incorporated into its NRC license in accordance with the NRC Confirmatory Action Letter (CAL) described below.

NRC Action:

The NRC retained a medical consultant to evaluate the circumstances of the misadministration and possible consequences. The consultant agreed with the licensee's evaluation. A special inspection was conducted by NRC Region III in April 1990 to review this incident (Ref. 11). The licensee's corrective actions were considered satisfactory. On April 4, 1990, a CAL was issued by NRC Region III (Ref. 12) to document the licensee's agreement to assure that two individuals review dose calculations and patient setups for all cobalt-60 teletherapy procedures. The licensee submitted its quality assurance procedures to the NRC and they have been incorporated into the facility's NRC license.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 900784 AO #: NRC 90-11 EVENT DATE: 03/28/1990
TITLE: DEFICIENCIES IN BRACHYTHERAPY PROGRAM
NAME: St. Mary Medical Center - Porter Memorial Hospital CITY: Gary, Hobart, Valparai STATE: IN

Nature and Probable Consequences:

On March 28, 1990, NRC Region III (Chicago) received allegations pertaining to brachytherapy treatments performed by one of authorized users at St. Mary Medical Center in Gary and Hobart, Indiana. The allover contended that the authorized user did not evaluate patients' treatment plans prior to treatment and that the patients therefore did not receive the prescribed dose of radiation during the procedure. Brachytherapy involves the use of small sealed capsules containing radioactive material. These capsules, which are used in the treatment of cancer, are either surgically implanted, placed in body cavities, or applied to the skin. Assisted by a medical consultant, the NRC conducted a preliminary inquiry into the allegations on March 30 - April 19, 1990. This inspection substantiated some of the allegations, and the NRC concluded that the two St. Mary facilities were not exercising adequate management control to assure that NRC requirements were met.

Because the same authorized user performed brachytherapy treatments at Porter Memorial Hospital, the NRC performed a special inspection April 5 - April 27, 1990, at this facility. The inspection determined that adequate records had not been maintained at the hospital to evaluate whether or not the brachytherapy procedures had been administered as prescribed and planned.

On April 27, 1990, the NRC Staff issued an Order to the two St. Mary Medical Center facilities suspending brachytherapy activities. The Order also directed the medical facilities to perform an independent evaluation of brachytherapy procedures performed since the brachytherapy program was started in May 1986. On May 2, 1990, the NRC Staff issued a Confirmatory Order to Porter Memorial Hospital confirming the licensee's agreement to suspend its brachytherapy program and to require an independent evaluation of previous brachytherapy procedures.

Planning for these two independent evaluation programs is underway. One of the goals of the programs is to determine if any patients received radiation exposures different from those that were prescribed.

The NRC special inspection at the St. Mary facilities identified several instances where the actual therapy radiation dose may have varied from the prescribed dose by more than 10 percent. The NRC requires that a therapy radiation dose that varies from the prescribed dose by more than 10 percent be reported to the NRC and that the patient's physician be notified. Such a deviation from the prescription would be a "misadministration."

At the Porter Memorial Hospital, sufficient records were not immediately available to determine if any misadministrations occurred.

The Orders did not affect other activities performed under NRC licenses issued to the three facilities, including diagnostic tests using radiopharmaceuticals and other radiation therapy programs.

Cause:

The NRC inspections determined that none of the three facilities had maintained adequate records of the treatment plans and prescriptions at the facility. The inspections also determined that licensee management at each of the facilities had not taken action to assure that established procedures were followed including maintenance of required records.

At the St. Mary facilities, hospital management was notified by a staff member as early as May 1988 that appropriate records were not being maintained nor established procedures followed, but the corrective actions taken were not effective and the inadequate recordkeeping and procedural failures continued.

Six brachytherapy procedures were performed at the Porter Memorial Hospital between 1987 and 1989. The hospital's Radiation Safety Committee and Radiation Safety Officer, however, were not aware when brachytherapy treatments were being performed when the radioactive sources for brachytherapy were ordered.

Licensee Action:

The two St. Mary facilities have submitted revisions to their NRC licenses to provide quality assurance procedures for brachytherapy procedures. Porter Memorial Hospital has also submitted revisions to its NRC license providing quality assurance procedures. The proposed license amendments are under review.

The two St. Mary facilities filed a request for a hearing on the NRC Order. The authorized user, who was involved in brachytherapy treatments at the facilities, also requested a hearing and he was admitted to the proceeding as an intervenor.

The proceeding is currently pending before an Atomic Safety and Licensing Board, although settlement discussions are underway.

NRC Action:

The NRC staff issued Orders to the three facilities, suspending brachytherapy procedures at the St. Mary facilities and confirming that Porter Memorial Hospital had ceased brachytherapy treatments. The Orders also required the licensees to undertake independent evaluation of completed brachytherapy procedures to determine if the treatments were consistent with the prescribed doses and treatment plans. The licensees were also required to submit proposed license amendments to provide quality

assurance procedures should they desire to continue their brachytherapy programs. The licensees were not to resume brachytherapy procedures without NRC authorization.

Future reports will be made as appropriate.

Update - NUREG-0090, Vol. 14, No. 4, Page 15 - The abnormal occurrence is updated, and closed out, as follows:

1. St. Mary Medical Center facilities - In a letter dated October 15, 1991, the licensee indicated it plans to seek reinstatement of radiation therapy program. It has not, however, submitted a formal request for the necessary license amendments.
2. Porter Memorial Hospital - On January 10, 1992, the NRC rescinded the Order suspending radiation therapy activities. The licensee has complied with the terms of the NRC Order. An audit report from an independent consultant, previously submitted December 27, 1990, identified no misadministrations identified during the audit of brachytherapy procedures. In the latter part of 1991, the licensee submitted a therapy quality management program to be incorporated into its license. Inspection findings have also been favorable.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 11 of "For all Licenses") of this report notes that an event involving serious deficiencies in management controls can be considered Abnormal Occurrence.

ITEM #:	900240	AO #:	NRC 90-12	EVENT DATE:	04/06/1990
TITLE:	RADIATION OVEREXPOSURE OF A RADIOGRAPHER				
NAME:	Barnett Industrial X-Ray	CITY:	Stillwater	STATE:	OK

Nature and Probable Consequences:

On the evening of April 6, 1990, the licensee notified the NRC that an incident had occurred earlier that evening while a radiographer and his assistant were working at a temporary jobsite. The radiographic operation involved the use of a radiograph device containing an approximately 80-curie iridium-192 sealed source. (A radiography device uses a radioactive sealed source make x-ray-like images of welds and heavy metal objects. The position of the source is controlled by a drive cable which is used to crank the source out of the exposure device and retract it back to a shielded position within the device via an unshielded source guide tube.) The licensee reported that the source became disconnected from the drive cable and remained in the source guide tube. Unaware that the source remained in the tube, the assistant wrapped the source guide tube around his neck while he moved equipment at the worksite. The licensee initially estimated that the assistant received an exposure of 4000 rem to the exposed side of his neck. Two NRC Region IV inspectors were dispatched the following morning to investigate the incident. The circumstances associated with the radiation overexposure are described below.

After completing two radiographs of a pipe weld, the radiographer proceeded to develop the radiographs while the assistant disassembled the equipment to move the exposure device to another location. While doing this, he removed the source guide tube and draped it around his neck so that his hands would be free to carry the remaining equipment. He walked approximately 30-50 feet before stopping to set the equipment down. As he removed the guide tube from around his neck, he noticed that the sealed source fell from the tube to ground. The assistant notified the radiographer who telephoned the company owner and, following the owner's direction, successfully retrieved the source to a shielded position within the exposure device. During his conversation with the owner, the radiographer identified: (1) that he failed to conduct a radiation survey of the exposure device after each exposure, (2) that the assistant's pocket dosimeter had gone offscale (greater than 200 millirem), and (3) that the assistant was not wearing his film badge during these operations. Under the owner's direction, the assistant was taken for medical examination at a local hospital later that evening.

Based on interviews conducted with the radiographer and company owner together with NRC reenactments of the radiographer's actions during the event, NRC inspectors determined that he might also have received an exposure in excess of regulatory limits. When the radiographer later confirmed that his pocket dosimeter had gone offscale, his film badge was sent for immediate processing. Both the assistant and radiographer were referred for examination by a radiation oncologist (a physician experienced in examining patients who have been treated with large doses of radiation) and blood samples were obtained for cytogenetic studies.

The cytogenetic studies revealed equivalent whole body doses of 17 rem for the radiographer and 24 rem for the assistant. The assistant developed an area of erythema on the left side of his neck, which later showed signs of more significant damage to skin tissue in an area approximately 10 centimeters in diameter. The oncologist determined that the observed effect corresponded to a local skin dose of 5000-7000 rem. As of June 1990, the skin tissue in this area had regenerated and the physician did not predict any long-term effects as a result of this exposure. The assistant remains under the physician's care, and the NRC continues to receive reports on his progress. There were no medical effects observed for the radiographer.

Cause:

The radiographer and assistant failed to conduct a radiation survey of the exposure device after either of the exposures was completed to ensure that the source had been retracted to its shielded position. The radiographer was exposed to the unshielded source as he changed films between the two exposures, and the assistant received a large exposure as he carried the source tube containing the source draped around his neck. Without a radiation survey, neither individual was aware that the source had not been connected to the drive cable and remained in the guide tube.

Licensee Action:

The licensee's proposed corrective actions included retraining the radiographer in radiation safety procedures and continued observation of his performance. The assistant radiographer is no longer employed by the licensee.

NRC Action:

During the investigation of this event, on April 12, 1990, an Order modifying the license was issued, prohibiting the radiographer and the assistant from participating in licensed activities (Ref. 3). This Order has since been relaxed due to the licensee's implementation of corrective action. NRC Region IV conducted an enforcement conference with the licensee on May 25, 1990, to discuss the event (Ref. 4). On September 7, 1990, the NRC issued to the licensee a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$7,500 (Ref. 5). The basis for the proposed penalty were violations associated with failure to conduct the required radiation survey and the resultant overexposures. These two violations collectively were classified as Severe Level I (on a scale of Levels I through V, in which Level I is the most significant).

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 1 of "For All Licensees") of this report notes that exposure of the skin of any individual to 150 rem or more of radiation be considered an abnormal occurrence.

ITEM #: 900347 AO #: NRC 90-13 EVENT DATE: 06/05/1990
TITLE: MEDICAL DIAGNOSTIC MISADMINISTRATION
NAME: Mercy Memorial Medical Center CITY: St. Joseph STATE: MI

Nature and Probable Consequences:

A 79-year-old female patient was scheduled to undergo a diagnostic evaluation to determine whether she was suffering from an enlarged thyroid gland (substernal thyroid). No prescribed dose was indicated.

The scan was scheduled for the following day. The technologist, in attempting to order the proper amount of radioactive material noted that her standard dose chart (created by authorized users) did not list dosage for a substernal thyroid gland study.

She then referred to the department's procedures manual, which indicated that the proper dose for a substernal thyroid gland study was 3-5 millicuries of iodine-131, or 100-200 microcuries of iodine-123. The technologist then asked an authorized user which isotope to use. He instructed her to order a sufficient quantity of iodine-131 to visualize the thyroid gland. On June 5, 1990, the patient was given 4.3 millicuries of iodine-131, which conformed to the procedures manual. The dosage listed in the procedure, however, was wrong. The standard dose for a substernal thyroid scan should have been 50 to 100 microcuries of iodine-131, or approximately one-fiftieth of the amount noted in the manual. The mistake was identified by the Chief of the Nuclear Medicine Department on June 6 and reported as a misadministration to the NRC on June 8, 1990.

The licensee estimated that the misadministration resulted in a mean dose to the thyroid gland of 5,752 rads. The NRC's medical consultant investigated the case. Based on certain assumptions, the consultant estimated the dose to be 3,400 rads to the thyroid gland which, according to the consultant, would yield a 10 percent chance of hypothyroidism over five years. The licensee is monitoring the patient's condition.

Cause:

The Nuclear Medicine Department's procedures manual listed the wrong iodine-131 dosage for a substernal thyroid scan. The dosage was not reviewed by an authorized user prior to its administration.

Licensee Action:

The license has been amended to incorporate the following changes in iodine-131 procedures: (1) Two nuclear medicine technologists will independently verify the prescribed dosage and check the dose calibrator assay; (2) A written prescription by an authorized user will be required before the procedure is carried out; and (3) Two signatures or initials will be required on all documents involving iodine-131. The licensee also corrected the department's procedures manual to reflect the proper dosage for a substernal thyroid scan. Dosage for a substernal thyroid scan also was added to the department's Standard Dose Chart.

NRC Action:

An NRC inspection was conducted on June 19, 1990 (Ref. 6). Seven violations of NRC requirements (unrelated to this event) were identified. The licensee's corrective actions to prevent recurrence were found to be satisfactory. The NRC notified its medical consultant who reviewed the circumstances. He made certain procedural recommendations for consideration by the licensee.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 900388 AO #: NRC 90-14 EVENT DATE: 06/19/1990
TITLE: ADMINISTRATION OF IODINE-131 TO A LACTATING FEMALE WITH UPTAKE BY HER INFANT
NAME: Tripler Army Medical Center CITY: Honolulu STATE: HI

Nature and Probable Consequences:

A nursing mother was given a 4.89 millicurie dose of iodine-131 at an NRC licensed medical facility that resulted in an unintentional radiation dose to her infant's thyroid gland estimated at 30,000 rads and a dose to the infant's whole body of 17 rads. The error was detected on June 21, 1990, when the patient returned to the medical center for a whole body scan. The scan indicated an unusually high breast uptake of iodine-131. In the opinion of the patient's physician and an NRC medical consultant, the infant's thyroid function will be completely lost. The infant will require artificial thyroid hormone medication for life to ensure normal growth and development.

Cause:

The physician and nuclear medicine technologist failed to confirm that the patient was not breast feeding. The patient arrived at medical center from a remote South Pacific island. Communication between the island physician and the Army physicians was poor and the Tripler physicians were not aware that the mother had given birth on June 1, 1990.

Licensee Action:

Immediately following discovery of the error the licensee began using a new questionnaire that more clearly requires the collection and documentation of information concerning patient pregnancy and breast feeding. The Commanding Officer has ordered a special investigation to define the cause and appropriate corrective actions. The licensee has contacted the patient and the patient's physician and is finalizing arrangement for long term follow-up care.

NRC Action:

An Enforcement Conference was held on August 16, 1990, and enforcement action is being considered.

Future reports will be made as appropriate.

UPDATE (from NUREG-0090, Vol. 14, No. 2, page 14). This event, which occurred at Tripler Army Medical Center in Honolulu, Hawaii, was originally reported as an abnormal occurrence in NUREG-0090, Vol. 13, No.2, "Report to congress on Abnormal Occurrences: April-June 1990". It is updated, and closed out, as follows:

Immediately following discovery of the error on June 21, 1990, the licensee began using a new questionnaire that more clearly requires the collection and documentation of information concerning patient pregnancy and breast feeding. A class was presented to all appropriate hospital staff to inform them of the new procedures. The Commanding Officer ordered a special investigation to define the cause and appropriate corrective actions. The licensee contacted the patient and the patient's physician and arranged for long term follow-up medical care. A new quality assurance procedure has been implemented to assure completeness of the new questionnaire and the understanding of the procedures by the technicians.

The NRC Region V inspection report was sent to the licensee on August 3, 1990 (Ref. B-5). An Enforcement Conference was held on August 16, 1990. A Notice of Violation and Proposed Imposition of Civil Penalty for \$5,000 was issued on October 22, 1990 (Ref. B-6). The notice documented one violation of 10 CFR 35.25(a)(2) which requires supervised individuals to follow the instructions to collect information on breast feeding was cited. The violation was categorized as a Severity Level I problem (on a scale in which Severity Levels I through V range from the most to least significant, respectively). After the staff received the licensee's replies dated December 7 and 21, 1990, they reconsidered the amount of the civil penalty and consulted with the Commission. An Order imposing a civil penalty of \$2,500 was issued on May 13, 1991 (Ref. B-7). The licensee paid the civil penalty.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 900391 AO #: NRC 90-15 EVENT DATE: 06/22/1990
TITLE: MEDICAL THERAPY MISADMINISTRATION
NAME: St. Luke's Hospital CITY: Cleveland STATE: OH

Nature and Probable Consequences:

A 57-year-old woman, being treated for lung cancer, was erroneously given a 178 rem radiation dose to the left side of the head June 22, 1990, using the licensee's cobalt-60 teletherapy unit. The patient was scheduled to receive a 200 rem radiation dose to the chest area at the time of the misadministration. The treatment was the ninth of a total of ten treatments in the series for a total of 2,000 rem to the chest. The treatment began June 11, 1990.

A technologist set the patient up for brain irradiation without looking at the treatment documents. After the left side of the head was treated, the patient asked if her chest would also be treated. At this time, the treatment staff discovered the error.

Because the misadministration involved a single treatment and because of the dosage involved, no adverse medical effects are expected. Subsequent to the misadministration, the patient received the intended 200 rem radiation dose to the chest area. The tenth treatment was administered, and the patient began a second phase of 25 radiation treatments of 150 rem each to the chest area.

Cause:

This misadministration was caused by the failure of the technologist to examine the treatment documentation (the setup sheet and a treatment field picture). Although the technologist had previously treated the patient, the technologist erroneously assumed that the brain was the area to be treated. (The staff determined that although lung cancers of this type often do metastasize to the brain, the irradiation of the brain in this case was a misadministration nonetheless.)

Licensee Action:

The licensee has revised its procedures to require the verification, when circumstances permit, of the treatment setup by a second technologist using the setup documentation. All technologists have been trained in the procedure. The NRC is requesting the licensee to amend its quality assurance procedures to include dual verification of treatment setups prior to any treatment.

NRC Action:

The NRC conducted a special inspection on June 27-29, 1990, to review the circumstances of the misadministration and to evaluate the licensee's radiation safety and management control programs (Ref. 7). The inspection also covered an earlier misadministration, a patient received a dose that 12 per cent less than that intended during a treatment series February 15 through April 3, 1990. A Notice of Violation was issued for two instances of failure to report the misadministrations within the required time period. The inspection also identified a concern about staff shortages that may adversely affect the licensee's radiation therapy program. The NRC requested the hospital's response to this concern.

This item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:	951030	AO #:	AS 90-01	EVENT DATE:	11/01/1989
TITLE:	MEDICAL DIAGNOSTIC MISADMINISTRATION				
NAME:	Desert Samaritan Hospital	CITY:	Phoenix	STATE:	AZ

Nature and Probable Consequences:

On November 1, 1989, a patient scheduled for the administration of 100 microcurie capsules of iodine-123 for a diagnostic thyroid scan was mistakenly administered a therapeutic dose of 100 millicuries of iodine-131 and sent home for 24 hours until normal imaging was scheduled.

When the patient returned on November 2, the imaging camera flooded out, which indicated a large overdose. The hospital immediately notified the Arizona Radiation Regulatory Agency (ARRA). The patient was immediately hospitalized and isolated, standard practice for thyroid ablation patients). The patient was discharged on November 5, 1989.

The patient's family was contacted and a bioassay was performed to determine the thyroid body burden of each family member. The thyroid burdens were above the action level for radiation workers (0.4 microcurie) but the level was not considered a serious health threat to any family member.

A hospital employee and an ARRA representative surveyed and decontaminated the patient's house. Wipe tests were used to verify the efficiency of the decontamination.

Cause:

There were several causes for this event. The hospital staff:

- did not assay the dose in the dose calibrator prior to administering it,
- did not compare the iodine-131 dose label with the physician's order, and
- did not maintain adequate records of incoming radiopharmaceuticals.

In addition, ARRA cited the hospital for allowing a patient who had been administered a therapeutic dose of iodine-131 to go home. Syncor International, Inc., the radiopharmacy that dispensed the dose:

- did not record the telephone order for iodine-131 legibly so that the units for microcurie and millicurie could be differentiated, and
- did not record the type of intended procedure (diagnostic or therapeutic).

Licensee Action:

The hospital amended its Nuclear Medicine Department administrative procedures and paid the civil penalty in full. The order restricting iodine-131 possession limits to 100 microcuries was rescinded by the ARRA on March 9, 1990.

NRC Action:

Other Agency Action:

Agency - The ARRA placed an order on the hospital that reduced the possession limit for iodine-131 from 500 millicuries to 100 microcuries (0.1 millicurie). The ARRA also cited Syncor and imposed an order limiting them from dispensing any dose of iodine-131 in excess of 1 millicurie unless a written order from the client licensee was in the possession of the radiopharmacist dispensing the dose. Later, the ARRA sent a Notice of Violation to the licensee and imposed a civil penalty in the amount of \$12,000.00.

Hospital: The hospital amended its Nuclear Medicine Department administrative procedures and paid the civil penalty in full. The order restricting iodine-131 possession limits to 100 microcuries was rescinded by the ARRA on March 9, 1990.

Radiopharmacy - The radiopharmacy adopted policies to be used when iodine-131 therapy orders were received and dispensed. The ARRA issued a license amendment incorporating required procedures for orders for more than 1 millicurie of iodine-131. The order limiting the amount of iodine-131 that could be dispensed was withdrawn by the ARRA on January 9, 1990.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health and safety can be considered an abnormal occurrence.

ITEM #: 900176 AO #: NRC 90-16 EVENT DATE: 02/20/1990
TITLE: MEDICAL THERAPY MISADMINISTRATION
NAME: Muskogee Regional Medical Center CITY: Muskogee STATE: OK

Nature and Probable Consequences:

On September 19, 1990, the licensee notified the NRC that a therapeutic misadministration had occurred involving a treatment administered from February 20 through March 12, 1990. The radiation oncologist had identified the treatment error on September 6, 1990, but had not immediately recognized it as a reportable misadministration. The treatment error involved administration of 2160 rads (from a cobalt-60 teletherapy unit) to the right posterior neck rather than the left posterior neck as prescribed.

The licensee reported that the oncologist had initially participated in the treatment simulation and had approved simulation radiographs prior to treatment; however, the physician failed to notice that the wrong side of the patient's neck had been the subject of the simulation. This error was attributed to the fact that the patient treatment was simulated in the prone position rather than the routine supine position. Several of the licensee's staff members, including the teletherapy physicist, therapy dosimetrist, technic staff, and oncologist, had reviewed the patient's chart and participated in treatment and follow-up observations although none had recognized the error. The oncologist had palpated an enlarged cervical lymph node on the patient's left side during the September 6, 1990, physical examination which prompted his subsequent review of the treatment chart and identification of the error. All treatment records indicated that the right side of the patient's neck was treated, although the prescription clearly indicated that treatment was to be given to the left side.

The licensee's radiation oncologist has advised the NRC that no adverse effects were observed during routine follow-up examinations, and that no significant effects are anticipated as a result of the misadministration.

Cause:

The cause is attributed to human error by the licensee's staff and failure to perform independent chart reviews in sufficient detail to detect the error. The simulation technologist had prepared a treatment simulation for, and had tattooed the right side of the patient's neck, because the oncologist had assisted in simulating the patient treatment and fluoroscoped the patient's right side. The technologist assumed that the correct treatment field had been fluoroscoped, and transcribed the treatment plan for the right posterior neck. The simulation radiographs were approved by the oncologist although they had not been labeled "right" or "left" at the time.

The treatment plan was not reviewed until seven treatment fractions had been administered, although neither the teletherapy physicist or dosimetrist recognized the error during this or subsequent reviews of the patient's chart. Additionally, the technical staff did not routinely review the physician's prescription after the patient treatment was simulated, and therefore, did not recognize that the prescription indicated treatment for the left side rather than the right.

Licensee Action:

The licensee's corrective actions as of October 15, 1990, included reformatting the treatment chart to include the physician's prescription more readily accessible for staff review during the course of treatment. The teletherapy physicist and dosimetrist plan to provide a more detailed review of the treatment plan, including verification of treatment field rather than focusing solely on dose calculations. Further corrective actions will be implemented pending the licensee's Radiation Safety Officer's full investigation and review.

NRC Action:

An NRC Region IV inspector conducted a special safety inspection on October 3 and 5, 1990, of the circumstances associated with the misadministration, and identified violations of NRC requirements as well as deviations from the licensee's documented procedures (Ref. 1). A Confirmatory Action Letter (CAL) was issued on October 10, 1990, to confirm commitments made by the licensee during this inspection (Ref. 2). These commitments include conducting a retrospective review of patient treatments to determine if similar errors had been made. A decision regarding enforcement action is currently under consideration.

Future reports will be made as appropriate.

UPDATE (from NUREG-0090, Vol. 13, No. 4, page 11). This abnormal occurrence, which occurred at Muskogee Regional Medical Center in Muskogee, Oklahoma, involved radiation therapy to the wrong side of a patient's neck. The event was originally reported in NUREG-0090, Vol. 13, No. 3, "Report to Congress on Abnormal Occurrences: July - September 1990." As previously reported, an NRC Region IV inspector conducted a special safety inspection on October 3 and 5, 1990, of the circumstances associated with the misadministration, and identified violations of NRC Requirements as well as deviations from the licensee's documented procedures (Ref. B-1). On October 10, 1990, the NRC issued a Confirmation of Action Letter confirming a commitment made by the licensee to conduct a review of patient treatments completed during the previous 12 months to determine if similar treatment errors had occurred and gone unrecognized (Ref. B-2).

The licensee reported on November 5, 1990, that the investigation of treatments initiated or completed during this period revealed no further misadministrations, although a few documentation errors had been identified and corrected. On December 13, 1990, an enforcement conference was conducted with licensee enforcement conference was conducted with licensee representatives to review the circumstances which contributed to the misadministration, the violations identified during NRC's investigation of the

incident, and the licensee's corrective actions taken in response to NRC's findings. The licensee had implemented corrective actions for each of the violations identified during the inspection and had addressed other concerns related to licensed activities documented in NRC Inspection Report 30-11571/90-02 (Ref.B-1).

On December 20, 1990, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,250 two violations associated with the therapy misadministration (Ref. B-3). These included:

(1) a failure by the licensee to require its staff to follow the instructions of the supervising physician, and (2) a failure on the part of the licensee, through its Radiation Safety Officer, to ensure that radiation safety activities were being performed in accordance with approved procedures and regulatory requirements in the daily operations of its byproduct material program. These violations were jointly categorized as a Severity Level III problem (on a scale in which Severity Levels I and V are the most and least significant respectively) and assessed a civil penalty of \$1,250. A third violation, involving the failure to notify NRC of the therapy misadministration within the time allotted by NRC regulations, was categorized as a Severity Level IV violation and was not assessed a civil penalty.

The licensee has paid the civil penalty and has responded to the Notice, acknowledging each of the violations. NRC will review effectiveness of the licensee's corrective actions during future, routine inspections.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 900313 AO #: NRC 90-17 EVENT DATE: 05/14/1990
TITLE: MEDICAL DIAGNOSTIC MISADMINISTRATION
NAME: Overlook Hospital CITY: Summit STATE: NJ

Nature and Probable Consequences:

On June 1, 1990, NRC Region I was notified by the licensee in writing that a diagnostic misadministration involving iodine-131 (I-131) had occurred at the hospital.

An outpatient was scheduled for a nuclear medicine study by the referring physician's office by telephone. The nuclear medicine department understood the doctor's office to request an appointment for an iodine-131 scan. The patient brought the written prescription to the outpatient department and then proceeded to the nuclear medicine department for the scheduled study. The patient brought the written prescription to the outpatient department and then proceeded to the nuclear medicine department for scheduled study. The written prescription was not received by the nuclear medicine department until after the study was completed. When the nuclear medicine department received the written prescription, it was noted that the referring physician's written prescription requested a thyroid scan, not a iodine-131 scan. (A thyroid scan typically means a study using approximately 100-500 microcuries of iodine-123 as the imaging radionuclide. An iodine-131 scan usually refers to a whole body scan, utilizing a dose of approximately 1 to 5 millicuries.)

The patient involved in the misadministration had a benign tumor removed from a lobe of the thyroid in June 1989. Subsequent thyroid scans of the individual (an uptake study was performed in November 1989, after the thyroid lobectomy) indicated that the patient had a normally functioning thyroid.

The intended dose to the patient's thyroid was approximately 4 rads from 300 microcuries of iodine-123. The administered dose to the patient's thyroid, as a result of the misunderstanding of the physician's request, was approximately 1820 rads from 1.4 millicuries of iodine-131. The licensee does not expect any significant consequences to the patient.

Cause:

The cause of the event is attributed to inadequate procedures. The verbal request for the nuclear medicine study had not been verified by a written prescription prior to the study being performed.

Licensee Action:

After a telephone call on September 21, 1990, from NRC Region I staff to the licensee in regard to the incident, the licensee convened a Radiation Safety Committee meeting on October 2, 1990, to review the cause of the misadministration and to determine the corrective actions required to prevent a recurrence. The licensee established a procedure requiring receipt of a written prescription by the nuclear medicine department prior to administering any iodine for studies. This information was communicated to NRC Region I by telephone on October 3, 1990.

NRC Action:

NRC Region I inspectors will review the incident during the next routine inspection at this facility. The timeliness of the licensee's response (reviewing the cause and determining corrective actions following the May 14, 1990 incident) will also be reviewed.

Unless new, significant information becomes available, this item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 900785 AO #: NRC 90-18 EVENT DATE: 07/19/1990
TITLE: SIGNIFICANT BREAKDOWN IN MANAGEMENT AND PROCEDURAL CONTROLS AT A MEDICAL FACILITY
NAME: North Detroit General Hospital CITY: Detroit STATE: MI

Nature and Probable Consequences:

This event involved the apparent use of fraudulent films from 30 diagnostic nuclear medicine studies that rendered all but one of invalid. Such an event could have potentially resulted in significant adverse health effects to patients (e.g., a serious disease not be diagnosed, or a correct diagnosis could be significantly delayed). The details of the event are as follows:

On August 14, 1990, the licensee reported to NRC Region III that films from diagnostic nuclear medicine studies were apparently fraudulent. The films involved 30 studies performed on 27 patients during the time period July 19-27, 1990. (Some patients had more than one diagnostic procedure.) During this time period, the licensee's staff nuclear medicine technologist was on leave and a replacement technologist was supplied by a temporary services contractor.

For the diagnostic procedures involved, a radioactive pharmaceutical is introduced into the patients by injection or inhalation. The movement and deposition of these radioactive pharmaceuticals is then recorded as a film image. The image is then evaluated by the physician as a diagnostic tool.

The licensee subsequently determined that the films for 29 of the 30 procedures were fraudulent or indeterminate and were, therefore, unreliable for patient diagnosis. The remaining film is from a procedure performed by the contract technologist under supervision of the staff technologist. It appears to be accurate. The films in question show evidence of tampering (i.e., handwritten names and dates which do not match the computer-generated display in the film, and faint underlying and overwritten labels on films). In addition, the licensee reported that about 100 old patient films and jackets were discovered to be missing from their file location.

The fraudulent films were discovered by the staff technologist by comparison with later films after the contract technologist had left. The licensee then reviewed the films from procedures performed by the contract technologist. The licensee's investigation determined "conclusively that [the individual] had doctored and provided fraudulent nuclear medicine studies for interpretation. [The technologist] had submitted nuclear medicine studies on patients who had previously been imaged within the Department during the past 2 years and altered the names on those images and placed the names of the patients he was to have performed studies on their place."

The licensee was unable to determine, in most cases, whether the patients had been administered the prescribed radiopharmaceutical for the procedures. The diagnostic procedures, with one exception, were not considered to be valid, and therefore of no use in their intended diagnostic function. The licensee offered to redo the procedures, although some patients or their physicians elected not to have the studies performed again.

In those instances where a second procedure was performed, the patient received additional radiation exposure as a result of the fraudulent films that rendered the first procedure unusable. Where the retest was refused, the patients may have received a radiation exposure without the benefit of a valid diagnostic procedure. However, the radiation doses associated with diagnostic procedures are small.

Cause:

The fraudulent films and resulting invalid studies were the result of the action by the contract technologist and the failure of the licensee to supervise and train the individual adequately.

A special NRC inspection, which reviewed the circumstances of the fraudulent films, identified 10 apparent violations of NRC requirements, some of which were directly associated with the work performed by the contract technologist. These violations were indicative of a breakdown of management control of the licensee's nuclear medicine program.

Licensee Action:

As a result of this occurrence, the licensee has strengthened its screening procedures for prospective employees, both temporary and permanent. Training procedures have also been broadened and intensified. There will be more ongoing supervision and review of work by new employees.

NRC Action:

The NRC conducted a special inspection August 15 through September 7, 1990, to review the circumstances surrounding the fraudulent films. A number of violations were identified. On October 29, 1990, the NRC issued a Notice of Violation and proposed a civil penalty of \$2,500 (Ref. 3), which was paid by the licensee on November 26, 1990.

This item is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on the public health or safety can be considered an abnormal occurrence. In addition, the third general criterion in Appendix A notes that major deficiencies in management controls for licensed facilities or material can be considered an abnormal occurrence.

ITEM #: 900478 AO #: NRC 90-19 EVENT DATE: 08/07/1990
TITLE: MEDICAL DIAGNOSTIC MISADMINISTRATION
NAME: Copley Hospital CITY: Morrisville STATE: VT

Nature and Probable Consequences:

On August 14, 1990, NRC Region I was notified by the licensee in writing that a diagnostic misadministration involving iodine-131 (I-131) had occurred at the hospital on August 7, 1990. Further information was obtained in a follow-up phone call to the licensee September 24, 1990. A 63-year-old woman patient, undergoing I-131 treatment for primary hypothyroidism, was administered 1 microcuries instead of a routinely prescribed 10 microcuries. The dose to the thyroid, based upon the results of an uptake scan, was calculated at 3.9% uptake, resulting in an estimated actual dose to the thyroid of 29 rads. The licensee does not expect an adverse consequences to the patient.

The hospital reported that a supply of I-131 capsules had been ordered with incorrect amounts of I-131. Instead of ordering 5 capsules with a total activity of 100 microcuries, the 5 capsules were ordered as 100 microcuries each. On the day of the event the technologist measured the capsule in the dose calibrator prior to administration and incorrectly interpreted the dose calibrator reading of 112 microcuries as 11.2 microcuries. The error was identified by another technologist measuring the uptake by the patient's thyroid the following day.

Cause:

The causes of the event were attributed to human errors. The wrong I-131 capsules had been ordered, and the technologist incorrectly interpreted the dose calibrator reading.

Licensee Action:

The licensee reviewed the policies and procedures for assaying doses with all nuclear medicine technologists. In addition, the licensee's procedure was revised to require that only the technologist who orders the iodine capsules is allowed to administer them to patients.

NRC Action:

NRC Region I inspectors will review the incident during the next routine inspection at this facility.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

UPDATE (from NUREG-0090, Vol. 15, No. 3, page 11): NUREG-0090, Vol. 13, No. 3, "Report to Congress on Abnormal Occurrences: July-September 1990." As previously mentioned, on August 14, 1990, NRC Region I was notified by the licensee writing that a diagnostic misadministration involving iodine-131 (I-131) had occurred at Copley Hospital, Morrisville, Vermont, on August 7, 1990. As a result, a patient received an estimated dose to the thyroid of 29 rads.

The NRC conducted an inspection of the licensed program on February 20 and 21, 1991. A Confirmatory Action Letter (CAL No. 91-005) was issued on March 1, 1991, relative to the issues identified during the inspection. The licensee committed in the CAL the specified actions to prevent recurrence.

On April 29, 1992, an Enforcement Conference was held to review the findings of Inspection No. 030-17125/91-001, the subsequent Office of Investigation findings and the licensee's response to CAL No. 1-91-005. The licensee described its corrective and preventive actions that would be taken as a result of the items of noncompliance identified relative to the misadministration.

On July 15, 1992, the NRC issued a Notice of Violation and the Proposed Imposition of a Civil Penalty of \$2,500 (Ref. B-1).

The licensee paid the civil penalty and provided their corrective and preventive actions in a letter dated August 10, 1992. The licensee admitted that the Diagnostic Misadministration Report contained inaccurate information, but stated there had been no effort on their part to deceive the NRC.

On October 7, 1992, the licensee's proposal for ensuring the safe administration of radiopharmaceuticals was approved. The procedure requires that technologists obtain the written or verbal approval of the RSO or an authorized user prior to the administration of radiopharmaceuticals, except for those procedures covered by the Quality Management Program, which require that a written directive from an authorized user physician be obtained prior to administration of the radiopharmaceutical.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:	900558	AO #:	NRC 90-20	EVENT DATE:	09/22/1990
TITLE:	MEDICAL DIAGNOSTIC MISADMINISTRATION				
NAME:	West Shore Hospital	CITY:	Manistee	STATE:	MI

Nature and Probable Consequences:

On September 24, 1990, the licensee's consultant informed Region III that an 84-year-old female cancer patient received a 175 millicurie dose of a technetium-99m (Tc-99m) labeled radiopharmaceutical for an imaging scan of her gall bladder instead of the millicurie dose prescribed in the Nuclear Medicine Department's procedures manual.

The misadministration occurred on Saturday, September 22, 1990, when the patient's physician ordered a hepatobiliary (liver and gall bladder) scan. The radiopharmaceutical was prepared and administered by a part-time technician who was on weekend call. The technician had received only two weeks of training in the Nuclear Medicine Department procedures the previous February and had performed only two nuclear medicine procedures since then (during one procedure, she was directly supervised by the Radiology Manager; during the other, the Radiology Manager "coached" her through the procedure by telephone). After receiving the order on September 22, the technician telephoned the Radiology Manager at home for guidance. She was told to prepare the dose according to the Department's procedures manual, which stated that an 8 millicurie (mCi) dose of Tc-99m mebrofenin was needed for hepatobiliary scans. Tc-99m mebrofenin is prepared by adding free Tc-99m to a reagent kit containing the mebrofenin.

According to the technician, she eluted 392 mCi from the molybdenum-technetium generator, and then took 4 milliliters of the eluate and injected it into the reagent kit. After mixing, she withdrew 1 milliliter of the solution, put it on a dose calibrator, which claimed to read 8 mCi, and then injected the radiopharmaceutical into the patient. When she saw a "bright spot" forming on the scanning screen where the sharp image of the gall bladder should have been, she telephoned the Radiology Manager and informed him that something was wrong.

A reconstruction of the event by NRC and licensee consultants indicated that the dose to the patient was 175 mCi instead of the intended 8 mCi. The amount of Tc-99m mixed with the mebrofenin was probably around 440 mCi, instead of the manufacturer's maximum recommendation of 100 mCi. The NRC consultant concluded that the technician misread or misunderstood the activity reading on the dose calibrator prior to injecting the patient. The medical consultant also evaluated the medical consequences of the incident and concluded that no biological effects should be expected from the misadministration. It is estimated that the doses to the patient's bladder and upper large intestine were about 36 rads and 26 rads, respectively.

Cause:

The cause of the event was the licensee's failure to properly train and supervise an inexperienced technician. The individual technician misread or misunderstood instructions, and in some cases used guesswork in carrying out the procedure.

Licensee Action:

The licensee's corrective action includes more orientation and training of new employees; additions to the computerized quality assurance system to remind staff to hold required meetings and perform required tests; and additional oversight of the licensee's program by management and the Radiation Safety Officer. Also, the technician is no longer employed at the hospital.

NRC Action:

NRC Region III conducted a special inspection on September 27, 1990, and identified 10 violations of NRC requirements. Seven of the 10 violations pertained to this incident, including failure to prepare the reagent kit in accordance with manufacturer's instructions. The Region contacted a medical consultant who reviewed the case. On November 16, 1990, the NRC issued a Notice of Violation and proposed a civil penalty of \$4,375 (Ref 4). The licensee has paid the civil penalty. The corrective action will be further reviewed during a future routine NRC inspection.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 900786 AO #: AS 90-02 EVENT DATE: 04/19/1990
TITLE: MEDICAL THERAPY MISADMINISTRATION
NAME: Yuma Regional Medical Center CITY: Yuma STATE: AZ

Nature and Probable Consequences:

On April 19, 1990, a patient's uterine tumor was implanted with 224 iridium-192 seeds using 32 trochars (a sharp, pointed surgic instrument fitted with a hollow tube) each containing 7 seeds on a ribbon. The prescribed dose was about 2000 rads. A problem was noted with snagging of the ribbon in one trochar; five seeds were stripped from the trochar when an attempt was being made to remove both the trochar and the seeds. The trochar had inadvertently been placed in a necrotic cavity within the tumor, permitting the seeds to 'pay out' into the cavity rather than being stopped by tissue.

An unsuccessful attempt was made to remove the five stripped seeds during removal of the other seeds. When the trochar that had contained the snagged ribbon was removed, it was discovered that the tip of the trochar had been bent, presumably by the stony hardness of the tumor. The trochar was not bent before it was inserted.

The five seeds were left in the necrotic tumor center. These seeds, from the time of emplacement until total decay, would deliver dose considerably in excess of the prescribed dose. However, a medical consultant stated that the patient's poor prognosis for her illness outweighed any harm from additional radiation. (The patient subsequently died from her illness.)

The Arizona Radiation Regulatory Agency (ARRA) asked for dose calculations and, in addition, asked the physician to describe nature of the tumor hardness and to describe the incident to the Drug Product Reporting Program at the United States Pharmacopeia (USP). However, since the physician left the state, the ARRA sent a report to the USP.

Cause:

There were several causes for this event:

The trochar was inadvertently placed inside a cavity within the tumor;

The trochar, which was flexible and bendable, was bent by the hardness of the tumor;

During an attempt to remove the seeds, fluoroscopes failed because there was an inadequate power supply to the operating room and

the length of the ribbons was not controlled, so that 'paying out' of the ribbons was possible.

Licensee Action:

The physician, no longer practicing in Arizona, stated that he would use only rigid tungsten alloy trochars and pre-measure all ribbons, limiting the length to 21 cm.

NRC Action:

Other Agency Action:

The agency notified the USP and the Arizona State Board of Medical Examiners.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health and safety can be considered an abnormal occurrence.

ITEM #: 900516 AO #: NRC 90-21 EVENT DATE: 08/29/1990
TITLE: MEDICAL THERAPY MISADMINISTRATION
NAME: University of Cincinnati CITY: Cincinnati STATE: OH

Nature and Probable Consequences:

On August 29, 1990, 86 iodine-125 seeds (small sealed radiation sources) were permanently implanted in an 86-year-old patient. The seeds totaled 27.5 millicuries of iodine-125. A dose of 16,000 rads was prescribed for the prostate gland. The seeds were implanted in the prostate using an ultrasonic probe to view and position the implants.

Subsequent review by the licensee determined that most of the seeds had been implanted too deeply and had passed through the prostate into the surrounding tissue. Many of the seeds were 5 to 10 centimeters beyond the prostate gland. As a result, the radiation dose to the prostate was negligible compared to the prescribed dose of 16,000 rads. The licensee estimated a dose of 15,000 rads to the tissue beyond the prostate gland, considerably greater than the dose which would have been received if the seeds had been positioned as intended.

The licensee does not anticipate any significant effects to the patient as a result of the misadministration. Further treatment, including a repeat of the implant procedure, was planned.

Cause:

The iodine-125 seed implant procedure was relatively new for the licensee, although it had been used 13 times previously. The attending radiation oncologist is an authorized-user who is certified in therapeutic radiology by the American Board of Radiology. The primary cause of the misadministration appears to be the difficulty in viewing the prostate area using the ultrasonic probe. Ultrasonic imaging is often difficult and inexact, especially when attempting to visualize a soft tissue organ like the prostate.

Licensee Action:

The licensee has adopted revised procedures to prevent recurrence of the misplacement of the iodine-125 seeds in procedures of this nature. The revisions included an improved measuring technique to ensure proper seed depth placement and improved ultrasonic image analysis. The attending radiation oncologist traveled to the research center where the implant procedure had been developed to evaluate the procedure and to gather further information to improve the licensee's implant techniques.

NRC Action:

An inspection was conducted in November and December 1990 to review the full scope of NRC licensed activities at the University of Cincinnati, including this misadministration (Ref. 1). Although unrelated violations and deficiencies in the licensee's program were identified, there were no violations associated with this misadministration. The licensee's corrective actions were determined to be acceptable.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:	900586	AO #:	NRC 90-22	EVENT DATE:	10/05/1990
TITLE:	RADIATION OVEREXPOSURE OF A RADIOGRAPHER				
NAME:	Western Stress, Inc.	CITY:	Houston	STATE:	TX

Nature and Probable Consequences:

During the evening of October 5, 1990, the licensee notified the NRC that an incident had occurred earlier that evening while a radiographer and his assistant were working at a temporary jobsite. The radiographic operation involved the use of a radiograph device containing an 80.5 curie iridium-192 sealed source. (A radiograph device uses a radioactive sealed source to make x-ray images of welds and heavy metal objects. The position of the source is controlled by a drive cable that is used to crank the source out of the exposure device and to retract it back to the shield position within the device via an unshielded source guide tube.)

The licensee reported that the source became disconnected from the drive cable and remained in the guide tube. The radiographer retracted the drive cable unaware that the source was no longer attached to it. At this point, the radiographer removed his personnel dosimetry and approached the end of the guide tube to adjust the guide tube end-cap and collimator. As he removed end-cap, the source chain containing the iridium-192 source fell to the ground. The radiographer immediately retreated from the area. The licensee notified the NRC, and two NRC Region I inspectors were sent and arrived on site at midnight to investigate the incident. The circumstances associated with the radiation overexposure are described below.

Radiographic operations to perform 35 exposures of welds on a waste water storage tank were planned. The source guide tube end-cap and attached collimator were clamped to a stand that was magnetically mounted to the exterior surface of the tank wall. The stand was moved along the weld for each successive 45-second exposure.

After cranking out the source for the sixth exposure, the radiographer heard a crash and saw that the magnetically mounted stand that held the collimator and end-cap, had fallen from the side of the tank and was lying on the concrete pad. The source guide tube end-cap with the collimator had been approximately 10 feet above the concrete pad for this exposure.

The radiographer attempted to crank the source back into the camera but found that the drive cable could only be retracted a short distance. He then looked around the tank and noticed the guide tube was looped. The radiographer then dragged the camera back by pulling on the drive cable housing in order to straighten out the guide tube. After straightening the guide tube, the radiographer was able to fully retract the cable, and consequently thought that the source was in the camera. Subsequently, the radiographer removed the chain from around his neck that held his two 200 millirem self-reading pocket dosimeters and his thermoluminescence dosimeter badge and laid the chain and dosimeters near the crank handle. The radiographer later admitted that he took this action to conceal the radiation exposure he would later receive.

The radiographer walked up to the end of the source guide tube with his survey meter in his hand, but did not refer to the instrument for any indication of radiation. At this time he grasped the end of the source guide tube with his left hand. With his right hand he removed the tape which held the collimator in place and cast the collimator aside. He then began to unscrew the source guide tube end-cap from the source guide tube to exchange the end-cap from the source guide tube to exchange the end-cap for a lighter end-cap assembly. As he removed the cap, the source chain containing the sealed source fell out of the end-cap assembly onto the concrete pad. The radiographer then dropped the source guide tube and end-cap, and rapidly left the immediate area.

A source recovery team from the camera manufacturer was sent to the site and safely recovered the source.

Based on interviews conducted with the radiographer and the Corporate Radiation Safety Officer, NRC inspectors determined that the radiographer received exposures in excess of regulatory limits. Dose estimates performed by the NRC indicated a whole body exposure to the radiographer of about 8.9 rem and an extremity exposure of about 1070 rem. The licensee sent the radiographer to a physician for examination and blood tests. No clinical manifestations of the overexposure were evident.

Cause:

The radiographer failed to conduct a radiation survey of the exposure device after the exposure. Without a radiation survey, the radiographer was not aware that the source was disconnected and had not returned to the shielded position. His willful removal of dosimetry devices complicated subsequent dose calculations.

Licensee Action:

The licensee's proposed corrective actions included temporarily removing the radiographer from radiography duties, doubling the number of management audits and safety meetings, revising company policy on the number of hours worked, and increasing safety training from 16 hours per year to 32 hours per year.

NRC Action:

NRC Region IV transmitted its inspection report on December 9, 1990 (Ref. 2), and conducted an Enforcement Conference with the licensee on December 7, 1990, to discuss the event. Escalated enforcement action is pending. NRC issued an immediately effective order on January 28, 1991 (Ref. 3), prohibiting the radiographer from engaging in NRC licensed activities on behalf of the licensee for a period of 1 year.

Future reports will be made as appropriate.

UPDATE (from NUREG-0090, Vol. 14, No. 2 page 15). This event involved an estimated radiation exposure of 1070 rem to the right hand of a radiographer employed by Western Stress, Inc., of Houston, Texas. It was originally reported as an abnormal occurrence in NUREG-0090, Vol. 13, No. 4, "Report to Congress on Abnormal Occurrences: October-December 1990". It is updated as follows:

The NRC inspection report of the incident was forwarded to the licensee on December 4, 1990 (Ref. B-8). NRC Region IV conducted an Enforcement Conference with the licensee on December 7, 1990, to discuss the event and the violations identified during the NRC investigation. On January 28, 1991, the NRC issued an immediately effective order prohibiting the radiographer from engaging in NRC-licensed activities on behalf of the licensee for a period of 1 year (Ref. B-9). This action was based upon the findings of an investigation conducted by the NRC Office of Investigations, which included admission by the radiographer that he had provided false statements to the NRC inspectors regarding the removal of his pocket dosimeter and film badge prior to attempting to recover the source.

On May 6, 1991, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$15,000 for five violations associated with the event (Ref. B-10). These included: (1) a quarterly extremity radiation exposure in excess of 18.75 rems, (2) a quarterly whole body radiation exposure in excess of 1.25 rems (3) failure to perform a survey following a radiograph exposure, (4) failure of a radiographer to wear required personal monitoring devices while performing radiography, and (5) failure to provide complete and accurate information to the NRC during the investigation. The first three violations were jointly categorized as a Severity Level I problem (on a scale in which Severity Levels I through V range from the most to the least significant, respectively) and assess a \$5,000 civil penalty. The remaining two violations were also categorized as a Severity Level I problem and assessed a civil penalty of \$10,000. The licensee subsequently paid the civil penalty.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 1 of "For All Licensees") of this report notes that an exposure of the feet, ankles, hands or forearms of any individual to 375 rem or more of radiation can be considered an abnormal occurrence.

ITEM #: 900597 AO #: NRC 90-23 EVENT DATE: 10/15/1990
TITLE: MEDICAL THERAPY MISADMINISTRATION
NAME: William Beaumont Hospital CITY: Royal Oak STATE: MI

Nature and Probable Consequences:

On October 10, 1990, a 60-year-old female patient was referred to the nuclear medicine department for iodine-131 thyroid ablation therapy after undergoing a thyroidectomy for cancer. After reviewing the clinical data on the patient, the authorized physician-user prescribed 175 millicuries of iodine-131 to be administered orally on October 15.

On October 15, the licensee received the patient's oral iodine-131 solution from a distributor. In addition, the licensee also received a second vial containing 140 millicuries of iodine-131. This vial is a weekly standing-order for the hospital and is used as needed during the week.

The two vials were assayed by a technologist. The one vial contained 180 millicuries, and this amount was later approved by the authorized physician for the patient's treatment. The standing-order vial contained 140 millicuries. After the assay, the technologist placed both vials side by side in the fume hood located in the nuclear pharmacy. Both were still in their original lead shields and labeled as to their contents.

At 10:30 a.m., the authorized physician-user was ready to administer the iodine-131 to the patient, and called for the material. Since the technologist who had prepared the dosage was not readily available, another technologist went to the pharmacy to obtain the radiopharmaceutical. The technologist who had prepared the dosage did not indicate to the administering technologist how many vials were to be administered. The administering technologist picked up both vials, assuming they were to be administered to the patient. The technologist did not review the labels on the containers, assuming they were the proper doses. The technologist also did not consider the administration of more than one vial to be unusual since this was a common occurrence at this facility.

After reviewing the dosage record, the authorized physician instructed the technologist to administer the dose to the patient. The technologist then proceeded with the administration of both vials containing 320 millicuries. The physician did not review the labeling on the containers, believing that since the patient's unit dose record was complete and indicated a dosage of 180 millicuries, the two vials were the proper ones for administration.

On October 16, the nuclear pharmacist received a request for 25 millicuries of iodine-131, but could not find the standing-order vial. The resulting investigation determined that the vial had been erroneously administered the previous day. The patient and doctor were subsequently informed of the misadministration. The licensee's radiation safety officer also was notified.

NRC Region III contracted with a medical consultant to evaluate the potential medical effects on the patient as a result of the misadministration. The consultant's evaluation indicated that the misadministration should not have any significant medical effect on the patient; the estimated bone marrow dose received by the patient was between 40 and 50 rads, which should be well tolerated by the patient.

Cause:

The three primary causes were: (1) the stock solution of iodine-131 was stored in the same location as the patient's dose, (2) the administering-technologist was never informed by the technologist who actually prepared the dose that only one vial was to be used and (3) the administering technologist and physician did not review the labels on the container.

Licensee Action:

On October 18, 1990, the hospital requested that its NRC license be amended to include the following modifications to its iodine-131 administration procedures: (1) on all iodine-131 therapy doses, the person administering the dose must either be present in radiopharmacy when the dose is assayed, or the person must personally assay the dose before it is taken out the radiopharmacy; (2) the dose sheeting must indicate the number of vials that comprise the dose; (3) just prior to the administration, the physician verify the assay dose activity with the prescribed dose and initial the dose sheet; and (4) the standing order of therapeutic iodine-131 will be stored in the hot locker and will be placed in the fume hood only when needed for dispensing. On October 29, 1990, these new procedures were incorporated into the hospital's NRC license via an amendment.

NRC Action:

NRC Region III conducted an inspection at the facility on October 17, 1990 (Ref. 4). Although no violations of NRC requirements were identified, concerns were expressed over the storage of stock iodine-131 with the patient's intended dose and the lack of communication between the technologist who prepared the dose and the technologist who administered the dose. The NRC medical consultant indicated that the licensee's corrective action program was appropriate. Corrective actions will be examined by the NRC Region III during future inspections.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 900691 AO #: NRC 90-24 EVENT DATE: 11/12/1990
TITLE: RADIATION OVEREXPOSURE OF A RADIOGRAPHER
NAME: Tumbleweed X-Ray Company CITY: Greenwood STATE: AR

Nature and Probable Consequences:

On November 26, 1990, the licensee notified the NRC that on November 12, 1990, a radiographer's assistant may have sustain a possible radiation overexposure to his right hand. The licensee stated that it was not informed of the incident by the radiographer until the morning of November 25, 1990, because the radiographer did not think an overexposure had occurred until the assistant radiographer's right hand became red and his fingers began to swell. On the day of the incident, the radiographer and his assistant were performing radiographic operations at a temporary jobsite with a radiography device that contained a 49 curies iridium-192 sealed source. NRC Region IV sent an inspector to investigate the incident; based on interviews with the radiographer, the assistant, and the owner of the company, the circumstances associated with the radiation overexposure are described below.

The radiographer and his assistant were performing radiographic exposures of welds on a 48-inch diameter tank at a fabrication shop. After the sixth exposure, the radiographer left the immediate area to load film in a belt. While the radiographer was away assistant set up the seventh exposure and cranked out the source. The assistant had turned the crank about two or three turns when he saw the magnetically mounted stand, that held the guide tube near the exterior of the tank, had fallen.

The assistant radiographer's alarming personnel dosimeter (chirper) had alarmed loudly when the guide tube had fallen. The assistant stated that he froze for about 5 seconds, then he cranked the source back to the shielded position. The assistant's chirper had quit alarming, so he thought the source was in the shielded position in the radiography device. The assistant radiographer then stated that he failed to pick up and use his survey instrument to perform a survey of the radiographer device and the source guide tube, because his chirper was not alarming. (The licensee later reported that the chirper had been dropped a couple of times that night and upon subsequent testing was found to be malfunctioning due to a shorted ground wire.) Instead, walked over to the tank and repositioned the magnetic stand and source guide tube. After the assistant radiographer correctly positioned the guide tube with his right hand, he returned to the crank handle to proceed with the exposure.

When he performed this exposure, he noted that his chirper did not alarm when the source was cranked out. Because of this, a the exposure was completed, he looked at his pocket dosimeter and noticed that it was off scale (greater than 200 millirem). At about the same time, the radiographer returned and the assistant told him what had happened and that his pocket dosimeter had gone off scale. The assistant told the radiographer that he did not think that he had received an overexposure, but that he thought his pocket dosimeter was off scale because he had bumped it earlier. The radiographer and his assistant continued to work and did not inform the Radiation Safety Officer of the incident until after the assistant's hand showed clinical signs of a radiation injury.

The assistant radiographer stated that he grasped the guide tube with his right hand just below where the guide tube was taped to the magnetic stand. The radiation injuries that the assistant radiographer sustained to his hand indicated that he grasped the guide tube with the thumb, index, and middle fingers, and that the source had to be directly beneath the point grasped. This information may indicate that the assistant radiographer mistakenly cranked the source out, instead of in, when the incident first occurred. From reenactments, clinical observations, and calculations, the dose to the assistant radiographer's hand was estimated by the NRC to be between 1500 to 3000 rem. The whole body dose to the assistant, as measured by his thermoluminescent dosimeter was 365 millirem. Blood samples were taken from the assistant for cytogenetic tests; the results indicated an equivalent whole body exposure of less than 10 rem.

On November 29, 1990, the NRC inspector noted that the assistant's thumb, index, and middle fingers were severely blistered and swollen. On this date the assistant was admitted to a burn center in Oklahoma city, Oklahoma, for medical care. The assistant remained in the hospital for approximately two weeks, and during that period had a skin graft performed on his index finger. On January 22, 1991, the physician contacted NRC and stated that the assistant's middle finger and thumb appeared to be healing but the index finger was grafted due to lesions that were not healing. The physician also stated that the assistant would remain under his care, and he would supply the NRC with periodic reports.

Cause:

The radiographer failed to supervise the assistant properly, and the assistant failed to conduct a radiation survey of the exposure device.

Licensee Action:

The assistant radiographer is no longer employed by the licensee. Additional actions to be taken by the licensee will be discussed at an upcoming enforcement conference with the NRC.

NRC Action:

During the investigation of this event, an Order modifying the license was issued on December 4, 1990, prohibiting the radiographer and the assistant from participating in licensed activities (Ref. 5). NRC Region IV issued an inspection report to the licensee on February 5, 1995 (Ref. 6) and plans to conduct an enforcement conference with the licensee.

Future reports will be made as appropriate.

UPDATE (from NUREG-0900, Vol. 14, No. 3, Page 10). This abnormal occurrence was originally reported in NUREG-0090, Vol 13, No. 4, "Report to Congress on Abnormal Occurrences: October-December 1990." The event involved a serious radiation overexposure to the right hand of a radiographer's assistant employed by Tumbleweed X-Ray Company (the licensee) of Greenwood, Arkansas. It is updated, and closed out, as follows:

On May 9, 1991, the NRC Office of Investigations (OI) issued a report of its findings pursuant to an investigation of the November 12, 1990, incident. OI concluded that the radiographer and assistant had willfully violated NRC regulations and licensee operating procedures. However, the investigation did not identify any deliberate violation of NRC requirements by licensee management. The licensee continued to perform radiographic operations under the authority of its NRC license until July 1991, when a request for termination of the license was submitted to NRC.

On September 6, 1991, NRC issued an immediately effective order suspending the licensee's NRC authority to operate under the General License granted by 10 CFR 150.20 for a period of 3 years and granted termination of its NRC license (Ref. B-5). Under the terms of the Order, the licensee may not conduct radiographic operations in any jurisdiction regulated by the NRC.

The Order was based on the licensee's history of failure to meet numerous regulatory requirements and commitments regarding licensing actions and its licensed operations. These failures were identified in several inspections and two investigations by OI. The inspections and initial investigation resulted in the licensee being cited for repetitive violations of failure to implement a quality assurance program for Type B packages (radiographic exposure devices), failure to conduct quarterly field audits of radiographic creation of false documents, failure to maintain records, and failures to respond to communications from NRC and Agreement State agencies. In addition, it considers the failure to comply with all of the provisions of a prior Order that was issued to the licensee in September 1990 (Ref. B-6).

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 1 of "For all Licensees") of this report notes that an exposure of the feet, ankles, hands or forearms of any individual to 375 rem or more of radiation can be considered an abnormal occurrence.

ITEM #: 900787 AO #: NRC 90-25 EVENT DATE: 11/26/1990
TITLE: MEDICAL DIAGNOSTIC MISADMINISTRATION
NAME: Veterans Administration Medical Center CITY: San Diego STATE: CA

Nature and Probable Consequences:

On November 26, 1990, a patient scheduled for the administration of 5 millicuries of indium-111 labeled anti-CEA monoclonal antibody for diagnostic imaging of colorectal cancer was mistakenly administered 168 millicuries of technetium-99m pertechnetate.

Prior to the administration, a nuclear medicine physician instructed his technical assistant to obtain the indium-111 from the Nuclear Medicine Preparation Lab. However, the assistant erroneously picked up a syringe containing the technetium-99m pertechnetate. The physician failed to positively identify the label on the syringe before injecting the contents of the syringe into patient.

The error was discovered by the licensee within minutes after the misadministration and the patient was administered 10 drops of potassium iodide and 1 gram of perchlorate to block and flush the thyroid gland respectively.

The patient was placed in an isolated room normally used for therapy for two days. The patient was scanned approximately three hours after the misadministration and the thyroid gland showed no elevated radioactivity. A small residual amount of technetium-99m was detected in the bladder. Following the scan, the patient was noted to be clinically unchanged and was discharged for the licensee's medical center.

Had the blocking and flushing agents not been administered, the organ receiving the highest exposure would have been the stomach wall, receiving an estimated 42 rem compared to about 5 rem for indium-111. Administration of the blocking and flushing agents reduced the radiation exposure to all organs except the bladder wall. It is estimated the bladder wall received about 17 r from the technetium-99m compared to about 3 rem for indium-111.

Cause:

The main cause of the misadministration was the failure of the nuclear medicine physician and his technical assistant to read the label on the technetium-99m syringe at the time of the injection. A contributing cause of the misadministration was inadequate training of the physician's technical assistant who was provided a description of the radiopharmaceutical based only on the color and shape of a container and not the label.

Licensee Action:

The physician's privilege to inject patients had been temporarily revoked. Additional training of the nuclear medicine staff is planned. Recommendations of a licensee internal quality assurance investigation board are currently being considered.

NRC Action:

A special NRC team inspection was conducted at the licensee's facility following the misadministration. An inspection report was issued on January 3, 1991 (Ref. 7) and an enforcement Conference was held with the licensee on January 10, 1991. On March 13, 1991, a Notice of Violation was issued to the licensee for violations identified during the inspection (Ref. 8). None of the violations pertained to the misadministration and no civil penalty was proposed.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 090326 AO #: NRC 91-01 EVENT DATE: 11/28/1990
TITLE: SIGNIFICANT DEGRADATION OF PLANT SAFETY AT NUCLEAR FUEL SERVICES, INC. IN ERWIN, TENNESSEE
NAME: Nuclear Fuel Service, Inc. CITY: Erwin STATE: TN

Nature and Probable Consequences:

Nuclear Fuel Services, Inc. is a fuel production facility that produces nuclear fuel for the U.S. Navy. On November 30, 1990, licensee personnel discovered that on November 28, 1990, 395 grams of uranium-235, contained in liquid waste, had been processed through the waste water treatment system for collection and disposal of the uranium. This quantity was above the administrative criticality safety limit of 350 grams for the unfavorable geometry tanks used to hold the waste. (A favorable geometry tank is one having dimensions specifically designed to prevent criticality of its fissile material contents. An unfavorable geometry tank can be used, however, if the amount of fissile material is kept below that needed to achieve criticality.)

While the amount of uranium-235 was well below the amount needed for criticality, the circumstances associated with the event were particularly safety significant. Highly concentrated uranium solutions in an adjoining part of the process were available in quantities that were more than sufficient to have caused a criticality accident in the unfavorable geometry tank. The hydrostatic head associated with those highly concentrated solutions would have been sufficient to force those solutions into the unfavorable geometry tank if the set of normally closed valves were faulty or were not fully closed. The event is briefly described as follows.

Filling of storage tanks with liquid waste from the solvent extraction system in the high enriched uranium recovery process began on November 27, 1990. When the tanks were full, the contents were recirculated prior to sampling. An operator collected two samples of the liquid and submitted them for analysis. The analytical results were received on November 28, 1990, and revealed that the uranium concentration in the liquid was well below the authorized discard limit, hence, the quantity of U-235 was below the safety limit of 350 grams. The liquid waste was then pumped to another tank where it was mixed again, sampled for material accountability purposes, and then pumped to the waste Water Treatment Facility (WWTF).

On November 30, 1990, the laboratory reported the results of the accountability sample to be above the authorized discard limit. This higher concentration was confirmed by analysis of another sample which had been obtained when the liquid was received at the WWTF. These analyses confirmed each other, and all discharges were halted as a special licensee investigation team initiated a detailed review to determine the causes and needed corrective actions. At about 4:15 p.m., the licensee reported the incident to the NRC.

The NRC issued written confirmation on November 30, 1990, that the licensee would refrain from transferring liquid waste until certain actions had been completed (Ref. 1). An NRC inspector was dispatched to the site on December 1 and two other NRC personnel arrived on December 2, 1990, to perform a special NRC team inspection (Ref 2).

Cause:

The licensee identified the probable causes of the November 28 event to be (1) less than adequate piping layout that allowed uranium solutions to flow into the unfavorable geometry tank and (2) personnel-related inadequacies in that operators had no knowledge of the potential for crossover of high concentrated uranium solutions into unfavorable tanks as a result of open valve or other anomalies in the piping system.

Following a review of the incident, the NRC concluded that there appeared to be other root causes in addition to those given by the licensee. These root causes included:

1. The safety basis for the plant was less than adequate because a documented safety analysis was not available.
2. As a result of the lack of a detailed safety analysis, equipment important to safety, such as valves, were not properly identified, protected, emphasized in plant control documents and training sessions, tested and maintained appropriate to their safety function and did not possess positive closure indication.
3. The design basis of the plant was less than adequate. The system drawings lacked adequate detail.

The licensee missed an opportunity to preclude the problems several years earlier when modifications were made to the piping system. The licensee's reviews of the modifications failed to identify the significant potential for uranium solutions to flow into unfavorable geometry vessels.

Licensee Action:

Corrective actions included modification of the piping system to prevent highly concentrated uranium solutions from flowing into unfavorable geometry tanks. A review of the fuel recovery facility was initiated to identify the nuclear safety features and control for each unfavorable geometry vessel. A Nuclear Criticality Safety Performance Improvement Program (PIP), that had been instituted prior to the incident, was accelerated and expanded to address the root causes. Training was also given to fuel recovery personnel to make them aware of the problem.

NRC Action:

The special NRC team inspection (Ref. 2) identified two violations dealing with (1) failure to perform an adequate evaluation of equipment joined by piping for the possibility of siphoning and (2) failure to adhere to the administrative criticality safety limit of 3 grams of uranium-235 in unfavorable geometry tanks.

The NRC inspected the actions taken and, following the licensee's identification of the safety features and controls, issued a letter authorizing resumption of solution transfers on December 18, 1990 (Ref. 3). An Enforcement Conference with the licensee was held on January 18, 1991. On March 20, 1991, the NRC forwarded a Notice of Violation (for the violations identified during the special NRC team inspection) and proposed a civil penalty of \$10,000 (Ref. 4). The two violations were classified as Severity Level II on a scale in which Severity Levels I and V are the most and least significant, respectively. The licensee has paid the civil penalty.

In early 1991, the NRC prepared an action plan for the licensee's facility. This plan is updated quarterly and tracks the completion of the licensee's PIP items, quarterly NRC and licensee management meetings on the pip status, and NRC technical reviews of PIP. Other items addressed in the plan included license renewal milestone and management meetings on decommissioning activities. A full-time resident inspector started at the facility on April 22, 1991.

The item is considered closed for the purpose of this report.

Other Agency Action:**Criteria:**

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 10 of "For All Licensees") of this report notes that a major deficiency in design, construction, or operation having safety implications requiring immediate remedial action can be considered an abnormal occurrence.

ITEM #: 910181 AO #: NRC 91-02 EVENT DATE: 01/17/1991
TITLE: MEDICAL DIAGNOSTIC MISADMINISTRATION AT HUTZEL HOSPITAL IN DETROIT, MICHIGAN
NAME: Hutzel Hospital CITY: Detroit STATE: MI

Nature and Probable Consequences:

On January 24, 1991, the licensee notified NRC Region III that a medical diagnostic misadministration had occurred at its facility on January 17, 1991, when a patient was administered a dosage of iodine-131 that was 100 times greater than prescribed. A written report was received by Region III on February 1, 1991.

On January 16, 1991, a 37-year-old female patient (who had given birth to a baby 2 days earlier) was scheduled to have a thyroid scan to determine if she had a substernal goiter (beneath the breastbone). The licensee's normal procedure for such a thyroid scan usually involves administration of a 50-microcurie dosage of iodine-131. This would typically result in a thyroid dose in the range of 50-70 rads. The prescription for the procedure was prepared by a physician's assistant at the direction of the referring physician. The nuclear medicine technologist subsequently discussed the procedure with the physician's assistant and questioned whether or not the thyroid scan was the appropriate procedure. The technologist indicated a whole body scan to identify thyroid tissue throughout the body would be the appropriate test. The physician's assistant agreed and submitted a new order for the whole body scan. The iodine-131 was administered to the patient on January 17, 1991, with the whole body scan performed on January 18, 1991. The procedure constitutes a misadministration because the referring physician had not intended to perform a whole body scan using iodine-131.

The whole body scan involved a dosage of 5 millicuries of iodine-131 instead of 50 microcuries, which would have been used for the diagnostic procedure actually prescribed by the referring physician. Although the whole body scan is a diagnostic test - intended for patients who have had their thyroid removed - the 5-millicurie dosage is in the range that may be used for treatment of thyroid disorders.

Prior to administering the iodine-131, the technologist determined that the patient was not breastfeeding her baby and did not intend to breast feed. (Breast-feeding a baby is a concern because the radioactive iodine can be passed to the baby through the milk.) Some direct radiation exposure was received by the baby due to the presence of the iodine-131 in the mother's body. This exposure, however, was minimal (estimated to be approximately 0.5 millirads) because the baby was with the mother for only a minute period because of the mother's medical problems. After the misadministration was discovered, contact between the mother and baby was restricted for two days to avoid further radiation exposure to the infant.

The NRC retained a medical consultant to evaluate the circumstances of this case. The consultant estimated that the patient received a dose of approximately 6500 rads to her thyroid. This exposure would carry a slightly increased risk of developing hypothyroidism or thyroid cancer. The consultant recommended periodic monitoring of the patient for hypothyroidism and for breast and thyroid cancer.

Cause:

This misadministration was caused by the modification of the intended diagnostic procedure as a result of the discussion between the physician's assistant and the nuclear medicine technologist. This modification, which involved substantially increasing the dosage of radioactive iodine-131, was not reviewed by or approved by the patient's physician. The physician, in fact, desired the thyroid scan procedure using the lower dosage.

An NRC inspection to review the circumstances of the misadministration (Ref. 5) also determined that the hospital had not provided training in the proper ordering and administration of radiopharmaceuticals to individuals working under the supervision of a physician designated on the NRC license.

Licensee Action:

The hospital adopted new procedures requiring specific approval by an authorized physician prior to the oral administration of more than 50 microcuries of iodine-131. This authorization is to be obtained immediately prior to the planned administration. The hospital also reaffirmed that the technologist and physician's assistants are not permitted to change an order given by an attending physician.

The hospital recommended that the patient be placed on a thyroid hormone to inhibit the growth of thyroid nodules and that she be monitored for possible development of hypothyroidism or other complications.

NRC Action:

A special inspection was conducted February 19, 1991, to review the circumstances surrounding the misadministration (Ref. 5). The inspection identified two apparent violations associated with the incident: (1) failure to instruct supervised individuals on the principles of radiation safety, and (2) use of NRC licensed material by unauthorized individuals. These inspection findings remain under review by the NRC, and enforcement action is pending.

Future reports will be made as appropriate.

UPDATE (from NUREG-0090, Vol. 16, No. 3, Page 14). This abnormal occurrence was originally reported in NUREG-0090, Vol

19, No. 1, "Report to Congress on Abnormal Occurrences," January-March 1991. The abnormal occurrence report is updated as follows:

On January 17, 1991, a patient received a dosage of iodine-131 in a diagnostic procedure that was 100 times greater than the dosage prescribed.

This misadministration was caused by a modification of the intended diagnostic procedure as a result of a discussion between the physician's assistant and the nuclear medical technologist. The modification was not reviewed or approved by the patient's physician.

No enforcement action was taken. This time is considered close for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 951055 AO #: NRC 91-04 EVENT DATE: 02/14/1991
TITLE: MEDICAL THERAPY MISADMINISTRATION AT HAHNEMANN UNIVERSITY HOSPITAL IN PHILADELPHIA, PENNSYLVANIA
NAME: Hahnemann University Hospital CITY: Philadelphia STATE: PA

Nature and Probable Consequences:

On February 22, 1991, NRC Region I was notified by the licensee that a therapeutic misadministration had occurred at its facility during the period from February 14 to 18, 1991, while a patient was undergoing radiation therapy for a tumor in the eye.

A radiotherapy physician prescribed a therapeutic dose of 30,000 rads to the base of the tumor and 14,300 rads to the apex of the tumor from an iodine-125 custom-designed eye plaque. The staff physicist who designed the eye plaque informed the radiotherapist that based on the eye plaque design, dose of 30,000 rads would be delivered to the base of the tumor and 9,925 rads to the apex over 127.8 hours. This treatment plan was found acceptable and agreed upon. While the physicist was designing the plaque and calculating the anticipated dose, he decided to change to an eye plaque with a different radius of curvature. The physicist changed the coordinates for placement of each iodine-125 seed used in the plaque but failed to change the associated points for calculation of dose to various depths within the eye.

On February 18, 1991, the physicist suspected that an error had occurred while planning a treatment for another patient with a similar tumor. At that point, he retrieved patient data from the computer for the treatment started on February 14, 1991, reviewed the data, and confirmed that an error had been made. The patient's eye plaque was then removed. At that time, a total of 99.25 hours had elapsed since the beginning of the treatment, resulting in a total treatment dose of about 59,000 rads to the base of the tumor and 19,500 rads to the apex of the tumor. The licensee stated that the dose received by the tumor was within acceptable medical treatment protocols for that type of tumor, and that no acute effects were observed in the patient.

NRC Region I contacted an NRC medical consultant to review the event. The consultant stated that there was an increased risk of long term adverse effects, (e.g., cataract, tissue damage).

Cause:

The causes are attributed to human error on the part of the licensee's staff physicist, lack of written procedures, and lack of dual verification of dose calculations prior to administration.

Licensee Action:

The licensee's planned corrective actions include establishing written protocol for this procedure, including a second verification of the treatment calculations prior to administration of dosages to patients.

NRC Action:

An NRC Region I inspector conducted a special inspection of the circumstances surrounding this misadministration on February 25, 1991. The inspection report was forwarded to the licensee on March 11, 1991 (Ref. 6). The report notes that the inspector suggested that the licensee establish a written protocol for the procedure and the licensee agreed. The report also identified one violation of NRC requirements, i.e., failure to notify the NRC of the therapy misadministration within 24 hours of discovery. A management meeting between NRC Region I and licensee management was conducted on March 21, 1991, to review the licensee's actions to prevent recurrence.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 910413 AO #: NRC 91-05 EVENT DATE: 03/28/1991
TITLE: MEDICAL THERAPY MISADMINISTRATION AT CLARA MAASS MEDICAL CENTER IN BELLEVILLE, NEW JERSEY
NAME: Clara Maass Medical Center CITY: Belleville STATE: NJ

Nature and Probable Consequences:

On March 28, 1991, the licensee informed NRC Region I that a therapeutic misadministration, involving administration of iodine-131 to the wrong patient, had occurred earlier that day.

A radiotherapy physician prescribed a therapeutic dosage of 10 millicuries of iodine-131 to a patient for the treatment of hyperthyroidism. The physician that was familiar with the patient was not able to administer the therapeutic dosage and asked another physician to administer it. In the meantime, a transporter, while reviewing the patient transport requests, noted that the patient was listed in a bed that she believed was occupied by another patient. The transporter notified the nuclear medicine secretary to check into the discrepancy. The secretary referred to a patient list for the patient's name, noted the area of the hospital where the patient's room was, and changed the request form. The secretary did not know that there were two patients in the hospital with the exact same names. (The second patient was in the hospital for a lung condition.) Also, the secretary did not know that the computer program that generated the patient list did not print duplicate entries. The patient's name who was to undergo treatment for hyperthyroidism was not printed on the list.

The physician who administered the dose picked up the request form and the iodine-131 dosage from the Nuclear Medicine Department and went to the nursing station on the floor of the patient with the lung problem. The physician did not inform the nursing staff that he was about to administer a therapeutic dosage to one of their patients and went to the lung patient's room. There, he asked the patient his name and verified the name on the wrist band but did not cross check the patient number on the wrist band with the patient number on the wrist band with the patient number on the request form. The physician completed the request form and returned the patient folder to the nurses' station. Within five minutes of the administration of the radiopharmaceutical, the nurses discovered the error and informed the physician and the Radiation Safety Officer. The licensee decided to administer a thyroid blocking agent of 1000 milligrams of potassium iodide immediately, with three subsequent doses 1000 milligrams each given at four hour intervals.

The licensee determined that the thyroid of the patient received an uptake of between 80 and 100 microcuries of iodine-131 which would give a dose of between 112 and 140 rads. An NRC medical consultant, who reviewed the event, concurred with these figures. The licensee advised the NRC that no adverse effects were anticipated during the lifetime of the patient as a result of the misadministration.

Cause:

The causes were attributed to failure to follow the hospital protocol of checking the patient identification number, and failure to inform the head nurse of the floor of the therapeutic procedure, prior to administration.

Licensee Action:

The licensee's planned corrective action includes establishing a check list that must be completed by individuals administering therapeutic dosages. The check list will require that the person administering the dosage to check, as a minimum, the type of radiopharmaceutical to be administered, the activity of the dosage, the name of the patient, and the patient number; it will also require notification of the nursing staff that one of their patients is undergoing radiopharmaceutical therapy. Other actions include changing the computer program so that all of the information is printed out on the patient list, and reinstruction to personnel regarding patient verification procedures.

NRC Action:

On April 1, 1991, Region I inspector conducted a special inspection of the circumstances surrounding this misadministration. The inspection report was forwarded to the licensee on April 17, 1991 (Ref. 7). No violations of regulatory requirements were identified. The licensee's corrective actions are considered satisfactory.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 951054 AO #: AS 91-01 EVENT DATE: 07/26/1989
TITLE: MEDICAL THERAPY MISADMINISTRATION AT GOOD SAMARITAN MEDICAL CENTER IN PHOENIX, ARIZONA
NAME: Good Samaritan Medical Center, February-June 1989 CITY: Phoenix STATE: AZ

Nature and Probable Consequences:

On July 26, 1989, the licensee reported to the Arizona Radiation Regulatory Agency (State Agency) a series of three misadministrations involving the use of a cobalt-60 teletherapy unit in the licensee's Radiation Oncology Department.

The three patients received exposures of approximately 14%, 11%, and 12% greater than the prescribed doses of 6200 rads, 6400 rads, and 5000 rads, respectively, from an AECL Theratron-80 unit containing 5529 curies of cobalt-60 assayed on September 1, 1988. A beam correcting sedge had been used along with a treatment planning computer. Although the computer already contained a wedge correction factor, the technologist and dosimetrist added a second wedge correction factor after checking with the consulting physicist and being told that a wedge factor would be required.

While preparing to treat a fifth patient assigned the same treatment protocol, a point hand calculation indicated a wide discrepancy when compared to the computer generated treatment time. This discrepancy led to a comprehensive search of past cases which revealed the three overexposures out of four possible cases.

All three patients showed signs of skin erythema (reddening) and the first two patients (who had received radiation to the larynx region) reported hoarseness and pain on swallowing. The licensee stated that these symptoms are not unusual for patients undergoing radiotherapy, and in fact, these same symptoms were mentioned to the patients as possible side effects of the treatment.

Cause:

A consulting physicist was retained to review patient records and the hospital's handling of this case. Among the findings were:

- a. The hospital staffing level was inadequate for the patient load.
- b. There was a loss of continuity in physics services with the departure of one physicist and the hiring of another physicist.
- c. There was poor communication (documentation) regarding the use of the computer generated treatment plans.

Licensee Action:

The licensee has hired a full time qualified therapy physicist and a technical administrator. These individuals will not have responsibilities outside of the therapy department.

All computer generated treatment plans will have point hand calculations to verify the computer readings. Procedures for use of this computer to generate patient treatment plans have been revised.

NRC Action:

Other Agency Action:

A civil penalty of \$3,000 was proposed on January 19, 1990, after a thorough review of the licensee's Radiation Safety Committee activities was conducted on December 22, 1989. The violation basis was centered on the Radiation Safety Committee's failure to adequately conduct its activities and supervise the use of therapy sources.

Litigation continues on this event and not all records have been received by the State Agency at this time. However, unless new significant information becomes available, this item is considered closed for the purposes of this report.

Criteria:

Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 910621 AO #: NRC 91-06 EVENT DATE: 05/29/1991
TITLE: POTENTIAL CRITICALITY ACCIDENT AT THE GENERAL ELECTRIC NUCLEAR FUEL AND COMPONENT MANUFACTURING FACILITY IN WILMINGTON, NORTH CAROLINA
NAME: GE Nuclear Fuel & Component Manufacturing Facility CITY: Wilmington STATE: NC

Nature and Probable Consequences:

On May 29, 1991, the licensee notified NRC Region II that it had identified higher than expected amounts of uranium in a process tank of the waste treatment system, posing a potential criticality safety problem. The amount was approximately 2300 parts per million or 150 kilograms total uranium (about four percent enriched in uranium-235). The administrative criticality safety limit for transferring uranium into the process tank vessel (an unfavorable geometry tank) was 150 parts per million. (Unfavorable geom refers to a process vessel that can hold enough uranium to produce a criticality.)

During the morning of May 29, the licensee identified higher than expected amounts of uranium in a favorable geometry vessel in a solvent extraction system as a result of earlier problems with controls and equipment in that system. The licensee shut down the solvent extraction process and subsequently discovered higher than expected amounts of uranium had also been improperly transferred into an unfavorable geometry waste tank. Licensee management was notified and a technical evaluation team was convened. In addition, sparging (i.e., mixing) was initiated in this tank to minimize the criticality potential by preventing an accumulation of material in the bottom of the tank. During the afternoon of May 29, the licensee notified NRC Region II of the incident. Later, the licensee also began uranium recovery operations from this tank via a centrifuge linked to the tank.

Also on May 29, the NRC dispatched a Region II site team and activated the headquarters and Region II incident response centers. The site team arrived early during the morning of May 30. At 6:38 a.m., EDT, on May 30, after discussions with the NRC response centers, the licensee declared an Alert in accordance with its Radiological Contingency and Emergency Plan.

On May 31, the NRC Executive Director for Operations (EDO) requested that the site team be upgraded to an eight-member NRC Incident Investigation Team (IIT). Also on May 31, the NRC issued a letter confirming the licensee's agreement to refrain from transferring material in certain portions of the waste streams, refrain from using the solvent extraction system, and cooperate with the IIT (Ref. 1). The licensee continued to remove uranium by centrifuge from the tank through June 1. On June 1, the licensee had transferred sufficient amounts of solution containing uranium from the tank via the centrifuge process and to other nearby tanks to reduce the uranium in the tank to an amount less than the criticality safety limit. The licensee then terminated the Alert status and the NRC went to a normal response mode in both its headquarters and regional response centers.

The IIT arrived onsite on June 2. The IIT was directed to determine the circumstances associated with the event, identify the probable causes of the event, and make appropriate findings and conclusions that would form the basis for any necessary follow-up actions. The IIT exited the site on June 13 and convened in Bethesda, Maryland, to prepare a formal investigation report. A Region II inspection team continued to monitor the licensee's follow-up actions at the site from May 30 through July 18.

On June 25, the licensee met with the NRC in the Region II office to discuss status of the systems shut down as a result of the event, the corrective actions needed prior to restart, and the longer-term corrective actions at the facility. The licensee certified that the corrective actions for restart of the waste systems, including a procedure for reporting all types of events to the NRC, were complete in letters dated July 4 and July 7, 1991 (Ref. 2 and 3). The NRC Region II onsite inspection team verified that these actions were complete. The NRC authorized the licensee to restart certain waste stream systems on July 7 and confirmed this on July 11, 1991, letter (Ref. 4). As of August 31, the solvent extraction system remained shut down.

Cause:

The IIT identified numerous problems at the plant including inadequate management oversight, design deficiencies, procedural noncompliance, inadequate incident investigation, and a general deterioration of criticality controls. The IIT concluded that the problems can be summarized by three interrelated root causes that contributed to the incident:

1. There was a pervasive licensee attitude that a nuclear criticality was not a credible accident scenario. While the licensee understood and recognized that a nuclear criticality with low-enriched uranium was technically possible, and that there were regulatory requirements to establish measures to guard against such an accident, the licensee's perception was that the risk was so low that a criticality accident inherently would not happen.
2. Licensee management did not provide effective guidance and oversight of licensed activities to assure that operations were conducted in a safe manner.
3. There was a deep-seated, production-minded orientation within the licensee's organization that was not sufficiently tempered by a "safety first" attitude, particularly regarding nuclear criticality safety.

In addition, the IIT identified various weaknesses in NRC regulatory guidance, licensing, and inspection programs that had the effect of contributing to the incident.

Licensee Action:

Corrective actions included the following: system walkdowns and verifying that documentation matched current plant configuration; revising procedures; retraining of operators; revamping sampling to ensure adequacy for measurement of uranium; sensitivity training of all plant personnel to follow procedures and report problems; documenting a scheme for reporting events; instituting additional management oversight of operators; establishing an audit system and, establishing a long-term plan to improve performance in staffing, emergency response, equipment reliability, and engineered systems to replace administrative criticality controls. The license reports the status of short-and long-term corrective actions to NRC Region II on a biweekly basis. The license will present to the NRC its corrective actions for restart of the solvent extraction system. The licensee presented an outline of these corrective actions to the NRC in an August 9, 1991, letter (Ref. 5).

NRC Action:

The special NRC Region II inspection team inspected all corrective actions taken by the licensee in response to the event. As previously mentioned, the NRC issued a letter authorizing restart of certain systems on July 11, 1991, after verifying that the licensee completed all items identified by the NRC as necessary prior to restart (Ref. 4). The NRC will continue to closely review the licensee's corrective actions to ensure that all safety issues have been satisfactorily addressed.

The NRC IIT formal report was published in August 1991 as NUREG-1450 ("Potential Criticality Accident at the General Electric Nuclear Fuel and Component Manufacturing Facility, May 29, 1991"). Based on the IIT's findings, on August 13, 1991, the NRC EDO issued a memorandum to identify and assign NRC staff responsibility for generic and facility-specific actions (Ref. 6). The resolution status or disposition of each IIT staff action will be included in the Annual Reports issued by the NRC Office for Analysis and Evaluation of Operational Data (NUREG-1272 series).

Future reports will be made as appropriate.

UPDATE (from NUREG-0900, Vol. 14, No. 3, page 9: This abnormal occurrence was originally reported in NUREG-0090, Vol. 1 No. 2, "Report to Congress on Abnormal Occurrences: April-June 1991." The event, involving degraded nuclear criticality safety controls, was investigated by an NRC Incident Investigation Team (IIT). As mentioned in the previous report, the NRC IIT formal report was published in August 1991 as NUREG-1450 ("Potential Criticality Accident at the General Electric Nuclear Fuel and Component Manufacturing Facility, May 29, 1991"). Also, as previously mentioned, that licensee's solvent extraction system remained shutdown as of August 31, 1991. The abnormal occurrence is updated as follows:

Significant NRC inspector presence was maintained at the site during the August through mid-October 1991 time period. The inspectors reviewed operations in progress, followed up on items identified in the IIT report, reviewed the licensee's corrective actions and improvement plans, and inspected the licensee's readiness for startup of the solvent extraction system.

On September 25, 1991, a management meeting was held between licensee and NRC representatives to discuss the licensee's plan for startup of the solvent extraction system. At the meeting, the licensee presented actions that it had taken and planned. Issues addressed included system modification, nuclear criticality safety controls, process controls, procedures, and training. A special NRC inspection team consisting of representatives from NRC Headquarters and the Region II office was sent to the site September 30, 1991. The team evaluated the licensee's readiness for restart of the solvent extraction system. The inspection involved review of procedures and training, interviews of operators and management personnel, and physical walkdown of system components. The team verified adequate controls were in place for restart. Therefore, on October 16, 1991, the NRC authorized the licensee to restart operation of the system.

In response to the IIT report findings, the NRC Executive Director of Operations provided direction to the staff to develop a Staff Action Plan as a means of identifying and following up on plant specifications, generic issues, and areas for regulatory improvement (Ref. B-1). In response to the directive, the Office of Nuclear Material Safety and Safeguards (NMSS), Office for Analysis and Evaluation of Operational Data (AEOD), and Region II developed action plans and established milestones. Some of the short term actions involving the plant are scheduled for completion during the latter part of 1991. Longer term actions involving regulatory changes may take several years to complete.

In addition to the Staff Action Plan, NMSS established a Material Regulatory Review Task Force to examine the entire regulatory program for large materials licensees. A draft task force report was completed in late September 1991 and is currently under internal NRC review.

On September 9, 1991, the Commission was briefed on the content of the IIT report by the IIT team (Ref. B-2). In addition, the Advisory Committee for Reactor Safeguards was briefed on the IIT report by the team on October 10, 1991. The licensee and the NRC staff presented their views of the incident and actions in a formal Commission briefing on October 18, 1991 (Ref. B-3).

Because of this event, and knowledge of similar circumstances at other licensed activities, the NRC is concerned that there may be insufficient attention by licensees to the need for internal reporting and prompt evaluation of failures of controlled parameters related to criticality safety. The NRC is also concerned that licensees may not have procedures in place to assure compliance with the requirements under 10 CFR 20.403 to report immediately to the NRC any significant failure of criticality safety controls. Therefore, on October 18, 1991, NRC Bulletin 91-01 ("Reporting Loss of Criticality Safety Controls") was issued to all fuel cycle and uranium fuel research and development licensees (Ref. B-4). The bulletin requested the licensees to evaluate their criticality safety criteria and procedures, modify them as appropriate to assure that events involving degradation of controls will be promptly evaluated and reported to licensee management and the NRC as appropriate, and provide a description of their criteria and procedures to the NRC. On November 19, 1991, the NRC staff sponsored a workshop on Bulletin 91-01.

Future reports will be made as appropriate.

UPDATE (from NUREG-0900, Vol. 14, No. 4, page 13: This abnormal occurrence was originally reported in NUREG-0090, Vol. 14, No. 2, "Report to Congress on Abnormal Occurrences: April-June 1991," and updated by an NRC Incident Investigation Team (IIT). As mentioned in the previous reports, the NRC IIT formal report was published in August 1991 as NUREG-1450 ("Potential Criticality Accident at the General Electric Nuclear Fuel and Component Manufacturing Facility, May 29, 1991"). Also, as previously mentioned, the licensee's solvent extraction system remained shutdown until October 16, 1991, when the NRC authorized the licensee to restart operation of the system. The abnormal occurrence is updated as follows:

Significant NRC inspector presence was maintained at the site during the mid-October to Mid-November 1991 time period. The inspectors reviewed operations in progress as the licensee restarted the solvent extraction process, and reviewed actions being taken by the licensee to improve its performance in the area of nuclear criticality safety. The licensee's solvent extraction process has been operated in a safe manner since operation was resumed in mid-October. In an emergency exercise on December 18, 1991, the licensee demonstrated effective corrective actions for problems in the licensee's emergency response program. These problems were identified by the IIT and NRC follow-up inspections.

The NRC held an enforcement conference with the licensee on February 7, 1992 to discuss causes and corrective actions for apparent violations identified as a result of the IIT and NRC follow-up inspections. Licensee attendees included the new plant manager for the facility, who officially assumed this position on February 9, 1992.

The licensee continues to evaluate its nuclear criticality safety program; as areas for improvement are identified, they are being added to the licensee's Performance Improvement Program (PIP). Status reports on the PIP have been submitted monthly by the licensee to the NRC. The NRC will be meeting with the licensee on a quarterly basis to review the licensee's progress in completing the elements specified in the licensee's PIP. The first such meeting is scheduled for March 4, 1992.

As mentioned in the previous reports, the NRC staff developed a Staff Action Plan in response to the IIT report findings. Some of the short term Staff Action Plan items were completed during the latter part of 1991. In addition, responses to NRC Bulletin 91-04 ("Reporting Loss of Criticality Safety Controls"), which requires all fuel cycle and uranium fuel research and development licensees to evaluate and modify as necessary their criticality safety criteria and procedures, are due by the end of January 1992 (Ref. B-1). These responses will be reviewed by the NRC's Office of Nuclear Material Safety and Safeguards (NMSS); then the licensee's implementation of any needed improvements will be reviewed during NRC inspections.

Also as previously mentioned, NMSS established a Material Regulatory Review Task Force. The purpose of the Task Force was to conduct a broad-based review of the Commission's current licensing and oversight programs for fuel cycle and large material plants. The Task Force was requested to define the components and subcomponents of an ideal regulatory evaluation system for these types of licensed plants and compare them to the components and subcomponents of the existing regulatory evaluation system. The Task Force prepared a report which discusses the findings from this comparison and proposes recommendations on the basis of the findings.

This report (Draft NUREG-1324) was issued for public comment during February 1992 (Ref. B-2).

Further updating of this item will be made as appropriate.

UPDATE (from NUREG-0900, Vol. 15, No. 1, page 13: This abnormal occurrence was originally reported in NUREG-0090, Vol. 14, No. 2, "Report to Congress on Abnormal Occurrences: April-June 1991." It was updated in Vol. 14, No. 3 and Vol. 14, No. 4. The event, involving degraded nuclear criticality safety controls, was investigated by an NRC Incident Investigation Team (IIT). As mentioned in the previous reports, the NRC IIT formal report was published in August 1991 as NUREG-1450 ("Potential Criticality Accident at the General Electric Nuclear Fuel and Component Manufacturing Facility, May 29, 1991"). The abnormal occurrence is further updated as follows:

Periodic NRC inspector presence was maintained at the site during the January through March 1992 time period. The inspector reviewed operations in progress as the licensee operated the solvent extraction process, and reviewed actions being taken by the licensee to improve its performance in the area of nuclear criticality safety. The licensee's solvent extraction process has been operated in a safe manner since operation was resumed in mid-October of 1991.

The licensee continues to evaluate its nuclear criticality safety program (PIP). Status reports on the PIP have been submitted monthly by the licensee to the NRC. The NRC will meet with the licensee on a quarterly basis to review the licensee's progress in completing the elements specified in the licensee's PIP. The first such meeting was held March 4, 1992, with a follow-up meeting to discuss additional details held on April 1, 1992.

The charter of the IIT did not include assessing violations of NRC rules and requirements. Therefore, NRC inspections were conducted at the facility from August 19-September 13, 1991, to review the IIT findings for possible enforcement actions. The inspections identified several apparent violations; the findings were documented in NRC Inspection Report No. 70-1113/91-04, which was forwarded to the licensee on December 23, 1991 (Ref. B-1). An enforcement conference was held on February 7, 1992, in the NRC Region II office to discuss the apparent violations, their causes, and the licensee's corrective actions to preclude recurrence (Ref. B-2).

On March 13, 1992, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$20,000 (Ref. B-2).

B-3). The action was based on violations related to inadequate procedures and the failure to follow procedures that collectively resulted in ineffective process and mass limit controls. These violations were classified in the aggregate as a Severity level II problem, on a scale in which Severity Levels I through V are the most and least significant, respectively. In addition, some other violations were identified; these were classified as Severity Level IV with no associated civil penalty. The licensee has responded to the Notice of Violation and paid the civil penalty in full.

As mentioned in the original report, on August 13, 1991, the NRC Executive director for Operations issued a memorandum to assign NRC office responsibility for generic and plant-specific staff actions resulting from the IIT (Ref. B-4). Numerous actions were identified under the general categories of (1) adequacy of criticality safety reviews, (2) adequacy of facility operational safe (3) adequacy of emergency preparedness, and (4) adequacy of operating experience review. Some of the short term actions were resolved during the latter part of 1991. The remaining items are scheduled for completion in the later parts of 1992, 1993, and 1994. The status of resolution of each of the staff action items will be included in the Annual Reports issued by the NRC Office Analysis and Evaluation of Operational Data (NUREG-1272 series).

This item will be updated from time to time in these quarterly reports to Congress as new, significant information becomes available.

UPDATE (from NUREG-0900, Vol. 16, No. 1, page 13: This abnormal occurrence was originally reported in NUREG-0090, Vol. 14, No 2, "Report to Congress on Abnormal Occurrences: April-June 1991." It was updated in Vol. 14, No. 3; Vol. 14, No. 4; and Vol. 15, No. 1. The May 29, 1991 event, involving degraded nuclear criticality safety controls, was investigated by an NRC Incident Investigation Team (IIT). The NRC IIT report was published in August 1991 as NUREG-1450 (Ref. B-1). The abnormal occurrence is further updated as follows:

NRC inspections of the facility continued at an increased frequency during 1992. The inspectors reviewed operations in progress including the preoperational testing and start-up of a new fuel conversion system and major modifications to waste processing systems. These inspections emphasized review of the implementation and maintenance of nuclear criticality safety controls. The inspections also reviewed the actions being taken by the licensee to improve performance in the area of nuclear criticality safety.

As reported earlier, the licensee conducted a review of actions needed to improve its nuclear criticality safety program following May 29, 1991 incident. These included long term actions to be completed to upgrade equipment, systems and programs. These actions were incorporated into a Performance Improvement Program (PIP). Initially, the licensee submitted status reports on the PIP biweekly which were supplemented by periodic meetings with NRC management. These meetings were conducted to provide NRC management the opportunity to discuss and review improvement activities and tour plant facilities where improvements have been implemented. After many of the immediate actions were completed, the status report frequency was changed to monthly and then to quarterly, with a corresponding decrease in the number of NRC management meetings. On March 1, 1993, the licensee submitted a status report indicating the closure of the last open items. A meeting was held with the licensee on April 20, 1993 to review the completion of the PIP.

In addition to those actions included in the PIP, the licensee identified other actions which will be taken to provide additional long term improvements to facility operations. These actions were not part of the PIP, but the NRC will continue to monitor their status during future routine inspections.

In August 1991, the director, Office of Nuclear Material Safety and Safeguards, appointed a task force to review the existing licensing and inspection programs for fuel cycle and major materials facilities. The task force conducted an in-depth reexamination of the regulatory system for these types of facilities and presented findings and recommendations for improving the licensing, inspection, training, guidance, and regulatory base associated with fuel cycle facilities and major materials licensees. The task force report, NUREG-1324, "Proposed Method for Regulating Major Materials Licensees," was published in February 1992 (Ref. 2). In October 1992, the staff informed the Commission of its action plan that responds to NUREG-1324. The staff presently is in the process of implementing this action plan, following guidance provided by the Commission in January 1993. The generic actions resulting from the IIT report will be completed within the framework of the staff action plan. The plant-specific items resulting from the IIT report are being handled individually.

This item is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 10 of "For All Licensees") of this report notes that a major deficiency in design, construction, or operation having safety implications requiring immediate remedial action can be considered an abnormal occurrence.

ITEM #:	910465	AO #:	NRC 91-07	EVENT DATE:	04/12/1991
TITLE:	MULTIPLE MEDICAL TELE THERAPY MISADMINISTRATIONS AT ST. JOHN'S REGIONAL MEDICAL CENTER IN JOPLIN, MISSOURI				
NAME:	St. John's Regional Medical Center	CITY:	Joplin	STATE:	MO

Nature and Probable Consequences:

On April 12, 1991, NRC Region III was notified by the licensee that a number of cobalt-60 teletherapy misadministrations had occurred between September 1989 and March 1991. The misadministrations (defined as therapeutic doses varying more than 10 percent from prescribed doses) were discovered during a review of past treatment data in March and April 1991. On April 25, the licensee formally reported that 12 misadministrations had occurred.

Of the 12, three patients received doses 10% to 18% higher than the prescribed doses, and nine patients received doses from 1 to 27% below the prescribed doses. All misadministrations resulted from erroneous information in the treatment planning computer program. All treatments, with one exception, involved the use of wedges which consist of compensating material, such as lead, placed in the radiation beam to more evenly distribute the prescribed dose of radiation to appropriate tissue. The one exception involved an arc treatment which is a technique used to deliver a greater dose to a selected point while minimizing the dose to other areas by rotating the cobalt-60 source around the patient.

The treatment discrepancies were first discovered in March 1991 when a therapy technologist, preparing for an upcoming board certification test, pulled the files of previously treated patients to practice hand-calculated dosimetry. The technologist later informed licensee management that her results did not match the wedge-related treatment doses indicated in the patient files. On March 22, the Radiation Safety Officer (RSO) was asked to investigate the apparently conflicting results. The RSO developed a list of patients who received wedge-related treatments since the inception of that type of treatment in August 1989. On March 29, the RSO presented the list to the Radiation Oncology staff who began hand calculations of all patient treatments. Reruns of the original computer calculations also were initiated.

By March 29, the reworks supported the technologist's original finding that actual administered doses had deviated significantly from prescribed doses. All of the patients' referring physicians were subsequently notified of the dose differentials, except for one physician who had left the area. In the latter case, the patient was notified directly. Subsequently, the patients have been seen by their physicians for follow-up care. The licensee stated that no adverse effects have been observed to date.

Cause:

In 11 of the 12 misadministrations, the licensee failed to calculate a computer program's "wedge normalization factor" in making initial dose calculations. The wedge normalization factor is described in the manufacturer's computer program instruction manual. Instead of using this factor, the licensee used different measured wedge factors which were not compatible with the computer program. The other misadministration resulted from the licensee's failure to correct the computer program as directed by the manufacturer's release notes. The manufacturer issues these notes to describe "bugs" or errors in the program that are identified following the program's production.

Licensee Action:

On April 12, 1991, the licensee requested an amendment to its NRC license requiring independent verification of cobalt-60 teletherapy treatment plans in order to prevent further misadministrations. In addition, the licensee has implemented an internal procedure which also requires independent verification of treatment plans prior to treatment.

NRC Action:

On April 18, 1991, NRC Region III conducted a special inspection at the Medical Center in response to the cobalt-60 misadministrations. On May 10, 1991, Region III issued a Severity Level IV violation (on a scale in which Severity Levels I through V range from the most to the least significant, respectively), citing the licensee for failing to notify the NRC with 24 hours of discovery of the initial misadministration (Ref. 7). The NRC was not notified of the misadministrations until April 12, 1991, even though the first misadministration was identified on March 29, 1991.

On April 15, 1991, Region III approved Amendment 18 of the Medical Center's teletherapy license, which requires the licensee to perform dual calculations for all cobalt-60 therapies prior to the initiation of treatment. The licensee also must maintain records of the dual verification.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 900365 AO #: AS 91-02 EVENT DATE: 06/14/1990
TITLE: OVEREXPOSURE OF A NON-RADIATION WORKER
NAME: H & G Inspection Company, Incorporated CITY: Port Arthur STATE: TX

Nature and Probable Consequences:

During radiography operations, an unmonitored, non-radiation worker employed by the Exxon Corporation received a whole body exposure estimated to be between 1.8 and 3.9 rem from a radioactive source that was not properly shielded. This exceeds the abnormal occurrence reporting threshold of 0.5 rem in one calendar year for a member of the general public. In addition, a radiographer received a whole body exposure of about 7.7 rem. [The exceeds the license limit for whole body exposure to a radiation worker in one calendar quarter; however, it is below the abnormal occurrence reporting threshold of 25 rem whole body. The details of the event are described below.

On July 14, 1990, two licensee radiographers were performing routine radiography of welds at Exxon's Texas Well #1, located in Sabine Lake.

They were using a Gulf Nuclear Model 20V camera containing 60 curies of iridium-192. At the completion of a radiograph, the licensee radiographer (Radiographer A) cranked in the source, approached and surveyed the camera and guide tube, and locked the camera. He removed the exposed film and took it to the darkroom for the second radiographer (Radiographer B) to develop. Radiographer A returned to the weld to set up for the next exposure. During this procedure an Exxon employee approached the radiography camera inside the restricted area to discuss the next shot with Radiographer A. Radiographer A had problems setting up the next shot and obtained Radiographer B's assistance. The Exxon employee left the area at this time.

The two radiographers completed the set-up and were leaving to make the radiograph when Radiographer B noticed that the licensee radiographer's survey meter was off-scale on the high side. This indicated that the source was not in the shielded position. They moved away from the camera and tried to return the source to the shielded position but could not. The camera was then unlocked and the crank-out handle retracted one-half turn. The camera was relocked and pocket dosimeters were checked. The pocket dosimeters were offscale and the radiation safety officer was notified of the incident. The employees were ordered to return to the shop and their thermoluminescent dosimeters (TLDs) were mailed in for immediate processing.

The TLDs indicated that Radiographers A and B received about 7.7 rem and 1.3 rem, respectively. Because the non-radiation worker was not wearing any radiation dosimetry, his exposure was estimated by a reenactment of the event and calculations; this indicated he received a whole body exposure between 1.8 and 3.9 rem.

Cause:

There were three root causes for the event. The first cause was the camera locking with the source in the unshielded position. [The licensee stated that this is a design flaw in the lock box and is not an unusual occurrence with the Gulf Nuclear Model 20V camera. The manufacturer of this camera is no longer in business.] The second cause was the failure of the radiographer to perform an adequate survey to determine whether the source was in the shielded position. Apparently, the radiographer went through the motions of performing the survey, became complacent in reading the meter, and failed to perceive what his meter was indicating. The third cause was inadequate procedures regarding unmonitored personnel entering a restricted area.

Licensee Action:

The radiographers and the Exxon employee were notified of their exposures. All licensee employees were notified of the incident memo. The incident was discussed during the next safety meeting. New procedures were developed pertaining to unmonitored personnel entering restricted areas. The requirements for performing a proper survey were reemphasized to ensure that a source has been properly retracted into its shielded position. When the camera is moved to a different job site, the guide tube will be disconnected and the safety plug inserted. Anyone not following the new procedures will be fined \$100.

NRC Action:

Other Agency Action:

The licensee was cited for allowing an unmonitored individual to receive an exposure greater than 2 millirem in an hour, for the exposures of the two radiographers, and for the failure to perform adequate surveys to determine whether the radiation source was secured. Additionally, because of overexposures which occurred more recently, a review is being conducted to determine whether escalated enforcement is necessary.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Criteria:

Appendix A (see Example 2 of "For All Licensees") of this report notes that an exposure to an individual in an unrestricted area, such that the whole body dose received exceeds 0.5 rem in one calendar year, can be considered an abnormal occurrence. This example is also applicable to a member of the general public who may inadvertently enter a restricted area.

This writeup is based on information provided to the NRC during late May 1991 by the Agreement State of Texas for inclusion in this report.

ITEM #: 900430 AO #: AS 91-03 EVENT DATE: 07/10/1990
TITLE: EXTREMITY OVEREXPOSURE OF A RADIATION WORKER
NAME: Rosemount, Inc., Kay-Ray/Sensall Division CITY: Mt. Prospect STATE: IL

Nature and Probable Consequences:

While extracting a 10 curie cesium-137 source from its housing, a licensee radiation worker received an overexposure to his left hand. As discussed in the details of the event below, the actual exposure is not precisely known but was likely between 200 and 714 rem. Because the higher value, which was indicated by the worker's dosimetry, could not be disproved, 714 rem to the left hand was entered into the worker's radiation records. The event was investigated by the Illinois Department of Nuclear Safety, referred to below as the State Agency.

On July 10, 1990, the worker was removing the source from a Model 7064P source housing so that the source could be transfer to a Model 7067 housing for resale to a customer. The worker had approximately three years experience in source loading, although this was the first time that he had removed a 10 curie source. Operating on this particular source holder (constructed of stainless steel and holding a larger than usual activity of cesium-137) was a special case requiring additional precautions including direct observation and timing of operations by the worker's supervisor. The removal of the source/source holder assembly from source housing was routine in every aspect. Using tongs, the source/source holder assembly was then moved to an area behind lead-shielded work station and clamped into place.

Extraction of the source from the source holder then began. This procedure consists of physically peeling back the crimp on top of the source holder using a pair of sidecutter hand tools. This phase of the operation was unusually difficult because the material was stainless steel rather than aluminum. After about 25% of the crimp was peeled back, the cylinder in which the source was contained separated from the base of the source holder. Using a pair of channel-locks in his right hand, the worker retrieved the cylinder containing the source and continued the extraction process using the channel-locks to hold the source/source holder assembly in place. Following the uncrimping of the broken source holder, the worker tried to extract the source twice, being successful on his second attempt. The source was then placed in a lead pig for eventual loading into the new device. The total time reported by the worker's supervisor for the entire procedure was 4 minutes and 45 seconds.

Previous recorded extremity doses to employees involved with source changes on 10 curie cesium-137 sources from stainless steel source holders were reported to be approximately 3 to 4 rem to the hand holding the sidecutters. However, because the source manipulation was unusual in this case, the supervisor suggested that the worker's ring thermoluminescent dosimeter (TL) be processed. On July 12, 1990, the results indicated an exposure of 714 rem to the left hand.

The worker was examined by a physician on the evening of July 12. This included a physical examination of his hand as well as a blood test. Aside from a slightly elevated white blood count due to the presence of a virus, no unusual results were reported by the physician. The worker showed no visible signs of acute radiation overexposure to his left hand. He stated that there was no discomfort, reddening, swelling or other ill effects suffered as a result of this event. On July 20, after further blood tests and physical examination, an oncologist/hematologist informed the worker that all tests were normal and that he could find no signs of damage to the worker's hands or forearms. Based on these findings, the doctor believed that the worker had not been exposed to the high level of radiation reported.

The ring TLD had only been worn for two days. On July 9, the worker prepared source capsules for disposal, an activity which usually results in minimal exposure. On July 10, the worker only performed the 10 curie source extraction. When not in use, the ring TLD was stored in a drawer at his desk in the stock room. The worker stated that no sources are allowed in the stock room and a survey of this storage area, performed by the State Agency inspectors, revealed no evidence of any reading in excess of natural background. The worker's explanation of this event is an error in reading the TLD or an imperfection in the TLD material itself. The worker stated that he knew of no enemies at the plant who would sabotage his dosimetry. He also stated that access to his dosimetry while not being worn is rather restricted.

The State Agency inspectors witnessed a reenactment of the source extraction procedure using a blank stainless steel source holder. Based upon observations, measurements, and data provided by the licensee, the State Agency concluded that, while possible, it is unlikely that the worker received an exposure to his left hand of 714 rem. However, the Agency concluded that an extremity overexposure did occur, estimated to be approximately 200-300 rem.

At the completion of the investigation, an exit interview was held with the licensee's President, Operations Manager, Source Loading supervisor, Radiation Safety Officer, and the involved radiation worker. During this interview the following findings were discussed:

1. There was insufficient evidence to discount or to prove whether the worker received a dose of 714 rem to his left hand. However, it appeared unlikely that this dose was actually received.
2. The licensee should continue medical follow-up observation and treatment if necessary. The State Agency was to be notified of any physical changes that occur.

The following recommendations were offered during the interview:

1. The licensee should contact the processor and have them check the TLD chip and reading system for proper response (quali

assurance).

2. The licensee should seriously consider engineering changes or changes in procedure that would increase the distance between the source and the source remover's hand. In the absence of this change, the licensee should consider discontinuing the practice of reusing high activity sources because of the potential for a radiation overexposure of this kind.

Cause:

The causes are attributed to inadequate procedures and supervision during operations involving a high activity source. Greater use of remote handling equipment could considerably reduce the potential for overexposure.

Licensee Action:

The licensee proposed the following corrective actions:

1. Effective immediately, no source capsule larger than 2 curies will be uncrimped from its holder. The source capsule involved in the referenced incident was a 10 curie source.
2. Effective immediately, no source capsule larger than 0.5 curie will be uncrimped from its holder without direct supervision of the operation.
3. Beginning September 17, 1990, as a precaution against tampering, and as suggested by State Agency personnel during the investigation of the referenced incident, all Source Loaders' dosimeters (body badges, TLD rings, etc.) will be kept under lock and key when not in use.

NRC Action:

Other Agency Action:

On July 31, 1990, the State Agency issued a notice of violation for the overexposure. The license was amended to include the licensee's proposed corrective actions and the letter transmitting the amendment included a strong suggestion that remote handling equipment be considered more often in the interest of keeping exposures as low as reasonably attainable.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see Example 1 of "For All Licensees") of this report notes that an exposure of the feet, ankles, hands or forearms of any individual to 375 rem or more of radiation can be considered an abnormal occurrence.

ITEM #: 900788 AO #: AS 91-04 EVENT DATE: 11/07/1990
TITLE: OVEREXPOSURE OF A RADIOGRAPHER
NAME: Big State X-Ray CITY: Eastland STATE: TX

Nature and Probable Consequences:

During radiography operations, a radiographer received an estimated exposure of 35 rem to his right thigh from a radioactive source that was not locked in its shielded position. The details of this event are described below.

On November 7, 1990, two licensee radiographers were performing radiography outside the Pride Refinery (Abilene, TX) when it started to rain. They moved their operations inside a building so they could continue working. At the completion of the first series of radiographs, Radiographer A proceeded to move the camera to the next weld for the next series of exposures. He stated that he surveyed the camera, got "no reading," locked the camera (but did not remove the key from the lock), then moved the camera. He moved to the next weld by picking up and carrying the camera, survey meter, and other equipment, dragging the crank-out cable behind him. He stepped over some obstacles and believes the key turned in the lock and released the source, which was allowed to move outside the shield by the crank out.

Upon arriving at the next weld, he resurveyed the camera and proceeded to setup the next exposure. [It was later determined that the survey meter was not operating correctly because of internal moisture from the rain.] After completing the setup, he noticed that the camera was unlocked and checked his pocket dosimeter. It was off-scale. He went to the crank-out handle and retracted the source about one and one-half turns. He then notified Radiographer B of the incident who stopped operations and had Radiographer A's film badge sent in for immediate processing. However, the film was damaged during shipment and could not be processed. Therefore, his exposure was estimated by a reenactment of the event and calculations; these indicated he received 35 rem exposure to the right thigh.

Cause:

The primary cause of this incident was the failure of the radiographer to properly lock the source in the camera and remove the key prior to moving the camera. The radiographer also failed to determine whether his survey meter was operating correctly after it became wet in the rain. If the radiographer had paid attention to the readings of the meter during the first radiograph under the shelter and compared it with previous readings he would have noticed the meter was not operating properly.

Licensee Action:

The incident was discussed with all radiographic personnel of the company and all were cautioned of the consequences of failing to follow proper procedures.

NRC Action:

Other Agency Action:

The licensee was cited for the overexposure and failure to properly lock and remove the key from the radiography camera before relocating it.

This item is considered closed for the purposes of this report.

Criteria:

Appendix a (see Example 1 of "For All Licensees") of this report notes that an exposure of the whole body of any individual to 25 rem or more of radiation can be considered an abnormal occurrence.

This writeup is based on information provided to the NRC during late May 1991 by the Agreement State of Texas for inclusion in this report.

ITEM #:	910998	AO #:	NRC 91-08	EVENT DATE:	09/05/1991
TITLE:	RADIATION EXPOSURE OF MEMBERS OF THE PUBLIC FROM A LOST RADIOACTIVE SOURCE				
NAME:	Western Atlas International	CITY:	Yukon	STATE:	OK

Nature and Probable Consequences:

The exposure occurred along an access road of Interstate 45 near Huntsville, Texas, from a source shipped by the licensee.

On September 5, 1991, Western Atlas International (the licensee) notified the State of Texas that a 2 curie cesium-137 sealed well logging source had been lost that morning from the licensee's vehicle enroute from the licensee's Yukon, Oklahoma, facility to its Houston, Texas, facility.

The licensee initiated a search for the source using radiation detectors and retraced the route of the vehicle. Meanwhile, at approximately 5:30 p.m. on the same day, a citizen spotted the shipping container lying on the gravel shoulder about 30 feet from the southeast corner of the intersection of the Interstate 45 Exit 118 road and underpass road, and notified the Huntsville Police Department. A police officer was dispatched to the scene. The underpass road passes under Interstate 45 to a service road and truck stop. The shipping container evidently had fallen out of the truck as it was turning.

The radioactive source was found approximately 7 feet from its shipping container. The police officer picked up the source and believed to have held it for about 5 seconds before dropping it approximately 6 to 12 inches from the container. The area was closed to the public until a member of the city's emergency management services retrieved the source using 2 knives as hand tools; at approximately 6:15 p.m., the source was placed back into the shipping container, which was missing its shield plug. Licensee personnel placed the source in a complete shipping container at approximately 7:30 p.m.

A large pin that is supposed to be attached to the safety bar securing the shipping container shield plug was determined to be missing. Without this pin, the safety bar could slide out of position, and the plug and source could come out of the shipping container.

In addition, the bed of the truck, from which the shipping container fell, was a flat steel deck with no obstructions at the rear of the truck except for a canvas cover held in place with four elastic straps. During transportation, several shipping containers were fastened to the truck bed by locks attached to the containers and to the 3/8-inch diameter links of a slack steel chain, which was attached to structural members of the truck. The chain did not surround the shipping containers, freeing them to move on the truck bed. Apparently, the slack allowed the shipping containers to accelerate when the vehicle turned corners, breaking a lock and allowing the subject shipping container to fall off the back of the truck.

The police officer who held the source received an estimated exposure of approximately 5 rem to his fingers. The individual who retrieved the source received an estimated exposure of approximately 150 millirem to his fingers.

Cause:

The event was attributed to human error. Licensee personnel did not follow the licensee's procedures or management instructions in correcting shipping container deficiencies and in properly securing the shipping containers to the transporting vehicle.

Licensee Action:

On September 6, 1991, the day after the incident, the licensee issued a memorandum to all their North American facilities. This memorandum concerned corrective measures that were effective immediately. Subsequently, the licensee took additional corrective actions to prevent such losses.

NRC Action:

On September 6, 7, and 11, 1991, NRC Region IV inspectors conducted a special, announced radiation safety inspection of the licensee's by-product material program (Ref. 1). The inspection included the review of organization, management, training, radiation protection, independent measurements, notification, and transportation activities. Seven apparent violations of NRC regulations were identified. Escalated enforcement action is under consideration.

Future reports will be made as appropriate.

UPDATE (from NUREG-0090, Vol 14, No. 4, page 15: This abnormal occurrence was originally reported in NUREG-0090, Vol. 1 No. 3, "Report to Congress on Abnormal Occurrences: July-September 1991." The abnormal occurrence is updated as follows:

As previously mentioned, on September 5, 1991, the licensee (Western Atlas International) reported the loss of a 2-curie cesium 137 sealed well logging source from a vehicle en route from the licensee's Yukon, Oklahoma, facility to its Houston, Texas, facility. As a result, two members of the general public received unnecessary radiation exposures.

On December 20, 1991, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$10,000 for violating NRC requirements in the loss of the radioactive source (Ref. B-6). The proposed civil penalty was based on two violations: (1) failure to block and brace the radioactive source container adequately during transportation; and (2) failure to ensure that the container's closure device was properly installed, secured, and free of defects. The NRC also cited the licensee for five

other violations which were not assessed a civil penalty.

The letter informing the licensee of the action indicated NRC's concern that a responsible licensee manager had disregarded findings of an August 1991 safety audit which had directed that the containers not be used until identified defects had been fixed. The letter noted that the violations resulted in an incident which had posed a significant threat to the health and safety of the general public.

This item remains open pending the licensee's response to the December 20, 1991, letter and pending further review of the company's licensed activities.

UPDATE (from NUREG-0090, Vol. 15, No. 1, page 14: The abnormal occurrence was originally reported in NUREG-0090, Vol. 14, No. 3, "Report to Congress on Abnormal Occurrences: July-September 1991," and updated in Vol. 14, No. 4. The abnormal occurrence is further updated as follows:

As previously mentioned, on December 20, 1991, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$10,000 to Western Atlas International for violating NRC requirements in the loss of the radioactive source (Ref. E-5). The proposed civil penalty was based on two violations: (1) failure to block and brace the radioactive source container adequately during transportation; and (2) failure to ensure that the container's closure device was properly installed, secured, and free of defects. The NRC also cited the licensee for five other violations which were not assessed a civil penalty.

On January 24, 1992, the licensee responded to the Notice of Violation, admitting the violations and describing the corrective actions which either have been taken, or will be taken. The company's licensed activities remain under NRC investigation. Final NRC enforcement action is pending.

Because the company is a licensee of the Agreement State of Texas, as well as of the NRC, the event was also investigated by Texas Bureau of Radiation Control (State Agency). In order to avoid duplication of effort, it was mutually agreed that the NRC would concentrate on violations of rules directly related to transport of the source, and the State Agency would concentrate on violations of rules pertaining to radiation levels in unrestricted areas and human exposures.

The State Agency identified three apparent violations of agency rules: (1) the transport container not being properly secured resulting in loss of the radiation source subsequent exposure to members of the public, (2) levels of radiation from an external source in an unrestricted area exceeding applicable regulatory limits, and (3) unnecessary exposure of an individual while recovering the source. Escalated enforcement actions have been initiated against the licensee.

Future reports will be made as appropriate.

UPDATE (from NUREG-0090, Vol. 15, No. 2, page 15: This abnormal occurrence was originally reported in NUREG-0090, Vol. 14, No. 3, "Report to Congress on Abnormal Occurrences: July-September 1991;" it was updated in Vol. 14, No. 4 and Vol. 15, No. 1. The abnormal occurrence is further updated as follows:

As previously mentioned, on September 5, 1991, Western Atlas International, an NRC licensee, reported the loss of a 2-curie cesium-137 sealed well logging source from a vehicle en route from the licensee's Yukon, Oklahoma, facility to its Houston, Texas facility. As a result, two members of the public received unnecessary radiation exposure.

On December 20, 1991, the NRC issued to the licensee a Notice of Violation (NOV) and a Proposed Imposition of Civil Penalty (CP) in the amount of \$10,000 for violating NRC requirements in the loss of the radioactive source (Ref. B-1).

The licensee replied to the NRC letter in two letters dated January 24, 1992. One letter admitted the violations described in the NOV. The second letter requested mitigation of the proposed CP.

After considering the licensee's responses, the NRC staff determined that the violations occurred as stated and that the \$10,000 CP should be imposed. Consequently, on June 5, 1992, NRC issued to the licensee an Order Imposing Civil Monetary Penalty in the amount of \$10,000 (Ref. B-2). The violations associated with the civil penalty were collectively categorized as a Severity Level problem, on a scale in which Severity Levels I through V are the most significant and least significant, respectively. On June 11, 1992, the licensee paid the civil penalty in full.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported in the Federal Register. Appendix A (see Example 5 of "All Licensees") of this report notes that any loss of licensed material, in such quantities and under such circumstances that substantial hazard may result to persons in unrestricted areas, can be considered an abnormal occurrence.

ITEM #: 910705 AO #: NRC 91-10 EVENT DATE: 06/17/1991

TITLE: MEDICAL DIAGNOSTIC MISADMINISTRATION AT I. GONZALEZ MARTINEZ ONCOLOGIC HOSPITAL IN HATO REY, PURERTO RICO

NAME: I. Gonzalez Martinez Oncologic Hospital CITY: Hato Rey STATE: PR

Nature and Probable Consequences:

On June 17, 1991, a patient scheduled to receive a diagnostic dose of iodine-131 (I-131), was mistakenly administered a dose of I-131 in the therapeutic range. The misadministration occurred when a nuclear medicine technologist misread the dose calibrator and administered 6.2 millicuries rather than 6.2 microcuries. The technologist realized the error nine minutes after the dose was administered when the printed dose label from the dose calibrator was checked. The physician-in-charge promptly administered potassium iodide solution to the patient to reduce the uptake of the radioactive iodine. The licensee estimated, based on 24-hour uptake measurements, that the uptake of radioactive iodine in the thyroid was approximately five percent resulting in an estimated dose to the thyroid of 1612 rem. The misadministration was promptly reported to the NRC.

The licensee continues to follow the patient's condition and has advised the NRC that the patient has not experienced any adverse effects because of the misadministration.

Cause:

The cause is attributed to human error by the nuclear medicine technologist. The technologist did not verify the dose by reviewing the printed dose label before administering the dose.

Licensee Action:

The licensee's corrective actions included taking disciplinary action against the technologist and requiring that the nuclear medicine supervisor check each dose before the dose is administered to a patient.

NRC Action:

NRC Region II conducted an inspection to review the circumstances associated with the misadministration, and to review the licensee's corrective actions. No violations of NRC requirements were identified during the inspection.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 910985 AO #: NRC 91-11 EVENT DATE: 08/30/1991
TITLE: MEDICAL THERAPY MISADMINISTRATION AT WILLIAM BEAUMONT ARMY MEDICAL CENTER IN EL PASO, TEXAS
NAME: William Beaumont Army Medical Center CITY: El Paso STATE: TX

Nature and Probable Consequences:

On August 30, 1991, a patient referred to the Medical Center for therapeutic radioiodine treatment of Graves' disease, mistakenly received a 28.6 millicurie (mCi) oral dosage of iodine-131 (I-131) instead of the prescribed oral dosage of 15.0 mCi I-131. As a result, the patient's thyroid received about 31,900 rads instead of the 16,700 rads intended.

Prior to the administration, the radiopharmacist involved was informed that a radioiodine treatment for Graves' disease had been requested. He assumed that it was a 29 mCi treatment rather than a 15 mCi treatment. [At the Medical Center, a 15.0 mCi dose routinely used for Graves' disease while a 29.0 mCi dosage is used for thyroid disorders such as multinodular toxic goiters.] He then requested a 29.0 mCi dose from Syncor, the commercial radiopharmacy. The actual dose received from Syncor was 28.6 mCi, and was labeled as such. When the radiopharmacist logged the dosage into the computer, after it had been measured by dose calibrator, he failed to take note of the intended therapy dose as reflected in the referring physician's prescription. In addition, the counseling nuclear medicine physician did not verify the dosage to be administered with the intended dosage. The 28.6 mCi incorrect dosage was then administered to the patient.

The referring physician was notified on the day of the misadministration. The licensee stated that no adverse effects on the patient were noted. The patient's condition will be appropriately followed in the licensee's Endocrine Clinic.

Cause:

The event was attributed to human error as a result of the radiopharmacist's and consulting nuclear medicine physician's inattentiveness and short experience at this facility. Although the prescribing physician's written request was available at the time the dosage was ordered and administered, both individuals failed to compare the prescribed dosage with the dose calibrator assay result or the radiopharmaceutical package label. Additionally, both the radiopharmacist and consulting nuclear medicine physician had only been working at the facility for a short time and were unfamiliar with the use of radioiodine dosages as low as 15 millicuries for the treatment of Graves' disease. The physician's previous experience and personal preference involved a routine dosage of 30 millicuries for a hyperthyroid disorder, and the radiopharmacist had dispensed on a few therapeutic radioiodine dosages, involving higher dosages, prior to this particular case. The licensee also acknowledged that the consulting nuclear medicine physician may not have realized that the patient was receiving treatment for Graves' disease rather than a multinodular toxic goiter at the time the dosage was administered.

Licensee Action:

The radiopharmacist and consulting nuclear medicine physician were counseled and re-instructed as to the proper dose verification techniques and safeguards. For future therapies using radiopharmaceuticals, the counseling nuclear medicine physician must visually check the activity of the radiopharmaceutical dosage, as measured by the radiopharmacist or technologist, with the written physician prescription. The licensee also intends to require that the consulting nuclear medicine physician be familiar with the patient's case history prior to administering a therapeutic radiopharmaceutical dosage.

Also, the licensee's Radiation Safety Officer will conduct a training session in which all nuclear medicine personnel will be required to review the videotape entitled, "Good Practices in Preparing and Administering Radiopharmaceuticals," prepared by the NRC's Office for Analysis and Evaluation of Operational Data.

NRC Action:

NRC Region IV conducted an inspection to review the circumstances associated with this misadministration and the licensee's corrective action as described above (Ref. 1). The inspection revealed no violations of regulatory requirements regarding this misadministration, and the licensee's determination of the cause of the event was considered accurate based upon interviews of individuals involved. The licensee had implemented corrective actions as reported, and had continued to closely observe individuals' performance with regard to therapeutic radiopharmaceutical dosages.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:	951059	AO #:	NRC 91-12	EVENT DATE:	10/25/1991
TITLE:	MEDICAL THERAPY MISADMINISTRATION AT ST. JOSEPH'S HOSPITAL AND MEDICAL CENTER IN PATERSON, NEW JERSEY				
NAME:	St. Joseph Hospital and Medical Center	CITY:	Paterson	STATE:	NJ

Nature and Probable Consequences:

On November 13, 1991, NRC Region I was notified by a letter dated October 30, 1991, from the licensee's acting Radiation Safety Officer (RSO), that a therapeutic misadministration involving a strontium-90 (Sr-90) beta applicator, with a nominal activity of 95 millicuries, had occurred on October 25, 1991. The therapeutic treatment had been administered to the wrong patient.

The misadministration involved a 52-year-old male who was scheduled for simulation for external beam therapy from a linear accelerator to the head and neck. This occurred when the radiation oncology department secretary placed the patient in the wrong treatment room without the patient's chart. The patient spoke minimal English and the radiation oncologist did not speak the patient's language. The physician questioned the patient more than once as to which area of his body was being treated. The patient pointed toward his head as the area to be treated. Based on this poor exchange of information, and without benefit of review of patient's chart, the oncology physician then proceeded to administer a Sr-90 dose to the patient's eye. The licensee estimated that about 1,000 rads were delivered in 11 seconds to the surface of the right eye. The licensee estimates that no harmful effects occurred to the patient as a result of this event.

An NRC medical consultant was retained to review the licensee's dosimetry, the possible biological effects of the dose, and the actions to prevent recurrence. The consultant concluded that:

1. The patient should receive a slit-lamp examination of both eyes immediately and annually thereafter for the rest of the patient's life,
2. The possibility of cataracts is low, and
3. The methods to identify patients should be improved.

Based on source and geometry considerations, the consultant agreed with the licensee's estimate of about 1000 rads to the patient's eye. The consultant reviewed the licensee's corrective actions and found them to be appropriate. The consultant provided suggestions to the licensee on how to improve the corrective actions.

Cause:

The cause was attributed to failure to follow the hospital protocol which requires reviewing the patient's chart prior to administering treatment.

Licensee Action:

The licensee's planned corrective actions include:

1. Patients will only be directed to the treatment area by an aide who will hand the treatment charts directly to the physician.
2. All patient's charts will include a Polaroid photograph of the patient.
3. Access to the Sr-90 beta applicator storage area will be limited to the Physics Department and the Chief Technologist.
4. Physics staff will accompany the physicians during all Sr-90 beta applicator treatments and assist in determining the treatment times.
5. Staff training and reinforcement of appropriate patient processing procedures and NRC notification and reporting requirements will be conducted.

NRC Action:

An NRC Region I inspector was dispatched to conduct a special inspection on November 15, 1991, of the circumstances surrounding this misadministration (Ref. 2).

On December 29, 1991, the NRC transmitted to the licensee a Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$6,250 (Ref. 3). Two violations were identified: (1) the failure to review the patient's prescription which resulted in the misadministration (\$3,750); and (2) the failure to report the misadministration to the NRC within 24 hours of its discovery (\$2,500). Both violations were classified as Severity Level III on a scale in which Severity Levels I through V range from the most significant to least significant, respectively. The licensee admitted the violations and paid the civil penalties in full.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A 9(see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 911306 AO #: NRC 91-14 EVENT DATE: 11/27/1991

TITLE: MEDICAL THERAPY MISADMINISTRATION AT UNIVERSITY OF WISCONSIN HOSPITAL IN MADISON, WISCONSIN

NAME: University of Wisconsin CITY: Madison STATE: WI

Nature and Probable Consequences:

A patient was undergoing a series of five treatments for a cancer of the nasal septum using a high dose rate iridium-192 afterloading unit. In this type of treatment, a brachytherapy catheter was positioned in the patient's nasal passage. The computerized device then moved the source through the catheter into the treatment area. The source had a nominal strength of 0.5 curies.

The initial four treatments were completed without incident. However, prior to the fifth treatment on November 27, 1991, the operating physicist picked up the wrong patient chart located next to the device's control panel and entered the treatment program information into the computerized device. While the treatment was underway, a student technologist inquired about the length of time to complete the treatment. The prescribing physician and the operating physicist indicated different lengths of time. The physician, realizing there was an error, directed that the treatment be stopped immediately. Subsequently, it was discovered that the physicist had used the wrong patient chart and, therefore, entered incorrect treatment program information into the computer. The correct treatment information was then entered into the computer and the treatment series completed.

The erroneous treatment information positioned the iridium-192 source so that the patient's lips received an unintended exposure for about one minute. The dose calculation by the licensee indicated the patient received approximately 73 rads to the lips. According to the licensee, the radiation exposure received by the lips, for a correctly administered treatment to the nasal septum would be about 25 rads. The licensee does not expect any consequences resulting from the additional exposure to the patient's lips from this misadministration.

Cause:

The physicist failed to verify the identity of the patient and assumed incorrectly that the chart at the control panel was for the patient undergoing treatment.

Licensee Action:

The licensee has directed that the operating physicist check the identity of each patient before treatment, using patient photos or other means of verification. Patient charts for treatment series will be placed in a specified location. No exceptions will be made to the training required of a user. In the future, training will include a general section on high dose rate afterloading devices.

NRC Action:

A special inspection was conducted on December 17, 1991, to review the circumstances surrounding the misadministration and review the licensee's corrective actions (Ref. 4). No violations of NRC requirements were identified. The corrective actions appeared sufficient to prevent a recurrence of the misadministration. While the licensee has a viable quality assurance program in place, the changes adopted will strengthen the previous procedures.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 951066 AO #: AS 91-05 EVENT DATE: 09/01/1989
TITLE: EXPOSURE OF A NON-RADIATION WORKER
NAME: San Gabriel Valley Medical Center CITY: San Gabriel STATE: CA

Nature and Probable Consequences:

On August 1, 1989, an intracavitary procedure was performed at San Gabriel Valley Medical Center. Two cesium-137 sources, 42.2 mCi each, were loaded into colpostat devices and inserted into the patient for treatment.

After the procedure was completed, the physician removed the devices and placed them in a lead container. The container was then transported to the room where the cesium storage safe was located; however, the sources were not removed from the insert and placed in the safe as they should have been. On September 1, an employee of the Medical Center removed the inserts, still containing the sources, from the lead transport container, and thinking they were empty, placed them in an envelope to be transported to Methodist Hospital where they were intended to be used. The envelope was placed in the Radiology Department where it was picked up by an employee of a private medical group a few days later. This individual placed the envelope in his private car and drove to Methodist Hospital which took approximately 25 minutes.

When the inserts were received by Methodist Hospital, the envelope was opened immediately and the sources were discovered inside. They were placed in a lead transport container and removed to the storage safe by staff of the hospital.

San Gabriel Valley Medical Center hired a medical physicist to evaluate and determine the extent of exposures that individuals received as the result of this incident. Extensive time and motion studies were conducted, as well as the processing of personnel monitoring devices, to determine dose received. The individual who had transported the sources from one hospital to the other a non-radiation worker and therefore did not wear a personnel monitoring device. It was estimated that he received about 106 rem to his right hand and 0.168 rem whole-body exposure. All others who came in contact with the sources wore personnel monitoring devices. It was estimated that their exposures were within the occupational dose limits specified by the State's Radiation Control Regulations.

The Medical Center was cited for causing the delivery man to receive 106 rem to his right hand as a result of this event. He was notified in writing by the hospital of the nature and extent of his exposure and was provided a medical review. A medical examination of his hands on the day after the exposure and three weeks later did not reveal any evidence of skin changes or other symptoms. Also, his blood count showed no significant abnormalities.

Cause:

The apparent cause of this exposure was the failure of hospital employees to follow proper procedures for storage of brachytherapy sources following their use. The individual who transported the sources from the patient's room to the cesium storage location at the Medical Center did not remove them from the colpostat source holders and place them in the storage safe. By leaving the sources in the holders, other personnel were easily exposed because the sources were invisible and could only be detected by careful examination or use of a survey meter.

Licensee Action:

The Medical Center purchased a bench top Geiger-Mueller detector equipped with an audible alarm and installed it at their cesium storage location. The detector will alarm if sources are not secured inside the storage safe. Also, a refresher training was held for all staff covering proper handling of brachytherapy sources held under the license. This training included removal and replacement of sources from the storage safe as well as quarterly inventories. Methods for surveying devices that contained cesium sources prior to taking them out of service was emphasized.

NRC Action:

Other Agency Action:

The inspection agency cited the Medical Center for six items of noncompliance. The licensee responded to the Notice of Violation on November 14, 1989, and the investigation was closed on November 30, 1989. A follow-up inspection was conducted in October 1990, and no similar type personnel exposures were found; therefore, the corrective actions appeared to be effective in preventing further similar incidents.

Unless new significant information becomes available, this item is considered closed for the purposes of this report.

Criteria:

Appendix A (see Example 5 of "For All Licensees") of this report notes that any loss of licensed material in such quantities and under such circumstances that substantial hazard may result to persons in unrestricted areas can be considered an abnormal occurrence.

ITEM #:	900789	AO #:	AS 91-06	EVENT DATE:	11/02/1990
TITLE:	EXPOSURES OF NON-RADIATION WORKERS				
NAME:	Anaheim Memorial Hospital	CITY:	Anaheim	STATE:	CA

Nature and Probable Consequences:

On November 2, 1990, Anaheim Memorial Hospital, Anaheim, California, shipped 7 cesium-137 sources that had been used for brachytherapy implant back to the supplier, Therapeutic Nuclides, Inc., Valencia California. The sources consisted of two 50 mCi, three 25 mCi, and two 12 mCi sizes.

The Type 7A package used for shipment consisted of a plastic source retainer, fitted into a lead pig that was then placed inside metal can. This metal can was then placed inside a 5-gallon metal container and was surrounded on all sides by a high-density polyurethane foam. The inside container was secured with a lid and a snap ring. The outside container was secured with a lid and a level lock ring.

The package was picked up by Federal Express on November 2, 1990, and was taken first to the Fullerton, California, sort facility and then to the Los Angeles Airport (LAX) Hub Sort Facility. At LAX, the package came open while descending 8 feet on a 45-degree angle conveyor belt. At the bottom of the descent, all contents of the package became separated and scattered on the conveyor belt and around the work area.

A Federal Express employee noticed that the package had a radioactive label and immediately repacked the 5-gallon container; however, he did not realize that the sources had fallen out. The employee reported the incident to his supervisor who called in a hazardous material specialist to examine the container. The specialist used a survey meter and determined that there was no radiation level at the surface of the drum. Rather than question why he did not register any reading, he assumed that all items inside the package had been properly secured and he allowed it to continue on to its destination.

The package arrived at Therapeutic Nuclides on Monday, November 5, 1990, but it was not opened until the following day. When the package was opened and discovered empty, the Radiation safety Officer for Therapeutic Nuclides immediately notified the Los Angeles County Radiation Control office (Agency) and an investigation was begun. An Agency inspector contacted Federal Express in an attempt to backtrack the route the package took from the time it was picked up at the hospital. She was able to find her search on the Hub facility at LAX and discovered the sources there as soon as she entered the facility.

All seven sources were located in various places throughout the facility by the inspector. Federal Express personnel who came in contact or worked near where the sources were found were interviewed. Those individuals who came in close contact with the sources were sent for medical evaluation and follow-up. Dose estimates were established for all workers and all were notified of their estimated doses. Individual dose estimates for the 24 employees involved ranged from 10 mrem to 1810 mrem whole body. Also, three individuals who said they touched the sources had estimated extremity doses that ranged from 90 to 260 rem.

The U.S. Department of Transportation (DOT) investigated whether the package of sources was properly secured prior to pick-up by Federal Express. There is strong evidence that the package was not properly sealed; therefore, when it fell down the conveyor belt it easily spilled open. The hospital staff supplied sworn statements to Radiation control Program staff that they had followed procedures when they packaged the sources; however, DOT has run extensive tests on the container and has concluded that if it had been sealed properly, it would not have spilled its contents.

Cause:

see Nature and Consequences above.

Licensee Action:

After long delays, the hospital complied with the dose notification requirements.

NRC Action:

Other Agency Action:

A Notice of Violation was issued to the hospital for failure to report the incident and also for the exposures to personnel in excess of permissible levels. The case was closed on November 13, 1991.

Other: Therapeutic Nuclides has redesigned their container to prevent this type of spill in the future.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Criteria:

Appendix A (see Example 5 of "For All Licensees") notes that any loss of licensed material in such quantities and under such circumstances that substantial hazard may result to persons in unrestricted areas can be considered an abnormal occurrence. In addition, Example 2 of "For All Licensees" in Appendix A notes that an exposure to an individual in an unrestricted area such that the whole body dose received exceeds 0.5 rem in one calendar year can be considered an abnormal occurrence.

This writeup is based on information provided to the NRC in December 1991 by the Agreement State of California for inclusion in this report.

ITEM #:	910535	AO #:	AS 91-07	EVENT DATE:	05/03/1991
TITLE:	MEDICAL THERAPY MISADMINISTRATION AT NORTHRIDGE HOSPITAL MEDICAL CENTER IN NORTHRIDGE, CALIFORNIA				
NAME:	Northridge Hospital Medical Center	CITY:	Northridge	STATE:	CA

Nature and Probable Consequences:

On May 3, 1991, 15 mCi of iodine-131 intended for patient "A" was administered in error to patient "B" who had the same first and last names as patient "A". The administration was made by the hospital's Certified Nuclear Medicine technologist without the responsible physician present, which is a violation of the California Radiation Control Regulations. Patient "B" had reported to the hospital's Outpatient Department for a preoperational chest x-ray instead of reporting to her doctor's private office as she was instructed. Patient "A" was scheduled to receive a hyperthyroidism treatment that same morning.

When her name was called, patient "B" answered and signed the consent form. She asked questions of her technologist about thyroid disorders and was given answers. The dose of 15 mCi was administered.

Later that same day, patient "A" presented herself for treatment. It was then that the hospital discovered that they had administered the dose to the wrong patient. Patient "B's" doctor was contacted and consulted with the Chief Nuclear Medicine physician. They decided to give patient "B" 15 drops of a potassium iodine solution three times daily for three days plus force fluids to reduce the uptake of the radioactive iodine. She underwent the previously scheduled surgical procedure three days after the dose was administered without any regard for the possible exposure of surgical room staff from the patient.

This incident was reported to the wrong unit of California's Department of Health Services by the hospital five days after it occurred. Not realizing the significance of the error, Radiologic Health was not contacted until May 31, 1991, 28 days after it occurred. An investigation was begun by the Radiologic Health Unit of the Los Angeles County Health Department, the inspecting agency for this licensee. The inspector discovered that the hospital had originally estimated the patient's thyroid dose to be much lower than it actually was. The agency retained a consultant who performed a complete workup of the patient. The patient's dose was established at 3000 rem to the thyroid and she was informed of this in writing by the hospital. She was placed into a treatment follow-up program.

An evaluation of exposures to the surgical room staff was also made by the consultant. Their exposures were determined to be minimal and they were also notified by the hospital.

Cause:

The administration was made by the hospital's Certified Nuclear Medicine Technologist without the responsible physician present.

Licensee Action:

An enforcement conference was held at the Los Angeles County Health Department between members of the hospital administrative staff and representatives of the County and State Radiation Control Program staff. The hospital presented an extensive corrective action plan and explained new controls that would be put in place.

NRC Action:

Other Agency Action:

Representative of the Radiologic Health Branch accepted the plan and the case was referred to the city attorney's office for determination if charges should be filed.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health and safety can be considered an abnormal occurrence.

This write-up is based on information provided to the NRC in December 1991 by the Agreement State of California for inclusion in this report.

ITEM #: 920048 AO #: NRC 92-01 EVENT DATE: 01/13/1992
TITLE: MEDICAL THERAPY MISADMINISTRATION AT ST. JOHN MEDICAL CENTER IN TULSA, OKLAHOMA
NAME: St. John Medical Center CITY: Tulsa STATE: OK

Nature and Probable Consequences:

On January 21, 1992, the licensee notified NRC Region IV that on January 20, 1992, a medical misadministration was discovered that involved two therapeutic radiation doses to a part of a patient's body that was not intended to be treated. The treatments were administered on January 13 and 14, 1992, by a cobalt-60 teletherapy unit.

The patient was scheduled to receive ten treatments of 300 rads each to the right scapula. After the second treatment was performed by the therapists, the oncologist reviewed the port film and noticed that 80 percent of the intended area had been missed. An investigation by the licensee determined that in simulating the treatment to be performed on the patient, the oncologist placed a mark on the patient's chest as indicated by the ceiling laser position. During treatment, however, the back pointer on the teletherapy unit was positioned on this mark. As the back pointer and ceiling laser result in different angles to the cobalt-60 radiation beam, the tissue volume treated was medial to the intended treatment site.

The oncologist amended the original prescription to include two additional treatment fractions to the appropriate area, bringing the treatment dose to that area to the intended 3000 rads.

The patient was notified of the treatment error. The licensee stated that the misadministration should have no adverse effect on the patient.

Cause:

There was a breakdown in communication between the oncologist and therapist during simulation. Either proper instruction was not given regarding patient positioning and which indicator to use, or it was not carried out correctly.

Licensee Action:

The licensee has reviewed this incident with all staff members and communicated by memo to all prescribing physicians explaining the different localization methods. In addition, the licensee's Quality Management Program was amended to require review of port films after the first treatment in a series; this would not have prevented a misadministration, but might have identified the error prior to the administration of the second treatment.

NRC Action:

An inspection was conducted on February 13-14, 1992, to review the circumstances associated with the misadministration. The inspection report was forwarded to the licensee by letter dated April 6, 1992 (Ref. 1). Although no violations of NRC requirements were identified, the NRC was concerned that the misadministration was a result of a verbal miscommunication between the oncologist and the therapist. The licensee was requested to describe corrective actions taken to prevent such miscommunication among staff members.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to a part of the body not scheduled to receive radiation can be considered an abnormal occurrence.

ITEM #: 920183 AO #: NRC 92-02 EVENT DATE: 02/24/1992
TITLE: MEDICAL THERAPY MISADMINISTRATION AT HARPER HOSPITAL IN DETROIT, MICHIGAN
NAME: Harper Hospital CITY: Detroit STATE: MI

Nature and Probable Consequences:

On March 16, 1992, the licensee notified NRC Region III that on February 24, 1992, a patient with cancer had received a therapeutic radiation dose to the incorrect side of the chest area. (In accordance with NRC requirements, the therapeutic misadministration should have been reported to the NRC on February 25, 1992, i.e., within 24 hours of the time of discovery on February 24, 1992. However, the licensee did not properly categorize the event as a therapeutic misadministration until March 1992.)

The patient was scheduled to receive 28 daily treatments of 180 rads each to the right collar bone area and 90 rads each to tangential areas of the right breast. The treatments began on February 12, 1992, and eight treatments were delivered as prescribed. On February 24, 1992, however, the radiation therapists erroneously treated the left collar bone area instead of the intended treatment area on the right. The therapists discovered the error as they prepared to treat the two tangential areas of the left breast. The therapist repositioned the patient to treat the prescribed right breast. The treatment plan was then continued until the balance of the prescribed 28 treatments was completed.

The treating physician stated that in her judgment the misadministration did not compromise the patient's treatment, either from underdose to the prescribed site or from the inadvertent dose to the incorrect area.

Cause:

The radiation therapy technologists stated that the error occurred because they confused a leveling tattoo on the left collar bone area with the treatment tattoo on the right collar bone area. They also did not follow the procedures for confirming the accuracy of the treatment site for agreement with the prescribed treatment site as specified in the licensee's Quality Management Program.

In regard to the lateness of reporting the event to the NRC, the misadministration had been promptly reported to hospital management. However, the person responsible for reviewing the incident to determine if an NRC report was required used an incorrect draft of the hospital's policy manual which contained an error in its definition of a misadministration. The incident was determined to be a misadministration and was therefore not reported to the NRC until March 16, 1992.

Licensee Action:

The remaining treatments in the patient's treatment series were performed by three technologists to assure treatment accuracy. The licensee is now using different tattoos for the treatment area and for leveling.

The licensee had implemented a written Quality Management Program on January 27, 1992. The program requires that before treatment is administered, the details of the treatment must be checked for agreement with the prescription and plan of treatment and the accuracy of the treatment site must also be confirmed. Therapists were provided further instruction on appropriate policies and procedures. The incomplete policy manual has been updated, and personnel have been trained on NRC misadministration reporting requirements.

NRC Action:

A special inspection was conducted on March 26-27, 1992, to review the circumstances associated with the misadministration (Ref. 2). On April 22, 1992, the NRC issued a Notice of violation (Ref. 3). Two violations of NRC requirements were identified: (1) failure to follow the instructions of the Quality Management Program, and (2) failure to report the misadministration no later than the next day following its discovery.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to a part of the body not scheduled to receive radiation can be considered an abnormal occurrence.

ITEM #:	920202	AO #:	NRC 92-03	EVENT DATE:	07/01/1990
TITLE:	MULTIPLE MEDICAL THERAPY MISADMINISTRATIONS AT G. ANTHONY DOENER, M.D., FACILITY IN FREEHOLD, NEW JERSEY				
NAME:	G. Anthony Doener, M.D.	CITY:	Freehold	STATE:	NJ

Nature and Probable Consequences:

On March 18, 1992, the current consulting teletherapy physicist for the licensee informed NRC Region I of numerous therapeutic misadministrations that occurred between July 1990 and February 28, 1992. The physicist reported that patients who had received external beam therapy from a Picker Corporation Model 6103 (C-1000) teletherapy unit may have been underdosed by about 15-40% of the intended doses.

The misadministrations appeared to have resulted from an error introduced by the licensee's previous consulting teletherapy physicist into tables of treatment times he generated for various field sizes and treatment depths. The erroneous treatment times were then used by the licensee in treating patients. According to the licensee, approximately 13 patients were involved. One patient was undergoing treatment when the error was identified on February 28, 1992, and this patient's treatment time was adjusted to correct for the error prior to completion of treatment.

On March 26, 1992, NRC issued Confirmatory Action Letter (CAL) No. 92-004 to confirm the actions taken, or to be taken, by the licensee (Ref. 4).

The previous teletherapy physicist was contacted by telephone on March 18, 1992, and interviewed by NRC Region I on April 2, 1992. On both occasions, the previous teletherapy physicist stated that he had discovered in late 1990 the error in the treatment time charts he had prepared for January through December 1991. He stated that he had mailed corrected time charts for 1991 along with a hand written note to the licensee the first week of January 1991. He did not recall what the note stated nor did he maintain a copy of the note. He did not send the charts via certified mail nor did he attempt to contact the licensee by telephone to inform the licensee of the error. He was not aware that a similar error had occurred in charts he provided to the licensee for the period July 1990 to December 1990. The authorized user and office manager stated that they had not received corrected time charts for either 1990 or 1991.

The licensee has submitted all required documentation/reports of the misadministrations to the NRC. Based on the licensee's review of patient treatment charts, two patients have received supplemental treatment. Three of the patients are deceased and the licensee reported that the remaining eight patients would not be adversely affected. According to the licensee, the patients were notified of the treatment error by phone and in writing.

Cause:

The probable causes are (1) failure of the authorized user to identify the previous physicist's error on treatment time charts through independent verification, and (2) failure of the previous physicist to perform a secondary check of treatment times for charts prepared for July 1990 through December 1990.

Licensee Action:

Corrected treatment time charts were provided to the licensee by the current teletherapy physicist. These charts are currently being used by the licensee. The current teletherapy physicist will provide treatment time charts to the licensee on a bimonthly basis.

Treatment times will be independently verified by the current teletherapy physicist on a weekly basis or when treatment times for patient currently being treated are changed.

The licensee has submitted a Quality Management Plan to the NRC. The plan is being reviewed.

NRC Action:

Inspections were conducted at the licensee's facility on March 19 and April 22, 1992. Activities authorized by the licensee were inspected. In addition, actions taken in response to the CAL were reviewed.

The inspector verified by calculation that the treatment time charts contained errors and that the error began on the July 1990 treatment time chart. The average error determined by the inspector was 20%. The inspector was unable to verify that corrected treatment time charts had been provided to the licensee for 1991. The licensee learned on March 13, 1992, that the misadministrations had occurred, but did not report them to NRC Region I until March 18, 1992. Records of misadministrations required by 10 CFR Part 35 were properly maintained by the licensee. Corrected treatment time charts provided by the current teletherapy physicist were checked by the inspector and found to contain accurate treatment times. The inspector reviewed treatment charts for patients currently being treated and found that corrected treatment times were being used.

The inspector found that seven of eight commitments listed in the CAL had been completed at the time of the inspection. The action not completed by the licensee was to have the teletherapy physicist independently review all patient charts from the date misadministration began through December 1991 to identify all patients subjected to a misadministration. A letter from the licensee dated May 1, 1992, stated that patient charts from July 1990 through December 1991 have been sent to the current teletherapy physicist for review. The CAL is considered closed and authorization was given to the licensee to resume patient treatments.

The misadministrations did not appear to be the result of violations of NRC requirements. However, the inspector identified a number of apparent violations of licensed activities, including: (1) failure to perform a full calibration at intervals not to exceed one year; (2) failure to notify NRC Region I by telephone within 24 hours of a therapeutic misadministration; (3) failure of monthly spot checks to include a determination of timer on-off error and timer linearity over the range of use; (4) failure of the licensee to require the teletherapy physicist to review teletherapy spot check results within 15 days; (5) failure to perform an adequate accuracy test of the dose calibrator; and (6) failure to mathematically correct dose calibrator reading for a linearity error exceeding 10 percent. Items 3, 4, and 5 above are repeat violations. A Notice of Violation was issued.

The licensee's Quality Management Plan has been submitted to the NRC and is being reviewed.

The NRC medical consultant is currently reviewing the incident.

Unless new significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic misadministration affecting two or more patients at the same facility can be considered an abnormal occurrence.

ITEM #: 920506 AO #: NRC 92-05 EVENT DATE: 08/23/1990
TITLE: MEDICAL THERAPY MISADMINISTRATION AT BETH ISRAEL HOSPITAL IN PASSAIC, NEW JERSEY
NAME: Beth Israel Hospital CITY: Passaic STATE: NJ

Nature and Probable Consequences:

During a routine inspection conducted on May 22, 1992, it was discovered that the therapeutic misadministration, as well as an overexposure to a radiation workers' hand, had not been reported to the NRC.

On August 23, 1990, a patient was scheduled to have an endobronchial implant procedure that required two ribbons containing total of 35 iridium-192 seeds (68.54 millicuries) to be implanted into the patient. One ribbon contained 20 iridium seeds and the other contained 15 iridium seeds. The medical physicist gave the attending physician the wrong end (portion that does not include radioactive sources) of one of the two ribbons and the physician inserted the wrong end into the patient. The other ribbon containing 20 iridium-192 seeds was inserted correctly. The remaining extra lengths of these ribbons were cut off by the physicist and given to the medical physicist. The medical physicist, assuming that these pieces of ribbons contained no radioactive material, coiled them and held them in her hand. One of these pieces contained 15 iridium-192 seeds (29.37 millicuries).

The medical physicist, following the completion of the procedure, discarded these pieces of ribbon into a waste basket located in a waiting room across from the patient's room thus creating a radiation dose rate of up to approximately 63 millirems per hour in an unrestricted area. This dose rate was well above the regulatory limit of 2 millirem in any one hour for unrestricted areas. The implant was performed at 2:30 p.m. and the patient was scheduled to have a dose of 1500 rads. The physician decided to remove the ribbons from the patient earlier than planned because the dose rate was higher than what he normally administers. The ribbons were removed at 8:30 p.m. on August 23, 1990. Neither the medical physicist nor the hospital's Radiation Safety Officer (RSO) was present during the removal procedure.

The following morning at approximately 8:30 a.m. the medical physicist inventoried the sources removed from the patient and found that one of the ribbons contained no seeds. She immediately informed the RSO, who conducted a search for the missing radioactive material and at approximately 11:00 a.m. found the two pieces of ribbon in the waste basket. The licensee determined that the dose to the hand of the medical physicist was approximately 272 rads assuming that she held the ribbon containing iridium-192 seeds in her hand for about 5 minutes. The physician stated that the patient received a dose of approximately 400 rads (which was only about 50 percent of the intended dose). No make up dose was given to the patient. Neither the therapeutic misadministration nor the overexposure to the physicist's hand was reported to the NRC.

Cause:

Neither the medical physicist nor the physician performed a survey of the ribbons before implanting into the patient. The licensee did not inventory the sources promptly after removal from the patient. Also, the licensee failed to follow established procedures involving the removal of temporary implants in that the RSO or his designee was not present during the removal of temporary implants from the patients.

Licensee Action:

The licensee's corrective actions include a mandatory requirement that the RSO or his designee must be present during all implant and removal of radioactive materials. The management of the licensee is now more deeply involved in the radiological safety affairs. The licensee is conducting an audit of its radiation safety program by an independent person.

NRC Action:

NRC Region I inspectors continued the inspection of the circumstances surrounding this misadministration on June 2, 1992 (Ref. 2). Numerous apparent violations were identified. A Confirmatory Action Letter was issued on June 5, 1992 (Ref. 3). An enforcement Conference was held with the licensee in Region I on June 25, 1992, to discuss the violations and the corrective actions proposed and implemented by the licensee (Ref. 4).

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$13,500 was sent to the licensee on August 7, 1992 (Ref. 5). The violations include: the overexposure of the hand of the medical physicist; the failure to perform a survey which directly contributed to the misadministration and the overexposure; the failure to report the misadministration and the overexposure to the NRC, as well as the failure to report the misadministration to the patient's referring physician; and a breakdown in control of licensed activities of the facility. The violations associated with the overexposure and the failure to perform a survey were classified in the aggregate as a Severity Level II problem (on a scale in which Severity Levels I through V are the most and least significant respectively), and assessed a civil penalty of \$6,000. The violations of reporting requirements were classified in the aggregate as a Severity Level III problem and assessed a civil penalty of \$3,750. The violations associated with the breakdown in control of licensed activities were classified in the aggregate as a Severity Level III problem and assessed a civil penalty of \$3,750.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic dose that is less than 0.5 times the prescribed dose can be considered an abnormal occurrence.

ITEM #:	920288	AO #:	NRC 92-06	EVENT DATE:	03/24/1992
TITLE:	MEDCAL THERAPY MISADMINISTRATION AT HOSPITAL METROPOLITANO IN RIO PIEDRAS, PUERTO RICO				
NAME:	Hospital Metropolitano	CITY:	Rio Piedras	STATE:	PR

Nature and Probable Consequences:

On April 8, 1992, the licensee informed the NRC that on March 24-25, 1992 a brachytherapy misadministration occurred involving a patient receiving a therapeutic dose to the wrong part of the body.

The misadministration occurred when incorrect, no-longer-in-use, cesium-137 sources were placed in a brachytherapy applicator and administered to the patient. Because all the sources were smaller in diameter than the intended sources, they slipped from prescribed position and irradiated normal tissue not intended to be irradiated. The applicator was loaded by a technologist who never performed the procedure. The technologist was supervised by a technologist who had not performed the procedure in eight years, when the incorrect sources were in active use. The incorrect sources were discovered at the midpoint of the treatment by the licensee's medical physicist during an unplanned training session for a new physicist. The incorrect sources were promptly removed from the patient and the treatment restarted and completed as directed by the authorized user.

The licensee estimated the dose to normal tissue was approximately 400-500 rads. The licensee advised the NRC that no adverse effects to the patient are anticipated as a result of the misadministration.

Cause:

The causes are attributed to the licensee's failure to: (1) properly train individuals handling brachytherapy sources, (2) adequately implement a Quality Management Program (QMP), (3) develop and implement adequate QMP procedures, and (4) properly label the storage vault for the brachytherapy sources.

Licensee Action:

The licensee's corrective actions included revision of the QMP policies and procedures, training all supervised individuals on brachytherapy procedures and in the revised QMP, arranging safe storage for the sources no longer in use, posting a map of the source storage vault indicating the type of source at each storage point, and enhancing source accountability practices.

NRC Action:

Region II reviewed the circumstances associated with the misadministration and the licensee's immediate corrective actions during a reactive inspection on April 10, 1993, and a follow-up inspection on April 22 and 23, 1992, which included NRC consultants in the area of medical physics, oncology, and risk assessment (Ref. 6). NRC Region II conducted an Enforcement Conference with the licensee on May 20, 1992, to discuss the event (Ref. 7). A Notice of violation and Proposed Imposition of Civil Penalty in the amount of \$2,500 was issued on June 26, 1996 (Ref. 8).

This action was based on two violations that contributed to the brachytherapy misadministration: (1) failure to instruct supervised individuals in the principles of radiation safety and the QMP. Each violation was categorized at Severity Level III on a scale in which Severity Levels I through V are the most significant and least significant, respectively. Each violation was assessed a proposed civil penalty of \$1,250. Six other violations (including the failure to notify the NRC within 24 hours after discovery of a therapy misadministration) were also cited at either Severity Level IV or V and involved the licensee's radiation safety program.

Unless new, significant information becomes available, the item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to a part of the body not scheduled to receive radiation can be considered an abnormal occurrence.

ITEM #: 920488 AO #: NRC 92-07 EVENT DATE: 05/19/1992
TITLE: MEDICAL DIAGNOSTIC MISADMINISTRATION AT BAYSTATE MEDICAL CENTER, INCORPORATED, IN SPRINGFIELD, MASSACHUSETTS
NAME: Baystate Medical Center, Incorporated (Baystate) CITY: Springfield, STATE: MA

Nature and Probable Consequences:

On May 20, 1992, the licensee notified the NRC by telephone that a medical misadministration involving iodine-131 (I-131) radiopharmaceuticals had occurred at the licensee's facility previous day. A diagnostic dose was intended; however, a therapeutic dose was administered. The details of the event are described below.

A nurse from the referring endocrine clinic called Baystate to make an appointment for a patient for a thyroid scan and I-131 uptake study. Baystate's departmental procedure for a thyroid scan and I-131 uptake is to perform the study using 16 microcuries of I-131 and 10 millicuries of technetium-99m. A whole body scan requires that approximately 4 millicuries of I-131 be given to the patient. Apparently, the order was entered in the patient's scheduling chart as a whole body scan rather than the thyroid scan and I-131 uptake study which was intended. Questions were raised on several occasions by licensee personnel because the patient was diagnosed with an enlarged thyroid and generally an I-131 whole body scan is not indicated for this diagnosis. Also, an authorized user was not consulted to review the study and prepare a written directive prior to the administration of greater than 30 microcuries of I-131 as required by 10 CFR 35.32. A nuclear medicine technologist administered 4.1 millicuries of I-131 for a whole body scan without following the department's procedures for administration of I-125 or I-131. The licensee evaluated the dose to the patient's thyroid to be approximately 14,300 rads based on an uptake of 66 percent and the dose to the whole body to be approximately 6 rads.

Cause:

It was determined that one of the causes of the misadministration was a miscommunication between staff at both the referring endocrine clinic and Baystate. Other causes were failure of the staff at Baystate to follow regulatory procedures involving radiiodine doses greater than 30 microcuries which require that an authorized user prepare a written directive prior to the administration. Nuclear Medicine Departmental procedures also require that when an order for a requested study is unclear or illegible, the referring physician be contacted prior to the performance of the study.

Licensee Action:

The licensee's corrective actions included: (1) instruction of nuclear medicine staff in the department procedures and regulatory requirements for radiiodine studies; (2) preparation, prior to the administration of a written directive by the director of endocrine (authorized user), or a designated authorized user before any iodine study using greater than 30 microcuries is performed; (3) prompt transmittal of written requests for nuclear medicine studies from the clinics to the Baystate Medical Center, Nuclear Medicine Division, in order to compare the request to the computer entry prior to the administration; and (4) review of this patient's progress once every six weeks for three months.

NRC Action:

An NRC Region I inspector conducted an inspection on May 27 and 28, 1992, to determine the circumstances associated with the misadministration (Ref. 9). An NRC medical consultant worked with the licensee to provide a clinical assessment of the misadministration. Although the medical consultant calculated the thyroid dose to be considerably less than the licensee's estimate, his evaluation of the event and consequences to the patient were similar to the licensee's evaluation. They were in agreement that because the patient was diagnosed as having Graves' disease, the ultimate therapy would be treatment with about 10 millicuries of iodine-131 (compared to about 4 millicuries that were mistakenly administered). Therefore, the patient did not suffer adverse health effects from the misadministration worse than those normally associated with treatment of Graves' disease.

The NRC inspector identified two apparent violations of NRC requirements: (1) failure of authorized user to prepare a written directive, and (2) failure to follow procedures. An enforcement conference was held on June 23, 1992. Enforcement action is pending.

Future reports will be made as appropriate.

UPDATE from NUREG-0090, Vol. 15, No. 4, page 17. This abnormal occurrence was originally reported in NUREG-0090, Vol. 15, No. 2, "Report to Congress on Abnormal Occurrences: April-June 1992." The abnormal occurrence is updated and closed as follows:

As previously mentioned, on May 20, 1992, the licensee, Baystate Medical Center, in Springfield, Massachusetts, notified the NRC by telephone that a medical misadministration involving iodine-131 radiopharmaceuticals had occurred at the licensee's facility on May 18, 1992. A diagnostic dose of 16 microcuries was intended; however, a therapeutic dose of 4.1 millicuries was administered.

The NRC inspection identified two apparent violations of NRC requirements: (1) failure of authorized user to prepare a written directive, and (2) failure to follow procedures. An enforcement conference was held on June 23, 1992. As a result, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$2,000. The licensee responded to the notice by requesting mitigation of the civil penalty amount and denying part of one violation.

The NRC considered the licensee's request for full mitigation of the \$2,000 Civil Penalty that was proposed on August 21, 1992, and concluded that an adequate basis was not provided for mitigation. An Order Imposing a Civil Monetary Penalty in the amount of \$2,000 was issued on January 6, 1993 (Ref. B-4). The licensee paid the civil penalty on January 21, 1993.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 4 in Table A-1) of this report notes that administering a diagnostic dose of a radiopharmaceutical that is greater than five times the prescribed dose can be considered an abnormal occurrence.

ITEM #: 920525 AO #: NRC 92-08 EVENT DATE: 05/29/1992
TITLE: MEDICAL THERAPY MISADMINISTRATION AT THE CHRIST HOSPITAL IN CINCINNATI, OHIO
NAME: The Christ Hospital CITY: Cincinnati STATE: OH

Nature and Probable Consequences:

On May 29, 1992, the licensee performed an implant of radiation seeds for treatment of a patient's prostate cancer. The patient had previously received radiation treatment to the prostate using a linear accelerator. The implant treatment plan called for placement of 58 seeds, each containing 0.31 millicuries of iodine-125. The seeds were to be implanted in the prostate using needles guided by an ultrasound image. The implanted seeds were to deliver a dose of 12,000 rads to the prostate.

The 58 seeds were implanted, but a subsequent computerized tomographic scan showed that 21 seeds were implanted in tissue surrounding the prostate rather than the intended sites. Two seeds were eliminated with the patient's urine. The licensee calculated that the mispositioning of the seeds resulted in the patient receiving a 5,000 rad dose to the prostate rather than the intended 12,000 rad dose.

The principal consequence of this misadministration is the potential effects of the underdosage to the prostate. In addition, tissue surrounding the prostate received a greater radiation dose than intended. The prescribing physician concluded that the delivered dose from the implanted seeds and from the previous linear accelerator treatment was sufficient. An NRC medical consultant, retained to evaluate the circumstances and response to the misadministration noted: "Tumor recurrence is the greatest risk, and will be monitored closely." The consultant also concluded that there was not a high probability of radiation damage to the rectum which would be the area of principal concern.

Cause:

The misadministration resulted from the difficulties in the ultrasound placement technique. The ultrasound image is difficult to interpret in guiding the placement of the seeds with the implanting needles. The prescribing physician, who is the Authorized User in the NRC license, had been trained and certified in the ultrasound guided implant technique, but had not actually performed the procedure.

Licensee Action:

The physicians recommended several improvements in the implanting technique, including more detailed pretreatment planning steps to improve the quality of the ultrasound image, and enhancements to the seed positioning technique.

NRC Action:

NRC Region III conducted a special inspection June 17-18, 1992, to review the circumstances of the misadministration and to evaluate the licensee's follow-up activities. No violations of NRC requirements associated with the misadministration were identified. The NRC also retained a medical consultant to review the case.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic dose that is less than 0.5 times the prescribed dose can be considered an abnormal occurrence. In addition, some tissue received considerably more radiation than it would have had the treatment been as prescribed.

ITEM #: 920085 AO #: NRC 92-09 EVENT DATE: 11/11/1991
TITLE: MEDICAL THERAPY MISADMINISTRATION AT COOPER HOSPITAL/UNIVERSITY MEDICAL CENTER IN CAMDEN, NEW JERSEY
NAME: Cooper Hospital/University Medical Center CITY: Camden STATE: NJ

Nature and Probable Consequences:

On January 27, 1992, the NRC Region I office was notified by telephone that five therapeutic misadministrations involving Iridium 192 (Ir-192) wire occurred at Cooper Hospital/University Medical Center at Camden, New Jersey from November 11, 1991 to January 7, 1992. The licensee had discovered the error on January 24, 1992, after the review of patient charts in preparation for the Quality Management Program submittal. The error caused a 12.2 percent underdosing of the patients.

Four patients received external beam therapy (Linear Accelerator) in addition to the radiation received from the Ir-192 implants. Patient A was to receive 1043 rads from an Ir-192 intracavitary bronchial implant for treatment of lung cancer and received 916 rads on November 11, 1991. Patient A later received 5576 rads from external beam therapy. Patient B was to receive 1266 rads to the head and neck from an Ir-192 interstitial implant for the treatment of cancer and received 1112 rads on November 12, 1991. Patient B later received 4600 rads from external beam therapy. Patient C was to receive 2150 rads from an Ir-192 interstitial implant for the treatment of breast cancer and received 1888 rads on December 2, 1991. Patient C later received 5940 rads from external beam therapy. Patient D was to receive 2000 rads to the tongue for treatment of cancer from Ir-192 interstitial implant and received 1756 rads on January 7, 1992. Patient D later received 5940 rads from external beam therapy. The licensee has determined that above patient's treatments were not compromised by the small decrease in the total dose received when the external beam therapy treatment is factored into the assessment.

One patient did not receive external beam therapy. On November 21, 1991, Patient E was prescribed to receive 4628 rads to the pelvis for the treatment of cancer from an Ir-192 interstitial implant and received 4063 rads. Patient E's attending physician had originally calculated a desired dose between 4000 and 4500 rads and wanted to include hyperthermia treatment. Hyperthermia treatment required insertion of interstitial microwave antennae so that heat treatment was terminated within one hour before the implants were inserted and was initiated within one hour after the implants were removed. The attending physician was informed the licensee's staff that the implants would have to be removed at unreasonable times in order to fall within the attending physician's desired dose range. The attending physician then agreed to give 4628 rads so the second hyperthermia treatment could be given at a more reasonable time. Since the actual delivered dose fell within the attending physician's initial range, the licensee does not foresee any adverse effects for Patient E.

Cause:

It was determined that the cause of the misadministration was an input error into the treatment planning computer. Specifically, source calibration factor was in non-Systeme Internationale (SI) units (non-metric), however, the computer was set to receive the data in SI units and the setting was not changed.

Licensee Action:

The licensee's corrective action was to include the calibration factor that is used during treatments in their records for Implant Source Inventory - Source Type Characteristics so that the licensee can verify that the proper factors are used.

NRC Action:

An NRC Region I inspector conducted an inspection of the incident on August 5, 1992, to determine the circumstances associated with the misadministration. The inspector's findings were in agreement with the licensee concerning the cause of the misadministration. The inspector determined that the licensee's corrective actions were adequate to prevent recurrence. Inspection findings regarding the misadministration are documented in Inspection Field Notes approved September 9, 1992. (Revised 1).

This item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic misadministration affecting two or more patients at the same facility can be considered an abnormal occurrence.

ITEM #: 920662 AO #: NRC 92-10 EVENT DATE: 07/06/1992
TITLE: EXTREMITY OVEREXPOSURE OF A RADIOGRAPHER AT MQS INSPECTION, INC., FIELD SITE IN TRENTON, MICHIGAN
NAME: A temporary radiography field site CITY: Trenton STATE: MI

Nature and Probable Consequences:

On July 6, 1992, a licensee radiographer was assigned to radiograph various pipes at a construction site. Radiography is a non destructive testing technique which uses a sealed radiation source to make X-ray-like images of heavy metal objects.

The configuration of this job required that the radiography exposure device (camera) be suspended 20 feet above the floor. The radiation source is exposed using a remote cable to make the film image and then is retracted into the shielded camera. After an exposure, the radiographer used an aerial platform to reach the camera. He performed a radiation survey as he approached to assure that the source was in the shield. The radiographer was wearing his audible alarm radiation measuring device, but it was turned off.

The radiographer then moved the camera to reach the camera port to lock the radiation source inside. When he removed the tube which guides the source, he discovered the radiation source was exposed about 4 inches outside the camera. The source had apparently shifted into the unshielded position when the radiographer moved the camera to lock it. The source was locked into place in its exposed condition. The radiographer immediately returned to ground level, but later returned to the camera to unlock so that the radiation source would be retracted into its shield.

The incident was subsequently reenacted by the licensee's Radiation Safety Officer and NRC inspectors to evaluate the radiation exposure received by the radiographer. The calculation by the Radiation Safety Officer, based on a series of reenactments, indicated a minimum 440 rem exposure to the individual's hand. NRC inspectors estimated that the dose was about 880 rem. A radiation measuring device worn by the worker indicated a whole body radiation exposure of about 250 millirem.

The worker's hand was evaluated and monitored by medical radiation specialists at an area medical center. No short-term physical changes to the skin of the hand were observed.

The NRC limit for extremity exposure is 18.75 rem in a calendar quarter. Therefore, the reenactment showed that the exposure received was substantially over the limit. The whole body radiation exposure was within the NRC limit of 3 rem in a calendar quarter.

Cause:

The overexposure occurred as a result of the failure of the radiographer to use an audible alarm exposure measuring device as required by NRC regulations. The locking mechanism allowed the source to be locked in place while it was still exposed.

The radiographer was wearing an audible alarm device required by the NRC for radiography work, but the device was turned off. The device had been turned off to conserve battery power while the radiographer was doing paperwork, but had not been turned back on for the remainder of the day. Use of an operable alarm device could have avoided or minimized the overexposure.

Licensee Action:

The licensee alerted its staff to the potential problem with the locking mechanism of this type of radiography camera. It also provided additional training on the use of the required audible alarm radiation devices and included verifying that the devices are turned on during routine internal audits of radiography activities. The radiographer was restricted indefinitely from further work with radioactive materials.

NRC Action:

The NRC Region III conducted a special inspection of the licensee's activities on July 8-10, 1992 (Ref. 2). The inspection identified three violations of NRC requirements associated with the overexposure incident: (1) the extremity exposure in excess of the 18.75 rem limit for a calendar quarter; (2) failure of the radiographer to wear an operable audible radiation monitoring device and (3) failure to perform an adequate radiation survey of the radiography camera in that the radiographer did not survey the full circumference of the camera. The first two violations were classified as a Severity Level I problem, violations were classified as Severity Level I problem, and the third as a Level IV violation (on a scale in which Severity Levels I through V are the most and I significant, respectively). On October 9, 1992, a \$5,000 fine was proposed for the first two violations. No fine was proposed for the third violation (Ref. 3). On November 2, 1992, the licensee paid the civil penalty.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported in the Federal Register. Appendix A (see Example 1 of 'All Licensees') of this report notes that an exposure of the feet, ankles, hands, or forearms of any individual to 375 rem or more radiation can be considered an abnormal occurrence.

ITEM #: 920777 AO #: NRC 92-11 EVENT DATE: 08/11/1992
TITLE: MEDICAL THERAPY MISADMINISTRATION AT THE MEDICAL CENTER OF DELAWARE, INCORPORATED, IN WILMINGTON, DELAWARE
NAME: The Medical Center of Delaware, Incorporated CITY: Wilmington STATE: DE

Nature and Probable Consequences:

On August 12, 1992, the NRC Region I office was notified by telephone by the licensee's radiation safety office that a therapeutic misadministration involving a cobalt-60 teletherapy unit occurred on August 11, 1992.

The physician's written directive called for 3015 rads in 15 fractions to be delivered to the central area of the pelvic region with the teletherapy machine set up in a fixed modality. During the 14th fraction, the radiation therapy technologist (RTT) did not ensure that the teletherapy machine was set in the fixed modality and started the treatment. The previous patient had received treatment in the rotational modality and the setting of the machine was not changed. The patient received a total of 160 rads to the pelvic treatment area instead of the prescribed 200 rads. In addition, the licensee estimates that the patient received an estimated dose of 80 to 110 rads to the left side of the pelvis outside of the treatment area and between 60 to 70 rads to the right side of the pelvis outside of the treatment area. The licensee has determined that the patient will not suffer any adverse effects in the areas that received an unintended radiation dose. The licensee will increase the prescribed dose for the 15th fraction to make up for the underdosing during the 14th fraction.

Cause:

It was determined that the cause of the misadministration was the failure of the licensee to follow the department's Quality Management (QM) Program. The licensee's QM Program calls for two RTTs to be present when a patient is being set up to ensure that the setup is done properly. The first RTT did not ensure that the setup was done correctly and the second RTT was out of the department getting another patient.

Licensee Action:

The licensee's corrective action was to provide a training session to all RTTs on the requirements of the Quality Management Program.

NRC Action:

An NRC Region Inspector conducted an inspection on November 19, 1992, to determine the circumstances associated with the misadministration. The inspection findings are still under review by the NRC, and enforcement action is under consideration.

Future reports will be made as appropriate.

UPDATE from NUREG-0090, Vol. 15, No. 4, page 18. This abnormal occurrence was originally reported in NUREG-0090, Vol. 15, No. 3, "Report to Congress on Abnormal Occurrences: July-September 1992." The abnormal occurrence is updated as follows:

As previously mentioned, on August 12, 1992, NRC Region I was notified by telephone by the licensee's radiation safety officer that a therapeutic misadministration involving a cobalt-60 teletherapy unit had occurred at the Medical Center of Delaware's Christian Hospital on the previous day.

The licensee's corrective and preventive actions included: (1) training for all Radiation therapy staff on August 12, 1992, to review standard operating procedures for external beam therapy; (2) increased supervisory review and evaluation of existing procedures to ensure comprehension and implementation; and (3) strengthening of other existing procedures to ensure that periodic reviews of the Radiation Therapy Technologist's activities are conducted.

The NRC Region I staff conducted an inspection on November 19, 1992 and held an enforcement conference with the licensee on December 17, 1992, to discuss the inspection finding (Ref. B-5). As a result, three violations of NRC requirements that related to the licensee's implementation of its Quality Management Program and that contributed to the misadministration were identified. The violations were classified in the aggregate as a Severity Level III problem (on a scale in which Severity Levels I through V are the most and least significant, respectively). The licensee's corrective and preventive actions will be reviewed during the next inspection of the licensee's program.

Unless new, significant information becomes available, the item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to a part of the body not scheduled to receive radiatic can be considered an abnormal occurrence.

ITEM #: 920106 AO #: AS 92-01 EVENT DATE: 01/20/1992
TITLE: MEDICAL DIAGNOSTIC MISADMINISTRATION AT SOUTHWEST TEXAS METHODIST HOSPITAL IN SAN ANTONIO, TEXAS
NAME: Southwest Texas Methodist Hospital CITY: San Antonio STATE: TX

Nature and Probable Consequences:

On January 30, 1992, an iodine-131 thyroid scan was requested for a patient to further evaluate a suspected right paratracheal mass to determine if the mass was a substernal goiter. The technologist confused the thyroid scan request with a whole body scan because the mass to be imaged was in the chest. As a result, the patient was administered 5 millicuries of iodine-131 for a whole body scan instead of 100 microcuries of iodine-131 for the prescribed procedure for a thyroid scan with substernal mass.

Because of the high activity in the thyroid at the time of the imaging on January 31, 1992, a doctor was asked to review the examination. He discovered the dose error. The doctor reported that based on a normal thyroid uptake of 15% for iodine-131, a dose of five millicuries would deliver exposure of 4000 rads to the thyroid and 2.35 rads to the whole body.

The misadministration was reported to the patient's referring physician, and he was advised that a radiation dose of this magnitude to the thyroid could result in development of hypothyroidism. The referring physician plans to follow the patient accordingly.

Cause:

The misadministration occurred because a nuclear medicine technologist confused the requested partial body thyroid scan procedure with a whole body scan because of the location of the mass to be imaged.

Licensee Action:

The licensee established a policy that the administration of any dosage of iodine-131 greater than 100 microcuries must be reviewed by a staff radiologist licensed to administer radioactive materials with full knowledge of the clinical problem. The significance of the error was discussed with the technologist.

NRC Action:

Other Agency Action:

The licensee was cited by the Texas Bureau of Radiation Control for the misadministration in violation of license procedures. This item is considered closed for the purposes of this report

Criteria:

Appendix A (see Event Type 4 in Table A-1) of this report notes that administering a diagnostic dose of a radiopharmaceutical that is greater than five times the prescribed dose can be considered an abnormal occurrence.

ITEM #: 920764 AO #: NRC 92-14 EVENT DATE: 08/19/1992
TITLE: MEDICAL THERAPY MISADMINISTRATION AT MEMORIAL HOSPITAL OF LARAMIE COUNTY IN CHEYENNE, WYOMING
NAME: Memorial Hospital of Laramie County CITY: Cheyenne STATE: WY

Nature and Probable Consequences:

On October 22, 1992, the licensee notified NRC Region IV that a therapeutic misadministration had occurred on August 19, 1992 involving a brachytherapy implant procedure utilizing iridium-192 as seeds encased in nylon ribbon (small sealed radiation source utilized for interstitial treatment of cancer). The proposed treatment included a prescribed dose of 3,258 rads for the patient's prostate gland.

On October 21, 1992, while reviewing the shipping documents associated with the implant performed on August 19, 1992, the licensee's dosimetrist noted a discrepancy in the units of measurement between what she had ordered as opposed to what she received. The licensee ordered brachytherapy ribbons containing 0.79 millicuries per ribbon. However, the vendor delivered brachytherapy ribbons containing 0.79 milligrams radium equivalent (1.36 millicuries) per ribbon. When the shipment was received, the dosimetrist checked the prescription order against what was received and noted that the quantities (0.79) matched but she failed to note that the amount received was measured in milligrams radium equivalent rather than the requested millicurie units. As a result, the radiation dose to the patient's prostate gland was 5,669 rads rather than the prescribed 3,258 rads.

The referring physician was notified and chose not to inform the patient.

The patient was examined during subsequent follow-up visits and has shown no adverse effects due to the increased radiation exposure. The licensee does not anticipate any significant effects to the patient as a result of the misadministration.

Cause:

The cause is attributed to human error by the licensee's staff resulting in the failure to perform an adequate verification of source strengths prior to implanting the brachytherapy sources. The licensee's dosimetrist had checked the prescription order against the receipt records but failed to note the discrepancy in units of measurement. Additionally, miscommunication between the licensee and the vendor also appears to have contributed to the error.

Licensee Action:

Revised procedures have been implemented to prevent recurrence of administering implants without complete verification of brachytherapy source strengths. This includes an implant checklist that must be completed and initialed to ensure that units of measurement received correspond to that which was ordered. Additionally, the licensee's physicists will verify source strengths by direct measurement prior to implantation.

NRC Action:

An NRC Region IV inspector conducted a special safety inspection on November 19-20, 1992, to review the circumstances associated with the misadministration and to review the licensee's corrective actions. The licensee's determination of the cause of the event was considered accurate based upon interviews of the individuals involved. The inspection revealed violations associated with the failure of the licensee's authorized user to instruct individuals under his supervision in the licensee's quality management program (Ref. 4). Enforcement action is under consideration.

Future reports will be made as appropriate.

UPDATE from NUREG-0090, Vol. 16, No. 1, page 14. This abnormal occurrence was originally reported in NUREG-0090, Vol. 15, No. 4, "Report to Congress on Abnormal Occurrences: October-December 1992." The abnormal occurrence is updated as follows:

As previously mentioned, on October 22, 1992, the licensee notified NRC Region IV that a therapeutic misadministration had occurred on August 19, 1992 involving a brachytherapy implant procedure utilizing iridium-192 as seeds encased in nylon ribbon (small sealed radiation sources utilized for interstitial treatment of cancer). Because of a discrepancy in the units of measurement of what was ordered and what was received, the radiation dose to the patient's prostate gland was 56.69 gray (Gy) (5,669 rad), rather than the 32.35 Gy (3,235 rad) that was prescribed.

On March 22, 1993, the NRC transmitted to the licensee a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,250 (Ref. B-3). Three violations were identified. Two of the violations identified were collectively classified as Severity Level III (Severity Levels I through V range from the most significant to the least significant, respectively). These violations involved the failure to perform an appropriate verification of source strengths of brachytherapy sources prior to implantation, and the failure to conduct training of the licensee's radiation physicist on the elements of the Quality Management Program.

The licensee admitted the violation and paid the civil penalty in full.

This item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic dose that is greater than 1.5 times the prescribed dose can be considered an abnormal occurrence.

ITEM #: 920930 AO #: NRC 92-15 EVENT DATE: 10/02/1992
TITLE: MEDICAL THERAPY MISADMINISTRATION AND UNPLANNED EXPOSURE AT ST. CLARES RIVERSIDE
MEDICAL CENTER IN DENVILLE, NEW JERSEY
NAME: St. Clares Riverside Medical Center CITY: Denville STATE: NJ

Nature and Probable Consequences:

On October 2, 1992, the licensee notified the NRC by telephone that a therapeutic misadministration involving the implant of two iridium-192 ribbons had occurred that day at its facility. At 2:30 p.m. on October 1, 1992, a patient was implanted with 48.25 millicuries of iridium-192 contained in two nylon ribbons. The ribbons were inserted into catheters that extended from the patient's abdomen into the common bile duct. The procedure was scheduled to last 20 to 23 hours during which a dose of 1,500 to 2,000 rads would be delivered to a colon tumor obstructing the common bile duct. After implanting the iridium-192 ribbons into the two catheters, the implant site was dressed and instructions were given to nursing personnel not to change the dressing. These instructions were not detailed on the patient's chart. Due to excessive drainage of bile at the implant site during the evening and early morning hours, the patient's dressings were changed several times and then reinforced with additional absorbent. At 4:15 a.m. on the morning of October 2, 1992, the nurse on duty noted that the dressing was completely displaced and acted to replace the dressing. The nurse noticed that the two ribbons were displaced but, not knowing what they were, coiled the ribbons in her hand and taped the ribbons to the patient's abdomen. A routine x-ray identified that the seeds were no longer implanted, and the coiled ribbons were removed from the surface of the patient's abdomen by a physician at approximately 12:00 p.m. on October 2, 1992.

The licensee estimated that the patient received 1,145 rads to the targeted tumor site, between 172 and 1,032 rads to the skin on the abdomen, 19.9 rads to the liver and small bowel, 12.7 rads to the kidneys, 50.9 rads to the colon, and 6.7 rads to the testes. The licensee estimated that the nurse who coiled the ribbons and taped them to the patient's abdomen received approximately 7 rads to her hands. The licensee expects no adverse clinical effects as a result of the reduced dose to the target organ since this brachytherapy treatment was a booster to the external beam dose that was yet to be administered.

Both the patient and nurse were notified of the misadministration.

Cause:

The misadministration was caused by: 1) lack of oversight of the procedure by the licensee's Radiation Safety Officer (RSO); and 2) inadequate training of the nursing staff in that they were unable to identify the brachytherapy source ribbon.

Licensee Action:

The licensee initiated an expanded training program that includes familiarization of personnel with the size and appearance of the radioactive sources used in brachytherapy treatments at the licensee's facility. The licensee stated that a manager will be responsible for ensuring that personnel on all shifts involved in the care and treatment of radiation therapy patients receive this training. The licensee decided to name a new RSO because the current RSO was unable to devote sufficient time to the radiation safety program due to his other responsibilities. The licensee's actions also included: 1) committing that a new RSO would be in place before another brachytherapy procedure is performed; 2) developing a nurses' procedure manual; 3) conducting formal inservice training in radiation safety with all nursing unit workers; and 4) requiring a written directive be initiated before ordering radioactive material.

NRC Action:

NRC Region I conducted an inspection on October 5, 6, 7, and 9, 1992, and held an Enforcement Conference on November 5, 1992, to discuss the inspection findings. The licensee's corrective and preventive findings. The licensee's corrective and preventive actions will be reviewed during the next inspection of the licensed program. Several violations of NRC requirements were identified including: 1) failure to adequately train nursing personnel to recognize brachytherapy procedures; 2) failure to train personnel on potential radiological emergencies for brachytherapy procedures; and 3) failure to implement radiation safety and quality management programs to ensure adequate safety.

A civil penalty of \$10,000 was proposed in a letter dated January 11, 1993 (Ref. 5). The licensee paid the civil penalty on February 5, 1993.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to a part of the body not scheduled to receive radiation can be considered an abnormal occurrence.

ITEM #: 920964 AO #: NRC 92-16 EVENT DATE: 10/14/1992
TITLE: MEDICAL THERAPY MISADMINISTRATION AT THE LAHEY CLINIC MEDICAL CENTER IN BURLINGTON, MASSACHUSETTS
NAME: Lahey Clinic Medical Center CITY: Burlington STATE: MA

Nature and Probable Consequences:

On October 19, 1992, the licensee notified the NRC Operations Center of a therapeutic misadministration involving a high dose rate remote afterloader (HDR) that occurred at the facility on October 14, 1992. A patient was scheduled to receive brachytherapy treatment to the right main stem bronchus in three fractions using a Gamma Med HDR. Each fraction was to deliver 700 rads to the targeted tumor site. On October 7, 1992, the patient was administered the first treatment as prescribed. On October 14, 1992, the therapist made an error during input of the offset distance into the treatment computer, entering an offset distance of 7 millimeters rather than 7 centimeters as required. This error resulted in the second fraction delivering 90 percent of the prescribed fractionated radiation dose to unintended tissues away from the tumor site and under-dosing the tumor site. The under-dose was made up during the administration of the third fraction on October 22, 1992. The physician stated that he expected no adverse clinical effect on the patient due to underdosing the tumor site as the dose was made up in the third and final fraction.

The referring physician and patient were both notified of the misadministration.

Cause:

The licensee followed established procedures; however, the procedure did not include a mechanism to verify data entries on the HDR console at the time of treatment.

Licensee Action:

The licensee instituted a new procedure that requires that a second individual verify the data input on the HDR console prior to administration of the therapy.

NRC Action:

NRC Region I conducted a routine inspection at the facility on December 3, 1992. The inspection resulted in the identification of six apparent violations: (1) failure to have a quality management program to meet the regulatory requirements; (2) failure to make timely notification to the NRC; (3) failure to provide radiation safety training to workers; (4) failure to provide radiation safety training to workers; (4) failure to perform the required tests of the dose calibrators; (5) failure to perform radiation surveys; and (6) failure to maintain the prior exposure record of a new employee (Ref. 6).

The licensee stated that there were no adverse effects to the patient as a result of the misadministration.

Enforcement action is under consideration

Future reports will be made as appropriate.

UPDATE from NUREG-0090, Vol. 17, No. 1, page 15. This abnormal occurrence was originally reported in NUREG-0090, Vol. 15, No. 4, "Report to congress on Abnormal Occurrences," October-December 1992. The information pertaining to this abnormal occurrence is updated as follows:

At the Lahey Clinic Medical Center in Burlington, Massachusetts, a patient was scheduled to receive brachytherapy treatment to right mainstem bronchus in three fractions using a Gamma Med high-dose-rate (HDR) remote afterloader. Each fraction was to deliver 700 centigray (700 rad) to the targeted tumor site. On October 7, 1992, the patient was administered the first treatment as prescribed. On October 14, 1992, the therapist incorrectly entered 7 millimeters (0.28 inch), versus the prescribed 7 centimeters (2.8 inch), for the offset distance into the treatment computer. This error resulted in the second fraction delivering 90 percent of prescribed fractionated radiation dose to unintended tissues away from the tumor site and underdosing the tumor site. The underdose was made up during the administration of the third and final fraction on October 22, 1992.

On January 21, 1993, NRC held an open Enforcement Conference to discuss the apparent violations and their causes, and the licensee's corrective actions. After consideration of the information presented by the licensee and the application of the mitigation/escalation factors, a Notice of Violation was issued to the licensee on August 4, 1993. In a letter dated November 11, 1993, the licensee provided its corrective actions for each violation. A routine inspection, including follow-up review of the licensee's corrective action was performed on February 1 and 2, 1994. No additional violations were identified.

This event is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to a part of the body not scheduled to receive radiatic can be considered an abnormal occurrence.

ITEM #: 921058 AO #: NRC 92-17 EVENT DATE: 11/13/1992
TITLE: MEDICAL THERAPY MISADMINISTRATION AT INDIANA UNIVERSITY MEDICAL CENTER IN INDIANAPOLIS, INDIANA
NAME: Indiana University Medical Center CITY: Indianapolis STATE: IN

Nature and Probable Consequences:

A 31-month old patient, being treated for a brain tumor, was to receive two cobalt-60 teletherapy treatments of 150 rads each for total dose of 300 rads to reduce swelling behind the patient's eye. The dosimetrist mistakenly prepared the dose calculations for 300 rads per treatment. The patient was treated November 13 and 14, 1992, with 300 rads per treatment for a total dose of 600 rads.

Prior to the treatment, the treatment plan was reviewed by the treating physician. Following the treatments, the dose calculation were reviewed by a medical physicist and approved. The error was discovered by a student technologist during a monthly chart review on December 2, 1992.

Both the patient's referring physician and guardian were informed of the misadministration. The treatment accomplished its intended purpose and the swelling was reduced. The licensee reported that no adverse medical effects were expected because the additional radiation exposure.

Cause:

The error was caused by the mistaken calculations by the dosimetrist and by the apparent inadequate review by the physician before the treatment began. The doses normal used for this type of treatment are 300 rads per treatment, and this further contributed to the failure to identify the error before treatments occurred. There was also a problem with the legibility and format of the treatment plan.

Licensee Action:

The licensee has provided additional training to treatment personnel to eliminate the types of problems that contributed to the misadministration. The licensee also intends to revise the treatment form to make it more understandable.

NRC Action:

The NRC retained a medical consultant to review the case and to provide clinical assessment of the misadministration. NRC Region III conducted a special inspection on December 14-15, 1992, to review the circumstances surrounding this misadministration. Enforcement action on the inspection findings is pending.

Future reports will be made as appropriate.

UPDATE from NUREG-0090, Vol. 17, No. 1 page 15. This abnormal occurrence was originally reported in NUREG-0090, Vol. 1 No. 4, "Report to Congress on Abnormal Occurrences," October-December 1992. The information pertaining to this abnormal occurrence is updated as follows.

On November 13 and 14, 1992, a 30-month-old patient received a radiation dose of 600 centigray (cGy) (600 rad) instead of the intended dose of 300 cGy (300 rad) as treatment for a brain tumor. The error was caused by erroneous calculations by the dosimetrist and by an apparently inadequate review by the physician before the treatments began.

On October 7, 1993, NRC proposed a \$5000 Civil Penalty against the medical center for failing to have procedures to assure that the written directive had all the necessary treatment information and to verify that the dose calculations in the treatment plan conformed to the written directive. The medical center protested the penalty and the NRC staff subsequently issued an Order imposing the \$5000 Civil Penalty on January 18, 1994. The medical center has requested a hearing on the issue and the hearing is pending.

This report will be further updated when additional information becomes available.

UPDATE from NUREG-0090, Vol. 17, No. 4, page 19. This AO was originally reported in NUREG-0090 Vol. 15, No. 4, "Report to Congress on Abnormal Occurrences, October-December 1992."

The AO criterion used was Event Type 5 in Table A-1 of appendix A of this report-Administering a therapeutic dose greater than 1.5 times the prescribed dose.

At the time, it was reported that a 31-month-old patient was prescribed two cobalt-60 teletherapy treatments of 150 centigray (cGy) (150 rads) each to treat a brain tumor. Due to an error by the dosimetrist, two treatments of 300 cGy (300 rads) each were delivered.

The AO report is updated and closed out as follows:

On October 7, 1993, NRC issued to the licensee a Notice of Violation and Proposed Imposition of Civil Penalty for \$5,000 (Ref. 1). On January 18, 1994, an Order Imposing Civil Monetary Penalty was issued to the licensee. The licensee requested (Ref. 2) a hearing on the Order and denied that it had violated the NRC's requirements as stated in the Order.

On September 29, 1994, a settlement agreement between the NRC and the licensee was approved by the Atomic Safety and Licensing Board. The settlement agreement provisions included: payment of \$2,500 by the licensee to NRC; submission by NRC to the licensee of a list of deficiencies in the licensee's written Quality Management Program; resolution by the licensee of the deficiencies; and retention by the licensee of an independent contractor to audit the implementation of its Quality Management Program.

This item is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic dose that is greater than 1.5 times the prescribed dose can be considered an abnormal occurrence.

ITEM #: 921064 AO #: NRC 92-18 EVENT DATE: 11/16/1992
TITLE: LOSS OF IRIIDIUM-192 SOURCE AND MEDICAL THERAPY MISADMINISTRATION AT INDIANA REGIONAL CANCER CENTER IN INDIANA, PENNSYLVANIA
NAME: Indiana Regional Cancer Center CITY: Indiana STATE: PA

Nature and Probable Consequences:

On December 1, 1992, the licensee, Oncology Services Corporation (OSC), notified NRC Region I of the loss of an approximate 4.3-curie sealed iridium-192 source from their high dose rate (HDR) remote afterloader unit at their Indiana Regional Cancer Center (IRCC), Indiana, Pennsylvania. The licensee stated that a manager from Browning-Ferris Industries (BFI), a biological and hazardous waste handler, found radioactive material in the biowaste that was picked up from the nursing home. The licensee performed radiological surveys of the HDR and noted that the iridium-192 source was missing.

On December 1, 1992, Region I dispatched a section chief and inspector to the IRCC to ascertain the facts surrounding the loss of the iridium-192 source and how it was transferred to BFI facilities. On December 3, 1992, the NRC upgraded its response to an Incident Investigation Team (IIT). On February 8, 1993, the IIT presented its finding (NUREG-1480) to the Nuclear Regulatory Commission (Ref. 7). The following are synopses of the Region I inspection and IIT findings.

On November 16, 1992, an elderly patient was treated for anal carcinoma at the IRCC in Indiana, Pennsylvania, using HDR brachytherapy. The patient died on the evening of November 21, 1992, five days after the treatment. Before the treatment, five catheters were placed in the tumor. During the treatment, an approximate 4.3-curie iridium-192 source was placed at various positions in each catheter to irradiate the tumor by use of a remotely controlled Omnitron 2000 afterloader. This treatment was the first of a series of three 600-rad treatments planned by the physician, and the five catheters were to remain in the patient for subsequent treatments.

On November 16, 1992, after a trial run through the five catheters with a dummy wire, the iridium source wire was placed in four catheters without difficulty. After several unsuccessful attempts to insert the source wire and the dummy wire into a fifth catheter the treatment was terminated. An area radiation monitor in the treatment area was observed in an alarm condition at various times when the source should have been retracted during the unsuccessful attempts to insert the source wire through the catheter. Although three technologists and the physician attending the patient were aware of the alarm condition, no one conducted a survey for radiation levels with the available portable radiation survey instrument. The only action taken was to check the console of the HDR remote afterloader. Because the console indicator showed "safe," they believed the source to be fully retracted into the lead shield and assumed the area radiation monitor was malfunctioning. They were unaware the source wire had broken, leaving the source in one of the catheters in the patient. The patient was transported by ambulance, with the source to a local nursing home.

The source remained in the patient's body for almost four days. The catheter with the source came loose on the fourth day and, eventually, the catheter fell out early on the morning of November 20, 1992. It was placed in a medical biohazards bag (red-bag) in a storage room by nursing home personnel who did not know it contained the radioactive source. Later, on the same day, the catheter containing the source was moved to another storage location at the nursing home and placed in a box with other red bags. From November 16, through November 25, 1992, numerous residents, employees, and visitors to the nursing home were unknowingly irradiated. The ambulance staff who returned the patient to the nursing home were irradiated along with employees and patients at the IRCC.

On November 25, 1992, a driver from BFI picked up the red-bag biowaste and transported it to a BFI facility in Carnegie, Pennsylvania, and from there, it was transported to a BFI medical waste incinerator in Warren, Ohio.

At the Warren facility, fixed radiation monitors identified radiation emanating from the trailer, and, on facility personnel direction, the trailer was returned to Carnegie the same day. It was left over the weekend and on Monday, November 30, 1992, the BFI staff searched the truck for the radiation source. They identified the box with the radiation source and looked at individual red bags to identify the origin of the waste. On December 1, 1992, BFI successfully identified a name found with the red-bag waste in the biowaste and traced it to the nursing home.

After being notified by BFI, the nursing home called the IRCC on December 1, 1992. The cancer center had not used the HDR afterloader after the single treatment on November 16, 1992. Upon being informed of the source discovery, the medical physicist determined that no source was present in the HDR afterloader and informed the NRC Region I office of this fact. The physician and the medical physicist drove to Carnegie and retrieved the source.

A second Omnitron 2000 source wire broke at the Greater Pittsburgh Cancer Center (GPCC) of OSC on December 7, 1992. The wire broke in the same approximate location as the first wire. The GPCC medical physicist who was conducting the treatment was aware of the first incident and immediately recognized the problem and promptly and appropriately intervened, thereby preventing significant dose consequences to the patient of the cancer center staff.

An NRC medical consultant concluded that an analysis of the medical records and physical dosimetry would indicate that the massive radiation dose was a probable contributing cause of death in this patient. The licensee reported the prescribed dose at one centimeter was 1,800 rads to be delivered in three treatments and that the delivered dose was 1,600,000 rads to the same point, an overdose of about three orders of magnitude. The licensee stated the effect on the patient would be significant local tissue damage and possible significant tissue damage to organs outside the treatment area, depending upon the progression of

radiation damage with time before the patient expired. The licensee stated the dose was of sufficient magnitude that it believed was highly probable that the radiation exposure was at least a contributing factor to the patient's subsequent death. In a press release dated January 26, 1993, the Indiana County Coroner stated that the cause of death listed in the official autopsy report was "Acute Radiation Exposure and Consequences Thereof."

In addition to the patient, the team evaluated the radiation doses to 94 persons associated with the IRCC event. Radiation dose received by these individuals ranged between 40 mrem and 22 rem.

Of these individuals, nine residents who were involved in recreational activities at the Scenery Hill Manor Nursing Home were not notified regarding the exposure they had received. The IIT was unable to determine their identity. The rest of the individuals were notified either by the NRC or were monitored by their employer for occupational dose.

Cytogenetic studies were also performed on a number of these exposed individuals and the results were consistent with calculated doses within the limits of accuracy of both techniques. The highest extremity dose was calculated to be between 73 to 160 rem to the hands of one of the Certified Nursing Assistants.

No personnel or property contamination occurred and no occupational worker received a whole body radiation dose above the NRC occupational limit of 1.25 rem. While members of the public received radiation doses above applicable limits, no one received a dose at which acute radiation injury or clinical signs are expected to occur.

Cause:

The IIT reported that the event was caused by the following:

1. OSC had weaknesses in their radiation safety program that were a major contributing cause of the seriousness of the event and radiation exposure consequences. Some of these were a result of a rapid expansion in their HDR brachytherapy program from one facility to ten facilities in less than a year. The Radiation Safety Officer (RSO) failed to ensure that the staff at all facilities received adequate radiation safety training and that all management instructions relating to HDR were being followed.

Informal and unwritten procedures that may have been adequate when the licensee possessed one HDR unit under the direct control of the RSO were ineffective for the expanded program.

2. A number of weaknesses were found in the design and testing of the Omnitron 2000. Weaknesses were identified in the testing and validation of source wire design, and in the design of certain safety features of the HDR afterloader. These could allow the undetected retraction and further use of a broken wire with no warning to the user. Although not contributing to this event, weaknesses were found in Omnitron's quality assurance/quality control (QA/QC) program. The cause of the wire failure is not known with certainty at this time. The vendor believes it has evidence to show that storage of the source wire in teflon, if moisture is present, causes degradation of the Teflon with release of fluorine or hydrogen fluoride that causes degradation of the Nitinol (nickel-titanium alloy) wire. The NRC and its consultant are still evaluating this hypothesis and conducting further studies.

3. The safety culture at IRCC contributed significantly to the event. Technologists routinely ignored the PrimAlert-10 alarm. Its problems were worked around and not fixed. Technologists did not survey patients, the afterloader, or the treatment room following HDR treatments. No one was sure who was responsible for radiation safety training or the radiation safety program. The authorized user failed to wear a film badge on both occasions when the source was encountered.

4. Overall regulatory oversight was weak. NRC regulations do not directly address HDR brachytherapy to the extent that teletherapy and low dose rate brachytherapy are addressed. Licensing guidance for HDR has been unchanged since 1986 in spite of significant changes in medical regulations and other medical licensing guidance. Inspection guidance for medical licensees does not specifically address HDR brachytherapy. Although inspected by the NRC Region I office within a year of initial licensing, the inspection program does not require early reinspection in cases where licensees significantly expand the scope of their program through licensed amendments. The regulatory interaction between the NRC, the FDA, and the involved Agreement States in the regulation and authorization of the Omnitron 2000 HDR afterloader is poorly defined.

Licensee Action:

Licensee actions to prevent recurrence are still undergoing NRC staff review.

NRC Action:

The NRC initiated the IIT. The NRC issued Bulletin 92-03 to users of Omnitron 2000 HDR afterloaders (Ref. 8), Information Notice 92-84 to all NRC licensees (Ref. 9), and Confirmatory Action Letter curtailing the use of Omnitron 2000 HDR and providing safety precautions.

On January 20, 1993, the NRC issued an Order suspending License (Effective Immediately) to preclude the licensee from performing licensed activities at any of its facilities pending further order (Ref. 10). Issuance of this order does not preclude additional enforcement actions.

Future reports will be made as appropriate.

UPDATE from NUREG-0090, Vol. 16, No. 2 page 15. This abnormal occurrence was originally reported in NUREG-0090, Vol. 1 No. 4, "Report to Congress on Abnormal Occurrences: October-December 1992." The abnormal occurrence is updated as follows:

On December 1, 1992, the licensee, Oncology Services Corporation (OSC), notified NRC Region I of the loss of an approximate 159.1 gigabecquerel (GBq) (4.3 curie [Ci]) sealed iridium-192 source from their high-dose-rate (HDR) remote afterloader unit at their Indiana Regional Cancer Center (IRCC), Indiana, Pennsylvania. The source was left within a patient on November 16, 1992, and as a result, the patient received an estimated dose at 1 centimeter (cm) (0.39 inches) of 16,000 gray (Gy) (1,600,000 rad) instead of the intended dose of 18 Gy (1800 rad). In addition, several members of the general public were also exposed and the radiation exposures ranged between 0.40 millisievert (mSv) to 0.22 sievert (Sv) (40 millirem [mrem] to 22 rem).

The NRC Region I conducted an inspection of the IRCC on December 1 and 2, 1992. On December 3, 1992, NRC upgraded its response to an Incident Investigation Team (IIT). An order suspending the OSC license was issued on January 20, 1993. On February 8, 1993, the IIT presented its findings to NRC.

NRC Region I conducted inspections of the licensee's facilities in Exton and Lehighton, Pennsylvania, on December 8, 1992. The inspectors identified several potential violations. In the Order suspending license, the issues discussed in the IIT report and the inspection report for the licensee's facilities in Exton and Lehighton, Pennsylvania, were outlined.

There were four main causes of the event as discussed in the IIT report: 1) OSC had weaknesses in its radiation safety program that contributed to the seriousness of the event and radiation exposure consequences; 2) a number of weaknesses were found in the design and testing of Omnitron 2000; 3) the safety culture at IRCC contributed significantly to the event; and 4) the overall regulatory oversight of HDR afterloaders was weak.

The manufacturer's (Omnitron) actions to prevent recurrence are still undergoing FDA review.

The licensee hired a consultant to assess its radiation safety program immediately after the event occurred. The consultant provided the licensee with audit findings and suggested program upgrades. The licensee addressed the audit findings, created new operating and emergency procedures, trained personnel on procedures and the NRC requirements, and requested a Management Meeting with NRC to discuss the implemented program upgrades. The licensee met with the NRC on January 27, 1993. NRC issued a meeting report on February 19, 1993, discussing all commitments the licensee made during the meeting. The licensee requested on February 9, 1993, permanent relaxation of the order suspending license to treat patients at the Great Harrisburg Cancer Center and the Greater Pittsburgh Cancer Center. The licensee submitted its action plan to NRC in a letter dated February 15, 1993. The NRC reviewed the action plan and issued a deficiency letter to the licensee on March 5, 1993. The licensee again requested a management meeting to discuss the issues described in the NRC's March 5, 1993, deficiency letter. The licensee met with NRC on March 23, 1993. On March 29, 1993, NRC issued a report discussing all commitments the licensee made during the meeting. On April 8, 1993, the licensee submitted its upgraded action plan and invited NRC to inspect Harrisburg and Pittsburgh facilities to verify that all licensee procedures and NRC requirements were being followed as required. On April 22, 1993, NRC acknowledged receipt of the licensee's April 8, 1993 letter and agreed to inspect the Harrisburg and the Pittsburgh facilities.

The licensee submitted its program upgrades in letters dated February 15, 1993, March 26, 1993, and April 8, 1993, that had been implemented to address all items outlined in the Order suspending license. NRC Region I conducted an inspection at the licensee's facility in Harrisburg, Pennsylvania on April 28 and 29, 1993. The inspectors concluded that the licensee had addressed all procedure requirements, order suspending license issues, Bulletin requirements, and other regulatory requirements. The inspectors also concluded that all personnel were trained on all licensee and NRC requirements as they pertain to their job.

The licensee requested that its NRC license be amended to include its current program as described in its February 15, 1993, March 26, 1993, April 8, 1993, May 7, 1993, and May 11, 1993, letters. NRC issued a license amendment on May 26, 1993, and an inspection report on May 28, 1993. On June 3, 1993, the NRC Region I Regional administrator approved a full Order relaxing request to treat patient limited to OSC's facility in Harrisburg and Pittsburgh.

Since learning of the loss of the HDR afterloader source and the death of the patient, the NRC conducted the incident investigation, issued the team's report, and completed the following actions: issued a Bulletin to Users of Omnitron 2000 HDR afterloaders (Bulletin 92-03), a Bulletin to Users of any HDR machine (Bulletin 93-01), and Information Notice to all NRC licensees (Information Notice 92-84) to assure the other users of HDRs were aware of the event. In addition, NRC issued Confirmatory Action Letters to both OSC and Omnitron documenting safety precautions, and Order on January 20, 1993, suspending the OSC license.

Future reports will be made as appropriate.

UPDATE from NUREG-0090, Vol. 16, No. 4 page 19. This abnormal occurrence was originally reported in NUREG-0090, Vol. 1 No. 4, "Report to Congress on Abnormal Occurrences," October-December 1992. The abnormal occurrence report is updated as follows:

On December 1, 1992, the licensee notified NRC Region I of the loss of a sealed iridium-192 source from the high dose rate remote afterloader unit at their Indiana Regional Cancer Center in Indiana, Pennsylvania. The source was left in the patient on November 16, 1992, and as a result the patient received an estimated dose at 1 centimeter (0.39 inch) of 1,600,000 centigray (cGy) (1,600,000 rad) instead of the intended dose of 1800 cGy (1800 rad). In addition, several members of the general public received

radiation exposures of between 400 microsievert (40 millirem) and 220 millisievert (22 rem).

In addition to the actions described in the abnormal occurrence report for the second quarter of 1993 (NUREG-0090, Vol. 16, No. 2), NRC prepared a deficiency letter dated September 17, 1993, requesting that the licensee submit a comprehensive description of its Radiation Safety Program and Procedures, including program audits, facilities certification, personnel training and qualifications, and any other information that it may consider necessary to support safe resumption of brachytherapy operations. The licensee responded to this request in letters dated September 19, 1993, and October 1, 1993. NRC reviewed the licensee's response using Policy and Guidance Directive, FC 86-4, Revision 1, "Information Required for Licensing Remote Afterloading Devices". A deficiency letter was prepared and sent to the licensee on November 4, 1993. The licensee responded to the deficiency letter on December 7, 1993, and "requested full and permanent relaxation of its entire license." The response is currently under NRC review.

This report will be further evaluated when additional information becomes available.

UPDATE NUREG-0090, Vol. 17, No. 2 page 19. This abnormal occurrence (AO) was originally reported in NUREG-0090, Vol. 17, No. 4, "Report to Congress on Abnormal Occurrences," October-December 1992, under the title "Loss of Iridium-192 Source and Medical Therapy Misadministration at Indiana Regional Cancer Center in Indiana, Pennsylvania."

At that time, it was reported on November 16, 1992, Oncology Services Corporation had lost a 159,000 gigabecquerel (4.3 curie) sealed iridium-192 source from a high dose rate (HDR) remote afterloader brachytherapy unit at its Indiana Regional Cancer Center in Indiana, Pennsylvania. The source had: (1) broken off of the HDR unit while in service; (2) subsequently killed a patient with a 1,600,000 centigray (1,600,000 rad) absorbed dose, after remaining on the patient's body for almost 4 days; and (3) caused 94 other people to receive radiation ranging from 400 microsievert to 220 millisievert (40 millirem to 22 rem). The source was eventually mixed by accident with medical biohazard waste and was subsequently found and recovered at the site of a company that had been contracted to dispose of biological waste material.

The event was reported as an AO because: (1) it involved a therapeutic dose that was greater than 1.5 times the prescribed dose and (2) it involved exposure to an individual in an unrestricted area such that the whole body dose received exceeded 0.5 rem in one calendar year.

This AO report is updated as follows:

The licensee provided information to NRC Region I which provided a basis to relax the Order Suspending License (Order) in full for its Pittsburgh and Harrisburg, Pennsylvania, facilities. All other locations authorized by the license remain under suspension. The licensee requested and was granted a Hearing on the Order. Interrogatories have been answered by the NRC staff, and members of the NRC staff have been deposed by the licensee's counsel.

On May 31, 1994, NRC Region I, after consultation with the Commission, issued a Notice of Violation (NOV) and Proposed Imposition of Civil Penalties for \$280,000. The NOV was based on the NRC Incident Investigation Team Report (NUREG-1480) which was published in February 1993, and NRC Inspection Report 030-31765/92-01, which was sent to the licensee on December 23, 1992. The NOV classified two violations in Section I and two violations in Section II as Severity Level I problems and the 17 violations in its Section III as a Severity Level III problem.

This event will be further updated when additional information becomes available.

UPDATE from NUREG-0090, Vol. 17, No. 3 Page 14. This abnormal occurrence (AO) was originally reported in NUREG-0090, Vol. 15, No. 4, "Report to Congress on Abnormal Occurrences," October-December 1992, under the title "Loss of Iridium-192 Source and Medical Therapy Misadministration at Indiana Regional Cancer Center in Indiana, Pennsylvania."

The AO criteria used were:

- (1) Event Type 5, in Table A-1-A therapeutic dose that is greater than 1.5 times the prescribed dose; and
- (2) For All Licensees, No. 2-An exposure to an individual in an unrestricted area such that the whole body dose received exceeded 0.5 rem in one calendar year.

At that time, it was reported on November 16, 1992, Oncology Services Corporation had lost a 159,000 gigabecquerel (4.3 curie) sealed iridium-192 source from a high dose rate (HDR) remote afterloader brachytherapy unit at its Indiana Regional Cancer Center in Indiana, Pennsylvania. The source had: (1) broken off of the HDR unit while in service; (2) subsequently killed a patient with a 1,600,000 centigray (1,600,000 rad) absorbed dose, after remaining on the patient's body for almost 4 days; and (3) caused 94 other people to receive radiation ranging from 400 microsievert to 220 millisievert (40 millirem to 22 rem). The source was eventually mixed by accident with medical biohazard waste and was subsequently found and recovered at the site of a company that had been contracted to dispose of biological waste material.

The AO report is updated as follows:

The licensee responded to the NRC's Notice of Violation and Proposed Imposition of Civil Penalties in a letter dated August 31, 1994, contesting a number of the violations and the amount of the civil penalty. NRC is evaluating the licensee's response.

This event will be updated when additional information becomes available.

UPDATE from NUREG-0090, Vol. 18, No. 1 page 9. This abnormal occurrence (AO) was originally reported in NUREG-0090, Vol. 15, No. 4, "Report to Congress on Abnormal Occurrences, October-December 1992," under the title "loss of Iridium-192 source and Medical Therapy Misadministration at Indiana Regional Cancer Center in Indiana, Pennsylvania."

The AO criteria used were:

- (1) Event Type 5, in Table A-1-A therapeutic dose that is greater than 1.5 times the prescribed dose; and
- (2) For All Licensees, No. 2-An exposure to an individual in an unrestricted area such that the whole body dose received exceeds 0.5 rem in one calendar year.

At that time, it was reported on November 16, 1992, Oncology Services Corporation had lost a 159,000 gigabecquerel (4.3 curie) sealed iridium-192 source from a high dose rate (HDR) remote afterloader brachytherapy unit at its Indiana Regional Cancer Center in Indiana, Pennsylvania. The source had: (1) broken off of the HDR unit while in service; (2) subsequently killed a patient with a 1,600,000 centigray (1,600,000 rad) absorbed dose, after remaining on the patient's body for almost 4 days; and (3) caused 94 other people to receive radiation ranging from 400 microsievert to 220 millisievert (40 millirem to 22 rem). The source was eventually mixed by accident with medical biohazard waste and was subsequently found and recovered at the site of a company that had been contracted to dispose of biological waste material.

The AO report is updated as follows:

The licensee submitted information in letters dated August 31, 1994, and October 4, 1994, in response to the NRC's Notice of Violation and Proposed Imposition of Civil Penalties dated May 31, 1994. After consideration of the licensee's responses, NRC concluded that an adequate basis was not provided for withdrawal of any of the violations or for mitigation of the civil penalties. "Order Imposing civil Penalties-\$280,000" (Order) was issued on April 24, 1995 (Ref. 1). The licensee has 30 days to pay the civil penalties. The licensee may also within 30 days of the date of the Order request a hearing on the Order.

Concurrent with the enforcement process, the licensee requested the termination of its license on December 13, 1993, with the license to be replaced by individual licenses issued to the facilities named as location of use on the Oncology Services Corporation (OSC) license. The OSC license was terminated on August 24, 1994, concurrent with new licenses being issued to the facilities which were previously listed as locations of use of the OSC license.

This event will be updated when additional information becomes available.

UPDATE from NUREG-0090, Vol. 18, No. 2, page 15. This abnormal occurrence (AO) was originally reported in NUREG-0090, Vol. 15, No. 4, "Report to Congress on Abnormal Occurrences, October-December 1992," under the title "loss of Iridium-192 Source and Medical Therapy Misadministration at Indiana Regional Cancer Center in Indiana, Pennsylvania."

The AO criteria used were:

- (1) Event Type 5, in Table A-1-A therapeutic dose that is greater than 1.5 times the prescribed dose; and
- (2) For All Licensees, Criterion No. 2-An exposure to an individual in an unrestricted area such that the whole body dose received exceeds 0.5 rem in one calendar year.

On November 16, 1992, Oncology Services Corporation lost a 159,000 gigabecquerel (4.3 curie) sealed iridium-192 source from high dose rate (HDR) remote afterloader brachytherapy unit at its Indiana Regional Cancer Center in Indiana, Pennsylvania. The source had: (1) broken off of the HDR unit while in service; (2) subsequently killed a patient with a 1,600,000 centigray (1,600,000 rad) absorbed dose, after remaining on the patient's body for almost 4 days; and (3) caused 94 other people to receive radiation ranging from 400 microsievert to 220 millisievert (40 millirem to 22 rem). The source was eventually mixed by accident with medical biohazard waste and was subsequently found and recovered at the site of a company that had been contracted to dispose of biological waste material.

The AO report is updated as follows:

The licensee submitted information in letters dated August 31, 1994 and October 4, 1994 in response to the NRC's Notice of Violation and Proposed Imposition of Civil Penalties dated May 31, 1994. After consideration of the licensee's responses, NRC concluded that an adequate basis was not provided for withdrawal of any of the violations or for mitigation of the civil penalties. Order Imposing Civil Penalties - \$280,000 (Order) was issued on April 24, 1995. The licensee had 30 days after the Order was issued to pay the civil penalties. The licensee also had 30 days after the Order was issued to request a hearing on the Order, and did so via a letter dated May 18, 1995.

Concurrent with the enforcement process, the licensee requested the termination of its license on December 13, 1993, with the license to be replaced by individual licenses issued to the facilities named as locations of use on the Oncology Services Corporation (OSC) license. The OSC license was terminated on August 24, 1994, concurrent with new licenses being issued to five of the six facilities which were previously listed as locations of use on the OSC license.

This event is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix a (see E Type 5 in Table A-1) of this report notes that a therapeutic dose that is greater than 1.5 times the prescribed dose can be considered an abnormal occurrence. In addition, Appendix A (see Event Type 2 if "For All Licensee") notes that an exposure to individual in an unrestricted area such that the whole body dose received exceeds 0.5 rem in one calendar year may be considered an abnormal occurrence.

ITEM #: 921098 AO #: NRC 92-19 EVENT DATE: 12/02/1992
TITLE: MEDICAL THERAPY MISADMINISTRATION AND TEMPORARY LOSS OF BRACHYTHERAPY SOURCE AT YALE-NEW HAVEN HOSPITAL IN NEW HAVEN, CONNECTICUT
NAME: Yale-New Haven Hospital CITY: New Haven STATE: CT

Nature and Probable Consequences:

On December 2, 1992, the NRC was notified by the licensee that it had recovered a 35 millicurie brachytherapy source that was discovered to be missing earlier that day. On December 3, 1992, NRC Region I was notified that the source had probably been before or during a brachytherapy treatment, resulting in a therapeutic misadministration. A female patient, approximately 39 years old, was to receive 1,848 rads to the cervix for cancer treatment. One of the sources that was prescribed was either never inserted or was removed from the applicator during treatment. Assuming maximum deviation from the planned treatment, the actual dose the patient was only 1,235 rads. The licensee stated that a source was also misplaced and was in contact with one of the patient's legs for a period of time, resulting in an estimated dose to the leg of 260 rads. The physicians responsible for the treatment, after reviewing the dose estimates, decided no additional treatments were necessary.

The misplaced source was inadvertently put with hospital linen. The linen with the brachytherapy source was taken to an off-site laundry facility, from which it was subsequently recovered.

The referring physician and patient were notified of the misadministration.

Cause:

The licensee failed to recognize the significance to radiation safety of a procedural change that eliminated the use of disposable pads in favor of reusable linen pads. Previously, the licensee disposed pads by putting them in infectious waste, which stayed in the room until after the final radiation survey was performed, after removal of the radiation sources. The reusable pads, when changed, were placed in laundry bags in the hallway, which were taken to the laundry facility daily. The nursing staff failed to follow the procedure that prohibited removing anything from the patient's room that had not been checked for the presence of a brachytherapy source.

Licensee Action:

The licensee has taken the following steps:

1. Physicians have been instructed to visually confirm that sources are properly loaded into applicators.
2. Dosimetrists have been instructed to observe the loading process and confirm that applicators are correctly loaded.
3. A linen hamper will be placed in each brachytherapy patient's room so that linen will not, generally, be removed until after the room survey to confirm that no sources have been lost.
4. Soiled linen that cannot be left in the room until the end of treatment will be surveyed to ensure that no sources are in the linen prior to its removal from the patient's room.
5. Physicians have been instructed to visually check for the presence of sources at the time they are removed from the patients.

NRC Action:

The NRC retained a medical consultant to review the case to provide clinical assessment of this misadministration. NRC Region I conducted a special inspection on December 3-4, 1992, and three violations of NRC requirements were identified: 1) failure to survey soiled linen pads prior to removing them from a patient's room; 2) loss of control of the radioactive source; and 3) existence of radiation levels above the regulatory limit in unrestricted areas. Enforcement action is under consideration.

Future reports will be made as appropriate.

UPDATE from NUREG-0090, Vol. 16, No. 1, page 14. This abnormal occurrence was originally reported in NUREG-0090, Vol. 15, No. 4, "Report to Congress on Abnormal Occurrences: October-December 1992." The abnormal occurrence is updated as follows:

As previously mentioned, on December 2, 1992, the licensee, Yale-New Haven Hospital in New Haven, Connecticut, notified the NRC that a 1.3 gigabecquerel (GBq)(35 millicurie [mCi]) brachytherapy source, was discovered to be missing earlier that day. It was subsequently learned that the source was probably lost before or during a brachytherapy treatment, which resulted in a therapeutic misadministration.

On the same day the patient, a 39-year old female, was to receive 18.48 gray (Gy) (1,848 rad), to the cervix for cancer treatment. Because one of the prescribed sources was lost, the actual dose to the patient was only 12.35 Gy (1,235 rad). In addition, another source was misplaced and was in contact with one of the patient's legs for a period of time, which resulted in an estimated dose to the leg of 2.6 Gy (260 rad). The referring physician and patient were notified of the misadministration. The misplaced source had

been inadvertently put with hospital linen, and was subsequently recovered at an offsite laundry facility.

An Enforcement Conference was held on January 6, 1993. On January 13, 1993, NRC Region I recommended to the Office of Enforcement (OE) that a Severity Level III violation (Severity Levels I through V range from the most significant to the least significant, respectively) with a Civil Penalty to be issued with the Notice of Violation. A Notice of Violation and Proposed Imposition of Civil Penalties, and Confirmatory Order Modifying License were issued on April 26, 1993 (Ref. B-4). (License modification required that the licensee's radiation safety program be improved as recommended by an outside expert.) The enforcement act was based on this event and AO 93-3, which is discussed in this report. The cumulative amount of \$10,000 for the violations was based on the combined events.

This item will be updated from time to time as new significant information becomes available.

UPDATE from NUREG-0090, Vol. 16, No. 4 page 19. This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 4, "Report to Congress on Abnormal Occurrences," October-December 1992. The abnormal occurrence report is updated as follows:

On December 3, 1992, NRC was notified by the licensee that a 39 year old female patient received a 33 percent undertreatment during a brachytherapy treatment to the cervix and an unplanned 260 centigray (260 rad) exposure to her leg. One of the prescribed sources was either never inserted or was removed from the applicator during treatment and left in her bedding.

NRC Region I conducted a special inspection on December 3 and 4, 1992. An enforcement Conference was held on January 6, 1993. An NRC medical consultant was retained to review the misadministration. For the violations identified during the special inspection NRC Region I proposed a Civil Penalty of \$2,500. On January 21, 1993, the licensee reported a second misadministration (AO 93-3). NRC elected to withhold issuance of the enforcement action for the first incident and issued one enforcement action for both incidents.

Following the staff's review of the second occurrence on April 26, 1993, NRC issued a Civil Penalty in the amount of \$10,000 and a Confirmatory Order Modifying License (Effective Immediately), which confirmed the licensee's proposal to have a program assessment performed by independent experts. The program assessment was completed on May 10 and 11, 1993. On August 24, 1993, the licensee submitted their Program Assessment Report and Program Improvement Plan which was formulated in response to the program assessment. On November 16, 1993, the licensee submitted the first of the required quarterly reports on the implementation of the Program Improvement Plan and stated that all actions were completed. NRC Region I has reviewed the Program Assessment Report and Program Improvement Plan and is currently preparing a response.

On June 10, 1993, the licensee responded to the Notice of Violation and Proposed Imposition of \$10,000 Civil Penalty. In this response, the licensee denied one violation, took issue with the manner in which the civil penalty was determined, and requested mitigation of the civil penalty based on minimal safety significance and lack of programmatic implications. On December 27, 1993, NRC responded to the licensee's request with an Order Imposing Civil Penalties in the amount of \$10,000. The licensee responded to the Order by letter dated January 26, 1994, and paid the Civil Penalty of \$10,000.

A routine inspection was conducted of the licensee's program from September 28 through 30, 1993. One minor violation of regulatory requirements was identified by the inspector. This violation has since been corrected by the licensee.

This report will be updated when additional information becomes available.

UPDATE from NUREG-0090, Vol. 17, No. 1 page 15. This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 4, "Report to Congress on Abnormal Occurrences," October-December 1992. It was updated in Vol. 16, No. 4, of NUREG-0090, October-December 1993. The information pertaining to this abnormal occurrence is updated as follows.

On December 3, 1992, NRC was notified by the licensee that a 39-year-old female patient received a 33 percent undertreatment during a brachytherapy treatment to the cervix and an unplanned 260 centigray (260 rad) exposure to her leg. One of the sources that was prescribed was either never inserted or was removed from the applicator during treatment, and left in her bedding.

This event is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to a part of the body not scheduled to receive radiation can be considered an abnormal occurrence.

ITEM #: 920467 AO #: NRC 93-02 EVENT DATE: 05/11/1992
TITLE: MEDICAL "SODIUM IODIDE" MISADMINISTRATION AT INGHAM MEDICAL CENTER IN LANSING, MICHIGAN
NAME: Ingham Medical Center CITY: Lansing STATE: MI

Nature and Probable Consequences:

The referring physician's staff telephoned the licensee's nuclear medicine department on May 5, 1992, to schedule a thyroid scan to detect or rule out thyroid cancer. There was a miscommunication between members of the support staff. The technologist who received the call understood that the referring physician wanted a whole body scan to rule out thyroid metastasis and to look at a thyroid nodule. The medical technologist entered a whole body scan into the scheduling record.

On May 11, 1992, a 47-year old patient received 366.3 megabecquerel (MBq) (9.9 millicurie [mCi]) of iodine-131 in capsule form preparation for a whole body scan. This procedure is normally used after a patient with thyroid cancer has had the thyroid removed or ablated to determine if the cancer originating in the thyroid has spread elsewhere in the patient's body. The patient still had an active thyroid and the patient's physician intended that the patient receive a thyroid scan to help determine if a thyroid nodule was cancerous. The thyroid scan is a different procedure from a whole body scan and as performed at the licensee's facility uses 37 MBq (10 mCi) technetium-99m, a different radiopharmaceutical than iodine-131.

On May 12, 1992, the patient returned to the licensee's nuclear medicine department for the scan. The image of the initial scan showed that the patient's thyroid was intact and that an error had been made. The technologist performing the scan immediately reported the situation to the supervising physicians. The licensee's procedures for an iodine-131 whole body scan specified that this diagnostic procedure be used only on individuals whose thyroid had been removed.

The referring physician and the patient were notified of the misadministration. The licensee has been monitoring the patient and observed decreased thyroid function.

Initially, the licensee determined that the incident was not a misadministration and did not report it to the NRC. This was because the correct dosage and procedure were used for the study, as understood by the technologist to have been requested. The licensee contacted NRC Region III about the incident after reading about a similar case in an NRC Office of Nuclear Material Safety and Safeguards newsletter. A licensee consultant reviewed the case with NRC Region III on February 19, 1993. Following that discussion, the consultant reported the incident as a misadministration because the procedure requested by the patient's physician, a thyroid scan, would normally use a different radiopharmaceutical technetium-99m.

Cause:

The basic causes of this misadministration were a miscommunication between the referring physician's office and the licensee, and a failure of the licensee to follow its Quality Management (QM) Program for procedures using radioactive pharmaceuticals.

The licensee's QM Program, which was implemented in January 1992, requires that a written directive be prepared for procedures using more than 1.11 MBq (30 microcurie [uCi]) of iodine-131. However, no written directive was prepared for this procedure.

The licensee's procedure for a whole body iodine-131 scan required that the patient's thyroid had been removed previously. The licensee's procedures were not effective in determining if the patient had an intact thyroid.

The nuclear medicine department staff had not received training on the requirements of the licensee's QM Program which included the provision that a written directive had to be issued for a whole body scan (using more than 1.11 MBq [30 uCi] of iodine-131).

Licensee Action:

The licensee has revised the procedures for thyroid cancer studies and provided training for nuclear medicine personnel in the QM Program requirements.

NRC Action:

A special inspection was conducted from February 25 to 26, 1993, to review the circumstances surrounding the iodine-131 misadministration (Ref. 2). The NRC has also retained a medical consultant to review the case.

The NRC consultant concluded that the most probable effect of the misadministration would be permanent hypothyroidism, and noted that evidence suggested that this condition had already occurred. No other health effects would be expected as a result of the misadministration.

Several violations of NRC requirements were identified in the inspection. These violations and the implementation of the licensee's QM Program are still under review by the NRC for possible enforcement action.

On March 2, 1993, NRC Region III issued a Confirmatory Action Letter to the licensee documenting its agreement to provide training to the nuclear medicine staff on the requirements of the QM Program, NRC regulations, and NRC licensee requirements (Ref. 3). No procedures using more than 1.11 MBq (30uCi) of iodine-131 were to be performed before the training was completed.

The licensee also agreed to make certain that its procedures for iodine-131 studies are consistent with the QM Program.

Future reports will be made as appropriate.

UPDATE from NUREG-0090, Vol. 16, No. 3 page 14. This abnormal occurrence was originally reported in NUREG-0090, Vol. 1 No. 1, "Report to Congress on Abnormal Occurrences: January-March 1993." The abnormal occurrence report is updated as follows:

In May 1992 a patient received a whole body scan using iodine-131 (I-131) instead of a thyroid scan, which uses technetium-99. The misadministration occurred because of an apparent misunderstanding during a telephone conversation between the referring physician's office and a technologist at Ingham Medical Center.

On September 9, 1993, NRC issued a Notice of Violation and proposed imposition of a fine for \$11,250 to the licensee. The licensee was cited for failing to have the physician authorized to use radioactive materials prepare a written directive as required, the dosage of I-131 involved in a whole body scan and for failing to follow the hospital's written instruction that I-131 whole body scans be used only for patients who had their thyroids removed. Since the patient in this case had an intact thyroid, the whole body I-131 scan should not have been performed.

This item is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 4 in Table A-1) of this report notes that a diagnostic dose of a radiopharmaceutical that is greater than five times the prescribed dose can be considered an abnormal occurrence.

ITEM #:	940003	AO #:	NRC 93-03	EVENT DATE:	01/21/1993
TITLE:	MEDICAL THERAPY MISADMINISTRATION INVOLVING THE USE OF A HIGH DOSE-RATE REMOTE AFTERLOADER BRACHYTHERAPY DEVICE AT YALE-NEW HAVEN HOSPITAL IN NEW HAVEN, CONNECTICUT				
NAME:	Yale-New Haven Hospital	CITY:	New Haven	STATE:	CT

Nature and Probable Consequences:

A patient was prescribed to receive three treatment so 700 centigray (cGy) (700 rad) per treatment to the vagina using a Gammamed high dose-rate remote afterloader brachytherapy device (HDR). During the first treatment on January 21, 1993, the physician mistakenly inserted the HDR applicator into the patient's rectum instead of the vagina, as prescribed. The licensee discovered the error immediately after the treatment was completed and the patient was immediately notified. The licensee estimated that the patient received approximately 350 cGy (350 rad) to the vagina and 700 cGy (700 rad) to the rectum. At the time of the NRC inspection on January 22, 1993, the licensee had planned to make up the dose to the vagina during the remaining two treatments and to use shielding to the applicator to prevent significant additional dose to the rectum.

The patient's physician, the physician who delivered the therapy, and an NRC Medical Consultant are presently evaluating the probable consequences of the misadministration.

Cause:

The licensee did not confirm the treatment site before the treatment was given as required by its Quality Management (QM) Program.

Licensee Action:

The licensee added a procedure requiring physicians to visually insert applicators. In addition, the licensee committed to a complete program assessment by an outside expert. This commitment was formalized by the NRC in a Confirmatory Order Modifying License issued on April 26, 1993 (Ref. 5).

NRC Action:

NRC Region I conducted a special inspection at the facility on January 22, 1993 (Ref. 3). An NRC medical consultant was contacted to provide a clinical assessment of the effects of this misadministration. The licensee was offered the opportunity to participate in an Enforcement Conference but declined, believing that it would not be able to provide the NRC with any additional information. NRC recommended an enforcement action. A Notice of Violation and Proposed Imposition of Civil Penalties, and Confirmatory Order Modifying License were issued on April 26, 1993 (Ref. 5). (License modification required that the licensee's radiation safety program be improved as recommended by an outside expert.) The enforcement action was based on this event and AO 92-19, which is discussed in Appendix B. The cumulative amount of \$10,000 for the violations was based on the combined events.

Future reports will be made as appropriate.

UPDATE from NUREG-0090, Vol. 16, No. 4 page 20. This abnormal occurrence was originally reported in NUREG-0090, Vol. 1 No. 1, "Report to Congress on Abnormal Occurrences," January-March 1993. The abnormal occurrence report is updated as follows:

On January 21, 1993, NRC was notified by the licensee that a female patient received a 50 percent undertreatment during a brachytherapy procedure to the vagina and unplanned 700 centigray (700 rad) exposure to her rectum when the physician mistakenly inserted the HDR applicator into the rectum instead of the vagina.

NRC Region I conducted a special inspection on January 26 and 27, 1993. The licensee was given the option of participating in an enforcement conference but declined. A medical consultant was retained to review the misadministration. On April 26, 1993, NRC proposed a Civil Penalty in the amount of \$10,000 and Confirmatory Order Modifying License (Effective Immediately) which confirmed the licensee's proposal to have a Program Assessment performed by independent experts. The Program Assessment was completed on May 10 and 11, 1993. On August 24, 1993, the licensee submitted the report of the Program Assessment and their Program Improvement Plan which was formulated in response to the Program Assessment. On November 16, 1993, the licensee submitted the first of the required quarterly reports on the implementation of the Improvement Plan and stated that all actions were completed. NRC Region I has reviewed the Program Assessment Report and the Program Improvement Plan and is currently preparing a response.

On June 10, 1993, the licensee responded to the Notice of Violation and Proposed Imposition of \$10,000 Civil Penalty. In this response, the licensee denied one violation, took issue with the manner in which the civil penalty was determined, and requested mitigation of the civil penalty based on minimal safety significance and lack of programmatic implications. On December 27, 1993, NRC responded to the licensee's requested mitigation of the civil penalty based on minimal safety significance and lack of programmatic implications. On December 27, 1993, NRC responded to the licensee's request with an Order Imposing Civil Penalties in the amount of \$10,000. The licensee responded to the Order by letter dated January 26, 1994, and paid the Civil Penalty of \$10,000.

A routine inspection was conducted of the licensee's program from September 28, through 30, 1993. One minor violation of regulatory requirements was identified by the inspector. This violation has since been corrected by the licensee.

This report will be updated when additional information becomes available.

UPDATE from NUREG-0090, Vol. 17, No. 1, page 16. This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 1, "Report to Congress on Abnormal Occurrences," January-March 1993. It was updated in Vol., 16, No. 4, of NUREG-0090, October-December 1993. The information pertaining to this abnormal occurrence is updated as follows.

On January 21, 1993, NRC was notified by the licensee that a female patient received a 50 percent undertreatment during a brachytherapy procedure to the vagina and an unplanned 700 centigray (700 rad) exposure to her rectum when the physician mistakenly inserted the HDR applicator into the rectum instead of the vagina.

This event is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that for a therapeutic exposure, if parts of the body receiving radiation improperly would have normally received radiation anyway, had the proper administration been used, and the actual dose is greater than 1. times that intended to the above described body part, the event can be considered an abnormal occurrence.

ITEM #: 940005 AO #: NRC 93-04 EVENT DATE: 01/14/1993
TITLE: MEDICAL THERAPY MISADMINISTRATION AT PAPA STRAVROS' ASSOCIATES MEDICAL IMAGING IN WILMINGTON, DELAWARE
NAME: Papastavros' Associates Medical Imaging CITY: Wilmington STATE: DE

Nature and Probable Consequences:

On February 1, 1993, NRC Region I was notified by telephone that a therapeutic misadministration of iodine-131 occurred at the licensee's facility. In early January, the nuclear medicine technologist received a telephone call from the referring physician requesting that a patient be scheduled for a third treatment for hyperthyroidism and that 1.11 gigabecquerel (GBq) (30 millicurie [mCi]) of iodine-131 be administered. On January 13, 1993, the technologist ordered a 1.11 GBq (30 mCi) dose from the radiopharmacy. The dose was received on January 14, 1993. The technologist noted that the label on the lead container indicated 1.07 GBq (29 mCi) of iodine-131, but did not note that the label indicated that two capsules were present in the vial. A second technologist who removed the vial from the lead container and placed it in the dose calibrator for assay also failed to note that label on both the lead container and the vial indicated the presence of two capsules. The assayed dose was consistent with the activity noted on the label. The technologist transferred the dose from the supplier's vial to a glass vial for administration to the patient. Only one of the capsules came out of the vial. The presumed empty lead container that still contained the plastic vial and remaining capsule was placed in the nuclear medicine hot laboratory for storage. The licensee discovered the remaining capsule on February 1, 1993, when the technologist was preparing lead containers for disposal. The patient was administered 0.56 GBq (15.1 mCi) of iodine-131, instead of the intended dose of 1.11 GBq (30 mCi). The misadministration was reported as required on February 1, 1993. The patient and the patient's physician were notified of the error and the patient was scheduled for follow-up therapy on February 10, 1993. The licensee's physician expected no adverse effects as a result of the misadministration. While the therapeutic dose administered was actually about 0.5 times the prescribed dose, the staff believes that this misadministration should still be considered an abnormal occurrence.

Cause:

The misadministration was caused by failure of the licensee to establish and implement a Quality Management (QM) Program as required by 10 CFR 35.32(a). In particular, failure of the licensee to establish procedures to ensure that each therapy administration is in accordance with the written directive contributed to the misadministration.

Licensee Action:

The licensee's plan for preventing recurrence of the misadministration includes three steps: (1) to prepare and implement a written QM Program and provide training; (2) to have the radiopharmaceutical supplier indicate the number of capsules in each vial on packing slip provided with iodine-131 therapy doses; and (3) to require the nuclear medicine technologist to read the label on the vials and lead containers to determine the number of capsules present in the vial, and then verify that the required number of capsules are administered to the patient. In addition, the vial into which the capsules are transferred after initial assay will be reassayed to ensure that all capsules are transferred. The written QM Program was received by the NRC on February 11, 1993.

NRC Action:

NRC Region I conducted an inspection on February 3, 1993 (Ref. 6). Because the misadministration resulted in an underdose to the patient and the therapy could be completed, the NRC did not contact a medical consultant to review this misadministration. Confirmatory Action Letter (CAL) (Ref. 7) was issued to the licensee on February 5, 1993, which described the commitments made by the licensee to establish and implement a QP Program. An Enforcement Conference was held March 1, 1993, to discuss the inspection findings and actions taken by the licensee in response to the CAL. On March 18, 1993, NRC Region I issued a Notice of Violation with a Severity Level III (Severity Levels I through V range from the most significant to the least significant) violation \$250 Civil Penalty (Ref. 8). The licensee paid the Civil Penalty. The licensee's corrective and preventive actions will be reviewed during the next NRC inspection of the licensed program.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic dose that is less than 0.5 times the prescribed dose can be considered an abnormal occurrence.

ITEM #: 940012 AO #: NRC 93-05 EVENT DATE: 12/09/1992
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT PARKVIEW MEMORIAL HOSPITAL IN FORT WAYNE, INDIANA
NAME: Parkview Memorial Hospital CITY: Fort Wayne STATE: IN

Nature and Probable Consequences:

On December 9, 1992, a 62-year-old patient was scheduled to receive a 500 centigray (cGy) (500 rad) radiation dose for vagina cancer using a high-dose-rate brchytherapy treatment device. The device uses a 296,000 megabequerel (MBq) (8 curie [Ci] iridium-192 (Ir-192) source.

The brachytherapy treatment was the final part of a curative radiation treatment series.

The location of the treatment area was unusual for vaginal treatments and required a different starting position for the Ir-192 sou than is normally used for such treatment. Both the dosimetrist and the medical physicist performed the treatment calculations working together (the second series of calculations was not an independent check) and both used the incorrect starting location the source position. The error was not detected, and the treatment was performed as scheduled. As a result, the intended 500 cGy (500 rad) radiation dose was delivered to an area 5.25 centimeters (2.07 inches) away from the intended treatment area. A small portion of the intended treatment area received a radiation dose ranging from 50 to 300 cGy (50 to 300 rad) according to t licensee.

On January 6, 1993, the error was discovered during a record review by a dosimetrist. The referring physician and the patient w informed of the error. The licensee reported the misadministration to NRC on January 7, 1993. The incident constitutes a misadministration because the radiation dose was administered to the wrong treatment site. On January 18, 1993, the patient received an additional treatment using the high dose rate brachytherapy treatment device. The treatment plan was revised to m the intended objectives of the earlier treatment, taking into account the lower dose already received by a portion of the treatment area.

The licensee reported that no physical effect was observed as a result of the misadministration. The NRC retained a medical consultant to evaluate the circumstances of the misadministration. The consultant concluded that no noticeable biological effect expected as a result of the misadministration.

Cause:

Because of the unusual configuration of the treatment area, the standard treatment parameters used for vaginal brachytherapy treatment were not applicable. A medical physicist and a dosimetrist prepared the dose calculations working together and made same error in assuming the initial position of the treatment source.

The licensee's Quality Management Program requires that an independent check of the dose calculations be performed by a qualified individual before the treatment is initiated. Such an independent check was not performed.

Licensee Action:

The licensee has revised its procedures for preparing the treatment plans for the high-dose-rate brachytherapy procedures. It ha made improvements in the calculation notebook and other related data used in preparing the treatment plans and the dose calculations.

NRC Action:

NRC Region III conducted a special inspection on January 28 and 29, 1993, to review the circumstances surrounding the misadministration (Ref. 1). An NRC medical consultant was also retained to review the case.

The NRC inspection determined that the licensee failed to follow its Quality Management Program requirement for an independe check of brachytherapy dose calculations. Other violations were identified which did not directly relate to the misadministration. notice of violation was issued to the licensee.

This item is considered closed for the purposes of this report.

The NRC inspection determined that the licensee failed to follow its Quality Management Program requirement for an independe check of brachytherapy dose calculations. Other violations were identified which did not directly relate to the misadministration. notice of violation was issued to the licensee.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to a part of the body not scheduled to receive radiatic should be considered an abnormal occurrence.

ITEM #:	940771	AO #:	NRC 93-06	EVENT DATE:	04/28/1993
TITLE:	INOPERABLE RESEARCH REACTOR SCRAMS AT UNIVERSITY OF VIRGINIA IN CHARLOTTESVILLE, VIRGINIA				
NAME:	University of Virginia	CITY:	Charlottesville	STATE:	VA

Nature and Probable Consequences:

Since November of 1992, the University of Virginia's research reactor had been experiencing a series of spurious scrams. The scrams were occurring without any annunciator indication. Because of the design of the scram annunciator system, the licensee staff did not believe that the unannounced scrams were being caused by electrical supply line noise. A member of the licensee staff who was in charge of the electronic maintenance at the facility concluded that the most likely source of the problem was in scram logic system. Therefore, when he experienced unannounced scrams on April 28, 1993, while performing the duties of the Senior Reactor Operator (SRO), he independently began trouble-shooting the problem to try to isolate the source of the scrams. There was no specific procedure in place to provide guidance for the trouble-shooting activities.

With the reactor shutdown, the SRO first interchanged some of the electronic equipment in the reactor control console. That act did not remedy the situation so he interchanged some other equipment, i.e., two mixer/driver (MD) modules. The MD modules appeared to be identical in their external appearance and both had the same identification number. After approximately 30 minutes no further scrams were received so the SRO briefly conferred with the Reactor Administrator about the situation, and the reactor was restarted. Neither the SRO nor the Reactor Administrator realized that the trouble-shooting actions (exchanging the MD modules) were maintenance activities. Therefore, no postmaintenance testing was performed to ensure that the safety systems were operating as required.

The reactor was operated a full power for the next 5.5 hours with a change in SROs every 2 hours. No scram signal was received during that period. During a normal shutdown of the reactor at the end of the day on April 28, another SRO, who was then in charge of reactor operations, decided to complete the shutdown by introducing an electronic period scram. The scram logic, however, failed to produce the expected period scram and the SRO manually scrambled the reactor, which resulted in safe shutdown of the reactor.

Cause:

The principal cause of the incident was the SRO exchanging the MD modules in the reactor control console. This inadvertently defeated five of the scrams required for reactor operation. Other contributing causes were not recognizing the exchanging of the modules as a maintenance activity, lack of adequate procedures defining maintenance and troubleshooting activities, and failure to perform post-maintenance testing of the safety system prior to restarting reactor operations.

Licensee Action:

The Reactor director was notified of the problem when no scram was received the evening of April 28 and an investigation was begun into the cause of the problem. As a result of the investigation, the licensee initiated various corrective actions including: (1) maintaining the reactor in safe shutdown until the problem was investigated, understood, and reviewed with the Reactor Safety Committee (RSC) and with the NRC; (2) notifying the University, the community, and the NRC of the problem; (3) requesting a peer review from the National Organization of Test, Research, and Training Reactors (TRTR); (4) determining the root cause(s) of the event and taking corrective actions; (5) determining if there were any problems with the hardware, schematics, and Standard Operating Procedures (SOPs) which may have contributed to this event and taking actions to correct the problems noted; and (6) determining if any administrative corrective actions were needed.

NRC Action:

A reactive inspection was conducted on May 3, 1993. Staff members from NRC Region II and headquarters participated in this inspection. A follow-up inspection was conducted on June 3 and 4, 1993, again with participation from NRC Region II and headquarters. Apparent violations of regulatory requirements were identified and discussed with licensee management and the SRO involved in the incident during a June 29, 1993, enforcement conference held in the NRC Region II Office. The licensee presented its perspective on the significance of the event, its causes, and the licensee's corrective actions. A notice of violation and proposed imposition of civil penalty was issued by the NRC on July 28, 1993. Violations were proposed for operating the reactor without five safety system channels required by the Technical Specifications and for failing to verify that the safety system channels were operable following maintenance, as required by the Technical Specifications. These were categorized in the aggregate as a Severity Level II problem (Severity Levels I through V range from the most significant to the least significant) and a civil penalty of \$2000 was proposed. The licensee paid the civil penalty on August 26, 1993.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Items No. 10 and 11 for all licensees) of this report notes that a major deficiency in operating, management, or procedural controls that impact safety should be considered an abnormal occurrence.

ITEM #: 940034 AO #: NRC 93-07 EVENT DATE: 02/16/1993
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MERCY MEMORIAL MEDICAL CENTER IN ST. JOSEPH, MICHIGAN
NAME: Mercy Memorial Medical Center CITY: St. Joseph STATE: MI

Nature and Probable Consequences:

On February 16, 1993, at 5:00 p.m., a patient was undergoing a brachytherapy procedure using cesium-137 (Cs-137) sources. The radiation oncologist involved in this procedure failed to properly rotate the insert of the brachytherapy device containing the sources, and one source containing 862.1 megabecquerel (MBq) (23.3 millicuries [mCi]) Cs-137 fell out of the insert onto the patient's bed. The source landed on an absorbent pad that was placed between the patient and the surface of the bed. The loss of the source was not observed by the oncologist or the medical physicist who was assisting him.

On February 17, at about 8:20 a.m., a nurse observed a small piece of metal between the patient and the absorbent pad. The nurse thought it was a small screw and retrieved it, placing it in a paper cup on the bedside table. The radiation oncologist and the medical physicist were notified, and they identified the object as a Cs-137 source. Using tongs, they placed it in a shielded storage container.

The dislodged source was subsequently placed in the treatment device, and the treatment plan was revised to reflect that the source was implanted for a reduced period of time. The revised treatment plan indicated that this implant time reduction for the source would result in an underdose of about 6 percent to the intended treatment site.

The licensee calculated that the dislodged source resulted in a radiation dose of about 45.8 centigray (cGy) (45.8 rad) to the perineum, an area different from the intended treatment site. In addition, the licensee stated that there is no evidence of clinical effects on the patient as a result of the radiation exposure from the dislodged source.

This incident is considered a misadministration because a part of the patient's body received unscheduled radiation exposure. The licensee reported that both the patient and the referring physician had been notified of the incident.

The NRC staff calculated the dose to the nurse who discovered and handled the dislodged source. Based on information supplied by the nurse on her handling of the source, NRC calculated that she received a 4.25 cGy (4.25 rad) radiation exposure to the surface of the hand in contact with the source.

Cause:

The cause of the misadministration was the radiation oncologist's failure to properly rotate the Cs-137 source insert while loading the source into the treatment device. In addition, the nurse who discovered the dislodged source had not received any training on the size and appearance of the brachytherapy sources.

Licensee Action:

The licensee conducted refresher training for its nurses to explain brachytherapy procedures and provided them with instructions.

NRC Action:

NRC Region III conducted a special inspection from March 26 through April 7, 1993, to review the circumstances surrounding the misadministration (Ref. 2). An NRC medical consultant was also retained to evaluate the circumstances of the event.

The inspection identified several apparent violations of NRC requirements including: (1) substantial failure to implement a Quality Management Program for brachytherapy procedures; (2) failure of the RSO to adequately investigate the accident to identify a misadministration, and to assess overexposure to the nurse's hands; (3) failure to adequately instruct nurses caring for brachytherapy patients; and (4) failure to make evaluations to assure compliance with NRC exposure limits for occupational workers. On August 2, 1993, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$6,250. The licensee paid the civil penalties on August 12, 1993.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to a part of the body not scheduled to receive radiation should be considered an abnormal occurrence.

ITEM #:	940134	AO #:	NRC 93-08	EVENT DATE:	06/10/1993
TITLE:	MEDICAL BRACHYTHERAPY MISADMINISTRATION AT KEESLER MEDICAL CENTER, KEESLER AIR FORCE BASE, IN BILOXI, MISSISSIPPI				
NAME:	Keesler Medical Center, Keesler Air Force Base	CITY:	Biloxi	STATE:	MS

Nature and Probable Consequences:

On June 14, 1993, the United States Air Force Radioisotope Committee Secretariat (RIC) notified NRC Region IV of an incident involving a brachytherapy treatment which occurred at Keesler Medical Center on June 10, 1993. The permittee's Radiation Safety Officer (RSO) was not present at the facility on June 10. The permittee staff involved with the treatment did not initially recognize the incident as a misadministration. The incident and related facts were reported to the RSO when he returned to the medical center on June 14. The RSO subsequently notified RIC of the incident, who in turn formally notified NRC. RIC's initial report noted that a patient who was to receive a total dose of 1400 centigray (cGy) (1400 rad) to the right lower lung had also received an unintended dose of approximately 2.09 cGy (2.09 rad) to the facial area.

The incident involved a brachytherapy treatment using an iridium-192 high-dose-rate remote afterloading device. The written directive prepared by the authorized user prescribed two treatment doses of 700 cGy (700 rad) each to be delivered to the lower lobe of the patient's right lung. The first treatment dose was administered on June 2, 1993, using a single endobronchial catheter as prescribed in the written directive. The second treatment dose was to be administered on June 10, 1993, using two endobronchial catheters, one positioned in the lower lobe of the right lung and the second positioned in the middle lobe of the lung. The fractional dose prescribed for the lower lobe was delivered as intended. The fractional dose for the middle lobe was not delivered as prescribed in the written directive due to incorrect positioning of the source.

The mispositioning of the source resulted from an error in entering the length of the catheter into the treatment planning computer. The treatment plan established by the authorized user called for use of two catheters, each with a length of 150 centimeters (cm) (59.1 inches [in.]). The length of the first catheter and source position was properly entered at the treatment planning computer console. The permittee's dosimetrist believed that the length and source position for the second catheter were properly entered. However, it was later discovered that due to an erroneous keystroke, a default value of 100 cm (39.4 in.) was entered as the length of the second catheter. This resulted in an error in the source position since the actual distance of source travel is determined by subtracting an "offset" value from the length of the catheter. The error in the source position was recognized by the authorized user as the treatment was underway and the treatment was promptly stopped.

Following consultation with the device manufacturer and review of the treatment planning computer data and the data available from the remote afterloading device control console, permittee representatives determined that the source had been positioned approximately 10 cm (3.9 in.) in front of the patient's face for a period of approximately 46 seconds. The estimated dose to the patient's face was determined to be approximately 2.09 cGy (2.09 rad). In the absence of the licensee's RSO, and based on advice provided by the manufacturer's representative, the permittee's staff determined that the incident did not constitute a therapeutic misadministration. The remainder of the prescribed treatment dose was delivered to the middle lobe of the patient's right lung later that day. Through discussions with the RSO, the RIC, and the NRC staff, the permittee subsequently determined on June 14 that a misadministration had occurred and reported the incident to NRC and the patient as required.

NRC inspectors were at the medical center on June 23 and 24, 1993, to review the circumstances associated with the misadministration and its probable cause(s).

Cause:

Based on interviews with permittee representatives and reenactment of the treatment planning and setup, the apparent root cause of the misadministration was determined to be an erroneous keystroke at the treatment planning computer console. The permittee's dosimetrist demonstrated for the NRC inspectors the sequence of steps taken during treatment planning, noting that the correct value of 150 cm (59.1 in.) had been entered for both catheters on June 10. However, the dosimetrist believed that as the length of the second catheter was entered, she depressed the "F2" function key to enter another treatment parameter and accidentally touched the "F1" function key with her hand at the same time. This caused the catheter length value to change to the default value of 100 cm (39.4 in.) with only the sound of a "beep" to warn the operator. Through repetitive testing of different keystroke sequences, the dosimetrist determined that this was the only sequence that would reproduce a reset of the catheter length to the default value once the length was manually entered at the treatment planning console. This sequence of steps was repeated for the inspectors several times during the inspection and in each instance, the catheter length defaulted to 100 cm (39.4 in.).

A contributing factor to the misadministration was the failure of permittee staff to verify the dwell positions for each catheter prior to performing the treatment as required by an "Operating Instruction" established by the permittee. Although this operating instruction was not incorporated in the permittee's Quality Management Program, it did require that individuals administering patient treatment using the high-dose-rate remote afterloading device verify both the source dwell time and source dwell positions prior to administering a treatment. This requirement was established to ensure that treatment parameters entered in the device control console matched the parameters entered in the treatment planning computer. Both the dosimetrist and medical physicist who administered the treatment on June 10 acknowledged that they had only verified the source dwell times noted on the treatment planning and device control computer printouts. Although the dwell position value on both records was incorrect (because the error was propagated in both computer systems), the dosimetrist and physicist stated that they probably would have identified the error if they had verified the dwell positions prior to treatment.

Licensee Action:

Permittee - Following the misadministration, the permittee modified a checklist that had been used by the staff to verify that certain actions were completed prior to treatment. The modifications included requirements to (1) physically measure each catheter prior to use for patient treatments and document the measured length of the catheter on the checklist form, (2) document the planned distance from the end of the catheter to the first dwell position on the checklist form, (3) have the authorized user and medical physicist verify the documented catheter length and dwell positions and sign the checklist for approval, and (4) include a review of the checklist in the permittee's Quality Management Program.

NRC Action:

An inspection was conducted on June 23 and 24, 1993, to review the misadministration and its probable cause(s) (Ref. 3). Based on the results of the inspection, two apparent violations were identified relative to the permittee's Quality Management Program. These included (1) a failure to implement and maintain a Quality Management Program that met the objective of ensuring that radiation from by-product material was administered in accordance with a written directive, and (2) failure to indicate the radioisotope to be used for brachytherapy treatments in 22 written directives. In addition, several weaknesses were identified in the permittee's written Quality Management Program. The inspection findings indicated that the failure to verify the source dwell positions prior to performing a patient treatment was an isolated event and that the permittee staff had complied with the applicable operating instruction during previous patient treatments. A Notice of Violation was issued on July 20, 1993. A Civil Penalty was proposed.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to a part of the body not scheduled to receive radiation should be considered an abnormal occurrence.

ITEM #:		AO #:	AS 93-01	EVENT DATE:	06/06/1988
TITLE:	CONTAMINATION OF POOL IRRADIATOR FACILITY OWNED BY RADIATION STERILIZERS, INC., IN DECATUR, GEORGIA				
NAME:	Radiation Sterilizers, Inc.	CITY:	Decatur	STATE:	GA

Nature and Probable Consequences:

On June 6, 1988, the Radiation Sterilizers, Inc. (RSI) facility in Decatur, Georgia, ceased sterilizer operations utilizing its pool irradiator because of the detection of dissolved radioactive cesium-137 (Cs-137) in a 25,000 gallon pool of water in which 252 stainless steel encapsulated radioactive sources were stored. The Cs-137 sources, which were leased from the Department of Energy (DOE), had a total activity of approximately 444,000 terabecquerel [TBq] (12 megacuries) [MCi]. The sources were at the Encapsulation Storage Facility (WESF) capsules manufactured by DOE, under the By-product Utilization Program (BUP). This DOE program was initiated with a mission to develop the means for application of radioactive fission products for the benefit of society. Under BUP, the sources were designed for waste storage, not as gamma radiation sources. In 1985, however, NRC agreed that use of WESF sources could be authorized in a limited number of commercial demonstration facilities, including irradiators such as RSI's that operate in the "wet load, wet storage, dry irradiation" mode.

Operators of the RSI pool irradiator notified the State of Georgia Radiation Control Program that the safety system had prevented them from raising sources from the storage pool. Subsequently, radiation levels of 600 microsievert (Sv) (60 millirem) per hour at the surface of the pool water were found, which indicated that one or more of the 252 Cs-137 source capsules used in the irradiator were leaking. Discrete samples of pool water were collected and analyzed and the analytical results showed elevated levels of Cs-137 dissolved in the pool water, confirming the presence of one or more leaking sources. This was the first recorded instance of a leaking WESF capsule. A joint Federal/State task force, consisting of the Georgia Department of Natural Resources (DNR), the Georgia Department of Human Resources (DHR), and NRC, was established to assist with the RSI incident.

After review and recommendation by the joint task force and upon discussion with RSI, on June 11, 1988, the State of Georgia formally requested that DOE manage the effort to identify the leaking capsule, develop a plan for the safe removal of the leaking capsule, manage the removal of the damaged capsule, and oversee the cleanup and recovery activities at RSI. DOE responded immediately to the State's request and dispatched resource from the Westinghouse Hanford Corporation. The joint Federal/State task force was also expanded to include representatives from the Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA).

This incident generally was confined to the RSI facility, with no evidence of major discharges to the environment. There was no evidence of overexposure, although areas of minor contamination were found in a warehouse, the office carpet, one automobile seat, one individual's pants and spots on a carpet at a residence, all of which were decontaminated. Some medical products sterilized at the RSI facility before the incident was discovered were contaminated; however, the only contaminated products released from the RSI facility were in a shipment that was recalled before it reached its destination.

Five suspected leaking (damaged) sources were initially removed from the storage pool. One was confirmed to be leaking. Subsequently, the remaining 247 source capsules were examined for leakage. None were found to be leaking. On November 11, 1990, the last of the capsules was shipped off site and final decontamination of the facility began. On September 11, 1992, the DOE contractor completed decontamination of the facility and began the survey. DOE estimated cost of the cleanup to be 45 million dollars. On November 11, 1992, the DOE contractor completed the free release survey and the DNR contractor completed the confirmatory survey. By December 16, 1992, DNR received the free release survey. On January 5, 1993, after review and evaluation of the reports, DNR returned control of the facility to the owner, Sterigenics International (formerly RSI), and terminated its radioactive materials license.

Cause:

The facility contamination resulted from one stainless steel cesium-137 source capsule, out of a total of 252 capsules, leaking in the source storage pool.

DOE has not identified the exact cause of failure of the Cs-137 source capsule.

Licensee Action:

The licensee requested that DOE (the source manufacturer and the source lessor) manage the effort to identify the leaking capsule, develop a plan for its safe removal, manage its removal, and oversee the cleanup and recovery activities at RSI.

NRC Action:

Following the incident, NRC reevaluated the WESF sources and determined in early 1991 that WESF sources were not appropriate for long-term use in commercial irradiator facilities and ensured that the remaining commercial users were so notified and advised to cooperate with DOE in scheduling removal of WESF sources from their facilities. As of the date of this report, WESF capsules remain in place in two licensed irradiators, one in Virginia and one in Colorado (licensed by the State of Colorado). According to DOE staff, if certain technical matters are resolved, DOE plans to begin removing the remaining WESF sources from these facilities by the end of 1993.

Other Agency Action:

The State of Georgia secured the services of an independent consultant to verify the results of decontamination efforts by the D contractor. Once it was verified that the facility met Federal and State regulatory standards for decontamination, the State terminated RSI's material license and returned control of the facility to its owner. Georgia will no longer license highly soluble cesium for this application.

Future reports will be made as appropriate.

Criteria:

Appendix A (see Example 5 of "For All Licensees") of this report notes that any loss of licensed material in such quantities and under such circumstances that substantial hazard may result to persons in unrestricted areas should be considered an abnormal occurrence.

This event occurred in June 1988 in Georgia, an Agreement State by a joint Georgia and NRC incident Evaluation Task Force. The investigated incident was documented in NUREG-1392, "Leakage of an Irradiator Source - the June 1988 Georgia RSI Incident," published in February 1990. At that time, neither the State nor NRC identified the event as an AO. The state reevaluated the incident against the reporting criteria in 1993 and concluded that the event should be classified as an AO.

ITEM #: 920329 AO #: AS 93-02 EVENT DATE: 04/01/1992
TITLE: MEDICAL "SODIUM IODIDE" MISADMINISTRATION AT GRENADA LAKE MEDICAL CENTER IN GRENADA, MISSISSIPPI
NAME: Grenada Lake Medical Center CITY: Grenada STATE: MS

Nature and Probable Consequences:

On April 1, 1992, a patient scheduled to receive 3.7 megabecquerel (MBq) (100 microcurie (uCi) of iodine-131 (I-131) for a thyroid uptake study was administered 218.3 MBq (5.9 millicuries [mCi] of I-131. The 218.3 MBq (5.9 mCi) dosage of I-131 was to be administered to another patient. The technologist immediately discovered the error and notified the physician (authorized user). Vomiting was induced within 5 minutes of administer the I-131 capsule. The patient was also administered a thyroid blocking agent. 1.2 milliliter (ml) (0.04 fluid ounces [fl. oz.]) of potassium iodide. The patient was also instructed to take additional thyroid blocking agent, 0.3 ml (0.01 fl. oz.) of potassium iodide, once a day for 14 days. A thyroid uptake and scan were performed 24 hours after the incident. The thyroid uptake was 0.3 percent. The referring physician and the patient were informed of the misadministration.

Cause:

The misadministration occurred because the nuclear medicine technologist failed to identify the patient prior to the administration of the radiopharmaceutical.

Licensee Action:

The Radiation Safety Officer has implemented new procedures for verification of patient identification and has committed to improve the supervision of personnel. The licensee also stated that patients who are prescribed radiation therapeutic procedure will no longer be included in the same schedule with patients who are prescribed diagnostic procedures.

NRC Action:

Other Agency Action:

The state agency staff has reviewed the circumstances of the misadministration and will evaluate the licensee's corrective action during the next inspection to be conducted in the near future.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see Event Type 4 in Table A-1) of this report notes that administering a diagnostic dose of a radiopharmaceutical that is greater than five times the prescribed dose should be considered an abnormal occurrence.

This report is based on information provided to the State of Mississippi on April 3, 1992.

ITEM #: 921049

AO #: AS 93-03

EVENT DATE: 11/11/1992

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MAINE MEDICAL CENTER IN PORTLAND, MAINE

NAME: Maine Medical Center

CITY: Portland

STATE: ME

Nature and Probable Consequences:

A patient was prescribed a brachytherapy treatment using 13 seeds of iridium-192 in a nylon ribbon. The catheter used for the treatment developed a kink and stopped 26 centimeters (cm) (10.24 inches [in.]) from the prescribed treatment area. This resulted in a dose to the patient's hypopharynx area of 3500 centigrays (cGy) (3500 rad), which was the prescribed dose to the lung. The intended treatment area of the lung was estimated to have received less than 10 cGy (10 rad).

Prior to implantation of the radioactive seeds, nonradioactive sources were implanted for visualization and dosimetry/treatment planning. The licensee performed x-rays which showed that the dummy seeds had reached their desired location. The active seeds were to be inserted immediately after withdrawal of the dummy seeds. However, because of scheduling difficulties with the patient's room, and not wanting a patient with radioactive seeds to remain in the therapy department for an undetermined period of time, the dummy seeds were withdrawn but the catheter remained in the patient. The radioactive seeds were implanted sometime later. In retrospect the licensee estimated that the kink in the catheter developed during the interval of removing the dummy seeds and inserting the active seeds.

After the treatment was completed and while removing the catheter and the nylon ribbon together, the doctor and the Radiation Safety Officer both noticed the kink. The licensee stated that no long-term effects are expected. The patient was notified of the misadministration.

Cause:

See Nature and Consequences above.

Licensee Action:

The licensee implemented the following actions: (1) measuring the nonradioactive seed strand when properly inserted (verified by x-ray) and marking the distance on the active strand; (2) the dummy strand or similar wire will be left in the catheter until immediately prior to insertion of the radioactive strand; and (3) a film will be taken of the area to be treated after the active seeds are inserted to ensure that they are in the correct location.

NRC Action:

Other Agency Action:

The state agency is reviewing this event to determine necessary actions.

Future reports will be made as appropriate.

UPDATE: from NUREG-0090, Vol. 16, No. 3, page 15. This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No.2, "Report to Congress on Abnormal Occurrences," April-June 1993. The abnormal occurrence is updated as follows:

The State of Maine has reviewed and approved the corrective actions taken by the licensee as a result of this misadministration. The State Agency considers this case closed.

Criteria:

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to a part of the body not scheduled to receive radiation should be considered an abnormal occurrence.

ITEM #: 940204 AO #: AS 93-04 EVENT DATE: 05/07/1993
TITLE: INDUSTRIAL RADIOGRAPHER OVEREXPOSURE EVENT AT MURPHY OIL REFINERY IN MERAUX,
LOUISIANA
NAME: Murphy Oil Refinery CITY: Meraux STATE: LA

Nature and Probable Consequences:

While working at a temporary job site at the Murphy Oil Refinery, a 21 year-old industrial radiographer employed by Inspection Specialists, Inc., using 3700 gigabecquerel (GBq) (100 curies) of iridium-192 in a SPEC 2-T exposure device, received a 276.6 millisievert (mSv) (27.66 rem) whole body exposure as indicated by a thermoluminescent dosimeter badge. Reenactment of the events appears to indicate that the radiographer received the whole body dose that would cause acute (short-term) injury. A preliminary physical examination with blood tests indicated no indication of excessive exposure.

The radiographer's assistant is estimated to have received a dose of 9.6 mSv (0.96 rems).

Cause:

Radiography operations were being conducted on a large, open-top steel tank. The radiographers and camera had to be moved from place to place along the side of the tank in personnel baskets. The radiographer failed to lock the exposure device, so that when the radiographer's assistant moved toward the device with the control handle, the source moved slightly out of the shielded position. The radiographer apparently failed to read the survey meter while the source was exposed. The radiographer and assistant realized after several additional exposures that their dosimeters were off scale.

Licensee Action:

The licensee provided retraining to the entire staff with special counseling for the Operations Manager, who apparently did not follow written operating procedures.

NRC Action:

Other Agency Action:

The Louisiana Radiation Protection Division (RPD) recommended to the licensee that routine physical examinations and blood v be performed. Enforcement actions included citations for violations associated with whole body and extremity overexposures ar lack of management control.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see example 1 of "For All Licensees") of this report notes that any loss of licensed material in such quantities and under such circumstances that substantial hazard my result to persons in unrestricted areas should be considered an abnormal occurrence.

ITEM #: 940090 AO #: NRC 93-09 EVENT DATE: 07/27/1993
TITLE: MEDICAL SODIUM IODIDE MISADMINISTRATION AT OSTEOPATHIC HOSPITAL FOUNDERS ASSOCIATION
DBA (doing business as) TULSA REGIONAL MEDICAL CENTER IN TULSA, OKLAHOMA
NAME: Osteopathic Hospital Founders Association CITY: Tulsa STATE: OK

Nature and Probable Consequences:

The licensee reported that on July 27, 1993, a wrong patient was administered 0.21 gigabecquerel (GBq) (5.7 millicuries [mCi] of iodine-131 (I-131). On July 27, 1993, diagnostic procedures were prescribed for two outpatients, patients A and B, using technetium-99m (Tc-99m) for patient A and I-131 for patient B. Prior to the administration, the technologist involved in the procedure believed that patient A was the one prescribed to receive I-131 and addressed patient A by name and requested a second form of identification. Patient A responded positively and presented a social security card as the second means of identification. The technologist copied the social security number and attached it to patient A's chart. However, the written directive was not checked for verification of the patient's name. As a result patient A was administered a 0.21 GBq (5.7 mCi) dosage of I-131 intended for patient B.

The technologist recognized the misadministration within minutes of its occurrence and immediately notified the nuclear medicine physician. The physician prescribed Ipecac to induce vomiting, which was administered within 15 minutes of the administration of I-131, and Lugol's solution (potassium iodide) as a blocking agent which was administered after emesis, approximately 45 minutes after the I-131 administration. The referring physician and patient were notified of the misadministration.

The licensee reported that the patient received a thyroid dose of about 1600 centigray (cGy) (1600 rad) as a result of the misadministration. The patient will be examined during subsequent follow-up visits to the medical center.

The NRC staff retained a medical consultant to evaluate the potential medical effects on the patient as a result of the misadministration. The medical consultant estimated that, due to the administration of Lugol's solution, the dose to the patient's thyroid is in the range of 400-700 cGy (400-700 rad). The medical consultant believes the medical consequences of the misadministration would be negligible.

Cause:

10 CFR Part 35 states that individuals under the supervision of authorized users must follow the instructions of supervising authorized users and follow the written radiation safety and quality management procedures established by the licensee. The licensee's Quality Management (QM) Program states that "prior to each administration the patient's identity as the individual named in the written directive will be verified by more than one method." The licensee's program also states that "The person administering the radiopharmaceutical must verify that the type of radiopharmaceutical, the dosage, and route of administration are in accordance with the written directive and check the dosage in a dose calibrator." However, the licensee staff failed to check the written directive

Licensee Action:

The licensee revised the QM procedures to prevent recurrence of similar misadministrations. The revisions include the following requirements: (1) the prescribing physician must be present at each administration of I-131 dosage for whole body scan; (2) the technologists must double check the radiopharmaceutical and patient identification against the written directive; and (3) the technologist must cross check the department's requisition with the name, the dose, and the patient's identifying documents.

NRC Action:

NRC Region IV conducted an inspection at Tulsa Regional Medical Center on August 10-11, 1993, to review the circumstances associated with the misadministration and its probable cause(s). The NRC staff is currently reviewing the inspection results for possible violations, and enforcement action is pending (Ref. 1).

Future reports will be made as appropriate.

UPDATE: from NUREG-0090, Vol. 16, No. 4, page 20. This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 3, "Report to Congress on Abnormal Occurrences: July-September 1993." The abnormal occurrence report is updated as follows:

In July 1993 the wrong patient was administered 0.21 gigabecquerel (GBq) (5.7 millicuries [mCi] of iodine-131 (I-131). The misadministration occurred because the licensee failed to verify patient identity.

The NRC staff retained a medical consultant to evaluate the potential medical effects to the patient as a result of the misadministration. The consultant provided a report in October 1993, which stated that the impact of the incident on the status of the patient's health should be negligible, with no expected long-term disability as a result of this misadministration.

On January 11, 1994, the NRC issued a Notice of Violation to the licensee. The licensee was cited for failing to require individuals working under the supervision of authorized users to follow the instructions of the supervising authorized user and the written radiation safety and quality management procedures established by the licensee. Because the misadministration was the result of an isolated failure to follow the quality management procedures and was of limited consequence to the patient, no escalated enforcement action was taken by the NRC.

This item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 1 in Table A-1) of this report notes that a diagnostic dose of a radiopharmaceutical to a part of the body receiving radiation improperly, if greater than five times the intended dose to that body part, should be considered an abnormal occurrence.

ITEM #: 810088 AO #: NRC 93-10 EVENT DATE: 01/22/1981
TITLE: 1981 FATAL RADIATION EXPOSURE OF A RADIOGRAPHER IN NORTHEAST OKLAHOMA
NAME: Bill Miller, Inc. CITY: Henryetta STATE: OK

Nature and Probable Consequences:

On January 22, 1981, the State of Oklahoma notified NRC Region IV that an individual had been admitted to the Okmulgee Memorial Hospital, Okmulgee, Oklahoma, with serious radiation injuries to his chest and left forearm. The individual was later determined to be an unemployed radiographer living in Henryetta, Oklahoma.

On January 5, 1981, an NRC licensee (Bill Miller, Inc.) in Henryetta, Oklahoma, reported that a radiographic exposure device containing a 1221 gigabecquerel (33 curie) iridium-192 source was discovered missing following a quarterly inventory on January 5, 1981. The licensee stated that the device had been stored in a locked enclosure in a company truck while the truck was parked in the back yard of a licensee employee's residence in Henryetta. NRC investigators later noted signs of forced entry on the truck's camper shell door and determined that the theft occurred about December 30, 1980. A search for the missing source by representatives of the licensee and the State of Oklahoma Department of Public Health was unsuccessful. The licensee subsequently reported on January 5, 1981, that the missing source had been anonymously returned intact to a licensee representative's residence.

NRC investigators interviewed the exposed individual, and he stated that he could not recall how or when he received the exposure. Medical authorities estimated his exposure occurred between December 15, 1980 and January 5, 1981. Cytogenetic studies of a sample of the patient's blood indicated that he received an equivalent whole body dose of 365 centigray (cGy) (365 rad) from iridium-192 or 405 cGy (405 rad) from cobalt-60. The individual maintained that he had last worked with a radioactive source during the first week of October 1980 and that he first noticed an irritation on his chest and arm in November 1980.

The exposed individual refused to be interviewed by NRC a second time. He directed that any further contact with him be made through his lawyer. On July 27, 1981, NRC Region IV was notified that the individual had died of his injuries. NRC conducted a second investigation, but no substantial additional facts were identified.

Cause:

Based on circumstantial evidence, it appears that the death was caused by a self-inflicted exposure to the stolen source. The licensee's security measures were found to meet NRC requirements in 10 CFR 20.207 and 34.23.

Licensee Action:

NRC documents indicate that no licensee actions were warranted or taken.

NRC Action:

The investigation identified no violations of NRC requirements (Ref. 2, 3, and 4).

This item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

In response to a 1993 General Accounting Office report entitled "Nuclear Regulation," NRC conducted a file review of this previously reported event.

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 1 of "For All Licensees") of this report notes that an exposure of the whole body of an individual to 250 millisievert (250 mSv) or more of radiation can be considered an abnormal occurrence.

Note - This event occurred in January 1981 in Oklahoma, and was previously reported to Congress in NUREG-0090, Vol. 4, No. 1, as "other event of interest." At that time, NRC did not identify the event as an AO because it had not been conclusively determined that the radiation exposure resulted from material subjected to licensing by NRC or by the Agreement States. NRC reevaluated the incident against the AO reporting criteria in 1993 and concluded that the event should be classified as an AO.

ITEM #: 940597 AO #: AS 93-05 EVENT DATE: 12/04/1987
TITLE: MEDICAL TELETHERAPY MISADMINISTRATION AT ALTA BATES MEDICAL CENTER IN BERKELEY, CALIFORNIA
NAME: Alta Bates Medical Center CITY: Berkeley STATE: CA

Nature and Probable Consequences:

A 9-year-old autistic boy was admitted to Childrens Hospital in Oakland, California, for a tonsillectomy. Post surgical pathologic examination identified a cancer of the patient's nasopharynx. The patient was given chemotherapy and was scheduled to receive radiation therapy at ABMC using a cobalt-60 (Co-60) source of 186850 gigabecquerel (5050 Curie). The treatment was to be performed at ABMC, because Childrens Hospital did not have the capability to provide radiation therapy.

ABMC used West Coast Cancer Foundation (WCCF), a medical physics consultant organization, to do treatment planning. Based on information provided by WCCF, radiation therapy treatments began on December 4, 1987. The treatments were temporarily stopped on December 24, 1987, and were to resume in January 1988. However, when the patient returned to restart treatment, there had been anatomical changes which required treatment replanning. The replanning was done by the same dosimetrist that had done the original plan. The dosimetrist discovered that an error had been made in planning the first treatment series. The error had resulted in doubling the prescribed dose that the patient was supposed to have received during the initial treatment phase. The fact that an error had occurred was promptly communicated to the patient's physicians and by them to the patient's mother. The subsequent prognosis provided by a consultant was grave, the patient was expected to die within 2 years. The patient died at Children's Hospital on August 21, 1988.

Cause:

The cause of the misadministration was an error made by a WCCF dosimetrist in planning the first radiation therapy treatment series. The error resulted in the patient receiving double the prescribed dose during the initial treatment phase and resulted in adverse health effects.

Licensee Action:

The State investigation reports that were sent to NRC did not discuss the actions taken by the licensee to prevent recurrence. At the time of this event, the licensee was not required to report this event as a misadministration, therefore, this information is not available.

NRC Action:

Other Agency Action:

As a result of the 1993 investigation, RHB recommended that the State take the following actions to minimize recurrences, and identify similar occurrences. (These recommendations have not yet been implemented.)

Require certification of specialists in the fields of radiological physics and dosimetry as those fields apply to the practice of radiation therapy, or provide for State recognition of such certification by appropriate national or international bodies.

Amend the California Radiation Control Regulations to be consistent with respect to use of radioactive materials and/or ionizing radiation, whether the radiation is produced by machine or radioactive materials.

Provide investigational techniques for inspectors who will or might be assigned to investigational duties.

Establish mechanisms for NRC support in RHB investigations of events of special or joint interest.

Require all individuals and organizations subject to State regulatory control involving the use of radioactive materials, and/or ionizing radiation producing machines, to report to the State Regulatory body all lawsuits or malpractice suits alleging injury or improper use of such materials or machines.

This event will be further evaluated when the information to prevent recurrence is available.

UPDATE: from NUREG-0090, Vol. 17, No. 4, page 23. This AO was originally reported in NUREG-0090, Vol. 16, No. 3, "Report to Congress on Abnormal Occurrences, July-September 1993."

The AO criterion used was Event Type 5 in Table A-1 of Appendix A of this report-Administering a therapeutic dose greater than 1.5 times the prescribed dose.

At the time, it was reported that after a 9-year-old autistic boy had a tonsillectomy at Children's Hospital in Oakland, California, a postsurgical pathological examination showed that he had cancer of the nasopharynx. After being given chemotherapy, he was scheduled to receive radiation therapy at Alta Bates Medical Center (ABMC) using a cobalt-60 source of 186,850 gigabecquerel

(5050 curie) activity. ABMC used a consultant, West Coast Cancer Foundation (WCCF), to do treatment planning. Because of error made by WCCF, the patient received a dose that was twice the prescribed dose on December 4, 1987. As a consequence of the overdose, the patient died on August 21, 1988.

The AO report is updated and closed out as follows:

The State of California's Radiological Health Branch (RHB) actions to prevent recurrence are as follows:

1. RHB's recommendation to require certification of specialists in the field of medical physics was addressed when RHB attempted to seek legal authority to require that these individuals become certified. The attempt involved a bill sponsored by one of the State Legislators which was introduced for consideration. The bill passed both Houses of the State Legislature and was sent to the Governor for signature in September 1993. It was vetoed by the Governor for a reason that was understood by RHB. An amended version will be introduced in the future. Certification of medical physicists cannot be required until a law is passed and signed by the Governor.

2. California's Radiation Control Regulations are consistent with respect to use of radioactive materials and/or ionizing radiation whether the radiation is produced by x-ray machines or radioactive material. The idea that the regulations are not consistent appears to have come from a misinterpretation of RHB's ABMC incident report. The intent of the recommendation by the RHB staff was to require that all therapy misadministrations be reported within the same time frame. At present, only those misadministrations that occur when the source is a teletherapy machine or brachytherapy source are required to be reported. Misadministrations that occur when the treatment source is a linear accelerator are not required to be reported.

Plans are still in place to amend the regulations to add a reporting requirement for a misadministration that occurs when the treatment source is a linear accelerator. These regulations have not been finalized or adopted yet.

3. RHB recommended providing investigational techniques for RHB inspectors who might be assigned investigation duties. This specialized training was given by NRC in Walnut Creek, California, in January 1994. This training should give inspectors added insight on how to gather evidence for a criminal investigation.

4. The mechanism for NRC support in RHB investigations was established during the investigation of the ABMC incident. In the future, NRC would answer a call for assistance by RHB to aid with an investigation. There should be no further action necessary to establish this type of working relationship.

5. RHB has not made any progress toward requiring the reporting of all law suits, or malpractice suits, alleging injury from the improper use of radioactive materials or x-ray machines in the diagnosis or treatment of disease within the State of California. The State's Department of Health Services employs a staff of attorneys who prepare cases against facilities or individuals who RHB finds have misused radioactive material or x-ray machines on patients. These attorneys review legislation reports from around the State on a regular basis, and would alert RHB if they become aware of a lawsuit involving sources of radiation. RHB has also been authorized to add an attorney to its staff who would devote full-time to the review of all legal needs of RHB.

This item is considered closed for the purpose of this report.

Criteria:

In response to an inquiry in April 1992, from The Plain Dealer, a Cleveland, Ohio, newspaper, the Radiologic Health Branch (RHB) of the State of California investigated a fatal radiation exposure that occurred in 1987 at Alta Bates Medical Center (ABMC) in Berkeley, California. At the request of the State, NRC assisted in the investigation. The West Coast Cancer Foundation (WCCF) the medical physics consulting firm that planned the radiation therapy treatment that resulted in the fatal exposure, was not included in this investigation. The investigation was completed in 1993.

As a result of this investigation, the State determined that the event was a misadministration and sent its investigation reports to NRC. However, the State in its final report stated "(Note: Medical misadministrations involving radioactive materials used in diagnostic and therapeutic procedures, became reportable in California, as a result of amendments to the regulations effective October 5, 1989. Misadministrations of machine produced ionizing radiation are not included in this reporting requirement.) Since no requirement to report misadministrations existed at the time of the event and the regulation to report misadministrations, which became effective, did not contain any retroactive reporting requirement, ABMC did not violate any regulatory requirements in not reporting the event. It appears that no institutional conspiracy or willful attempt to mislead the State Regulatory agency existed. Any appearance of conspiracy or willful failure to provide complete and truthful information appears to have resulted from miscommunications and misunderstandings."

After reviewing the State's reports of this event, NRC determined that this event was an abnormal occurrence. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic exposure that differs from the final prescribed treatment by more than 10 percent and that results in adverse effects worse than would be expected for the normal range of exposures prescribed, should be considered an abnormal occurrence.

ITEM #:	940628	AO #:	AS 93-06	EVENT DATE:	05/22/1993
TITLE:	OVEREXPOSURE OF A RADIOGRAPHER AT X-CEL GROUP IN CORPUS CHRISTI, TEXAS				
NAME:	X-Cel Group	CITY:	Corpus Christi	STATE:	TX

Nature and Probable Consequences:

On May 22, 1993, an Agreement State licensee, X-Cel Group, reported a radiography event involving a camera locking mechanism that came apart from the camera. This allowed the source assembly (pigtail) and 3626 gigabecquerel (98 curie) iridium-192 source to be pulled from the camera. A radiographer is believed to have picked up the source with the thumb and index finger of his right hand resulting in an overexposure. An immediate call was made to the regional State inspector in Corpus Christi requesting an investigation of the incident.

The incident occurred after midnight on May 22, 1993. Two radiographers working in low light conditions were performing radiography using a Gamma Century Model SA camera. Approximately 30 radiographs had been performed. The radiographs were taken for development and the radiographer took off his film badge and placed it on his clipboard, thinking the radiography was completed. Several shots needed to be retaken, and the radiographer forgot to put his film badge back on.

To move the camera from the first retake location to the second retake location, the radiographer took the crank-out cable in his hand and lifted the camera with his right hand. He took a few steps and the cable fell from the camera to the ground. He placed the camera on a truck tailgate, thinking he had a disconnect. He picked up the crank-out approximately 122 centimeters (cm) (4 feet) from the end, and moved his hand quickly toward the connector end. He grabbed what he thought was the cable connector and brought it to within 15 cm (6 in) of his face. When he realized it was the source, he dropped it, alerted his partner and ran from the area.

A follow-up investigation was performed on May 27, 1993. A reenactment and radiation exposure calculation indicated the radiographer received an estimated whole body exposure of 6 millisievert (mSv) (0.600 rem). A worst case extremity exposure to the fingers was estimated to be 19.25 sievert (1925 rem). At the time, no symptoms of radiation injury were noted on the fingers.

No dose to the lens of the eyes was estimated because the source was held in proximity of the face for only 1 to 2 seconds. However, the State of Texas was contacted by NRC to determine the related exposure. NRC was informed that due to the short duration of exposure, the dose to the lens of the eyes was estimated to be equal to the whole body dose (6 mSv [0.600 rem]).

Cause:

The lock insert of the radiography camera is held in place by two roll pins. One roll pin was missing, and may have been missing for some time. The second roll pin was in the camera housing, but not inside the lock insert. This allowed the lock insert, the spring, and the movable insert to be pulled from the lock box. The drive cable was connected to the pigtail, and when the lock insert pulled from the lock box, the drive cable pulled the pigtail from the camera, thereby exposing the source. Routine maintenance had been performed on the camera, but a missing roll pin is not readily noticeable during routine maintenance. Two radiographers operated the camera immediately prior to the incident without any difficulty.

Licensee Action:

The radiographer who was exposed was restricted from conducting radiation work. All personnel were informed that future failure to wear a film badge would result in termination of employment. A letter was sent to sub-offices and other radiography licensees in the area describing the incident.

NRC Action:

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Other Agency Action:

A Notice of Violation was sent to the licensee and radiographer for an extremity exposure in excess of 187.5 mSv (18.75 rem) and a failure of the radiographer to wear personnel monitoring. The manufacturer was questioned about the pins, which are ordinary 2 millimeter (1/8 inch) in diameter by 1.0 centimeter (3/8 inch) in long-length roll pins. The specific reason for inquiring about the dimensions of the roll pins and the insight(s) obtained from this information were not provided in the information provided by the State.

This item is considered closed for the purpose of this report.

Criteria:

Appendix A (see Example 1 of "For All Licensees") of this report notes that an exposure of the feet, ankles, hands, or forearms of any individual of 375 rem or more should be considered an abnormal occurrence.

ITEM #: 920934 AO #: AS 93-07 EVENT DATE: 10/05/1992
TITLE: MEDICAL RADIOPHARMACEUTICAL MISADMINISTRATION BY "UNSPECIFIED LICENSEE" IN ALBANY, NEW YORK
NAME: Unspecified Facility CITY: Albany STATE: NY

Nature and Probable Consequences:

A patient was administered 303.4 megabecquerel (MBq) (8.2 millicurie [mCi] of phosphorus-32 (P-32), instead of the prescribed 185 MBq (5 mCi) of P-32, as an outpatient receiving radiation therapy treatment. The patient was discharged in stable condition. The attending physician and the patient were notified of the misadministration.

UPDATE: from NUREG-0090, Vol. 16, No. 4, page 22. A patient was administered 303.4 megabecquerel (MBq) (8.2 millicurie [mCi] of phosphorus (P-32), instead of the prescribed 185 MBq (5 mCi) of P-32, as an outpatient receiving radiation therapy treatment. The patient was discharged in stable condition. The mistake was caught when the chief Technologist was reviewing records of doses prescribed and comparing these to the doses administered. Immediate action was taken to follow-up on the discrepancy. The attending physician and patient were notified of the misadministration. The patient's blood count monitoring frequency was changed from monthly to bi-weekly and the patient was monitored for potential infections. Six weeks after the administration of P-32, the patient's blood count was normal except for a decrease in the platelet count, which remained within the range of safety and represented the expected therapeutic response.

Cause:

Insufficient information is available on the cause(s) of this event. NRC has asked the State of New York to provide additional information regarding the cause(s) of this event.

As of February 3, 1994, it was known that the State of New York informed NRC that it will provide the requested information on the causes of this abnormal occurrence within 30 days.

UPDATE: from NUREG-0090, Vol. 16, No. 4, page 22. The licensee's account of the cause is as follows: The stated package dose was 185 MBq (5 mCi), calibrated to a date 10 days after the date on which the technologist drew the dose. The technologist failed to take notice of the calibration date and assumed that the stated packaged dose of 185 MBq (5 mCi) was drawn for administration. Although the dose calibrator measurement of the prepared (drawn) dose indicated a significant discrepancy between the prescribed dose and the measured dose, the technologist failed to investigate the cause of this discrepancy and did not notify the physician in regard to the discrepancy. A dose of 303.4 MBq (8.2 mCi) was administered to the patient by the physician, a Board Certified Radiologist.

Licensee Action:

The corrective actions reported by the licensee included modifying the radiopharmaceutical therapy protocol for P-32 and iodine 131 administrations, and providing training for the technologists. In addition, a work sheet was developed for P-32 therapy and the physician involved in the procedure was counselled.

UPDATE: from NUREG-0090, Vol. 16, No. 4, page 22. The corrective actions reported by the licensee included the implementation of a modified radiopharmaceutical therapy protocol for P-32 and iodine-131 administrations, and training for the technologists. In addition, a work sheet and check list, designed with several checks for technologists and physicians prior to administration of the dose, were developed for P-32 therapy. The physician involved in the procedure was counselled and the technologist was suspended from administration of therapy doses for a minimum period of six months. The Chief Technologist and Nuclear Medicine Physician will evaluate the technologist prior to allowing him or her to begin administering therapeutic doses again.

NRC Action:

The name of the licensee was not provided by the State of New York. NRC has asked the State of New York to provide this information, but it has been reported that State law limits its ability to report this information.

NRC legal staff has reviewed the relevant New York State laws regarding disclosure of the identity of facilities in which incidents occurred warranting reporting as abnormal occurrences. The New York State Public Health Law provides that "any incident reporting requirement imposed upon diagnostic and treatment centers...shall be kept confidential and shall not be released..." (NYS Pub Health, Article 28, Section 2805-M). The only exceptions provided in the law are release to the NYS Health Department or to other hospitals. Discussions with the staff and attorneys for the NYS Health Department indicate that the department will provide a description of the incident but will delete the identity of the facility and patient. The NRC Office of General Counsel advises that NRC is not itself bound by this State law so NRC could release the information if the State provided it to NRC. However, if the State refuses to provide it to the NRC, there is no conflict with Federal law because the abnormal occurrence reporting requirement, Section 208 of the Energy Reorganization Act of 1974, does not apply to Agreement State licensees nor Agreement State agencies. However, if investigation of the incident results in enforcement action, then the information provided to NRC regarding the abnormal occurrence will be updated to include the enforcement action and since that is public information, the identity of the facility would be provided at that time.

The name of the licensee has been withheld by the State of New York due to provisions in New York State Public Health Law.

Other Agency Action:

Insufficient information is available on the action(s) taken by the State Agency to prevent recurrence. NRC has asked the State New York to provide additional information regarding the State Agency's action(s).

As of February 3, 1994, it was known that the State of New York informed NRC that it will provide the requested information on the likelihood of harmful effects to the patients within 30 days.

This event will be further evaluated when additional information becomes available.

UPDATE: from NUREG-0090, Vol. 16, No. 4, page 22. The State required the licensee to submit a plan of corrective action designed to prevent recurrence. The corrective actions reported by the facility appear to be satisfactory.

This item is considered closed for purpose of this report.

Criteria:

Appendix A (see Event Type 5 in Table A-1) of this report notes that administering a therapeutic dose that is greater than 1.5 times the prescribed dose should be considered an abnormal occurrence.

ITEM #: 921116 AO #: AS 93-08 EVENT DATE: 12/14/1992
TITLE: MEDICAL SODIUM IODIDE MISADMINISTRATION AT INLAND IMAGING IN SPOKANE, WASHINGTON
NAME: Inland Imaging CITY: Spokane STATE: WA

Nature and Probable Consequences:

A patient that was prescribed a diagnostic thyroid procedure using 0.26 to 0.37 megabecquerel (MBq) (0.007 to 0.010 millicurie [mCi] of iodine-131 (I-131) erroneously received 196.1 MBq (5.3 mCi) of I-131. As a result, the licensee stated that the patient's thyroid received a dose of approximately 7950 centigray (7950 rad). NRC has asked the State of Washington to identify if the patient had borderline hypothyroidism prior to the misadministration.

The licensee reported that both a whole body scan and the requested thyroid uptake study were performed 3 days after the misadministration "with no patient complaints or immediate side effects." No NRC or State medical consultant was retained to evaluate this event.

The referring physician and the patient were notified of the misadministration.

UPDATE: from NUREG-0090, Vol. 16, No. 4, page 23. On December 14, 1992, a patient diagnosed as hyperthyroid was referred to the licensee by the Fairchild Air Force Base Hospital for a thyroid uptake scan of .26 megabecquerel (MBq) to 3.7 MBq (7-10 microcuries) of iodine-131 (I-131). The patient was mistakenly administered a 1996 MBq (5.3 millicurie) dose of I-131, sodium iodide for a whole body scan. As a result, the patient's thyroid received a dose of approximately 7950 centigray (7950 rad).

The nuclear medicine technologist misinterpreted the orally requested procedure and failed to verify the requested procedure through review of the referring physician's written requisition. The patient's physician, an endocrinologist, was notified and did inform the patient.

The licensee reported that both a whole body scan and the requested thyroid uptake study were performed three days after the misadministration "with no patient complaints or immediate side effects." The licensee has noted that the patient will most probably be hypothyroid for the rest of his life and that future litigation remains a possibility. No NRC or State medical consultant has been contracted to review this event.

Cause:

Based on information relating to the actions taken, it was determined that the nuclear medicine technologist misinterpreted the orally requested procedure and failed to review the referring physician's written directive. The licensee stated that this event was attributed to human error as a result of the technologist's inattentiveness and relatively short work experience, and the patient will most likely develop a hypothyroidism.

UPDATE: from NUREG-0090, Vol. 16, No. 4, page 23. This event was attributed to human error as a result of the technologist's inattentiveness and relatively short experience at this facility. Although the referring physician's written request was available at the time the dosage was prepared and administered, the technologist failed to reconcile the dose and study prescribed with the dose and study given.

Licensee Action:

The technologist involved in the procedure and the chief technologist were counseled and reinstructed by the physician designated as the authorized user and by the Radiation Safety Officer. In addition, the licensee stated that in the future, all sodium iodide procedures will be required to be verified against the written directive prior to administration.

UPDATE: from NUREG-0090, Vol. 16, No. 4, page 23. The technologist and the lead technologist (who was not present) were counseled and reinstructed by the authorized physician user/radiation safety officer. A review by the licensee of all such administrations for the prior 6 months revealed that the technologists were inconsistent in verifying written referrals with the study given, prior to administration. The licensee stated that all iodine studies are required to be verified against the written request list prior to any iodine administration.

NRC Action:

The State Agency informed NRC that it will review the cause of this event and initiate any necessary actions. NRC has asked the State of Washington to provide additional information regarding the State Agency's action(s).

This event will be further evaluated when additional information becomes available.

This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 3, "Report to Congress on Abnormal Occurrence," updated as follows: See Nature and Probable, Consequences, Cause or Causes, Licensee Actions and State Agency for update.

Other Agency Action:

See in NRC action above.

UPDATE: from NUREG-0090, Vol. 16, No. 4, page 23. The State has accepted the licensee's determination for the cause of this event and subsequent actions taken to prevent recurrence. This will be reviewed at the time of the next routine compliance inspection. As a result of this incident, the next inspection has been scheduled for the second quarter of 1994.

This time is considered closed for the purposes of this report.

Criteria:

Appendix A (see Event Type 4 in Table A-1) of this report notes that administering a diagnostic dose that is greater than 5 times prescribed dose should be considered an abnormal occurrence.

ITEM #: 941693 AO #: AS 93-09 EVENT DATE: 07/11/1992
TITLE: MEDICAL TELE THERAPY MISADMINISTRATION BY "UNSPECIFIED LICENSEE" IN NEW YORK, NEW YORK
NAME: Unspecified Facility CITY: New York STATE: NY

Nature and Probable Consequences:

Cobalt-60 teletherapy treatments of 200 centigray (200 rad) each were to be administered to the right axilla of a patient. However, the first five treatments were given to the left axilla in error. NRC has asked the State of New York to provide additional information regarding the treatment plan and the administered doses.

Cause:

Insufficient information is available to identify the cause(s) of this event. NRC has asked the State of New York to provide additional information regarding the cause(s) of this event.

As of February 3, 1994, it was known that the State of New York informed NRC that it will provide the requested information on the causes of this abnormal occurrence within 30 days.

Licensee Action:

Insufficient information is available on the action(s) taken by the licensee to prevent recurrence. NRC has asked the State of New York to provide additional information regarding the licensee's actions(s).

NRC Action:

The name of the licensee was not provided by the State of New York to provide this information, but it has been reported that State law limits its ability to report this information.

NRC legal staff has reviewed the relevant New York State laws regarding disclosure of the identity of facilities in which incidents occurred warranting reporting as abnormal occurrences. The New York State Public Health Law provides that "any incident reporting requirement imposed upon diagnostic and treatment centers...shall be kept confidential and shall not be released..." (NYS Public Health, Article 28, Section 2805-M.) The only exceptions provided in the law are released to the NYS Health Department or to other hospitals. Discussions with the staff and attorneys for the NYS Health Department indicate that the department will provide a description of the incident but will delete the identity of the facility and patient. The NRC Office of General Counsel advises that NRC is not itself bound by this State law so NRC could release the information if the State provided it to NRC. However, if the State refuses to provide it to the NRC, there is no conflict with Federal law because the abnormal occurrence reporting requirement, Section 208 of the Energy Reorganization Act of 1974, does not apply to Agreement State licensees, nor Agreement State agencies. However, if investigation of the incident results in enforcement action, then the information provided NRC regarding the abnormal occurrence will be updated to include the enforcement action and since that is public information, the identity of the facility would be provided at that time.

UPDATE: from NUREG-0090, Vol. 18, No. 1, page 10. This abnormal occurrence (AO) was originally reported in NUREG-0090 Vol. 16, No. 3, "Report to Congress on Abnormal Occurrences, July-September 1993," under the title "Medical Teletherapy Misadministration by "Unspecified Licensee" in New York, New York."

The AO criterion used was administering a therapeutic dose to a part of the body not scheduled to receive radiation.

At that time, it was reported that on July 11, 1992, cobalt-60 teletherapy treatments of 200 centigray (cGy) (200 rad) each were to be administered to the right axilla (armpit) of a patient.

The AO report is updated and closed out as follows:

A 65-year-old patient undergoing a cobalt-60 teletherapy treatment was prescribed to receive a dose of 3600 cGy (3600 rad) to the right axilla in 18 fractions of 200 cGy (200 rad) per fraction and two fields (anterior and posterior) per fraction at a rate of 5 fractions per week. This course was to be followed by a booster dose of 400 cGy (400 rad) 2 days following the end of the fractionated-course of treatment.

During the course of simulation, the attending radiation oncologist was called from the room for an emergency case. During simulation the technologist accidentally photographed the wrong side of the patient, namely the left axilla instead of the right axilla as prescribed. The attending radiation oncologist subsequently reviewed the simulation films, which were incorrectly marked as "right side," and approved them without recognizing the error. The port films taken at the initial patient set-up prior to therapy were correctly marked "left side," but were not recognized as the wrong treatment site by the attending oncologist.

The patient was treated for five fractions of 200 cGy (200 rad) each for one week by three different technologists, and received a total dose of 1000 cGy (1000 rad) before the error was discovered. Upon discovery, the treatment was discontinued, the patient was correctly resimulated, and the treatment was administered as prescribed. Both the patient and the patient's physician were informed of the event and the patient was told that there would be no adverse effects. The patient verbally indicated that he understood. The patient was followed clinically by the licensee and there have been no adverse effects to date. A medical

consultant was not involved.

The underlying causes of the event are as follows: (1) while the attending radiation oncologist was absent, the simulation technologist did not follow the initial prescription which was correct, and incorrectly set up the patient for treatment; (2) the attending radiation oncologist approved the incorrectly marked films without recognizing the error; (3) the patient was incorrectly set up for initial treatment based on erroneous simulator films; (4) the portal films taken at the time of set up were marked correctly, but the simulation error remained undetected by the personnel involved; and (5) an independent verification of the correct treatment site was not performed by the three different technologists who treated the patient although they entered the treatment site as "right axilla" in the treatment chart.

To prevent recurrence, the licensee took the following corrective actions: (1) the internal procedures were amended to require the presence of the attending radiation oncologist throughout the simulation procedure, and to require unambiguous marking of the simulator films; (2) the senior technologist was required to independently verify the correct patient, set-up, dose, and treatment parameters before initiating treatment; and (3) the personnel involved were reprimanded and counseled.

The City of New York concurred with the licensee's evaluation of the event and corrective actions.

This event is closed for the purpose of this report.

Other Agency Action:

Insufficient information is available on the action(s) taken by the State Agency to prevent recurrence. NRC has asked the State of New York to provide additional information regarding the action(s) taken to prevent recurrence. The State was also asked to verify that the referring physician and patient were notified.

As of February 3, 1994, it was known that the State of New York informed NRC that it will provide the requested information on the likelihood of harmful effects to the patients within 30 days.

The event will be further evaluated when additional information becomes available.

Criteria:

Appendix A (see Event Type 3 in Table A-1) of this report notes that administering a therapeutic dose to a part of the body not scheduled to receive radiation should be considered an abnormal occurrence.

ITEM #: 940958 AO #: NRC 93-11 EVENT DATE: 01/07/1993
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT WASHINGTON UNIVERSITY MEDICAL SCHOOL IN ST. LOUIS, MISSOURI
NAME: Washington University Medical School CITY: St. Louis STATE: MO

Nature and Probable Consequences:

On January 7, 1993, a Nucletron Micro-Selectron low-dose-rate (LDR) remote afterloader unit ejected a radioactive source without being programmed to do so and without a guide tube and applicator attached to the channel. The unguided source lay at an approximate distance of 3 centimeters (cm) (1.2 inches [in]) from the nearest skin surface for approximately 5 minutes. The licensee estimated that less than 0.1 centigray (cGy)(0.1 rad) of additional dose was delivered to the skin surface.

On February 26, 1993, a very similar incident occurred at the same facility. The incident involved a different patient and the same remote afterloader unit. The device again ejected the same strength and type of radioactive source without being programmed to do so. However, in this case, the source lay near the patient's leg for approximately 60 to 75 minutes, at an approximate distance of 5 cm (2 in) from the nearest skin surface. The licensee estimated the additional dose to the patient's leg to be approximately 3.5 cGy (3.5 rad).

In both cases, the treatment of each patient was completed on another LDR remote afterloader unit in another room of the medical center.

Cause:

After the first incident on January 7, 1993, a manufacturer service engineer, who studied the device malfunction, was unable to identify the cause of the failure during his repair visit. The licensee's staff subsequently tested the device for 20 hours without discovering the cause of the failure, and concluded that the device was acceptable for use. This decision was based on the fact that they could not reproduce the malfunction. The remote afterloader was put back into service. On February 26, 1993, the device failed again when a second unprogrammed source was ejected by the afterloader. After this incident, which resulted in the second misadministration, the manufacturer provided a different field engineer who correctly diagnosed the problem as a failure in an operational amplifier.

A previous recommendation made by the manufacturer to store unused sources in the auxiliary storage safe, instead of the remote afterloader's mobile storage container, may have contributed to the incident. The second field engineer indicated that some of the safety features which prevent sources from being erroneously ejected were not in effect or were not monitored by the device for unprogrammed channels containing the unused sources.

Licensee Action:

The licensee informed the NRC that use of the two Micro-Selectron-LDR remote afterloader units will be discontinued and a new model LDR afterloader will be installed. NRC has also asked the licensee to address the manufacturer's recommendation for storing the sources and the removal of some of safety features, and any resulting corrective actions.

NRC Action:

The vendor has not revised the device's operating software to monitor and generate error messages and audible alarms for unprogrammed (unused) channels. The NRC has sent a letter (Ref. 1) to the licensee requesting that the licensee ensure the required notifications to the referring physicians and patients have been made.

During an NRC safety inspection conducted from November 15 to 18, 1993, the inspectors focused on these two incidents in addition to other inspection areas. The result of this inspection are still under review.

This report will be further evaluated when additional information becomes available.

UPDATE: from NUREG-0900, Vol. 17, No. 3, page 14. This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 4, "Report to Congress on Abnormal Occurrence," October-December 1993.

The AO criterion used was Event Type 3 in Table A-1-A therapeutic dose that results in any part of the body receiving unscheduled radiation.

At that time, it was reported that in two separate incidents in January and February 1993, a Nucletron Micro-Selectron low-dose-rate remote afterloader ejected a radiation source without being programmed to do so and without a guide tube and applicator. In each instance, the source lay close to the patients' skin and resulted in a portion of the patient's body receiving an unscheduled radiation dose.

The AO report is updated as follows:

On June 10, 1994, NRC Region III issued a Notice of Violation (NOV)(Ref. 2) to the licensee, citing it for failing to provide written notifications to the patient of the misadministration within 15 days, as required. The licensee had notified the referring physician but the written patient notifications were not made until May 1994. There was no civil penalty associated with the NOV.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

ITEM #: 940098 AO #: NRC 93-12 EVENT DATE: 10/15/1993
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MERCY HOSPITAL IN SCRANTON, PENNSYLVANIA
NAME: Mercy Hospital CITY: Scranton STATE: PA

Nature and Probable Consequences:

On October 15, 1993, Mercy Hospital in Scranton, Pennsylvania, notified NRC Region I of a therapeutic misadministration involving a Nucletron MicroSelectron high dose rate (HDR) remote afterloader which occurred at the facility on April 23, 1993. The licensee identified this misadministration during a review of the past treatment records.

A patient was scheduled to receive brachytherapy treatment to the apex of her vagina in three fractions using a Nucletron Micro Selectron HDR remote afterloader. The prescribed dose was 500 centigray (cGy) (rad) for each fraction and the use of a ring applicator was specified. On April 13, 1993, the patient was administered the first fractional treatment. After an examination of patient following the first treatment, the physician revised the written directive and prescribed a change from the ring applicator to standard vaginal cylindrical applicator for the remaining two treatments. On April 23, 1993, during the administration of the second treatment, the therapist erroneously entered the catheter length of 920 millimeter (mm) (36.2 inch) into the treatment computer instead of the intended 992 mm (39.1 inch). The physician failed to identify this error during his review of the treatment parameters prior to the initiation of the treatment.

As a result of this erroneous entry, a majority of the treatment dose was administered to an unintended region near the opening of the vagina, and the intended site received an underdose differing from the prescribed dose by more than 20 percent. The physician stated that no adverse clinical effects are expected as a result of the underdose to the target site because this treatment was intended to administer a booster radiation dose. The oncologist also stated that the patient is not expected to experience any adverse effects as a result of the 500 cGy (500 rad) overexposure to the wrong treatment site misadministration. The NRC medical consultant, in his report to Region I, also stated a similar opinion (that it is unlikely the patient will suffer any adverse effects from the misadministration).

The third fraction of the treatment was administered to the patient on April 29, 1993, as prescribed.

The referring physician and the patient have been notified. The licensee submitted a written report of the misadministration to NRC Region I on October 29, 1993.

Cause:

The therapist did not enter the correct catheter length during initial setup for the second treatment. The licensee followed established procedures, however, the procedure did not require verification of all parameters at the time of the second check prior to each treatment.

Licensee Action:

The licensee has instituted a requirement that a medical physicist also review the final treatment plan prior to initiating the treatment. The treatment parameters for all brachytherapy (HDR) treatments will be transferred electronically to the magnetic card directly from the simulator. The output of this card will be reviewed by the medical physicist and the oncologist before the initiation of the treatment.

NRC Action:

Region I conducted a special inspection at Mercy Hospital on October 19, 1993. Inspection Report No. 030-02983/93-001, issued November 5, 1993, identified two apparent violations: (1) failure to require supervised individual to follow written quality management procedures (QMP) 10 CFR 35.25 (a)(2); (2) failure to include policies and procedures in the QMP to meet the objective that each administration is in accordance with the written directive 10 CFR 35.32(a). After receipt and review of the medical consultant's report, Region I issued a Notice of Violation to the licensee on February 9, 1994, classifying the two violations at Severity Level IV in accordance with the NRC Enforcement Policy.

An NRC medical consultant has been retained to review this misadministration. The medical consultant's report (Ref. 3) was received by Region I on February 3, 1994. The medical consultant questioned the licensee concerning its identification of a radiation oncologist as the referring physician. After discussion with the NRC's medical consultant, the licensee identified the patient's physician as the primary referring physician and then agreed to notify the physician. Following a review of the medical consultant's report, Region I confirmed in a telephone conversation that the licensee had contacted the patient's physician regarding the misadministration. The licensee stated that both referring physicians have been notified of this misadministration. The radiation oncologist had discussed the misadministration with the patient on October 21, 1993.

This item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

ITEM #: 940616 AO #: NRC 93-13 EVENT DATE: 07/01/1993
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MOUNTAINSIDE HOSPITAL IN MONTCLAIR, NEW JERSEY
NAME: Mountainside Hospital CITY: Montclair STATE: NJ

Nature and Probable Consequences:

On December 1, 1993, during a routine inspection, NRC identified a therapeutic misadministration involving a high-dose-rate (HDR) remote afterloader, which occurred at the Mountainside Hospital in Montclair, New Jersey, on July 1, 1993. NRC identified the misadministration while reviewing the licensee's Radiation Safety Committee (RSC) meeting minutes for 1993.

On July 1, 1993, a patient was scheduled to receive the last of three brachytherapy treatments to the right mainstem bronchus. Each fraction was to deliver 750 centigray (cGy) (750 rad) to the target using a Nucletron Micro-Selectron HDR remote afterloader and an intrabronchial catheter. During the July 1, 1993 treatment, the radiation oncologist mistakenly connected the catheter to the HDR afterloader with a 750 mm (29.5 inch) transfer tube instead of a short connector. This prevented the source from entering intrabronchial catheter, and while delivering a negligible dose to the tumor, the face, and the lenses of the eyes, the thyroid, and whole body of the patient received unscheduled exposure.

The source strength at the time of the incident was 161,000 megabecquerel (4.35 curie) of iridium-192 and the exposure time was 445.5 seconds. Following the reconstruction of the incident by the licensee, the surface dose to the lens of the left eye was determined by the licensee to be 1.97 cGy (1.97 rad), the dose to the chin (the closest surface of the body) was 4.56 cGy (4.56 rad), and the dose to the thyroid was 3.07 cGy (3.07 rad). The physician identified the error upon termination of the treatment and wrote a memorandum about the incident to the hospital's physicist and radiation safety officer (RSO).

The physician mistakenly determined that the incident was not a misadministration, and so advised the RSO. The RSO, relying on the physician's judgment, did not notify NRC and filed the report in the RSC minutes folder. The radiation oncologist decided against making up the missed third fraction of therapy.

On December 3, 1993, NRC notified the licensee by telephone that the event constituted a misadministration and the licensee notified the NRC Operations Center on the same day. The licensee's written report of the misadministration, dated December 1, 1993, was received in the NRC Region I office on December 17, 1993.

After review of the report, Region I called the licensee to determine if the referring physician and the patient were notified of the misadministration. The licensee forwarded a copy of a letter dated December 20, 1993, from the radiation oncologist to the referring physician confirming a December 6, 1993, telephone conversation in which the referring physician was informed of the misadministration. The letter indicated that the referring physician did not feel it would be in the patient's best interest to be notified of the misadministration.

NRC contacted a medical consultant to determine the significance of the misadministration to the patient. The medical consultant's report was received by Region I on February 3, 1994. The consultant's calculations of doses to the lens of the left eye, the chin, and the thyroid of the patient agreed with the licensee's estimates, based on the strength of the source, the time of exposure and the distances of the source from the patient. The consultant concluded that the patient would not suffer any adverse effects from the misadministration. The medical consultant also determined that the oncologist failed to notify the patient of the misadministration because he did not fully understand the requirements of 10 CFR 35.33(a)(3). After discussions with the consultant, the referring physician agreed to inform the patient of the misadministration.

Cause:

An error by the attending physician in connecting the catheter to the HDR remote afterloader, and the failure of the console operator to recognize the faulty connection were the direct causes of the event. Both individuals relied on the treatment computer to indicate any problems with the therapy setup. The computer on a Nucletron HDR is not designed to alert the user to an incorrect connection of a longer transfer tube.

In addition, the medical consultant's report indicated that the second individual observing the transfer tube connection during each treatment setup was a different console operator. Since the console operator in attendance during the third treatment had not been present during the prior treatments, he/she was unaware of the intended setup.

Licensee Action:

The licensee arranged for additional training by Nucletron on July 30, 1993. The training was attended by both HDR remote afterloader units authorized users and by three technologist-console operators.

NRC Action:

NRC is reviewing the licensee's December 17, 1993 misadministration report (Ref. 4) and the findings of the December 1, 1993 NRC inspection. An NRC medical consultant was retained to review the misadministration.

The medical consultant's report dated February 1, 1994, was received by the NRC Region I office on February 3, 1994. In addition,

to the comment made in the above sections, the consultant indicated that if the licensee had required a medical physicist to be present during every setup and treatment as recommended NRC Bulletin 93-01, it is likely that this misadministration would not have occurred. In the consultant's opinion, a medical physicist would have been more likely to have noticed the human error in set up of the third HDR treatment.

An enforcement conference has been scheduled.

This report will be further updated when additional information becomes available.

UPDATE: from NUREG-0090, Vol. 17, No. 1, page 16. This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 4, "Report to Congress on Abnormal Occurrences," October-December 1993. The information pertaining to this abnormal occurrence is updated as follows.

On July 1, 1993, a patient was administered a therapeutic dose to a part of the body not scheduled to receive exposure. The patient was prescribed 3 brachytherapy treatments of 700 centigray (cGy) (700 rad) to the right mainstem bronchus using a Nucletron Micro-Selectron HDR remote afterloader. During the last treatment, a longer than required catheter was used preventing the source from reaching the target site. It also resulted in a surface dose to the lens of the eyes of 1.97 cGy (1.97 rad), a dose to the chin of 4.56 cGy (4.56 rad), and dose to the thyroid of 3.07 cGy (3.07 rad).

Actions taken by the NRC include the following activities: (1) a special safety inspection, limited to gathering additional information on the licensee's Quality Management program, was performed on March 8, 1994; (2) an open Enforcement Conference to discuss the apparent violations identified in the December 1, 1993, and March 8, 1994, inspections, its cause and the licensee's corrective actions held on March 11, 1994; and (3) a Notice of Violation was issued to the licensee on March 31, 1994. The licensee responded to the Notice of Violation and has admitted to three of the violations. The NRC is evaluating the licensee's denial of a fourth violation.

This report will be further updated when additional information becomes available.

UPDATE: from NUREG-0090, Vol. 17, No. 2, page 20. This abnormal occurrence (AO) was originally reported in NUREG-0090, Vol. 16, No. 4, "Report to Congress on Abnormal Occurrences," October-December 1993. At that time it was reported that on December 1, 1993, during a routine inspection, NRC identified a therapeutic misadministration involving a high dose rate remote afterloader which occurred on July 1, 1993. Because of an error in selecting the wrong transfer tube, the source delivered a negligible dose to the tumor but exposed the face, the lenses of the eyes, the thyroid, and the whole body to unscheduled radiation. The event was reported as an AO because it involved a therapeutic dose that resulted in a part of the body receiving unscheduled radiation.

The AO report is updated as follows:

NRC conducted a special safety inspection limited to gathering additional information on the licensee's Quality Management Program (QMP) on March 8, 1994. An Open Enforcement Conference to discuss the apparent violations identified in the December 1, 1993, and the March 8, 1994, inspections, their causes, and the licensee's corrective actions was held on March 11, 1994. After consideration of the information presented by the licensee, a Notice of Violation (NOV) was issued to the licensee on March 31, 1994. The licensee has 30 days to respond to the NOV.

The licensee responded with corrective actions by letter dated April 21, 1994. The licensee admitted three of the violations and presented corrective actions acceptable to NRC. The licensee denied a fourth violation of Part 35.32(a) of Title 10 of the Code of Federal Regulations, which involved establishment of a QMP having written policy and procedures requiring that the final treatment plan and related calculations be done in compliance with the written directive. However, the licensee did present modifications to the QMP to ensure an independent verification of patient treatment setup in the future. NRC is evaluating the licensee's response.

This item is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

ITEM #: 941775 AO #: NRC 93-14 EVENT DATE: 12/02/1991
TITLE: EXPOSURE TO A NURSING INFANT AT QUEEN'S HOSPITAL IN HONOLULU, HAWAII
NAME: Queen's Medical Center CITY: Honolulu STATE: HI

Nature and Probable Consequences:

On October 25, 1993, during a routine safety inspection, a Region V inspector discovered an unreported unscheduled exposure the thyroid of a 9-month-old nursing infant. On December 2, 1991, a patient was administered 0.56 megabecquerel (15 microcuries) of iodine-131 for a diagnostic scan. Although the patient noted on a hospital form that she was breast-feeding, the technologist failed to notice this notation until the patient returned for a scan the following day. The patient was informed of the oversight by the licensee and was instructed to stop breast-feeding. The authorized user and the referring physician were also notified on December 3, 1991.

The licensee's Radiation Safety Officer calculated the infant's absorbed thyroid dose to be approximately 250 millisievert (mSv rem) based on information obtained during an uptake scan of the mother 6 hours after the administration.

The NRC retained a medical consultant to evaluate the circumstances of this misadministration. The consultant estimated the dose to the infant's thyroid to be between 160 to 650 mSv (16 to 65 rem). The medical consultant concluded that the infant is not likely to experience any adverse effects as a result of this misadministration.

Cause:

Failure of a supervised technologist to adequately review the hospital form used to inform the hospital staff that a patient is pregnant or breast-feeding as he/she was instructed by the authorized user.

Licensee Action:

The screening procedure used to inform the hospital staff that a patient is pregnant or breast-feeding was incorporated into the clinical procedure manual. It was reviewed by each of the technologists, and it will be reviewed by all new technologists upon being hired. It will also be reviewed annually during a radiation safety training course.

NRC Action:

NRC conducted inspections on September 18 and October 25-27, 1993. The December 2, 1991 misadministration was noted and reviewed during these inspections. A number of violations were identified as a result of these inspections and escalated enforcement actions are being considered. An NRC medical consultant was also retained to review the case.

This report will be further updated when additional information becomes available.

UPDATE: from NUREG-0900, Vol. 17, No. 1, Page 16. This abnormal occurrence was originally reported in NUREG-0090, Vol. 14, No. 4, "Report to Congress on Abnormal Occurrence," October-December 1993. The information pertaining to this abnormal occurrence is updated as follows.

On December 2, 1991, a breast-feeding patient was administered 0.56 megabecquerel (15 microcurie) of iodine-131 for a diagnostic scan, because the technologist failed to notice the notation on a hospital form that the patient was breast-feeding. As a result, her infant received an absorbed thyroid dose in the range of 160 to 650 millisievert (16 to 65 rem).

An NRC inspection was conducted on September 28, and October 25 to 27, 1993. This incident was discussed during the inspection. On December 29, 1993, a Notice of Violation was issued because the technician administered a dose to a breast-feeding mother in violation of the licensee's procedures. This item was classified as a Severity Level IV item and no Civil Penalty was imposed.

The licensee responded to the Notice of Violation on January 25, 1995. The licensee stated that the Radiation Safety Officer reminded the staff in a memorandum, dated November 19, 1993, to be diligent in the breast-feeding screening procedure. Further, the procedure has been documented and reviewed by each technologist. The procedure was also incorporated in the clinical procedure manual and will be reviewed at the annual safety inservice training.

NRC accepted the licensee's response to this item in a letter dated February 10, 1994.

This event is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see General Criterion 1) of this report notes that a moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission can be considered an abnormal occurrence.

ITEM #: 940072 AO #: NRC 93-15 EVENT DATE: 11/10/1993
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT GOOD SAMARITAN MEDICAL CENTER IN ZANESVILLE, OHIO
NAME: Good Samaritan Hospital CITY: Zanesville STATE: OH

Nature and Probable Consequences:

A patient was being treated for lung cancer. The treatment included performing an iridium-192 therapeutic implant. The prescribed treatment dose was 6000 rad to the patient's lung. On November 10, 1993, a catheter was surgically implanted in the patient. Iridium-192 seeds, contained in a ribbon, were inserted into the catheter.

Following normal licensee procedure, the physicist requested that the attending nurse order a "stat" chest x-ray in order to verify source position. The "stat" radiograph was completed and two hours later upon review of the film, the seed positions could not be visualized. Two additional radiographs using different techniques were done. In the second radiograph, completed one hour later, the seeds were located in the patient's throat. The ribbon was removed and the physician successfully reinserted the ribbon to its proper location. Another radiograph was done to verify the source location. The treatment time was recalculated to deliver the original intended dose and the treatment was completed without further difficulty.

The sources were in the improper location for about three hours, delivering an estimated dose to the larynx area of about 282 centigray (282 rad). An NRC medical consultant evaluated the medical aspects of the brachytherapy misadministration and concluded that the dose to the larynx and surrounding area is not clinically significant.

The physician verbally notified the patient of the misadministration following the successful reinsertion of the source ribbon. A written report was provided to the patient on November 15, 1993.

Cause:

The immediate cause of the misadministration was an apparent crimp in the catheter which resulted in the seeds not being placed correctly. The seeds were blocked by the crimp at the level of the patient's larynx.

An inexperienced radiation therapy technician implanted the source. During interviews, the physician stated that it would be difficult for an inexperienced person to know the difference between a properly seated ribbon and when ribbon insertion was impeded by a crimp in the catheter.

Licensee Action:

The licensee's plan for preventing recurrence of the misadministration included: (1) formalizing the dosimetrist's "rule of Practice" regarding comparison of the ribbon and catheter lengths prior to source implantation in order to ensure that the ribbon is properly seated; (2) providing training to all radiation therapy technologists and each medical physicist in the new procedure; (3) requiring that the authorized user physically implant source ribbons; (4) requiring that each radiation therapy technologist receive hands-on training and instruction in source implantation; and (5) requiring that the "stat" post-insertion radiograph be hand carried to the prescribing physician for evaluation as soon as possible to determine proper source placement.

NRC Action:

A special safety inspection was conducted by NRC Region III on January 19, 1994 to review the circumstances surrounding this misadministration. An NRC medical consultant was also retained to review this case. Based on the results of the special inspection (Ref. 2), NRC identified an apparent violation that is being considered for escalated enforcement action.

This report will be further evaluated when additional information becomes available.

UPDATE: from NUREG-0900, Vol. 17, No. 1, page 17. This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 4, "Report to Congress on Abnormal Occurrences," October-December 1993. The information relating to this abnormal occurrence is updated as follows.

A therapeutic misadministration occurred November 10, 1993, at Good Samaritan Hospital in Zanesville, Ohio, when a crimp in the catheter prevented iridium-192 seeds contained in a ribbon from being fully inserted to the treatment position. As a result, the patient's throat area received an unintended radiation exposure. The seeds were subsequently placed in their correct position to deliver the intended dose to the patient's lung.

An NRC inspection on January 19, 1994, identified three violations associated with this misadministration. These violations were (1) failure to instruct the medical technologist and medical physicist in proper implanting procedure; (2) failure to review radiograph to confirm the source location until three hours after the implant; and (3) failure to provide the required radiation safety instruction. A Notice of Violation was issued on February 28, 1994, but no Civil Penalty was proposed.

This event is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

ITEM #: 940036 AO #: NRC 93-16 EVENT DATE: 11/17/1993
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MARQUETTE GENERAL HOSPITAL IN MARQUETTE, MICHIGAN
NAME: Marquette General Hospital CITY: Marquette STATE: MI

Nature and Probable Consequences:

On November 17, 1993, a patient was undergoing a brachytherapy procedure using cesium-137 sealed sources placed in a treatment device (catheter) inserted into the patient's uterus. When the catheter was removed on November 19, it was observed that it was too short to have been fully inserted into the uterine cavity. The three sources in the catheter had actually been in the patient's vagina instead of the uterus.

The case was evaluated by an NRC medical consultant who concluded that the lower vagina received a radiation dose of 2,700 centigray (2,700 rad) when it would not have received a significant dose if the treatment had been performed as planned. The medical consultant concluded that the radiation doses to the vagina would not be expected to cause any acute or long term effects because the vaginal tissue is extraordinarily tolerant of radiation.

This placement error did not result in additional exposure to other organs.

The intended treatment area received about 50 percent of the intended dose. Subsequently, the patient received an additional dose to the uterus to complete the prescribed treatment. The licensee informed the patient of the treatment error.

Cause:

The hospital routinely uses two lengths of catheters for brachytherapy treatments, a shorter catheter for vaginal procedures and longer on for uterine procedures. The medical physicist inadvertently placed the cesium-137 sources in the shorter (vaginal) catheter instead of the required long catheter for the uterine procedure prescribed.

Licensee Action:

The hospital has revised its procedures to include added precautions for assuring the correct length catheter is used in each brachytherapy procedure.

NRC Action:

The NRC conducted a special inspection beginning November 29, 1993, to review the circumstances surrounding the misadministration. No violations of NRC regulations were identified, but the licensee was directed to review its Quality Management Program to determine what modifications were needed to prevent similar misadministrations in the future. The NRC also retained a medical consultant to evaluate this case.

This report will be further updated when additional information becomes available.

UPDATE: from NUREG-0900, Vol. 17, No. 3, page 14. This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 4, "Report to Congress on Abnormal Occurrence," October-December 1993.

The AO criterion used was Event Type 3 in Table A-1-A therapeutic dose that results in any part of the body receiving unscheduled radiation.

At the time, it was reported that a patient underwent a brachytherapy procedure using a cesium-137 sealed sources in a catheter inserted into the uterus from November 17 to 19, 1993. When the catheter was removed on November 19, it was determined that it had not been fully inserted into the uterus and that the patient's vagina received an unintended radiation dose.

The abnormal occurrence is updated as follows:

On May 16, 1994, NRC Region III issued a Notice of Violation (Ref. 3) to the hospital, citing it for failing to provide written notification to the patient of the misadministration within 15 days, as required. The patient was informed orally of the misadministration at the time it was discovered, but was not provided with written notification until April 27, 1994. No fine was assessed.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

ITEM #: 940953 AO #: AS 93-10 EVENT DATE: 02/07/1993
TITLE: THEFT OF RADIOACTIVE MATERIAL DURING TRANSPORT AND IMPROPER DISPOSAL
NAME: Missouri and Illinois CITY: STATE: IL

Nature and Probable Consequences:

This event involved the diversion of nuclear medicine generators from the transportation stream by an employee of a courier service who delivers them to hospitals and picks them up for return to the manufacturer. They were apparently stolen in order to reclaim the lead shielding as scrap metal. The generator internals were burned in an open barrel in a residential area and the ashes were often discarded in rural wooded areas. The practice had gone on for several years before authorities became aware that it was occurring. The details are as follows:

On February 7, 1993, local police in Bunker Hill, Illinois, reported the discovery in a public park of medical vials that appeared to have contained radioactive material. Investigation by the Illinois Department of Nuclear Safety (Department) revealed that the material was partially burnt glassware and saline vials from several nuclear medicine generators. Surveys revealed that some of the items were contaminated with radioactive material.

Further investigation revealed that a resident of Bunker Hill worked for a courier service in St. Louis, Missouri, and delivered and picked up packages containing radioactive material at area hospitals. The same resident, and his landlord, had been approached by local law enforcement officials on several occasions to cease burning in a steel drum next to his residence. An examination of the grounds around his apartment building revealed other glassware similar to that found in the city park. Several attempts by Department personnel and local police to interview this individual were unsuccessful and on February 22, the Department was informed that the individual had passed away the day before from natural causes. The individual's daughter was contacted by name and was asked to allow the Department to perform surveys for radioactive contamination in the residence she and her husband shared with her father and her small children. She did not respond to the request.

Several months before these events, a resident of the rural Alton, Illinois, area, reported to the Department the discovery of a stainless steel cylinder that bore the marking "radioactive" along with "Union Carbide, Tuxedo, NY." At the time, the purpose of the cylinder was not known, but other markings indicated that it contained depleted uranium for shielding. During March and April of 1993, several more cylinders were reported by citizens in the rural Alton area. Some of these cylinders bore the marking "Cintichem" instead of "Union Carbide," were otherwise identical. When contacted, Cintichem personnel stated they had reported to their courier that 29 uranium-shielded generators, enroute to New York from pharmacies and hospitals throughout the country had not arrived. All of these generators were apparently part of a weekly shipment of such generators by the same courier service in St. Louis for whom the deceased Bunker Hill resident had worked.

At this point, the Department requested the Illinois State Police to assist in the investigation. The State Police investigator interviewed the daughter and son-in-law of the deceased individual and discovered that the individual had been stealing nuclear medicine generators for several years in order to reclaim the lead and to sell it to a local metal recycler. The daughter and son-in-law said that the generators' accessories were burned in a steel drum on the grounds of the apartment building in which they lived and that the ashes were usually dumped in rural wooded areas. The individual in question had assumed that the uranium-shielded generators also contained lead shielding and had stolen an entire palette of them while they were awaiting transport back to New York.

The daughter and son-in-law also stated that the scrap yard had originally accepted the uranium shields until they discovered the "Radioactive" markings. The recycler then made the individual retrieve the shields from the facility. After taking back the shields, the deceased individual, along with his daughter and son-in-law, discarded the shields in the wooded and low-lying areas along rural roads between the scrap yard and their residence in Bunker Hill. The daughter and son-in-law identified locations where they recalled discarding the shields.

On May 6, and 7, 1993, Department staff along with State Police personnel performed radiation detectors and metal detector surveys in the areas where the shields were known to have been discarded. That search, along with previous discoveries by citizens, allowed the recovery of approximately half of the 29 missing uranium shields. The shields were retrieved by the courier company for transport back to New York. The search was suspended until the water level in the creeks had dropped to a level that allowed the creek beds to be searched.

Although the risk to the general public from this prolonged diversion of radioactive material is not significant, the radiation exposure to the deceased individual could have been significant due to his direct contact with the generators. The individual apparently believed that, since the hospitals could no longer use the generators, there was not radioactive material left in them. However, an estimate of his exposure could be made without more information. The daughter and son-in-law stated that the material was never stored or processed in their apartment, so no contamination or related exposure to minor children would have occurred.

The findings of the investigation did reveal accountability problems in the current method for returning used generators. In the case of lead-shielded generators used in community hospitals, once a return authorization is issued by the manufacturers, no mechanism exists to confirm that they have arrived. In the case of the uranium-shielded generators, the inherent value of \$1800 the uranium shield caused each one to have a serial number etched on it along with the other required markings. These generators were known to be missing during the fall of 1992. The individual was able to cover up the thefts by removing the bills of lading from the shipping documents and destroying them so the courier service had no record that the packages existed.

Since the courier service operated in Missouri, the Department could not compel it to implement any corrective action. Additionally, the U.S. Nuclear Regulatory Commission apparently has no jurisdiction over these transportation activities. Jurisdiction resides with the U.S. Department of Transportation, but no violation of Title 49 of the Code of Federal Regulations (49 CFR) appears to have been committed by the courier service. Legal action could not be pursued against the individual since he is deceased.

Cause:

The cause of the incident was criminal theft of radioactive material from the transportation stream. The failure to detect the theft in a timely manner was due to inadequate accountability of packages in the return process.

Licensee Action:

No licensee was directly involved in this incident. The individual responsible for the occurrence died from natural causes before legal action could be taken.

NRC Action:

No federal regulations were violated. The radiation levels involved were low and represented a very small risk to the public's health and safety. Extended and repeated exposure to low level radiation and the possible inhalation from burning the vials could have adverse effects to those directly involved in the theft and destruction of the generator remains but there was no indication of such effects. No NRC actions were taken.

This item is considered closed for purposes of this report.

Other Agency Action:

No violation of the Illinois Administrative Code or the Code of Federal Regulations had occurred. The Illinois Department of Nuclear Safety could have issued an order against the individual to cease the diversion or pursued criminal action with the cooperation of the State Police, but he died before such action could be taken. The Department could not compel a courier operating in Missouri to take corrective action when no violation of regulations could be identified on the courier's part.

Criteria:

Appendix A (see Example 6 of "For All Licensees") of this report notes that a substantiated case of actual or attempted theft or diversion of licensed material should be considered as an abnormal occurrence.

ITEM #: 940952 AO #: AS 93-11 EVENT DATE: 03/24/1993
TITLE: FOUND SOURCE AT SCRAP METAL FACILITY IN MAGNOLIA, ARKANSAS
NAME: Tallman Scrap Yard CITY: Magnolia STATE: AR

Nature and Probable Consequences:

On March 24, 1993, approximately 4:15 p.m., an employee with TN Technologies notified the State by phone that a cesium-137 (Cs-137) source had been located at Tillman Scrap Yard in Magnolia, Arkansas.

The source was described as a Texas Nuclear Model 5176 source holder, Serial Number 82656, containing 148 gigabecquerel (curies) of Cs-137. The source was distributed under TN Technologies general license.

A TN Technologies Project Engineer traced the serial number to Elk Roofing Plant in Stevens, Arkansas. This facility has been sold to Lapry Paper Company.

Upon completion of the phone call, the State Health Physicist called Tillman Scrap Yard to ensure that the source was located in an area away from the general public and personnel working in the scrap yard. An employee with Tillman Scrap Yard informed the State that the source had been placed in a metal bin and moved to the back of the scrap yard. The scrap yard employee was instructed to keep everyone away from the source and was given assurance that the State would be responding as soon as possible.

A team was dispatched to the Tillman Scrap Yard where they immediately went to the area where the source was located. The source had been placed in a metal scrap bin for relocation to the back of the yard. The source and the detector were mounted to a piece of pipe. A swipe was taken on the surface of the source holder to determine if the sealed source had been damaged in any way. No contamination was detected.

The source was then removed from the bin. The shutter was found to be padlocked in the open position. The padlock was cut away and the shutter was secured in the closed position. The mounting bolts were also removed isolating the source from the associated equipment.

The source was packed in a 133-liter (35-gallon) drum and labeled as a Yellow-II package. The radiation readings on contact were 0.23 microcoulomb per kilogram per hour (C/kg/hr) (0.9 milliroentgen per hour [mR/hr]) and at 1 meter (3.3 feet) 0.015 C/kg/hr (0.06 mR/hr). The source was removed from the affected area. A contamination survey of the entire work area was carried out. No contamination was found. The area was released for unrestricted use.

After several discussions with the lawyers of Elk Roofing Company and Lapry Paper Company, it was decided that Elk Roofing Company would pay for the final disposal of the gauge. A representative from TN Technologies came to the department on April 26, 1993, and took final possession of the device.

Cause:

Insufficient information is available to determine the cause(s) of this event. NRC has asked the State of Arkansas to provide any additional information regarding the cause(s) of this event.

Licensee Action:

Insufficient information is available on the action(s) taken by the licensee to prevent recurrence. NRC has asked the State of Arkansas to identify any licensee action(s).

NRC Action:

Other Agency Action:

Insufficient information is available on the action(s) taken by the State Agency to prevent recurrence. NRC has asked the State of Arkansas to provide additional information regarding the State Agency's action(s).

This report will be further evaluated when additional information becomes available.

UPDATE: from NUREG-0900, Vol. 17, No. 2, page 22. This abnormal occurrence (AO) was originally reported in NUREG-0090 Vol. 16, No. 4, "Report to Congress on Abnormal Occurrences, October-December 1993." At that time it was reported that on March 24, 1993, a cesium-137 source was found at the Tillman Scrap Yard in Magnolia, Arkansas. The source had an activity of 148 gigabecquerel (4 curie), and was part of a Texas Nuclear Model 5176 gauge. The event was reported as an AO because it involved the loss of licensed material in such quantities and under such circumstances that substantial hazard may result to persons in unrestricted areas.

It was determined that the owner of the source was the Elk roofing Company of Stevens, Arkansas, and that Elk Roofing Company would pay for the final disposal of the source by Texas Nuclear who manufactured the Model 5176 gauge. The Model 5176 gauge and its source were properly disposed of by Texas Nuclear. This item is considered closed for the purpose of this report.

Criteria:

Appendix A (see Example 5 of "For All Licensees") of this report notes that any loss of licensed material in such quantities and under such circumstances that substantial hazard may result to persons in unrestricted areas should be considered an abnormal occurrence.

ITEM #: 940802 AO #: AS 93-12 EVENT DATE: 07/08/1993
TITLE: MEDICAL TELETHAPY MISADMINISTRATION AT ROCKY MOUNTAIN GAMMA KNIFE CENTER, DENVER, COLORADO
NAME: Rocky Mountain Gamma Knife Limited Liability Co. CITY: Denver STATE: CO

Nature and Probable Consequences:

A patient was admitted on July 8, 1993, for treatment of a longstanding arteriovenous malformation (AVM) in the left posterior du of the brain. The patient was taken to the special procedures room in the radiology department of the hospital where a series of lateral and posterior/anterior (P/A) angiograms were performed. These were used to identify the AVM targets. The films were given to the physicist who optically scanned them into the computer planning system. Concurrently, the patient was taken to Magnetic Resonance Imaging (MRI) where a series of scans was performed.

The physicist and neurosurgeon worked to complete the dose planning function, however, several anomalous events were note during the process: (1) during the "definition process," the screen showed a sudden "floating point error" message. This was described as serious but the cause of the message was not known; (2) the definition program in the Leksell Gamma Plan (LGP) refused to accept on at least two occasions the "correct" orientation of the image, as viewed by the physicist and neurosurgeon. Eventually, the neurosurgeon and physicist had to instruct the LGP to accept the image they knew to be intuitively correct, but which the computer had failed to recognize. At this point, the screen images appeared correct as to orientation for diagnosis, however, the planning team did no realize that the P/A image was reversed in regard to the LGP dose-planning system.

The team then generated two separate treatment plans for the two separate targets. The radiation oncologist was consulted an concurred with the dose prescription. It was noted that the "X" coordinates for the targets indicated a right-of-midline stereotacti position, but the patient's head was tilted inside the frame, placing the midline of the brain to the left of the midline of the stereotactic system. Therefore, the coordinates were accepted as plausible. After initiating the treatment sequence for the next exposure, the physician reviewed the target points and noticed that the X coordinates indicated a definite right-side target. The physicist immediately terminated the exposure and notified the physician of a possible treatment error. It was determined that th and Z coordinates were accurate, but the X offset resulted in a target miss by 16 millimeter (0.63 inches).

The brainstem was stated to be the only critical structure within the 10 percent isodose contour. Reconstruction of the dose pro indicated that less than 10 cubic millimeters received no more than 2.5 gray (Gy) (250 rad). The remainder of the dose within th 10 percent isodose line was stated to be of in the cerebrum and cerebellum. It was the opinion of the neurosurgeon that the dos delivered was well below the dose-volume threshold for inducing any neurological damage.

Cause:

The angiographic study was done in an x-ray room with the patient supine and with the x-ray tube on the patient's left. This room was different than that previously used for gamma knife studies. The physicist had been aware of only one angiography room a the hospital in which the x-ray tube was always on the patient's right.

Although the images were "intuitively correct" to the neurosurgeon and physicist, they were perceived as incorrect by the compu software. The physicist was apparently able to override the computer rejection of the data to continue with the procedure.

The floating point error is described as an error resident in the calculation code of the software platform, and is not a part of the LGP program. The licensee was assured by the software developers that this error message would result in two outcomes if it e happened again. The program would crash on the next command, or it would self-correct prior to the next command. None of t participants has been able to recreate this floating point error.

Licensee Action:

The licensee has implemented a policy that any computer error message, regardless of origin or seriousness, will require termination of the preparation for treatment. The software will not be overridden under any circumstances. A Quality Assurance (QA) Program has been instituted for angiographic images, including the use of proximal and distal markers. The physicist will personally observe the acquisition of the angiographic images. A policy has been implemented that no treatment will be based i angiographic images alone. Confirmation will be obtained by superimposing the dose profiles over the MRI and other images obtained with the same sterotactic frame placement as the angiographic images. All treatment plans are sent to and verified by Director of the Hospital of the Good Samaritan in Los Angeles, California. The Director, a physician, was stated to have perform several hundred gamma knife procedures and is a member of the gamma knife QA team.

NRC Action:

Other Agency Action:

Two on-site inspections have been conducted by the State staff, to verify the adequacy of corrective actions. The information submitted to the State department has been reviewed and accepted by the Division's Medical Advisory committee as being accurate and corrective actions appropriate. The Division has required and accepted an application to name the teletherapy

physicist on the license. Because no alternate teletherapy physicist has been submitted on the license, the license will allow no treatments to be performed in the absence of the primary teletherapy physicist.

No enforcement actions or penalties have been imposed on the licensee. The new procedures and policies submitted by the licensee have been reviewed by the Division and appear appropriate to prevent a recurrence.

The application to amend the license to include the teletherapy physicist, and two additional radiation oncologists is currently under review by the State.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

ITEM #: 940209 AO #: AS 93-13 EVENT DATE: 09/02/1993
TITLE: LOST OR STOLEN RADIATION SOURCE AT BPB INSTRUMENTS, INC., IN MIDLAND, TEXAS
NAME: BPB Instruments, Inc. CITY: Midland STATE: TX

Nature and Probable Consequences:

BPB Instruments, Inc., notified the State of Texas agency that during a physical inventory a 555 gigabecquerel (GBq) (15 curie) americium/beryllium source made by Amersham (Serial Number 7004NE) was not located and may have been lost or stolen. BPB again notified the State agency on September 8, 1993, that after a thorough search, the source was not found.

A State agency investigation determined that the source was documented to be present and in the control of BPB on March 31, 1992. An inventory conducted on July 7, 1992, did not indicate that the source was present. The most likely scenario is that the source was lost or stolen between the dates of March 31, 1992, and July 7, 1992. NRC has asked the State of Texas to determine why this event was not reported sooner.

BPB believes that a disgruntled employee may have taken the source to cause problems for the company. Employees and exemployees were interviewed concerning the lost source and all interviewees claimed to have no knowledge of its disappearance. The possible loss or theft was reported to the Midland County Sheriff's Department.

Surveys were performed in areas around Midland. BPB placed an ad in the Midland newspaper offering a \$10,000 reward for information leading to the recovery of the source. The State agency issued a press release describing the source, warning that it should not be handled, and requesting that BPB or the State agency be contacted if the source is found. All attempts to locate the source have been unsuccessful.

According to the manufacturer, Amersham, the radiation profile for the 555 GBq (15 Ci) americium/beryllium source indicates 5.5 millicoulomb per kilogram (mC/kg)(20 roentgen) per hour gamma dose rate and 4.64 mC/kg (18 roentgen) per hour neutron dose rate at 5 centimeters (2 inches).

Cause:

The State agency investigation determined that the major contributing factor was lack of an adequate tracking system for receipt and shipping of radioactive sources. Also, a high turnover rate at the local manager/radiation safety officer position contributed to the lack of proper tracking controls of the source.

Licensee Action:

BPB is rewriting the job duties for the local and corporate radiation safety officers and is also reviewing and rewriting the procedures manual to aid in tracking each source of radiation.

NRC Action:

Other Agency Action:

The State agency is reviewing the incident to determine the nature and extent of enforcement action. NRC has asked the State of Texas to provide additional information on the State's action(s) upon completing their review of the incident.

This report will be further evaluated when additional information becomes available.

UPDATE: from NUREG-0900, Vol 17, No. 2, page 23. This abnormal occurrence (AO) was originally reported in NUREG-0090 Vol. 16, No. 4, "Report to Congress on Abnormal Occurrences, October-December 1993." At the time it was reported that a 555 gigabecquerel (15 curie) americium/beryllium source was not located during an inventory and may have been lost or stolen. The event was reported as an AO because it involved a loss of licensed material in such quantities and under such circumstances that a substantial hazard may result.

The State of Texas has since reported that the source is still missing, and is believed to be stolen. The State is attempting to involve its Attorney General's office in the investigation.

This report will be updated when additional information becomes available.

UPDATE: from NUREG-0900, Vol. 17, No. 4, page 24. This AO was originally reported in NUREG-0090, Vol. 16, No. 4, "Report to Congress on Abnormal Occurrences, October-December 1993."

The AO criterion used was Example 5 in "For All Licensees" of Appendix A of this report-A loss of licensed material in such quantities and under such circumstances that a substantial hazard may result.

At the time, it was reported that a 555 gigabecquerel (15 curie) americium/beryllium source could not be located during inventory and may have been lost or stolen.

The AO report is updated as follows:

The State of Texas Attorney General's office has been notified and the State conducted an investigation. No new information was identified and the source is still missing. The State is holding this case open and will notify NRC when it has any additional information.

This report will be updated when additional information becomes available.

Criteria:

Appendix A (see Example 5 of "For All Licensees") of this report notes that a loss of licensed material in such quantities and under such circumstances that a substantial hazard may result can be considered as an abnormal occurrence.

ITEM #: 940457 AO #: AS 93-14 EVENT DATE: 10/06/1993
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MICHAEL REESE MEDICAL CENTER IN CHICAGO, ILLINOIS
NAME: Michael Reese Hospital and Medical Center CITY: Chicago STATE: IL

Nature and Probable Consequences:

A 68-year-old woman with Stage II vaginal cancer was referred to the hospital's radiation therapy department for treatment. A plan was developed to deliver a total dose of 6000 centigray (cGy) (6000 rad) by a combination of 4000 cGy (4000 rad) from an external beam (linear accelerator) and 2000 cGy (2000 rad) from vaginal implant therapy. The external beam therapy was completed on September 9, 1993. The patient was then evaluated and plans were made to complete the implantation portion of the treatment. The treatment plan for the implant therapy included calculations for the time required to deliver 6000 cGy (600 rad). The dose already delivered by the external beam was not considered in the plan.

The attending physician reviewed the dose calculations on October 9, the fourth day of the implant, and determined that the duration of the implant treatment was likely to have been too long. He immediately removed the implants. Calculations revealed that the patient received 4000 to 4500 cGy (4000 to 4500 rad) from the brachytherapy treatment. Two days later, on Monday October 11, the attending physician verified with the physics staff that his dose calculations were correct. A telephone report was made to the Illinois Department of Nuclear Safety (IDNS) on Tuesday October 12, 1993, and an on-site investigation by IDNS staff was conducted on October 14. A written report from the licensee was submitted to IDNS on October 26. The patient had been notified of the event by the attending physician on October 20.

Cause:

The reportable event was caused by a failure to account for the previously administered external beam therapy. The incident occurred due to lack of communication of the prior therapy during the planning of the brachytherapy treatment.

Licensee Action:

As soon as the licensee's management determined that a reportable event had occurred, they formed a committee of professional staff not involved in the patient's care to conduct a quality assurance review. The committee concluded that the incident occurred due to lack of communication of the prior therapy during the planning of the brachytherapy treatment. They recommended that no brachytherapy be given without a signed, written prescription by the attending physician. The written prescription must contain information about all radiation therapy given to the patient. The medical center has adopted the committee's recommendations and has initiated training to the affected staff. This action should prevent a recurrence of a similar event.

NRC Action:

Other Agency Action:

The results of the on-site investigation by IDNS agrees with the findings of the licensee's quality assurance review. The licensee's proposal appears to be adequate to prevent recurrence.

This item is considered closed for the purpose of this report.

Criteria:

Appendix A (see Event Type 5 in Table A-1) of this report notes that administering a therapeutic dose that is greater than 1.5 times the prescribed dose should be considered an abnormal occurrence.

ITEM #: 941001 AO #: AS 93-15 EVENT DATE: 09/28/1993
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MT. SINAI MEDICAL CENTER IN MIAMI BEACH, FLORIDA
NAME: Mt. Sinai Medical Center CITY: Miami Beach STATE: FL

Nature and Probable Consequences:

On December 3, 1993, the State of Florida, Office of Radiation control (ORC) was notified by phone that eight patients with a total of 22 treatments, had received therapeutic exposure to parts of the body not scheduled to receive radiation. These exposures were delivered by a Nucletron Micro-Selectron high-dose-rate (HDR) remote afterloader brachytherapy treatment unit. The device uses an iridium-192 (Ir-192) sealed source of approximately 300 gigabecquerel (8.1 curie) as of December 1, 1993. All the patients were receiving gynecological booster treatment after external beam radiotherapy.

The licensee reported that the cause of the misadministrations was due to the use of a 1.5 meter (4.9 foot) Obstetrical/Gynecological (OB/Gyn) transfer tube/applicator combination length instead of a 1.0 meter (3.3 foot) length as intended. Seven of the eight patients were treated with a single transfer tube with an average exposure per treatment of 3.6 centigray (cGy) (3.6 rad). The exposures were given at approximately 51 centimeter (cm) (20 inch) from the intended site and outside of the patients' bodies, with the source being approximately 30 to 34 cm (12 to 13 inch) from the patients' knee area. The licensee reported that no physical effects were observed or expected in these patients. One patient was treated with four catheters and one transfer tube per treatment. The transfer tube was used to treat the vaginal vault and the four shorter catheters were used to treat the interstitial tissues. Since the transfer tube was longer than the four interstitial catheters, it was looped over the patient's knee for comfort. The patient developed skin erythema in this area and a conservative estimated dose of 4000 to 6000 cGy (40 to 6000 rad) to the knee area was calculated.

On the same day as the telephone report of the misadministration, an ORC inspector went to the licensee's facility to investigate the cause and assure immediate corrective actions were taken. The ORC inspector confirmed the two different size OB/Gyn transfer tubes and assured that immediate action was taken to segregate the tubes and assure that all transfer tubes were properly measured and marked. Since adequate actions were taken and the authorized user physician stated that it would be difficult and not advisable to switch from the HDR to other treatments for the patients already undergoing HDR treatments, the licensee was allowed to complete the therapy for patients that were currently undergoing HDR treatments. These treatments have now been completed and the license has been temporarily amended to a "storage only" status.

The investigation will continue with emphasis on determining the causes of the use of incorrect length transfer tubes, and assure the necessary corrective actions are in place prior to initiating any new HDR treatments.

UPDATE: from NUREG-0900, Vol. 17, No. 2, page 23. The Mt. Sinai Medical Center in Miami Beach, Florida, initiated a gynecological high dose rate (HDR) brachytherapy treatment program in September 1993. A Nucletron Micro-Selectron device containing a 300 gigabecquerel (8.1 curie) Ir-192 sealed source was used. A number of accessories used for these treatments were also purchased. These accessories included gynecological applicators and transfer tubes used to connect the patient applicator to the treatment device.

During the period September 28 to November 24, 1993, eight patients with a variety of gynecological cancers were treated with a total of 23 separate HDR brachytherapy insertions. A discrepancy between the length of the transfer tube, used to connect the patient applicator to the treatment machine, and the length of travel indicated in the software program was discovered.

The transfer tubes that connect the applicator in the patient to the treatment machine can be ordered in either 74-centimeter (9cr (29-inch) or 120-cm (47-inch) length. The 74-centimeter (cm) (29-inch) length is most commonly used. The applicator, plus the 74-cm (29-inch) transfer tube, together, allow for a maximum source extension of 100 cm (40 inch). The applicator, plus the 120-cm (47-inch) transfer tube, together, allow for a maximum source extension of 150 cm (59 inch). The computer treatment planning software programs the source extension to a maximum of 100 cm (40 inch) or 150 cm (59 inch) source extension must be combined to achieve correct source placement in the patient.

The transfer tubes used for the first 23 treatments were 120 cm (47 inch) long. When combined with the applicator, the length of maximum source travel was 150 cm (59 inch). However, the computer software used for planning the HDR treatment indicated that the maximum source travel could be 100 cm (40 inch). Therefore, during these treatments, the source stopped 50 cm (20 inch) short of the applicator inside the patient. This placed the radioactive source approximately at each patient's knees.

Two of the patients sustained third-degree skin injury at the site where the iridium source resided in the long transfer tube. Five of the patients had no physical manifestations as a result of the misadministration. Follow-up evaluations continue to be made.

Cause:

UPDATE: from NUREG-0900, Vol. 17, No. 2, page 23. The misadministrations were caused by treatment unit difficulties as well as the licensee's procedural weaknesses. The transfer tubes were not easily differentiated and the software was not programmed to account for the correct transfer tube length. In addition, the complete treatment procedure was not simulated which would have revealed the problem.

Licensee Action:

The licensee's immediate corrective actions consisted of the following: (1) removed long transfer tubes from treatment room and made inaccessible; (2) requested Nucletron to place some type of identification on transfer tubes; (3) marked all existing transfer tubes in HDR room; (4) revise the procedure and checklist used to verify equipment set-up; (5) obtained an outside consultant to assist in reviewing and modifying the Quality Assurance Program as needed; (6) scheduled retraining by Nucletron of all individuals involved in the use of the HDR; and (7) disallowed any new patient treatments on the unit.

UPDATE: from NUREG-0900, Vol. 17, No. 2, page 23. The licensee took immediate corrective actions as described in the inter abnormal occurrence report. The license is still on a "storage only" status until all issues of concern are addressed.

NRC Action:**Other Agency Action:**

The State agency has placed the license on a "storage only" status and is continuing with the investigation as stated above. An independent consultant will be obtained by the State to review the incident and advise on the appropriateness of all findings, conclusions and necessary actions prior to the licensee being authorized to place the HDR unit back in service. The remainder of the investigation is expected to be completed in the next several weeks. NRC has asked the State of Florida to provide additional information regarding their follow-up of this incident.

This report will be further evaluated when additional information becomes available.

UPDATE: from NUREG-0900, Vol. 17, No. 2, page 23. This abnormal occurrence (AO) was originally reported in NUREG-0090 Vol. 16, No. 4, "Report to Congress on Abnormal Occurrences, October-December 1993" using information supplied in an interim AO report issued by the State of Florida. At that time it was reported that between September 28 and November 24, 1993, eight patients had received therapeutic exposures to parts of the body not scheduled to receive radiation during 22 treatments. The exposures were delivered by a high dose rate remote afterloader brachytherapy unit using an iridium-192 (Ir-192) sealed source approximately 300 gigabecquerel (8.1 curie) activity. The cause of the misadministrations was the use of a 1.5 meter (4.9 foot) obstetrical/gynecological (OB/Gyn) transfer tube/applicator combination length instead of a 1.0 meter (3.3 foot) length as intended. The events were reported as an AO because they involve therapeutic doses that resulted in any part of the body receiving unscheduled radiation.

The following update and closeout information was supplied in a final AO report that was issued by the State of Florida.

This misadministration was originally selected for abnormal occurrence (AO) reporting because it met the guidelines given in Appendix A (see Event Type 3 in Table A-1) of this report, wherein it is noted that a therapeutic exposure that results in any part of the body receiving unscheduled radiation can be considered an AO. As a consequence of more information becoming available the criteria have been expanded to include that given in Appendix A (see Event Type 5[d] in Table A-1) wherein it is noted that a therapeutic exposure that affects two or more patients at the same facility (regardless of any health effects) can be considered an abnormal occurrence. (Updates entered in Nature and Consequences, Cause or Causes, Licensee and State Agency.)

UPDATE: from NUREG-0900, Vol. 17, No. 2, page 23. The State agency retained an independent medical consultant who reviewed the gynecological HDR procedures and the management of the patients involved in the misadministration. The consultant's report verified the initial findings and confirmed that appropriate patient follow-up occurred. The State will assure that the findings of the investigation are properly addressed prior to the licensee resuming its HDR brachytherapy treatment program. Enforcement action has been proposed by the State due to several regulatory violations found during the investigation.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

ITEM #:	920901	AO #:	AS 93-16	EVENT DATE:	09/24/1992
TITLE:	MEDICAL BRACHYTHERAPY MISADMINISTRATION AT RICHLAND MEMORIAL HOSPITAL IN COLUMBIA, SOUTH CAROLINA				
NAME:	Richland Memorial Hospital	CITY:	Columbia	STATE:	SC

Nature and Probable Consequences:

A radiation oncology nurse notified the Radiation Safety Officer that she retrieved a 1.1 gigabecquerel (CBq) (30 millicurie [mCi]) cesium-137 (Cs-137) source from a female patient's bed. The patient eventually developed an ulceration beneath her right thigh a result of being exposed to this source.

The oncology nurse stated that the attending nurse was putting the patient on a bed pan (approximately 10:00 a.m.) when she discovered the source and contacted the oncology nurse. The licensee stated that the patient was undergoing a 42-hour Cs-137 brachytherapy treatment using an applicator. The applicator contained three sources of 1.39, 0.93, and 0.93 GBq (37.5, 25, and mCi) of Cs-137. Each of the two ovoids were to have on 1.39 GBq (37.5 mCi) source. However, one ovoid applicator was found empty. NRC has asked the State of South Carolina to provide clarification and additional details on the treatment plan including sources used, the planned exposure time, the planned dose schedule, the intended dose, and the dose received up to the time of the incident.

The entire applicator system was then unloaded and returned to the brachytherapy vault where all of the sources were accounted for. A radiation survey of the patient's room after the unloading showed no additional sources in the patient's room.

In an effort to determine the length of time that the source was out of place, several people were interviewed. The patient was asked and did not know how the source could have gotten out of the applicator. The nurse, who two days earlier loaded the Cs-sources into the patient's applicators, said that there was nothing unusual about the loading and that she was confident that she had loaded the applicator properly.

The patient's radiation oncologist said that he had checked the applicator after the insertion and each morning and evening of the treatment and had noticed nothing unusual or any loose sources. His most recent visit was at 8:00 a.m., on the morning of September 24, 1992. The attending nurse said that she had checked the patient and noticed nothing until the morning of September 24, 1992, when she went to help the patient with the bed pan. Upon discovery of the sources, she then contacted radiation oncology. She said that the patient had been on the bed pan several times during her treatment, and that she had checked under the patient and did not see any sources. The chief resident of gynecological services checked the patient during treatment but did not manipulate the applicator.

The licensee's radiation safety officer report stated that there were no staff overexposures as a result of this incident. The patient and family were notified. NRC has asked the State of South Carolina to identify the dose to the wrong treatment site, and to verify that the referring physician was notified of the misadministration.

Since the nurse who inserted the Cs-137 sources insisted that she inserted them properly, and that the physician had just checked the patient that morning and saw nothing, the time of source removal was estimated to be about 8:00 a.m.

This was to be the patient's first of two treatments, and the dose deficit could be made up with the subsequent treatment. However, a second treatment was not attempted because the patient was unable to cooperate enough to undergo a second treatment.

The licensee stated that this event does not meet the State's criteria for a misadministration because if the source was removed sometime after 8:00 a.m. the dose could be corrected with the subsequent treatment. However, NRC does not have sufficient information to verify this and to complete an analysis.

NRC has received additional information since the 1993 third quarter report. Although this information has allowed the NRC to conclude that this misadministration is an abnormal occurrence, some concerns with the content of the information provided by the licensee have been identified. NRC has asked the State of South Carolina to investigate this event and to provide a follow-up description.

Cause:

The licensee stated that either the source fell out of the applicator as it was being inserted and it was not noticed, or a person or the staff opened the applicator out of curiosity and improperly reinserted the source in a loose manner.

Licensee Action:

To prevent recurrence of this event, the nursing staff was given refresher radiation safety instruction regarding the use of radioactive sources for cancer treatment.

NRC Action:

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Other Agency Action:

Insufficient information is available on the action(s) taken by the State Agency to prevent recurrence. NRC has asked the State South Carolina to provide additional information regarding the State agency's actions(s).

This event will be further evaluated when additional information becomes available.

UPDATE: from NUREG-0900, Vol. 17, No. 1, page 17. This abnormal occurrence was originally reported in NUREG-0090, Vol. 14, No. 4, "Report to Congress on Abnormal Occurrences," October-December 1993. The information pertaining to this abnormal occurrence is updated as follows.

A patient was prescribed a 41.5-hour brachytherapy treatment utilizing cesium-137 (Cs-137) for insertion with tandem and ovoid applicators. The tandem applicator had three sources, and each of the ovoid applicators were to have one source. At 10:00 a.m. on September 24, 1992, nursing personnel discovered a 1.11 gigabecquerel (30 millicurie) source in the patient's bed, 37 hours into the treatment. The entire system was unloaded and returned to the brachytherapy vault. The sources were inventoried and certified that none was missing.

The licensee stated that ideal doses for the treatment of stage II-B carcinomas of the cervix call for 8500 centigray (cGy) (8500 rads) to Point A and 5500 cGy (5500 rad) to the external iliac nodes. This dose was to be administered through the use of implants at an external beam irradiator. After finding the source out of place, the second intracavitary insertion was cancelled. The remaining desired doses to the pertinent points of treatment were obtained by additional external beam irradiation. The Point A dose was 8752 cGy (8752 rad) on the left, and 8271 cGy (8271 rad) on the right.

Efforts were taken to determine the length of time that the source was out of place; however, no conclusive determinations could be made. Days after the treatment, the patient developed an ulceration beneath the right thigh. The licensee estimated the dose to the wrong treatment site to be 2000 to 4000 cGy (2000 to 4000 rad), based on the degree and severity of ulceration. The licensee indicated that there would be no way to determine a more specific dose since it is not known when the source came out of the applicator, and the proximity of the source to the patient's thigh was also unknown. The licensee stated that no long-term health effects other than scarring are expected.

The patient and her family were notified of the misadministration.

To prevent recurrence, the following actions have been taken: (1) the Gynecology/Oncology nursing staff has been given refresher radiation safety instruction regarding the use of, and treatment with, radiative Cs-137; (2) the presence of two individuals during insertion of low-dose-rate brachytherapy sources is required as well as the loading to be reviewed afterwards by a physician; and (3) tamper resistant tape will be used to seal the tandem and ovoid applicators.

The State agency staff has also reviewed the circumstances of the misadministration. The staff has reviewed and approved the procedures requiring the licensee to use tamper resistant tape, have two individuals present during source loading, and have independent review of all loads by qualified physicians.

This event is considered closed for the purpose of this report.

Criteria:

The following information was provided by the licensee to the State of South Carolina and presented in the 1993 third quarter "Report to Congress on Abnormal Occurrences," Appendix D, "Agreement States Events Being Considered as Abnormal Occurrences". This event has been determined to be an abnormal occurrence based on new information received since the initial report to Congress. This abnormal occurrence report is updated as follows:

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

ITEM #: 940155 AO #: NRC 94-02 EVENT DATE: 12/11/1993
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT HOSPITAL METROPOLITANO IN RIO PIEDRAS, PUERTO RICO
NAME: Hospital Metropolitano CITY: Rio Piedras STATE: PR

Nature and Probable Consequences:

On December 9, 1993, at 5:20 p.m., a patient began a gynecological low-dose-rate brachytherapy treatment. The patient was prescribed a treatment of 3000 centigray (cGy) (3000 rad) by a 48-hour exposure to approximately 2.3 gigabecquerel (61.3 millicurie [mCi] of cesium-137 (Cs-137).

On December 11, 1993, at approximately 7:30 a.m., (about 10 hours before the end of the prescribed treatment), the patient intervened with the procedure by removing the implant containing three Cs-137 sources of approximately 730 megabecquerel (2 mCi) each, and placed it next to her thigh. Shortly after removing the implant, the patient showed the device to the floor nurse. The nurse recognized the implant and understood the need for concern. She did not take the device from the patient but reported the situation to her supervisor. The patient apparently returned the device next to her thigh beneath the bed linen.

At the time of being informed, the nursing supervisor was experiencing difficulty with another patient, and was involved in shift turnover. Due to these distractions, the supervisor failed to realize the urgent nature of the situation and did not make required notifications.

On several occasions that morning, other licensee personnel entered the patient's room without realizing that the radioactive source was exposed because it was covered by bed linen; the patient did not notify any additional staff members that she had removed the implant. Approximately 2-1/2 hours after the estimated time of the source removal, the attending physician attempted to perform a routine check of the implant and discovered that it had been removed and placed next to the patient's thigh.

After properly accounting for and storing the sources, the physician examined and interviewed the patient. Based on discussion with the patient and review of the exposure received, the attending physician terminated the treatment. This decision was based on the physician's determination that the treatment received was clinically adequate and his concern that the patient was a threat to herself and others.

The actual dose delivered to the intended treatment site was calculated to be 2270 cGy (2270 rad). The written directive was revised to reflect the lower dose delivered.

The licensee's evaluation of the incident indicated that assuming the implant remained in the same location for three hours, the maximum dose to the skin of the patient's thigh (the wrong treatment site) was 572 cGy (572 rad). The licensee reported that no adverse effects to the patient are expected.

The patient was notified verbally at the time the misadministration was discovered and then notified in writing on January 13, 1994.

Cause:

The initial cause of the misadministration was the patient's removal of the implant which was compounded by the failure of the two nurses to follow emergency procedures. The nurses' failure to respond to the emergency resulted in approximately 2-1/2 hours of unnecessary exposure.

Licensee Action:

The licensee determined that the nursing supervisor's failure to make the required notification was due to the lack of familiarity with established radiation safety procedures to which he/she had been trained. The licensee's investigation of the event revealed that the lack of familiarity with radiation safety procedures was caused by the infrequent handling of patients undergoing therapy with licensed materials (Ref. 3). The licensee held a Radiation Safety Committee meeting in which the incident and corrective actions to prevent recurrence were discussed.

The licensee decided to dedicate one floor of the hospital for all therapies involving NRC-licensed materials. This will provide additional controls to allow the licensee to better ensure that nurses assigned to the floor are kept current and familiar with operating and emergency procedures. The licensee is also evaluating the need to increase patient awareness regarding non-intervention of procedures.

The licensee is revising its procedures for responding to radiological emergencies involving patients undergoing radiopharmaceutical or sealed source therapy. As a minimum, the procedures will define what is a radiological emergency and provide examples of situations which must be considered radiological emergencies or which could result in misadministrations. The licensee also committed to developing and implementing a retraining program based on the revised emergency procedures for all hospital employees who may be involved in handling patients receiving radiation therapy.

NRC Action:

A special inspection was conducted on December 15 and 17, 1993, to review the circumstances surrounding the misadministration and the licensee's Quality Management program. A Confirmatory Action Letter (CAL) was issued to the licensee on December 17, 1993.

1993 (Ref. 4). The CAL confirmed that the licensee would revise its emergency procedures and implement a training program, based on new procedures, for all licensee employees who may handle patients undergoing radiation therapy. An NRC medical consultant has been retained to perform a clinical assessment of this misadministration. The medical consultant's report is expected to be available in time to discuss his findings in the second quarter AO Report. As of the issuance of this report, NRC pursuing escalated enforcement action against the licensee.

This report will be further updated when additional information becomes available.

UPDATE: from NUREG-0900, Vol. 17, No. 2, page 20. This abnormal occurrence (AO) was originally reported in NUREG-0090 Vol. 17, No. 1, "Report to Congress on Abnormal Occurrences," January-March 1994. At that time it was reported that on December 11, 1993, a patient intervened during brachytherapy treatment by removing an implant and then informing the nurse of her action. (The nurse informed the supervisor who failed to realize the urgent nature of the situation.) The patient then returned the implant to a location next to her thigh beneath the bed linen, where it lay for 2 and 1/2 hours before being discovered by the attending physician. The event was reported as an AO because it involved a therapeutic exposure to a part of the body not scheduled to receive radiation.

The AO report is updated and closed out as follows:

The NRC's medical consultant reviewed the events surrounding the misadministration and concluded that the dose delivered to intended treatment site was sufficient to treat the carcinoma. The consultant also concluded that acute or late effects are not expected as a result of the unplanned dose to the normal tissue.

NRC held an Enforcement conference with the licensee on May 20, 1994, to discuss the inspection findings and actions taken by the licensee in response to the misadministration. On June 13, 1994, NRC Region II issued a Notice of Violation with a Severity Level IV violation for failure of the licensee to implement procedures for emergency action when control of byproduct material was lost, and a Severity Level V violation for failure of the licensee to submit a written misadministration report to the NRC within 15 days of the discovery of the misadministration (Severity Levels I through V range from the most significant to the least significant). No civil penalty was assessed for the violations. The licensee's corrective and preventive actions will be reviewed during the next NRC inspection of the licensed program.

This item is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an abnormal occurrence.

ITEM #:	941012	AO #:	NRC 94-03	EVENT DATE:	12/20/1993
TITLE:	TELETHERAPY MISADMINISTRATION AT TRIANGLE RADIATION ONCOLOGY ASSOCIATES IN PITTSBURGH, PENNSYLVANIA				
NAME:	Triangle Radiation Oncology Associates	CITY:	Pittsburgh	STATE:	PA

Nature and Probable Consequences:

On December 20, 1993, Triangle Radiation Oncology Associates in Beaver Pennsylvania, notified NRC of two potential teletherapy misadministrations that occurred between December 13 and 17, 1993, at the licensee's Pittsburgh, Pennsylvania, facility. The potential misadministrations were identified during a review of patient records on December 17, 1993 when the licensee observed calculation errors involving the depth of the dose given to each of the two patients.

Both cases involved breast treatments where the original treatment plan prescribed 28 treatments of 180 centigray (cGy)(180 rad) from a cobalt-60 teletherapy source (using 2 parallel opposed fields) for a total absorbed dose of 5040 cGy (5040 rad). The primary breast treatments were concluded on December 10, 1993. The physician wrote separate written directives for each patient to receive an additional 1000 cGy (1000 rad) to the scar in 5 treatments of 200 cGy (200 rad) per day. One of the written directives indicated that the absorbed dose was to be delivered at dmax, the maximum extension of the teletherapy unit, which, as stated by the physicist, is typically a depth of 0.5 centimeter (cm) (0.2 inch). The other written directive did not indicate a depth; however, the physician stated that the intended depth was dmax.

As described above, such a treatment plan would typically have been calculated by the teletherapy technologist at the Pittsburgh facility and communicated by telephone to the teletherapy physicist at the Beaver facility to be checked. However, this procedure changed when the computer at the Pittsburgh facility was taken out of service on December 1, 1993.

On December 9, 1993, the teletherapy technologist hand wrote a paraphrased request of the written directive for the two breast-treatment patients needing scar booster dose calculations. Rather than writing dmax, the technologist stated the tumor dose at a depth of 5 cm (2 inch) and sent the request, via facsimile transmissions, to the teletherapy physicist at the Beaver facility. Hand calculations were performed for 200 cGy (200 rad) treatments at a 5 cm (2 inch) depth, checked by a certified physicist, and sent back to the technologist, via facsimile transmissions, on December 9, 1993.

The patients were treated from December 13 to 17, 1993, and received doses of 1300 and 1320 cGy (1300 and 1320 rad) respectively, rather than the 100 cGy (1000 rad) intended. This resulted in misadministrations of 30 and 32 percent greater than the intended dose. The licensee's physician stated that no adverse clinical effects are expected as a result of the overexposure.

After the initial report, the licensee told NRC in subsequent telephone conversations that a recalculation of the dose averaged over the entire tumor volume did not exceed 30 percent and, therefore, the licensee no longer thought the definition of a misadministration applied in this case.

NRC performed a special inspection on December 28 and 29, 1993, to review the potential misadministrations. Information gathered during this inspection, including the calculations of the administered doses, was given to an NRC scientific consultant to evaluate. The scientific consultant, in his report to NRC, stated that "the dose prescription was to dmax (i.e., 0.5 cm [0.2 inch] depth on the central axis) and a misadministration can only be judged by considering the dose given to this point...clearly in both cases a misadministration has taken place." On March 25, 1994, the licensee was informed that the doses to both patients were deemed to be misadministrations. The licensee submitted its report of misadministrations in a letter dated April 7, 1994.

After receiving the scientific consultant's report, an NRC medical consultant was retained to perform a clinical evaluation of the patients. The medical consultant is still in reviewing the potential health effects to the patients. The consultant's report is expected to be completed in time to update this write-up in the next AO report to Congress.

The referring physician was notified and determined that, based on medical judgment, informing the patients of the misadministrations would be harmful.

Cause:

The technologist incorrectly transposed the treatment depth on the facsimile used to prepare the treatment plan. The technologist failed to make reference to dmax and entered the depth value incorrectly as 5.0 cm (2 inch) instead of the intended 0.5 cm (0.2 inch).

Licensee Action:

The licensee implemented a requirement for a stamp to be placed on all written directives that prompts a clear documentation of key treatment parameters such as site, method, daily dose, fractions, total dose, depth of calculation spinal blocks, other blocks and date. Previously, key parameters had been informally handwritten on patients' treatment charts. The licensee also formalized its requirement to include the written directive for all dosimetry calculation requests from the Beaver facility, and revised its "weekly chart check" procedure to increase chart reviews from once a week to twice a week, as was the practice prior to December 1, 1993.

NRC Action:

NRC is reviewing the licensee's April 7, 1994, misadministration report and the findings of the December 28 to 29, 1993, NRC inspection. Once the NRC medical consultant's report is received, enforcement action will be considered.

This report will be further updated when additional information becomes available.

UPDATE: from NUREG-0090, Vol. 17, No. 2, page 21. This abnormal occurrence (AO) was originally reported in NUREG-0090, Vol. 17, No. 1, "Report to Congress on Abnormal Occurrences," January-March 1994. At the time it was reported that between December 13 and 17, 1993, two therapeutic misadministrations occurred because of calculation errors involving the depth of the dose given to each of two patients. The event was a therapeutic misadministration that affected two or more patients at the same facility regardless of any health effects.

The AO report is updated as follows:

The licensee implemented and required the use of a stamp to be placed on the written directive that includes a prompt to write in the site, method, daily dose, fractions, total dose, depth of calculation, spinal blocks, other blocks and date. Previously boost fields had been informal hand written directives on the patients treatment chart. The licensee also formalized in writing its previous informal requirement to include the written directive with all requests for dosimetry calculations from the Beaver facility. Finally the licensee revised its weekly chart check procedure to include checks of charts twice per week as was previously performed prior December 1, 1993.

NRC is reviewing the licensee's April 7, 1994, misadministration report and the findings of the December 28 and 29, 1993, NRC inspection. The NRC medical consultant reviewed the circumstances surrounding the misadministration and concluded that in both cases there was no evidence of adverse radiation reaction in the breast, and neither patient suffered clinical side effects from the dose received.

On June 16, 1994, an enforcement conference was conducted by telephone with the licensee's representatives. Representatives of North Hills Passavant Hospital were also in attendance by telephone because the licensed material (cobalt-60 in a teletherapy unit) had been transferred to them and the licensee requested termination of its license. As a result, NRC Region I issued a Notice of Violation (NOV) on June 21, 1994, classifying the three violations cited in the aggregate as a Severity Level III problem. No Civil Penalty was assessed due to the licensee identifying the misadministration and the associated violations, its prompt and comprehensive corrective actions, and past good enforcement history. The licensee has 30 days to respond to the NOV.

The licensee responded with its corrective actions which were reviewed and found acceptable to the NRC. The license will be terminated by Region I.

This item is considered closed for the purpose of this report.

Other Agency Action:**Criteria:**

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic misadministration that affects two or more patients at the same facility, regardless of any health effects, can be considered an abnormal occurrence.

ITEM #: 940266 AO #: NRC 94-04 EVENT DATE: 09/22/1993
TITLE: LOST REFERENCE SOURCES AT BROOKS AIR FORCE BASE IN SAN ANTONIO, TEXAS
NAME: Armstrong Laboratory, Brooks Air Force Base (AFB) CITY: San Antonio STATE: TX

Nature and Probable Consequences:

As prescribed by the licensees' Compliance Accountability and Control Procedures, in 1993, the licensee performed an audit of licensed sources at Armstrong Laboratory. During this audit, the licensee identified four missing strontium-90 (Sr-90) reference sources of approximately 14.8 megabecquerel (400 microcurie) each. The licensee conducted an extensive physical search for sources and reviewed all radioactive material permits issued to other organizations at Brooks AFB. When the disposition of the 90 sealed sources could not be determined, the licensee reported the loss of the four sealed sources to NRC by telephone on September 22, 1993. The licensee informed NRC that the United States Air Force (USAF) Inspector General would review this incident. The licensee suspected that the sources had been inadvertently discarded and transported to a sanitary landfill.

The licensee evaluated possible radiation exposure to members of the general public and concluded that unless the sources were removed from the container, the radiation levels from the sources would be near background level. Furthermore, unless a deliberate effort was made to open the source capsules, an individual handling the sources would receive less exposure than allowed by regulatory limits for the general public.

Cause:

During 1991, the timeframe during which the sources were apparently lost, a number of individuals were responsible for the radiation safety program at Brooks AFB. These individuals were temporary or part-time Radiation Safety Officers (RSOs), and had extensive, temporary duties at other sites.

The results of the USAF Inspector General's investigation determined that "programmatically issues started to plague radiation safety at Brooks AFB after the dismantling of the base/clinic program and the inception of additional duty RSOs." The report explained that in 1986, the radiation safety function and responsibility was transferred to the base clinic at Brooks AFB. Almost simultaneously, a Joint Military Medical Command (JMMC) was established and the base clinic became a part of JMMC. JMMC was a medical command established to service all branches of the Armed Forces in the San Antonio, Texas, area. With this action, the radiation safety program was managed by an organization that was not responsible to any management level at Brooks AFB. Furthermore, the report stated that JMMC dismantled the clinic's radiation safety program, and "requested that all organizations previously under the clinic's program establish and run their own radiation safety program." Exacerbating the problem was the appointment of the additional duty RSOs, who had "limited to general knowledge of radiation safety," and no directives or other guidance to assist them. Additionally, "the additional duty RSOs received little management oversight after they had been appointed to the RSO position."

The investigation concluded that from 1986 through 1991, there had been a lack of commitment to management oversight, and a serious disregard for safety issues.

Licensee Action:

In 1991, Armstrong Laboratory was placed under a new Air Force Command. The Command committed to increased management oversight of the radiation safety programs. Additionally, physical inventory procedures were revised.

NRC Action:

NRC conducted an inspection (Ref. 5) at Brooks AFB on December 21, 1993, to review the circumstances associated with the loss of licensed material, after receiving a written report from the licensee on December 10, 1993. NRC also held an Enforcement Conference with the licensee on February 3, 1994, to review the findings of the inspection and to determine enforcement action.

On February 11, 1994, NRC issued a Notice of Violation (Ref. 6) for violations involving (1) a failure to secure licensed material and (2) failure to include in one USAF permit a requirement to conduct a periodic physical inventory of all licensed materials.

These violations were categorized as a Severity Level III and a Severity Level IV, respectively (Severity Level I through V range from the most significant to the least significant, respectively). No civil penalty was assessed because of the Air Force's discovery of this violation and the promptness and comprehensiveness of the corrective actions. The licensee has responded in writing to the Notice of Violation and no additional actions are required.

This event is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 11 from Examples For All Licensees) of this report notes that any serious deficiency in management or procedural controls in a major area can be considered an abnormal occurrence.

ITEM #: 941090 AO #: NRC 94-05 EVENT DATE: 01/07/1994
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT THE UNIVERSITY OF CINCINNATI IN CINCINNATI, OHIO
NAME: University of Cincinnati CITY: Cincinnati STATE: OH

Nature and Probable Consequences:

On January 14, 1994, NRC was notified by telephone of a misadministration involving a leaking iodine-125 (I-125) brachytherapy implant seed. On January 7, 1994, 16 I-125 seeds, each ranging from 370 to 1110 megabecquerel (MBq) (10 to 30 millicurie [mCi]) activity, were implanted in the brain of a 30-year-old male patient. Following the explant procedure on January 14, 1994, licensee identified radioactive contamination in the surgical room and bathroom used by the patient. Personnel from the licensee radiation safety office identified the contamination to be I-125 and, based on an assay of the explanted source, the licensee estimated that the loss was approximately 74 MBq (2.0 mCi).

Thyroid monitoring of the patient's visitors and hospital employees involved in the care of the patient was performed by the licensee. One of the licensee's employees was determined to have received a committed dose equivalent to the thyroid of 50 microsievert (uSv) (5 millirem [mrem]). In addition, a visitor was determined to have received a committed dose equivalent to the thyroid of 540 uSv (54 mrem), or a total effective dose equivalent of 160 uSv (1.6 mrem), which is less than the annual limit for members of the general public of 1000 uSv (100 mrem).

Through patient monitoring, the licensee estimates that approximately 5 percent of the free I-125 was taken up in the patient's thyroid. (In a normally functioning, unblocked thyroid, approximately 25 percent of the free iodine would be taken up in an individual's thyroid.) The licensee estimates that the uptake would result in a radiation dose to the thyroid of approximately 300 centigray (300 rad). The licensee does not expect any adverse medical effects to the patient as a result of the misadministration. An NRC medical consultant concluded that the non-radioactive iodinated contrast agent used during an imaging procedure performed on the patient prior to the implant blocked the absorption of the I-125. He also concluded that exposure to the radiation levels described has resulted in an increased probability of developing thyroid tumor(s) in the future.

The licensee notified the referring physician, the patient, and the patient's family of the misadministration.

Cause:

The seed leaked after being inadvertently crushed by a surgical staple used to secure the catheters during the implant procedure.

Licensee Action:

For future procedures, the licensee plans to ensure that the implanted seeds are located further down the catheter in order to reduce the likelihood of seed damage from surgical staples. The licensee also plans to examine each I-125 seed for leakage following each explant procedure.

NRC Action:

NRC dispatched two inspectors on January 16, 1994, to monitor the licensee's decontamination efforts and to obtain more detail on the misadministration. NRC also obtained the services of a medical consultant to review the medical implications of the incident. A follow-up NRC inspection (Ref. 7) was conducted from February 7 to 11, 1994. On March 16, 1994, NRC held a telephone Enforcement Conference with the licensee to discuss the safety inspections conducted in January and February 1994 at the University of Cincinnati.

A Notice of Violation was issued by NRC on March 25, 1994, which imposed a fine of \$5000 for a violation not associated with this misadministration. In the Notice of Violation, NRC determined that the inadvertent opening of the I-125 sealed source did not constitute a violation of the University of Cincinnati license.

This event is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to a part of the body not scheduled to receive radiation can be considered an abnormal occurrence.

ITEM #: 941471 AO #: NRC 94-06 EVENT DATE: 01/13/1994
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT KEESLER MEDICAL CENTER AT KEESLER AIR FORCE BASE IN BILOXI, MISSISSIPPI
NAME: Keesler Medical Center, Keesler Air Force Base CITY: Biloxi STATE: MS

Nature and Probable Consequences:

A patient was prescribed a lung brachytherapy treatment delivered by an Omnitron 2000 high-dose-rate (HDR) remote afterload system. The prescribed tumor treatment plan included 1000 centigray (cGy) (1000 rad) absorbed doses at 5 treatment positions using a 144.3 gigabecquerel (3.9 curie) iridium-192 source within a special needle. At the end of fifth and last treatment, the source wire retracted 0.5 centimeter (cm) (0.2 inch) and stopped. Alarms immediately alerted Keesler staff that the source remained inside the patient's body. Licensee personnel followed emergency procedures, entered the therapy room and remove the needle from the patient. Once outside the patient's body, the radioactive source retracted to the stored position.

The licensee determined that the source remained stuck at 0.5 cm (0.2 inches) above the fifth position for approximately 2-1/2 minutes. The treatment plan called for the delivery of 1000 centigray (cGy) (1000 rad) at 1 cm from each of the 5 treatment positions. As a result of the additional 2-1/2 minutes exposure, the last treatment position received 1732 cGy (1732 rad) absorb dose, or 73.2 percent over the prescribed dose. The treatment plan also predicted an 800 cGy (800 rad) absorbed dose at 0.5 cm (0.2 inch) from each of the 5 treatment positions. The point 0.5 cm (0.2 inch) above the last treatment position, where the movement of the source stopped, received approximately 1400 cGy (1400 rad), or 75 percent greater than the absorbed dose stipulation in the prescribed treatment plan. The failure of the source to retract resulted in a single overexposure, causing an ov absorbed dose of 75 percent greater than that prescribed, for all the tissue surrounding the position 0.5 cm (0.2 inch) above the treatment site.

The licensee reported that no adverse health effects to the patient are expected. The patient was immediately notified of the misadministration.

Cause:

The patient had made a sudden move near the end of the treatment causing the special needle to bend at the point where it extended beyond the biopsy needle. The bend prevented the radioactive source from retracting to the stored position, causing t misadministration.

Licensee Action:

The licensee immediately stopped the use of the HDR device pending a complete check of the system by the manufacturer (Ref. 9). The licensee also evaluated the practice of extending special needles beyond biopsy needles and the probability of pat movement causing damage, and decided to discontinue this practice (Ref. 10, Ref. 11).

NRC Action:

A special inspection was conducted from January 19 to 21, 1994, to review the circumstances surrounding the misadministration and the licensee's Quality Management program. A representative of the U.S. Food and Drug Administration (FDA) also participated in this inspection. No violations of regulatory requirements were identified during the inspection, but NRC initiated t following actions: (1) a Confirmatory Action Letter (Ref. 12) was issued to the licensee on January 18, 1994, which prohibited the use of the HDR unit until serviced by the manufacturer; (2) a medical consultant was contracted to evaluate the clinical effects a to assess the events that led to this misadministration; (3) the manufacturer was asked to analyze the source wire involved in th misadministration for damage as a result of the stresses experienced during this event; (4) Southwest Research Institute was contracted to analyze the special needle for mechanical failure; (5) a generic communication is being developed to notify other t users of the results of the inspection and related research; and (6) NRC is coordinating with FDA an evaluation of the generic implications surrounding this event.

This report will be updated when additional information becomes available.

UPDATE: from NUREG-0900, Vol. 17, No. 2, page 21. This abnormal occurrence (AO) was originally reported in NUREG-0090 Vol. 17, No. 1, "Report to Congress on Abnormal Occurrences," January-March 1994. At the time it was reported that on Janua 13, 1994, the failure of a high dose rate remote afterloader brachytherapy source to retract resulted in an absorbed dose that wa 75 percent greater than prescribed. The event was reported as an AO because it was a therapeutic exposure to a part of the bc scheduled to receive radiation such that the actual dose received was greater than 1.5 times the prescribed dose.

The AO report is updated and closed out as follows:

The NRC medical consultant reviewed the events surrounding the misadministration and concluded that no harm is to be expect from the excess dose received by the patient as a result of the misadministration.

The equipment manufacturer evaluated the equipment used in the administration of the treatment and found that there were no equipment malfunctions. In addition, the equipment manufacturer evaluated the stresses the source wire was subjected to durin the event and found no abnormalities. Southwest Research Institute performed a mechanical failure analysis of the source wire and needle configuration, and found no evidence of radiation-induced embrittlement of the needle or any other abnormalities in t

needle.

On May 27, 1994, NRC issued Information Notice 94-37 alerting NRC licensees of the incident.

On July 5, 1994, NRC Region IV issued a Notice of Violation with a Severity Level IV violation for failure of the licensee to notify patient in writing within 15 days of the misadministration. (Severity Levels I through V range from the most significant to the least significant.) The licensee's corrective and preventive actions will be reviewed during the next NRC inspection of the facility.

This item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic exposure to a part of the body scheduled to receive radiation such that the actual dose received is greater than 1.5 times the prescribed dose can be considered an abnormal occurrence.

ITEM #: 941470 AO #: NRC 94-07 EVENT DATE: 01/27/1994
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT ALEXANDRIA HOSPITAL IN ALEXANDRIA, VIRGINIA
NAME: Alexandria Hospital CITY: Alexandria STATE: VA

Nature and Probable Consequences:

On January 27, 1994, a patient was scheduled to receive a 500 centigray (cGy) (500 rad) brachytherapy treatment to the trachea using a Nucletron high-dose-rate (HDR) remote afterloader system. A single catheter was used for this endobronchial treatment. During this simulation, the oncologist established a 3 centimeter (cm) (1.2 inch) tumor treatment site and added a 1 cm (0.4 inch) margin on both ends of the tumor site.

Normally, at this point the medical physicist and the dosimetrist plot distances, measured in centimeters along the length of the catheter shown in the simulation film, in order to program the HDR for precise treatment at the prescribed treatment site. This step was not performed and the procedure was initiated without the HDR being properly programmed. The unprogrammed source was allowed to travel beyond the treatment site into the left lung area where the catheter ended. The treatment resulted in the prescribed 500 cGy (500 rad) effective dose equivalent being delivered to the left lung instead of the trachea target site. Prior to administering the dose, the treatment plan and treatment console printout were reviewed by the dosimetrist, the medical physicist, and the oncologist. All three individuals failed to identify the failure to plot the treatment site.

Immediately following the treatment, the licensee's medical physicist realized that the plotting and programming of the treatment were not performed. After discovery of the treatment error, the oncologist determined that the patient should be treated again using the correct treatment parameters.

The licensee has advised NRC that no adverse effects to the patient are anticipated as a result of this misadministration. The licensee has informed the patient of the misadministration.

Cause:

The licensee's radiation therapy staff failed to follow the licensee's normal protocol for treatment with the HDR remote afterloader. The failure to administer the treatment as prescribed resulted from performing the treatment planning and independent verification in the vicinity of the HDR console, where there were a number of distractions.

Licensee Action:

The licensee's corrective actions included immediate retraining of all personnel involved in brachytherapy treatments and the addition of a checklist for each step in the treatment process. The licensee also added steps to its Quality Management program for HDR brachytherapy. These steps now require the use of the treatment planning computer with manual verification of the input parameter and the use of the treatment parameter card generated by the planning computer to program the HDR rather than programming the HDR treatment parameters manually.

NRC Action:

NRC conducted a special inspection from February 2 to 4, 1994, to review the circumstances associated with the misadministration, the licensee's Quality Management program, and the licensee's immediate corrective actions. In addition, on February 25, 1994, NRC employed a medical consultant to provide an assessment of the potential clinical effects of this misadministration and the events that led to it.

The inspection report, medical consultant's assessment, and enforcement actions for the misadministration are being completed. This report will be updated when additional information becomes available.

UPDATE: NUREG-0900, Vol. 17, No. 2, page 22. This abnormal occurrence (AO) was originally reported in NUREG-0090, Vol. 17, No. 1, "Report to Congress on Abnormal Occurrences," January-March 1994. At the time it was reported that on January 27, 1994, an unprogrammed high dose rate remote afterloader brachytherapy source was allowed to travel beyond the treatment site into the left lung area. The treatment resulted in the prescribed 500 centigray (500 rad) effective dose equivalent being delivered to the left lung instead of the trachea target site. The event was reported as an AO because it was a therapeutic exposure to a patient the body not scheduled to receive radiation.

The AO report is updated as follows:

The NRC medical consultant reviewed the events surrounding the misadministration and concluded that there should be no risk of delayed complications secondary to this misadministration and that the patient is receiving appropriate follow-up care for her illness.

NRC Region II has scheduled an Enforcement Conference to discuss the inspection findings with the licensee.

This event will be further updated when additional information becomes available.

UPDATE: NUREG-0900, Vol. 17, No. 4, page 19. This AO was originally reported in NUREG-0090, Vol. 17, No. 1, "Report to Congress on Abnormal Occurrences, January-March 1994."

The AO criterion used was Event Type 3 in Table A-1 of Appendix A of this report-A therapeutic exposure to a part of the body not scheduled to receive radiation.

At the time, it was reported that a patient was scheduled to receive a 500 centigray (cGy) (500 rads) brachytherapy treatment to trachea using a Nucletron high-dose-rate (HDR) remote afterloader system. Because the HDR was not properly programmed for the correct treatment site, the prescribed 500 cGy (500 rads) dose was delivered to the left lung instead of the trachea target site.

The AO report is updated and closed out as follows:

NRC held an Enforcement Conference on July 21, 1994, to discuss the inspection findings with the licensee. A Notice of Violation was issued to the licensee for failure to follow NRC requirements.

This item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to a part of the body not scheduled to receive radiation can be considered an abnormal occurrence.

ITEM #: 940473 AO #: AS 94-01 EVENT DATE: 06/17/1993
TITLE: THERAPEUTIC RADIOPHARMACEUTICAL MISADMINISTRATION AT NORTH CAROLINA BAPTIST HOSPITAL IN WINSTON SALEM, NORTH CAROLINA
NAME: North Carolina Baptist Hospital CITY: Winston Salem STATE: NC

Nature and Probable Consequences:

The nuclear medicine technologist had prepared dosages for two different patients and then prepared both patients for injection. The technologist was temporarily sidetracked and then returned to complete administration of the prepared dosages. The first patient received a 592 megabecquerel (MBq) (16 millicurie [mCi]) therapeutic dose of iodine-131 instead of the prescribed 37 MBq (1 mCi) diagnostic dose of thallium-201 for a myocardial perfusion scan. Upon entering the next room to administer the dosage the second patient, the technologist discovered the error.

NRC was notified of this event on August 10, 1993. Immediate action taken by the licensee included notifying the referring physician and patient. An approved iodine contrast agent was injected into the patient, hemodialysis was initiated, and daily doses of potassium iodine were started and continued for 2 weeks. The patient was also held overnight for observation. No thyroid uptake was performed.

The Radiation Safety Officer concluded that without the uptake data only rough estimates of the patient's exposure can be made. According to the International Commission on Radiological Protection, publication 53, "Radiation Dose to Patients from Radiopharmaceuticals," 100 percent blocking of the thyroid would result in all organ doses being less than 50 millisievert (mSv) (5 rem), and the effective dose equivalent would be approximately 43 mSv (4.3 rem). Assuming incomplete blockage, some parts of the gastrointestinal (GI) tract, the bladder wall, and the thyroid would have significantly higher doses.

In addition, the National Council on Radiation Protection and Measurements Report No. 80, "Induction of Thyroid Cancer by Ionizing Radiation," states that a significantly increased risk of thyroid cancer has not been detected in several studies on human beings at the dose level misadministration to the patient. However, due to the likelihood of incomplete thyroid blockage, the patient will need to be monitored for signs of hypothyroidism.

Cause:

This misadministration occurred due to personnel error during a time of heavy workload.

Licensee Action:

A new policy to color-code prepared dosages was implemented to more clearly and easily distinguish between therapeutic and diagnostic dosages.

NRC Action:

Other Agency Action:

The licensee's corrective and preventative actions will be reviewed during the next inspection of the licensed activities by the North Carolina Division of Radiation Protection.

The patient has been contacted several times for follow-up observations; however, the patient lives out of town and has not been willing to cooperate. Therefore, no additional actions are expected.

This event is considered closed for the purpose of this report.

Criteria:

Appendix A (see Event Type 2 in Table A-1) of this report notes that administering any therapeutic dose to the wrong patient should be considered an abnormal occurrence.

ITEM #:	940876	AO #:	NRC 94-08	EVENT DATE:	
TITLE:	MULTIPLE MEDICAL BRACHYTHERAPY MISADMINISTRATIONS AT DEACONESS MEDICAL CENTER IN BILLINGS, MONTANA				
NAME:	Deaconess Medical Center	CITY:	Billings	STATE:	MT

Nature and Probable Consequences:

On March 22, 1994, representatives from Northern Rockies Cancer Center (NRCC), Deaconess Medical Center (DMC), and St. Vincent Hospital and Health Center (SVHHC) notified the NRC Region IV office of a misadministration involving a brachytherapy treatment performed at DMC and SVHHC under treatment plans developed at NRCC. The three licensees participated in the telephonic notification because NRCC provides brachytherapy planning services to both DMC and SVHHC, and the potential cause of the misadministration involved errors in treatment plans developed by at NRCC. (NRCC is jointly owned by DMC and SVHHC)

The following day, March 23, 1994, the licensees reported an additional brachytherapy misadministration at DMC, and nine other incidents due to the same error that resulted in administered doses greater than prescribed (one at DMC and eight at SVHHC) (Ref. 2). The misadministrations reported by DMC involved administration of radiation such that the doses received by the patient exceeded the prescribed doses by 21 and 24 percent. In each case, the patient had received radiation by external beam as well "boost" doses administered via brachytherapy. The overdoses noted above pertain only to the brachytherapy component of each treatment.

During the initial telephonic report, NRCC staff explained that during a recent routine treatment setup a new staff member identified errors in a dose table generated by a Theratronics Theraplan L treatment planning system. Following considerable review of treatment plans and data generated using the treatment planning system, the physics staff at NRCC, with assistance from Theratronics, concluded that the data in a software file used to compute dose tables for cesium-137 (Cs-137) sources were deleted and were later replaced with data which did not properly characterize the Cs-137 sources used by DMC and SVHHC. The computer-generated dose tables that were computed using erroneous data were in error by as much as 20 to 25 percent. The errors were not detected because an incorrect reference dose table was used to verify and adjust the output of the treatment planning algorithm and individual patient treatment plans.

An NRC inspection was conducted at the facility on March 28 through April 1 and April 5 through 29, 1994. In addition, the events were reviewed by regional and headquarters NRC staff accompanied by personnel from the Idaho National Engineering Laboratory on April 6 through 8, 1994, to examine generic aspects of the root causes and contributing factors.

The physics staff at NRCC promptly corrected the data in the Theraplan L software and recalculated the doses received by the patients. Based upon a review of the recalculated doses conducted by the authorized users and an independent medical consultant contracted by NRCC, the authorized users have determined that no long-term adverse health effects beyond those normally expected for this form of treatment are anticipated for the patients. The licensee has been informed that an NRC medical consultant will review each case in order to provide an independent assessment of the potential consequences of the overdoses.

The patients involved in the misadministrations were notified both orally and in writing.

Cause:

The inspection disclosed that the root cause of the misadministrations was a failure to conduct independent (manual) verification checks of treatment plans that were adequate to determine the accuracy of computer-generated dose tables (Ref. 3, Ref. 4). Several factors involving clarity of instructions provided in the Theraplan user's manual, and in prompts and data presented to treatment planning system users in printed format and at the system console, were identified as contributing factors to the inadvertent entry of and failure to detect the erroneous data entered in program software for linear Cs-137 sources.

The inspection also disclosed significant weaknesses in DMC's implementation of its quality management program (QMP) for brachytherapy procedures. In addition, several apparent violations of NRC requirements relating to DMC's QMP and its implementation were identified. One apparent violation involved a failure to establish a QMP in January 1992, as required, although the inspection confirmed that DMC later established a QMP in May 1992. However, the QMP established by DMC failed to meet the following requirements: (1) that written directives are signed by authorized users and completed in accordance with NRC regulations; (2) that final plans of treatment are in accordance with the respective written directive; and (3) that each administration of radiation is in accordance with the applicable written directive. Other apparent violations included failures to (1) conduct an annual review of the QMP during the calendar years 1992 and 1993, (2) train all individuals working under the supervision of DMC's authorized users in the provisions of its QMP, (3) train nursing personnel who cared for patients undergoing brachytherapy treatment in accordance with the conditions of DMC's license, and (4) record all required information in survey records related to brachytherapy and in brachytherapy source usage records.

Licensee Action:

DMC voluntarily suspended its brachytherapy program until certain corrective measures could be implemented. However, because the findings of the inspection indicated significant, programmatic weaknesses in DMC's QMP and its implementation, the NRC sought to confirm with DMC staff the specific actions planned for completion prior to resuming brachytherapy treatments. The licensee's proposed corrective actions were documented in a Confirmatory Action Letter (CAL) issued by the NRC on May 3, 1994 (Ref. 5). As of the date of this report, the licensee has not yet completed each of the actions described in the CAL and has continued suspension of its brachytherapy program.

NRC Action:

An enforcement conference was held with the licensee on June 28, 1994, to discuss the apparent violations described above and review the corrective actions taken by the licensee. NRC is continuing its deliberations regarding any proposed enforcement action.

An NRC Information Notice has been drafted to inform other licensees of the particulars of this case and of the importance of conducting adequate checks of computer-generated treatment plans. NRC has also discussed concerns related to the Theratron treatment planning system software, and related instructions provided by the manufacturer, with representatives from the U.S. Food and Drug Administration (FDA). FDA has recently cleared the software for the treatment planning system to allow modifications to existing software to be imported into the United States.

A medical consultant will review each misadministration and provide NRC with an assessment of the overdoses and the potential adverse health effects to patients.

This event will be updated when additional information becomes available.

UPDATE: NUREG-0900, Vol. 17, No. 4 page 20. This AO was originally reported in NUREG-0090, Vol. 17, No. 2, "Report to Congress on Abnormal Occurrences, April-June 1994."

The AO criterion used was Event Type 5(d) in Table A-1 of Appendix A of this report-A therapeutic exposure which effects two or more patients at the same facility (regardless of any health effects).

At the time, it was reported that multiple brachytherapy misadministrations had occurred because of erroneous data in treatment planning computer software.

The AO report is updated and closed out as follows:

On June 28, 1994, an Enforcement Conference was conducted with Deaconess Medical Center of Billings, Montana, to discuss several apparent violations relating to the licensee's Quality Management Program (QMP). Some of the apparent violations were associated with two brachytherapy misadministrations which occurred at the licensee's facility in March 1994.

NRC issued a Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$7,500 and a Demand For Information to the licensee on August 23, 1994 (Ref. 3). The Notice of Violation described one violation, with several examples, associated with the misadministrations which was assessed a \$2,500 civil penalty. A second violation, which included multiple examples of failures to comply with the licensee's QMP and NRC's Quality Management Rule, was assessed a \$5,000 civil penalty. Four other violations were cited although no civil penalty was associated with them.

The licensee responded to the Notice of Violation and Proposed Imposition of Civil Penalties and Demand For Information by letter dated September 12, 1994 (Ref. 4, Ref. 5). The licensee paid the civil penalties in full, acknowledged each of the violations, and provided a description of the corrective actions taken. The licensee also responded to the Demand For Information by describing actions taken to ensure that certain authorized users were aware of the requirements to complete written directives for brachytherapy treatments and of the licensee's QMP. NRC acknowledged the licensee's response and no further information was requested.

NRC had previously issued a Confirmatory Action Letter (CAL) on May 3, 1994 (Ref. 6). This documented the licensee's commitments to temporarily suspend brachytherapy treatments at its facility until certain reviews and evaluations for its computerized treatment planning systems, and treatment planning programs used by its contractors, could be completed. The licensee responded, in part, to the CAL in a letter dated June 17, 1994 (Ref. 7), wherein the licensee described the results of tests and evaluations for one of three treatment planning systems used by its contractors. NRC reviewed the licensee's response and acknowledged the licensee's request to resume use of a Theratronics Theraplan L treatment planning system by letter dated July 21, 1994 (Ref. 8).

The licensee provided a second response to the CAL by letter dated August 22, 1994, which documented the results of tests performed on an Applied Research System (ARS) treatment planning system used by one of the licensee's consultants (Ref. 9). In the above noted letter, the licensee stated that the third treatment planning system would no longer be used to develop brachytherapy treatment plans for treatments at the licensee's facility. In the August 22, 1994 letter, the licensee also acknowledged that one item identified in the CAL had not yet been addressed. The latter item involved re-evaluation of several patient treatments completed at the licensee's facility after January 1992. The licensee had committed to reviewing these treatments to determine whether any recordable events or misadministrations had gone unrecognized prior to NRC's inspection March-April 1994. NRC reviewed the licensee's response and acknowledged that the licensee could resume use of the ARS treatment planning system for brachytherapy treatments by letter dated October 14, 1994 (Ref. 10).

This item is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to the events is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5[d] in Table A-1) of this report notes that a therapeutic exposure which affects two or more patients at the same facility (regardless of any health effects) can be considered an abnormal occurrence.

This report documents two misadministrations involving brachytherapy procedures performed at the licensee's facility in September and November 1993, (Itemno 940876 and Itemno 941281) which are related to nine other events identified at another NRC-licensed medical facility, because the events are the result of a common root cause.

ITEM #: 941116 AO #: NRC 94-09 EVENT DATE: 04/13/1992
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MEMORIAL HOSPITAL IN SOUTH BEND, INDIANA
NAME: Memorial Hospital CITY: South Bend STATE: IN

Nature and Probable Consequences:

On April 13, 1992, the first of two brachytherapy treatments was begun. Each of the treatments was to deliver 15 grays (Gy) (15 rad) to the patient's cervix. For the first treatment, five cesium-137 (Cs-137) sources were to be loaded into a treatment device, known as a Fletcher-suit applicator, which was placed in the patient's vagina. The sources were placed into afterloaders by a dosimetrist in preparation for placement in the applicator. The afterloaders were then placed in the applicator by the treating physician.

About eight hours later, the patient's care provider discovered a Cs-137 source on the floor near the foot of the patient's bed. The source was found after the care provider had changed the patient's bed linen. The care provider recovered the source with long handled forceps and placed it in a shielded container.

The treating physician and the licensee's Radiation Safety Officer (RSO) were notified. They determined that one afterloader in applicator was empty and that the Cs-137 source had not been placed in the applicator. The source was then placed in the afterloader and loaded into the applicator to continue the patient's treatment.

The first treatment was then completed, giving the patient a dose to the treatment site of 13.83 Gy (1383 rad), which was 8 percent less than the intended dose. The second treatment was then performed on April 27 and 28, 1992, without incident.

The licensee investigated the incident and concluded that the source had fallen on the floor while it was being placed in the afterloading device by the dosimetrist. The incident was not reported to NRC because the radiation dose to the treatment site differed by only 8 percent from the intended dose. This variance would not require reporting as a misadministration.

During an NRC inspection on May 4 and 5, 1994, the inspector reviewed the circumstances surrounding the treatment incident. The inspector evaluated the routine radiation surveys of the patient's room that were done after the radiation sources were placed in the applicator. The surveys showed that it was unlikely that there was an unshielded Cs-137 source on the floor of the room.

Further inquiry by the inspector led to the determination that the source likely fell from the afterloader while it was being placed in the applicator. The physician reported having difficulty in placing the afterloader in the applicator, and, according to the treatment chart, the patient had reported that she felt a small metal object fall next to her skin during the source placement.

As a result, the source may have been next to the skin of the patient's thigh for about 7.5 hours resulting in a radiation dose of up to 10.34 Gy (1034 rad), according to the licensee's calculation.

An NRC medical consultant was retained to evaluate the case and concluded that the radiation dose to the patient's thigh could result in some later damage to the tissue of the patient's thigh.

Because this incident resulted in a radiation dose to the wrong treatment site, this constitutes a misadministration.

The licensee notified the patient and the patient's physician of the misadministration on May 6, 1994. However, the licensee did not provide a written report to the patient until June 27, 1994, after NRC inquired about patient notification.

Cause:

The incident apparently was the result of the source falling out of the afterloader as it was being placed in the applicator. The physician reported some difficulty in placing the sources and apparently did not observe the source when it fell.

Licensee Action:

The licensee has revised its procedures for placing the radiation sources, including use of a pillow under a patient's pelvis in difficult situations. Its investigation of any future incidents will also include an evaluation of radiation doses to unintended treatment sites.

NRC Action:

The NRC inspection during May 4 and 5, 1994, identified two violations of NRC requirements. They were (1) failure of the licensee's Radiation Safety Committee and RSO to adequately investigate a possible misadministration to include consideration of possible radiation doses to the wrong treatment sites; and (2) failure to provide a written report to the patient within 15 days of the discovery of a misadministration. A notice of Violation (Ref. 6) was issued to the licensee on July 15, 1995. There was no Civil Penalty involved.

This item is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to the event is also being reported concurrently in the Federal Register. Appendix A (see E Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiat can be considered an abnormal occurrence.

ITEM #: 941038 AO #: NRC 94-10 EVENT DATE: 04/22/1994
TITLE: TELETHERAPY MISADMINISTRATION AT JEWISH HOSPITAL, WASHINGTON UNIVERSITY MEDICAL CENTER, IN ST. LOUIS, MISSOURI
NAME: Jewish Hospital, Washington University Medical Ctr CITY: St. Louis STATE: MO

Nature and Probable Consequences:

A patient was being treated for cancer of the brain. The written prescription directed that a 3000 centigray (cGy) (3000 rad) total absorbed dose be delivered in a series of 10 treatments of 150 cGy (150 rad) from the left side, and 150 cGy (150 rad) from the right side. The eyes were to be shielded during the treatments. The patient's first treatment on April 21, 1994, was delivered without incident in accordance with the prescription.

On April 22, 1994, the licensee informed NRC that after administering the first treatment to the patient, the physicians decided to include the patient's right eye orbit into the whole brain treatment field for subsequent treatment fractions. The radiation therapist was verbally instructed of the change, but the written directive was not changed.

The first portion of the second treatment was properly delivered using the modified treatment plan. However, the radiation therapist erroneously changed the treatment angle for the second portion of the treatment. The error meant that the left eye orbit received the radiation dose instead of the right eye orbit. Consequently, the left eye orbit received 150 cGy (150 rad) and the right eye orbit received 150 cGy (150 rad) less than intended. The licensee stated that the patient received an explanation of the event and that the error did not affect the treatment. The entire treatment was completed on May 6, 1994, without further incident. The patient subsequently died as a result of the cancer. The NRC consultant determined that the misadministration had no impact on the patient's death.

Cause:

Failure of the authorized physician to prepare a change in the written directive, and failure to effectively supervise the administration of the treatment.

Licensee Action:

The licensee's corrective actions included (1) policy changes to clarify the radiation therapists' responsibility when treatment plan changes are made; (2) retraining staff on quality management program (QMP) procedures; (3) requiring that on the first day of treatment the setup is supervised by a physician; (4) modifying the written directive form used for documenting written directives and subsequent revisions; and (5) reviewing and revising the current QMP and submitting the changes to NRC for review.

NRC Action:

NRC Region III conducted an inspection from May 2 through June 9, 1994, to review the misadministration. NRC also contacted a medical consultant to review the incident. Significant violations of NRC requirements were identified during the inspection. The violations included (1) failure to make a written revision to a written directive prior to administering a revised teletherapy dose to a patient; (2) failure to review the written prescription; (3) failure to verify that details of the administration of the verbally revised dose were in accordance with the written directive and plan of treatment; (4) failure to follow the written QMP procedures established by the licensee; and (5) failure to include in written directives the overall treatment period. On July 11, 1994, NRC Region III issued a Notice of Violation (NOV) with a Severity Level III violation with no fine assessed (Ref. 7). The NOV requires the licensee to document the specific actions taken and any additional actions planned to prevent recurrence.

This item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to the event is also being reported concurrently in the Federal Register. Appendix A (see E Table 3 in Table A-1) of this report indicates that a therapeutic exposure to a part of the body not scheduled to receive radiation can be considered as an abnormal occurrence.

ITEM #: 941084 AO #: NRC 94-11 EVENT DATE: 05/02/1994
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT THE QUEEN'S MEDICAL CENTER IN HONOLULU, HAWAII
NAME: The Queen's Medical Center CITY: Honolulu STATE: HI

Nature and Probable Consequences:

A patient was prescribed to receive two treatments of 1000 centigray (cGy) (1000 rad) to the patient's right eye using a strontium 90 (Sr-90) eye applicator. The treatment plan called for the two treatments to be scheduled one week apart. The first treatment was properly delivered on April 25, 1994, by keeping the source in contact with the patient's right eye for 18 seconds. On May 2, 1994, when the patient returned for the second treatment, the same physician treated the patient, but a different oncology nurse assisted. The physician did not refer to the written directive or to the dose rate information available with the eye applicator, although he had used other applicators in the past. He also did not discuss the procedure with the oncology nurse prior to the second treatment. At the end of the desired 18-second period, the nurse raised her voice and paused at the count of "18" (as she had been trained) without saying "stop" as the physician expected. As a result, the treatment continued until 32 seconds had passed, when the physician realized that the desired time must have elapsed. As a result, the patient received 1778 cGy (1778 rad) to the right eye during the second treatment, rather than the prescribed 1000 cGy (1000 rad).

The Radiation Safety Officer reported the misadministration to the NRC Operations Center at 8:37 p.m. on May 2, 1994. The referring physician was also notified on the same day. The patient was notified of the event during follow-up examinations by the referring physician on May 5 and May 14, 1994. No clinical damage was observed by the referring physician, and none is expected. The patient will be examined during subsequent follow-up visits to the medical center.

The NRC staff retained a medical consultant to evaluate the potential medical effects on the patient as a result of the misadministration. The medical consultant stated that dosimetry for Sr-90 eye applicators is difficult, due to calibration in the near future. The medical consultant stated that the increased unintended dose is within the range of normal treatments. He indicated that the medical consequences of the misadministration would be negligible.

Cause:

Part 35 of Title 10 of the Code of Federal Regulations states that licensees must establish and maintain a written quality management program (QMP) to provide high confidence that each administration is in accordance with the written directive. However, at the time of the treatment, the licensee did not have a written procedure to require that staff members confirm that the planned administration will be as specified in the written directive. Consequently, neither the physician nor the oncology nurse referred to the written directive, nor did they discuss the procedure before it took place. Inconsistent training given to the oncology nurses in the method of timing treatments was also a contributing factor.

Licensee Action:

The licensee revised the QMP procedures to prevent recurrence of similar misadministrations. The new procedure specifies that prior to the procedure, the staff will determine that the eye applicator is as specified in the written directive. It also states that the staff must seek guidance prior to continuing if they do not understand any aspect of the written directive.

NRC Action:

NRC Region IV conducted an inspection at The Queen's Medical Center on May 16-17, 1994, to review the circumstances associated with the misadministration and its probable cause(s). The NRC staff is currently reviewing the inspection results for possible violations and enforcement action is pending.

Future reports will be made as appropriate.

UPDATE: NUREG-0900, Vol. 17, No. 4, page 21. This AO was originally reported in NUREG-0090, Vol. 17, No. 2, "Report to Congress on Abnormal Occurrence, April-June 1994."

The AO criterion used was Event Type 1 in Table A-1 of Appendix A of this-Administering a therapeutic dose greater than 1.5 times the prescribed dose can be considered an AO.

At that time, it was reported that on May 2, 1994, a patient received 1778 centigray (cGy) (1778 rads) to the right eye during the second of a two-part treatment, rather than the prescribed 1000 cGy (1000 rads), because of an error in timing a strontium-90 (Sr-90) eye treatment.

The AO report is updated and closed out as follows:

An NRC inspection was conducted from May 1 to July 13, 1994. Consequently it was concluded that the licensee's Quality Management Program (QMP) lacked appropriate procedures for use of Sr-90 eye applicators, as required by Title 10 of the Code of Federal Regulations, Part 35.32, "Quality Management Program." However, based on additional information provided by the licensee during an Enforcement Conference on August 4, 1994, NRC concluded that the licensee's QMP, although marginal, was adequate and that the QMP was violated in this specific instance by the involved physician. Accordingly, a Severity Level IV violation with no civil penalty was issued on August 11, 1994.

The licensee responded to the violation on August 22, 1994, by identifying several corrective actions to preclude recurrence. The response included additional clarification of the QMP and Sr-90 procedure, additional training of nurses and physicians, and additional independent auditing of Sr-90 procedures.

NRC accepted the licensee's response to this item in a letter dated September 16, 1994.

This item event is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported in the Federal Register. Appendix A (see Event Type 1[Table A-1) of this report notes that administering a therapeutic radiation dose greater than 1.5 times that intended from a sealed source should be considered an abnormal occurrence.

ITEM #: 941355 AO #: NRC 94-12 EVENT DATE: 05/17/1994
TITLE: MEDICAL SODIUM IODIDE MISADMINISTRATION AT STAMFORD HOSPITAL IN STAMFORD, CONNECTICUT
NAME: Stamford Hospital CITY: Stamford STATE: CT

Nature and Probable Consequences:

On May 19, 1994, the licensee notified the NRC Operations Center that on May 17, 1994, a patient was administered 37 megabecquerel (MBq) (1 millicurie [mCi]) of sodium iodide iodine-131 (I-131) for a whole body scan when no such study was prescribed. The licensee identified this misadministration during review of the scan by the authorized user.

A patient was scheduled by a referring physician to have a "whole blood red cell mass" test, correctly known as a "red blood cell volume" test. This test involves withdrawing an amount of blood from the patient, and labeling the patient's red blood cells in vitro with the radionuclide chromium-51 have a nominal activity of 1.02 to 3.7 MBq (30-100 microcurie [uCi]). This is followed by reinjection of the labeled red blood cells into the patient, and measurement of radioactivity in blood samples withdrawn from the patient 10 to 30 minutes later. The referring physician contacted the patient's Health Maintenance Organization (HMO), as the HMO requires that it place the order with Stamford Hospital. The HMO wrongly contacted the central booking area for Nuclear Medicine at Stamford Hospital, rather than the Clinical Laboratory which performs this test as authorized in Part 35.100 of Title 10 of the Code of Federal Regulations. The central booking secretary, and the HMO secretary, in an attempt to fit the procedure in one of those listed under Nuclear Medicine, converted the prescribed "Whole Blood Red Cell Mass" test into "Whole Body I-131 Scan," a scan that uses 37 MBq (1 mCi) of I-131. The central booking secretary then printed the name of the referring physician at the bottom of the form for "Consultation for Nuclear Medicine," and sent it to the Nuclear Medicine Department where it was received on May 13, 1994. A nuclear medicine technologist (NMT) looked at the form and saw that it was for "total red cell mass" but since the NMT knew the referring physician, the NMT assumed that this was a new test using I-131 to determine "total red cell mass." The NMT ordered the requested 37 MBq (1 mCi) I-131 capsule, which was administered on May 16, 1994. The patient was scanned on May 17, 1994, and May 18, 1994, the authorized user (AU), who is also the Radiation Safety Officer (RSO), reviewed the films. The AU immediately noticed the error and notified the referring physician, who notified the patient.

The licensee estimated that the patient received a whole body dose equivalent of 4.7 millisievert (470 millirem) and a thyroid absorbed dose of 800 centigray (cGy) (800 rad). NRC was notified within 24 hours of the discovery of the misadministration. The licensee submitted a written report of the misadministration to NRC Region I on May 31, 1994.

Cause:

The licensee had failed to establish a quality management program (QMP) for administering quantities of I-131 and iodine-125 (I-125) greater than 1.11 MBq (30 uCi) which would require written directives and failed to instruct supervised individuals in NRC requirements of a QMP.

Licensee Action:

The licensee now requires that (1) all requests for diagnostic or therapeutic procedures be in writing and sent via facsimile transmission from the referring physician's office; (2) all administrations above 1.11 MBq (30 uCi) of I-131 be done only by written order from the AU/RSO or other AU's authorized to do so; (3) all diagnostic and therapy requisitions will be reviewed by a radiologist, and designated as approved or not approved; (4) all technologists will be trained in regard to the clinical diagnosis for which each test is applicable; (5) the central booking staff will meet with the RSO and will be informed that the clinical diagnosis must match the test being requested, and that any deviation from the match or any diagnosis that they don't understand must be challenged and brought to the attention of the radiologist; and (6) the RSO and physicist will review the QMP annually and discuss it at the Radiation Safety Committee meeting and with the entire nuclear medicine staff.

NRC Action:

NRC Region I conducted a special inspection on May 23 and 24, and June 1 and 6, 1994, to investigate the circumstances of the misadministration. An NRC inspection report (Ref. 8) was issued June 15, 1994, and identified the following five apparent violations: (1) failure to establish a QMP for amounts of I-125 and I-131 greater than 1.11 MBq (30 uCi); (2) failure to conduct annual reviews of the QMP; (3) failure to have records specifying the methods used to verify patient identity which can be audited; (4) failure to have written directives signed by the authorized user; and (5) failure to instruct individuals in the QMP. An NRC medical consultant reviewed the information in the NRC's inspection report, the licensee's 15-day misadministration report, and preliminary notification, and conducted telephone interviews with the RSO/AU. The medical consultant further stated that it is unlikely that the misadministration will result in a clinically detectable effect on the patient's thyroid. The impact on the patient's health should be negligible, with no long-term disability.

An enforcement conference was held with the licensee on June 24, 1994. The five violations were classified as a Severity Level 2 problem and a Notice of Violation and Proposed Imposition of Civil Penalty (Ref. 9) for \$1,250 was issued on July 11, 1994.

UPDATE: NUREG-0900, Vol. 17, No. 3, page 15. This abnormal occurrence (AO) was originally reported in NUREG-0900, Vol. 17, No. 2, "Report to Congress on Abnormal Occurrences," April-June 1994.

The AO criterion used was Event Type 1 in Table A-1-Administering a radiopharmaceutical other than the one intended which results in any part of the body receiving unscheduled diagnostic radiation, and the actual dose to the wrong body part is five times the upper limit of the normal range of exposure prescribed for diagnostic procedures involving that body part.

At the time, it was reported that on May 17, 1994, a patient was administered 37 megabecquerel (MBq)(1 millicurie [mCi]) of sodium iodide iodine-131 (I-131) for a whole body scan when no such study was prescribed.

This AO report is updated as follows:

The licensee responded to the NRC's Notice of Violation and Proposed Imposition of Civil Penalties in a letter dated August 10, 1994, contesting a number of the violations and the civil penalty. NRC is evaluating the licensee's response.

This event will be updated when additional information becomes available.

UPDATE: NUREG-0900, Vol. 17, No. 4 page 21. This AO was originally reported as AO 94-12 in NUREG-0090, Vol. 17, No. 2, "Report to Congress on Abnormal Occurrences, April-June 1994."

The AO criterion used was Event Type 1 in Table A-1 of Appendix A of this report-Administering a diagnostic radiopharmaceutical other than the one prescribed that result in a wrong part of the body receiving five times the upper limit of the normal range of exposure prescribed for diagnostic procedures involving that body part can be considered an AO.

At the time, it was reported that on May 17, 1994, a patient was administered 37 megabecquerel (1 millicurie) of sodium iodide iodine-131 (I-131) for a whole body scan when no such study was prescribed. It was estimated that the patient received a whole body dose equivalent of 4.7 millisievert (470 millirems) and a thyroid absorbed dose of 800 centigray (800 rads).

The AO report is updated and closed out as follows:

In a letter (Ref. 11) dated November 17, 1994, NRC rescinded the proposed civil penalty based on a reconsideration of the licensee's good performance on previous NRC inspections.

This item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to the event is also being reported concurrently in the Federal Register. Appendix A (see E Type 1 in Table A-1) of this report notes that administering a radiopharmaceutical other than the one intended which results in a part of the body receiving unscheduled diagnostic radiation, and the actual dose to the wrong body part, is five times the upper limit of the normal range of exposures prescribed for diagnostic procedures involving that body part, can be considered an abnormal occurrence.

ITEM #: 941581 AO #: NRC 94-13 EVENT DATE: 06/14/1994
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT BLODGETT MEMORIAL HOSPITAL IN EAST GRAND RAPIDS, MICHIGAN
NAME: Blodgett Memorial Medical Center CITY: East Grand Rapids STATE: MI

Nature and Probable Consequences:

On June 15, 1994, the licensee notified NRC that a misadministration occurred on June 14, 1994, during the second of a series three treatments to an eye surface lesion using a strontium-90 (Sr-90) eye applicator. The misadministration resulted in the patient receiving a total dose that was 53.6 percent above the intended total doses.

The patient was to receive 25.5 gray (Gy) (2550 rad) in a series of three equal treatments. The intended treatment time for each the three treatments was 19.1 seconds. The first treatment was performed as intended. During the second treatment, the treatment time was misread and the patient received treatment for 1 minute and 9 seconds. The second treatment dose was 30 Gy (3068 rad) instead of the intended 8.5 Gy (850 rad). The third treatment was not administered. Therefore, the patient's eye received a total dose of 39.18 Gy (3918 rad).

The patient and referring physician were notified of the incident by the licensee. The licensee and the referring physician do not anticipate any serious health consequences to the patient and have conducted follow-up medical examinations.

Cause:

The licensee reported that when the first treatment fraction was performed on June 7, 1994, the treatment time of 19.1 seconds was erroneously recorded on the medical chart as 1.91 seconds. When it came time for the second treatment fraction to be administered, the therapist made the assumption that the treatment time was 1 minute 9 seconds. The physician did not verify the specific details of the administration prior to administering the brachytherapy dose, and did not confirm the treatment time. In addition, the licensee failed to establish a written Quality Management Program (QMP) for the Sr-90 eye application, and the therapist was not instructed in the licensee's QMP.

Licensee Action:

The licensee reported that in the future the brachytherapy quality management program (QMP) will be strictly adhered to when performing eye applications, and a physics check will be done before each treatment fraction. In addition, a source activity decay chart for Sr-90 will be provided to the physicians for immediate reference.

NRC Action:

NRC Region III conducted an inspection from June 28 through July 6, 1994, to review the circumstances of the misadministration. An NRC medical consultant, retained to review the case, concluded that chances are favorable that the patient will suffer no health complications, but the risk of future complications is not zero.

On August 18, Region III issued a Notice of Violation (Ref. 10) to the licensee for the following violations: (1) treating a patient with the Sr-90 eye applicator without preparation of a written directive; (2) failure to establish and use a written QMP for the Sr-90 eye applicator; (3) investigation of the misadministration by the Radiation Oncology Department instead of the Radiation Safety Office as required; (4) failure to maintain required records of the Sr-90 source usage; (5) failure to maintain the manufacturer's instructions for the eye applicator as required. There was no Civil Penalty assessed for the violation.

This item is considered closed for the purpose of the report.

Other Agency Action:

Criteria:

The following information pertaining to the event is also being reported concurrently in the Federal Register. Appendix A (see E Type 5 in Table A-1) of this report notes that a therapeutic dose is greater than 1.5 times the prescribed dose can be considered an abnormal occurrence.

ITEM #:	941575	AO #:	NRC 94-14	EVENT DATE:	06/21/1994
TITLE:	MEDICAL BRACHYTHERAPY MISADMINISTRATION AT THE WILLIAM W. BACKUS HOSPITAL IN NORWICH, CONNECTICUT				
NAME:	The William W. Backus Hospital	CITY:	Norwich	STATE:	CT

Nature and Probable Consequences:

NRC Region I was notified by the licensee on June 21, 1994, of a therapeutic misadministration that had occurred at its facility earlier that day. The misadministration involved a patient who was prescribed to receive a prostate implant of 112 iodine-125 (I-125) seeds having a radionuclide activity per seed of between 15.9 and 17.0 megabecquerel (MBq) (0.43 and 0.46 millicurie [mCi] but who instead was implanted with 112 I-125 seeds having an activity of 166 MBq (4.49 mCi) each.

Following the preplanning dosimetry performed at Yale-New Haven Hospital (YNHH), a written directive was prepared by an authorized user and was sent via facsimile transmission to The William W. Backus Hospital on June 16, 1994, by the dosimetrist from YNHH. (YNHH is under contract with The William Backus Hospital to provide radiation oncologists, dosimetrists and health physicists, and two of the physicians from YNHH are listed as authorized users on The William W. Backus Hospital's NRC license). The Chief Nuclear Medicine Technologist (NMT) received the directive and called Medi-Physics in Arlington Heights, Illinois, to place the order for the required I-125 seeds. The package containing the seeds arrived at The William W. Backus Hospital on June 17, 1994, and was received by one of the NMTs, who was not the same individual who had ordered the seeds. The NMT opened the package after making the required radiation surveys. In accordance with the licensee's established procedure, information on the packing slip that accompanied the package was compared with the information that was posted on the lead "pig" that contained the seeds. The verified information included the number of seeds (112), activity per seed (166 MBq [4.49 mCi] per seed), and total activity (18,600 MBq [502.88 mCi]), and was entered into the sealed source inventory log book by the NMT.

On June 21, 1994, the dosimetrist from YNHH arrived at The William W. Backus Hospital to assist in the implant procedure. The same dosimetrist had performed the preplanning dosimetry, and had prepared the written directive that was signed by the authorized user. The dosimetrist took the package after reviewing the documentation, but failed to notice that the activity of the seeds was 10 times higher than the prescribed activity. The dosimetrist made entries into the log book before removing the container from the nuclear medicine hot lab, and the entries documented that 112 seeds with activity of 166 MBq (4.49 mCi) each were taken to the operating room.

The implant procedure was completed between 10 and 11 a.m. on June 21, 1994, in the presence of the authorized user, who at the completion of the procedure documented that 112 I-125 seeds with total activity of 1840 MBq (49.73 mCi) were implanted. Following the implant procedure, the required radiation surveys were made by the dosimetrist and the dose rate of 1 microcurie per kilogram (4 milliroentgen) per hour at 1 meter (39 inch) from the patient was recorded by the dosimetrist.

The patient was moved to the recovery area, and the dosimetrist returned to the nuclear medicine department to complete the documentation required by the licensee's procedure. At this time, the dosimetrist noted discrepancies between the entries made in the log book by the NMT at the time of receipt of the package, and those made by himself earlier that morning. The dosimetrist assumed that these were clerical errors, and therefore "corrected" two of the three sets of entries in the log book by drawing lines across them and entering the "correct" figures as 16.6 MBq (0.449 mCi) per seed and 1860 MBq (50.288 mCi) total, respectively.

The dosimetrist realized the possibility of an error when it was noted that the packing slip also indicated that each seed had an activity of 166 MBq (4.49 mCi). The dosimetrist contacted the Chief NMT, and together they both called Medi-Physics to verify activity of the seeds. Upon confirmation by Medi-Physics that each seed had an activity of 166 MBq (4.49 mCi), the surgeon was notified of the error. (The surgeon was also the patient's referring physician.) Unable to contact the authorized user who had supervised the implant procedure, the surgeon consulted with a second authorized user (also from YNHH) and the two agreed that a surgery to explant as many seeds as possible was the most appropriate approach under the circumstances. This involved removal of the patient's prostate gland where a majority of seeds were located. The patient and his family were informed of the misadministration, and the patient was brought back to the operating room and prostatectomy was completed at approximately 4 p.m.

The licensee was able to explant 69 of the 112 seeds that were implanted, leaving 43 seeds still remaining inside the patient's body. During the explanting procedure, one of the I-125 seeds was ruptured. The patient was administered prophylactic potassium iodide to block the possible uptake of I-125 by the patient's thyroid. The licensee also collected the fluids and the tissue that may have been contaminated. Approximately 5 liters (5.28 quarts) of fluid were collected and appeared to be contaminated with approximately 1.85 MBq (0.050 mCi) of I-125. The personnel who were present in the operating room during the surgery were also monitored for possible uptake, and the results indicated no internal contamination of these personnel.

The patient was transferred to YNHH on June 23, 1994, in order that a more precise localization of the remaining seeds could be made by the use of equipment available at that facility. At YNHH three-dimensional scans were taken, and on June 27, 1994, the patient was again operated on and an additional 15 seeds were explanted. This left 28 seeds still remaining in the patient. The remaining seeds appeared to be scattered in the lower pelvic region and the licensee decided that further mitigating surgery at that time was not warranted. The patient appeared to be in stable condition. Preliminary dose calculations by the licensee indicated remaining seeds would cause the body tissue to receive a radiation dose of the same order of magnitude as would have been received by the surrounding organs and tissue if the originally planned seeds were permanently implanted. The patient was discharged from YNHH on July 4, 1994.

Cause:

There was a misunderstanding in communications between the Chief NMT who ordered the seeds, and the representative of Medi-Physics who received the order. The Chief NMT and the NMT were not familiar with the magnitude of the radionuclide activities that are used in prostate implant procedures. The NMT did not inform the Chief NMT as to the activity received. The Chief NMT was confused by the two telephone calls that were received from Medi-Physics subsequent to placing of the order, but failed to clear the confusion. The licensee did not have any procedure that required a comparison of the material ordered and the material received. The YNHH dosimetrist failed to notice that the activity of the seeds was 10 times higher when he logged out the seeds. The licensee did not have a procedure that required an independent verification of the activity that was being loaded into the implant needles. The authorized user relied totally on the dosimetrist and did not verify the activity of the seeds. Dual control (by the licensee and YNHH) of the radiation safety program related to brachytherapy procedures caused the YNHH to assume that the Chief NMT was familiar with the ordering of the radioactive material and did not need additional training.

Licensee Action:

The licensee made a commitment to voluntarily suspend its brachytherapy program until written authorization is granted by NRC to resume the program. This commitment was documented in a Confirmatory Action Letter (Ref. 11). The licensee was considering a requirement that radioactive sources be assayed prior to implantation, and that the implant sources be ordered in writing from the supplier.

NRC Action:

NRC Region I dispatched an inspection team, which arrived at the facility at approximately 2:00 p.m. on June 22, 1994, to review the circumstances surrounding the misadministration. An NRC medical consultant was engaged to assess the effects of the misadministration on the patient. The medical consultant reviewed the events and the mitigating actions that the licensee had taken to minimize the impact of the misadministration on the patient. The consultant advised NRC that the licensee's actions appear appropriate. On June 23, 1994, NRC Region I, in consultation with the NRC Office for Nuclear Material Safety and Safeguards (NMSS) and the NRC Office for Analysis and Evaluation of Operational Data, upgraded its inspection effort to an Augmented Inspection Team (AIT). NMSS contacted the U.S. Department of Energy Idaho National Engineering Laboratory (INEL), who formed a team of consultants to provide technical support to the AIT. The AIT and INEL support consultants returned to The William W. Backus Hospital on June 28, 1994, and also to YNHH. NRC Region I issued a press release on June 23, 1994, and the AIT held a public exit meeting with the licensee at The William W. Backus Hospital on July 7, 1994 (Ref. 12). In a letter to the licensee dated August 10, 1994, NRC indicated that its review of the AIT report noted two apparent violations: (1) 10 CFR 35.32 and (2) 10 CFR 35.25(a) (Ref. 13). NRC will discuss these apparent violations at an Enforcement Conference scheduled for August 24, 1994.

This event will be further updated when additional information becomes available.

UPDATE: from NUREG-0090, Vol. 17, No. 3 page 15. This abnormal occurrence (AO) was originally reported in NUREG-0090, Vol. 17, No. 2, "Report to Congress on Abnormal Occurrences," April-June 1994.

The AO criterion used was Event Type 5 in Table A-1-A therapeutic dose that is greater than 1.5 times the prescribed dose.

At the time, it was reported that on June 21, 1994, a patient was implanted with 112 iodine-125 seeds having an activity of 166 megabecquerel (MBq)(4.49 millicurie [mCi]) each, rather than the prescribed 112 I-125 seeds having an activity of between 15.9 and 17.0 MBq (0.43 and 0.46 mCi) each.

The AO report is updated as follows:

The licensee submitted its 15-day report on the misadministration by letter dated July 6, 1994, (Ref. 4). The report stated that in addition to the prostatectomy performed during the initial surgery on June 21, 1994, the patient's bowel was diverted via a colostomy. The initial dose was intended to deliver a peripheral target dose of 16,000 centigray (cGy) (16,000 rad). A conservative estimate of the final dose is 55,137 cGy (55,137 rad) based on the remaining residual seeds. The NRC medical consultant's final report was in agreement with the licensee's report. The consultant indicated that the misadministration, and subsequent multiple surgical procedures to remove the isotope, predisposes the patient to a variety of future medical problems. The licensee agrees to provide monthly updates on the patient's condition to NRC for at least one year.

At the Enforcement Conference held on August 24, 1994, the licensee presented corrective actions that included: (1) requiring nuclear medicine technologists to verify all information contained in the packing slip, certificate of activity, vial label, and written directive at the time the package is received, as well as requiring the Radiation Safety Officer to be notified if any discrepancy is identified; (2) confirming all orders in writing with the supplier prior to implantation; (3) providing training to the nuclear medicine staff; (4) revising procedures to require verification in accordance with the written directive prior to administration of doses; (5) revising the Quality Management program; and (6) creating the staff position of Brachytherapy Safety Nurse Coordinator to provide increased control over these activities.

NRC is evaluating the licensee's corrective actions, and is reviewing its enforcement options as a result of the Enforcement Conference held on August 24, 1994.

NRC performed an inspection on September 19, 1994, and observed that all of the corrective actions had not yet been fully implemented. The licensee agreed to notify NRC Region I in writing when implementation of the corrective actions was complete.

This event will be updated when additional information becomes available.

UPDATE: from NUREG-0090, Vol. 17, No. 4 page 21. This AO was originally reported as AO 94-12 in NUREG-0090, Vol. 17, No. 2, "Report to Congress on Abnormal Occurrences, April-June 1994."

The AO criterion used was Event Type 1 in Table A-1 of Appendix A of this report-Administering a therapeutic dose greater than 1.5 times the prescribed dose can be considered an AO.

At the time, it was reported that on June 21, 1994, a patient was implanted with 112 iodine-125 (I-125) seeds having an activity of 166 megabecquerel (MBq) (4.49 millicurie [mCi]) each, rather than the prescribed 112 I-125 seeds having an activity of between 15.9 and 17.0 MBq (0.43 and 0.46 mCi) each.

The AO report is updated and closed out as follows:

On November 7, 1994, the NRC issued a Notice of Violation (Ref. 12) and Proposed Imposition of Civil Penalty (Ref. 13) in the amount of \$15,000 for the two violations indicated in the Notice. On December 6, 1994, the Licensee submitted its corrective actions for the violations cited and paid the proposed civil penalty of \$15,000.

This event is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to the event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic dose that results in an actual dose greater than 1.5 times the prescribed dose can be considered an abnormal occurrence.

ITEM #: 940738 AO #: AS 94-02 EVENT DATE: 08/04/1993
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MEMORIAL MEDICAL CENTER IN LUFKIN, TEXAS
NAME: Memorial Medical Center CITY: Lufkin STATE: TX

Nature and Probable Consequences:

On August 4, 1993, brachytherapy treatment began on an obese 90-year-old patient using a Delclos vaginal cylinder implant. Two cesium-137 implant sources of 25 milligram radium-equivalent strength (2323.6 megabecquerel [62.8 millicurie]) were loaded at 2:40 p.m. for a 20-hour treatment of 30000 centigray (cGy) (3000 rad). The estimated dose to the abdomen due to the prescribed procedure would be 20 cGy (20 rad).

The implant was secured at the implant site with surgical tape. During the treatment period, the patient became distressed and repositioned to ease her breathing. The implant placement was last verified at 6:00 a.m. on August 5, 1993. At 10:30 a.m. that day, the doctor terminated the treatment. At the time he noted that one implant was positioned on the patient's abdomen. The doctor believes that the repositioning of the patient may have dislodged the implant the tape pulled the implant onto the patient's abdomen. The doctor indicated that the tape was the only method used to secure the implant because of the design and location.

The hospital's radiation physicist calculated that the skin dose rate from the implant was 150 cGy (150 rad) per hour. If the implant was on the patient's abdomen for 4.5 hours, the unintended doses would have been 675 cGy (675 rad) to the abdomen and 2325 cGy (2325 rad) to the tumor. This is a 655 cGy (655 rad) unintended to the abdomen and a 675 cGy (675 rad) underdose to the tumor. A review of personnel monitoring records for the doctor and nurses caring for the patient indicated there were no elevated radiation exposures. The patient was informed of the incident.

On September 2, 1993, the patient was examined by her doctor and no evidence of radiation damage to the abdomen was noted. The patient has since died. (The misadministration did not contribute to the patient's death.)

Cause:

Repositioning of the patient to relieve breathing distress was the probable cause of the implant relocation.

Licensee Action:

The hospital increased nursing in-service training with emphasis on source and implant apparatus identification, and the importance of verifying implant placement during each patient check. The doctors are reviewing different means to secure these devices in patients.

NRC Action:

Other Agency Action:

The State agency investigated the incident and reviewed care procedures for radiation therapy patients for violations. No violations were noted. The State agency also reviewed the subject matter covered during the nurses increased in-service training.

Criteria:

Appendix A (see Event Type 3 in Table A-1) of this report indicates that a therapeutic exposure to a part of the body not scheduled to receive radiation can be considered as an AO.

ITEM #: 941441 AO #: AS 94-03 EVENT DATE: 02/23/1994
TITLE: RADIATION BURN OF AN INDUSTRIAL RADIOGRAPHER AT BLAZER INSPECTION IN TEXAS CITY, TEXAS
NAME: Blazer Inspection CITY: Texas City STATE: TX

Nature and Probable Consequences:

On February 23, 1994, a radiography crew was radiographing welds on a 30.5-centimeter (cm) (12-inch) diameter pipe line in a meter (5-feet) deep ditch at Amoco Pipeline, using a 3552 gigabecquerel (96 curie) iridium-192 source. They had experienced difficulty with the source exiting from and retracting into the camera earlier in the day. In trying to retract the source to the shield position after a radiograph, it was apparent from the survey meter readings that the source was in an unshielded position. In working the crank-outs, the source was pushed from the camera but would not retract into the camera which indicated a source disconnect. The radiographer got a 2.5-cm (1-inch) thick lead sheet from the radiography truck and covered the source in the guide tube. He then sent his helper to get the Amoco inspector, but by that time it was dark.

The radiographer had his helper rope off a larger area and stay at a distance from the source. He then asked the Amoco inspector to call the radiography Radiation Safety Officer (RSO), to tell him that everything was under control and that the radiographer could handle the situation. The radiographer then disconnected the guide tube and the source fell into the mud at the bottom of the ditch. In picking up the source from the mud with channel-lock pliers the source slipped, and reaching to straighten the pigtail with his hand he apparently touched the source in the process. He placed the pigtail into the camera, intending to place the source caps in first, but the survey meter indicated that the source was still extending from the camera.

The radiographer then removed the pigtail and placed it under the lead sheet. He removed the lock-box from the camera, inserted the source end of the pigtail, replaced the lock-box, and locked it. The source was now secured in the shielded position. The barricades were taken down, the equipment loaded on the truck, and the crew returned to the office. The company did not notify the State agency of the disconnect.

About 10 days later, the radiographer started experiencing discomfort in his left thumb and index finger and visited a doctor for treatment on March 9, 1994, and again on March 14, and April 1, 1994. On April 11, 1994, the RSO and the radiographer visited the State agency office and reported the incident. The State agency investigated the incident at this time, and found that the film badge reading was 10.5 millisievert (1.05 rem) whole body.

An inspection of the camera was performed by the radiography company's RSO the day after the incident. The company had ordered two model number 22 pigtails and sources from Industrial Nuclear Co., Inc. (INC), for the company's Gamma Century radiography cameras. INC inadvertently sent the radiography company a model number 22 and a model number 23 pigtail, instead of the two model number 22 pigtails that were ordered. The two models appeared similar but close examination revealed two differences. The model number 22 is manufactured with a 0.32-cm (0.13-inch) aircraft cable and a 1.9-cm (0.75-inch) connector while the model number 23 is manufactured with teleflex cable, which is the same as the drive cable, and a 2.5-cm (1-inch) connector. The model number 23 is not made to be used in the Gamma Century camera. The radiography company assumed the two pigtails sent to it were each a model number 22. The model number 23 was mistakenly placed in the Gamma Century camera being used at Amoco Pipeline and is apparently the cause of the disconnect. The radiography company thought it was placing a model number 22 in the Gamma Century camera. The California Radiation Control Program (INC is licensed in California) was informed of the incident and investigated INC's mistake in sending the two different pigtails to the radiography company.

Cause:

The manufacturer's mistaken delivery of a pigtail model number, different than the one ordered, and the radiography company's assumption that the pig tails received were the models ordered, resulted in a pigtail being used in a camera for which it was not manufactured.

Also, the radiographer knowing he was not authorized to do so, attempted to recover the disconnected source. He stated that due to the darkness and the mud in the ditch, he felt the circumstances warranted his attempt to recover the source. The radiographer was not trained in source recovery and had no previous experience with source disconnects.

Licensee Action:

Actions will be given at the Enforcement conference.

NRC Action:

Other Agency Action:

The licensee and radiographer were cited for violations of the Texas Regulations for Control of Radiation and are being called in an escalated Enforcement Conference.

This event will be updated when additional information becomes available.

UPDATE: from NUREG-0090, vol. 17, No. 3, page 16. This abnormal occurrence (AO) was originally reported in NUREG-0090, Vol. 11, No. 4, "Report to congress on Abnormal Occurrences," October-December 1998.

The AO criterion used was For All Licensees, No. 11-A serious deficiency in management or procedural controls.

At that time it was reported that the incident occurred during a source disconnect on February 23, 1994, when a radiographer accidentally dropped a source into a muddy ditch and then attempted to retrieve it with a pair of pliers. As the source was slipping loose from the pliers, the radiographer instinctively caught it with the forefinger and thumb of his left hand for a brief instant and received an overexposure. Consequently, blisters appeared on his fingers about 10 days later.

As reported by the State of Texas, one of the causes of the event was the mistaken delivery of the wrong radioactive source pig by the manufacturer, and the radiography company's attempt to use the wrong pigtail in a radiography camera for which it would not fit properly. (The manufacturer and supplier was Industrial Nuclear Company, Inc., which is licensed by the State of California, and the radiography company was Blazer Inspection, which is licensed by the State of Texas.)

Before closing out the AO report, NRC asked the State of California to provide the following additional information concerning its investigation: (1) the cause for the supplier's mistake; (2) whether other instances of mistaken shipments were found; (3) what violations were found; and (4) whether the supplier's procedures are adequate to prevent a recurrence or, if not, what changes were made. The requested information from the State of California's investigation is as follows:

(1) The cause of the supplier's mistake was employee error; the employee fabricated the wrong source for the licensee. However, it is noted that Blazer Inspection, Inc., is an authorized user for the sources and customarily ordered both model 22 and model 32 sources. It would appear that failure to properly use the model 32 source would be Blazer's error. Please note that the two sources are easily identified; the model 22 uses a flexible aircraft cable pigtail and the model 32 uses a stiff TeleflexR cable. (Please note that based on incorrect preliminary information, AS 94-3 in NUREG-0090, Vol. 17, No. 2, erroneously reported a model 23 source instead of the correct model 32.)

(2) There were no other mistaken shipments.

(3) No violations were identified based on the State's inspection.

(4) The State of California indicated in its inspection that Industrial Nuclear Company, Inc., should improve its methods to assure that proper sources are sent to authorized recipients. The State is following up with a letter to the licensee.

NRC also asked the State of Texas to provide an estimate of the extremity dose received by the radiographer. The State of Texas reported that the estimated dose received to the radiographer's left hand, as determined by the extent of the injury, was between 1200 and 1700 centigray (1200 and 1700 rad).

This event is closed for the purpose of this report.

Criteria:

Appendix A (see Example 11 of "For All Licensees") of this report notes that serious deficiency in management or procedural controls in major areas can be considered an AO.

ITEM #: 941442 AO #: AS 94-04 EVENT DATE: 04/19/1994
TITLE: LOST WELL LOGGING SOURCE AT TUCKER WIRELINE SERVICE OF CORPUS CHRISTI, TEXAS
NAME: Outside of CITY: Freer STATE: TX

Nature and Probable Consequences:

On April 19, 1994, a well logging crew with Tucker Wireline Services completed a job for Amoco Production Company at the Los Lomas Ranch, Peters Estate, Well Number 1, which is 16 miles south of Freer, Texas. They loaded all tools and equipment onto their truck along with a 111 gigabecquerel (3 curie) americium/beryllium-214 source and its shield, which were chained in a left rear compartment. The shield is a 36-centimeter (14-inch) diameter cylinder, which is painted purple and weighs 347 newtons (78 pounds).

The well logging crew stopped in Freer to report to the office and noticed that the compartment was open. They checked the compartment and found that the source and shield were missing. They called the office and reported the source missing.

The crew then back-tracked to the job site and attempted to locate the source. The office also sent four people to help find the source. The source was not found, but a depression in the road with purple paint indicated the spot where the source and shield fell from the truck. It was apparent that someone had found and taken possession of the source.

On April 20, 1994, the State agency and licensee personnel searched from ranch to ranch attempting to locate the individual who had taken possession of the source. The source was not located and the licensee issued a formal press release to the area newspapers and television stations offering a reward.

On April 21, 1994, the Texas Board of Health issued a press release. That afternoon a ranch owner called and reported that he had found the source, and had placed it in his barn thinking it was a tool box. He agreed to meet the next morning and return the source to the licensee.

On April 22, 1994, the State agency and licensee personnel met with the ranch owner who returned the source to the licensee. The ranch owner had found the source beside the road, and placed it in the back of his truck. He drove it to his barn and kicked the source off the back of his truck. State agency calculations indicated the ranch owner received less than 50 microsievert (5 millirem) exposure during the handling of the source. The required labeling information was not on the shield.

Cause:

The source and shield were not properly secured against accidental loss from the truck. Although the well logging crew indicated they chained and locked the source and shield to the truck, circumstances do not support that contention.

Licensee Action:

The licensee will address the incident at its Enforcement Conference.

NRC Action:

Other Agency Action:

The State agency cited the licensee for failure to secure the source against accidental loss and violations of labeling requirements. The licensee has been called in for an escalated Enforcement Conference.

This event is considered closed for the purpose of this report.

Criteria:

Appendix A (see Example 11 of "For All Licensees") of this report notes that serious deficiency in management or procedural controls in major areas can be considered an AO.

ITEM #: 941371 AO #: AS 94-05 EVENT DATE: 05/17/1994
TITLE: MULTIPLE BRACHYTHERAPY MISADMINISTRATIONS AT CEDARS MEDICAL CENTER IN MIAMI, FLORIDA
NAME: Cedars Medical Center CITY: Miami STATE: FL

Nature and Probable Consequences:

On May 17, 1994, an error was discovered in the treatment of seven patients with low dose rate cesium-137 (Cs-137) brachytherapy sources. One patient was treated with three Cs-137 sources during a gynecological implant procedure, during the period of May 4 through 8, 1994. The patient received approximately 9130 centigray (9120 rad) to the treatment area, which was about 238 percent greater than prescribed. Further investigation of the incident revealed that the error involved six additional patients, with the patients each receiving doses ranging from 37 percent to 144 percent in excess of their intended doses.

The licensee reported that the misadministrations for all seven patients were of similar magnitude. Possible consequences apply uniformly to the patients, and will be due to the dose received to organs near the implants. The licensee stated that all of the organs may have had similar complications even if there had been no overdose, and the risks for complications have increased even though the possibility for cure has also increased. The referring physicians and patients have been notified, and patient follow-up has been implemented to include routine examinations.

Cause:

The misadministrations were caused by a calculation error when the physicist entered the wrong gamma constant when he edited the computer program on March 29, 1994. The physicist was attempting to convert from "milligram radium equivalent" to "millicurie," resulting in an error ratio that was 2.5 times greater than expected. (The treatment planning system was developed Computerized Medical System of St. Louis, Missouri.) The initial error was confirmed by another physicist who performed independent calculations utilizing a computer treatment planning system at another facility. A third physicist has independently confirmed the calculations on all patients involved. An extensive record review was performed to ensure that no other patients were involved.

Licensee Action:

To prevent any possibility of a repeat of this occurrence, the licensee discussed the incident with the manufacturer of the treatment planning system. The licensee also instituted more thorough training and supervision of personnel in brachytherapy calculation methods, which includes independent hand calculations of at least one key point for confirmation of dose.

NRC Action:

Other Agency Action:

The Stage agency performed an on-site visit on May 17, 1994, to confirm the cause of the error, to verify that appropriate corrective actions were being taken, and that proper review was taking place to determine if other patients were involved. An additional visit was conducted on May 26, 1994, to further investigate the incident and to assure that proper patient notification and follow-up was taking place. The investigation found that the cause of the event appeared to be as stated by the licensee. An independent medical consultant has been retained by the State to review the incident and advise on the appropriateness of all findings, conclusions, and patient follow-up.

This event is considered closed for the purpose of this report.

Criteria:

Appendix A (see Events Type [5][a] and [5][d] in Table A-1) of this report notes that a therapeutic exposure to a part of the body scheduled to receive radiation such that the actual dose received is greater than 1.5 times the prescribed dose, or the event (regardless of any health effects) affects two or more patients at the same facility, can be considered an AO.

ITEM #: 941413 AO #: NRC 94-15 EVENT DATE: 03/09/1994
TITLE: SODIUM IODIDE EVENT AT WELBORN MEMORIAL BAPTIST HOSPITAL IN EVANSVILLE, INDIANA
NAME: Welborn Memorial Baptist Hospital, Inc. CITY: Evansville STATE: IN

Nature and Probable Consequences:

On May 16, 1994, the licensee reported to NRC that a pregnant patient was administered 185 megabecquerel (MBq) (5 millicuri [mCi]) of sodium iodide-131 (I-131) on March 9, 1994, as prescribed in the written directive for the treatment of Graves' disease (hyperthyroidism). The licensee did not know that the patient was pregnant at the time of the administration. On May 10, 1994 the licensee was informed by a private practice physician that the patient was 22-weeks pregnant at the time of treatment. As a result, the patient's fetus received an unintended radiation dose.

The patient was referred to the licensee with possible hyperthyroidism. To confirm the suspect condition, the licensee administered a 440.3 kilobecquerel (11.9 microcurie) I-131 capsule to the patient on March 7, 1994, and measured an 82-percent thyroid uptake over the ensuing 25 hours. The licensee stated that prior to administering the I-131 diagnostic capsule on March 7, 1994, the patient was questioned and informed both the treating physician and the nuclear medicine technologist administering the capsule that she was not pregnant. The licensee diagnosed the patient's condition as Graves' disease and the treating physician prescribed a 185 MBq (5 mCi) I-131 therapy treatment. On March 9, 1994, a 185 MBq (5 mCi) I-131 capsule was orally administered by one of the licensee's nuclear medicine technologists, as prescribed. Prior to the treatment on March 9, 1994, the technologist questioned the patient once more and was again informed by the patient that she was not pregnant.

Oak Ridge Institute for Science and Education calculated the fetal whole body and thyroid doses at NRC request. The fetal dose to the thyroid was calculated as 7,000-12,000 centigray (cGy) (7,000-12,000 rad), and the fetal whole body dose was calculated as 0.55 cGy (0.55 rad). Based on the calculated fetal dose there are a range of possible consequences, the most likely being no significant harm to the fetus. At NRC request, the Radiation Emergency Assistance Center/Training Site in Oak Ridge, Tennessee, contacted the licensee to discuss the dose assessment and potential fetal effects.

On May 10, 1994, a physician specializing in maternal fetal medicine, not affiliated with the licensee, discussed the incident with the licensee. The patient was informed of the exposure and possible consequences to the fetus by the maternal fetal specialist.

Cause:

The principal cause for the event was licensee reliance on the patient's assurance of non-pregnancy. Licensee procedures do not require determination of pregnancy status through serum testing, or other appropriately documented means, for all female patients of child bearing age. The patient was apparently unaware of her pregnancy status at the time of I-131 administration on March 9, 1994.

Licensee Action:

The licensee is in the process of developing internal policies which will address options for pregnancy status determination including serum pregnancy testing or suitable written proof, such as evidence of a hysterectomy. The legal implications and options for written proof of non-pregnancy tests to all female patients of child bearing age, unless appropriate proof of non-pregnancy is available as determined by the authorized user. For patients unwilling to undergo pregnancy testing, radiopharmaceuticals will not be administered and the authorized user will be consulted for the appropriate course of action.

NRC Action:

NRC Region III conducted a safety inspection from May 18 through June 8, 1994, to review the circumstances surrounding the event and to evaluate aspects of the licensee's radiopharmaceutical Quality Management Program (Ref. 1). No regulatory violations associated with the event were identified. The licensee's procedure appears to have been followed in this specific case. NRC regulations do not include requirements for patient pregnancy verification prior to administration of radiopharmaceuticals. However, NRC is in the process of developing regulations which will address the administration of radiopharmaceuticals to breastfeeding and pregnant patients.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see General Criterion 1) of this report notes that a moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission can be an abnormal occurrence.

ITEM #: 941675 AO #: NRC 94-16 EVENT DATE: 07/21/1994
TITLE: TELETHERAPY MISADMINISTRATION AT MEDICAL CENTER HOSPITAL IN CHILLICOTHE, OHIO
NAME: Medical Center Hospital CITY: Chillicothe STATE: OH

Nature and Probable Consequences:

On July 27, 1994, the licensee reported that a patient received a radiation dose of approximately 300 centigray (cGy) (300 rad) to an unintended treatment site using a cobalt-60 teletherapy unit.

A patient was scheduled to receive 1400 cGy (1400 rad) in a series of seven treatments for cancer of the esophagus. Each of the treatments was to consist of two radiation exposures of 100 cGy (100 rad) each delivered from different angles. The first treatment was performed on July 21. Following the first of the two exposures during the second treatment on July 22, the technologist found inconsistencies in the angles of treatment documented in the written directive and in the patient simulation sheet. Upon further review, the licensee determined that the wrong treatment site would have received approximately 20-50 cGy (20-50 rad).

The treatment angles were corrected on the patient's chart, and the radiation dose was modified to compensate for the reduced dosage delivered in the initial treatments. The patient was informed and no adverse medical effects are expected.

The patient was notified verbally on July 26, 1994 and in writing as required by 10 CFR 35.33. According to the medical consultant, there will be no medical consequences as a result of the misadministration.

Cause:

The error occurred because the simulated gantry angles had not been converted to the treatment unit gantry angles, and gantry angle conversion factors were not included in the licensee's treatment chart checks conducted by the technologists.

The root causes of the problem were discussed with the licensee on September 1, 1994, during an Enforcement Conference. The causes appeared to be the following: (1) written procedures were not developed to address gantry angle conversions; (2) the technologist did not have an adequate understanding of the informal gantry angle conversion procedures; (3) the informal gantry angle conversion procedure was not part of the licensee's annual refresher training program; (4) technologists did not fully understand their responsibilities to resolve discrepancies in a treatment plan; and (5) gantry angle conversion factors were not included in the licensee's treatment chart checks conducted by the technologists.

Licensee Action:

The licensee's corrective actions included: (1) revising the simulation data form to include a specific location to document the converted gantry angles; (2) initialing all angle conversions by the person performing the conversion, and having a second individual independently verify the conversions prior to treatment; (3) instructing the technologist to review all treatment information and to resolve any discrepancy prior to continuing treatment; (4) performing all future gantry angle conversions by the licensee rather than by the licensee's simulation contractor; and (5) conducting a review of past treatment plans back to 1988, with emphasis on those which did not identify any additional errors.

NRC Action:

NRC Region III conducted an inspection on August 1, 1994, to review the circumstances surrounding the misadministration (Ref: 2). NRC also retained a medical consultant to review the case. An Enforcement Conference was held on September 1, 1994, to discuss the inspection findings and actions taken by the licensee. On September 20, 1994, NRC Region III issued a Notice of Violation with a Severity Level III (Severity Levels I through V range from the most significant to the least significant) violation with no civil penalty assessed. The licensee's corrective and preventive actions will be reviewed during the next NRC inspection of the licensed program.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

ITEM #: 941670 AO #: NRC 94-17 EVENT DATE: 07/26/1994
TITLE: SODIUM IODIDE MISADMINISTRATION AT ST. JOSEPH MERCY HOSPITAL IN PONTIAC, MICHIGAN
NAME: St. Joseph Mercy Hospital CITY: Pontiac STATE: MI

Nature and Probable Consequences:

On July 27, 1994, the licensee reported to NRC that a misadministration occurred involving a patient receiving the wrong radiopharmaceutical for a diagnostic procedure.

The patient's referring physician requested a thyroid scan which involves administration of a standard prescription at St. Joseph Mercy Hospital of a 9.25 megabecquerel (MBq) (0.25 millicurie [mCi]) sodium iodide-123 (I-123) capsule. However, the licensee administered a 92.5 MBq (2.5 mCi) I-131 capsule. The amount of activity that was administered is normally used following removal of the thyroid to examine a patient for the spread of cancer from the thyroid through the body.

NRC retained a medical consultant to review the case. The medical consultant concluded that the resultant unnecessary dose to the patient's thyroid would result in a low, but finite, probability of hypothyroidism developing in the future. Also, there is a lifetime probability of developing radiation-induced thyroid cancer of 10 percent, including a risk of fatal thyroid carcinoma of approximately 1 percent. The licensee has arranged for the patient to be seen by an endocrinologist, and for repeat thyroid imaging with I-123 to be performed several months after the misadministration.

The patient was notified in person by the Radiation Safety Officer on July 27, 1994. Subsequently, the patient was also given a written report that was dated August 5, 1994.

Cause:

Part of the cause of the misadministration was the lack of the treating physician's involvement in the patient's examination prior to the I-131 administration. The administrative staff and technologists failed to have the examination clarified by a treating physician with the referring physician prior to administration of the I-131. Causal factors for this event also included the failure of licensee management to ensure implementation of the licensee's written Quality Management Program. Contributing factors also appear to include deficiencies in training, and a failure to follow through on matters.

Licensee Action:

The licensee took the following corrective actions: (1) held a training session which included the Radiation Safety Officer, treating physicians and technologists; (2) instituted a limit on the number of individuals who will be involved in the use of I-131; and (3) required a written directive to be filled out and signed by a treating physician.

NRC Action:

NRC Region III conducted an inspection on August 1, 1994, to review the misadministration (Ref. 3). A Confirmatory Action Letter (CAL) was issued to the licensee on August 2, 1994, which described the commitments made by the licensee as to which actions will be taken prior to the administration of I-131. An enforcement Conference was held on August 24, 1994, to discuss the inspection findings and actions taken by the licensee in response to the CAL.

In October 1994, NRC proposed an \$8,000 fine against the licensee for violations of NRC requirements involved in a diagnostic procedure using radioactive iodine at the hospital. The violations of NRC requirements involved in a diagnostic procedure using radioactive iodine at the hospital. The violations involve: (1) failure to have signed written directives by an authorized user prior to administration of I-131 in quantities greater than 1.11 MBq (0.03 mCi) on July 26, and in two previous instances where the I-131 was the intended radiopharmaceutical; (2) failure to have a clinical procedure for the proper administration of I-131 for whole body scans; and (3) failure to provide proper instruction to the nuclear medicine staff. The licensee paid the civil penalty.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A of this report notes that administering a diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent in which the event results in adverse health effects worse than expected for the normal range of exposures prescribed for the diagnostic procedure can be considered an abnormal occurrence.

ITEM #: 940717 AO #: NRC 94-18 EVENT DATE: 07/28/1994
TITLE: MULTIPLE TELETHERAPY MISADMINISTRATIONS AT SINAI HOSPITAL IN DETROIT, MICHIGAN (ITEMNOS 940717 AND 941727 August 3, 1994)
NAME: Sinai Hospital CITY: Detroit STATE: MI

Nature and Probable Consequences:

On July 28, 1994, and August 3, 1994, misadministrations occurred on two separate patients when the licensee's therapists failed to verify correct teletherapy machine parameters prior to treatment.

Beginning on July 19, 1994, a patient was to receive 4500 centigray (cGy) (4500 rad) in a series of 25 treatments to the left neck area. The first seven treatments were completed without incident. However, on the eighth treatment on July 28, one fraction was set up using the wrong treatment angle. This resulted in a radiation dose of 90 cGy (90 rad) being received by the right shoulder and neck area instead of the left neck area.

Beginning July 5, 1994, another patient was to receive 5000 cGy (5000 rad) in a series of 25 treatments to the right shoulder area. The first 20 treatments were completed without incident. However, on the 21st treatment on August 3, the teletherapy unit was positioned using the wrong treatment angle. This resulted in a radiation dose of 100 cGy (100 rad) being received by the right lung area instead of the right shoulder area.

An NRC medical consultant reviewed both cases and concluded that no significant adverse side effects or tissue injury are expected.

Cause:

The cause of both misadministrations was human errors by several of the licensee's therapists. The therapists failed to verify the collimator angle, the wedge setting, and the treatment site before administering the teletherapy dose to the patients.

Licensee Action:

The corrective actions taken included: (1) suspending all teletherapy treatments pending an internal investigation, and identifying appropriate corrective actions prior to re-start of the teletherapy treatments; (2) developing procedures which require independent verification of proper treatment parameters during patient set-up; and (3) installing a record-and-verify system on the teletherapy unit to ensure that all major treatment parameters are checked prior to a treatment.

NRC Action:

NRC Region III conducted an inspection July 29 through August 12, 1994, to review the circumstances surrounding the two misadministrations (Ref. 4). NRC also retained a medical consultant to review the case. An Enforcement Conference was held September 8, 1994, to discuss the inspection findings and actions taken by the licensee. On September 21, 1994, NRC Region III issued a Notice of Violation with a Severity Level III (Severity Levels I through V range from the most significant to the least significant) violation with no civil penalty assessed. The review during the next NRC inspection of the licensed program.

As required by 10 CFR 35.33(a), the licensee, for each misadministration, notified the referring physician and patient after the discovery of the incident and submitted a written report to the patient, including a statement that the report submitted to NRC Region III will be made available upon request.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the federal register. Appendix A of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

ITEM #: 941712 AO #: NRC 94-19 EVENT DATE: 07/29/1994
TITLE: BRACHYTHERAPY MISADMINISTRATION INVOLVING THE USE OF A STRONTIUM-90 EYE APPLICATOR AT THE UNIVERSITY OF MASSACHUSETTS MEDICAL CENTER IN WORCESTER, MASSACHUSETTS
NAME: University of Massachusetts Medical Center CITY: Worcester STATE: MA

Nature and Probable Consequences:

NRC Region I was notified on August 1, 1994, by the licensee of a brachytherapy misadministration involving the use of a strontium-90 (Sr-90) eye applicator. On July 29, 1994, a physician performed an ophthalmic treatment on a patient using an Sr-90 eye applicator without first removing the stainless steel mask from the source. Because of this oversight, the licensee estimated that the treatment site received 107 centigray (cGy) (107 rad) of radiation, rather than the 1250 to 2000 cGy (1250 to 2000 rad) that was intended. In addition, whereas the beta radiation from the eye applicator source only affects the surface of the eye, the bremsstrahlung lung radiation resulting from the interaction of the beta particles on the stainless steel mask is more penetrating. The patient returned on August 2, 1994, for the completion of the therapy to bring the total dose delivered within the originally prescribed range. The licensee expects that the clinical outcome of the misadministration will be inconsequential for the patient.

Cause:

According to the licensee a combination of factors led to the misadministration: (1) infrequent use of the ophthalmic applicator and the fact that its appearance with the mask is similar to its appearance with the mask removed; (2) the event occurred on a Friday afternoon and the stress of the licensee's work affected the alertness of the individuals involved; and (3) the most experienced physicists were not available, and a relatively inexperienced physicist prepared the source and was unaware that the source was equipped with a stainless steel mask.

Licensee Action:

The licensee is reviewing the feasibility of modifying the mask in some manner to make it more easily distinguished from the unmasked source. In addition, the licensee has employed two new radiation oncology physicians and a new chief physicist.

NRC Action:

NRC conducted a special inspection on August 3, 1994. The inspector determined that the physician was assisted by a dosimetrist who had not previously been directly involved with the procedure. When the physician requested that the dosimetrist provide him with the eye applicator source in order to perform the treatment, the dosimetrist handed him the source with the stainless steel mask in place. The dosimetrist stated that she was unaware that the source was equipped with a mask and that the mask needed to be removed. The physician and other licensee staff stated that it is the assistant's responsibility, in this case the dosimetrist's responsibility to remove the stainless steel mask from the source before handing the eye applicator to the physician. The treatment was administered by the physician with the mask in place. While cleaning the eye applicator later that same day, the licensee determined that the treatment had been performed with the mask in place. The licensee stated that the patient and the patient's physician were notified that there had been an underdose and the patient returned on August 2, 1994, for the completion of the therapy. The patient was given a written report of the misadministration on August 9, 1994. The licensee submitted a report for the misadministration on August 10, 1994. NRC Region I has enlisted the services of a medical consultant to evaluate the clinical consequences of this misadministration and awaits his report.

This event will be updated when additional information becomes available.

UPDATE: from NUREG-0090, Vol. 17, No. 4, page 22. This AO was originally reported in NUREG-0090, Vol. 17, No. 3, "Report to Congress on Abnormal Occurrence, July-September 1994."

The AO criteria used was Event Type 5 in Table A-1 of Appendix A of this report-Administering a therapeutic dose that results in an actual dose less than 0.5 times the prescribed dose.

On July 29, 1994, it was reported that a physician performed an ophthalmic treatment on a patient using a strontium-90 (Sr-90) eye applicator without first removing the stainless steel mask from the source. Because of this oversight, the licensee estimated that the treatment site received 107 centigray (cGy) (107 rads) of radiation, rather than the 1250 to 2000 cGy (1250 to 2000 rads) that was intended. In addition, whereas the beta radiation from the eye applicator source only affects the surface of the eye, the bremsstrahlung lung radiation resulting from the interaction of the beta particles on the stainless steel mask is more penetrating.

The AO report is updated and closed out as follows:

The NRC received the medical consultant's evaluation of the clinical aspects of this misadministration on October 21, 1994. The medical consultant agreed with the licensee that the misadministration and the subsequent completion of the dose intended had no adverse effects on the patient. NRC issued a Severity Level IV violation to the licensee for failure to follow the written Quality Management Program established by the licensee in a letter dated December 27, 1994 (Ref. 14).

This item is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic dose that results in an actual dose less than 0.5 times the prescribed dose can be considered an abnormal occurrence (AO). In addition, Criterion No. 11 under "For All Licensees" in Appendix A notes that a serious deficiency in management or procedural controls in major areas can be considered an AO.

ITEM #:	940303	AO #:	AS 94-06	EVENT DATE:	04/01/1993
TITLE:	LOSS OF MANAGEMENT AND PROCEDURAL CONTROL OF A RADIOACTIVE SOURCE LICENSED BY THE STATE OF ILLINOIS TO KAY-RAY, INC., AT A GEORGIA-PACIFIC CORPORATION PAPER MILL IN PALATKA, FLORIDA (Between January and April 1993)				
NAME:	Georgia-Pacific Corporation	CITY:	Palatka	STATE:	FL

Nature and Probable Consequences:

On April 1, 1993, the State of Florida, Office of Radiation Control (ORC) was notified by phone that a Kay-Ray, Inc., Model 7063 fixed gauge that was presumed to be empty had been found to still contain its 7400 gigabecquerel (200 millicurie) cesium-137 sealed source. The licensee's radiation safety officer (RSO) reported that the gauge was one of 16 damaged devices removed from service between March 10 and 19, 1993, for repair or replacement. Following the removal and reloading of their source holders into new housings by a manufacturer's factory service technician, four of the damaged gauges were stored on-site pending the disposal as scrap metal. Twenty-one days later, a radiation survey of the housings revealed the presence of a source in one of the gauges.

The RSO reported that the cause of the incident was the failure of the Kay-Ray service technician to successfully transfer the gauge's sealed source from its damaged source housing to a replacement housing. The gauges operated as level indicators in a corrosive environment of a paper mill. Extensive corrosion of four of the 16 gauges that were removed from service had left the source holders as the only salvageable components. The manufacturer was contracted to load the source holders into new housings and reinstall them. The Model 7063P source holder assembly consists of a 6.4-centimeter (2.5-inch) long aluminum tube crimped at one end to contain the source, with the opposite open end of the tube attached to an aluminum plate which is secured to the housing by three screws. Internal corrosion of one of the gauges caused the manufacturer's service technician to experience difficulty removing it, and in the process the source holder assembly was broken and the sealed source became detached. The source holder and plate were installed into the new source housing as two separate pieces while the sealed source remained in the old housing. The new housing was installed and the old housing, with its broken shutter left in the open position, was stored with the three empty source housings. The manufacturer's service technician failed to perform, or improperly performed, required surveys and failed to verify the proper operation of the reinstalled gauge.

Following the telephone report of the incident, an ORC inspector went to the licensee's facility to investigate the cause and assure that immediate corrective actions were taken. The ORC inspector confirmed the presence of the source, measuring the radiation level at 30.5 centimeters (12 inches) from the open shutter at 151 microcoulomb per kilogram (585 milliroentgen) per hour. (The ORC inspector also found that Kay-Ray, Inc., which is an IDNS licensee, had not filed for reciprocity and was operating illegally in the State of Florida.)

A consultant hired by the licensee performed wipe tests which found no leakage from the source. All personnel handling or working in the vicinity of the source were interviewed to calculate their exposures. Based on the consultant's calculations, the highest dose received was 700 microsievert (70 millirem). No physical effects were observed or expected.

Cause:

The primary cause of the incident was the failure of the manufacturer's service technician to transfer the source to its new housing and subsequent failure to follow procedures which would have identified the location of the source. A contributing factor was the failure of both plant personnel and the service technician to note the deteriorating condition of the gauges and take corrective measures. The State of Florida ORC licensee failed to perform annual physical inventories as required, and the manufacturer's service technicians contracted to perform annual leak tests of the gauges failed to inform its client of the safety hazard created by the corroded gauges.

Licensee Action:

The fixed gauge licensee's corrective actions included hiring a consultant to assist in the resolution of the gauge incident and in assessment of the exposures received by its personnel, and to evaluate the implementation of revisions to its radiation protection program to ensure compliance. A meeting was held with the gauge manufacturer's management to ensure that all required safety precautions are taken when the manufacturer's service technicians are on-site. Additional radiation safety training was provided to all of the licensee's personnel.

IDNS indicated that the manufacturer's corrective actions included providing immediate assistance in resolving the incident and cooperating with its client's management to enact corrective measures to prevent recurrence. A consultant was hired to (1) study the regulatory requirements of all State and Federal agencies to ensure compliance with reciprocity and other regulatory requirements, (2) review the manufacturer's procedures and recommend revisions, and (3) ensure that all of the manufacturer's personnel understood the requirements and procedures. Increased management oversight of its field service personnel was also implemented. Additional instruction on radiation safety and procedures was provided to all field service personnel, and an annual recertification program was implemented.

NRC Action:

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Other Agency Action:

The ORC reviewed the circumstances associated with the incident and the licensee's and manufacturer's immediate and follow-up corrective actions during (1) a reactive inspection on April 4, 1993, (2) evaluation of the report compiled by the licensee, and (3) follow-up inspection on September 9, 1993. An Enforcement Conference with representatives of the manufacturer was conducted on January 24, 1994. A Notice of Violation (NOV) (annual inventory requirements) was issued to the fixed gauge licensee on October 7, 1993. Due to the licensee's identification and immediate notification of its violation and its immediate corrective actions to prevent recurrence, no Civil Penalty was imposed.

A NOV and Proposed Imposition of Administrative Fine in the amount of \$3,000 was issued to the manufacturer on August 12, 1993. This action was based on six violations related to the incident: (1) repeated failures to provide required notification of entry into the State by the licensee's employees in which licensed activities were conducted (reciprocity), (2) failure to make surveys to evaluate the extent of radiation hazards, (3) failure to take reasonable measures to maintain radiation exposures as low as reasonably achievable, (4) and (5) failures to comply with required procedures for safe performance of licensed activities, and (6) failure to take precautions sufficient to prevent loss of a source of radiation. Each violation was categorized at Severity Level III on a scale in which Severity Levels I through V are the most significant and least significant, respectively. Each violation was assessed a proposed administrative fine of \$500. The fine was paid on January 24, 1994.

The State of Florida's ORC provided information package on this event to the states of Georgia and Illinois.

This event is closed for the purpose of this report.

Criteria:

Appendix A (see Item No. 12 of "For All Licensees") of this report notes that a series of events (where individual events are not of major importance), recurring incidents, and incidents with implications for similar facilities (generic incidents) that create major safety concern should be considered an abnormal occurrence (AO).

The State of Florida's decision to select the stated AO criteria is based on its belief that the violations committed by the gauge manufacturer's representatives, who perform licensed activities nationwide, has implications for similar facilities. The State of Florida stated that its decision appears to be supported by the occurrence of another gauge incident in Cedar Springs, Georgia. The State of Florida has discussed the incident at Palatka, Florida, with the State of Georgia.

Also, since the gauge manufacturer is Kay-Ray, Inc., which is licensed by the State of Illinois, the State of Florida worked closely with the Illinois Department of Nuclear Safety (IDNS) during its investigation of this incident. The State of Florida received copies of the Kay-Ray license and procedures from IDNS, which facilitated the investigation.

ITEM #: 940600 AO #: NRC 94-21 EVENT DATE: 07/19/1993

TITLE: RECURRING INCIDENTS OF ADMINISTERING HIGHER DOSES THAN PROCEDURALLY ALLOWED FOR DIAGNOSTIC IMAGING AT BALL MEMORIAL HOSPITAL IN MUNCIE, INDIANA (October 1988 through June 1993)

NAME: Ball Memorial Hospital CITY: Muncie STATE: IN

Nature and Probable Consequences:

On July 19, 1993, NRC was notified that nuclear medicine technologists employed by the licensee had increased the dosages of radiopharmaceuticals used in diagnostic studies. NRC was also informed that the technologists had falsified the required record of the dosages administered.

On July 21 through August 9, 1993, NRC conducted an inspection of the licensed facility. The inspection revealed that since 19 nuclear medicine technologists employed by the licensee have been administering radiopharmaceutical dosages above the approved dose ranges for diagnostic image studies by as much as 40 percent. The inspection also verified that subsequent to administering high doses, the technologists entered false information in NRC- required records. The doses were increased for imaging studies of the lung, liver, bone, and gastrointestinal tract using technetium-99m and xenon-133.

NRC inspectors did not identify any medical misadministrations, as defined in 10 CFR 35.2, as a result of this practice of administering higher than approved doses for diagnostic imaging.

Cause:

According to the licensee, one technologist told licensee officials that dosages were increased to minimize patient discomfort, to reduce imaging time for critically ill patients and to enhance the clarity of images for studies performed on obese patients.

Licensee Action:

The licensee conducted an internal review. Based on the findings from this review, the licensee initially suspended two nuclear medicine technologists from all NRC-licensed activities. Subsequently, the licensee terminated one of the two individuals and the other individual was allowed to continue to perform duties that do not involve NRC-licensed activities.

The licensee also committed to a number of corrective actions. Some of the corrective actions include: assigning a pharmacist radiologist to verify all radioisotope dosages; implementing a unit dose system; obtaining the services of an assistant radiation safety officer; and conducting monthly and quarterly audits of the Nuclear Medicine Section for at least one year.

NRC Action:

A special safety inspection was conducted by NRC from July 21 to August 9, 1993. Subsequent to that inspection, NRC conducted a follow-up review.

NRC issued a Confirmatory Action Letter (Ref. 9) on July 26, 1993, and Confirmatory Order Modifying License (Ref. 10) on October 20, 1993. These documented specific procedures and verifications to prevent any further unauthorized increases in patient doses.

On May 23, 1994, NRC issued an Order against a former nuclear medicine technologist of the licensee. The Order required the following: (1) prohibited the technologist from involvement in NRC-licensed activities for a period of one year; (2) required the technologist to provide a copy of the Order to any prospective employer who engages in NRC-licensed activities for a three-year period; and (3) required the technologist to notify NRC within 20 days of accepting employment involving NRC-licensed activities.

On May 27, 1994, the technologist requested a hearing and on September 26, 1994, a settlement agreement was reached. The settlement was reviewed and approved by the Atomic Safety and Licensing Board on October 3, 1994 (Ref. 11). The agreement resulted in the withdrawal of the requirement for the technologist to provide a copy of the Order to any prospective employer who engages in NRC-licensed activities. The settlement retained provisions (1) and (3) of the Order.

This item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 11 from Examples For All Licensees) of this report notes that a serious deficiency in management or procedural controls in a major area can be considered an AO.

Due to the nature of this occurrence, NRC performed an extensive review requiring interviews and an historical review of licensee

||records. This detailed review resulted in a delay in the prompt reporting of this information. _____

ITEM #: 941719 AO #: NRC 94-22 EVENT DATE: 08/09/1994
TITLE: MEDICAL THERAPY MISADMINISTRATION AT VETERANS AFFAIRS MEDICAL CENTER IN LONG BEACH, CALIFORNIA
NAME: Veterans Affairs Medical Center CITY: Long Beach STATE: CA

Nature and Probable Consequences:

On August 9, 1994, the licensee's radiation safety officer (RSO) notified NRC of a misadministration involving a therapeutic dose Strontium-89 (Sr-89) (Ref. 12).

The RSO reported that a patient scheduled to receive 185 megabecquerel (MBq) (5 millicurie [mCi]) of thallium-201 (a radiopharmaceutical not regulated by NRC) for a myocardial perfusion study was mistakenly administered 148 MBq (4 mCi) of Sr-89 (which is regulated by NRC). Based on the misadministration of the Sr-89, the licensee estimated that the patient received 2 centigray (250 rads) to the surface of the bone. The RSO reported that no action was taken to mitigate the consequences of the dose (i.e., administration of calcium as a blocking agent) because the patient had a preexisting heart condition which could have been exacerbated by administering calcium. The licensee also stated that medical experts were contacted to assist in an assessment of potential health effects to the patient. In addition, the licensee reported that with the exception of emergency procedures, it had voluntarily suspended all nuclear medicine procedures involving the intravenous administration of radiopharmaceuticals and had initiated an internal review of the misadministration.

On August 10, 1994, NRC issued a Confirmatory Action Letter (Ref. 13) to confirm the licensee's actions as stated above.

Cause:

The cause of the misadministration was attributed to the administering technologist's failure to verify the isotope as well as dose (by reading the label on the syringe) prior to injection.

Licensee Action:

Corrective actions initially proposed by the licensee included the following: (1) physically separating diagnostic unit dosages from therapeutic radiopharmaceutical dosages in the licensee's hot lab; (2) packaging unit dosages received from a local radiopharm in different containers, according to isotopes; and (3) retraining technologists in requirements for identifying radiopharmaceuticals prior to injection.

NRC Action:

Two NRC inspectors conducted a special safety inspection on August 10-12 and 17-19, 1994, to review the circumstances associated with the misadministration and to review the licensee's corrective actions (Ref. 14). In addition, NRC contracted a medical physician consultant to assist in its evaluation of the potential consequences of the patient's radiation exposure. The consultant stated that there were no adverse health effects to the patient.

An Enforcement conference was held with the licensee on November 30, 1994, to discuss an apparent violation involving the failure of an individual working under the supervision of an authorized user physician to follow the licensee's written radiation safety procedures. Additional concerns discussed during the conference included the licensee's use of an informal labeling system for unit radiopharmaceuticals which was identified as a potential programmatic weakness. The licensee presented information during the conference which supported its view that the error which led to the August 9, 1994, misadministration was an isolated failure rather than a programmatic problem.

Based on its review of information developed during the inspection and information provided during the enforcement Conference, NRC concluded that the misadministration was the result of an isolated failure. A Notice of Violation (Ref. 15) was issued on December 29, 1994, for a violation involving the failure of an individual working under the supervision of a physician authorized to follow the licensee's written procedures for verifying a radiopharmaceutical dose prior to administration to a patient. The violation was categorized as a Severity level IV violation.

This item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported in the Federal Register. Appendix A (see Event Type 3 Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

ITEM #: 941746 AO #: NRC 94-23 EVENT DATE: 08/03/1994
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT NORTH MEMORIAL MEDICAL CENTER IN ROBBINSDALE, MINNESOTA
NAME: North Memorial Medical Center CITY: Robbinsdale STATE: MN

Nature and Probable Consequences:

On August 15, 1994, a licensee informed NRC that a patient received 1380 centigray (cGy) (1380 rads) to a wrong treatment site during a brachytherapy treatment for metastatic lung cancer.

On August 3, 1994, a catheter was inserted into the patient's bronchus and a ribbon containing 20 seeds of iridium-192 having a total activity of 673.4 megabecquerel (18.2 millicuries) was then inserted into the catheter and moved to the proper treatment location. The treatment plan was intended to deliver a prescribed dose of 2000 cGy (2000 rads) to the intended target. The treatment began at 11:15 a.m. on August 3, 1994, and continued until its scheduled completion at 10:15 a.m. on August 4, 1994.

At about 7:00 p.m. on August 3, 1994, a nurse informed the physician that the visible portion of the catheter appeared to be protruding approximately 25.4 to 30.5 centimeters (10 to 12 inches) from the patient's nose. This was a significantly greater protrusion than previously observed, indicating that the catheter had moved from its initial placement. The nurse secured the catheter in place with additional tape. The physician stated that, based on the information available to him at that time, he determined that the catheter and ribbon had moved; but that the tumor was receiving some radiation dose and therefore he continued the treatment. The iridium-192 seeds were removed on August 4 as planned. On August 4, 1994, a staff radiologist read the portable x-ray film taken on August 3, 1994, and indicated that the iridium implant was not seen.

Due to catheter displacement, the tumor dose was significantly reduced and estimated to be 620 cGy (620 rads) or 31 percent of the intended dose. The remaining dose of 1380 cGy (1380 rads) was delivered to an unintended site.

The patient was notified of the event by the treating physician on August 4, 1994, and again by another physician on August 17, 1994. The referring physician was informed by the treating physician on August 4, 1994.

An NRC medical consultant was retained to perform a clinical assessment of this misadministration. The medical consultant concluded that it is improbable that the patient will experience any long term consequences as a result of the exposure to the unintended treatment site.

Cause:

The licensee has determined that the catheter movement caused a misadministration of the intended dose. Two possible explanations for the catheter movement could be the following: (1) failure to properly secure the catheter in place with tape; or (2) nasal discharge decreasing the adhesive capability of the tape.

Licensee Action:

The licensee's corrective actions include: amending the nursing staff procedure so that the attending physician will be contacted there are further questions; directing nurses to follow the standing protocol for obtaining an administrative consult; providing additional inservice training; documenting the final length of the catheter in the patient chart; and documenting the catheter position on each visit to the patient's room.

NRC Action:

NRC conducted a safety inspection from August 15 through September 7, 1994 (Ref. 16), to review the circumstances of the misadministration. One apparent violation and one area of concern were identified. An Enforcement Conference was held with licensee on October 11, 1994. Enforcement action is pending. NRC is continuing its review.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5 in Table A-1) of this report indicates that a therapeutic exposure to any part of a body not scheduled to receive radiation can be considered an AO.

ITEM #: 942062 AO #: AS 94-07 EVENT DATE: 04/21/1994
TITLE: MAJOR CONTAMINATION EVENT DUE TO A BREACHED SOURCE AT KAY-RAY/SENSALL, INC., IN MT. PROSPECT, ILLINOIS
NAME: Kay-Ray/Sensall, Inc. CITY: Mt. Prospect STATE: IL

Nature and Probable Consequences:

A sealed source containing 74,000 megabecquerel (2 curies) of cesium-137 in a fixed gauge was breached on Thursday, April 21, 1994, as the manufacturer of the measuring system tried to remove the source with a steel rod and hammer from its housing. The source rupture was not detected by the licensee until the day after the breach occurred. During this time, personnel, facilities, homes, and vehicles, including the radiological consultant's (who was on-site when the breach occurred) vehicle, facility, and his employees' homes and vehicles became contaminated with unsealed radioactive material.

A total of 102 vehicles and 18 homes in Illinois and Wisconsin were surveyed by the State of Illinois. All contamination found was reduced to background levels, or the items or areas were removed or excised for disposal. The highest off-site contamination level was found in a rental truck used by the consultant on the day of the breach. The vehicle was decontaminated and returned to its owner. The State spent approximately 100 person-days in April and May characterizing the extent of the contamination and monitoring the effectiveness of the decontamination. The licensee's facility returned to full operation on April 26, with shoe cover required for production personnel.

One individual was found, through in vivo and in vitro measurements, to have an intake of 44.4 kilobecquerel (1.2 microcurie) or 0.74 percent of the annual limit intake. This resulted in a commitment effective dose equivalent (CEDE) of 0.4 millisievert (mSv) (40 millirem [mrem]). Of the seven other individuals who submitted urine samples, CEDE was estimated at 0.01 mSv (1 mrem) for one individual and 0.002 mSv (0.20 mrem) for another. No intake was detected for the other five individuals. Since the annual limit for occupational exposure is 50 mSv (5000 mrem), no long term health effect is expected for any individual involved in the incident.

Cause:

Because of the possibility of generic corrosion problems in their application environments, testing was performed by an NRC contractor on a source similar to the one breached in this incident to determine if any inherent defect contributed to the consequences. The contractor concluded that the capsule had no generic construction or materials defect and that it failed because a hammer and steel rod were used to remove it from its holder. The source had apparently been used in a corrosive environment, causing it to become stuck in the holder. Staff concluded that the primary cause of the widespread contamination was failure to perform adequate surveys and failure to analyze the leak test sample until the day after it was collected. Another contributor was the method used to remove the source from the source holder. The licensee used a steel rod and a hammer to remove the source. The source had apparently been used in a corrosive environment, causing it to become stuck in the holder.

Licensee Action:

In the licensee's written report of the incident, they proposed that they would no longer unload source capsules from returned source heads. Their customers would be directed to send returned source heads to a third party for source removal. The licensee also proposed that hand and foot surveys would be required after handling a source head, whether at the licensee's facility, a customer site, or a third party licensed facility. Weekly surveys are to be performed on an interim basis in the production area of the Mt. Prospect plant. A complete shutdown of all plant operations and personnel movement in the production area would occur if any contamination was found.

NRC Action:

Other Agency Action:

The results of the testing by the NRC contractor will be reviewed to determine if further action is warranted for this licensee and the source supplier, located in another Agreement State.

This item is considered closed for the purpose of this report.

Criteria:

Appendix A (see Event Example 10, For All Licensees) of this report indicates that a major deficiency in design, construction, or operation having safety implications requiring immediate remedial action can be considered an AO.

ITEM #: 941957 AO #: AS 94-08 EVENT DATE: 10/17/1994
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT ST. JOSEPH'S HOSPITAL IN ORANGE, CALIFORNIA
NAME: St. Joseph's Hospital CITY: Orange STATE: CA

Nature and Probable Consequences:

The State was notified on October 19, 1994, that a brachytherapy overexposure had occurred at St. Joseph's Hospital in Orange California. The overexposure involved a 1110 megabecquerel (30 millicurie) cesium-137 source. The intended dose to the patient was 1400 centigray (cGy)(1400 rads), of which 1268 cGy (1268 rads) was to be administered 0.25 centimeters (0.1 inches) below the surface. The source fell out of the applicator as the radiation oncologist was attempting to load the source into an intracavity applicator. This was not observed by the physician. Approximately seven hours later the patient's nurse found the source on the bed while she was attending the patient. The nurse removed the source from the bed with long forceps and placed it in the lead provided in the room. When the radiation oncologist later checked with the nurse, she was informed of the incident and confirmed that the source was not in the applicator.

After consulting with the radiation safety officer (RSO), the radiation oncologist proceeded to reinsert the source into the applicator. The treatment time was rechecked to give the full, originally, prescribed dose. The treatment was completed without further complications. The patient and the referring physician were both notified.

The source was present on the bed, next to the skin of the patient for seven hours. The legs, back, and pelvic area of the patient were immediately checked for acute radiation exposure of the skin. No effects were identified. The patient was also examined two and three weeks post incident and remains symptom free.

Using National Council on Radiation Protection and Measurements Commentary No. 40 and reenacting the event, the licensee calculated a dose of 7000 cGy (7000 rads) to the skin of this patient. The dose estimate was verified by the State for the Radiological Emergency Assistance Center/Training Site (REAC/TS). No other consultants were contacted for this incident.

Cause:

After a review of the incident by the radiation oncologist and the RSO, it was determined that the source fell out of the source carrier during initial insertion because of the location and position of the applicator. Insertion required the carrier to be placed in upward, tilting direction and this, coupled with the twisting of the carrier to position it in the applicator, caused the source to drop.

Licensee Action:

The licensee will not visually check the source after the carrier has been placed in the applicator for each source loading.

NRC Action:

Other Agency Action:

The State agency staff has reviewed the circumstances of the misadministration and will evaluate the licensee's corrective action during the next inspection to be conducted in the near future.

This item is considered closed for the purpose of this report.

Criteria:

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

ITEM #: 941975 **AO #:** AS 94-09 **EVENT DATE:** 12/07/1993
TITLE: BRACHYTHERAPY MISADMINISTRATION AT THE UNIVERSITY OF CALIFORNIA'S LONG HOSPITAL IN SAN FRANCISCO, CALIFORNIA
NAME: University of California's Long Hospital **CITY:** San Francisco **STATE:** CA

Nature and Probable Consequences:

A female patient was prescribed to receive 3500 centigray (3500 rads) to treat a cervical tumor using a pulsed Selectron high-dose rate (HDR) remote afterloader brachytherapy device. (She was also treated with external beam therapy.)

The HDR treatment plan was prepared via computer and consisted of the following: (1) 161 dwell positions of varying times, and expected total treatment time of 535.5 seconds per pulse; and (2) a total of 58 pulses for the treatment. The computer generated times and positions were manually programmed into the HDR unit to initiate treatment. One of the dwell times was incorrectly entered as 52.9 seconds, instead of the computer-calculated 2.9 seconds. Six other positions required the same dwell-time, so programming for the first dwell-time entry was stored and recalled for the others. This resulted in seven positions being programmed for 52.9 seconds instead of the correct value of 2.9 seconds.

The consequence of the seven dwell-time errors was a total treatment time of 885.5 seconds per pulse, or 1.65 times the correct total treatment time. The data entry error probably occurred because the physicist entering the data on the keyboard accidentally hit the number 5 and number 2 keys at the same time, which resulted in a programmed time of 52.9 seconds.

Further procedures required that the total radiation time be hand-calculated and entered on the treatment planning sheet prior to programming the HDR unit. The machine-printed tape displaying total radiation time programmed into the HDR must be compared with the hand-calculated value to verify agreement between the two values. This verification was not performed contributing to the misadministration.

The misadministration occurred on December 7, 1993. Because the hand-and computer-calculated time values were not compared, the mistake was not detected at the time of treatment. In June of 1994, the patient developed a recto-vaginal fistula which required admission to San Francisco General Hospital for a bypass colostomy. The family of the patient was verbally notified of the misadministration.

On July 8, 1994, a copy of the discharge summary was forwarded to the radiation oncology physician at University of California, San Francisco. The physician asked a medical physicist to recalculate the doses that were delivered during the HDR treatment December 1993. The review was performed on July 10, 1994, and revealed the results shown in the following table.

Region	Expected Dose(rads) centigray	Delivered Dose(rads) centigray	Variation from Intended Dose (percent)
Tumor	3500 (presc)	3784-10500	8 - 300
Bladder	2774	3000	8
Rectum(UP)	2925	3200	9.4
Rectum(Low)	3000	5000-6000	167-200
Vagina(Low)	4000	6000-8000	150-200

The licensee determined that the combined doses from external beam therapy and the HDR misadministration could have caused recto-vaginal fistula.

Cause:

The root cause of this incident was determined to be keyboard entry errors while programming the HDR unit. A second contributing factor was the failure to verify the total time programmed with the manually calculated total time as required by license procedures.

Licensee Action:

The licensee changed its procedures to require that a physician review and sign the machine-printed tape that shows the plan details, in addition to signing the prescription in the chart. In addition, the machine programmer must write the "total radiation time calculated by the machine on the planning sheet that contains the prior hand-calculation of this value. The two values must be checked by a second person, and both people must initial the sheet. The second person can be a physicist, dosimetrist, physicist or brachytherapy technologist. All of these actions must be completed prior to the initiation of treatment.

The licensee is also discussing possible corrective actions with the manufacturer. One option being explored is the possibility of having the computer-calculated treatment plan written to a disk, which will then be used to program the afterloader. The

manufacturer has also been asked to recommend other software changes to prevent this type of event from recurring.

NRC Action:

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Other Agency Action:

The State of California reviewed the licensee's action and was satisfied that appropriate actions were taken. The State of California considers this event closed.

This item is considered closed for the purpose of this report.

Criteria:

Appendix A (see Event Type 5 in Table A-1) of this report notes that administering a therapeutic dose that is greater than 1.5 times the prescribed dose can be considered an AO).

ITEM #: 940524 AO #: AS 94-10 EVENT DATE: 05/10/1993
TITLE: MEDICAL TELETHERAPY MISADMINISTRATION BY AN "UNSPECIFIED LICENSEE" AT AN "UNSPECIFIED LOCATION" IN NEW YORK
NAME: New York State DOH "Unspecified Licensees." CITY: New York City STATE: NY

Nature and Probable Consequences:

A patient, with a sarcoma on the palm of the hand, was prescribed a treatment of 100 centigray (100 rad) each to the anterior and posterior of the hand. The posterior part of a fractional treatment to the palm of the hand was administered using a larger field size (16 by 20 centimeters [cm][6.3 by 7.8 inches]) than prescribed (11 by 14 cm [4.3 by 5.5 inches]). The prescription called for 100 centigray (100 rad) each to the anterior and posterior of the hand. The field size had been increased for the second exposure of port film, and the technologist failed to reduce it to the proper size prior to delivering the dose for the posterior treatment. There radiation was delivered to a larger field than prescribed, resulting in normal tissue outside the treatment field being irradiated. The error was detected when the set-up was being prepared for the anterior field. The patient and the referring physician were notified of the error. The treatment course was not altered as a result of the error. The licensee indicated that no adverse effect to the patient is anticipated as a result of this error.

Cause:

The technologist failed to follow existing procedures which require that treatment parameters be checked prior to delivering the dose.

Licensee Action:

The licensee counseled the technologist and reviewed the existing procedures. The need to check parameters before treatment was emphasized. The licensee's Quality Assurance Committee also reviewed the incident and actions taken. The licensee has procedures in place which are designed to prevent such mistakes.

NRC Action:

The name of the licensee was not provided by the State of New York. NRC has asked the State of New York to provide this information, but the State law limits its ability to report this information.

Other Agency Action:

The State of New York reviewed the licensee's action and was satisfied that appropriate actions were taken. The State of New York considers this event closed.

This item is considered closed for the purpose of this report.

Criteria:

Appendix A (see Event Type 1 in Table A-1) of this report notes that a therapeutic exposure that results in any part of the body receiving unscheduled radiation can be considered an AO.

ITEM #: 942059 AO #: NRC 95-01 EVENT DATE: 11/18/1994
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT WELBORN MEMORIAL BAPTIST HOSPITAL IN EVANSVILLE, INDIANA
NAME: Welborn Memorial Baptist Hospital, Inc. CITY: Evansville STATE: IN

Nature and Probable Consequences:

On November 18, 1994, a 73-year-old female patient was prescribed to receive a brachytherapy treatment dose of 600 centigray (cGy) (600 rad) at the vaginal cavity using a GammaMed Ili high dose rate afterloading unit. However, because of a treatment error the patient received a 1250 cGy (1250 rad) dose instead of the prescribed dose.

The licensee identified the misadministration during a quality management review on November 21, 1994. The licensee reported the event to the NRC on November 23, 1994, and followed up with a written report on December 6, 1994. The referring physician was notified. The patient was notified on November 23, 1994, by the licensee's Radiation Safety Officer and was provided with a written report of the incident.

An NRC medical consultant was retained to evaluate the medical consequences of the misadministration. The medical consultant expressed concern that long term effects such as fibrosis or loss of blood supply may occur as a result of the 1250 cGy (1250 rad) treatment. The medical consultant also suggested that this case be considered for the U.S. Department of Energy (DOE), Office of Epidemiology and Health Surveillance long term medical study program. Information regarding the DOE program and a copy of NRC medical consultant's report were provided to the referring physician.

Cause:

NRC concluded that the cause of the misadministration was twofold: (1) the technologist failed to activate a button that automatically corrects for treatment time based on source decay, failed to notice a display indicating the treatment time correction that would have been entered automatically, reentered the treatment time instead, and failed to notice the error; and (2) the treatment software did not stop the technologist from proceeding after the initial error was made as it was supposed to because an integrated circuit containing the software code failed to operate.

Licensee Action:

In order to prevent recurrence of the incident as of November 25, 1995, the licensee revised its internal "Policy and Procedure for all HDR's" to require both individuals operating the unit to verify the displayed time factor and compare it to the factor supplied by the manufacturer. Prior to this misadministration, the device operators were required to verify only operator entered data. Also, the unit was evaluated by the licensee's medical physicist and a GammaMed service representative. As a result of the evaluation, the printed circuit board (card) with the read-only-memory integrated circuits containing the defective software program was replaced with a card having the correct software program.

NRC Action:

NRC conducted a safety inspection on November 30 and December 1, 1994 (Ref. 1). An interoffice review of the event was conducted through December 8, 1994, to review the circumstances of the misadministration. No violations of NRC requirements were identified. As a result of the incident, NRC contacted the manufacturer of the GammaMed Ili and sent a letter to all GammaMed Ili users to inform them of this potential problem and tell them how to test their software to prevent similar events.

This item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to the event is also being reported in the Federal Register. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic dose that is greater than 1.5 times the prescribed dose can be considered an abnormal occurrence.

ITEM #: 950842 **AO #:** NRC 95-07 **EVENT DATE:** 06/08/1995
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MARSHFIELD CLINIC IN MARSHFIELD, WISCONSIN
NAME: Marshfield Clinic **CITY:** Marshfield **STATE:** WI

Nature and Probable Consequences:

A patient was prescribed a dose of 1640 centigray (cGy) (1640 rad) for a low dose rate brachytherapy treatment of the cervix using cesium-137 sources.

After the sources were implanted, but prior to completion of the treatment, the physician entered the wrong date for removal of the sources into the final treatment plan. Because of this error the treatment was extended for an additional day. As a result, the calculated administered dose was 2440 cGy (2440 rad) which was approximately 50 percent greater than the prescribed dose.

The physician informed the patient of the misadministration both verbally and in writing. The licensee evaluated the consequences of the misadministration and determined that there would be no adverse health effects.

An NRC medical consultant evaluated the consequences of the misadministration and agreed with the licensee's conclusion.

Cause:

The licensee failed to notice that the planned explant time documented in the final treatment plan did not represent the prescribed treatment time documented in the written directive. Also, the licensee's written directive/low dose rate brachytherapy log form, used to record events occurring during low dose rate brachytherapy treatments, did not contain a location to document the prescribed time for source removal.

Licensee Action:

The licensee revised its written directive/low dose rate brachytherapy log form to include documentation of the actual implantation time, and the time for the prescribed and actual removal of sources. Additionally, the revised form will include verification of such times by a licensee staff member.

NRC Action:

NRC conducted an inspection and reviewed the circumstances surrounding the misadministration. NRC also retained a medical consultant to review the case. A Confirmatory Action Letter was issued which confirms that the licensee will verify that its authorized users meet training and experience requirements. A Notice of Violation was issued with five Severity Level IV violations.

This event is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5[a] in Table A-1) of this report notes that administering a therapeutic dose from a sealed source such that the calculated total treatment dose differs from the prescribed total treatment dose by more than 10 percent and the actual dose is greater than 1.5 times the prescribed dose can be considered an AO.

ITEM #: 951007 AO #: NRC 95-08 EVENT DATE: 07/25/1995
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT PROVIDENCE HOSPITAL IN SOUTHFIELD, MICHIGAN
NAME: Providence Hospital CITY: Southfield STATE: MI

Nature and Probable Consequences:

A patient was prescribed a dose of 1230 centigray (cGy) (1230 rad) for a palliative manual brachytherapy treatment of the brain using an iridium-192 seed.

After implantation, confirmatory x-rays were taken but could not confirm the location of the seed and the treatment was terminated about 31 hours after implantation. The licensee determined that the seed was implanted about 4 centimeters (1.57 inches) from the intended treatment site of the brain. Consequently, the wrong treatment site received an unintended radiation dose of about 739 cGy (739 rad) and the tumor received only about 72 cGy (72 rad).

The licensee determined that no adverse health effects would result from the misadministration. An NRC medical consultant has reviewed the case but has not yet submitted a report to the NRC. The licensee notified the referring physician and the patient of the misadministration.

Cause:

The licensee said that the seed became detained at the elbow of the applicator during implantation and changed direction. The physician consequently encountered resistance while inserting the source and assumed that it reached the intended treatment site. A confirmatory x-ray taken at the time of insertion did not show the location of the source. (The licensee had used a fluoroscope [real time imaging] during simulation of the treatment, but a fluoroscope was not used to observe the actual seed implantation.)

Licensee Action:

The licensee reported that when using this type of applicator in the future, fluoroscopy will be used to assure proper implantation of radioactive material.

NRC Action:

NRC conducted an investigation to review the circumstances surrounding the misadministration. The NRC staff is currently reviewing the inspection results for possible violations, and enforcement action is pending.

This event is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

ITEM #: 950033 AO #: AS 95-05 EVENT DATE: 12/20/1994
TITLE: IMPORTATION OF A PACKAGE HAVING EXCESSIVE EXTERNAL RADIATION INTO THE UNITED STATES FROM THE REPUBLIC OF KOREA
NAME: Omnitron International, Inc. CITY: Edgerly STATE: LA

Nature and Probable Consequences:

Omnitron International received a package of radioactive material with external radiation levels approximately 18 times higher than allowed by the U.S. Department of Transportation (DOT). The package was one of two packages received from a shipper in the Republic of Korea. Each package contained an iridium-192 source in the form of a wire that had an activity of approximately 16 650 megabecquerel (450 millicurie).

The high radiation levels were discovered during a routine survey of the packages upon receipt by Omnitron personnel. The package had radiation readings of 37 millisievert (mSv) (3700 millirem [mrem]) per hour at its surface and 1.4 mSv (140 mrem) per hour at 1 meter (39.37 inches). The maximum levels allowed by DOT, which regulates the transport of radioactive materials in the United States, are 2 mSv (200 mrem) per hour at the surface and 0.1 mSv (10 mrem) per hour at 1 meter (39.37 inches).

Omnitron notified the State of Louisiana's Radiation Protection Division of the event. Inspectors from the State agency found that the package had a narrow beam of radiation from its top surface of approximately 180 mSv (18 rem) per hour, and 22 to 37 mSv (2.2 to 3.7 rem) per hour at other surface locations. The radiation levels were approximately 4 times the levels measured at the surface of the container ("overpak") in which the package arrived.

During the ensuing investigation by State and Federal agencies, it was learned that the packages arrived in the United States at Angeles International Airport and were subsequently sent by truck to a Continental Freight facility in Houston, Texas, where they cleared Customs. After being placed in "overpaks" by a repackager, the packages were sent by Federal Express truck from Houston to Omnitron International in Edgerly, Louisiana. (It should be noted that at least eight companies [two brokers, two truck companies, one repackager, and three freight forwarders] handled the packages in the United States before they left Houston.)

The investigation also determined that at least 32 people in the United States were probably exposed to the excessive radiation from the package. The estimated doses for the people who received maximum exposure are as follows: (1) Los Angeles International Airport to Houston, Texas, 5.82 mSv (582 mrem); (2) Houston, Texas, (freight companies, brokers and a repackager) 46.13 mSv (4613 mrem); and (3) Houston, Texas, to Edgerly, Louisiana 0.84 mSv (84 mrem). The maximum estimated dose was received by an employee of a Texas repackaging firm because the packages were stored near the employee's workbench for a day or more while the "overpaks" were constructed.

Cause:

The State of Louisiana's Radiation Protection Division concluded that the reason the one package had an excessive radiation problem was that the source wire was not secured in the safe or completely shielded position. This suggests an improper preparation for shipment and a failure to perform a proper radiation survey by the shipper in the Republic of Korea. There was no indication of damage to the package, or any evidence to suggest that the source changed position during transport. The source wire was properly secured in the shielded position for the second package.

The safe handling and transportation of radioactive materials imported into the United States are highly dependent on the action taken by foreign shippers and their agents to properly prepare the packages for shipment. There are no DOT or NRC requirements for carriers or shipping agents to monitor or survey shipments during transit in the United States.

Licensee Action:

Omnitron International provides training on source exchange procedures to both its foreign and domestic customers. In this case it supplied training to a Korean service company, which included training for a service manager and two service engineers. Its training procedures are being reviewed to emphasize the regulatory requirements for transportation in the United States.

NRC Action:

Other Agency Action:

DOT wrote two letters to the Competent Authority for Radioactive Materials Transportation in the Republic of Korea asking for information about the shipper and the procedures or requirements for shipping such packages. NRC does not know of any other actions that are being taken to prevent recurrence.

It should be noted that in response to a similar event which occurred in 1990 that involved an NRC licensee, NRC dispatched an Incident Investigation Team (IIT). The IIT's findings are documented in NUREG-1405, "Inadvertent Shipment of a Radioactive Source from Korea to Amersham Corporation, Burlington, Massachusetts."

This event is considered closed for the purpose of this report.

Criteria:

Appendix A (see For All Licensees, Example 11) of this report notes that serious deficiency in management or procedural controls in major areas can be considered an AO.

ITEM #: [] AO #: NRC 89-04 EVENT DATE: 08/09/1989

TITLE: MEDICAL THERAPY MISADMINISTRATION

NAME: Kennebec Valley Medical Center CITY: Augusta STATE: ME

Nature and Probable Consequences:

A radiotherapy physician had prescribed therapeutic treatments in fractionated doses to two elderly patients from a Veteran's Administration facility. One patient was to be treated for a brain tumor, while the second patient was to be treated for a lesion near the lower palate. Both patients were brought to the hospital at the same time. Because of an identification error, the second (lower palate) patient was brought into the treatment room and the procedure for the brain tumor was begun. When the error was discovered, the procedure was stopped. A total of 100 rads had been delivered to the brain of the patient. The patient had previously received 2400 rads to the lower palate from previous treatments.

The licensee has advised the NRC that no adverse effects are anticipated as a result of the misadministration.

Cause:

The misadministration was caused by human error on the part of the staff of the radiotherapy department at the medical center. The names, physical appearances, and treatment planning pictures of both patients were similar.

Licensee Action:

The licensee's planned corrective actions included a strengthening of its patient identification policies along with second person confirmation of patient identity and treatment parameters.

NRC Action:

NRC Region I will conduct an inspection to review the circumstances associated with this misadministration.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 89-05	EVENT DATE:	03/14/1989
TITLE:	MEDICAL DIAGNOSTIC MISADMINISTRATION				
NAME:	New England Medical Center Hospitals	CITY:	Boston	STATE:	MA

Nature and Probable Consequences:

A patient was intended to receive an iodine-123 uptake and diagnostic scan. This would result in an exposure to the thyroid of about 7 rads. However, a staff endocrinologist mistakenly requested an iodine-131 uptake and scan. A floor administrator, transcribing the request to a computer, selected an iodine-131 whole body scan as the intended request. The dosage for this incorrect procedure was prepared and administered to the patient by nuclear medicine department personnel, resulting in the patient receiving five millicuries of iodine-131. This administration resulted in a therapeutic dose to the thyroid of approximately 4,000 to 5,000 rads, with a possible range between 1,200 and 9,000 rads. This dosage could affect the function of the thyroid.

The licensee stated that the patient, a cardiac patient under the care of an endocrinologist, might later have been administered a similar dosage of iodine-131 for thyroid ablation as treatment for his cardiac condition. However, this is no basis for the misadministration; the incident should not have occurred if proper controls had been in place and followed.

Cause:

The licensee stated that the misadministration was caused by human error on the part of the staff endocrinologist and lack of training of involved personnel. The root cause was due to inadequate supervision of activities.

Licensee Action:

The licensee stated that: (1) the Chief of Nuclear Medicine will review all requests for iodine-131 whole body scans, and (2) there will be weekly interdepartmental meetings of the Nuclear Medicine Department and the Department of endocrinology.

NRC Action:

NRC Region I conducted a special inspection on June 5, 1989, to review the circumstances associated with the event, and the appropriateness of the licensee's corrective actions. The results of the inspection are under review. Region I requested an NRC medical consultant to review the incident.

Future reports will be made as appropriate.

UPDATE: from NUREG-0090 Vol 12 No. 2, page 18. This abnormal occurrence, which occurred at New England Medical Center Hospitals, Boston, Massachusetts, was originally reported in NUREG-0090, Vol. 12, No. 1, "Report to Congress on Abnormal Occurrences: January-March 1989." It is updated, and closed out as follows:

As discussed in the previous report, on March 14, 1989, a patient was administered five millicuries of iodine-131, rather than the intended dose of one millicurie of iodine-123. This resulted in a therapeutic dose to the patient's thyroid of 4,000 to 5,000 rads, with a possible range between 1,200 and 9,000 rads.

A special safety inspection was conducted by NRC Region I on June 5, 1989, to review the circumstances associated with the event (Ref. B-8). An apparent violation was identified in regard to a license condition that requires that licensed material be used by, or under the supervision of, individuals designated by the licensee's Radiation Safety Committee.

On July 10, 1989, an enforcement conference was conducted to discuss the violation, its cause, and the licensee's corrective actions. The licensee's corrective actions included: a change in the radiopharmaceutical requisition forms to include the patient's name, type of study and isotope; approval of all iodine-131 used by the Chief Nuclear Medicine Technologist before administration of doses to patients; and additional training to all radiology residents, endocrinologists, and technologists during regularly scheduled Quality Assurance Meetings.

This incident was also reviewed by an NRC medical consultant. One of the consultant's recommended courses of action was to follow the patient yearly with thyroid function and imaging studies and palpation to reduce the risk of thyroid cancer and hypothyroidism. The hospital committed to follow this course of action; however, prior to the July 10, 1989, enforcement conference, the patient died due to a longstanding cardiac condition.

On July 25, 1989, the NRC issued a Notice of Violation to the licensee (Ref. B-9) regarding the previously mentioned apparent violation identified during the inspection on June 5, 1989. No civil penalty was proposed because of the licensee's (a) prompt identification of the misadministration, (b) prompt and extensive corrective actions, and (c) good enforcement history.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 89-03	EVENT DATE:	01/23/1989
TITLE:	MEDICAL THERAPY MISADMINISTRATION				
NAME:	Abbott Northwestern Hospital	CITY:	Minneapolis	STATE:	MN

Nature and Probable Consequences:

A patient suffering from a malignant tumor on his right femur (thigh) received a 250 rad radiation dose to the left femur by mistake.

The patient was scheduled for 12 treatments of 250 rads each to the right thigh using a cobalt-60 teletherapy device. The procedure was for the patient to be brought to the teletherapy simulator to begin preparation for the actual treatment. The simulator is used to chart or map the exact area on the patient's body to be exposed to the cobalt-60. Once this area is determined, it is outlined with indelible ink by the simulator technologist. The patient is then transferred to the cobalt-60 teletherapy room for treatment.

On January 23, 1989, the patient was placed on the simulator table. Due to machine restrictions, however, the table had to be turned 180 degrees, placing the patient's left thigh closest to the technician and the thigh to be treated furthest away. With the patient's position reversed, the technician mistakenly marked the wrong thigh. Once the marking was completed, the therapy physician reviewed and approved the incorrect setup. The patient was then taken to the treatment room where the left femur was exposed to 250 rads of radiation. The therapy technologist discovered the error within minutes of the exposure when she received a copy of the simulator check list. The check list specified that the right femur was the area to be treated. Treatment was subsequently performed on the correct femur and the treatment schedule continued.

The patient's referring physician and the NRC's Region III Office were informed of the misadministration on January 23, 1989. The licensee determined that the misadministration could possibly cause the patient increased fatigue and possible bone marrow suppression the left femur.

Cause:

Several personnel errors occurred in this misadministration. The simulator technologist, in turning the table, apparently disoriented herself, and marked the wrong thigh. The therapy physician checked and approved the incorrect thigh marking and treatment. The therapy technologist should have waited until the patient's simulator check list was available in the teletherapy unit before commencing treatment.

Licensee Action:

As documented in an NRC Region III Confirmatory Action Letter dated January 25, 1989 (Ref. 4), the licensee committed to: (1) provide additional guidance to the simulator and operator technologists and the therapy physician on procedures governing teletherapy administration; (2) inform the operator technologist that the completed simulation check list describing the treatment must be on hand and reviewed prior to setup; (3) provide NRC Region III within 30 days a comprehensive quality assurance/quality control (QA/QC) program which will incorporate Item 2; and (4) assure that the QA/QC procedure also will cover dosimetry, treatment planning and implementation, and radiation safety practices.

On February 16, 1989, the licensee notified NRC Region III that it had completed all items listed in the Confirmatory Action Letter. The licensee's QA/QC program includes dosimetry checks by three independent reviewers, chart checks by two independent reviewers, and treatment prescription by a physician. The hospital had a QA/QC policy prior to the misadministration that included some of the above procedures.

NRC Action:

An NRC inspection was conducted on February 14-15, 1989, to review the circumstances associated with the event (Ref. 5). For minor violations of NRC requirements were identified-none relating to the misadministration. An NRC consulting physician reviewed the patient misadministration and determined that the misadministration would not, likely have any significant or deleterious effect on the patient. The licensee's revised policy, and its implementation, will be reviewed by the NRC at the next routine inspection at the hospital.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 89-07	EVENT DATE:	03/13/1989
TITLE:	MEDICAL THERAPY MISADMINISTRATION				
NAME:	Indiana University School of Medicine	CITY:	Indianapolis	STATE:	IN

Nature and Probable Consequences:

The misadministration was reported to the NRC Region III Office on April 10, 1989. A 68-year old male patient suffering from metastatic lung disease involving the spine and both hips began receiving cobalt-60 treatments to the lumbosacral spine area on March 11, 1989. Treatment to the spine was to be given at 300 rads per day for 10 days.

On March 13, the senior resident oncologist in the school changed the prescription to include cobalt-60 treatments to the patient left hip. The new prescription was based on the result of a bone scan. Treatment was to consist of a total dose of 2,700 rads to the hip over a period of nine days.

In the simulation room where the patient's left hip was to be marked for eventual treatment, the patient was placed in the "prone" position (face done) and his hip marked and fluoroscoped. However, the wrong hip was marked. The bone scan, which was the basis for the treatment, had been taken of the patient while he was in the "supine" position (face up). When the patient was placed on the table face down, the patient was now in the opposite position from the bone scan. This mispositioning went unnoticed and the right hip, which was closest to the technologist, was erroneously marked and received the treatment.

Treatment began March 13 and ended March 27, when the resident oncologist discovered the error while reviewing the patient's chart. The patient and the patient's referring physicians were notified of the misadministration; however, the licensee did not notify the NRC until April 10, 1989, contrary to the requirements of 10 CFR 35.33(a) which states that initial notification must be made within 24 hours after discovery of the misadministration. Treatment on the patient's left hip was subsequently begun on April 10.

An NRC medical consultant was requested to evaluate the medical significance of the event. The consultant concluded that in view of the patient's widespread metastatic disease, the inadvertent 2,700 rads dose to the right hip would not result in a significant, untoward consequence to the patient.

Cause:

It appears that the lack of a written prescription given to the simulator technologist contributed to the mispositioning of the patient on the simulator table and the wrong hip being treated. In addition, the absence of left or right side markers on the simulator radiograph and failure to audit positioning early in the treatment allowed the misadministration to go unnoticed during the treatment period.

In regard to the delay in reporting the event to the NRC, the licensee's communication system apparently broke down in that the facility's radiation protection officer was not told of the misadministration until April 10, 1989.

Licensee Action:

In response to the Region III Confirmatory Action Letter, and Notice of Violation, described below, on May 17, 1989, the licensee documented its specific corrective actions which have been implemented in regard to teletherapy procedures and reporting requirements.

In regard to teletherapy procedures, the licensee submitted a copy of its Radiation Oncology Department's quality assurance/quality control (QA/QC) procedure for external beam radiation therapy. The procedure describes precautionary steps to be taken before initiating treatments, a separate review by a physicist, and a weekly review of treatment charts for all patients undergoing treatment.

In regard to reporting requirements, each staff member signed a form that he or she has reviewed 10 CFR 35.33 requirements; requirements were added to the department manual; and the requirements have been posted in the department. Training will be provided for new personnel.

NRC Action:

An NRC inspection was conducted on April 18, 1989, to review the incident. On May 8, 1989, a Notice of Violation was issued for the licensee's failure to report the misadministration to the NRC within 24 hours of discovery (Ref. 16).

On April 26, 1989, NRC Region III forwarded a Confirmatory Action Letter (Ref. 17) to the licensee documenting the licensee's agreement to (a) provide training to the radiation oncology staff in specific NRC reporting requirements, and (b) incorporate into teletherapy QA/QC program a comprehensive chart review procedure to be performed at least once a week for all patient charts.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: [] AO #: AS 89-01 EVENT DATE: 02/11/1989
TITLE: INDUSTRIAL RADIOGRAPHY OVEREXPOSURES
NAME: Technical Welding Laboratory, Incorporated CITY: Pasadena STATE: TX

Nature and Probable Consequences:

During radiography operations, while performing radiography at Gulf Railcar (GRC), a manufacturing plant in Houston, Texas, a source disconnect occurred resulting in overexposures to two radiographers and one trainee. The radiographic device was a Te Ops Model 660 containing a 115 curie iridium-192 source. The event was investigated by the Texas Department of Health - Bureau of Radiation Control (referred to as the Agency below). The Agency stated that: (a) Radiographer A received an exposure calculated to be between 66 and 179 rem, based on the Agency's reenactment of the incident; and (b) Radiographer B and Trainee B received about 7 rem and 4.3 rem, respectively, as measured by their personnel monitoring devices. Information regarding the incident is based on the Agency's investigation.

Shortly before midnight on February 11, 1989, three two-man crews (Crews A, B, and C) arrived at GRC and began radiographic operations. Crew A (consisting of Radiographer A and Trainee A) and B (consisting of Radiographer B and Trainee B) worked at one end of the tank assembly building while Crew C (consisting of two radiographers) worked at the opposite end of the building. Crew C was not involved in the incident. Crews A and B worked on the same end of the building as the lead radiographer, Radiographer A, who felt that Radiographer B required some assistance.

After setting up, Crews A and B performed a test shot to test the density of the steel. The radiographers entered the tank that Crew B was radiographing. Neither radiographer performed a survey to ensure the source was in the shielded position. Prior to developing the test film, Trainee B passed equipment to the radiographers in the tank. While in the tank, Radiographer A assisted Radiographer B in the placement of his markers and he ensured that the guide tube was in the proper position for the next radiograph. The radiographers were in the tank for between 15 and 20 minutes, and were approximately 5 feet from the end of the guide tube.

While climbing the ladder to exit the tank, Radiographer B bumped the guide tube. Radiographer A told him he would readjust the guide tube and Radiographer B exited the tank. It took Radiographer A approximately 15 minutes to readjust the guide tube. During this time, he was approximately a foot from the end of the guide tube. When he finished adjusting the tube, Radiographer B exited the tank and proceeded to prepare the tank he was radiographing for the next radiograph.

When Radiographer B prepared to crankout the source for the next shot, he saw that his survey meter, set next to the crankout, showed that the source was not in its shielded position. He then informed Radiographer A that the source appeared to be out of the camera. Radiographer A, using Radiographer B's survey meter, surveyed the tank; the meter went off-scale. He attempted to return the source to its shielded position without success. Radiographer A instructed all personnel to leave the area and had everyone check their pocket dosimeters. Each dosimeter was discharged beyond its limit.

After being unable to contact the licensee's radiation safety officer, Radiographer A contacted the licensee's Office Manager (OM). Later, the OM and the licensee's Vice President (VP) arrived to perform source recovery. The VP estimated that Radiographer A had received about 13 rem. After some difficulty, the VP was able to remove the source and camera from the tank, reconnect the source, and return the source to its shielded position. During the recovery operations, it was found that the disconnected source was apparently about one foot from the end of the guide tube. Crew B was dismissed for the evening. The OM and VP continued radiographic operations themselves, using Crew A only to deliver and develop films.

The Agency's investigations included a number of issues associated with the event, including:

- (1) An allegation that management suggested personnel to lose or damage their personnel monitoring devices. This could not be substantiated.
- (2) The VP and OM performed radiography without first having their personnel monitoring devices evaluated.
- (3) The personnel monitoring devices for Radiographers A and B and Trainee B were not collected until February 14, 1989, when the Agency instructed the VP to do so.
- (4) The Agency was informed that daily records were falsified and that training records were inaccurate. A radiographer was present only a portion of the time he was to be supervising a trainee. The trainee actually performed radiography without the radiographer present. These allegations were found to be accurate.
- (5) When Radiographer A's personnel monitoring device was processed, it showed that it received only a minimal exposure. This would be highly unlikely because he should have received considerably more radiation than Radiographer B. Based on reenactments, the Agency calculated that Radiographer A received between about 66 and 179 rem; based on a lack of symptoms, the Agency believes the exposure was closer to about 66 rem.

Cause:

It is the conclusion of the Agency that there was no equipment failure. The disconnect occurred when Radiographer B initially failed to properly connect the source assembly to the drive cable. If the required survey of the radiographic device and guide tube

had been performed after the first radiograph, the disconnect would have been discovered and the radiographers, and Trainee E would not have received overexposures.

Licensee Action:

The licensee has held several safety meetings to discuss the importance of performing proper surveys after each radiograph.

NRC Action:

Other Agency Action:

The Agency is determining what level of escalated enforcement will be taken against the licensee. The Agency is also determining what, if any, action will be taken against the VP and OM for returning to work before having their personnel monitoring evaluated. The Agency is also determining what, if any, action to take against the radiographer who said he was providing training when he was not supervising the trainee or was not at the jobsite.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Criteria:

Appendix A (see Example 1 of "For All Licensees") of this report notes that an exposure of the whole body of any individual to 21 rems or more of radiation can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 89-09	EVENT DATE:	05/23/1989
TITLE:	MEDICAL DIAGNOSTIC MISADMINISTRATION				
NAME:	Abbott Northwestern Hospital	CITY:	Minneapolis	STATE:	MN

Nature and Probable Consequences:

A female patient, intended to receive a diagnostic administration, was administered the wrong radiopharmaceutical that resulted radiation dose in the therapeutic range. Prior to the date of administration, the patient's physician telephoned the licensee's nuclear medicine department requesting that his patient be given a thyroid scan. The woman, who had been diagnosed as having a thyroid nodule, was to be treated on an outpatient basis. A thyroid scan typically utilizes 300 microcuries of iodine-123 (which would result in a dose to the thyroid of about 5 rads) and is designed to locate a thyroid disorder. (Iodine-123 is accelerator-produced and is under NRC regulatory jurisdiction.)

When the referring physician telephoned the order, a scheduling secretary incorrectly wrote "thyroid iodine-131 caps," rather than "thyroid scan." This may have resulted from a misunderstanding with the physician. A technologist, seeing the order for thyroid iodine-131 caps, assumed the female patient was to receive a whole-body scan, and administered 3 millicuries of iodine-131 to the patient on May 23, 1989. (A millicurie is one-thousandth of a curie; a micro-curie is one-millionth of a curie.) The purpose of the whole-body scan is to look for thyroid cancer tissue that has traveled to other parts of the body. Patients who receive such a scan have had their thyroids removed or made "non-functional" by therapy. Three millicuries of iodine-131 can damage a normal thyroid gland.

The licensee's chief nuclear medicine technologist discovered the error about 30 minutes after the patient received the iodine-131. The patient was given Lugol's solution to reduce the effects of the iodine on the thyroid, and the patient's physician was notified. The NRC also was notified of the misadministration by telephone on May 25, 1989, and a written report was submitted on June 1, 1989.

The licensee estimated the patient's thyroid radiation dose to be in the range of 3000 rads. However, the NRC's medical consultant estimated the dose to be 4700 rads. The NRC's medical consultant also observed that the patient would have a 10 percent chance of developing hypothyroidism within two years, and a 25 percent chance in 12 years. He recommended that the patient receive routine testing for thyroid function every four to six months.

Cause:

The licensee did not have adequate procedures to assure that prescriptions were in writing and that dosages were verified before they were administered. As a result, there was an error in communication between the patient's physician and the secretary scheduling the nuclear medicine exam (she listed the wrong isotope on the nuclear medicine schedule). The technologist assumed that a whole-body thyroid scan had been ordered because "iodine-131 caps" was listed on the schedule. The technologist stated that if he had checked the admitting diagnosis, "thyroid nodule," he would have known that iodine-131 was the wrong isotope to use. The hospital had no procedure or requirement that technologists check the admitting diagnosis before giving radiopharmaceuticals to patients.

Licensee Action:

The hospital established procedures requiring that iodine-131 be given to patients only with the prior approval of those individuals listed on the hospital's NRC license as "authorized physicians." The licensee also established a procedure requiring a physician submit a written prescription for the use of iodine-131. In addition, nuclear medicine technologists will review a physician's reasons for giving a patient iodine-131 to make sure that the right isotope is used with the prescribed procedure. They also will make certain that the proper amount of iodine-131 is administered.

NRC Action:

The NRC conducted a special safety inspection of the facility on June 20-21, 1989 (Ref. 5). No violations of NRC requirements were identified during the course of the inspection. However, the NRC raised concerns about the licensee's procedures. A management meeting was held by telephone on July 18, 1989, to discuss the misadministration and the NRC's concern about the adequacy of the licensee's procedures. The licensee outlined new procedures it had instituted and agreed to add these procedures to its NRC license. The procedure changes included a check with the referring physician prior to administration in cases where a physician requests a specific radiopharmaceutical dose. The licensee also reviewed its nuclear medicine and therapy program for additional problems that could lead to a misadministration. The procedure modifications were added to the license on November 14, 1989.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 89-11	EVENT DATE:	08/02/1989
TITLE:	RADIATION OVEREXPOSURE OF A RADIOGRAPHER				
NAME:	Glitsch Field Services/NDE, Inc.	CITY:	North Canton	STATE:	OH

Nature and Probable Consequences:

The radiation overexposure occurred at a customer's site near the licensee's Erie, Pennsylvania facility. On August 3, 1989, the licensee notified the NRC that a licensee-trained and qualified radiographer with six years experience may have received a whole body radiation exposure of 93.4 rem on August 2, 1989, while involved in radiographic operations using a radiography device containing an 87 curie, iridium-192 sealed source. (A radiography device uses a radioactive sealed source to make X-ray-like pictures of welds and heavy metal objects.) The circumstances associated with the radiation overexposure are described below.

After completing a radiograph, the radiographer retracted the source into its shielded position inside the device and surveyed the device and guide tube to verify that the source was fully retracted. He failed, however, to "lock" the source into its shielded position. As a result, while setting up the next radiograph and repositioning the radiography device, the iridium-192 source apparently moved outside its shielded position when the source's crack mechanism rotated. He continued his activities, not knowing that he was working within the radiation field of the unshielded radioactive source. After performing the radiograph, he took the exposed film to a darkroom for development and analysis.

At this time, he checked his pocket dosimeter, a radiation measuring device, and noticed it was offscale (greater than 200 milliroentgen). He reset his dosimeter to zero and continued radiographic operations, completing the remaining planned radiographs even though he reportedly was aware that NRC regulations and licensee procedures require that all work be stopped and immediate notification made when a dosimeter is discovered offscale. The individual later said he believed that his radiograph work had been done properly and that the dosimeter had drifted or been jarred offscale. He notified one of the licensee's Assistant Radiation Officers of the offscale dosimeter at 7 a.m., August 2, 1989, several hours after the event.

A TLD (dosimeter) worn by the individual during radiographic operations from July 10, 1989 to August 2, 1989, revealed a cumulative exposure of about 93.5 rem. (The applicable NRC limit for whole-body exposure to a radiation worker is 3 rem per calendar quarter.)

Based on licensee statements, interviews with the involved radiographer and NRC reenactments of the individual's actions during the event, NRC inspectors concluded that the 93.4 rem exposure was valid and localized to the individual's right hip. The major portion of the radiation dose (greater than 90 percent) was to the radiographer's right hip, which was as close as two inches from the unshielded source during radiograph preparation. As of December 1989, no significant medical effects have been observed. The radiographer remains under a doctor's care, and an NRC medical consultant continues to monitor the individual.

Cause:

The radiographer failed to lock or otherwise secure the radioactive source into its shielded position. Movement of the radiography device and the rotation of the source crank handle allowed the source to move from its fully shielded position and expose the radiographer to direct radiation. The radiographer also failed to make an adequate radiation survey to ensure the source was in the shielding before he approached the device.

Licensee Action:

For corrective actions, the licensee revoked the radiographer's radiographic certification pending retraining and testing; obtained physician's care for the individual; ordered a drug test (results were negative); and conducted tests of the radiography equipment to rule out a malfunction. The day after the incident, the licensee conducted a two-hour radiation safety training class for radiography personnel in the Erie, Pennsylvania, facility. Refresher safety training was conducted for all of the licensee's radiography personnel.

NRC Action:

The NRC conducted a special safety inspection on August 4 and August 14-15, 1989, at the licensee's Erie, Pennsylvania, and North Canton, Ohio, facilities (Ref. 7). During the inspection, the NRC reviewed and reenacted circumstances surrounding the overexposure, verifying that the reported 93.4 rem overexposure was valid. NRC Region III conducted an enforcement conference with the licensee on September 7, 1989, to discuss the event. The licensee agreed to modify its procedures to ensure that sources are locked in the devices and to take disciplinary actions for failure to follow procedures. A Notice of Violation was sent to the licensee on December 27, 1989 (Ref. 8). No civil penalty was proposed.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 1 of "For All Licensees") of this report notes that exposure of the whole-body of an individual to 25 rem or more of radiation can be considered an abnormal occurrence.

ITEM #: AO #: EVENT DATE:
TITLE:
NAME: CITY: STATE:

Nature and Probable Consequences:

On July 24, 1989, the licensee notified the NRC that a misadministration occurred earlier that day when the wrong patient was administered 250 rads (from a cobalt-60 teletherapy unit) to the lumbar/sacral spine. The radiation therapy technician called the right patient's name, but did not confirm the patient's identity with the available photograph. The wrong patient responded and was set up using freckles on his back which were mistaken for the patient's treatment positioning tattoos. When the patient indicated that his set-up wasn't correct, the technician called the Oncology Physician to verify that the required treatment was correct on the patient's chart. The physician verified that the treatment was correct on the chart but did not speak to or examine the patient. The patient was in the therapy department for treatment of his right lung.

The licensee has advised the NRC that no adverse effects are anticipated as a result of the misadministration.

Cause:

The cause is attributed to human error by the staff of the licensee's Radiotherapy Department. The radiation therapy technician had been on vacation and had not previously seen the patient. She did not confirm the patient's identity with the available photograph and did not recognize the absence of treatment positioning tattoos in the patient's lumbar-sacral spine area. In verifying the correctness of treatment, the Oncology Physician performed a chart review, but did not verify patient identity.

Licensee Action:

The licensee's corrective actions included strengthening of their patient identification policies and training of technicians to obtain physician verification of patient set-up before initiating treatment of questionable cases.

NRC Action:

NRC Region I inspectors conducted a special safety inspection on August 28, 1989, of the circumstances associated with the misadministration, and agreed with the licensee's actions to prevent recurrence (Ref. 6). No violations of NRC requirements were identified.

This item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health and safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 89-12	EVENT DATE:	
TITLE:	SIGNIFICANT BREAKDOWN AND CARELESS DISREGARD OF THE RADIATION SAFETY PROGRAM AT THREE GENERAL ELECTRIC MANUFACTURING FACILITIES				
NAME:	Three facilities in Ohio operated by General Elec.	CITY:	see below	STATE:	OH

Nature and Probable Consequences:

During 1988 and 1989, major deficiencies were identified in the radiation safety program at three facilities in Ohio operated by General Electric (GE) Company's Lighting Business Group. Two of the facilities, the Tungsten Products Plant and the Chemical Products Plant, are in Cleveland, and the third, the Ravenna Lamp Plant, is in Ravenna.

Major deficiencies in control in the NRC-licensed use of dispersible powdered thorium (a naturally-occurring, radioactive alpha-emitting material) were identified at the licensee's facilities. The deficiencies posed a possible threat to plant workers due to potential internal deposition of the thorium.

The licensee uses a thorium compound prepared at the Chemical Products Plant to coat lamp electrodes at the Ravenna plant. The Tungsten Products Plant produces lamp filaments made from thorium and tungsten. Periodic radiation surveys are required the facilities to identify any thorium contamination in and around work areas. The licensee is also required to perform surveys a evaluations necessary to control radiation exposures to employees.

NRC inspections in August 1988 and June 1989 determined that the licensee was not performing some of the required contamination surveys or radiation exposure evaluations. Because of these deficiencies, some contaminated areas were not be identified and there were uncertainties in determining employees' exposure to airborne thorium.

The June 1989, inspection identified ten violations of NRC license requirements, some of which were repetitive from earlier inspections. Six violations involved failure to perform various required radiation surveys for surface and airborne contamination to alpha radiation. Others included failure to initiate cleanup procedures when radioactive contamination was detected above an NRC-specified level, failure to evaluate possible hazards during thorium handling and maintenance activities, failure to evaluate means for reducing radiation exposures when two employees exceeded an NRC-specified action level for exposure to airborne radioactivity in January 1989, and failure to post an area as having a potential airborne radioactivity hazard. The repetitive viola included two for failing to perform surveys or monitoring, one for failing to decontaminate when required, and one for failing to po an airborne radioactivity area.

During preparation for replacement of the ventilating system at Ravenna in August 1989, a licensee contractor found thorium contamination in the room containing the thorium processing equipment. The contamination levels, while low, exceeded the lev specified in the NRC license as requiring decontamination. The contamination apparently occurred when a loss of power for the ventilation system allowed the backflow of air containing thorium into the work area.

Although there were major deficiencies in the licensee's survey and monitoring programs, subsequent bioassay tests of employ have indicated that no GE employee exceeded NRC limits for exposure to thorium.

Cause:

Inadequate management attention to radiation safety provisions and past corrective actions that were not implemented or that w ineffective in resolving the problems were the cause of the existence of problems for extended periods and the repetition of problems. This demonstrated a serious breakdown in management controls of the radiation control program, as well as a carele disregard for NRC requirements.

Licensee Action:

Subsequent to the August 1988 and June 1989 inspections, the licensee has revamped its radiation safety programs, emphasis closer supervision at Ravenna by corporate and plant management, and undertaken a major modification of the thorium handl system at the Ravenna plant. The electrode coating was previously performed in a vented hood. The licensee has installed an enclosed glove box system to minimize the possible exposure of workers to airborne thorium. The glove box system includes a ventilation system which prevents the back flow of thorium contamination into the work area.

As a result of NRC findings on the inadequacy of the licensees monitoring and exposure assessment, the licensee performed whole-body radiation counts of employees who routinely handled thorium and contract personnel involved in work on the filtering system for the thorium work area at Ravenna. (The whole-body count, conducted by an independent, outside consultant, would determine if there had been any internal deposition of thorium as a result of inhalation or ingestion.) Since a number of licensee workers expressed concern about the thorium contamination of the Ravenna facility, the licensee provided whole-body counts fc any employees who requested them. More than 400 employees and contract workers were given whole-body counts. No GE employees or contract workers at the Ravenna facility showed any evidence of internal deposition of thorium in the whole-body counts. Two GE workers at the Tungsten Products Plant showed possible evidence of low-level internal deposition of thorium. T licensee is currently evaluating the test data and may perform additional bioassay testing.

NRC Action:

As a result of the June inspection findings, the NRC issued a Confirmatory Action Letter on June 2, 1989 (Ref. 9), documenting licensee's agreement to take prompt corrective actions to deal with the violations identified. These actions included performing radiation and contamination surveys, decontamination of any contaminated area, and a daily program for surveying employees using thorium. The licensee also agreed to institute a monthly management audit plan to assure compliance with NRC requirements. The NRC conducted an Enforcement Conference with the licensee on July 12, 1989, to review the inspection findings and to assure that the licensee was taking appropriate actions.

On August 25, 1989, the NRC issued a proposed \$24,000 fine for the violations identified in the June 1989 inspection (Ref. 10). breakdown in a licensee's program is usually classified as a Severity Level III violation (out of five severity levels in which Sever Level I and V are the most and least significant, respectively). The NRC staff determined, however, that the licensee's continue poor performance reflected a careless disregard for NRC requirements, and categorized the violations as Severity Level II, carry a higher civil penalty. The base value for a Severity Level II violation is \$8,000 but the civil penalty was increased 200 percent to \$24,000 because previous corrective actions were not timely or comprehensive, the NRC identified all of the violations, and the licensee's past performance was poor. The licensee subsequently paid the fine in full.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the third general criterion) of this report notes that major deficiencies in the use of, or management controls for licensed facilities or material can be considered an abnormal occurrence. In addition, Example 11 of "For All Licensees" of Appendix A notes that serious deficiency in management or procedural controls in major areas can be considered an abnormal concurrence.

ITEM #: AO #: EVENT DATE:
TITLE:
NAME: CITY: STATE:

Nature and Probable Consequences:

On October 27, 1989, the licensee reported to NRC Region III that on October 18, 1989, a patient received a diagnostic dose of radioactive iodine compound that was 10 times the intended dose.

The referring physician intended that a patient receive a neck scan using 100 microcuries of iodine-131, but checked the box on referral form indicating a scan using 1 millicurie of iodine-131. The hospital reported that the patient received an additional radi exposure of about 1200 rem to the thyroid beyond that intended by the referring physician. Had the intended dose of 100 microcuries been administered, the thyroid would be expected to receive an exposure of no more than about 140 rem.

A medical consultant, retained by the NRC, indicated that the added dose would result in a very slight increase in the risk that the patient could develop hypothyroidism or thyroid cancer. The consultant recommended that the hospital monitor the patient with annual thyroid function tests.

Cause:

This misadministration occurred because the referring physician checked the wrong box on the nuclear medicine referral sheet. The nuclear medicine physician approved the neck scan procedure, but did not specify that it should be the neck scan with the lower dose of 100 microcuries (i.e., the nuclear medicine physician did not write the prescription on the order form).

Licensee Action:

The hospital has revised its procedures to require additional precautions for procedures involving greater than 20 microcuries of radioactive iodine. Under the revised procedures, the nuclear medicine physician is to review the request for the diagnostic test and the patient's chart and not only approve the test but also write the prescribed dosage on the referral request form. The hospital's radiopharmacy will not dispense any quantities of iodine greater than 20 microcuries without a properly prepared referral request form, which includes a prescription by a nuclear medicine physician.

NRC Action:

A special inspection will be conducted at the hospital to review the incident and other aspects of the licensee's nuclear medicine program.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 89-14 EVENT DATE: 11/30/1989
TITLE: MEDICAL THERAPY MISADMINISTRATION
NAME: Kaukini Medical Center CITY: Honolulu STATE: HI

Nature and Probable Consequences:

On November 30, 1989, a licensee reported to the NRC that a medical therapy misadministration had taken place at its facility earlier that day when a therapeutic dose of 9 millicuries of iodine-131 was inadvertently given to the wrong patient (Patient A rather than Patient B).

Patient A was intended to receive a 20 millicurie diagnostic dose of technetium-99m MDP. This dose was administered and the patient was seated in the waiting room pending a bone scan. Meanwhile, Patient B arrived. Patient B, who was scheduled to receive an iodine-131 hyperthyroidism treatment, completed an interview, signed a consent form, and was seated in the waiting room pending the iodine treatment.

The technologist prepared a dose of 9 millicuries of iodine-131 for administration and reportedly called Patient B. However, Patient A responded. The technologist explained the iodine-131 treatment, scheduled a follow-up appointment, and administered the dose to Patient A. The patient then questioned the technologist, and it became evident that the wrong patient had been treated.

Patient A was immediately informed of the error, and the patient's stomach was pumped, retrieving 3.2 millicuries of the material. The patient was then given potassium perchlorate and Lugol's solution to release any iodine-131 already trapped in the thyroid gland to block further uptake. The use of Lugol's solution continued for 14 days.

This misadministration resulted in an estimated dose to the thyroid of from 560 to 820 rem. This dosage would result in a very slight increase in the risk that the patient could develop hypothyroidism or throat cancer. The licensee plans to monitor the patient with annual thyroid function tests.

An NRC medical consultant reviewed the incident. He concurred with the immediate actions taken by the licensee, and with the licensee's planned corrective actions to prevent recurrence that are described below.

Cause:

The licensee stated that the misadministration was caused by human error on the part of the technologist and by inadequate procedural controls. The root cause was due to inadequate supervision of activities.

Licensee Action:

The licensee stated that: (1) a training class had been scheduled for all technologists, (2) a single technologist will be required to handle all aspects of the iodine-131 therapy and must be able to recognize the correct patient prior to the treatment, and (3) the technologist, physician, and patient are required to concurrently sign the therapy worksheet prior to the administration.

NRC Action:

An NRC inspection was performed on February 6 and 8, 1990. No violations of license requirements were identified. The licensee's corrective actions to prevent recurrence were satisfactory.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the generic criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: [] AO #: AS 89-02 EVENT DATE: 08/26/1989
TITLE: INDUSTRIAL RADIOGRAPHER OVEREXPOSURE
NAME: Mobil-Lab, Inc. (licensee)/Shell Oil Refinery CITY: Norco STATE: LA

Nature and Probable Consequences:

On August 26, 1989, the licensee notified the Louisiana Department of Environment Quality, Nuclear Energy Division ("Agency") that earlier that day one of the licensee's radiographers had apparently received a significant exposure to his left hand while performing radiography with a SPEC 2-T exposure device containing an 82 curie iridium-192 source.

The Agency performed an investigation on August 29, 1989, to determine the circumstances associated with the incident. This involved interviews with the radiographer and the licensee, and an reenactment of the incident using a dummy source. The incident is briefly described below.

After performing an exposure, the radiographer cranked in the source, however, the source was not fully retracted into the exposure device. The radiographer then performed an inadequate radiation survey that failed to detect the exposed source. He locked the exposure device, took it to a pipe rack, and set the device into a rack. While preparing for the next exposure, he was located approximately 2 feet from the front of the exposure device in a squatting position, with his back to the device. After an estimated minutes, he reached back, without turning around, and disconnected the source tube with his left hand. He pulled the tube away and may have grazed the source capsule with his left palm.

Within a couple of seconds, he noticed that the source was protruding from the nipple about 4 inches. He immediately left the area and notified the lead radiographer. The lead radiographer saw the exposed source, cranked it fully into the exposure device, and then surveyed and locked the device. After directing the radiographer to return to Mobil-Lab to turn in his TLD badge, he carried the exposure device to SPEC, Inc., in Kenner, Louisiana, for inspection. The exposure device appeared to be working properly.

The original calculated exposure was 3000 to 3500 rem. However, this was revised downward to about 1400 rem, based on the Agency's investigation. The whole-body exposure was about 12.9 rem, based on the reading of the radiographer's thermoluminescent dosimeter (TLD). The Agency advised the licensee to provide immediate medical attention, including a doctor's examination of the hand and obtaining blood tests. Though the calculated exposure of the radiographer's hand may have been high as 1400 rem (as estimated from an reenactment of the incident), the hand showed no indications of injury. Blood tests taken shortly after the incident, and again 48 hours later, were normal.

Cause:

The Agency investigator concluded that the primary cause was the radiographer's failure to perform a proper radiation survey to determine if the source was in the safe position following a radiographic exposure. No training or significant management deficiencies were identified.

Licensee Action:

The licensee circulated a notice to its employees with their paychecks; the notice described the incident and stated the cause was due to the radiographer not performing a proper radiation survey. In addition, the licensee increased the number of field audits of radiography work being performed at job sites.

NRC Action:

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Other Agency Action:

Agency - The licensee was cited for three violations: (1) failure of the radiographer to perform a proper survey following exposure, (b) permitting an individual to receive an exposure in excess of specified limits, and (c) permitting the individual to act as a radiographer prior to the licensee's submission of proper forms to the Agency.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see Example 1 of "For All Licensees") of this report notes that an exposure of the feet, ankles, hands, or forearms of any individual to 375 rem or more of radiation can be considered an abnormal occurrence

ITEM #: [] AO #: NRC 86-04 EVENT DATE: 02/07/1986
TITLE: THERAPEUTIC MEDICAL MISADMINISTRATION
NAME: Washington Hospital Center CITY: Washington STATE: DC

Nature and Probable Consequences:

On February 6, 1986, an attending surgeon of the Renal Transplant Unit ordered radiation therapy as follows for one of his patients: 150 rads per day to be repeated every other day for a total of 600 rads. The treatment was intended to forestall rejection of the kidney implanted on the previous day. The Unit clerk, in entering the order for the treatment into the computer for transmission to the Radiation Therapy Department for scheduling purposes, ordered the treatment for the wrong patient through careless use of the computer light pen.

The wrong patient, who was also a kidney transplant recipient, was brought to the radiation therapy department on the morning February 7. The radiation therapy physician checked her chart, noted that there was no order in the chart for radiation therapy, in contrary to hospital policy, directed the technologist to administer the treatment, since the computer scheduled showed this patient's name. The mistake was discovered that afternoon and the correct patient was subsequently treated.

The consequences of this incident was that the patient received 150 rads to the abdomen contrary to the wishes of her physician. It should be noted, however, that her physician stated later that if in the future she showed signs of rejection of the kidney that had just been implanted, he would prescribe a similar course of radiation therapy. It should also be noted that some physicians who perform renal implants routinely prescribe radiation therapy without waiting for evidence of rejection.

The licensee's medical staff has concluded that the patient should experience no clinical complications.

Cause:

The cause of the event was the failure of the radiation therapy physician to follow proper procedure. The physician should have investigated why a patient presented for radiation therapy did not have an order for such therapy written in her chart.

Licensee Action:

The licensee voluntarily suspended patient treatment pending the results of an internal investigation, and discussion of these results with NRC Region I.

Subsequently, the licensee committed to assure that an authorized physician reviews every patient chart prior to initiation of treatment and confirms that treatment has been requested and is appropriate, and to require consultation between an authorized user and the referring physician prior to the initiation of treatment of any patient.

NRC Action:

The licensee was inspected by an NRC Region I inspector on February 20-11, 1986. The subject event was reviewed in detail. February 11, 1986, Region I issued a Confirmatory Action Letter documenting the licensee's commitment described above.

The incident was reviewed by an NRC medical consultant.

A Confirmatory Order Modifying License was issued on May 29, 1986 (Ref. 24). The Order required that an authorized physician user review every teletherapy patient chart to confirm that cobalt-60 teletherapy treatment has been requested and that the authorized physician user consult with the referring physician or the Chief Resident prior to the initial treatment of each teletherapy patient. In their response to the Order, Washington Hospital Center confirmed that the required procedures had been in place since February 18, 1986.

The May 29, 1986 NRC letter (Ref. 24) also forwarded a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$5,000.

Unless new significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criteria) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 86-05 EVENT DATE: 02/19/1986
TITLE: OVEREXPOSURE TO A MEMBER OF THE PUBLIC FROM AN INDUSTRIAL GAUGE
NAME: C-E Glass, Inc. (Div. of Combustion Engineering) CITY: St. Louis STATE: MO

Nature and Probable Consequences:

On February 19, 1986, while checking a licensee which had apparently ceased operations, an NRC Region III inspector determined that an industrial gauge, containing a sealed source of cobalt-60, was in an unrestricted area of the former factory site. Subsequent inspection determined that at least two members of the public received exposures to radiation as a result of the improper disposal of the gauge.

C-E Glass, Inc., was licensed in 1971 for the use of a level measurement gauge containing 2.5 curies of cobalt-60. The source was replaced in June 1978. In October 1981, the facility and equipment at C-E Glass's site was transferred to Hordis Brothers, Inc., which continued operations until May 1982.

C-E Glass violated two NRC regulations - (1) transferring the gauge to an unauthorized organization (Hordis Brothers did not have an NRC licensee) and (2) failing to notify the NRC that it had ceased all operations at the St. Louis facility.

The facility and equipment were later sold by Hordis Brothers to a salvage company. The gauge was placed near a scrap pile at the site, and a salvage company employee removed the gauge's shutter control in early December 1984. For the next two months two employees of the salvage company handled the gauge and worked near it. It was later moved to a scrap pile where access to other individuals was limited.

The gauge was then located by the NRC inspector, assisted by salvage company employees, on February 19, 1986, and later removed from the site by representatives of Combustion Engineering Company, who took it to another Combustion Engineering facility for storage and eventual disposal.

Interviews with the two salvage company employees determined that they frequently worked or took breaks in the vicinity of the gauge. Calculations based on the radiation level--with the shutter of the gauge open--concluded that one individual would have received a radiation exposure to his buttocks of 0.6 to 1.7 rem and to his leg of 69 to 208 rem. (A rem is a standard measure of radiation exposure.) NRC regulations do not permit radiation exposures to members of the public from licensed activities to exceed 0.5 rem.

The second individual would have received a significantly lower radiation dose. The first individual has been examined by a physician and his blood count, bone marrow, and physical condition were reported to be normal.

Cause:

The uncontrolled use of the gauge and radiation exposure of at least two individuals were caused by the transfer of the gauge by the licensee to an unauthorized organization. There was therefore no control over access to the gauge, and a salvage company employee removed the shutter control, allowing the shutter of the gauge to open. (Had the shutter of the gauge remained closed the radiation dose to persons in the area would be substantially less than with an open shutter.)

Licensee Action:

The licensee is longer in business and has no other gauges in its possession.

NRC Action:

An NRC inspector located the gauge and locked the shutter in its closed position. He then arranged for the licensee's corporate organization to remove the gauge to another site for storage and eventual disposal. NRC inspectors surveyed the former C-E Glass site to make certain there were no other gauges there.

A medical consultant was retained to review the circumstances of the case and to provide assistance to the exposed individual's physicians.

On June 30, 1986, the NRC forwarded to the licensee a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$15,000, for violations associated with the handling of the gauge (Ref. 25).

On May 5, 1986, the NRC issued Inspection and Enforcement Information Notice No. 86-31 to all NRC licensees authorized to possess and use industrial nuclear gauges to inform them of this event (Ref. 26). Further information was provided to these licensees on July 14, 1986 by Supplement 1 to the Information Notice (Ref. 27).

This incident is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 2 of "For All Licensees") of this report notes that an exposure to an individual in an unrestricted area such that the whole body dose received exceeds 0.5 rem in one calendar year can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 86-06	EVENT DATE:	03/03/1986
TITLE:	BREAKDOWN OF MANAGEMENT CONTROLS AT AN IRRADIATOR FACILITY				
NAME:	Radiation Technology, Incorporated (RTI)	CITY:	Rockaway	STATE:	NJ

Nature and Probable Consequences:

On March 3, 1986, the NRC issued an Order Suspending License (Effective Immediately) to Radiation Technology, Incorporated (RTI) of Rockaway New Jersey (Ref. 28). The Order as based on NRC inspections which identified a number of instances of bypassing safety interlock systems; these indicated a significant breakdown in the licensee's management control system.

RTI has been licensed to operate a large irradiator near Rockaway, New Jersey, since November 1970. The licensee's irradiator uses sealed cobalt-60 sources to produce high intensity gamma ray fields for the sterilization of medical equipment and supplies and for various other industrial and scientific applications. In addition, the licensee has long sought FDA approval to irradiate food products for routine consumption. At the time of the March 3, 1986 NRC Order, the President of the company was also the Chairman of the Board of Directors, and the Radiation Safety Officer.

RTI also owns and operates irradiators through wholly owned subsidiaries in North Carolina and Arkansas, both Agreement States. Another wholly owned subsidiary, South Jersey Process Technology, recently built in Salem, New Jersey, was licensed Region I on March 14, 1986.

RTI has been the subject of several escalated enforcement actions in the past; the most noteworthy was in 1977 when a plant worker at the Rockaway facility was able to walk into the irradiation room while the cobalt-60 was exposed because safety interlock on the personnel access door, designed to prevent such entry, had been made inoperable. The employee received a radiation dose of 150-300 rem, far in excess of regulatory limits. The license was temporarily suspended following this incident until the licensee took necessary corrective actions. (This incident was reported as abnormal occurrence No. 77-10 in NUREG-0090-10, "Report to Congress on Abnormal Occurrences: October-December 1977.")

The events giving rise to the most recent Suspension Order first came to light during a routine NRC inspection in September 1984. The inspector discovered that the licensee had been operating the irradiator since April 1984 with an inoperable safety interlock on one of the two conveyor openings used to transfer product into the irradiation room. On September 26, 1984, Region I issued a Confirmatory Action Letter that documented the licensee's commitment to operate the facility only if all safety interlocks were operable and to cease operations if any safety interlock failed to function as required. Review of relevant documentation by the inspector indicated that this bypassing of interlocks was implemented by the operators under the supervision of the Operating Manager. In November 1985, the interlock was replaced with a new design without required NRC approval.

During a recent inspection on February 26, 1986, the staff determined that the licensee had been operating the facility for several days prior to the inspection in spite of the malfunction of a radiation monitor which actuates the lock that assures that the personnel door to the irradiation room cannot be opened while the sources are exposed. Rather than fix the monitor prior to the continued operation, as is required by the license, the licensee chose to operate the irradiator and, when necessary, opened the door by improperly tripping the door lock when the cobalt-60 appeared to have returned to its shielded position. Following this discovery the staff requested that the licensee cease all operations until the monitor was repaired; conducted daily inspections to assure that the facility was being operated safely and that all interlocks were functioning; and prepared the previously mentioned Order Suspending the License which was issued on March 3, 1986 (Ref. 28).

Subsequently, the licensee requested lifting of the suspension by letters to the NRC dated March 4 and 5, 1986. After Region I staff met with the licensee on March 6, a more complete submission was provided by the licensee on March 10. This latter submission proposed interim plant operations under the surveillance of an independent Third Party, reporting directly to a member of the RTI Board of Directors, who, along with the licensee, would be responsible for assuring that the facility would be operated safely and in compliance with all NRC requirements. Further, an independent Fourth Party would monitor the activities of the Third Party on a weekly basis. Both parties would provide uncensored reports directly to the NRC. Following consideration of the proposal and agreement of the licensee to additional items, the staff concluded that temporary resumption of facility operations under these conditions would not endanger the health and safety of the public. Accordingly, a Conditional Rescinding of the Order Suspending License was issued on March 13, 1986 (Ref. 29). The licensee agreed to the terms of this Order in a letter dated March 13, 1986.

Cause:

The root cause can be attributed to a serious breakdown in the licensee's management controls.

Licensee Action:

The actions taken by the licensee are described above.

NRC Action:

The NRC is continuing to inspect the performance of this licensee at frequent intervals.

A recent license amendment appointed an individual, who joined the company in March 1986, as the new Radiation Safety Officer. The individual who formerly held this position no longer has direct contact with, or responsibility for, this function. At a recent meeting of the Board of Directors, this same individual resigned as President, but remains Chairman of the Board. The responsibilities of President are being shared among three Vice Presidents while a new President is sought.

In addition to the previously described actions taken by the NRC, on June 23, 1986 the NRC suspended the license again based on investigative findings indicating repeated and intentional violations of NRC requirements and impeding NRC inspection and investigations (Ref. 30). The license is presently suspended pending further action by the NRC. South Jersey Process Technology, a subsidiary, has recently begun commercial operation of a more modern in-air irradiator in Salem, New Jersey. The licensee is attempting to build another irradiator in the Port of Elizabeth, New Jersey. No formal application has been received by the NRC for this facility.

Further reports will be made as appropriate.

UPDATE: from NUREG-0090 Vol. 9, No. 1 page 40. On June 23, 1986, the license was again suspended, effective immediately based on the findings of an NRC investigation that management directed the bypass of interlocks and safety features and that management had provided false information to the NRC. The suspension was effective pending review of the licensee's request to renew the license. On August 22, 1986, the license was renewed and the suspension lifted following extensive changes in licensee management and procedures. An augmented inspection program is in place and the license will expire in February 1988 requiring a second renewal application and review.

Future reports will be made as appropriate.

UPDATE: From NUREG-0090, Vol. 10, No. 1, page 29. From August 1986 through April 1987, there have been 15 inspections of the licensee's facilities, 13 of which identified no violations of NRC requirements. The violations identified during the other two inspections were generally caused by failure to follow procedures, but did not indicate a programmatic weakness nor did they compromise public health and safety. A special Systematic Assessment of Licensee Performance (SALP) conducted for the period from August 1986 through February 1987 indicated generally acceptable performance, with improvement needed in the areas of procedure adherence, quality assurance, and plant maintenance.

In December 1986, the then Radiation Safety Officer of the licensee initiated a site characterization in an effort to determine the presence, on the licensee's property, of burials of radioactive material. Initial radiation surveys were performed and exploratory excavations were made in areas where burials were believed to have occurred. One of the excavations resulted in a positive indication of radiation. Subsequent soil and water samples from the location did not reveal any abnormal levels of radioactivity, leading to the conclusion that a contained radioactive source may be buried at this spot. Subsequently, other information has been obtained which supports this conclusion.

In response to this finding, a Confirmatory Action Letter, dated March 24, 1987, was issued which documented the licensee's commitments to: 1) comprehensively survey the portion of the property suspected to contain buried radioactive material, 2) develop a plan to non-invasively detect buried matter, and 3) inform the NRC Region I Office prior to performing any invasive action to explore or uncover buried material. These actions have been completed by the licensee, and several areas have been identified that require further evaluation. An excavation of one of these areas on June 4, 1987, revealed an object that read 200 millirem per hour at contact.

To supplement this effort, Region I contracted with Oak Ridge Associated Universities (ORAU) to perform an independent radiological survey of the unrestricted areas of RTI's property (that is, the areas not covered by the licensee's survey described above) in Rockaway, New Jersey. While several items containing low-level radioactivity were found on the property, nothing of health or safety significance was detected.

On May 8, 1987, representatives from NRC Region I met with representatives from the New Jersey Department of Environment and Protection (NJDEP) to discuss items of mutual interest relative to RTI. The NJDEP informed Region I representatives of its intent to perform, beginning about June 8, 1987, a major site characterization effort, i.e., a Remedial Investigation/Feasibility Study (RIFS), to identify the presence and source of hazardous chemicals known to be contaminating the groundwater in the area of F. A public meeting to describe this effort was held by NJDEP on May 14, 1987, and was attended by Region I representatives. Public interest appeared to focus primarily on the nature and extent of the hazardous chemical waste and its impact on the local environment. No significant interest has yet been expressed relative to burial of radioactive material.

A License Renewal Application was submitted by RTI on February 20, 1987. The present license expired on February 28, 1987 but is currently being maintained effective based on this timely renewal application.

The Renewable Application is under review. At the present time, RTI is operating normally.

Future reports will be made as appropriate.

UPDATE: From NUREG-0090, Vol. 11, No. 2, page 15. From May 1987 through May 1988 there were 13 inspections of the

licensee's facilities, none of which identified any violations of NRC requirements. During June and July 1987, the licensee completed its exploratory excavations for previously buried radioactive material and site characterization to establish the levels of remaining radioactive contamination. Approximately twelve drums and other various artifacts and debris contaminated with low levels of radioactivity were unearthed. These items were consolidated and shipped to an authorized radioactive burial site on December 28, 1987. Soil contaminated with low levels of radioactive material remains on site, but it does not pose a threat to health and safety.

On March 16, 1988, RTI and a former operations manager for the company pleaded guilty to federal charges resulting from willful disregard of NRC requirements. The company pleaded guilty to charges that its former officers submitted falsified documents to the NRC concerning safety procedures at its plant in Rockway, N. J. The company acknowledged its legal responsibility for these actions and admitted that its officials lied to NRC investigators and radiation specialists about the length of time it operated with required radiation safety monitoring equipment. The former operations manager pleaded guilty to conspiring with other employees to obstruct NRC's investigation. RTI's former chief executive officer pleaded not guilty to similar charges, and another former operations manager pleaded guilty to one count of conspiring to defraud the NRC. On July 13, the former president of RTI was convicted in U.S. District Court of conspiring to defraud the NRC, lying to NRC investigators, and intentionally violating the Atomic Energy Act.

On October 11, 1988, the former president was sentenced to serve two concurrent sentences of two years, and was assessed a \$50,000 fine. RTI was fined a total of \$100,000. The two former operations managers were each sentenced to three years probation and were assessed fines of \$10,000 and \$2,500, respectively.

On March 17, 1988, the NRC renewed RTI's license for a two year probationary period. The license was renewed because: (1) management and employees primarily responsible for the previous performance of licensed activities, including deliberate attempt to mislead the NRC, had resigned from the company, and (2) NRC's observations indicated that the new RTI management team had significantly improved facility operations, enhanced safety, performed extensive decontamination of the plant, and was committed to renovate safety systems and facilities to assure continued safe operation. To assure that adequate performance continues, the licensee requires frequent periodic audits by an independent agent who will report findings to both the NRC and the licensee.

At the end of the reporting period, RTI was operating normally.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 11 of "For All Licensees") of this report notes that serious deficiency in management for procedural controls in major areas can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 86-07 EVENT DATE: 03/12/1986
TITLE: TRITIUM OVEREXPOSURE AND LABORATORY CONTAMINATION
NAME: Ferris State College CITY: Big Rapids STATE: MI

Nature and Probable Consequences:

During a routine inspection on March 12, 1986 at Ferris State College, an NRC inspector determined that, based on a review of bioassay test results, a licensee researcher had received an overexposure to tritium (hydrogen 3) during experiments on August 1985, equivalent to a whole-body exposure of about 21 rem.

Continuing NRC inspections showed that two laboratories were contaminated. In addition, numerous deficiencies in the license use and control of by-product radioactive material were identified.

Ferris State College had a broad scope license from the NRC for the possession an dose of by-product radioactive material for training and research purposes.

The NRC found that on August 3, 1985 a researcher was performing work in a ventilated glove box using 5 curies of tritium in a laboratory at the licensee's facility. (A glove box is a sealed box with viewing windows and gloves affixed to the box, allowing hazardous materials to be normally handled safely.) After completing the work, the researcher performed a urine bioassay test, which showed a tritium level of 520,000 counts per minute per 0.2 milli-liters of urine. This level of tritium would indicate an inter uptake of 10,000 MPC hours, compared to the NRC quarterly limit of 520 MPC hours for occupational radiation exposures. (An MPC hour is equivalent to one hour of exposure to the maximum permissible concentration of a specific radioactive material.) T intake would be equivalent to a whole-body exposure of 21 rem. A second bioassay test, 20 hours later, showed an internal intake of 1,210 PMC hours.

A radiation exposure of 21 rem (a rem is a standard measure of radiation exposure) would not normally be expected to produce medically observable effects.

Bioassay test results following another 5-curie experiment on December 1, 1985, showed a level of 239 MPC hours. This exposure was within the NRC limit, but, was required to be reported to the NRC because of the urine concentration.

Surveys by the NRC--and subsequently by the licensee--showed the laboratory to be contaminated. A second laboratory on a different level of the same building was also found to be contaminated. Surveys by the licensee and the NRC did not identify an contamination in the hallways or other public areas of the building.

Cause:

The tritium overexposure appeared to result from the failure of the researcher to properly seal off the glove box in which the tritium was being used. The glove box was pressurized with nitrogen gas which apparently forced the tritium gas through a blower fan the laboratory rather than through the glove box vent system. The discharge of the tritium into the laboratory caused both the exposure to the researcher and the contamination of the laboratory. A research assistant also received some exposure as a result of the experiment or the laboratory contamination, but this exposure was within the NRC limits, according to bioassay test result

NRC inspections identified numerous violations of NRC requirements (as discussed below), some of which may have contribute to the overexposure and laboratory contamination.

Licensee Action:

After being notified of the initial NRC inspection findings, the licensee removed the researcher from any work involving radioactive material, restricted access to the laboratory areas, and began decontamination of the laboratory facilities. Decontamination was subsequently completed, and the facility was released for normal use.

The licensee also provided information on the contamination to students or other persons who may have used the building where the laboratories are located and offered to provide bioassay testing for any concerned individuals. No one requested the testing

Additional actions may be necessary in response to the numerous violations identified during the NRC inspections.

NRC Action:

The NRC issued Confirmatory Action Letters to the licensee on March 19 and 21, 1986, documenting the licensee's agreement to remove the researcher from work involving radioactive materials, to restrict access to the laboratory areas, to undertake decontamination of the facility, and to stop all licensed activities except those associated with the nuclear medicine school.

NRC inspectors inspected the facility on several occasions to gather additional information on the licensee's handling of radioactive materials and to monitor the decontamination efforts. Confirmatory radiation surveys were also performed.

NRC inspections, which began March 12, 1986 and continued through April 17, 1986, also identified a total of 20 violations of NRC requirements. These violations included failure to perform required surveys for radioactive contamination, failure to check the glove box ventilation system for proper operation, failure to perform required bioassay tests in some instances, failure to take required

follow-up actions when certain bioassay results are obtained, failure to report the overexposure, and failure to restrict access to laboratory.

On April 28, 1986, the licensee's NRC license was amended, significantly restricting the scope of the authorized activities and providing that any new activities must be reviewed and approved by the NRC.

Enforcement action is pending on the violations identified during the NRC inspections.

Further reports will be made as appropriate.

UPDATE: From NUREG-0090, Vol. 9, No. 3, page 36. On July 11, 1986, the NRC sent to the licensee a Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$10,500 (Ref. B-15).

Item I in the Notice of Violation involved an individual who was exposed in a restricted area on August 3, 1985 to a tritium vapor concentration approximately 20 times the permissible limit. This resulted in the individual receiving a calculated whole-body dose of 21 rem. This event is of particular concern because the individual performed an experiment using curie quantities of tritium in liquid form without functional monitoring instruments.

Item II involved the licensee's failure to report to the NRC, as required, the August 3, 1985 event and a second event that occurred on December 17, 1985, after urinalysis tests, performed by the individual described above, showed tritium concentrations in excess of NRC limits. The individual knew the concentrations were excessive but failed to recognize the radiological significance of the event and therefore decided not to inform the Radiation Control Office. NRC holds licensees responsible for acts such as this because licensees are responsible to properly train their employees and monitor their work activities.

Item III described additional violations that resulted from inadequate surveys and evaluations, inadequate training and supervising individuals that used licensed material, failure to take adequate corrective action after radiological hazards were identified, failure to follow procedures, and failure to maintain adequate records.

The NRC forwarding letter stated that collectively, these violations indicated a serious lack of management oversight of the radiation safety program, lack of an effective audit program to monitor personnel, and a failure to reasonably ensure that NRC requirements are being followed.

The licensee paid the \$10,500 civil penalty and as corrective action, the licensee upgraded its procedures governing the use of radioactive materials and its system of auditing these uses. Further, the licensee's NRC license was amended in April 1986 changing the license classification from broad scope, which permitted the licensee to authorize individual users of radioactive materials and to approve operating procedures, to a limited scope license which requires the NRC approval of users and procedures.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 11 of "For All Licensees") of this report notes that serious deficiency in management or procedural control in major areas can be considered an abnormal occurrence.

ITEM #:		AO #:	AS 86-01	EVENT DATE:	04/20/1984
TITLE:	RADIATION INJURY OF AN INDUSTRIAL RADIOGRAPHER				
NAME:	BF Inspection Services (of Midland, Texas)	CITY:	Seminole	STATE:	TX

Nature and Probable Consequences:

On April 20, 1984, an individual employed by BF Inspection Services in Midland, Texas, received an exposure that resulted in a radiation burn while performing radiography in Seminole, Texas. The licensee failed to notify the Texas Bureau of Radiation Co (Agency) of the incident after it knew the radiographer had received a radiation burn. The burn was reported by Permian Industri X-ray, present employer of the individual, to the Agency on November 8, 1985, when the radiographer had an apparent recurren of the wound.

The radiographer and assistant arrived at the job site at 9:00 a.m. and used a 90 curie iridium-192 source to x-ray pipe in a pipe rack until 11:00 a.m. The job was being performed by Conan Inspection, and BF Inspection had been subcontracted to assist o the job.

The radiographer worked on the pipe rack removing exposed film and placing new film on the weld to be x-rayed. The assistant worked the crank out. The radiographer did not have a survey instrument with him. He depended on the assistant to tell him w the radiation levels decreased on the survey meter kept at the crank out.

At approximately 10:00 a.m., the radiographer took the exposed film to the central processing facility. When this film was developed, it was darker than it should have been and appeared to be exposed longer than necessary.

At 11:00 a.m., the radiographer decided to stop work and go to lunch. At this time he locked the radiographer device, removed t guide tube and put the dust cover on the front of the device. No survey was performed on the radiographic device or guide tube this time. The equipment was placed in a bucket used to transport equipment on the pipe rack and left there during lunch.

Prior to leaving the job site, the radiographer went to the job supervisor. The radiographer was informed that it appeared that he needed to decrease his exposure time and was asked for an other exposed film. The radiographer told the supervisor that he w bring the remaining exposed film for developing after lunch.

When the crew returned from lunch, the radiographer decided to quit for the day, since he could not determine the cause of the being overexposed. The equipment was moved from the bucket to the back of the truck. The radiographer carried the guide tube and crankout in his left hand and the radiographic device in his right hand. When the radiographer disconnected the crankout fro the radiographic device, he discovered that the source was not connected to the drive cable. The radiographer then looked at h pocket dosimeter and found that it was discharged beyond its range. He than asked the assistant to look at his dosimeter and v informed that it was not discharged beyond its range. The assistant radiographer was instructed to check the radiation level anc told the radiographer that he had a reading of 90. (The radiographer and the assistant did not remember what scale the survey meter was set on.)

The radiographer shook the guide tube and heard something rattling. He carried the guide tube, still rolled up, and the radiograp device to a large concrete slab approximately 60 feet from the truck. The guide tube was unrolled and when he shook it, the sou fell out. The radiographic device was placed on top of the source and the radiographer went back to the truck. He than approached the device with the crankout and passed the drive cable through the radiographic device. The device was then mov behind the connector end of the source pigtail and the pigtail and the drive cable were connected. The source was returned to i shielded position and locked in place.

When the crew left the job site, the radiographer notified the job supervisor of the disconnect. The supervisor instructed the radiographer that he should notify his radiation safety officer (RSO) of the disconnect and to leave his film for processing. The supervisor stated that when this film was developed, it appeared that it may have been fogged.

When the radiographer returned to the office, he found that the RSO was gone for the weekend and did not attempt to notify him the disconnect until Monday, April 22.

On Monday, the RSO and the radiographer inspected the equipment. According to the radiographer, nothing was found to be wrong with the equipment. The radiographer stated he turned in his and his assistants film badges for immediate processing. A this time, the radiographer did not demonstrate any symptoms of a radiation injury.

Approximately five to seven days after the disconnect, the thumb, index and middle fingers of both the radiographers hands bec red and swollen. The radiographer was seen by a doctor and the three blood tests performed were within normal limits. The medical expenses were paid for by BF Inspections. After a period of approximately two months, the radiographer's hands appea to heal.

During the first week of November 1985, the radiographer was working for another company and the middle and index fingers of left hand became red and swollen. He again went to see a doctor. He notified his employer of the injury. The company RSO th notified the Agency of the injury.

Based on statements by the radiographer, Agency investigators calculated his exposure from carrying the equipment to the truc

and recovering the source. The radiographer may have received up to about 29,000 rems to his left hand and about 47 rems w/ body exposure.

During the Agency's investigation, several items of disagreement arose. While the radiographer stated that he turned in his and assistant's film badges, the RSO for BF Inspection Services stated that he asked for the badges and was informed that they were in the truck used at the job site. The RSO instructed the radiographer to give him the film badges but did not follow up when he did not receive the badges. The question also arose as to whether there was an equipment malfunction. According to the radiographer, there was no equipment malfunction. The RSO stated during the investigation that the connector on the drive cable was worn and caused the disconnect.

When questioned concerning the cause of the disconnect, the radiographer stated that the only conclusion he could reach is that he did not connect the source pigtail to the drive cable when he assembled the device.

Cause:

The apparent cause of the disconnect is that the source pigtail was not correctly connected to the drive cable when the equipment was set up. The exposure and subsequent burn resulted when the radiographer did not follow the licensee's Operating Procedure or the Texas Regulations for Control of Radiation, and failed to perform a survey of the radiographic device or guide tube between radiographs, when the equipment was secured for lunch, or at the end of the day. The radiographer also failed to follow the licensee's Emergency Procedures for source disconnect.

Licensee Action:

At this time, the licensee's response to the Agency's compliance letter was not satisfactory as to what actions it has taken to prevent occurrence of this type of accident. The licensee's initial report of the incident did not address calculations of the radiographer's exposure, nor measures taken to prevent a recurrence.

NRC Action:

Other Agency Action:

The Agency has cited the licensee for 14 items of non-compliance with the Texas Regulations for Control of Radiation and is undertaking escalated enforcement. The investigation of this incident is continuing in an attempt to obtain additional information.

Unless new significant information becomes available, this incident is closed for the purposes of this report.

Criteria:

Appendix A (see Example 1 of "For All Licensees") of this report notes that exposure of the whole-body of any individual to 25 rems or more of radiation, or exposure of the extremities of any individual to 375 rems or more of radiation, can be considered an abnormal occurrence.

ITEM #:		AO #:	AS 86-02	EVENT DATE:	05/24/1985
TITLE:	CONTAMINATION OF A SCRAP STEEL FACILITY				
NAME:	Tamco Steel Company	CITY:	Ontario	STATE:	CA

Nature and Probable Consequences:

On May 24, 1985 it was discovered that some facilities of Tamco Steel Company were contaminated with radioactive material (later determined to be cesium).

On May 23, 1985, two 20 cubic yard roll boxes being transported to the hazardous waste site at Kettlemen Hills, California, set off the radiation alarms at the weight station at Newhall, California. The trucks were returned to the originator of the shipment at the direction of the California Highway Patrol (CHP) on advice of the California Radiological Health Branch (RHB). The licensee voluntarily ceased operations upon notice by the CHP of the incident at the weigh station. The furnace was turned off and operations began to go to a cold shutdown. Shipments of product steel were suspended.

On May 24, 1985 inspectors from the California Department of Occupational Health and Safety conducted an initial survey of the roll boxes and the facilities of Tamco Steel Company. The survey indicated contamination was limited to flue dust, slag piles, bag house (containing flue dust) and associated ducting, in addition to surface of the furnace itself. Samples were collected and sent for analysis. Direct radiation levels ranged from 0.3 mR/hr to 15 mR/hr. Analysis of the samples indicated cesium contamination ranging from 2.0 pCi/gr to 4 uCi/gr.

On May 25, 1985 Tamco had a contractor on site to begin a thorough survey and develop a clean up plan. The initial plan for decontamination was developed with the RHB. A planned incremental decontamination program began on May 30, 1985. Priority was given to operational equipment and facilities. Clearance inspections conducted by the State followed the progress of the decontamination effort.

Because of its chemical form, the cesium was removed from work areas in the mill through flue dust ducting and the waste slag. Workers in the furnace area and bag house most likely to receive internal contamination by inhalation of airborne dust containing cesium were sent to the University of California at Los Angeles where detailed examinations were conducted. The examinations did not detect any contamination of the workers.

On August 1, 1985 the State Compliance Inspection Team completed its final survey. The RHB issued a departmental letter dated October 8, 1985, which released the facilities and equipment for unrestricted use.

Cause:

The Tamco Steel Company processes scrap steel purchased from various suppliers throughout California, Nevada, and Arizona into construction rebar. The scrap is segregated by metal type and sent directly to the melting furnace without inspection. The device or source of the approximately 1.5 curies of cesium was brought into the scrap yard undetected and sent to the furnace as part of a routine melt. Scrap metal dealers as a normal practice do not screen for radioactive material.

Licensee Action:

Tamco Steel installed low-level radiation monitors at the gate to check scrap steel coming into the facilities and product shipment leaving. They also now physically inspect all scrap steel before it is placed in the furnace.

NRC Action:

Other Agency Action:

As discussed above, the cognizant State Agencies monitored the decontamination of the facility, the actions taken to prevent recurrence by Tamco Steel, and after a final survey of the facility, released the facilities and equipment for unrestricted use. This incident is considered closed for the purposes of this report.

Criteria:

Appendix A (see the general criterion) of this report notes that a moderate or more severe impact on the public health or safety could be considered an abnormal occurrence.

ITEM #:		AO #:	AS 86-03	EVENT DATE:	08/25/1985
TITLE:	RADIATION INJURY OF AN INDUSTRIAL RADIOGRAPHER				
NAME:	Boothe-Twining, Inc. (Kern River Oil Field)	CITY:	Bakersfield	STATE:	CA

Nature and Probable Consequences:

On August 25, 1985, an industrial radiographer received a radiation injury to his left hand and a whole body overexposure. At the time of the incident, the employee was performing radiography at the company's field site in the Kern River oil field in Bakersfield California. He was using a 46 curie iridium-192 source contained in a radiographic projector.

The radiographer (who had four years of radiography experience with Boothe-Twining) encountered great resistance with the source "crankout." He then approached and manually adjusted the camera to reduce the kink in the guide tube. During this act his hands grasped the lock box and guide tube connector. At the completion of this readjustment, he moved away from the camera and observed that his 200 mR pocket dosimeter read off scale. However, he did not report his dosimeter was off-scale but reported a pocket dosimeter reading of 119 mR to his supervisor. His film badge was sent in for reading approximately seven days after the accident after symptoms of high dose to the left hand were manifested and reported to management. He was seen by and continues to be under the care of a physician. In addition, another doctor is participating as the State Agency medical consultant. Based on time and motion studies, preliminary estimates indicated a left hand dose of about 2,000 rem and a whole body dose of about 6 rads.

The radiographer was accompanied at the work site by a helper who was acting as an assistant radiographer. She was only indirectly involved in actual performance of radiography, and registered no excessive dose. She kept back from the shooting area but had observed most of the radiographer's movements during the accident.

A State Investigating Panel was convened pursuant to an Order dated October 16, 1985, to determine the causes of the radiatic accident, establish the nature and extent of radiation exposure and any injury, and to recommend corrective action to prevent future recurrence of such accidents. The findings of the Investigative Panel are discussed below.

The radiographer had failed to adhere to established radiation safety and operating procedures. He did not assure that the radiography source was returned to the safe shielded position with the crank and did not perform a radiation survey on his approach to the camera; therefore, he had no warning that the source was out.

Management had failed to communicate forcefully its intolerance of deviation from established safety procedures, particularly the failure to survey while approaching the radiographic projector. The Investigative Panel found that such deviation was common practice with the overexposed radiographer, and that management knew of it. Had the radiographer used his survey instrument as required, he would have detected early on that the source was out, in an unsafe position.

Instruction of radiographers, and specifically the overexposed radiographer, was found to be unacceptable in that, (a) there was a failure to convey the crucial safety problem to the employee, i.e., that the performance of field radiography constituted a serious hazard and therefore requires strict adherence to safety procedures, (b) the licensee's attempted requirement that employees attend refresher training on their own time is unenforceable and contrary to State labor law--the license assigns the responsibility for providing refresher training to the licensee, not the employee, (c) semi-annual refresher training consisted of infrequent safety "bull sessions" with no structure and no record other than the fact of the bull session, and (d) radiographers were not checked on equipment prior to use. General operating procedures were available to radiographers, however, no step-by-step operating, radiation safety and emergency procedures were provided that were specific to the make and model of projector used.

Responsibility for the radiation safety program, although vested in the Radiation Safety Officer (RSO) of the licensee, was in fact abrogated by the president of the company. In his own testimony to the Investigative Panel, the president accepted this responsibility and authority, but did very little to implement the program and clearly would not delegate to others. In the current case, he prevented the RSO from conducting the investigation. To compound the situation, the compliance history and the president's testimony clearly illustrated his failure to comprehend the company's direct responsibilities for the employee hand burn and the numerous overexposures. He maintained that the accident was the employee's fault.

The company's RSO asserted that the conduct of training and management audits were his safety assignment, but his heavy responsibilities in sales, customer relations and quality assurance often took precedence.

Management audits of the overexposed employee's work as a radiographer were not conducted as required by license conditions and records were not maintained. Records for August 23, 1985 of the inspection and maintenance of the Gamm Century projector involved in the accident were reviewed. These suggest that the equipment was in good functioning condition, yet the Investigative Panel discovered that the lock could be actuated over the drive cable, thus locking the source outside the shield.

According to the Investigative Panel, the compliance history of Boothe-Twining is unacceptably poor. The company was found to be at fault and cited, in the serious overexposure/injury of an employee, in a 1981 radiography accident. Since then repeat and serious violations have continued, necessitating an office compliance conference on July 5, 1985. In spite of agreements arising out of that conference, the company continued to fail to provide adequate training and audits of employees so that there is a clear and unambiguous understanding of the seriousness of the performance of field radiographers and the need therefore to follow required safety procedures. For example, in July 1985, the radiographer involved in the present incident received a whole body dose of 2 rem. The report of this did not stimulate an appropriate response by management. Failures of the RSO to conduct job

site management, audits at frequencies promised, and to provide comprehensive refresher training for radiographers were contrary to license conditions. Refresher training for radiographers is required to include review of, (1) radiation safety and operating procedures, while (2) stressing changes in such procedures and (3) measures to be taken to avoid excessive exposures.

Cause:

The immediate cause of the overexposure was the failure of the radiographer to adhere to established radiation safety and operating procedures.

As discussed above, contributing causes are the serious breakdowns in management and procedural controls in the licensee's conduct of radiographic operations.

Licensee Action:

A Notice of Violation was issued to the Licensee by the California Division of Occupational Safety and Health (Agency) on December 11, 1985. The testimony of company employees including management affirmed that the violations did in fact occur. The response also outlined corrective action to prevent recurrence of these violations.

The licensee's response to the matter of management audits was judged to be inadequate. The licensee was provided additional opportunity to develop an internal audit program to assure that radiographers and radiographer's assistants comply with the State Department of Health Services' regulations and license conditions, and the company's operating and emergency procedures.

NRC Action:

Other Agency Action:

The State held an enforcement conference with the licensee. A consent agreement will be signed between the Director of the State Department of Health and Services and the licensee. The licensee will be placed on a 3 year probation with provisions for suspension if serious noncompliance occurs within that period. The license will be amended to require a full time RSO and will detail the RSO's duties.

The State Investigative Panel concluded that if the radiographer had been wearing a functional pocket radiation alarm, the radiographer would have had ample warning that the source was not in its proper shielded position. The Panel further agreed that the introduction of pocket alarms into the practice of industrial radiographer is now imperative. Reliability had improved as a result of demand by the nuclear power industry so that the pocket alarm can reasonably be expected to withstand field service, provided radiographers are given appropriate instruction in the use of these devices. Instruction will also be necessary to prevent use of radiation alarm as a substitute for quantitative assessment by radiation survey meters of radiation fields in conducting radiation surveys. The introduction of pocket radiation alarms is expected to reduce the frequency of excessive exposures and minimize incident of injuries by giving radiographers timely warning of exposed sources.

California will consider adopting regulations which would require use of appropriate pocket radiation alarms for all radiographers and radiographer's assistants. This requirement would supplement and not in any way displace the present requirement for use of a survey meter in conducting required radiation protection surveys for industrial radiography.

California will consider promulgating regulatory requirements and otherwise encouraging the development of a radiographer projector with an integral warning system built into the device to indicate in unambiguous fashion the safe, intermediate or unsafe position of the source. This may be done by announcing proposed legislative requirements to authorize only devices with this feature, starting in 1990.

Unless new significant information becomes available, this incident is considered closed for the purposes of this report.

Criteria:

Appendix A (see Example 1 of "For All Licensees") of this report notes that exposure of the whole body of any individual to 25 rems or more of radiation, or exposure of the extremities of any individual to 375 rems or more of radiation, can be considered an abnormal occurrence.

ITEM #:		AO #:	AS 86-04	EVENT DATE:	11/09/1985
TITLE:	RADIATION INJURY OF AN INDUSTRIAL ASSISTANT RADIOGRAPHER				
NAME:	Basin Industrial X-Ray	CITY:	Odessa	STATE:	TX

Nature and Probable Consequences:

On November 9, 1985, an individual employed as an assistant radiographer by Basin Industrial X-Ray in Odessa, Texas, received radiation burn of his left hand and an estimated 129 rems whole body exposure. The licensee failed to notify the Texas Bureau of Radiation Control (Agency) of the incident. Another licensee informed the Agency on November 26, 1985 that an incident had occurred involving Basin Industrial X-Ray.

The radiography crew was performing work at Fabricators Contractors, Inc. during the evening of November 9, 1985. The assistant radiographer was shooting the welds and the radiographer was developing the exposed film. At approximately 11:30 p.m. the assistant radiographer noticed that his survey meter, placed approximately two feet in front and to the right of the radiography device (a 76 curie iridium-192 radiography camera), was off scale after the source was supposed to have been returned to its shielded position. He then checked his pocket dosimeter and found it was discharged beyond its range. He notified the radiographer, who was unsuccessful in his attempt to return the source to its shield using the crankout. The radiographer checked his pocket dosimeter and found that it was not discharged beyond its limit. He then notified the local supervisor, who was acting as the local radiation safety officer. The radiographer was instructed to isolate the area and wait for the supervisor.

The supervisor did not retrieve the source but instructed the radiographer in the procedures. The first action was to remove the crankout from the radiographic device. At this time it was found that the drive cable had broken just behind the connection with the source pigtail. The radiographer then removed the guide tube from the device with a pair of 12 inch channel lock pliers. Using the pliers and holding the guide tube at arms length, he carried it to an open area of the shop and shook the source out of the guide tube. Using the pliers, the pigtail was placed in the device source end first. The pigtail was then reversed using the pliers and pushed in with the dust cap. When the connector end of the pigtail exited the lock box, it was locked in place. After the source retrieval, it was found that the radiographer's pocket dosimeter had been discharged beyond its range of 200 millirems.

The equipment was loaded in a truck and the three employees proceeded to the licensee's facility. After arriving at the facility, the supervisor notified the company's radiation consultant of the disconnect and that the employees' pocket dosimeters had been discharged beyond their limits. The supervisor was instructed to return both badges for immediate processing and to send the assistant radiographer for a blood test. The blood sample taken at this time was within normal limits.

On November 29, 1985, the assistant radiographer met with an Agency representative. At this time, the individual's left hand had redness from the wrist to the base of the little finger. On December 2, 1985, the individual had a blister from the wrist to the base of the little finger on this left hand.

On December 6, 1985, the Agency contacted the radiation safety officer (RSO) and requested the film badge results. The Agency was informed that the film badge had been sent in for routine processing and the results were not available. The licensee was instructed to contact its film badge supplier and to have the radiographer's and assistant's film badges immediately processed. When the assistant's film badge was processed, it indicated an exposure of 129 rems. When asked about the radiographer's exposure, the RSO stated that he did not have his badge processed with the assistant's. The Agency again instructed the RSO to have the radiographer's film badge immediately processed. The radiographer's exposure was determined to be 28 rems.

Based on statements made by the assistant radiographer and a re-enactment of the incident, Agency investigators calculated the exposure to the assistant to be about 129 rems whole body. The estimated exposure to his left hand is subject to considerable uncertainty. The value may have been as high as 30,000 rems, or even considerably higher.

The Agency's investigation found that the individual had not received radiation safety training or formal training in industrial radiography from the licensee. It also appears that the individual had falsified his application stating that he had previous experience.

When asked why the licensee did not report the incident to the Agency, the RSO stated that he did not realize the severity of the incident, since he had not been provided the full details by the radiography crew. The RSO knew that the assistant radiographer's pocket dosimeter was discharged beyond its range but did not return his film badge for immediate processing. The licensee failed to perform a detailed investigation of the incident when it appeared that there could have been a serious radiation exposure. The RSO also informed the Agency that he did not know that the drive cable had been broken. When asked by the Agency investigators, the RSO stated that he could not locate the broken crankout cable.

Cause:

The apparent cause of the exposure and burn appears to be that the licensee permitted an individual to perform the functions of a radiographer without providing the proper safety training, and that the individual failed to perform surveys between radiographs.

Licensee Action:

The licensee has started tighter controls on its initial training program and hiring procedures.

NRC Action:

Other Agency Action:

The Agency has cited the Licensee for items of non-compliance with the Texas Regulations for Control of Radiation. In addition complaint has been issued to the licensee, notifying him that the Agency intends to revoke the license. The investigation of this incident is continuing in an attempt to obtain additional information.

Unless new significant information becomes available, this incident is considered closed for the purposes of this report.

Criteria:

Appendix A (see Example 1 of "For All Licensees") of this report notes that exposure of the whole body of any individual to 25 re or more of radiation, or exposure of the extremities of any individual to 375 rems or more of radiation, can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 86-10	EVENT DATE:	05/08/1985
TITLE:	WILLFUL FAILURE TO REPORT A DIAGNOSTIC MEDICAL MISADMINISTRATION				
NAME:	Mercy Hospital	CITY:	Wilkes-Barre	STATE:	PA

Nature and Probable Consequences:

On May 8, 1985, a patient at Mercy Hospital, Wilkes-Barre, Pennsylvania, received an injection of a radiopharmaceutical (a diagnostic dose of technetium-99m) intended for another patient. The misadministration was willfully not reported to the NRC as required by 10 CFR 35.43.

An anonymous allegation was received by NRC Region I on May 8, 1985. The allegor stated that a misadministration had occu that morning at Mercy Hospital when the Chief Nuclear Medicine Technician mistakenly injected the wrong patient with a radiopharmaceutical. Further, the allegor stated that the misadministration would not be reported to the NRC. The required rep of the misadministration was due to the NRC by July 10, 1985.

On July 17, 1985, two NRC Region I inspectors performed a routine unannounced inspection and follow-up of the allegation at t licensee's facility. During the inspection, the Chief Nuclear Medicine Technician stated that no misadministrations had occurred since the one reported to the NRC in 1984. However, the inspectors noted that records showed one patient had received two radiopharmaceutical injections in a one hour period on May 8, 1985. The Chief Nuclear Medicine Technician stated that this wa not because of a misadministration.

On August 7, 1985, an investigator from the NRC's Office of Investigations (OI) went to Mercy Hospital. During an interview with the Chief Nuclear Medicine Technician, she admitted she had lied to the NRC on July 17, 1985. The Chief Nuclear Medicine Technician also stated she was told that the Medical Director of Radiology, who is also the licensee's Radiation Safety Officer (RSO), did not want the misadministration reported. The RSO stated during an interview with the OI investigator on August 7, 1985, that he had informed some of his staff not to report the misadministration.

The consequences of the licensee's actions in this incident are that (1) it decreases the NRC's confidence that his licensee will report incidents as required by regulation and (2) it delays implementation of procedures to prevent further misadministrations of similar nature.

The effects on the patient, mistakenly receiving the radiopharmaceutical, would be expected to be small due to the relatively low levels of exposure involved. However, it did represent an unnecessary exposure.

Cause:

The cause is due to the deliberate failure of the RSO to follow the NRC requirements for reporting misadministrations and instructing the hospital staff not to report this particular misadministration.

Licensee Action:

The licensee, as well as another licensee in which the RSO is involved, requested an extension to respond to the NRC enforcer actions described below.

NRC Action:

On June 17, 1986, the NRC forwarded to Mercy Hospital (1) an Order requiring the licensee to show cause why the Chief Nucle Medicine Technician and the RSO should not be prohibited from the performance or supervision of any licensed activities, and (a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$5,000 (Ref. 5).

The RSO at Mercy Hospital is also listed as an authorized user of NRC licensed material on the license of Valley Radiology Associates, Inc., Kingston, Pennsylvania. Therefore, on June 17, 1986, the NRC issued a similar Order to this licensee (Ref. 6.

Information regarding these enforcement actions was sent to all NRC medical licensees on October 3, 1986 by Inspection and Enforcement Information Notice No. 86-85 (Ref. 7).

Future reports will be made as appropriate.

UPDATE: From NUREG-0090, Vol. 9, No. 4, page 39. As discussed in the previous report, on June 17, 1986, the NRC forward to Mercy Hospital of Wilkes-Barre, Pennsylvania (1) an Order requiring the licensee to show cause why the Chief Nuclear Medic Technician and the Radiation Safety Officer (RSO) should not be prohibited from the performance or supervision of any licensec activities, and (2) a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$5,000 (Ref. B-11). The reaso was that the individuals willfully failed to report a diagnostic medical misadministration to the NRC as required by 10 CFR 35.43. addition, the RSO at Mercy Hospital is also listed as an authorized user of NRC licensed material on the license of Valley Radio Associates, Inc., Kingston, Pennsylvania. Therefore, on June 17, 1986, the NRC issued a similar Order to this license (Ref. B-1

The technologist involved at Mercy Hospital no longer works in the field of Nuclear Medicine. On July 15, 1986, NRC Region I, the consent of the licensee, issued an amendment to the Mercy Hospital license which did not include the RSO involved. While

individual will continue to work at the hospital, his activities will be under the supervision of an authorized user. He will not manage the Nuclear Medicine Program and is no longer the RSO. Region I has agreed to reconsider adding the individual as an authorized user, if the hospital formally requests it, after a period of one year. On October 17, 1986, the licensee sent a check in full payment of the \$5,000 civil penalty. On December 24, 1986, the NRC found that the licensee's corrective actions provided adequate cause why the license should not be modified (Ref. B-13).

On December 15, 1986, the license of Valley Radiology Associates, Inc. was amended to delete the same individual as an authorized user, with the consent of the licensee. On December 24, 1986, the NRC found that the licensee's corrective actions provided adequate cause why the license should not be modified (Ref. B-14).

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence. In addition, Example 11 of "For All Licensees" of Appendix A notes that serious deficiencies in management or procedural controls can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 86-11 EVENT DATE: 04/09/1986
TITLE: THERAPEUTIC MEDICAL MISADMINISTRATION
NAME: Maryview Hospital CITY: Portsmouth STATE: VA

Nature and Probable Consequences:

On April 9, 1986, at Maryview Hospital, Portsmouth, Virginia, a patient received a therapy dose in a chemical form other than the intended. This resulted in an unintended dose of several hundred rads to the patient's bone marrow.

A physician asked the Nuclear Medicine Department to order a dose of phosphorus-32 as colloidal chromic phosphate on April 9, 1986, for administration to a kidney carcinoma patient for abdominal ascites reduction on April 9, 1986. This verbal order was relayed to Nuclear Medicine through a third party, and the chemical form of phosphorus-32 was not made clear. Nuclear Medicine proceeded to order 15 millicuries of phosphorus-32 as sodium phosphate because this chemical form was used more frequently than the colloidal form. The order was processed and received in the hospital in the normal manner.

On April 9, 1986, the physicist drew up the dose in a syringe, assayed it in the dose calibrator, and then put it aside. Shortly thereafter, a physician (other than the physician who ordered the dose) administered the dose intraperitoneally to the patient. Later the same day, the Chief Nuclear Medicine Technologist, while discussing this particular patient with a nurse, discovered that the soluble form, in lieu of the colloidal form of the phosphorus-32, was administered intraperitoneally. Subsequently, the radionuclide was no longer confined in the peritoneal cavity. This information was relayed to several physicians and was also reported later that day to the NRC.

On April 10, 1986, the patient was administered stable phosphorus to accelerate excretion of the phosphorus-32. Blood counts leucocytes, red blood cells, hematocrits and platelets showed no significant depression as of April 21, 1986.

The consequences of the misadministration was a significant unintended dose to the patient's bone marrow. The licensee estimated the dose to be at least 150 rads. However, the NRC's medical consultant believes the dose could have been as much as 700-800 rads to the patient's bone marrow with an increased chance of the patient contracting leukemia.

The misadministration constituted a significant failure to comply with NRC regulatory requirements. The patient was subjected to a procedure unrelated to the authorized uses of phosphorus-32 as sodium phosphate.

Cause:

The root cause was the lack of written prescriptions for ordering therapeutic doses.

Licensee Action:

The licensee established written procedures and forms to provide for written prescriptions and therapeutic radionuclide procedures. The licensee's agreement to establish procedures for ordering and administering therapy doses had been previously documented in an NRC Confirmation of Action Letter, dated April 10, 1986.

NRC Action:

In addition to engaging a medical consultant and issuing the Confirmation of Action Letter, the NRC Region II conducted a special inspection at the hospital on April 11, 1986. An Enforcement Conference with the licensee was held on May 2, 1986, to discuss NRC concerns regarding the inspection findings. At the conference, the licensee presented the previously mentioned written procedures and forms.

On August 7, 1986, the NRC issued to the licensee (1) a Confirmatory Order Modifying License, and, (2) a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$2,500 (Ref. 8). The Order, effective immediately, was issued to confirm implementation of corrective procedures and to ensure their continued implementation. The licensee paid the civil penalty.

NRC Region II will review the effectiveness of the procedures during subsequent inspections.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 86-12 EVENT DATE: 04/22/1986
TITLE: WILLFUL FAILURE TO REPORT DIAGNOSTIC MEDICAL MISADMINISTRATIONS
NAME: Bloomington Hospital CITY: Bloomington STATE: IN

Nature and Probable Consequences:

On April 22, 1986, the NRC Office of Inspection and Enforcement issued an Order, effective immediately, removing a physician from the position of Radiation Safety Officer (RSO) and Authorized User at Bloomington Hospital.

On October 12, 1984, NRC Region III received an allegation that five diagnostic misadministrations had occurred at Bloomington Hospital and that they had not been reported to the NRC as required. (A diagnostic misadministration involves an error in the administration of a radioactive pharmaceutical used for a diagnostic medical test.) During a subsequent inspection, the physician serving as RSO informed the NRC that only one misadministration had occurred. After further interviews were conducted, and additional information gathered by the inspectors, the physician admitted that the other four diagnostic misadministrations did occur.

During the inspection, however, the physician obstructed the inspection and misled the inspectors by instructing hospital employees to inform the inspectors that the misadministrations had not occurred and by withholding or concealing nuclear medicine films from the inspectors.

Because of the low levels of radiation exposures to the patients in diagnostic tests, no detrimental medical effects are anticipated as a result of these administrations.

Cause:

The NRC determined that the failure to report the misadministrations was willful.

Licensee Action:

As required by the NRC Order dated April 22, 1986 (Ref. 9), the licensee removed the physician from the position of RSO and an Authorized User designated in the NRC license. Another individual on the hospital staff was placed in the position of RSO with the approval of NRC Region III.

NRC Action:

The NRC (including the Office of Investigations) investigated the allegation and the RSO's subsequent actions described above and concluded that there was no longer reasonable assurance that the physician could be relied upon to comply with Commission requirements in the performance or supervision of licensed activities, or that the licensee would comply with Commission requirements while the physician is conducting or supervising licensed activities as an Authorized User or as the RSO at the hospital.

The license was subsequently amended to designate the new RSO.

Information regarding this enforcement action was sent to all NRC medical licensees on October 3, 1986 by Inspection and Enforcement Information Notice No. 86-85 (Ref. 7).

This item is considered closed for the purposes of this report.

Other Agency Action:

[]

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence. In addition, Example 11 of "For All Licensees" of Appendix A notes that serious deficiency management or procedural controls in major areas can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 86-13 EVENT DATE: 05/07/1986

TITLE: DIAGNOSTIC MEDICAL MISADMINISTRATION

NAME: Robert Packer Hospital/Guthrie Clinic CITY: Sayre STATE: PA

Nature and Probable Consequences:

On May 16, 1986, NRC received written notification that on May 7, 1986, an out-patient of the Robert Packer Hospital and Guthrie Clinic in Sayre, Pennsylvania, received 10 millicuries of iodine-131 rather than the prescribed radiopharmaceutical for a bone scan technetium-99m.

Approximately two weeks before the scheduled appointment, an out-patient was mistakenly scheduled for a whole body iodine-131 scan rather than a whole body bone scan. At the time of scheduling, a verbal confirmation for an iodine-131 whole body scan was received from the doctor's office.

The patient arrived without a requisition for the study and the technician administered 10 millicuries of iodine-131 without the consultation with a radiologist required by department policy. The patient was instructed to return the following day for the imaging procedure. On return to the hospital the following morning, the patient produced an order from her physician requesting that a technetium-99m bone scan be performed. The technician proceeded to perform the whole body iodine-131 scan and then notified the radiologist of the misadministration.

The licensee informed the NRC of the misadministration and the probable medical effects were explained to the patient. The misadministration would result in a considerable dose to the thyroid. The patient was given Lugol's Solution (to help reduce the uptake of the iodine-131 by the thyroid) and instructed to take six milliliters four times per day for four days. Arrangements were made for the patient's thyroid function to be evaluated and followed.

Cause:

The cause was failure on the part of a nuclear medicine technologist to adhere to department policy on the prerequisites required for radiopharmaceutical administration.

Licensee Action:

All concerned personnel have been retrained on the policy of not administering radioisotopes without a written requisition and of requirement to obtain the specific consent of a radiologist for all cases requiring the administration of greater than 300 microcuries of iodine-131.

NRC Action:

The incident was reviewed by the NRC medical consultant who concluded there was a probability of inducing hypothyroidism and that medical care provided the individual was adequate. NRC Region I plans to review the incident as part of a routine inspection.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 86-14 EVENT DATE: 06/17/1986
TITLE: DIAGNOSTIC MEDICAL MISADMINISTRATION
NAME: Tripler Army Medical Center CITY: Tripler AMC STATE: HI

Nature and Probable Consequences:

A 54 year old female patient was given a 3.09 mCi dose of I-131 by mistake. The patient was scheduled for a thyroid imaging procedure which utilizes only 50 uCi of I-131. The radiation exposure received by the patient due to the 3.09 mCi I-131 dose is estimated to be 2472 rad to the thyroid, 0.43 rad to the ovaries, and 1.45 rad to the whole body.

Contact with the licensee was made on July 9, 1986, regarding any possible clinical symptoms or adverse health effects due to 3.09 mCi I-131 dose. The licensee stated that the patient had been hospitalized for observation. On July 6, 1986, the patient was discharged due to the lack of any clinical symptoms. The patient has been scheduled for 90 days interval checkups at her duty station in Guam. An annual medical workup has also been scheduled. The high exposure to the thyroid may result in some degree of impairment in its function.

Cause:

This misadministration was the result of an isolated incident of misreading the consultation sheet.

Licensee Action:

Effective immediately, the dispensing procedure for radioactive iodine is as follows:

- (a) In all cases, the final dispensing and checking of the dose will be done by a staff physician or radiology resident assigned to Nuclear Medicine Service.
- (b) The identification of the patient as well as the final amount dispensed will be co-signed by the physician involved in that particular procedure.
- (c) The quality assurance manual for Nuclear Medicine Service is being updated to stipulate the new review procedures.

NRC Action:

The circumstances of the misadministration were discussed in detail with the licensee on July 3, 1986 by a member of the NRC Region V management staff. The licensee's corrective actions appear to be acceptable. The NRC will not issue any further requirements in this matter at this time. The matter will be reviewed again during the next inspection.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: [] AO #: AS 86-05 EVENT DATE: 05/08/1985
TITLE: UNCONTROLLED RELEASE OF KRYPTON-85 TO AN UNRESTRICTED AREA
NAME: Micro-Rel Division, Medtronic, Incorporated CITY: Tempe STATE: AZ

Nature and Probable Consequences:

On May 8, 1985, during routine operation of a Trio-Tech "Tracer-Flo" system at Micro-Rel Division, Medtronic, Incorporated, of Tempe, Arizona, a malfunction occurred which caused approximately 11.2 curies of radioactive krypton-85 to be vented into the atmosphere.

"Tracer-Flow" systems are used to test sealed objects, such as electronic components, to determine whether they are, in fact, sealed. Tested objects are placed in a test chamber which is evacuated and a mixture of nitrogen and radioactive krypton-85 is introduced. This mixture is then removed and replaced by air. The objects are then tested for residual radioactivity. If none is detected, this would indicate that the objects have been properly sealed.

On May 8, 1985, during routine operation of the "Tracer-Flo" fine leak system, the unit "locked" into the first cycle of operation. The unit then began to run through the other cycles while maintaining the mechanical conditions of the first cycle. This situation resulted in the krypton-85 being released to an unrestricted area, rather than being retained within the system. There was no evidence that any overexposure occurred.

Cause:

A thorough inspection of the machine was made and all mechanical systems were found to function properly. The failure was attributed to the machine's logic board. This was concluded by a step-by-step replacement of integrated circuits on the logic P.C. board until control panel indications were normal. The unit was then cycled a number of times and found to work properly.

Licensee Action:

Even though the licensee has an exemplary maintenance program, it would not have prevented this type of release. The P.C. board logic failure can only be rectified by design changes by the manufacturer.

NRC Action:

Other Agency Action:

The Agency monitored the licensee's response to this event and confirmation completion of the actions described above. The Agency performed an inspection of the circumstances associated with the event and the licensee was assessed a civil penalty in the amount of \$3,000. Due to the licensee's good past history and cooperation with the Agency, the civil penalty was mitigated to \$1,500, which was imposed upon and paid by the licensee.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see the first general subcriteria) of this report notes that moderate exposure to, or release of, radioactive material can be considered an abnormal occurrence. In addition, Example 3 of "For All Licensees" of Appendix A of this report notes that the release of radioactive material to an unrestricted area in concentrations of which, if averaged over a period of 24 hours, exceed ten times the regulatory limit of Appendix B, Table II, 10 CFR Part 20 (10 CFR 20.403(b)), can be considered an abnormal occurrence.

ITEM #:		AO #:	AS 86-06	EVENT DATE:	05/09/1985
TITLE:	CONTAMINATED RADIOPHARMACEUTICAL USED IN DIAGNOSTIC ADMINISTRATIONS				
NAME:	Scripps Memorial Hospital	CITY:	Encinitas	STATE:	CA

Nature and Probable Consequences:

On May 9, 1985, a breakthrough of molybdenum-99 (a radioactive contaminant) occurred in a molybdenum-99/technetium-99m generator at Scripps Memorial Hospital of Encinitas, California. The breakthrough went unrecognized and the contaminated technetium-99m radiopharmaceutical was administered to four patients scheduled for diagnostic medical tests. Therefore, these patients received exposures higher than necessary.

Technetium-99m is a radiopharmaceutical which is widely used in hospitals and doctor's offices for diagnosing a variety of diseases. It has a short half-life of 6 hours (i.e., it loses half of its radioactivity every 6 hours). It is a product of the decay of another radioactive material, molybdenum-99.

The technetium-99m producing devices, called generators, contain molybdenum-99. Technetium-99m, the short-lived product, removed from the generator as needed by using a saline solution which combines with the technetium-99m, but leaves most of molybdenum-99 in place. Molybdenum-99 has no medical application and is considered a contaminant; NRC requirements permit no more than 5 microcuries molybdenum-99 contaminant in a dose of technetium-99m.

The generator was purchased from New England Nuclear by Nuclear Pharmacy, Inc. and used to process unit doses in the San Diego, California area. Later, the generator was transferred to Scripps Hospital (a State of California licensee). (The practice of retransfers of generators for human use has since been discontinued.) After a few days of use of the generator, the licensee's nuclear medicine scanning equipment developed anomalies which made the scanning results useless (no image, but with indications of a high energy background).

After determining that the scanning equipment was not at fault, the licensee suspected molybdenum-99 breakthrough. A physicist at the San Diego Veterans Administration Hospital confirmed the presence of the contaminant. He estimated liver doses to the patients ranging from 130 rads to 260 rads. As discussed further below, it is believed that DTPA was inadvertently used, rather than the saline solution, for removing technetium-99m from the generator. Therefore, due to possible rapid clearance of the DTI from the body, the actual doses may have been less than those estimated.

Blood test results of the patients were reported to be normal, perhaps because the material may not have deposited in the vascular compartment. The whole body dose for each patient was estimated to be a few mRad. The nuclear medicine physician at the hospital reported in January 1986 that "no adverse effects have been identified in any of the four patients."

Cause:

After many milkings of the generator with normal eluants, it appears that DTPA, a chelating agent, was inadvertently used in place of the usual saline solution (the vials were almost identical). This DTPA removed a substantial amount of the molybdenum-99 from the column. After the fact tests estimate that as much as 1.0 mCi/cc of molybdenum-99 may have ended up in the doses. Secondly, although molybdenum-99 breakthrough testing was routinely performed, it appears that the nuclear medicine technician observing the dose calibrator readings had come to ignore which indicator light was lit, i.e., millicurie or microcurie and to simply record the digital readout assuming it was microcurie. There is a practical certainty that the calibrator was indicating millicuries which should have been noticed by the technologist.

Licensee Action:

Upon suggestion of Mo-99 breakthrough, the generator was taken out of service and affected patients identified. The dose calibrator which had been independently checked and calibrated only one month earlier was reapproved by the licensee's consultant. All succeeding molybdenum-99 and aluminum breakthrough safety checks were confirmed by either a second nuclear medicine technician or nuclear medicine physician.

Later, the hospital discontinued the use of generators and began using bulk technetium-99m. But tests for molybdenum-99 breakthrough were continued as a precautionary measure.

NRC Action:

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Other Agency Action:

The event was investigated during an onsite visit by the Agency. The licensee was cited under one of its license conditions for failure to perform adequate molybdenum-99 breakthrough tests on the generator eluate.

This report by the Agency was considerably delayed because the Agency's medical consultant, who was asked to evaluate the patients' doses, provided vastly different (and lower) estimates than the VA hospital physician but did not provide further information to explain the discrepancies. Having received no response from the consultant to its inquiries, the Agency has accepted the VA

hospital physician's dose estimates.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 86-19	EVENT DATE:	08/27/1984
TITLE:	THERAPEUTIC MEDICAL MISADMINISTRATION				
NAME:	University of Cincinnati Medical Center	CITY:	Cincinnati	STATE:	OH

Nature and Probable Consequences:

On September 4, 1984, NRC Region III was notified by the University of Cincinnati Medical Center, Cincinnati, Ohio, that an iodine-125 radiation source, which had been implanted in a patient, had leaked, causing an unintended radiation exposure of 2,087 rads to the patient's thyroid. The leaking radioactive source was one of eight implanted in a patient August 27, 1984, for treatment of a brain tumor. The eight sources were removed on September 1, 1984.

The event has not been previously reported as an abnormal occurrence because at the time of the incident it was not classified as a medical misadministration as defined in 10 CFR 35.41-35.45. However, a recent reevaluation of the event by the NRC Staff concluded that the event should have properly been classified as a medical misadministration, and reportable as an abnormal occurrence, because the treatment was intended to irradiate only the patient's brain tumor, but because of the leaking source, a radiation source, irradiated the thyroid. (In the body, iodine is deposited in the thyroid, and therefore, the radiation from the leaking iodine source would be concentrated there.)

On August 27, a total of eight seeds were placed in thin plastic catheter tubes and were temporarily implanted in the brain of a terminally ill patient. The next day, iodine-125 contamination was detected in the brachytherapy source storage room (BSR). Bioassay results showed that the technicians who had worked with the iodine-125 seeds had measurable uptakes of iodine. When the seeds were removed from the patient on September 1, a radiation survey of the patient's neck revealed a radiation level of 1 millirem per hour at two inches from the thyroid, which confirmed the seeds were leaking inside the patient. The patient was discharged from the hospital with instructions to return for further bioassay analyses.

Subsequent bioassay testing of the patient's thyroid determined that there had been a deposition of 557 microcuries of the iodine-125 in the thyroid. This level of deposition would result in a radiation dose to the thyroid of 2,087 rad. (A rad is a standard measure of absorbed dose.) Such an exposure would be expected to compensate for the reduced thyroid function.

The licensee found that the patient's friend and about 60 hospital personnel had received thyroid uptakes of 0.04 to 209 nanocuries. The NRC's maximum permissible thyroid burden for iodine-125 is 720 nanocuries. The 209 nanocuries was received by one of the technicians involved in preparing the iodine-125 seeds, and would result in a thyroid dose of about 0.8 rad. This dose would not be expected to result in any clinically detectable effects. The doses received by the other people were all considerably less than that received by this technician. Follow-up 24 hour urine bioassay testing of the two technicians involved in preparing the iodine-125 seeds showed a thyroid deposition of 29 nanocuries for one and no detectable activity for the other. The results of thyroid function testing of both individuals were normal.

The hospital personnel who received iodine uptakes included those who had handled or were in close vicinity of the leaking source, those involved in the control and cleanup of the contamination of the BSR, and those who frequented the areas outside of the BSR. In regard to the latter, the licensee found that a positive differential pressure between the BSR and the area outside it had existed for several days following the discovery of contamination in the BSR. This positive pressure contributed to the airborne migration of the iodine-125 into adjacent areas. (The licensee later changed the room to be under negative pressure.)

The licensee's investigation of the contamination incident determined that one of the iodine-125 seeds had been cut, apparently when it was being removed from a catheter tube from a previous patient implanted on August 13-17, 1984. Two technicians were involved in removing the seeds, and reported that after the tubes were removed from the previous patient, they were discolored and the seeds were difficult to see. One technician stated that he believed the damage most likely occurred when the ends of the catheter tubes were cut off with scissors.

The use of high activity iodine-125 seeds as removable brachytherapy sources was a new procedure at the University of Cincinnati. Previous uses (treatment protocols) involved the use of low activity iodine-125 seeds (0.1-1 millicurie) as permanent brachytherapy implants.

Although the contamination of the BSR was extensive, wipe surveys and air samples revealed that the contamination was essentially limited to the BSR. The room was decontaminated and then painted to fix any remaining contamination in place. Subsequent air samples in the room and in adjoining areas showed no detectable radioactivity. Some equipment (i.e., a sink, shelving, and storage safe) were found to have some residual contamination; they were covered in plastic to allow for radioactive decay prior to use.

Cause:

The cause of the misadministration was found to be an inadequate procedure used in removing the iodine-125 seeds from the catheter tubes for reuse. Further, there were inadequate radiation surveys performed in the work area where the source preparation was performed. Had adequate surveys been performed, the leaking seed might have been discovered prior to its being implanted in the patient.

Licensee Action:

The licensee's Radioisotope Committee recommended that the use of the high activity iodine-125 seeds be discontinued for this type of radiation therapy, pending a thorough review of the health physics aspect of their use. The hospital also constructed a new radiation source storage room with a greater distance between the storage area and the source preparation area. A fume hood also installed in the room.

NRC Action:

Region III conducted a special inspection at the hospital on October 10-12, 1984, to evaluate the circumstances of the source leakage and patient use. A Notice of Violation was issued for two violations, i.e., opening a sealed source and failure to make an adequate survey for the source storage area following the preparation of the iodine-125 seeds for patient use (Ref. 16).

Follow-up inspections have been conducted to determine the adequacy of the licensee's corrective actions.

On September 30, 1986, the NRC issued Inspection and Enforcement Information Notice No. 86-84 (Ref. 17) to all NRC medical institution licensees to inform them of this event.

The NRC's Office of Nuclear Material Safety and Safeguards, and the NRC's Region Office, are evaluating what additional measures should be taken by the manufacturer and medical licensees to improve handling procedures for iodine seeds.

The NRC Office for Analysis and Evaluation of Operational Data undertook a review of the incident to determine if there was a generic problem associated with the reuse of high activity iodine-125 seeds in brachytherapy implant protocols, and to assess associated health and safety problems. The findings, and recommendations for action by various NRC offices, were issued in AEOD/C601 during August 1986 (Ref. 18).

This incident is considered closed for the purposes of this report.

Other Agency Action:**Criteria:**

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	AS 86-07	EVENT DATE:	09/05/1986
TITLE:	THERAPEUTIC MEDICAL MISADMINISTRATION				
NAME:	University of Iowa Hospitals and Clinics	CITY:	Iowa City	STATE:	IA

Nature and Probable Consequences:

On September 5, 1986, the Iowa Radiological Health Section, Bureau of Environmental Health (State Agency), was notified of a therapeutic medical misadministration received by a patient at the University of Iowa Hospitals and Clinics, Iowa City, Iowa.

An elderly male patient, dying of lung cancer, who had gone through chemo and external radiation therapy, was experiencing difficulty breathing because the tumor growth was preventing air flow through the bronchial tubes. A decision had to be made to either perform surgery or do further radiation treatment to relieve the patient's labored breathing. Because of the patient's condition the decision was to do further radiation therapy in an effort to shrink the size of the bronchial tumor. A plastic tube (not including radioactive sources) was inserted by a pulmonary physician through the nose and down into the bronchus tube. The plastic tube was of specific length and was placed at an exact tumor location in the bronchus tube. After the tube was in place, a radiation oncologist after-loaded 34 millicuries of iridium(Ir)-192 sealed seeds.

The above mentioned procedure has a normal treatment time of 12-18 hours. The misadministration occurred three to four hours before the treatment was to terminate. At approximately 4 p.m. the radiation oncologist checked the patient and the source was properly positioned. He rechecked the patient at 5:40 p.m. and found the plastic tube and source lying on the patient's chest. Immediately upon noticing this, the doctor used tongs to place the plastic tube and Ir-192 source into the transport pig which had been left in the patient's room. The Radiation Oncology Dosimetrist was advised of the incident. He calculated that the patient received 1500 R to the chest in an area 3.4 cm long and 2 mm wide. The Radiation Protection Office (RPO) of the University was also notified. Personnel from the RPO conducted a radiation survey with the Ir-192 source as a standard. Using data collected, it was determined that the people coming into the patient's room, when the source was out of the patient, would not have received more than 80 mr. All individuals entering the patient's room during the treatment period were equipped with personnel monitoring devices. The devices were returned to the supplier for interpretation. Results were minimal for all.

Cause:

A patient undergoing the above mentioned procedure is kept under sedation. Based on data collected, it is the opinion of the staff of the University that the source was inadvertently removed by the patient. It is theorized by the physicians that during sleep the patient hooked the loop of the plastic tube with his hand and pulled it out, and the tube containing the source came to rest on his chest. It is further surmised that the patient was unaware of his actions.

Licensee Action:

It is the opinion of the physician that it may be unavoidable to completely restrain the patient during the 12-18 hour treatment time because of the patient's medical condition. The action taken to minimize exposure to staff and patients undergoing this type of treatment was to establish standing orders which would require that each patient be checked on a 30-minute basis. It is recognized that this would not stop a patient from removing the source, but would minimize the amount of time that the source would be dislodged from the patient.

NRC Action:

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Other Agency Action:

No actions are planned by the State Agency.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 86-23	EVENT DATE:	09/18/1986
TITLE:	RELEASE OF AMERICIUM 241 INSIDE A WASTE STORAGE BUILDING AT WRIGHT-PATTERSON AIR FORCE BASE				
NAME:	Wright-Patterson Air Force Base	CITY:	Dayton	STATE:	OH

Nature and Probable Consequences:

On September 18 and October 6, 1986, a drum containing radioactive waste was opened to inspect its contents at Wright-Patterson Air Force Base, located near Dayton, Ohio. Opening the drum caused a significant release of americium-241 inside the waste storage building, resulting in extensive contamination of the facility; significant efforts and costs have been incurred in decontaminating the facility, as well as in the investigations being performed by the NRC and other agencies.

Background: The United States Air Force (USAF) holds a license, issued by the NRC on June 26, 1985, which grants the USAF the authority to issue Permits to Air Force locations where the NRC has regulatory jurisdiction. The management and control of this license are the responsibilities of the USAF Radioisotope Committee. The Executive Secretary of this Committee is located Brooks Air Force Base near San Antonio, Texas. Wright-Patterson Air Force Base is the holder of a USAF Radioactive Material Permit issued by the Committee on December 18, 1985, as a conversion of a previously issued NRC specific license.

Nature and Probable Consequences: In response to a request by the USAF Radioisotope Committee, the Wright-Patterson Radiation Safety Officer and another individual began an inventory on September 18, 1985 of radioactive waste drums which were in storage at the Air Base. Five drums were not labeled as to their contents. When one of the unlabeled drums was opened, the two individuals performing the inspection noticed that their alpha radiation detector had gone "off scale" (caused by a radiation level in excess of the measuring scale). The individuals immediately left the storage building and were assisted by two additional individuals in removing their protective garments. The two individuals who had opened the drum and one of the additional technicians had some minor radioactive contamination remaining on their hands, necks, and shoes. They subsequently decontaminated themselves using soap and water.

Subsequent radiation surveys revealed the presence of radioactive contamination inside the building. There were also detectable releases outside the structure, but these were below NRC release criteria for unrestricted areas. The waste storage building is located in a remote controlled-access munitions storage area.

On October 1, 1986, the Air Force Radiological Assistance Team and a private contractor (Chem-Nuclear Services) arrived at the Air Base to assist in decontamination work and repackaging the waste. Because of an unexplained high radiation level emanating from one of the drums, the drum was opened on October 6, 1986, and the contents transferred to a larger drum. The drum which was opened on October 6 was the same drum that was opened on September 18, and the reopening resulted in further release of radioactive materials inside the building. Although they were wearing anti-contamination clothing, the workers received contamination on their personal clothing, and one individual received an uptake (inhalation) of airborne americium-241, which may have exceeded the NRC limit of 3.8 nanocuries. The actual uptake is in the process of being determined, pending further testing and analysis. The preliminary evidence, however, is that the uptake is below the level at which detectable medical effects would be expected.

A technician reentered the building three days later and determined that the removable surface contaminated levels had increased to as high as 2,875,000 disintegrations per minute. This level of contamination requires cleanup to prevent personnel contamination or release to the environment. Workers in the facility would have to wear respiratory protection. For an area that is open to the public, the NRC guidelines call for removal of contamination above 20 disintegrations per minute. In addition to the surface contamination, the measurement of airborne radioactivity in the building was approximately one million times the NRC limit for a restricted area.

Actual decontamination work began October 30, 1986, and continued until November 18, 1986. At that time all radioactive waste drums had been examined and repackaged (with the exception of the drum which was the source of the americium-241 contamination). Most radioactive contamination was successfully decontaminated by the Air Force's contractor. Approximately microcuries of contamination remained in the building, awaiting a decision on further decontamination work or dismantling and disposal of the building. Access to the building remains restricted.

The drum containing the americium-241 (estimated by external measurements to be 1.6 to 2.2 curies) will be transferred to a Department of Energy facility for storage.

The cost to date (as of mid to late February 1986) for decontamination, repackaging, and disposal are approximately \$500,000. Additional costs will be incurred during final disposition of the storage building.

Subsequent investigation by the Air Force and by the NRC determined that the barrel containing the americium-241 had originally been at a former licensee's facility and had been accepted by an individual at the Air Base for disposal in the 1970s. (The circumstances of the transfer of the waste remain under investigation.) The waste barrel had apparently remained in storage since that time.

Cause:

The root cause appears to be attributed to deficient management/procedural controls. However, the event remains under investigation by the NRC Office of Investigations, and a complete understanding of all contributing causes awaits their report.

Licensee Action:

The licensee's investigation of the incident is continuing. The Radiation Safety Officer and two other individuals associated with handling of the incident have been removed from any work involving NRC licensed radioactive materials; this was documented in a Confirmatory Action Letter issued by NRC Region III on February 5, 1987 (Ref. 13).

The licensee has provided information to other Air Force bases on handling practices for opening waste drums and on the NRC reporting requirements.

In addition, the USAF will have to decide whether further decontamination attempts should be undertaken, or whether the waste storage building should be dismantled and disposed of as radioactive waste.

NRC Action:

After the NRC learned of the scope of the contamination incident, NRC inspection personnel were dispatched from Region III to review the circumstances of the incident and to monitor the licensee's decontamination activities. Personnel from Oak Ridge Associated Universities were also retained by the NRC to perform radiation surveys at the Air Base to assist the NRC in reviewing the decontamination plans and activities.

Region III issued a Confirmatory Action Letter on October 27, 1986, documenting the Air Force's agreement (a) not to enter the building without NRC authorization; (b) to provide training for fire protection personnel; (c) to maintain a fire and security watch at the site; (d) to notify the NRC promptly of any problems concerning the contaminated building such as fire, damage due to storm or detection of contamination outside the building; and (e) to provide an Incident Report to the NRC within seven days (Ref. 14).

The NRC is continuing its investigation of the circumstances surrounding the contamination incident and its handling by the Air Force, including the reporting of this incident to NRC. On February 19, 1987, the NRC issued a letter (Ref. 15) to the Air Force requiring it to submit written information on how it will assure (a) that the NRC receives complete, timely, and accurate information; (b) that appropriate individuals will be fully aware of NRC reporting requirements; and (c) that NRC-licensed activities will be conducted in compliance with NRC regulations. This information is necessary for the NRC to determine whether the license should be modified or other enforcement action taken.

Future reports will be made as appropriate.

UPDATE: from NUREG-0090, Vol. 10, No. 4, page 14. The licensee has completed the decontamination of the facility where americium-241 spills occurred on September 18, 1986, and on October 6, 1986. The major decontamination was completed in November 1986, leaving less than 500 microcuries of residual mixed contamination in the structure. Radioactive waste generated during the 1986 decontamination effort was shipped off-site to a licensed low-level radioactive waste burial site at Richland, Washington.

In September 1987 the building was dismantled and prepared for shipment to a waste disposal site at Barnwell, South Carolina. Surveys of the building site have been completed by the licensee and by an NRC contractor, Oak Ridge Associated Universities and the results are still being evaluated prior to releasing the site for unrestricted use.

During the investigation of the original contamination incident, it was learned that the individuals involved had stopped at a water faucet to wash off before going to the base radiation services office. The water faucet is located in an area which is used periodically as a camping area for Boy Scouts. Surveys by the licensee shortly after the contamination incidents and subsequent by the NRC determined that there was no detectable radioactive contamination of the faucet area or camping area.

The NRC Office of Investigation (OI) conducted an investigation of the circumstances surrounding the contamination incident and the subsequent handling of the event by the licensee.

The investigation determined that the americium-241 involved in the spill was informally transferred without authorization to the Air Force in the 1970s by John C. Haynes of Newark, Ohio. Haynes was licensed by the Atomic Energy Commission to possess and use the americium-241 for research in changing the color of gemstones. (Contamination and subsequent cleanup of Haynes' laboratory was reported as abnormal occurrence 85-4 in NUREG-0090, Vol. 8, No. 1, "Report to Congress on Abnormal Occurrences: January-March 1985.")

The OI report was forwarded to the Department of Justice in October 1987 for further review and possible investigation.

There was significant interest by Ohio news media in the contamination and subsequent investigation. A hearing was held by Ohio's Senators John Glenn and Howard M. Metzenbaum on November 21, 1987, in Dayton, Ohio, to review the circumstances of the incident.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

UPDATE: from NUREG-0090, Vol. 11, No. 2, page 17. On June 17, 1988, the NRC staff proposed a \$102,500 fine against the United States Air Force for two violations associated with the spills of americium-241 on September 18 and October 6, 1986, at Wright-Patterson Air Force Base near Dayton, Ohio (Ref. B-6).

The proposed fines includes \$100,000 for the failure of the Air Force to notify the NRC of the significant spill within 24 hours. The event involved NRC-licensed materials, caused the loss of operation of a the waste storage facility, and resulted in property damage exceeding \$2,000. (Cleanup costs exceeded \$1.4 million.) An NRC investigation determined that there was a willful effort by some members of the Wright-Patterson staff to conceal the spill and the circumstances surrounding it.

The second portion of the fine, \$2,500, was for an overexposure to airborne radioactivity which was received by a member of the Wright-Patterson staff when an unmarked drum containing americium-241 was opened during cleanup efforts.

The Air Force responded to the proposed fine on July 15, 1988, protesting the violations and the proposed fine. The response is currently under review by the NRC staff.

In a related matter, on May 17, 1988, a federal Grand Jury in Dayton, Ohio, indicted the former Radiation Safety Office (RSO) at Wright-Patterson for two alleged violations of federal statutes due to charges arising out of the NRC's Office of Investigations inquiry into the americium-241 contamination incident.

The former RSO was charged with the unauthorized possession of americium-241 and with making a false statement to NRC inspectors who were investigating an allegation that americium-241 had been transferred to the base by John C. Haynes, a New Ohio jeweler, who had used the radioactive material in experiments to change the color of gemstones.

The former RSO has pleaded "not guilty" to the charges and is awaiting trial.

Future reports will be made as appropriate.

UPDATE: from NUREG-0090, Vol. 12, No. 3, page 19. On June 8, 1989, the NRC issued an order to the United States Air Force Radioisotope Committee, imposing civil monetary penalties in the amount of \$102,500 (Ref. B-2) for two violations associated with the spills of americium-241 in 1986 at Wright-Patterson Air Force Base (WPAFB) near Dayton, Ohio. The first violation, pertaining to the accuracy and timeliness of reporting the event to the NRC, was assessed a civil penalty of \$100,000. The violation was categorized as Severity Level I (out of five severity levels in which Severity Levels I and V are the most and least significant, respectively). The second violation, categorized as Severity Level III and assessed a civil penalty of \$2,500, pertained to an apparent overexposure to airborne radioactivity to a member of the WPAFB staff during cleanup activities.

The Air Force has paid the civil penalties, but has contested the \$2,500 civil penalty for the apparent overexposure. The NRC staff is reviewing information submitted by the Air Force in support of its position.

On October 21, 1988, the former Radiation Safety Officer at Wright-Patterson pleaded guilty to possession of a radioactive material (americium-241) without NRC authorization. On December 13, 1988, he received a suspended sentence of two years imprisonment and a requirement to perform 200 hours of community service. A second charge of making a false statement to the NRC was dismissed.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 11 "For All Licensees") of this report notes that serious deficiency in management/ procedural controls in major area can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 86-24	EVENT DATE:	10/06/1986
TITLE:	THERAPEUTIC MEDICAL MISADMINISTRATION				
NAME:	Cleveland Clinic Foundation	CITY:	Cleveland	STATE:	OH

Nature and Probable Consequences:

On October 6-8, 1986, a patient at the Cleveland Clinic Foundation, Cleveland, Ohio, received a series of cobalt-60 therapeutic radiation exposures which resulted in a radiation exposure that was about 67 percent greater than the prescribed dosage.

A 58-year old female patient received two radiation treatments a day for three consecutive days, October 6-8, 1986, for treatment of bone marrow disease. Because of an error in calculating treatment time, these treatments resulted in the patient receiving a radiation dose of approximately 2,000 rads head-to-waist, as opposed to the intended 1,200 rads.

The patient was discharged from the hospital on October 10, 1986, but was readmitted on October 20, 1986 for symptoms believed to result from the radiation exposure (unable to swallow, fever, and chills). She was discharged after treatment, but later admitted to Cleveland Metropolitan Hospital Burn Clinic on November 10, 1986, with skin burns. The patient died on November 18, 1986.

The licensee did not discover the therapeutic treatment error until November 11, 1986, when a dosimetrist reviewed the patient's treatment records and checked the calculations. NRC regulations stipulate that such misadministrations be reported to the NRC within 24 hours after they are discovered; however, the licensee did not report it to the NRC until November 17, 1986. The delay was apparently due to the licensee's failure to realize that a misadministration of this type requires immediate notification.

A panel of NRC medical consultants reviewed the case and concluded that the radiation treatments had "minimal effect, if any, upon the fatal outcome of her disease." The skin burns were not attributable to the radiation treatment, but rather to a variety of drugs (i.e., chemotherapy) given to the patient prior to and in addition to her radiation treatments.

Cause:

The misadministration was caused by an error in the calculations performed to determine the exposure time to deliver the desired radiation dosage. The physicist who performed the calculations used the distance from the cobalt-60 radiation source to the patient, instead of the distance from the exterior of the radiation therapy device to the patient. The physicist entered the measurement into a programmable calculator that already accounted for the internal distance from the radiation source to the exterior of the device. Therefore, the internal distance was added twice with the result that a longer treatment time was scheduled. (The further the source is from the patient, the longer the treatment time required.)

In 1982, Cleveland Clinic adopted new procedures as a result of a therapeutic misadministration at that time. These new procedures included a system of dual verification of all dose calculations prior to the first day of treatment. In this case, however, the procedure was not followed and there was no recheck of the physicist's calculations prior to treatment.

Licensee Action:

The licensee has adopted revisions to its procedures providing that all dose calculations will be independently performed by two qualified individuals and that, prior to the first treatment, the technologist will verify that the duplicate calculations have been performed. In addition, the treatment data will be reviewed weekly by the chief technologist. A quality assurance audit by the licensee's Radioisotope Committee is to be performed quarterly for a year and then annually thereafter.

NRC Action:

On November 20, 1986, NRC Region III issued a Confirmatory Action Letter documenting the licensee's agreement to institute the improvements in its procedures listed above (Ref. 16).

A special NRC inspection was conducted beginning November 20, 1986 (Ref. 17). The inspection identified two violations of NRC requirements, i.e., failure to report the therapeutic misadministration within 24 hours and failure to obtain approval of the licensee's Radioisotope Committee for physicians to use NRC licensed materials. (This second violation is not directly related to the misadministration.) On April 15, 1987, the NRC issued a proposed civil penalty of \$2,500 which the licensee subsequently paid.

The NRC retained a special medical panel to review the case, consisting of two physicians and a physicist. As previously mentioned, the panel concluded that the patient's deteriorating condition, ending in her death, was not the result of the misadministration.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 86-25	EVENT DATE:	10/10/1986
TITLE:	SUSPENSION OF LICENSE FOR SERVICING TELETHERAPY AND RADIOGRAPHY UNITS				
NAME:	Advanced Medical Systems, Inc.	CITY:	Geneva	STATE:	OH

Nature and Probable Consequences:

On October 10, 1986, the NRC Office of Inspection and Enforcement issued an order suspending certain NRC licensed service activities of Advanced Medical Systems, Inc., of Geneva, Ohio (Ref. 18). This action was taken after the NRC determined that the firm had been using untrained and unqualified employees to service cobalt-60 teletherapy units.

Advanced Medical Systems (AMS) is licensed by the NRC to install, service, maintain, and dismantle radiography and teletherapy units. (A teletherapy machine contains cobalt-60 and is used in medical facilities for the radiation treatment of cancer. A radiography unit contains cesium-137 or cobalt-60 and is used to make x-ray like pictures of metal products and welds.) AMS is also licensed to possess cobalt-60 and cesium-137 for manufacturing the sealed sources used in the teletherapy and radiography units. This source manufacturing, which is performed at a separate AMS facility in Cleveland, Ohio, was not affected by the NRC Order.

By a special safety inspection conducted on September 17 through November 12, 1986 at AMS (Ref. 19), the NRC confirmed allegations that since the Spring of 1985, and as recently as September 1986, licensee employees were directed to perform certain service and maintenance activities on teletherapy equipment at medical facilities even though these individuals lacked (1) NRC authorization, (2) the required training to perform the directed maintenance, and (3) the appropriate radiation detection and monitoring equipment or the required service manuals.

Only those AMS technicians who are specifically named on the NRC license, or who were approved by the AMS Safety Committee may service safety-related components on a teletherapy unit. Prior to either NRC or AMS Safety Committee approval, the technician must have had 40 hours of classroom and 40 hours of laboratory training; approximately six months of on-the-job training or prior related employment; and satisfactorily completed a written examination.

The potential safety consequences of work performed by an unqualified or unauthorized technician is that a faulty repaired or serviced teletherapy unit could expose the AMS repairman, a medical patient, or a hospital technician to excessive radiation.

Through the course of its inspection efforts, NRC Region III determined that unqualified AMS repairmen had serviced teletherapy units at seven medical institutions in the midwestern and eastern United States. An Order was sent to each institution by the NRC's Office of Investigation and Enforcement requiring the institution to perform full calibration measurements on its teletherapy units prior to the treatment of patients, unless "those calibration requirements have been satisfactorily completed subsequent to maintenance or service by AMS representatives." In addition, each institution was required to have its teletherapy unit(s) fully inspected and serviced within 90 days of the Order by technicians other than AMS; until the full inspection and servicing were completed, each licensee was to perform periodic spot-checks of its teletherapy unit(s) every seven days.

The NRC's inspection of AMS also disclosed that the firm has been installing a defective teletherapy unit timer. Operational malfunction of the timer could result in radiation misadministrations to patients and possible excessive radiation exposures to teletherapy unit operators.

Cause:

The cause of this event was the apparent disregard of NRC's regulations and requirements by the licensee.

Licensee Action:

The NRC's October 10, 1986, Suspension Order required AMS to make available to the NRC all employee training records on the servicing of teletherapy units, all leak test records of sealed cobalt-60 sources, and all invoice and service reports of teletherapy maintenance and service work.

AMS was given 20 days from the date of the Order to show-cause why the Order should not have been issued.

On December 23, 1986, the licensee met with NRC Region III officials in Glen Ellyn, Illinois, seeking a rescission of the October 10, 1986 Order. On January 7, 1987, the NRC denied the licensee's request, in part because the licensee failed to "provide reasonable assurance of the protection of the public health and safety..."

In a letter dated January 23, 1987, the licensee agreed to perform all work on teletherapy units with only licensed, qualified technicians. AMS also agreed to conduct more frequent field inspections of their employees' work, including conducting a field audit of an individual's first job, followed by quarterly audits for the next six months, and semiannual audits thereafter. AMS also committed to bringing in an outside consultant semiannually to independently audit their service and repair program.

NRC Action:

On October 29, 1986, the NRC issued Inspection and Enforcement Bulletin No. 86-04 to all NRC licensees authorized to use cobalt-60 teletherapy units (Ref. 20). The Bulletin directed licensees to instruct their technicians on how to recognize defective timers and the mitigating actions to be taken if a malfunction occurs. It also required the licensee to notify the NRC of the presence of any defective timer and the corrective actions taken.

On February 2, 1987, the Regional Administrator of NRC Region III relaxed the October 10, 1986 Order, following a review of the licensee's stated corrective actions. In addition to the licensee's commitments described above, Region III required AMS to (1) notify a Regional Branch Chief within 24 hours of a teletherapy unit service request, (2) provide a description of the work to be done, (3) name the individual assigned to perform the work, and (4) notify the NRC of the date the work is to be performed.

The licensee has asked for a hearing on the Suspension Order. A hearing date before an NRC Administrative Law Judge has not yet been scheduled.

On April 8, 1987, the NRC issued Inspection and Enforcement Information Notice No. 87-18, to caution applicable licensees (Ref. 21).

Future reports will be made as appropriate.

UPDATE: from NUREG-0090, Vol. 10, No. 2, page 28. The previous report mentioned that the NRC issued an order to the licensee on October 10, 1986 (Ref. B-8), suspending certain NRC-licensed service activities. The licensee had been using untrained and unqualified employees to service cobalt-60 teletherapy units. On February 2, 1987, the NRC relaxed the order based (1) on the licensee's stated corrective actions, and (2) some additional requirements imposed by the NRC. The circumstances associated with this event remains under investigation.

Meanwhile, a separate issue pertaining to the licensee's teletherapy source fabrication facility (located at 1020 London Road in Cleveland, Ohio) has resulted in the NRC issuing to the licensee on July 23, 1987 a Order Modifying License, Effective Immediately, and a Demand for Information (Ref. B-9). The issue involves excessive radioactive contamination and radiation levels at the licensee's London Road facility, which results in a significant potential for unnecessary radiation exposures for workers at facility.

Since the first quarter of 1986, the NRC has made repeated efforts (including license amendments) to get the licensee to take steps to initiate meaningful decontamination efforts at the facility and modify the facility to minimize contamination. AMS has failed to take such steps and has indicated that it will not begin such steps until March 1988 at the earliest, citing lack of available profit from its business due to the NRC suspension of its service license from October 10, 1986 to February 2, 1987. Meanwhile, corrective efforts have been minimal and contamination and radiation levels remain excessive and are increasing.

Therefore, the July 23, 1987 NRC Order Modifying License, Effective Immediately, requires the licensee to commence decontamination of the London Road facility by August 31, 1987, and to commence the required redesign, reconstruction, and upgrading of the facility, also by August 31, 1987. The Demand for Information requires AMS to submit certain financial information in order for the NRC to determine whether it can have reasonable assurance that in the future the licensee will conduct its activities in accordance with the Commission's requirements and expeditiously conduct required decontamination, redesign, reconstruction, and upgrading of its facilities and programs.

Under the terms of the Order, the licensee or any other person who has an interest adversely affected by this Order may, within 30 days of the date of receipt of the Order, file a written answer under oath or affirmation and may also request a hearing.

Further reports will be made as appropriate.

UPDATE: This abnormal occurrence (AO) was originally reported in NUREG-0090, Vol. 9, No. 4, "Report to Congress on Abnormal Occurrences," October-December 1986, under the title "Suspension of License for Servicing Teletherapy and Radiological Units." At that time it was reported that on October 10, 1986, the NRC Office of Inspection and Enforcement issued an order suspending certain NRC-licensed service activities of Advanced Medical Systems, Inc., of Geneva, Ohio. This action was taken after NRC determined that the firm had been using untrained and unqualified employees to service cobalt-60 teletherapy units. The event was reported as an AO because: (1) it involved a moderate or more severe impact on public health or safety; and (2) involved a serious deficiency in management or procedural controls.

The AO report is updated and closed out as follows:

On October 10, 1986, the NRC staff issued an Order Suspending License (Order) immediately suspending certain NRC-licensed service activities of Advanced Medical Systems, Inc., of Geneva, Ohio. This action was taken after the NRC staff determined that the licensee's employees had been performing service and maintenance on radiation therapy equipment at various medical facilities, even though (1) the employees lacked required training; (2) did not have radiation detection and monitoring equipment; (3) the required service manuals; and (3) had objected to performing maintenance without proper training.

Advanced Medical Systems filed a request for a Hearing on the Order. The Hearing was delayed at the request of the U.S. Department of Justice (DOJ) pending evaluation of potential criminal prosecution of the company. In the interim, the company took actions to resolve the issues which led to the Order. The Order was revoked by the NRC staff in 1987. The Hearing proceeding

however, continued.

The DOJ determined not to undertake prosecution in the case, and the Stay on the Hearing proceedings was lifted in 1988. In 1990, the Atomic Safety and Licensing Board (ASLAB) issued a summary disposition decision in the case, affirming the issuance of the Order.

The company appealed that decision. The Appeal was considered initially by the ASLAB and, subsequently, by the Commission. On June 9, 1994, the Commission denied the company's Appeal, determining that the NRC staff had acted reasonably and had substantial basis to issue an Order effective immediately.

This item is considered closed for the purpose of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving moderate or more severe impact on public health or safety can be considered an abnormal occurrence. In addition, Example 11, "For All Licensees" in Appendix A notes that serious deficiency in management or procedural controls in major areas can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 86-26 EVENT DATE: 10/21/1986
TITLE: DIAGNOSTIC MEDICAL MISADMINISTRATION
NAME: St. Luke's Hospital CITY: Racine STATE: WI

Nature and Probable Consequences:

On October 21, 1986, a patient at St. Luke's Hospital, Racine, Wisconsin, received a whole body iodine-131 diagnostic scan when the intended procedure was to be a thyroid scan.

The patient received a diagnostic thyroid scan using iodine-123, an accelerator-produced radioisotope (accelerator-produced radioisotopes are not subject to NRC regulation, but are under State jurisdiction). The attending physician then gave oral instructions for an iodine-131 scan because the previous scan was not definitive. The nuclear medicine technologist erroneously arranged for a whole body scan instead of a thyroid scan as intended by the physician. The whole body scan involved 1.53 millicuries of iodine-131, which is approximately 30 times the normal 50 microcuries dosage for a thyroid scan.

After the scan was performed on October 21, 1986, the attending physician discovered the error. The whole body scan, however, did provide the physician with the diagnostic information desired.

The radiation exposure, while in excess of that intended, did not result in any immediate medical effects, according to the licensee. Had a typical dosage of iodine-131 for a therapeutic procedure been administered (i.e., 4 to 6 millicuries), rather than the 1.53 millicuries actually administered, a significant reduction in thyroid activity could have resulted. Thyroid damage, however, can be compensated for through the use of medication.

Cause:

The misadministration was caused by the nuclear medicine technologist's misinterpreting the attending physician's oral instructions. The physician requested an "iodine-131 scan," which the technologist incorrectly assumed to be a whole body scan. Typically, the licensee uses iodine-123 for thyroid scans and iodine-131 for either thyroid scans or whole body scans.

Licensee Action:

The licensee has revised its procedures for prescribing radioiodine for medical procedures and provided training on the revised procedures. All prescriptions are now to be in written form and will be reviewed by a nuclear medicine physician and verified by the technologist prior to administration of the radiopharmaceutical to the patient.

NRC Action:

The NRC conducted a special inspection on December 15, 1986, to review the circumstances of the misadministration (Ref. 22). The inspection did not identify any violations of NRC requirements, but determined that improvements were needed in the patient prescription process to preclude similar misadministrations in the future.

NRC Region III issued a Confirmatory Action Letter on January 9, 1987 (Ref. 23), documenting the licensee's agreement to change its procedures. The changes will be incorporated into the facility's NRC license.

The NRC also retained a medical consultant to evaluate the misadministration and its possible medical effects. The consultant's report is pending.

On April 15, 1987, the NRC issued Information Notice No. 85-61, Supplement 1 ("Misadministrations to Patients Undergoing Thyroid Scans") to licensees which described various misadministrations and corrective actions taken by some licensees which have been found to be effective to prevent such misadministrations (Ref. 24). Information Notice No. 85-61, previously issued on July 22, 1985, discussed several other similar misadministrations (Ref. 25).

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 86-27	EVENT DATE:	11/18/1996
TITLE:	DIAGNOSTIC MEDICAL MISADMINISTRATION				
NAME:	Toledo Hospital	CITY:	Toledo	STATE:	OH

Nature and Probable Consequences:

On November 18, 1986, a patient at Toledo Hospital, Toledo, Ohio, received a misadministration of a radiopharmaceutical when wrong radioactive material was administered. It is estimated that the patient's thyroid received a dose of about 6,760 rads.

The physician of a 62-year old female patient planned a bone scan for the patient as an outpatient at the Diagnostic Center at Toledo Hospital. The bone scan normally involves a 20 millicurie dose of technetium-99m MDP. The hospital's procedures provide that the referring physician's office notify the Diagnostic Center by telephone of the scheduled procedure. The procedure is then scheduled, and the hospital's Nuclear Medicine Department is notified to order the radiopharmaceutical.

In this instance, the physician's office notified the Diagnostic Center, but kept no record of the telephone conversation. The intended procedure was a bone scan, but the Center's receptionist recorded a "total body scan, rule out metastases, carcinoma." This was interpreted by the Nuclear Medicine Department as an order for a thyroid metastatic disease scan, which is also known as a "total body scan." Toledo Hospital normally uses a 20 millicurie dose of iodine-131 for such procedure, which is usually performed on patients who have had their thyroid removed. (The organ principally affected by an iodine dose is the thyroid.) The Nuclear Medicine Department confirmed with the Center's receptionist that the thyroid metastatic disease scan was the prescribed procedure. The receptionist, however, did not verify the procedure with the referring physician's office.

On November 18, 1986, the patient was administered the iodine-131. She returned to the Diagnostic Center the following day and said she was scheduled for a bone scan. Since the Center had no bone scan scheduled, the error was consequently discovered.

The patient had previously been diagnosed as having mild hypothyroidism (under-active thyroid) and was taking medication to make up for the decreased thyroid function. The iodine-131 dosage was estimated to cause a 6,760 rad dose to the thyroid, while other organs received a relatively small dose. (A rad is a standard measure of absorbed dose.) This dose to the thyroid is less than would normally be expected for 20 millicuries of iodine-131, because of the patient's reduced thyroid function. If the patient had a normally functioning thyroid, the expected dose would have been three to seven times what this patient is estimated to have actually received.

Nevertheless, the 6,760 rad thyroid dose is expected to significantly decrease the patient's thyroid function, necessitating an increase in the medication (thyroxin) the patient was already receiving. The prescribed thyroxin dosage was increased to three times the original prescribed dose. Both the hospital and the patient's physician plan to continue to monitor the patient.

Cause:

The apparent cause of the misadministration was failure to accurately communicate the prescribed procedure to the hospital's Diagnostic Center. The precise method of failure could not be determined since the patient's physician did not have a record of telephone conversation in which the procedure was scheduled.

Licensee Action:

The hospital has instituted a change in its procedures for scheduling outpatient diagnostic doses. All prescriptions for nuclear medicine procedures are to be in written form and reviewed by a nuclear medicine physician and verified by a technologist prior to the administration of the radiopharmaceutical to the patient.

NRC Action:

NRC Region III conducted a special inspection at Toledo Hospital on November 25, 1986, to review the circumstances of the misadministration (Ref. 26). No violations of NRC requirements were found during the inspection. NRC Region III issued a Confirmatory Action Letter to the hospital on November 21, 1986, documenting the hospital's agreement to change its procedure for scheduling procedures involving radiopharmaceuticals (Ref. 27). The NRC also retained a medical consultant to review the possible health effects of the misadministration.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 86-28	EVENT DATE:	12/30/1986
TITLE:	IMMEDIATELY EFFECTIVE ORDER MODIFYING LICENSE AND ORDER TO SHOW CAUSE ISSUED TO AN INDUSTRIAL RADIOGRAPHY COMPANY				
NAME:	Met-Chem Testing Laboratories of Utah, Inc.	CITY:	Salt Lake City	STATE:	UT

Nature and Probable Consequences:

On December 30, 1986, the NRC issued an Order to Met-Chem Testing Laboratories of Utah, Inc. that in effect prohibits the company from involving a senior management employee in the performance or supervision of any NRC licensed activities (Ref.

Background: The licensee is the holder of both a general license pursuant to 10 CFR 150.20 and a specific license (License No. 43-26821-01) pursuant to 10 CFR Part 30, issued by the NRC. The general license authorizes the licensee to conduct the same activity in non-Agreement States pursuant to the provisions of 10 CFR 150.20 as the licensee is authorized to conduct by its specific license from the State of Utah, an Agreement State. The NRC specific license authorizes the licensee to use the license materials in performing industrial radiography and replacing sources, and to use an EON Model 64-764 calibrator (which contain radioactive source) for calibration of survey instruments at locations where NRC maintains jurisdiction. The NRC license for industrial radiography was issued in July 1986.

Nature and Probable Consequences: The NRC Order was issued to remove the senior vice president from any assignment or position influencing or involving the performance or supervision of any licensed activities. This action was taken following an NRC investigation initiated in 1985 as a result of inspector observations made during a routine inspection. The NRC decided to issue the Order after an NRC inspector obtained a sworn statement on August 21, 1986, from the senior vice president in which he admitted that while employed as the office manager for the predecessor radiography company (Met-Chem Engineering Laboratories, Inc.) he had typed a letter and forged on it the signature of a radiographer for the purposes of explaining away an overexposure indicated on the radiographer's film badge.

The overexposure, while not clinically significant, was reportable according to NRC regulations. The letter falsely stated that the radiographer's dosimeter and film badge were left in a shirt pocket and the shirt was placed in an area near a radiation source resulting in an overexposure reading, but not an overexposure to the radiographer himself.

Had the NRC been provided with correct information, inspection actions regarding the overexposure would have been taken against Met-Chem Engineering Laboratory, Inc., the now defunct former company. Further, had the NRC known that a senior management employee of the licensee had withheld reportable information concerning radiation exposures, the specific license for the present company would not have been issued. The false statements made by the senior vice president call into question his candor in dealing with the NRC, and demonstrate that there was no longer reasonable assurance that the licensee would comply with NRC requirements while the individual was involved in licensed activities.

Cause:

The employee willfully made false statements to, and withheld information from, the NRC. On August 13, 1986, the employee denied to an NRC inspector and an NRC investigator any knowledge of how the forged letter was generated. However, on August 21, 1986, he admitted that he had indeed generated, and signed, the letter.

The employee has stated that the reasons he wrote the forged letter were (1) he did not want anything to stop the sale of certain Met-Chem Engineering Laboratory, Inc. properties to a third party, and (2) he did not want the NRC to know about the overexposure because he believed it would not have been desirable to have the NRC looking into the matter during the sale negotiation period.

Licensee Action:

The licensee responded to the NRC Order on January 15, 1987. The licensee stated that the employee terminated employment with Met-Chem Testing Laboratories during November 1986, to accept employment with a company which neither has a radioactive materials license nor handles any radioactive materials.

The licensee held meetings with all authorized users of radioactive materials to restate the instructions they are given during training, which includes total compliance to NRC requirements and to be honest and cooperate totally with NRC personnel. On January 5, 1986, the authorized users of radioactive materials signed a statement that they have read and understand the December 31, 1986 NRC Order.

NRC Action:

The NRC Order contained the following provisions, effective immediately:

- (1) License No. 43-26821-01 is amended by adding the following condition:

The employee shall be removed from any assignment or position influencing or involving the performance or supervision of any licensed activities (e.g., as an authorized user), including the super-

vision of any Radiation Safety Officer (RSO).

(2) The licensee shall show cause in the manner hereinafter provided why the license amendment set out in paragraph (1) above should not become permanent.

(3) The employee shall be removed from an assignment or position influencing or involving the performance or supervision of a licensed activities permitted under the general license issued pursuant to 10 CFR K150.20.

(4) The licensee shall show cause in the manner hereinafter provided why the provisions in paragraph (3) above should not become permanent.

(5) Prior to conducting any licensed activities after receipt of this Order, the licensee shall (a) notify in writing all personnel involved in the performance and supervision of licensed activities at Met-Chem Testing Laboratories of Utah, Inc. of this Order and the importance of strict adherence to NRC requirements and complete candor with NRC personnel, and (b) certify to the NRC that each Authorized User and RSO has read the notification and Order and understands its contents.

(6) The NRC Region IV Regional Administrator may relax or rescind any of the above provisions for good cause shown by the licensee.

The NRC is evaluating the licensee's response to the Order, to determine whether it is satisfactory, and/or whether further enforcement action is required.

Future reports will be made as appropriate.

This abnormal occurrence was originally reported in NUREG-0090, Vol. 9, No. 4, "Report to Congress on Abnormal Occurrence October- December 1986." The Order involved an employee of Met-Chem Testing Laboratories of Utah, Inc. of Salt Lake City, who had also been employed by the predecessor company Met-Chem Engineering Laboratories, Inc. (The predecessor company's assets were purchased by Met-Chem Testing Laboratories of Utah, Inc., on September 10, 1984, and a new license was issued July 31, 1986.) The abnormal occurrence is updated, and closed out, as follows:

An investigation by the NRC Office of Investigations (OI) was initiated to determine whether the employee, while employed by the predecessor company, deliberately forged a letter to cover up a radiation exposure of a radiographer. The results of this investigation demonstrated that the employee knowingly and willfully wrote a fictitious letter to suppress and/or conceal information about the overexposure.

This area was referred to the U.S. Department of Justice for potential prosecution. The U.S. District Court for the District of Utah sentenced the individual for violation of 18 USC 1018, "making a false statement," on May 25, 1989.

By request of the licensee, on May 28, 1987, the NRC retired License No. 43-19662-01, which had expired on March 31, 1987.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the third general subcriterion) of this report notes that major deficiencies in management controls for licensed facilities or material can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 87-02 EVENT DATE: 11/21/1986

TITLE: DIAGNOSTIC MEDICAL MISADMINISTRATION

NAME: Allegheny Valley Hospital CITY: Natrona Heights STATE: PA

Nature and Probable Consequences:

In a January 6, 1987 letter, Allegheny Valley Hospital, Natrona Heights, Pennsylvania, notified NRC Region I that on November 1986, a patient received an intravenous dose of 100 millicuries of technetium-99m rather than the prescribed does of 20 millicur

On November 21, 1986, a technologist prepared a 20 millicurie syringe of technetium-99m to be used for a brain scan. The syri was properly labeled. The technologist, while waiting for the brain scan patient to arrive, prepared a syringe of 100 millicuries of technetium-99m to be used in preparing multiple doses of another radiopharmaceutical.

As she completed preparation of the 100 millicurie syringe, the telephone rang and she put down the 100 millicurie syringe. Whi the technologist was on the telephone, the brain scan patient arrived. As soon as the telephone call was finished, the technician mistakenly grabbed the syringe containing 100 millicuries and injected the patient. As a result, the patient received five times th prescribed dose of the radiopharmaceutical.

Estimated doses to various organs of the patient are: stomach wall, 25 rads; thyroid, 13 rads; intestinal wall, 6-7 rads; and blad wall, 5 rads. These doses are about five times those which would have been expected had the prescribed doses been administered. The Nuclear Medicine physician examined the patient and decided that there was no adverse effect on the patier and that no action regarding patient care was needed.

Cause:

The cause was due to human error by the technologist.

Licensee Action:

The licensee concludes that a cause of the misadministration was that the technologist was rushed and doing too many duties a once. As a result, the licensee states that it is committed to reorganizing the scheduling responsibilities for nuclear medicine personnel. However, the corrective actions described are not sufficiently specific and have not yet been implemented.

NRC Action:

The licensee's corrective actions were reviewed by Region I during an inspection on February 4, 1987. Region I has requested the licensee describe and take more comprehensive and specific corrective actions.

Unless new, significant information becomes available, this item is considered closed for the purpose of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see th general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 87-03	EVENT DATE:	01/12/1987
TITLE:	DIAGNOSTIC MEDICAL MISADMINISTRATION				
NAME:	St. Anthony Hospital	CITY:	Oklahoma City	STATE:	OK

Nature and Probable Consequences:

On January 21, 1987, NRC Region IV was notified by St. Anthony Hospital, that on January 12, 1987, a 15 year old female was administered 400 microcuries of I-131 rather than the prescribed dose of 400 microcuries of I-123, resulting in a thyroid dose of about 1490 rads.

The patient had been scheduled for a diagnostic, thyroid update study. The diagnostic procedure called for 400 microcuries of I-123 in capsule form to be administered orally. Four capsules (100 microcuries each) had been ordered by telephone from the University of Oklahoma Regional Nuclear Pharmacy. The technologist who placed the order maintained that the proper isotope dose had been ordered, although no record of the phone order was made. When the dose was delivered on January 12, 1987, package was correctly labelled as 0.40 millicurie of I-131 capsules. However, not checking the label, and assuming the capsules were I-123, the technologist assayed the dose in the calibrator using the I-123 window. The dose calibrator purportedly assayed about 340 microcuries which, considering decay, would be expected for four capsules of I-123.

Again, without checking the label, the I-131 capsules were administered to the patient. The scan was performed the next day and the scatter observed indicated that the isotope was I-131 rather than I-123.

The licensee calculated the thyroid dose to be about 1490 rads (for a 20 gram thyroid) while the prescribed I-123 would have yielded a thyroid dose of about 21 rads. The licensee concluded that the amount of radioactivity administered was not dangerous.

Cause:

The root cause was the licensee's failure to properly check the dose label with the prescribed dose.

Licensee Action:

The licensee's corrective actions were to revise procedures to require all I-123 and I-131 doses be assayed in the dose calibrator both the K-123 and I-131 settings. If the ratios and indicated doses are not compatible, the licensee will recheck with the nuclear pharmacy as to what isotope and dosage had been sent. Additionally, if any doubt exists as to the proper isotope or dosage, the Radiation Safety Officer is to be consulted before proceeding.

NRC Action:

Upon being notified of the event, NRC Region IV requested additional information; this was received on February 17, 1987. Region IV conducted a follow-up inspection on March 27, 1987, to obtain additional information and to review proposed corrective action. NRC concluded that the root cause of this event was as described above. The licensee's corrective action was deemed appropriate.

Evaluations by two NRC medical consultants indicate that while the administered dose was well below the threshold for observing acute effects, there would be a small increased risk of reduction in thyroid function, and a small increased risk of latent thyroid cancer.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 87-04 EVENT DATE: 02/19/1987
TITLE: DIAGNOSTIC MEDICAL MISADMINISTRATION
NAME: University of Massachusetts Medical Center CITY: Worcester STATE: MA

Nature and Probable Consequences:

In a letter dated March 2, 1987, the NRC received written notification that on February 19, 1987 a patient referred to the Nuclear Medicine Department of the University of Massachusetts Medical Center received a 5 millicurie dose of iodine-131 rather than the prescribed 5.0 microcuries.

The misadministration was discovered during a routine review of the doses administered the previous day. A review of the event the licensee's Radiation Safety Officer showed no defects in the system used to order, prepare, or administer radiopharmaceutical in Nuclear Medicine. The patient's physician clearly requested a 24 hour uptake study using iodine-131. Although iodine-123 is routinely used for uptake studies, iodine-131 was prescribed for the convenience of the patient. A procedure which includes the appropriate dose range is available in the hospital's Procedure manual; however, because of a human error, the nuclear medicine technologist failed to follow the established procedure.

Based on the 24 hour uptake and the measured effective half-life, the licensee estimated that the radiation dose to the patient's thyroid was 730 rads and the total body dose was 1.7 rads. The effect on the thyroid, if any, would be of no importance because prior to the event, the patient was scheduled for a thyroidectomy to be performed in March.

The licensee has advised the NRC that no adverse effects have been noted nor are any anticipated as a result of the misadministration.

Cause:

The cause was due to human error by a nuclear medicine technologist.

Licensee Action:

The records of the preparation of each patient dose of iodine-131, diagnostic or therapeutic, will be reviewed and countersigned by the Chief Nuclear Medicine Technologist or the Clinical Director of Nuclear Medicine prior to administering the dose to the patient. The technologist involved in the event was cautioned to be more careful in the future.

NRC Action:

The incident is being reviewed by an NRC medicine consultant.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 87-05 EVENT DATE: 03/17/1987
TITLE: SIGNIFICANT BREAKDOWN IN MANAGEMENT OVERSIGHT AND CONTROL OF RADIATION SAFETY PROGRAM AT TWO OF A LICENSEE'S IRRADIATOR FACILITIES
NAME: Radiation Sterilizers, Inc. CITY: Menlo Park STATE: CA

Nature and Probable Consequences:

On March 17, 1987, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$10,000 to Radiation Sterilizers, Inc., of Menlo Park, California (Ref. 4). The proposed time represents a 100% escalation for violations found at the licensee's irradiator facilities in Schaumburg, Illinois and Westerville, Ohio. Some of the violations related to unsafe practices which could have resulted in serious overexposures of licensee personnel.

On January 14, 1987 and January 27, 1987, unannounced, routine safety inspections were performed by the NRC at the licensee's Schaumburg and Westerville facilities. The licensee uses sealed sources in pool type irradiators to sterilize medical products. At the time of the inspections, the Schaumburg facility possessed about 2.5 million curies of cobalt-60 and the Westerville irradiator was loaded with 8.4 million curies of cesium-137.

During the inspections at the two facilities, the NRC inspectors identified numerous violations of NRC requirements, including: (1) failure to test smoke and temperature alarms at required intervals; (2) failure to maintain an operable warning beacon in the maze entrance to the gamma cell; (3) failure to maintain an operable access barrier to the gamma cell, a situation which could lead to accidental personnel entry; (4) failure to maintain operable control panel water level indication and an operable system to detect and shut down the irradiator in the event of source storage pool excessive water loss; (5) failure to make a thorough visual check of the entire gamma cell before exposing the source; (6) failure to use personal identification tags for access control as required, (7) failure to maintain a seismic detector in an operable condition, and (8) failure to post an emergency telephone call list in the control room [As discussed further below, Items (3) and (7) were later deleted from the list of violations, and the civil penalty reduced accordingly.]

Two of the violations at the Schaumburg facility (i.e., failure to test the gamma cell smoke and temperature alarms and failure to maintain an operable warning beacon at the entrance to the irradiator area) were repeat violations which had been previously identified during an inspection in March 1985.

Following each of the inspections, Region III sent a Confirmatory Action Letter to the licensee confirming corrective actions which either had already been taken, or were to be taken by the licensee. The Confirmatory Action Letters were issued on January 16, 1987 and February 4, 1987, for the Schaumburg facility (Ref. 5) and Westerville facility (Ref. 6), respectively. On February 12, 1987, NRC Region III forwarded the inspection findings to the licensee (Ref. 7).

While there were no actual instances of licensee personnel receiving radiation exposures as a result of the violations found, the unsafe practices subjected the personnel to an unnecessary increased risk of such exposures.

Cause:

The causes of the violations were generally attributed to a breakdown in the management control and oversight of the radiation safety program at the two facilities. Equipment was not properly maintained and safety procedures were not consistently followed.

Licensee Action:

The licensee has repaired the affected equipment, revised its operating procedures, and retrained its personnel to assure compliance with the NRC regulations.

NRC Action:

As previously mentioned, on March 17, 1987, the NRC forwarded to the licensee a Notice of Violation and proposed Imposition of Civil Penalty in the amount of \$10,000 for the violations found (Ref. 4). The base civil penalty for the violation would be \$5,000. However, this was increased by 100 percent because of: (1) the licensee's prior knowledge of the problems, (2) the licensee's failure to take prompt and effective corrective measures for previously identified violations, and (3) the duration of some of the violations (some had existed for several months).

The licensee protested the proposed fine and disagreed with some of the inspection findings. Upon review, the NRC staff determined that two of the eight violations originally cited did not occur. These two were the failure to maintain an operable access barrier to the gamma cell (the defective door was promptly repaired when it was discovered to be inoperable) and the failure to maintain a seismic detector in an operable condition (the detector was not required in the NRC license). The fine was reduced to \$7,500 and an Order Imposing Civil Penalty was issued to the licensee on August 18, 1987.

The NRC will perform further inspections to review the adequacy of the licensee's corrective actions. (Note: On June 1, 1987, the State of Illinois assumed regulatory authority over the users by-product material in the State of Illinois, including the Radiation Sterilizer facility in Schaumburg, Illinois. Subsequent inspections of that facility will be conducted by the Illinois Department of Nuclear Safety.)

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 11 of "For All Licensees") of this report notes that a major deficiency in management or procedural controls in major ar can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 87-06	EVENT DATE:	04/01/1987
TITLE:	DIAGNOSTIC MEDICAL MISADMINISTRATION				
NAME:	Veterans Administration Medical Center	CITY:	Boise	STATE:	ID

Nature and Probable Consequences:

On April 27, 1987, NRC Region IV was notified by Veterans Administration Medical Center, Boise, Idaho, that on April 1, 1987, 4 microcuries of I-131 was administered to an adult male for a total body scan; on April 6, 1987 it was discovered that a bone scan using technetium-99m was the desired study.

On April 1, 1987, based only on telephone information without having authorization forms which would indicate the specific procedure desired by the prescribing physician, the licensee's nuclear medicine staff proceeded with the total body scan procedure using 400 microcuries of I-131. On April 6, 1987, an evaluation of the scan indicated that the radioactive isotope and dosage were inappropriate for the scan desired. The desired study was a bone scan using technetium-99m. The licensee calculated that the patient received a whole body and thyroid dose of about 0.47 and 400 rads, respectively.

The physician user evaluated the exposure and concluded that the irradiation posed a small, but still significant, risk of reduced thyroid function. The patient will be recommended by the licensee for long term follow-up by a qualified physician. The risk of eventual thyroid cancer is small but cannot be discounted.

Cause:

The cause was due to the nuclear medicine staff proceeding with a procedure on the basis of telephone information, without having authorization forms to verify the procedure desired.

Licensee Action:

The licensee's investigative committee made the following recommendations that will be implemented: the physician-user will review each case prior to the staff proceeding with the procedure; appropriate forms will be provided to the nuclear medicine staff before they start a procedure; deviations from the dosages listed in the Nuclear Medicine Procedure Manual will not occur unless authorized by the physician-user; and the physician-user will review the procedure manual and operating policies with this technical and clerical staff.

NRC Action:

Region IV conducted a follow-up inspection at the licensee's facility on May 19, 1987, to obtain additional information concerning the incident and to review proposed corrective actions. The inspector considered the corrective actions to be appropriate.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 87-07	EVENT DATE:	04/01/1987
TITLE:	SIGNIFICANT BREAKDOWN IN MANAGEMENT OVERSIGHT AND CONTROL OF RADIATION SAFETY PROGRAM AT AN INDUSTRIAL RADIOGRAPHY LICENSEE				
NAME:	Grede Foundries, Inc.	CITY:	Milwaukee	STATE:	WI

Nature and Probable Consequences:

On April 1, the NRC issued a Demand for Information and Notice of Violation and Proposed Imposition of Civil Penalties to Grede Foundries, Inc., Milwaukee, Wisconsin (Ref. 8). This action was taken after an October 1986 inspection showed a significant breakdown in the licensee's oversight and control of its radiation safety program.

The company's NRC license stipulates that only individuals who have passed an approved training program and whose name has been added to the license may work alone as a radiographer. The NRC conducted the October 1986 inspection to review the circumstances surrounding misleading statements made by Grede Foundries in letters to the NRC on June 5 and September 11, 1986. In the letters, Grede requested that its license be amended to add an additional person to the license as an authorized radiographer. The June 5 letter stated that the individual had been a radiographer at another company, had taken and passed the Magnaflux Quality Services Radiation Safety and Control Program, and had passed the licensee's Emergency Procedures Test.

The NRC learned, however, that the individual had not been listed as a radiographer at her previous place of employment, as G had stated. A deficiency letter dated August 14, 1986 was then sent to the licensee from the NRC's Region III office requesting documentation of the individual's Magnaflux training and confirmation that she had been instructed in the licensee's operating and emergency procedures and had demonstrated competence in the use of the licensee's radiographic devices. The licensee's September 11, 1986 response included a copy of a test taken by the alleged radiographer, entitled "Radiation Safety Control Program - Assistant Radiographer Examination." The word "assistant" was crossed out.

The NRC then conducted a special safety inspection on October 8, 9, 27, and 28, 1986, to review the validity of the information supplied by Grede, concluding that the Radiation Safety Officer (RSO) was not familiar with NRC requirements for the training of radiographers. The RSO believed the same test could be given to both an assistant radiographer and a radiographer. And since he was requesting a radiographer be added to the license, he lined out the word "assistant" on the test. However, examinations of assistants and radiographers are different. The NRC concluded that the licensee had submitted inaccurate information.

Further, it was determined that the unqualified/untrained radiographer made 43 radiographic exposures on August 6, 7, and 8, 1986, which was in violation of NRC requirements and contrary to the conditions of Grede's license. In addition, the individual made the exposures with the knowledge of an authorized radiographer, who in turn entered the information into a log and signed on it as though he had made the exposures himself.

The inspection findings (Ref. 9) were discussed with the licensee on October 28, 1986, and at an enforcement conference held at the Region III Office on November 20, 1986. In addressing the violations, the licensee acknowledged the facts as presented and discussed corrective actions to prevent recurrence.

On April 1, 1987, the NRC issued the previously mentioned Demand for Information and Notice of Violation and Proposed Imposition of Civil Penalties. The Demand for Information required the licensee to submit, under oath, actions to be taken or will take to prevent a recurrence of the violations. The proposed civil penalty was for \$7,500, which represented a 50% escalation because of the multiple examples of unauthorized radiographer exposures.

Cause:

The root cause was a lack of regard for and adherence to procedures, and a lack of management control and supervision over licensed activities.

Licensee Action:

On April 14, 1987, the licensee paid the civil penalty in full, and presented a corrective action program. On April 24, 1987, the licensee amended its April 14, 1987 response and provided additional information. The corrective action program implemented specifies that: no one may enter the radiographic facility unless he or she is listed on the company's NRC license; all repairs to building, and all moving of castings or other material in or out of the facility will be supervised or monitored by a licensed radiographer; the daily log will include the signatures of only those radiographers who actually performed the work; and finally, individuals performing radiographer must meet all license requirements, including formal training in Radiation Health Physics.

NRC Action:

The NRC carefully considered the licensee's response in a letter to the licensee dated May 7, 1987 (Ref. 10) stated that it was determined that no further enforcement actions need be taken at this time if the corrective actions are implemented and continued as described in the licensee's response. Region III will continue to closely monitor licensee performance.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 11 for "For All Licensees") of this report notes that a major deficiency in management or procedural controls in major areas can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 87-08	EVENT DATE:	04/10/1987
TITLE:	SIGNIFICANT BREAKDOWN OF MANAGEMENT CONTROLS FOR RADIOGRAPHIC OPERATIONS				
NAME:	A-1 Inspection Incorporated	CITY:	Evanston	STATE:	WY

Nature and Probable Consequences:

On April 10, 1987, the NRC issued an Order Temporarily Suspending Licensee (Effective Immediately) and Order to Show Cause why the license should not be revoked to A-1 Inspection, Incorporated of Evanston, Wyoming (Ref. 11). The Order was based on NRC inspections which identified two instances where the licensee permitted unauthorized individuals to conduct radiography. In one instance, the licensee stated to the NRC inspector that he had not employed such individuals to conduct radiography while he admitted to an investigator that he had. These actions indicated a disregard for requirements and lack of reasonable assurance that the licensee could be trusted in the future.

A-1 Inspection, Incorporated has been licensed to possess and use tridium-192 sources of up to 100 curies per source in industrial radiography and replacement of sources in accordance with the conditions specified therein, since May 2, 1984.

The events leading to issuance of the Order first came to light during a routine inspection in December 1984. The inspector discovered that the licensee had permitted the performance of radiography by an unauthorized individual, who, in so doing, received a whole body exposure in excess of that permitted by regulatory requirements. On February 28, 1985, Region IV issued a Notice of Violation and Proposed Imposition of Civil Penalty (Ref. 12). By letter (Ref. 13) dated March 21, 1985, the licensee responded to the Notice of Violation, in which it was admitted that an individual not specifically named on the license had been allowed to act as a radiographer, explaining that there was not enough time during his employment to add this individual to the license. The licensee also stated that it would not employ anyone in the future until approved by the NRC and added to the license. On March 26, 1985, the licensee paid the proposed civil penalty.

Subsequent to the above described enforcement action, it was alleged to NRC that the licensee had again employed unauthorized personnel to conduct radiographic operations at the Shute Creek Job Site. On February 27, 1986, licensee management responded "no" to an NRC Region IV inspector who asked if the licensee presently had or ever had in the past employed such individuals to conduct radiography at the LaBarge or Shute Creek areas of Wyoming. To the contrary, on March 18, 1987, the licensee management admitted in a written statement to an NRC investigator that it had employed such an individual in the subject area to work as an assistant radiographer and had allowed that individual to independently conduct radiographic operations (i.e. function as a radiographer) on November 18, 19, 1985.

The licensee's actions in attempting to deceive the NRC regarding whether it had utilized the radiographer and in disregarding requirements demonstrate that it is either unable or unwilling to comply with Commission requirements. Continued conduct of licensed activities could pose a threat to the health and safety of the public.

Cause:

The root cause can be attributed to a serious breakdown in the licensee's management controls.

Licensee Action:

On April 27, 1986, the licensee responded to the requirements of the Order.

NRC Action:

The licensee's response to the Order is still under review by the NRC staff.

Future reports will be made as appropriate.

UPDATE: This abnormal occurrence was originally reported in NUREG-0090, Vol. 10, No. 1, "Report to Congress on Abnormal Occurrences: January-March 1987." The event involved A-1 Inspection, Inc., of Evanston, Wyoming. The abnormal occurrence is updated, and closed out, as follows:

As previously mentioned, the NRC issued an Order on April 10, 1987, suspending this byproduct material license and requiring licensee to show cause why the license should not be revoked (Ref. B-3). The licensee responded in a letter dated April 27, 1987. The NRC deferred consideration of this matter pending the completion of an investigation of related matters conducted by the NRC's Office of Investigations.

In view of the fact that this license expired on May 31, 1989, and in view of the actions already taken in this case, the NRC concluded that no purpose would be served by considering additional enforcement action. Therefore, NRC terminated A-1 Inspection, Inc.'s license effective July 10, 1989, and NRC's enforcement actions in this case were considered closed.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 11 of "For All Licensees") of this report notes that serious deficiency in management or procedural controls in major areas can be considered an abnormal occurrence.

ITEM #:		AO #:	AS 87-01	EVENT DATE:	02/17/1987
TITLE:	BREAKDOWN IN MANAGEMENT AND PROCEDURAL CONTROLS AT AN INDUSTRIAL RADIOGRAPHY LICENSEE				
NAME:	U.S. Testing Company/Unitech Services Group	CITY:	Page	STATE:	AZ

Nature and Probable Consequences:

On February 17, 1987, the Arizona Radiation Regulatory Agency (State Agency) issued an order to U.S. Testing Company, Unit Services Group, San Leandro, California, to cease all radiographic operations within the State of Arizona.

The order was issued based on the findings of an inspection performed on February 6 and 7, 1987, to investigate the circumstances associated with two employees (a radiographer and an assistant radiographer) of the licensee receiving radiation exposures in excess of regulatory limits while performing radiographic operations at the Navajo Generating Station, Page, Arizo. The inspection results are described below.

The radiographer and assistant began the radiography evaluation at approximately 10:00 p.m. on February 5, 1987. They completed shooting a 4-inch Hammond valve at approximately 12:00 midnight, and moved into the penthouse to begin shooting reheat pendants. It appeared that the two survey meters and the camera were in good working order at that time. At that time, camera contained a 103.5 curie iridium-192 source.

During this series of exposures, the radiographer (who had previously been cranking the source in and out) asked the assistant radiographer if he would like to crank the source in and out to give him a break from the routine. This would also allow the radiographer to perform set-up of the source and film around the super-heat piping welds.

During one of the exposures, the assistant cranked the source in. The assistant radiographer then approached the camera with survey meter and the crank handle in his hands. The radiographer also approached the area after the source was cranked back and asked the assistant if everything was all right. The assistant stated that the meter was reading zero as they approached the camera. The assistant radiographer got up to the camera, surveyed the source tube, and the meter was still reading zero.

The radiographer removed the film from the weld area, and as he was doing so the assistant radiographer experience difficulty locking the camera. The assistant asked the radiographer how to lock the camera and he stated that you just turn the knob on t end. The assistant stated the camera would still not lock. The radiographer asked the assistant radiographer what the survey meter read. He stated the meter still read zero and the radiographer told him to place it up against the camera and take another reading. The assistant stated that the survey meter was still reading zero at that time, and the radiographer instructed him to tal to the Battery Check Position. At that point, the meter would still not function and the radiographer said they should both immediately leave.

The radiographer retreated back to where the source was cranked out, and checked their pocket dosimeters. Both pocket dosimeters (200mR) were off scale. The radiographer then crawled up to the crank assembly and turned the crank back and for He was then able to crank the source back in approximately one-half to one-full turn. The camera was locked and the radiograp went to notify their night supervisor. The Plant Supervisor for U.S. Testing as then notified by phone.

It should be noted that the radiographers had originally planned to use a GE Smith and Associates Model GS-10R survey meter Serial No. 3326, calibrated on January 23, 1987. However, they stated that this survey meter was not functioning on the times-c scale, so they left the survey meter at the manway to the penthouse, approximately 6 to 10 feet from where the crank assembly located for this shot. The radiographers then used a Victoreen survey meter, Model 492, Serial No. 1732 that either failed while radiographer was approaching the camera, or saturated after the assistant radiographer reached the camera.

Upon inspecting the meter, it was noted that it was calibrated on January 23, 1987, and was due for calibration on April 23, 1987. The meter was not functioning at the time of the inspection, and the meter was taken to the site electronic shop and the batteries tested at 1-1/2 volts each. The meter would not function on the Battery Test Position even with the batteries still in good conditi

The personnel that the company Radiation Safety Officer (RSO) had authorized to be radiographers at the site were not those actually involved in the event. One of the authorized individuals was the Acting Plant Manager for U.S. Testing at the time of the incident, and the other was not on site at that time. The U.S. Testing Acting Plant Manager had instructed the assistant radiographer to assist the radiographer with radiography on the evening of February 5, 1987. The assistant stated to the State Agency inspector that he had not received any additional training prior to the incident. The radiographer stated that he could no remember the last time he had received training. The radiographer possessed a certification card from U.S. Testing stated that was qualified as a Level II Radiographer on August 11, 1986. This card stated that he had been examined in accordance with "SNT-TC-1A."

The crank assembly for the camera was 25 feet long and the source tube being utilized at the time of the incident was seven fee long. One turn on the crank assembly was measured to move the drive cable approximately 8-1/2 inches. The body of the cam is 10 inches across, and the length of the S-tube within the camera is estimated to be approximately 12 inches. This would mea that the source itself was positioned approximately six inches along the S-tube in the shielded position, and 1/2 to one-full turn o the crank assembly would move the source an additional 4-1/4 to 8-1/2 inches, positioning the source right in the vicinity of the source tube connection just at the exterior of the camera body.

A reenactment of the incident was made and measurements were taken from the radiographer's film badge locations to major portions of their bodies. The radiographers film badge indicated that he had received 3100 millirems; however, based on the proximity of his upper trunk, head and eyes to the source compared to the film badge location, the whole body exposure could have been as high as 16.9 rem. Calculations for the assistant radiographer indicated that his right hand and forearm could have received 850 millirem in addition to his 2,650 millirem whole body exposure. It was determined during the reenactment that the assistant's film badge exposure gave a very good representation of his actual whole body exposure.

The State Agency's investigation revealed a number of concerns regarding the licensee's management and procedural controls to assure compliance with the Agency's rules and license conditions. Contrary to the rules and license conditions for performing radiographer procedures in Arizona, the credentials, training and experience records for the newly appointed RSO, the radiographer and the assistant radiographer had not been submitted to the State Agency for evaluation and approval. One of the contributing factors for the overexposures was the failure of the licensee to properly train the assistant radiographer.

Therefore, on February 17, 1987, the State Agency directed the licensee to cease and further radiographic procedures within the State of Arizona until the licensee submitted, and the State Agency approved, documentation which corrected the discrepancies. On March 9, 1987, the State Agency sent to the licensee a letter of non-compliance and proposed civil penalty in the amount of \$17,000.

Cause:

The root cause was a breakdown in management and procedural controls. This was a contributing cause of the overexposures experienced.

Licensee Action:

The licensee terminated radiographic operations in Arizona as directed. The licensee submitted training and experience records to the State Agency for the RSO and for the radiographers they proposed to work within the state. The licensee also reached agreement with the State Agency to pay the civil penalty in three installments over a three month period.

NRC Action:

Other Agency Action:

In addition to the actions previously discussed, on March 16, 1987, the Agency sent a letter to the licensee stating that the licensee could resume radiographic operations within the state with eight named radiographers allowed to perform radiographic procedures.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Criteria:

Appendix A (see Example 11 for "For All Licensees") of this report notes that a serious deficiency in management or procedural controls in major areas can be considered an abnormal occurrence.

ITEM #:		AO #:	AS 87-02	EVENT DATE:	02/27/1987
TITLE:	BREAKDOWN IN MANAGEMENT AND PROCEDURAL CONTROLS AT AN INDUSTRIAL RADIOGRAPHY LICENSEE				
NAME:	Continental Testing and Inspections	CITY:	Signal Hill	STATE:	CA

Nature and Probable Consequences:

On February 27, 1987, an Emergency Order suspending all radiographic operations was issued by an inspector for the California Department of Industrial Relations to Continental Testing and Inspection (CTI), Signal Hill, California.

During a routine compliance inspection of CTI's licensed radiographic operations conducted by the California Department of Industrial Relations, working under contract with the California Department of Health Services' Radiologic Health Branch, it was determined that individuals acting as radiographers may have lacked the required training and experience.

The radioactive material license issued to CTI permitted the Radiation Safety Officer (RSO) to designate individuals meeting the Department's minimum standards to act as radiographers. The licensee was required to maintain records documenting the qualifying criteria and the qualification of persons authorized to perform radiography. Records required for each person included statement of training and experience, a certification of satisfactorily completing a radiation safety training course (approved by the Department), a copy of results of field audits and written examinations, and a certification from the RSO that the radiographer had met the requirements established in Departmental Regulations relative to required training and experience prior to their acting as a radiographer and radiographer's assistant.

Records which would substantiate that individuals acting as radiographers had received training and experience considered by the Department to be a minimum standard were not available for inspection. Therefore, pursuant to California Health and Safety Code Section 25603, and to assure health and safety of workers and the general public, an Emergency Order was issued by the inspector and all CTI radiographic crews were required to immediately cease operations.

On March 2, 1987, a Departmental Order confirmed the order issued by the inspector.

The inspection also identified an overexposure during the first quarter of 1987. During the quarter, an individual acting as a radiographer's assistant received an exposure of 2000 millirem to the whole body.

Cause:

The root cause was a breakdown in management and procedural controls.

Licensee Action:

As directed, the licensee ceased operations. The licensee proposed six individuals be authorized to perform radiographer.

NRC Action:

Other Agency Action:

On March 9, 1987 the Department modified the radioactive material license issued to CTI so that all radiographic operations be conducted only by individuals specifically authorized by the Department. The amendment issued on March 9, 1987 authorized individuals to act as radiographers and rescinded the Emergency Order.

In regard to the overexposure during the first quarter of 1987, the Agency determined it was caused by human error and failure to perform required surveys. The Agency issued a Notice of Violation; the licensee has not yet responded to the Notice, but has removed the individual from working with radioactive sources for three months.

On May 15, 1987 the Agency was informed that another radiographer's assistant had exceeded the quarterly dose limits. This individual received 1300 millirem for the second quarter of 1987 and has been removed from working with sources of radiation for three months. This overexposure is being investigated and to date no Notice of Violation has been issued.

The investigation into the operations of CTI is continuing and escalated enforcement actions are being considered.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Criteria:

Appendix A (see Example 11 of "For All Licensee") of this report notes that a serious deficiency in management or procedural controls in major areas can be considered an abnormal occurrence.

ITEM #: AO #: NRC 87-09 EVENT DATE: 01/21/1987
TITLE: DIAGNOSTIC MEDICAL MISADMINISTRATION
NAME: Halifax-South Boston Community Hospital CITY: South Boston STATE: VA

Nature and Probable Consequences:

On January 21, 1987, a 66 year old female received 782 microcuries of I-131 instead of a 100-microcurie dose usually given for thyroid scan.

The purpose of the scan was to rule out the presence of a substernal thyroid, following removal of the normal thyroid many year ago. The thyroid scan and confirming computerized axial tomography (CAT) scan demonstrated the presence of a nonfunctional substernal thyroid.

No adverse effects to the patient are expected from the reported misadministration. The dose to the whole body was estimated 0.37 rem (assuming a 15% thyroid tissue uptake) and a thyroid tissue dose of 625 rem. Patients are often administered radioiodine following surgical or radioactive thyroid removal to check for hidden thyroid tissue.

Cause:

The misadministration was caused by the nuclear medicine technician's misinterpretation of the dose calibrator value.

Licensee Action:

The nuclear medicine technician was instructed to verify that the dose was within the proper range for a given procedure and to check with the radiologist prior to administration.

NRC Action:

A telephonic contact was made to the radiologist reporting this misadministration for additional information and assurance that corrective action had been taken. The incident will be reviewed during the next NRC routine inspection at the hospital.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 87-10	EVENT DATE:	04/20/1987
TITLE:	THERAPEUTIC MEDICAL MISADMINISTRATION				
NAME:	St. Peter's Medical Center	CITY:	New Brunswick	STATE:	NJ

Nature and Probable Consequences:

From April 20-22, 1987, a patient treated on the cobalt-60 teletherapy unit at St. Peter's Medical Center received a radiotherapy administration of 600 rads to the lumbar spine area, which was not the prescribed treatment site.

The patient, diagnosed as having breast cancer with metastasis to the bone, was undergoing treatment to the thoracic spine of 3000 rads in 15 fractionated doses of 200 rads each. She had previously undergone palliative treatment to the lumbar spine and sacral hip areas and still retained the tattoo marks for those treatment fields. The technologist mistakenly used these tattoos to position the patient for treatment, rather than the tattoos defining the thoracic spine treatment area.

During the course of treatment, the patient was treated as both an in-patient and out-patient. The misadministration occurred while the patient was an in-patient. During treatment set-up on April 20, 21 and 22, 1987, the patient's gown was only raised far enough to expose the tattoos in the previously treated lumbar spine and sacral hip areas and the technologist involved mistakenly assumed that the lumbar spine tattoos defined the currently prescribed treatment field. Had the technologist raised the gown to expose the entire back, the tattoos in the thoracic spine area would have been seen.

The technologists involved with the patient's treatment noted that the light field was larger than the tattooed field, but assumed the discrepancy was due to skin shifting and did not notify the supervising technologist, radiation oncologist, or medical physicist. When the patient returned for treatment on April 23, 1987 as an out-patient, the gown she wore opened in the back and the entire back was exposed during treatment set-ups. The technologist then realized that the patient had been erroneously treated in the lumbar spine area, rather than the prescribed thoracic spine area. They immediately notified the supervising technologist and radiation oncology physician.

The consequences of this incident was that a patient received an unprescribed dose to the lumbar spine of 600 rads. The patient's referring physician and radiotherapist concluded that the dose would have not detrimental clinical effect due to the patient's current disease state.

Cause:

The causes are attributed to human errors, including failures to comply with established procedures, i.e.,

1. The technologist did not expose the patient's entire back during treatment set-up;
2. The two technologists did not perform all simulation and set-up procedures together;
3. The technologist who originally simulated, tattooed and set up the patient for the initial treatments did not realize the error in subsequent set-ups; and
4. The technologists did not follow established procedures in the event the light field does not match the patient tattoo marks, which require notifying the supervising technologist, the radiation oncologist, or the medical physicist.

Licensee Action:

The licensee's immediate and planned corrective actions included: a review of internal policies to evaluate possible changes to prevent further misadministrations; a training session with all technologists to review the incident and internal policies; special training for the technologists involved and review of all their work; and immediate probation of the two technologists.

NRC Action:

A senior Region I NRC inspector conducted a routine inspection of the teletherapy program and review of the misadministration on April 28, 1987. No violations of NRC regulations were associated with this incident. An NRC medical consultant is reviewing the care.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on the public health or safety can be considered an abnormal occurrence.

ITEM #:
AO #:
EVENT DATE:

TITLE:

NAME:
CITY:
STATE:

Nature and Probable Consequences:

On June 3, 1987, NRC received written notification that on May 20, 1987, a patient at the National Institute for Health received 1 millicuries of technetium-99m pertechnetate rather than the prescribed radiopharmaceutical, 10 millicuries of gallium-67 citrate.

A patient, scheduled to be injected with 10 millicuries of gallium-67 on May 20, 1987, was administered a radiopharmaceutical on that day and asked to return on May 22 for a scan. The patient study did not show the typical gallium-67 citrate uptake and an energy spectrum obtained by the gamma camera indicated that technetium-99m had been injected, and not the prescribed gallium-67.

The radiopharmacist reviewed the usage records for May 20, 1987 and discovered a 3.3 milliliter excess of gallium-67. The only technetium-99m radiopharmaceutical which could not be accounted for was technetium-99m pertechnetate. The radiopharmacist concluded that approximately 120 millicuries of technetium-99m in 3.3 milliliters were withdrawn by mistake by the radiopharmacist and was not assayed for activity in a dose calibrator. This radiopharmaceutical was then dispensed to a physician who administered it to the patient.

The licensee informed the NRC that the Chief of the Nuclear Medicine Department, the Chief of the Radiopharmacy and the Chief of the Radiation Safety Branch were notified as soon as the misadministration was discovered. The referring physician was notified by written memorandum. The patient experienced no adverse effect from this administration but received the following unwarra approximate organ doses:

TISSUES	RADS
Bladder Wall	10.2
Gastrointestinal Tract	
Stomach Wall	6.1
Upper Large Intestinal Wall	14.4
Lower Large Intestinal Wall	13.2
Red Marrow	2.0
Testes	1.1
Thyroid	15.6
Brain	1.4
Whole Body	1.3

Cause:

The causes are attributed to failure on part of the radiopharmacist to read labels on stock solutions and the failure to assay for activity before administration to the patient.

Licensee Action:

All radiopharmacy personnel have been retrained in the existing policies requiring that all labels be checked and all radiopharmaceuticals assayed in a dose calibrator before being dispensed.

NRC Action:

Region I reviewed this incident during a routine inspection of the licensee on June 8-12, 1987. One apparent violation, failure to assay the dose before administration to the patient, was associated with this incident.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 87-12	EVENT DATE:	06/15/1987
TITLE:	NRC ORDER ISSUED TO REMOVE A HOSPITAL'S RADIATION SAFETY OFFICER				
NAME:	Milford Memorial Hospital	CITY:	Milford	STATE:	DE

Nature and Probable Consequences:

On June 15, 1987, an Order Modifying License, Effective Immediately, was issued to Milford Memorial Hospital, Milford, Delaware (Ref. 1). The action was based on (1) the falsification of daily constancy checks of the dose calibrator by the licensee's two technologists, and (2) the falsification of records of Radiation Safety Committee (RSC) meetings by the Radiation Safety Officer (RSO) for about 15 years.

As part of an NRC inspection at Milford Hospital on December 17, 1986, an NRC inspector reviewed the records of daily constancy checks performed on the dose calibrator. The inspector observed that during a period of time in 1986, the recorded results of the constancy checks were almost always the same value. In the presence of the licensee's RSO at the time, the inspector asked each of the two licensee technologists responsible for performing the constancy checks if these tests had been performed. She initially stated that the constancy checks had been performed daily.

However, when the technologist performed the constancy check procedure a short time later in the presence of the inspector and obtained a significantly different value than previously recorded, she admitted that she had recorded data in the past without actually performing the check. The other technologist also admitted that she had documented the results of daily constancy checks without having performed the checks. Subsequent to the inspection, the investigation determined that these records were falsified for the period May 6, 1986 through December 17, 1986.

Although the RSO at that time stated that he had performed an audit of these specific records of constancy checks on November 16, 1986, he did not recognize that the records had been falsified. Apparently, the RSO verified that records of constancy checks existed, but he did not assess the accuracy of the records.

During an interview with investigators from the NRC Office of Investigations (OI) on May 18, 1987, the Assistant Administrator of the hospital stated that during a review of previous RSC meeting minutes, he noticed that there were minutes for a January 20, 1987 meeting that he neither attended nor was given notice of despite his previous instructions to the RSO that he or the Hospital Administrator be present at those meetings. As a result of his inquiries he had found that these RSC meetings, which were required by the license to be conducted quarterly, had not been conducted for at least the past year, but that the RSO had created a record each quarter to represent that the meetings had occurred.

The RSO subsequently admitted to OI investigators that no RSC meetings had been held since approximately 1970, but that false records had been prepared to indicate that the meetings had occurred. These false records had been presented to NRC inspectors during various NRC inspections as evidence that the RSC meetings occurred, as required. Specific meeting minutes from the RSC also had been provided to the NRC, in letters dated April 7, and May 14, 1982, to resolve NRC concerns regarding the licensee's application for license renewal dated February 23, 1982.

The consequences of these occurrences was a reduction in the level of safety associated with the use of licensed material by the licensee. No specific hazard was identified.

Cause:

The cause of these occurrences appear to be a lack of adequate management control by the licensee and a lack of integrity on part of individual members of the licensee's staff.

Licensee Action:

The licensee suspended the RSO (a physician) from his duties as RSO shortly after determining that he had falsified the records. Subsequent to the NRC Order, the licensee suspended him from all duties but later permitted him to function in accordance with the restriction specified by the NRC Order. The licensee is conforming to the various provisions of the NRC Order described below.

NRC Action:

The June 15, 1987 Order required: (1) the removal of the RSO; (2) the suspension of the RSO's authorization to independently use or supervise the use of licensed material as currently permitted by the license; (3) the performance of monthly independent audits of the licensee's radiation safety program by an independent party; and (4) a review of the Radiation Safety Program by the new RSO, correction of deficiencies identified, and certification by the licensee to the NRC that the nuclear medicine program is being operated safely and in accordance with NRC requirements.

A subsequent NRC inspection has shown that the licensee is in compliance with the Order.

This item is considered closed for the purposes of this report.

UPDATE: from NUREG-0090, Vol. 11, No. 3, page 17. Reopened (and reclosed) to report new significant information.

As discussed in the previous report, on June 15, 1987, an Order Modifying License, Effective Immediately, was issued to the

licensee (Ref. B-12). The action was based on: (1) the falsification of daily constancy checks of the dose calibrator by the licensee's two technologists, and (2) the falsification of records of Radiation Safety Committee (RSC) meetings by the Radiation Safety Officer (RSO) for about 15 years.

The Order required: (1) the removal of the RSO; (2) the suspension of the RSO's authorization to independently use or supervise the use of licensed material as currently permitted by the licensee; (3) the performance of monthly independent audits of the licensee's radiation safety program by an independent party; and (4) a review of the Radiation Safety Program by the new RSO, correction of deficiencies identified, and certification by the licensee to the NRC that the Nuclear Medicine Program is being operated safely and in accordance with the NRC requirements. A subsequent NRC inspection showed that the licensee was in compliance with the Order.

The NRC continued its review of the findings of the NRC Office of Investigations to determine what additional enforcement action would be appropriate. On June 6, 1988, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$27,500 (Ref. B-13). The violations included: (1) the falsification of records of constancy checks of their isotope dose calibrator by two technologists from approximately May 6, 1986 to December 17, 1986; (2) the initial deliberate denial of that falsification by one of the nuclear medicine technologists during the inspection; (3) the falsification of the RSC meeting minutes for several years by the former RSO; (4) the submittal of falsified RSC meeting minutes to the NRC for review during several inspections, and in support of license renewal on one occasion; (5) the failure to secure licensed material stored in an unrestricted area from unauthorized removal; and (6) the failure to obtain NRC approval prior to moving the Nuclear Medicine Department in facilities other than those described in the license application.

The licensee maintained compliance with the Order, as determined by a subsequent NRC inspection and review of monthly audit reports from the licensee's consultant. The licensee has admitted the violations, paid the civil penalty, and proposed corrective actions acceptable to the NRC. These actions will be reviewed during future inspections of their program.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 11 of "For All Licensees") of this report notes that serious deficiency in management or procedural controls in major areas can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 87-13	EVENT DATE:	06/17/1987
TITLE:	SIGNIFICANT BREAKDOWN IN MANAGEMENT AND PROCEDURAL CONTROLS AT AN INDUSTRIAL RADIOGRAPHY LICENSEE				
NAME:	United States Testing Company, Inc.	CITY:	San Leandro	STATE:	CA

Nature and Probable Consequences:

On June 17, 1987, the NRC issued an Order Modifying License (Effective Immediately) to United States Testing Company, Inc., Unitech Services Group (USTU), San Leandro, California, which required the licensee to temporarily cease all operations until certain specific corrective actions were taken (Ref. 2).

During an indepth special safety inspection (Ref. 3) on February 10 through June 1, 1987 of USTU in San Leandro, California, it was determined that the large radiography firm had committed numerous violations of NRC and Agreement State requirements. Based on initial findings, a Confirmatory Action Letter (CAL) (Ref. 4) was sent to the licensee regarding radiation safety certification of radiographers and radiographer assistants on February 13, 1987. Upon completion of the full inspection, which covered the licensee's activities from January 1, 1985 to March 1, 1987, NRC issued the previously mentioned Order Modifying License on June 17, 1987 (Ref. 2).

At the time of the inspection, USTU was licensed by the NRC and several Agreement States to perform industrial radiography. The licensee employed approximately 200-300 radiographers, assistant radiographers and trainees, and conducted radiographic operations at 11 locations under NRC jurisdiction and 35 locations under Agreement State jurisdiction. As the result of the inspection, it was determined that the licensee was (1) allowing individuals to perform radiography after failing one or more certification examinations, (2) allowing individuals to perform radiography before all training and examinations were completed, (3) allowing individuals with expired certifications to perform radiography. Also three radiation overexposures and associated evaluations were not reported. In addition, numerous other radiation safety violations associated with field audits, radiation survey inoperable survey instruments, surveillance over high radiation areas, and proper maintenance and equipment inspections were identified at the NRC and Agreement State locations.

Deficient implementation of radiation safety requirements by this licensee resulted in the use of radioactive materials by inadequately trained personnel, thereby endangering themselves and co-workers. In fact, the NRC inspection was initiated by a incident on February 5, 1987, involving the overexposure of inadequately trained personnel (a radiographer and an assistant radiographers) at a USTU job site in Arizona, an Agreement State. This event was reported as Agreement State abnormal occurrence AS87-1 ("Breakdown in Management and Procedural Controls at an Industrial Radiography Licensee") in NUREG-0090, Vol. 10, No. 1 ("Report to Congress on Abnormal Occurrences: January-March 1987").

Cause:

The root cause appears to be attributed to widespread disregard for compliance with regulatory requirements. However, the event remains under investigation by the NRC Office of Investigations, and a complete understanding of all contributing causes awaits their report.

Licensee Action:

As discussed further below, the licensee has taken, or is taking, appropriate actions in response to the February 13, 1987 CAL, the June 17, 1987 NRC Order.

NRC Action:

Initial findings of the NRC indepth special safety inspection indicated that the licensee was using radiographers that had not received required radiation training. The CAL issued on February 13, 1987, required a licensee official to verify in writing that assigned radiographers, by name, have received appropriate training. Subsequent inspections by the NRC and Agreement State have verified licensee conformance with the CAL.

The Order Modifying License incorporated a two-phase action plan. The licensee is required to enlist a consultant to assist in performing an assessment of program deficiencies and necessary corrective actions. In the interim, the licensee may continue operations only if very stringent on-site management controls are in place as prescribed by the Order. This includes assignment a qualified Radiation Safety Officer (RSO) at each major project site or centralized facilities for temporary job sites, with responsibility for radiation safety program implementation and the authority to shut down any operation not in regulatory compliance.

The NRC Region V staff has reviewed the training and certification documentation of the new RSO submitted in compliance with the Order. All documentation was acceptable.

A reinspection schedule has been established which will examine the actions taken by the licensee, pursuant to the Order, at selected job sites under NRC and Agreement State jurisdiction.

The consultant's action plan has been evaluated and approved with minor revisions by Region V as stipulated in the Order.

On September 25, 1987, NRC Information Notice No. 87-45 ("Recent Safety-Related Violations of NRC Requirements by Indust

Radiography Licensees") was issued to all NRC licensees authorized to possess and use sealed sources for industrial radiography to inform them of the event (Ref. 5).

Future reports will be made as appropriate.

UPDATE: from NUREG-0090, Vol. 11, No. 2, page 17. United States (U.S.) Testing has undergone a third party independent audit of its radiation safety program. This audit identified 135 items for improvement that the licensee is currently implementing.

A new President, appointed in late 1987 to correct the many radiation safety problems, resigned in May 1988. A newly appointed Group Vice President has replaced the past President, and the changes in management direction, if any, will be evaluated during subsequent NRC inspections.

An additional NRC enforcement action is pending until completion of the NRC Office of Investigation report, now anticipated in the latter part of 1988.

A recent inspection completed on June 8, 1988, indicated the June 17, 1987 Order Modifying License (Ref. B-7) should remain in effect and continue to require direct radiation safety management and control at each job site by a qualified radiation safety officer.

Having recently undergone extensive top and mid-level management changes, the licensee's revised radiation safety management program continues to be in early phases of development. The licensee's top management have not achieved the nationwide coordination necessary to ensure radiography activities are conducted in accordance with NRC regulatory requirements and the U.S. Testing Radiation Safety Procedures.

Future reports will be made as appropriate.

UPDATE: from NUREG-0090, Vol. 11, No. 4, page 14. United States (U.S.) Testing has satisfactorily completed 95% of their improvement action items and should achieve 100% in the first quarter of 1989.

The licensee's Chief Executive Officer, President, and Vice President are personally involved in radiation safety management, and provide oversight needed to coordinate the licensee's wide ranging radiation safety program.

Recent inspections at U.S. Testing's Modesto, California, and Hoboken, New Jersey, offices indicate that strong upper and mid-level management have organized a unified radiation safety program and eliminated the confusion that had been pervasive in the licensee's organization at all levels.

Additional NRC enforcement action is pending until the NRC Office of Investigation report is released.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

UPDATE: from NUREG-0090, Vol. 12, No. 3, page 20. On September 22, 1989, the NRC issued a notice of violation (NOV) and proposed imposition of civil penalties in the amount of \$280,000 (Ref. B-3), based on inspections performed during 1987. Prior to the September 22, 1989, enforcement action, the NRC had issued to the licensee: (1) a Confirmatory Action Letter on February 13, 1987 (Ref. B-4), confirming actions taken by the licensee to assure compliance with radiography training and certification procedures; (2) Inspection Report No. 30-20402/87-01 on June 16, 1987 (Ref. B-5), documenting the 1987 inspection findings; and (3) an Order Modifying License on June 17, 1987 (Ref. B-6), specifying stringent conditions for continued operations.

As discussed in the September 22, 1989, enforcement letter, the violations were grouped as follows: (1) violations involving use of untested and uncertified radiographers and assistant radiographers; (2) violations involving unauthorized use of licensee's facilities in Hoboken, New Jersey; and (3) violations involving radiation protection, unauthorized use of equipment, transportation, record keeping, and audit requirements. The enforcement action was delayed pending completion of the NRC Office of Investigations inquiry as to whether certain of the violations were willful.

The OI has completed its investigation and concluded that: (1) the licensee's former Radiation Safety Director knowingly allowed numerous violations of NRC requirements to occur, constituting a disregard for the NRC license conditions and the safety of licensee employees; (2) the licensee's former President and Vice President willfully neglected their responsibilities to manage radiographic activities in a safe manner throughout the United States; and (3) management's neglect was motivated by profit incentives to give the licensee an unfair business advantage over its radiography competitors.

The three groups of violations were categorized as Severity Levels I, II, and III, respectively (out of five severity levels in which Severity Level I and V are the most and least significant, respectively). The proposed civil penalties for the three groups were \$100,000, \$100,000, and \$80,000, respectively, for a total of \$280,000. The NRC recognized that, since these violations occurred, significant corrective action has been taken by U.S. Testing. The corrective action involved major management changes, including the resignation of the Vice President and Radiation Safety Director, and the retirement of the President. The civil penalty reflects that corrective action. But for these changes that appear to have addressed the root cause of the violations, NRC would have initiated action to suspend or revoke U.S. Testing's license in addition to the civil penalty.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 11 of "For All Licensees") of this report notes that a major deficiency in management or procedural controls in major ar can be considered an abnormal occurrence.

ITEM #:		AO #:	AS 87-03	EVENT DATE:	12/09/1986
TITLE:	RADIOGRAPHER OVEREXPOSURES				
NAME:	Northwest X-ray	CITY:	Idaho Falls	STATE:	ID

Nature and Probable Consequences:

On December 9, 1986, an industrial radiographer and a radiographer's assistant, employed by Northwest X-ray, Idaho Falls, Idaho received whole body exposures while performing radiography in a multi-level hot cell at the Chemical Processing Plant at the Idaho National Engineering Laboratory (INEL) near Idaho Falls. In addition, the radiographer received an overexposure to both hands

The individuals were using a 50 curie Industrial Nuclear Company (INC) Model 7 iridium-192 source in a Tech/Ops Model 660 exposure device. The radiographer (who had 5 years of experience) had difficulty in climbing with the survey meter in hand. It was left with the exposure device and was not used to survey the guide tube between exposures. During attempts to lock the exposure device, the assistant noticed the survey meter was off scale. The assistant took the survey meter behind a concrete wall to check it out. The meter was still off scale. He switched it to the X100 position, but it remained off scale. He then switched the meter to battery test position, the off position and finally the X1 position where it read zero. The radiographer and the assistant assumed that the meter was acting up so they returned to work (the reading remained zero thus confirming the assumption).

The exposure device was moved to another level of the scaffolding despite the fact that the camera could not be locked) and the guide tube was coiled and uncoiled and otherwise handled by the radiographer. The radiographer cranked out the source, the assistant picked up the survey meter (it still read zero on the X1 scale) and went behind a concrete wall. When the exposure was completed, they started to enter the room but the survey meter immediately went off scale. At this point, they decided that a problem existed, and left the area and roped off the entrance to the area. They removed their anti-contamination coveralls (which had precluded ready access to their pocket dosimeters) and verified that their dosimeters were off scale. Emergency procedure were then implemented. The source was later verified to be disconnected.

The assistant received a documented exposure of 3.4 rem whole body, and INEL-estimated exposures of 6 rem to the lens of the right eye, 5 rem to the left hand, and 20 rem to the right hand.

The radiographer received documented exposure of 7.8 rem whole body and INEL-estimated exposures of 50 rem to the lens of the left eye, 70 rem to the lens of the right eye, and entrance doses of 2000 and 1700 rem to the left and right hands, respectively. The licensee's consultant estimated the radiographer's hand entrance doses to be 560 rem and 380 rem for the left and right hand, respectively.

Both individuals were examined by INEL's Medical Director. No signs of injury were found. The assistant was released and the radiographer will be followed medically for several months.

Due to the question of State jurisdiction on a Department of Energy (DOE) facility, DOE was asked to conduct the investigation and forward the results to the State. The licensee retained a consultant to conduct an independent investigation of the incident. The findings are as follows:

The radiographers did not follow proper procedures as detailed below.

1. Proper surveys of the guide tube were not made after each exposure (due to the difficulty in climbing with a survey meter in hand);
2. Radiography was performed with a camera that was thought to be malfunctioning (it would not lock);
3. Radiography was performed with a survey meter that was thought to be malfunctioning (it was thought to be "acting up"); and
4. Pocket dosimeters were not readily available for viewing during the job (they were covered by anti-contamination clothing).

The Tech/Ops representative determined (on site) that the camera and a "dummy" Tech/Ops source worked properly and a disconnect situation could not be produced.

The INC representative determined (on site) that the pigtail connection (drive cable to pigtail) appeared to have greater end play than normal. It was also determined that, when bending the pigtail and drive cable at a 90-degree angle, the connection (due to end play) could become disconnected. When a good pigtail (from INC's stock) and drive cable were tested, the disconnect did not occur.

For one of the exposures, the guide tube had an extremely tight radius. This, combined with the excessive end play and a sudden jerk of the drive cable upon retraction at the end of the exposure, are likely to have caused the disconnect.

Cause:

The causes of the overexposures were failure to perform proper surveys after each exposure and continued use of a survey meter which was suspected to be malfunctioning. The causes of the disconnect were use of a source with excessive end play and use of too tight a radius for the guide tube.

Licensee Action:

The licensee immediately provided reinstruction to all radiographic personnel on radiation safety and operating procedures with emphasis on surveys and emergency procedures.

NRC Action:

Other Agency Action:

Manufacturer: The sealed source with the excessive end play has been returned to the manufacturer for disposal. The manufacturer will set up an in-house quality assurance procedure to test all source pigtails for proper connection and end play.

State Agency: The State Agency has reviewed the licensee's procedures and training programs to assure that they are adequate.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see Example 1 of "For All Licensees") of this report notes that exposure of the whole body of any individual to 25 rems or more of radiation; exposure of the skin of the whole body of any individual to 150 rems or more of radiation; or exposure of the feet, ankles, hands or forearms of any individual to 375 rems or more of radiation can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 87-16 EVENT DATE: 08/24/1987

TITLE: THERAPEUTIC MEDICAL MISADMINISTRATION

NAME: Parkview Memorial Hospital CITY: Fort Wayne STATE: IN

Nature and Probable Consequences:

On August 24, 1987, the NRC was notified that a 75-year old patient at Parkview Memorial Hospital, Fort Wayne, Indiana, received two therapeutic radiation exposures to the wrong part of the body.

The patient was scheduled to receive radiation therapy exposures of 250 rads per exposure to the right hip. The treatments were continued for 12 days for a total of 3000 rads.

During the pretreatment planning, a technologist placed treatment marks on the patient's left hip in error. The patient was then taken to the treatment room where another technologist noted the markings on the left hip and treated the left hip. A second 250 rad exposure was administered on the next day, but prior to the third exposure, the patient informed the technologist that the wrong hip was being treated. The treatments were halted when the error was discovered.

The patient has been examined by a physician and no medical side effects have been noted as a result of the misadministration.

Cause:

The misadministration was caused by the technologist's error in marking the treatment area. The second technologist, who administered the radiation therapy, also failed to verify the treatment area by checking the patient's records.

Licensee Action:

The hospital agreed to institute a quality assurance program for cobalt-60 teletherapy procedures that included the independent determination of dose calculations by two qualified individuals and other aspects of treatment procedures and planning.

The hospital subsequently decided to terminate its radiation therapy program using a cobalt-60 teletherapy unit. It will continue to utilize a high energy linear accelerator which is not subject to NRC jurisdiction.

NRC Action:

On August 25, 1987, the NRC issued a Confirmatory Action Letter (Ref. 5) to the hospital documenting its agreement to institute a quality assurance program for cobalt-60 teletherapy procedures. The NRC also retained a medical consultant to evaluate the circumstances and possible effects of the misadministration. The medical consultant concluded that the misadministration would not cause a significant long term biological effect on the patient and would not require modification of the patient's follow-up medical care.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 87-17 EVENT DATE: 08/24/1987
TITLE: FAILURE TO REPORT DIAGNOSTIC MEDICAL MISADMINISTRATION
NAME: Edward Hines, Jr., Veterans Administration Hospital CITY: Hines STATE: IL

Nature and Probable Consequences:

On August 24, 1987, the NRC issued an Order to Show Cause Why the License Should Not Be Modified (Ref. 6) to the Edward Hines, Jr., Veterans Administration Hospital directing that a hospital staff member be removed from NRC licensed activities and that the hospital take certain steps to improve its control over its nuclear medicine program. The hospital is located in Hines, Illinois, near Chicago.

An NRC investigation between December 16, 1986 and June 30, 1987, determined that the Assistant Chief Physician of the Hospital's Nuclear Medicine Service failed to ensure that two diagnostic misadministrations of radioactive pharmaceuticals were reported to the NRC, as required. The investigation also determined that the physician made a false statement to a Veterans Administration Investigatory Board and to NRC investigators, destroyed evidence, and attempted to impede the NRC investigation by influencing the testimony of a witness.

The investigation was made after an August 14, 1986 anonymous allegation was made to the NRC that three misadministrations had occurred at the facility during the week of August 4-8, 1986 and which had not been reported to the NRC.

The investigation showed that while all three misadministrations had taken place, as alleged, one of them was not required to be reported to the NRC since it involved a radioactive material not subject to NRC jurisdiction. The two which were not reported to NRC, as required, were:

1. On August 4, 1986, a patient who was scheduled for a bone scan was injected with a different radioactive pharmaceutical, which is used for brain scan.
2. On August 6, 1986, a patient scheduled for a gallium-67 scan, received a different NRC licensed radiopharmaceutical than was scheduled for another patient.

Because of the small quantities of the radioactive pharmaceuticals involved, no adverse medical reaction would be expected in patients, although they did receive some unnecessary radiation exposure.

Cause:

The misadministrations were attributed to a lack of communication among the staff members of the Nuclear Medicine Service and the medical staff of the hospital.

The NRC investigation and previous inspections at the hospital determined that the licensee's management and staff had failed adequately control its program for administration of radiopharmaceuticals to patients. These failures included not properly controlling dose administration records, inadequate training, and not verifying procedure orders.

Licensee Action:

The licensee has implemented the terms of the NRC Order and has selected, with NRC concurrence, the outside auditor for its nuclear medicine program. The Assistant Chief Physician has been reassigned to duties that do not involve the use or supervision of the use of NRC licensed materials.

The Assistant Chief Physician has requested a hearing on the order as it affects him. The proceeding is pending.

NRC Action:

The NRC Order, which was effective immediately, removed the authority of the Assistant Chief Physician in the Nuclear Medicine Service to use or supervise the use of NRC licensed radioactive materials. In addition, the hospital was directed to undertake further training for its Nuclear Medicine Service staff; to assure that all prescriptions for nuclear medicine procedures are in writing, reviewed by a nuclear medicine physician, and verified by the technologist; and to maintain a record of dosage measurement and administration. In addition, the hospital was directed to retain an independent organization to perform quarterly audits of the nuclear medicine department.

This item is considered closed for the purposes of this report.

UPDATE: from NUREG-0090, Vol 11, No. 2, page 18. Report was reopened to report the following new significant information.

The former assistant chief physician of the Nuclear Medicine Service at the Edward Hines, Jr. Veterans Administration (VA) Hospital in Hines, Illinois pleaded guilty on July 14, 1988, to two federal charges in connection with the failure to report two diagnostic misadministration of radioactive pharmaceuticals at the hospital in August 1986. The physician pleaded guilty to a willful failure to report the misadministrations and to knowingly concealing and covering up material facts during NRC and VA investigations. The NRC staff had issued an Order to the licensee in August 1987 directing that the physician be removed from activities licensed by the NRC (Ref. B-8).

The physician received three years probation, A \$10,000 fine, and a requirement to perform 300 hours of community service.
This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 11 of "For All Licensees") of this report notes that serious deficiency in management or procedural controls in major an can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 87-18	EVENT DATE:	09/08/1987
TITLE:	SUSPENSION OF A WELL LOGGING COMPANY'S LICENSE				
NAME:	Log-Tec	CITY:	Cleveland	STATE:	OK

Nature and Probable Consequences:

On September 8, 1987, the NRC issued an immediate effective order (Ref. 7) to Log-Tec of Cleveland, Oklahoma, that suspend the NRC license, ordered all by-product material be placed in locked storage, and ordered the licensee to show cause why the license should not be revoked.

The license, which had been issued on June 14, 1984, authorized the use and possession of sealed radioactive sources to perform well logging. During a routine NRC inspection at Log-Tec facilities on August 19, 1987, eleven apparent violations of NRC requirements were identified. These apparent violations included failure to (a) store radioactive material in an authorized location (b) survey storage facilities, (c) provide personnel monitoring, (d) maintain utilization records, (e) properly label radioactive shipping packages, (f) perform leak tests on sealed sources, and (g) calibrate survey instruments (h) perform job site contamination surveys, (i) perform radiation surveys of vehicles transporting radioactive materials, (j) use authorized methods of storing radioactive material, and (k) maintain complete personnel monitoring records. When these violations were discussed with the company's sole proprietor, the NRC inspector was told that the sources had not been used since about June of 1986.

However, on August 21, 1987, the President of Inland Oil Corporation (IOC) provided a sworn statement that the licensee had conducted well logging operations for IOC on July 9, 1987. According to the President, he and another person witnessed a Log-Tec representative conducting the logging process. IOC also provided NRC with written documentation (i.e., neutron log) received from the licensee that verified the results of the logging process.

On August 21, 1987, an NRC investigator and an NRC inspector interviewed Log-Tec's sole proprietor about his use of radioactive sources. Again, he reiterated that he had done no logging using radioactive sources since June 1986. However, when confronted with the copy of the neutron log received from IOC, the sole proprietor admitted that he had performed this work and had used a radioactive source to do so. Also, he stated that he had no records of his work at IOC. He further stated that he told the NRC inspector that he had not used radioactive sources because he knew his records were not up to date and he was afraid to admit this. He stated that he had none of the records required by NRC and never thought about keeping such records. He stated that survey equipment was out of calibration because he did not have the money for such maintenance. He also admitted that he had not used film badges in a long time because he could not afford such associated expenses. Also, he admitted that he, doing business as Log-Tec, had conducted licensed well logging activities for other companies (i.e., Continental Oil, JGW Exploration, Inc.; and Covenant Oil) since June 1986 besides that done for IOC. NRC contacted and subsequently obtained from the Covenant Oil Company gamma ray logs that documented Log-Tec's use of radioactive sources for logging operations on September 9, 1986, December 10, 1986, and June 30, 1987.

The action of the sole proprietor of Log-Tec in deceiving the NRC inspector demonstrated that he was not trustworthy and not committed to complying with Commission requirements. Therefore, the NRC did not have the requested reasonable assurance that the sole proprietor, doing business as Log-Tec, would comply with Commission requirements in the future. Consequently, the license was suspended.

Cause:

The root cause can be attributed to a serious breakdown in the licensee's management controls.

Licensee Action:

The licensee has requested that the license be terminated. The licensee has transferred all sealed sources to an authorized recipient.

NRC Action:

The NRC is terminating the license.
This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 11 "For All Licensees") of this report notes that serious deficiency in management or procedural controls in major areas can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 87-19 EVENT DATE: 09/21/1987
TITLE: SUSPENSION OF AN INDUSTRIAL RADIOGRAPHY COMPANY'S LICENSE
NAME: Finlay Testing Laboratories, Inc. CITY: Aiea STATE: HI

Nature and Probable Consequences:

On September 21, 1987, the NRC issued an Order Suspending License (effective immediately) to Finlay Testing Laboratories, Inc. Aiea, Hawaii (Ref. 8). The Order required the licensee to suspend all activities authorized by the license and to place all by-product material in the licensee's possession in locked storage.

During inspections and investigations conducted in September 1987 in the State of Hawaii, it was determined that licensee employees had caused the shipment of radiographic exposure devices containing radioactive sources on passenger-carrying aircraft by concealing the nature of the material being offered for transport. NRC and Department of Transportation (DOT) regulations specifically prohibit industrial radiographic sources from being transported aboard passenger carrying aircraft. It was further noted that licensee personnel failed to make surveys to assure the sources were in their shielded positions, and failed to prepare and use required shipping papers and labels for these shipments.

It was also ascertained by NRC inspectors and investigators that licensee representatives (including the Radiation Safety Office) had failed to maintain required records of licensed activities.

Cause:

The causes contributing to the violations appear to be a disregard for licensee operating procedures and the NRC license conditions and regulations. However, the case remains under investigation by the NRC Office of Investigation, and a complete understanding of all contributing causes awaits their report.

Licensee Action:

The licensee has complied with the Order and has forwarded a written request for an enforcement hearing.

NRC Action:

The NRC Order continues in effect and a decision by the NRC on whether to allow the licensee to resume licensed activities has not been made. The NRC staff is reviewing the licensee's response to the Order at this time.

Future reports will be made as appropriate

UPDATE: from NUREG-0090, Vol 11, No. 2, page 18. Following issuance on April 11, 1988, of an inspection report, a Notice of Violation, and a Revocation Order (Refs. B-9 and B-10) detailing numerous willful Severity Level I violations (on a scale in which most significant and least significant are categorized as Severity Levels I and V respectively), the licensee and the NRC staff reached a settlement agreement on May 12, 1988 (Ref. B-11), six days prior to the scheduled Atomic Safety and Licensing Board Panel hearing to review the original license suspension.

The agreement calls for G. Finaly, the owner and President of Finaly Testing Laboratories, to terminate his NRC license, transfer all licensed material to persons authorized to receive it, and not reapply for a license or engage in any radiography activities for three years. The licensee also agreed to terminate legal action against NRC staff that had been pending in the U.S. District Court. In return, the NRC staff agreed not to pursue any further civil enforcement sanctions pertaining to the licensee.

On August 22, 1988, the NRC issued Information Notice No. 88-66 ("Industrial Radiography Inspection and Enforcement") to all NRC industrial radiography licensees (Ref. B-12). The Notice informed the licensees of the event and its consequences and emphasized the importance of compliance with NRC regulations in all aspects of industrial radiography.

This item is considered closed for the purposes of this report.

Other Agency Action:

[]

Criteria:

The following information pertaining to this event is also being reported in the Federal Register. Appendix A (see Example 11 of "For All Licensees") notes that a major deficiency in management or procedural controls in major areas can be considered an abnormal occurrence.

ITEM #:		AO #:	AS 87-04	EVENT DATE:	06/03/1987
TITLE:	HOSPITAL CONTAMINATION INCIDENT				
NAME:	Buffalo General Hospital	CITY:	Buffalo	STATE:	NY

Nature and Probable Consequences:

On June 3, 1987, a contamination incident occurred at Buffalo General Hospital, Buffalo, New York, during resuscitation efforts for a patient.

On the morning of June 2, an 87 year old patient at the hospital was administered a 200-millicurie therapy dose of iodine-131 in hope of relieving esophageal compression caused by metastatic thyroid carcinoma. The patient had a total thyroidectomy in April 1987, and had a gastrostomy tube and a foley catheter in place. On the evening of June 3, 1987, approximately 34 hours after receiving the dose, the patient had a cardiopulmonary arrest and expired. During an attempt at resuscitation in the patient's room by sixteen staff members, which included insertion of a pacemaker, contaminated blood and urine were spilled and no surveys of the clothing of those present were done. The hospital is part of an unusual broad license which includes several different hospital

The patient was disoriented and was known to have dislodged the foley catheter before the radioiodine dose was administered, no special precautions were taken to prevent contamination and no special instructions were given to nursing staff. Room preparation was minimal with most surfaces left uncovered and no shielding was provided for the catheter bag. It was later uncovered that the patient had removed the foley catheter at least twice after receiving the dose and leaked urine onto the floor. The staff, apparently not aware of the amounts of iodine contained in the urine, cleaned it up and apparently did not inform anyone that this had occurred.

When the patient went into cardiac arrest, the physician who administered the radioactive dose was called and gave no instructions relating to the possibility of contamination. The physician in turn called the health physicist for the board license, but did not call site radiation safety officer. The health physicist gave no instructions relating to the spread of contamination except to secure the patient's room. Neither the physician nor the physicist responded to the scene until the following day.

Contamination was eventually found on almost all the furniture in the patient's room, on the floor of the room and surrounding hallways, on the shoes of several staff and on the equipment such as a blood pressure cuff and stethoscope used in the resuscitation attempt. However, subsequent thyroid bioassay showed no uptakes by involved staff, and the highest personnel monitoring badge reading was 30 millirem for one of the nurses.

Cause:

The hospital's procedures for preparing for such a therapy, especially when the patient could not cooperate, were severely deficient. In addition, instruction of personnel was totally inadequate and procedures for responding to emergencies were disorganized. Management control over this program was judged to be inadequate.

Licensee Action:

The hospital has revised its procedures for preparing for radioiodine therapy treatments, and its criteria for patient selection.

NRC Action:

Other Agency Action:

The Agency is in the process of making changes in the structure of this license to clarify responsibilities.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see Example 11 of "For All Licensees") of this report notes that serious deficiency in management or procedural controls in major areas can be considered an abnormal occurrence. In addition, one of the general criteria notes that moderate exposure to, or release of, radioactive material can be considered an abnormal occurrence.

ITEM #:	960281	AO #:	AS 87-05	EVENT DATE:	08/05/1987
TITLE:	THERAPEUTIC MEDICAL MISADMINISTRATION				
NAME:	Northern Westchester Medical Center	CITY:	Westchester County	STATE:	NY

Nature and Probable Consequences:

On August 5, 1987, the New York Department of Health, Bureau of Environmental Radiation Protection (State Agency) was notified of a series of therapeutic medical misadministrations to patients at Northern Westchester Medical Center.

The hospital had contracted with a consulting group (Radiological Physics Associates of Elmsford, New York) to provide health physics services; a dosimetrist from the group normally prepared the cobalt teletherapy treatment plans. While the dosimetrist was on vacation, a physicist from the group was called by the hospital to make a change in a treatment plan for a patient. In making the change, the physicist discovered a serious error in the treatment times calculated by the dosimetrist, and reported this to the radiotherapy physician. The physicist then reviewed other plans and found more errors.

Independent physicists were retained by the hospital to do a complete review of all treatment plans since their program began in 1982, and eventually found 22 cases in which the therapy doses delivered to patients differed from the prescribed doses by more than 10% (this included overtreatments as well as undertreatments). The largest error found was an administered dose that was about 204 times the prescribed dose. All the plans containing errors involved computer generated data and all were prepared by the same dosimetrist.

As soon as the first misadministrations were verified, the Agency contacted by telephone the two other hospitals (Columbia Memorial in Hudson, New York; and Samaritan Hospital in Troy, New York) where the dosimetrist did treatment planning and instructed them to have an independent physicist review their patient treatment plans with emphasis on plans involving computer generated data. Two misadministrations were found at Columbia Hospital on many other treatment plans contained the same type of errors; however, the administered dose did not differ from the prescribed dose by greater than 10%. Samaritan Hospital utilized a computer system which computes the treatment time; therefore, the mathematical operations had been correctly done by the computer.

To date, the latter two hospitals report no observable physical effects in the affected patients attributable to the treatment errors.

All available data on the 22 patients affected at Northern Westchester Medical Center were provided by the hospital to the State Agency and are under review by its Radiological Health Advisory Committee. At this hospital, some patients receiving overtreatment had exhibited physical symptoms apparently due to the exposures.

UPDATE: The hospital had contracted with a physics consulting group (Radiological Physics Associates, Elmsford, New York) to provide physics services. A dosimetrist from the group, who normally prepared treatment plans, was not available and upon review of one plan by another physicist from the group, it was discovered that the dosimetrist had made errors in his calculations. The State Health Department was notified of the mistakes and the hospital was directed to discontinue therapy until treatment plans had been reviewed and verified as correct and the cobalt teletherapy unit recalibrated. Twenty-two patients were identified as having received incorrect treatments ranging from 50 percent underdose to approximately 100 percent overdose (total dose). All the associated plans were prepared by the same dosimetrist.

An outside radiological physicist reviewed about 250 treatment plans including those of affected patients. The conclusion was that the dosimetrist made somewhat random mistakes, that is, plans were done with the correct methods in some cases and incorrect at other times. Overall, the cases indicated a lack of understanding of the computer program used for treatment planning and the methods of calculation of timer settings from the computer output. Furthermore, there were not second checks performed which may have caught these mistakes.

Northern Westchester Hospital Center was directed by the State Health Department to follow-up on the affected patients for at least 1 year and to provide status reports to the department. At the time of the last report (May 1988), 11 of the 22 patients had died. Some of the deaths may have been from complications related to the misadministration in question. Other patients return for further treatment. All treatment records for the affected patients were requested for review by the State's Radiological Health Advisory Committee. The committee did not have any comments that could counter the assertions by the hospital. The New York State Department of Health notified the NRC that the dosimetrist involved is no longer working at the hospital or any other facility in New York State. The physicist in charge of the consulting group stopped providing therapy services in New York State after the incident and only performed diagnostic x-ray and nuclear medicine consulting services.

The State requested the names of other facilities where physics services were performed by the same dosimetrist. Two other hospitals and a private office were identified where the dosimetrist performed treatment planning. All three facilities were notified and had independent physics review of treatment plans. At one of the hospitals, mistakes were found in two treatments involving a wedge; however, the total dose delivered was within 10 percent of that prescribed. At the same hospital, a mistake in the calibration of an orthovoltage unit was discovered which resulted in 22 patients receiving doses in excess of 10 percent of those prescribed. That calibration was performed by the senior member of the physics consulting group. Those patients were followed up and no adverse outcomes were reported.

Cause:

The errors which resulted in the misadministrations were due to mistakes in calculations made by the dosimetrist utilizing computer-generated data. They were of several different kinds, were not made consistently and seem to demonstrate a lack of understanding of the computer systems used.

UPDATE: The dosimetrist involved lacked understanding of the computer treatment planning software and other basic methods determining treatment times. Quality assurance of treatment planning was inadequate and no second checks of treatment plans were performed.

Licensee Action:

The licensees have instituted quality assurance measures which include a second check of all treatment plan calculations. The dosimetrist who made the errors will no longer be doing computerized therapy treatment planning.

UPDATE: Insufficient information is available on the action(s) taken by the licensee to prevent recurrence. NRC has asked the State of New York to provide additional information regarding the licensee action (s).

NRC Action:**Other Agency Action:**

The Agency is drafting therapy misadministration reporting requirements and quality assurance requirements for providers of radiation therapy services.

This item is considered closed for the purposes of this report.

UPDATE: License conditions concerning the qualifications of physicists, treatment prescriptions, second checks, and misadministrations were added to all teletherapy licenses in 1988. Since that time, the State Sanitary code has been revised to include specific requirements for quality assurance in radiation therapy for all therapy modalities. The State of New York believes that the dosimetrist involved no longer performs treatment planning in New York State. The senior physicist in the consulting group did not perform any therapy functions in New York State after the incident.

This report will be further evaluated when additional information becomes available.

Criteria:

Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

UPDATE: This abnormal occurrence was originally reported in NUREG-0090, Vol. 10, No. 3., "Report to Congress on Abnormal Occurrences," July-September 1987, and closed out at that time. It was reported that 22 patients received cobalt teletherapy misadministrations at Northern Westchester Hospital in Westchester County, New York, between 1982 and 1987.

This abnormal occurrence was reopened because the original report contained several incorrect statements. The following was prepared by the State of New York to correct the errors. (see the specific categories below for the updates in each area). DATE AND PLACE: On August 5, 1987, the New York State Department of Health Bureau of Environmental Radiation Protection was notified that mistakes in treatment planning had been discovered and that some cobalt teletherapy patients had received excess radiation at Northern Westchester Hospital Center.

ITEM #: AO #: EVENT DATE:
TITLE:
NAME: CITY: STATE:

Nature and Probable Consequences:

On October 30, 1987, the NRC issued an Order Suspending License (Effective Immediately) and Order to Show Cause why the license should not be revoked to Tracer Profiles, Inc., of Oklahoma City, Oklahoma (Ref. 1).

During an NRC inspection at the company on March 5-6, 1987, several violations of NRC requirements were identified (Ref. 2). Prior to and following an enforcement conference held on March 26, 1987 with the Vice President of the company, the licensee agreed to several specific corrective actions which were documented in Confirmatory Action Letters (CALs) dated March 13 and April 22, 1987 (Refs. 3 and 4, respectively). Among other actions, these included obtaining the services of a qualified consultant audit operations, develop management controls to ensure compliance with license requirements, and prepare a report of finding which should be forwarded to the NRC.

On June 8, 1987, a Notice of Violation (NOV) (Ref. 5) was issued in which the violations were categorized in the aggregate as a Severity Level III (on a scale in which Severity Levels I and V represent the most and least severe, respectively) without the usual proposed imposition of a civil penalty in consideration of the licensee's past good enforcement history and agreement to implement the corrective actions documented in the CALs.

The licensee failed to respond to the CALs and the NOV. Subsequent attempts to contact licensee management were unsuccessful until July 20, 1987, when the President of the company called the NRC Region IV office and advised that he was unaware of the Vice President's whereabouts and the company's commitments to the NRC and the subsequent NOV. The President consequently committed to additional corrective actions, including securing licensed materials in locked storage until NRC approved resumption of licensed activities. (The licensee apparently possessed only short-lived radionuclides, which had decayed to insignificant levels.) The commitments were formalized in a CAL dated July 31, 1987 (Ref. 6).

However, the NRC did not receive a response. In addition, it has been determined that the company vacated its offices and moved to a new and unknown location without notifying the NRC. Consequently, the NRC issued the previously mentioned Order on October 30, 1987 (Ref. 1).

Cause:

The cause is the licensee's failure to fulfill its commitments to the NRC and its apparent inability and unwillingness to comply with NRC regulatory requirements.

Licensee Action:

None.

NRC Action:

The NRC is considering action to revoke the license.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that major deficiencies in management controls for licensed facilities or material can be considered an abnormal occurrence.

ITEM #: AO #: EVENT DATE:

TITLE:

NAME: CITY: STATE:

Nature and Probable Consequences:

A patient was administered 50 millicuries of technetium-99m (as sodium pertechnetate) instead of 3 millicuries of thallium-201 prescribed by the physician.

The purpose of the administration was for a Myocardial Perfusion Stress Test. The licensee reported that there were no deleterious effects to the patient. The licensee calculated that the patient incurred the following doses: thyroid - 6.1 to 10.2 rads stomach - 5.1 to 15.3 rads; colon - 5.1 to 15.3 rads; gonads - 0.5 to 2.0 rads; and whole body - 0.5 rad.

Cause:

The misadministration was caused by a student technologist selecting the wrong syringe from the dosage cart.

Licensee Action:

The student technologist was reprimanded, new procedures for radiopharmaceutical labeling and handling will be implemented, personnel will be retrained, and the supervision of personnel will be improved.

NRC Action:

NRC Region IV telephoned the radiation safety officer reporting this misadministration for additional details on the incident. The details were subsequently provided by a February 1, 1988 memorandum from the licensee. The incident will be reviewed during special NRC inspection at the center.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 88-05	EVENT DATE:	01/20/1988
TITLE:	BREAKDOWN IN MANAGEMENT CONTROLS AT GEORGIA INSTITUTE OF TECHNOLOGY RESEARCH REACTOR FACILITY				
NAME:	Georgia Institute of Technology (Georgia Tech)	CITY:	Atlanta	STATE:	GA

Nature and Probable Consequences:

This occurrence addresses licensee performance over a period of time until January 20, 1988, when the NRC issued an Order Modifying License (effective immediately) to the Georgia Institute of Technology (Georgia Tech) regarding their research reactor (GTRR). The GTRR is a 5 megawatt (thermal) facility, located in Atlanta, Georgia, and utilized for teaching and research including the performance of irradiation experiments.

The NRC Order required the licensee to cease using the reactor facility for irradiation experiments until certain conditions are met and the NRC approves the resumption of irradiation experiments (Ref. 12).

NRC concerns with regard to the licensee's management control has been the subject of enforcement actions in the past. An inspection conducted February 9-23, 1987, which included a review of the licensee's operations program, identified numerous failures to comply with NRC regulatory requirements. The areas of non-compliance included inadequate procedures, failures to follow procedures, and problems in keeping adequate records documenting compliance with NRC requirements. Based on these inspection findings, the NRC raised concerns about programmatic weaknesses in the licensee's implementation of Technical Specification requirements.

Inspections conducted February 17-23 and April 7-10, 1987, which included a review of the licensee's operations and radiation protection programs, also identified significant failures to comply with NRC regulatory requirements in the same areas described above. The findings of these inspections clearly indicated the licensee's need for improved management control to ensure adherence to NRC requirements and safe performance of licensed activities. On May 4, 1987, an enforcement conference was held at the NRC Region II office in which the licensee outlined steps to be implemented to improve management controls over operations and health physics at the facility to assure safe operation. These actions include a change in the research facility's organizational structure.

The events leading to issuance of the NRC Order were identified during recent inspections which showed that the licensee's actions have not been fully successful and indicated that management control problems continue. On December 16, 1987, while reviewing management reorganization concerns for the GTRR program, an NRC inspector learned of a contamination event which occurred at the reactor facility during the week of August 17, 1987. The event involved the improper opening of an irradiated material container which resulted in the release of radioactive contamination within the reactor containment building. At the time of the December 1987 NRC inspection, a detailed description and evaluation of the event had not been prepared by licensee or management staff. This inspection was continued on January 4-5, 1988, and a team inspection was conducted from January 14-22, 1988.

The inspection findings (Ref. 13) revealed that the experiment conditions and manipulation of the experiment materials resulted in unexpected elevated radiation levels from the experiment container and also the unmonitored release of cadmium-115 in the reactor building. The dose rate at one foot from the experiment material was approximately 3 rem per hour on August 18, 1987, and qualitative measurements of radioactive contamination indicated levels on Masolin wipes of approximately 20 millirem per hour on August 19, 1987.

The following violations were identified from the inspection findings: failure to have adequate procedures and failure to follow procedures for handling and manipulating experiment material and for surveying and evaluating potential radiological hazards; failure to conduct adequate radiation surveys of the reactor building and GTRR personnel and their personal property for evaluation of exposure to radioactive material; failure to conduct adequate air sampling and bioassay analyses for evaluation of personnel exposure to airborne radioactive material during experiment and decontamination activities; and failure to document and maintain records of radioactive material contamination surveys.

At the time of the inspection, the licensee had failed to complete a thorough review of the August 1987 contamination event regarding its cause or causes, nor had any corrective measures been implemented as of January 5, 1988 to prevent recurrence during future experiments.

The issuance of the NRC Order was a direct result of NRC concerns over the licensee's past performance, their unsatisfactory slow rate of improvement, and most importantly, the licensee's lack of management control needed to assure that continued irradiation experiments would not result in more significant safety problems.

Cause:

The root cause was a lack of regard for and adherence to procedures, and a lack of management control over licensed activities.

Licensee Action:

The licensee voluntarily shut down the GTRR on February 15, 1988. The enforcement history and recent inspection findings were discussed with the licensee at the enforcement conference held at the NRC Region II office on February 23, 1988. The licensee addressed the violations identified and presented an action plan directed towards upgrading their operations and health physics programs. Also, the licensee committed not to restart the reactor without NRC concurrence.

NRC Action:

The January 20, 1988 NRC Order (Ref. 12) required the licensee to immediately suspend certain activities under its NRC license until requirements of the Order are satisfied which includes: an assessment of management controls; review whether any other events similar to the August 1987 incident have occurred; assessment of personnel exposures for the August 1987 event, and a other similar events, and associated cleanup activities; review of health physics and operating procedures; identification of corrective actions and schedule for implementation; and development and implementation of necessary training programs.

On March 17, 1988, the NRC issued to the licensee a Confirmatory Order Modifying License (effective immediately) confirming the licensee's commitments made at the February 23, 1988 enforcement conference (Ref. 14). The Order did not modify the conditions of the January 20, 1988 Order.

The inspection report forwarded to the licensee on February 10, 1988 (Ref. 13) identified several apparent violations of NRC requirements. However, no formal Notice of Violation was issued at the time since the apparent violations are under consideration for escalated enforcement action.

Future reports will be made as appropriate.

UPDATE: from NUREG-0090, Vol. 11, No. 4, page 14. As discussed in the previous report, on January 20, 1988, the NRC issued an Order Modifying License (Ref. B-2) to the Georgia Institute of Technology (Georgia Tech) because of management and program deficiencies at their research reactor (GTRR). The immediately effective Order required the licensee to suspend irradiation experiments at the facility until requirements of the Order were satisfied and the NRC approved the resumption of irradiation experiments. The licensee voluntarily shut down the GTRR on February 15, 1988. On March 17, 1988, the NRC issued to the licensee a Confirmatory Order Modifying License (effective immediately) confirming the licensee's commitments made at the enforcement conference on February 23, 1988 (Ref. B-3).

An NRC team inspection was conducted from August 29 to September 9, 1988, and from November 7-10, 1988, in order to address the licensee's commitments to the NRC Orders. The inspection also examined subjects which are usually addressed in routine operations and health physics inspections of research reactors. The initial results of this special inspection concluded that there were numerous examples of inadequate or absent procedures for the conduct of routine operations and surveillance. However, by the close of the inspection, adequate procedures and practices were in place, and the facility staff had received training in the new procedures. The inspection findings substantiated that appropriate actions had been taken to correct the major deficiencies that led to the issuance of the two Orders. The inspection findings also indicated that certain other activities, although of lesser safety significance, appeared to violate NRC requirements. The licensee was issued a Notice of Violation concerning these activities, details of which are discussed in the inspection report forwarded to the licensee on December 29, 1988 (Ref. B-4). By the end of the inspection, all corrective actions for these violations had been completed; therefore, no response to the inspection report was required from the licensee.

In a letter to Georgia Tech dated November 15, 1988, NRC Region II stated that based on the previously mentioned inspections and corrective actions taken by the licensee, the NRC had determined that the reactor could be restarted and that irradiation experiments could be resumed (Ref. B-5).

Also on November 15, 1988, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty for the GTRR management and program deficiencies from 1987 (Ref. B-6). The civil penalty was escalated 100% to \$5,000 because of prior poor performance and failure to take prompt corrective action on the management control problems. The licensee paid the civil penalty on December 20, 1988.

This item is considered closed for the purposes of this report.

Other Agency Action:**Criteria:**

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the third general criterion) of this report notes that major deficiencies in design, construction, use of, or management controls for licensed facilities or material can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 88-06 EVENT DATE: 01/21/1988
TITLE: RELEASE OF POLONIUM-210 FROM STATIC ELIMINATION DEVICES MANUFACTURED BY 3M COMPANY
NAME: Ashland Chemical Company CITY: Easton STATE: PA

Nature and Probable Consequences:

January 21, 1988; Ashland Chemical Company (Ashland) plant in Easton, Pennsylvania, and various other locations.

On January 22, 1988, the radiation safety consultant for Ashland reported to NRC Region I that radioactive contamination had been discovered at their plant on the previous day. Subsequent determination of the cause of the contamination led to extensive investigations which showed that similar contamination problems existed in many plants in many states.

The cause of the contamination involved the failure of static elimination devices manufactured by the Minnesota Mining and Manufacturing Company (3M Company), St. Paul, Minnesota, containing polonium-210 (Po-210). Po-210 decays by emission of a 5.3 MeV alpha particle and has a half life of 138 days. The devices in 3M Company's Model 900 series are used to ionize a stream of air in order to remove static electricity. Even-numbered models in the 900 series (Models 902, 902F, 906, and 908) are used in conjunction with compressed air; odd-numbered models (Models 905, 907, and 909) are used with blown air. (The devices used by Ashland were of the even-numbered models and were connected to a source of compressed air.) The 3M Company also manufactures bar-type static elimination devices.

The Po-210 in these devices is contained in microspheres of zirconium pyro-phosphate that have been plated with nickel and are held in place with an epoxy adhesive. The microspheres are about 0.001 inch diameter and are hard, dense, and insoluble. The 3M Company manufactures the devices under NRC License No. 22-00057-06 and distributes them to general licensees (such as Ashland) under NRC Licensee No. 22-00057-32G as permitted by the general license provisions of 10 CFR 31.5. Because general licensees lack the expertise to leak-test the devices, the 3M Company requires that the devices be leased for a one-year period and returned to the 3M Company, and tested for leakage of radioactivity.

The discovery at Ashland resulted from an investigation occasioned by a complaint from one of Ashland's customers that its product was radioactively contaminated. Subsequent to discovery of contamination at its Easton plant, Ashland conducted surveys at its other plants. On January 23, 1988, its plant at Dallas, Texas, was also found to be contaminated; its other plants were free of contamination. Surveys were begun at other plants using the 3M devices, and contamination was discovered at a KTI Chemical Corporation plant in Carrollton, Texas, on January 28, 1988. On February 1, 1988, two beverage plants in Dallas, Texas, were found to be contaminated. At this time, the U.S. Food and Drug Administration (FDA) began investigation for possible product contamination at plants using the 3M Models 902, 902F, 906, and 908 devices where similar device failure had been found in preceding years. No contaminated product was found.

Inspectors from the NRC examined 3M Company records of quality assurance on returned devices for the years 1986 and 1987 and discovered a large number of devices that were leaking upon return to the 3M Company. Most of these failures had not been reported to the NRC because the 3M Company believed that the failure was caused by some kind of damage to the device. Inspectors from the NRC and individual states have now (as of late April 1988) surveyed scores of plants using 3M Company static elimination devices and have identified a large number of plants that show contamination levels exceeding 0.005 microcuries. It is expected that the total number of such plants may be several hundred. For each plant in which contamination was found, the contamination was not widespread; rather, it appears to result from discrete Po-210 particles.

Po-210 emits alpha radiation which will not penetrate the outer layers of the skin. The size and density of the Po-210 microspheres indicate that they are not repairable and, if ingested they are expected to pass through the digestive tract in a short time without significant release to the bloodstream because they are invaluable. Bioassay of workers at Ashland's plants at Easton, Pennsylvania and Dallas, Texas, demonstrated no uptake of polonium. No adverse health effects are expected because of the defective static elimination devices, and none have been found.

Cause:

No cause for failure of the static elimination devices has been ascertained. A postulated cause is moisture or solvents in the environment that affect the epoxy adhesive, which holds the radioactive material in the device.

Licensee Action:

(3M Company) - The licensee's investigation of the cause of the failures and possible corrective actions continues. The licensee is carrying out the requirements of the below described NRC Orders.

General Licensees - Plants where contamination has been found have been, or are being, cleaned up and returned to production. All 3M Company devices are being returned to the manufacturer (except as permitted by the February 18, 1988 NRC Order described below). As of mid-April 1988, about half of all static elimination devices have been returned to the 3M Company (this includes 86% of the devices used in food, beverage, pharmaceutical, and cosmetic applications). Of the devices returned, 1.84% had leakages greater than 0.005 microcuries.

UPDATE - 3M Actions: On April 28, 1988, 3M sent a followup letter to those customers (general licensees) that had not yet

returned their devices in accordance with the Order of February 18, 1988. General licensees that then did not return their devices were followed up further by 3M with additional letters and telephone calls.

3M surveyed each returned device. Those devices found to be leaking were reported to the NRC or Agreement State having jurisdiction and to the customer. Followup surveys are being made at the facilities with leaking devices to ensure that contamination has been detected and removed.

Section V of the NRC Order of February 18, 1988, required 3M, within 60 days, to show cause why License No. 22-00057-32G should not be revoked in its entirety and why License No. 22-00057-06 should not be revoked to the extent that it authorizes manufacturing of static elimination devices containing polonium-210. The due date was subsequently extended to July 18. On February 18, 1988, 3M submitted its response to the "Show Cause" portion of the Order. That response is now under evaluation by the NRC.

NRC Action:

On January 25, 1988, the NRC ordered the 3M Company to suspend distribution of Models 902, 902F, 906, and 908 devices; to inform users of these devices of the problem discovered by Ashland; to survey a suitable sample of users to ascertain the extent of the problem; and to determine the cause of the failure of the devices (Ref. 15). On February 5, 1988, the NRC issued a confirmatory order, confirming the 3M Company's commitments to remove all devices with the above model numbers from applications related to the packaging of food, beverages, cosmetics, and pharmaceuticals (Ref. 16). On February 12, 1988, the NRC ordered the 3M Company to remove all static elimination devices (not just the 900 series) from all applications relating to the production and packaging of food, beverage, cosmetics, and pharmaceuticals (Ref. 17). These actions were coordinated with the FDA.

On February 18, 1988, the NRC ordered the 3M Company to suspend transfer of all static elimination devices using Po-210; to instruct users of the devices to return them to the 3M Company; to test returned devices for leakage and report any leakage to the NRC (or Agreement State) and the user; and to report the status of these activities to the NRC every 30 days (Ref. 18). The February 18, 1988 NRC letter also ordered all general licensees using the 3M Company static elimination devices to suspend use of the devices and to return them to the 3M Company as soon as feasible but no more than 90 days from the date of the Order. An exception was made for continued use of the devices, under certain conditions, for applications where use of the device is essential for work place safety (e.g., where static electricity may pose a significant fire, explosion or other hazard). On April 13, 1988, the NRC Order of February 18, 1988 was modified to allow the 3M Company to respond to the show cause order by July 18, 1988.

The NRC actions were coordinated with the Agreement States. As of March 25, 1988 (the latest date, as of April 30, 1988, for which an estimate of total Agreement State efforts are available) the Agreement States have applied 8,224 professional staff-hours (equivalent to about 4.5 full-time staff persons) to conduct on-site surveys of facilities identified as possessing these sources. The Agreement States took appropriate enforcement actions when contamination was found, and their survey data were incorporated into the NRC database which served as a basis for NRC enforcement decisions.

Many of the non-Agreement States assisted NRC by surveying NRC generally licensed users of these devices at NRC's request and their survey data were also used by NRC in assessing the scope of the problem.

The International Atomic Energy Agency (IAEA) and regulatory and safety authorities in 44 countries were advised through the Department of State's cable system and directly via airmail of NRC concerns and subsequent actions related to the 3M static elimination devices. The IAEA and the safety contacts in all 44 countries received copies of NRC orders and background material on the defective devices in two separate mailings, dated February 12 and 19, 1988. Subsequent mailings also were sent to update the IAEA and foreign safety contacts on developments in this area. On March 31, 1988, to prevent further exports of the defective devices, NRC issued an order confirming that 3M would not be permitted to export any polonium-210 static elimination devices under the general license for export in 10 CFR Part 110.

Future reports will be made as appropriate.

UPDATE: from NUREG-0090, Vol. 11, No. 3, page 17. NRC inspectors performed a Special safety inspection of the 3M Company (3M) from January 25 through April 29, 1988, in response to the identification of polonium-210 contamination at Ashland Chemical Company. The results of this inspection are documented in Inspection Report Nos. 030-04971/88-1 and 030-04951/88-1, which were forwarded to the licensee on July 1, 1988 (Ref. 8-14). On April 27-29, 1988, NRC inspectors conducted an inspection to ascertain the extent to which 3M was complying with the Orders of January 25, February 5, 12, and 18, 1988 (Refs. 15, B-16, B-17, and B-18, respectively). The results of this inspection are documented in Inspection Report No. 030-04971/88-2 which was forwarded to the licensee on June 16, 1988 (Ref. B-19). No violations were identified. On June 14-17, 1988, an inspection was made of 3M radioactive products other than the polonium static elimination devices. The results of the inspection are documented in Inspection Report Nos. 030-04951/88-1, 030-04971/88-1, and 030-10825/88-1, which were forwarded to the licensee on August 19, 1988 (Ref. B-20).

Based on the latter inspection effort, a Confirmatory Action Letter (R III-CAL-88-016) was issued on June 21, 1988 (Ref. B-21). The letter suspended distribution by 3M, under certain conditions, of Model 703 static meters containing tritium and medical sources containing cesium-137 until the licensee improved certain operating practices and properly instructed operating personnel. On August 1-5, 1988, a team inspection was made with representatives of state and other federal agencies. The report for that inspection was issued on September 21, 1988. The team inspection revealed only minor violations.

Surveys were conducted by NRC inspectors at a sample of plants that had been stated by 3M or its contractor to be free of

polonium-210 contamination. These surveys confirmed that the 3M follow-up had been adequately done.

The NRC, through a contract with Brookhaven National Laboratory, has produced a report, "Failure Investigation of 3M Series 9 Static Elimination Devices," NUREG/CR-5145, published July 1988 (Ref. B-22). A subsequent report, now in preparation, will present the results of investigation of selected 3M static elimination devices manufactured prior to 1984, the year that 3M made certain design and processing changes to the devices.

UPDATE from the Report to Congress, April-June 1990.

The NRC staff proposed a \$160,000 fine for willful violations of NRC requirements associated with the leakage of polonium-210 from static elimination devices manufactured and distributed by 3M (Ref. B-1). The enforcement action was based on inspection conducted by the NRC staff in 1988 and an investigation in 1988 and 1989 by the agency's Office of Investigations. The case was reviewed by the U.S. Attorney in Minneapolis, Minnesota, and that office decided not to undertake prosecution in lieu of the civil sanctions proposed by the NRC.

As a result of the contamination resulting from leakage of the devices, in 1988 the NRC staff issued a series of four Orders requiring recall of all 3M static elimination devices and prohibiting further distribution. The company was subsequently permitted to perform research and development work on the design of the device, but the prohibition of distribution remains in effect.

While there was a significant potential for unnecessary and widespread contamination, the radioactive material was in a form that made it unlikely that any person received a significant radiation exposure or that consumer products were significantly contaminated by the radioactive material.

The NRC investigation and inspection concluded that 3M personnel willfully failed to assure that customers would use the static eliminators in acceptable environments and that the company failed to determine properly the amount of radioactive contamination on static elimination devices returned to the company by its customers. An \$80,000 fine was proposed for these two violations.

A second \$80,000 fine was proposed for four additional violations: the failure of 3M to identify all results of testing and evaluation of returned static eliminators classified by 3M as damaged in annual reports submitted to the NRC for 1986 (violation 1) and 1987 (violation 2); the failure of the company to notify all of its customers (violation 3) and to follow up with its customers (violation 4) if return of damaged leak detectors after it had determined that some returned static elimination devices had removable radioactive contamination on surfaces in excess of NRC limits.

No fine as assessed for a seventh violation: the failure to obtain NRC review and approval for changes in components in static elimination devices distributed between 1983 and 1988.

The NRC Office of Investigations concluded that one 3M employee: (1) willfully failed to notify 3M's customers of leaking static eliminators, and (2) willfully failed to provide information to the NRC staff. Two more employees likely failed to make accurate reports to the NRC staff and likely demonstrated a careless disregard for the agency's requirements. A fourth employee failed to become familiar with NRC reporting requirements and, as a result, also submitted inaccurate information to the NRC staff.

The enforcement action (Ref. B-1) also included a "Demand for Information" to assist in determining if there is a reasonable assurance that 3M's licensed activities would be conducted in compliance with agency requirements if these four individuals are associated with NRC-licensed activities.

This item is considered closed for the purposes of this report.

Other Agency Action:

UPDATE - Return of Devices by General Licensees.

It is estimated that, prior to this problem, 3M had distributed as many as 50,000 devices. As of September 2, 1988, all devices used in food, beverage, cosmetic, and pharmaceutical applications had been returned except for a few devices that cannot be located. Of those returned, about 1.9% were found to have leakage less than 5 nanocuries and 4.7% had leakage exceeding 5 nanocuries. Of the devices in other applications, about 4500 devices had not been returned as of early November 1988.

Samples of products made using the 3M devices were taken by the NRC, Agreement States, and the U.S. Food and Drug Administration. No confirmed evidence of product contamination was found in any of the samples. Urinalyses from workers in contaminated plants indicated no health problems.

By May 18, 1988, a majority of devices had been returned for testing and evaluation. Review of the information on these devices indicated to the NRC that the potential health and safety hazards for uses of the devices not involved with food, beverage, pharmaceuticals, or cosmetics were not as extensive as initially considered possible. Devices still possessed by customers were continuing to undergo radioactive decay, reducing the amount of polonium-210 in the devices. In addition, replacement devices were in short supply preventing the replacement of 3M devices without causing severe hardship. Thus, on May 18, 1988, the NRC issued a notice that permitted licensees to retain their devices until the expiration of their leases. (Leases were for a one-year term.) After this notice was issued, the rate of return slowed considerably.

UPDATE: Action at Contaminated Sites

Surveys have been made at all plants from which returned devices were found to be leaking. Where contamination was found, general licensee (device user) was required to have the plant cleaned up until a survey showed that it was free of contamination. 192 plant sites identified as having actual or potential contamination, all but 10 have now been cleared for unrestricted use. Most of these 10 have been decontaminated, but reports of the final surveys have not yet been received.

UPDATE: Exceptions for Continued Use on the Basis of Workplace Safety.

Prior to the notice of May 18, 1988, requests from 10 companies desiring authorization for continued use were denied because they claimed, but failed to show, that the devices were essential to safety. On the other hand, 52 companies were granted authorization for continued use because the devices were essential to workplace safety. Five companies transferred authorization for possession and use of their devices from their general license to a specific license.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 12 of "For All Licensees") of this report notes that a series of events (where individual events are not of major importance) and incidents with implications for similar facilities (generic implications), which create a major safety concern, can be considered an abnormal occurrence. In addition, the first general criterion notes that a moderate release of radioactive material licensed by otherwise regulated by the Commission can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 88-07 EVENT DATE: 02/04/1988

TITLE: THERAPEUTIC MEDICAL MISADMINISTRATION

NAME: Medical X-Ray Center CITY: Sioux Falls STATE: SD

Nature and Probable Consequences:

A patient was administered 7.5 millicuries of phosphorus-32 (as sodium phosphate) instead of 4.0 millicuries of the same radiopharmaceutical prescribed by the physician.

The purpose of the administration was to treat polycythemia vera (excess blood red platelets). As a result of the misadministration the patient received a dose of about 270 rads and 75 rads to the bone marrow and whole body, respectively, instead of about 14 rads and 40 rads, respectively, had the prescribed amount of pharmaceutical been administered. There were no apparent effects to the patient. The licensee reported that blood counts will be followed for several weeks post-therapy and that the last report of February 16, 1988, showed normal blood elements.

Cause:

The misadministration was caused by a miscalculation of the dose by the technician.

Licensee Action:

The technician administering the dose was re-instructed in the proper technique for calculating therapy doses and for reviewing written physician orders prior to administering the doses.

NRC Action:

NRC Region IV telephoned the radiation safety officer reporting this misadministration for additional information and assurance corrective action had been taken. The incident will be reviewed during the next NRC inspection at the medical center.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 88-08	EVENT DATE:	02/15/1988
TITLE:	THERAPEUTIC MEDICAL MISADMINISTRATION				
NAME:	St. Joseph's Hospital	CITY:	Milwaukee	STATE:	WI

Nature and Probable Consequences:

On February 23, 1988, NRC Region III was notified by the licensee that an 86-year old patient with a 10-year history of bladder cancer received a cobalt-60 therapeutic radiation dose of 2000 rads to the wrong side of his pelvis.

On January 19, 1988, the patient was admitted to the hospital with severe right rib pain. A CAT scan of his abdomen (January 2) a bone scan (January 25) and a mid-spine and pelvic scan (January 28) confirmed the patient had a metastatic cancer. The Radiation Oncologist determined that two local areas should be treated, the spine and the left pelvis. Beginning February 3, 1988 the licensee commenced treating the patient with cobalt-60 with a prescribed dose of 5000 rads to the spine (20 treatments of 250 rads each) and 4000 rads to the pelvis (20 treatments of 200 rads each).

On February 15, after 10 treatments totaling 2000 rads, the Dosimetrist became suspicious that an error had been made and that the wrong side of the patient's pelvis (the right side) had been treated. This was confirmed on February 16 by the Radiation Oncologist. The patient and referring physician were notified, and treatment on the left side of the pelvis was begun the following day.

In evaluating the event, the licensee said the patient had "documented bone destruction of the dorsal spine and left pelvis, and therefore, it is most probable there is disease throughout all the pelvic areas. The patient also had reported right side pain prior to the therapeutic treatment. Therefore, the dose given to the palliative right pelvis, rather than having caused him harm, could be considered prophylactic treatment."

In a report to NRC Region III dated March 9, the licensee said it was unclear whether the right-side treatment was "inadvertent or a conscious decision due to a misread of the bone scan." According to the referring physician, the patient exhibited no adverse aftereffect as a result of the misadministration.

Cause:

The event is attributed to personnel errors and inadequate procedures. The radiation therapist had prescribed treatment to the dorsal spine and left pelvis. However, a therapy technologist set the patient up and marked the right pelvis. Neither the physicist who performed the dose calculations, or the chief technologist, who performed the treatment, noted the discrepancy between the treatment plan and the prescription. In addition, the dosimetrist, while performing a weekly chart check, failed to notice the error. About 10 days later, the dosimetrist again performed a chart check and noticed the discrepancy. She brought this to the attention of the physicist, who then discussed it with the radiation therapist. Treatment to the right pelvis was terminated at 2000 rads.

Licensee Action:

The licensee agreed to develop and implement procedures which require its staff to thoroughly review all aspects of therapy prescriptions and treatment parameters when the following events occur: (1) during the initial dose calculations, (2) just prior to initial treatment, and (3) during weekly chart checks.

NRC Action:

A region-based inspector went to the hospital to review the incident on March 3 and 4, 1988. The NRC also retained an NRC medical consultant to review the misadministration. In the meantime, Region III conferred with the licensee on corrective action and the licensee agreed to the above procedural changes. In a letter confirming the licensee's course of action dated March 10, 1988, Region III also requested that the procedural changes be formalized as a license amendment (Ref. 19).

On April 14, 1988, a Notice of Violation was issued to the licensee; the therapy misadministration had not been reported to the NRC Regional Office until seven days after discovery, contrary to 10 CFR 35.33(a) which requires telephone notification within 24 hours.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 040611 AO #: AS 04-08 EVENT DATE: 07/01/2004
TITLE: Therapeutic Medical Event at Southern Regional Medical Center in Riverdale, Georgia
NAME: Southern Regional Medical Center CITY: Riverdale STATE: GA

Nature and Probable Consequences:

The licensee informed the Georgia Department of Natural Resources (GDNR) that a patient received 3.7 GBq (100 mCi) of I-131 instead of the prescribed dose of 0.64 GBq (17.3 mCi). Three patients were scheduled for I-131 treatments on the same day. An inpatient was scheduled to receive 3.7 GBq (100 mCi), and two outpatients were scheduled to receive less than 1.2 GBq (33 mCi). One of the outpatients was mistakenly injected with the 3.7 GBq (100 mCi) dose intended for the inpatient and was also allowed leave the facility without receiving proper instructions. The licensee did not discover the error until after the patient had left the facility with her children. The authorized user who signed the written directive was at the facility when the dose was administered. The temporary RSO was at South Fulton Hospital, but was notified of the event. The patient and referring physician were immediately notified of the event by the licensee. The GDNR received a report from the licensee's medical physicist consultant estimating the dose to the patient's children was 0.5 mSv (0.05 rem), with a maximum possible dose of 1.0 mSv (0.1 rem). The radiation should not have any effects on the patient's children or other individuals. The medical significance to the patient is the possibility of developing hypothyroidism which would require thyroid medication.

Cause:

This event was attributed to human error. The wrong patient was administered a therapeutic dose of I-131 that was prescribed for someone else.

Licensee Action:

The licensee discussed the incident with all technicians who prepare and administer I-131, revised nuclear medicine protocols pertaining to the therapeutic use of I-131 and patient instructions, and revised procedures to incorporate better practices to prevent this type of error from recurring.

NRC Action:

Other Agency Action:

The State agency reviewed and approved the corrective actions that the licensee implemented to prevent recurrence.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and is a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 040003 AO #: AS 04-09 EVENT DATE: 12/22/2003

TITLE: Intravascular Brachytherapy Medical Event at Ireland Cancer Center in Middleburg Heights, Ohio.

NAME: Ireland Cancer Center CITY: Middleburg Heights STATE: OH

Nature and Probable Consequences:

The licensee reported that a patient received a radiation dose to an unintended site 3 cm proximal to the prescribed treatment site during an intravascular brachytherapy (IVB) treatment procedure. The dose delivered to the unintended site was approximately 18.40 Gy (1,840 rads). The event involved an IVB device that used a 3.5-mm catheter and a source train that contained Sr-90 with an activity of 2.0 GBq (53.8 mCi). The source train traveled to a location approximately 3 cm proximal to the intended treatment site. It was determined that there was a kink in the delivery catheter, which kept the source train from traveling to the correct site. The kink was not substantial enough to affect the flow of sterile water used to send and retrieve the source train. The kink was discovered the following day during medical physics quality checks. The referring physician and patient were notified of the event. According to the licensee, no adverse effects are expected.

Cause:

The cause of the event was determined to be a kink in the delivery catheter, which kept the source train from traveling to the correct site.

Licensee Action:

Corrective actions incorporated by the licensee included additional films taken during procedures to verify the placement of the catheter. When there is any doubt of the placement of the catheter, the treatment will be aborted. The treatment team will then evaluate whether to attempt treatment with a different catheter.

NRC Action:

Other Agency Action:

The Ohio Department of Health conducted an investigation, reviewed the licensee's corrective actions, and found them adequate to prevent recurrence.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 951311 AO #: NRC 96-18 EVENT DATE: 12/08/1995
TITLE: Radiopharmaceutical Misadministration at Queen's Medical Center
NAME: Queen's Medical Center CITY: Honolulu STATE: HI

Nature and Probable Consequences:

A patient was prescribed a dosage of 18.5 megabecquerel (MBq) (0.5 millicurie [mCi]) of phosphorus-32 (P-32) to be administered to the wrist for treatment of symptoms related to rheumatoid arthritis, but was administered 6.179 MBq (0.167 mCi) instead. The dosage was administered via a saline solution.

Prior to treatment, the volume of the patient's wrist-joint space was to be determined using fluoroscopy so that the proper volume of liquid would be injected. Also, two syringes were to be prepared. One was to contain 18.5 MBq (0.5 mCi) of P-32 in a 0.25 milliliter (ml) volume, and the other was to contain 18.5 MBq (0.5 mCi) of P-32 in a 0.5 ml volume. The appropriate syringe was to be chosen based upon the results of the fluoroscopy.

Because of poor communication, a technologist erroneously prepared one syringe containing 6.179 MBq (0.167 mCi) in a 0.25 ml volume and another syringe containing 12.32 MBq (0.333 mCi) in a 0.5 ml volume. The syringes were not labeled.

Based upon the results of the fluoroscopy, the administering physician chose the syringe with the 0.25 ml volume, believing that it contained 18.5 MBq (0.5 mCi) of P-32. However, the 0.25 ml volume contained only 6.179 MBq (0.167 mCi), which was one-third of the intended dosage. After the administration, the technologist who prepared the dosages asked why both syringes had not been used and explained how they were prepared.

The patient was notified of the misadministration in writing.

The two physicians involved with the misadministration have not observed any adverse health effects to the patient, and do not expect any. NRC determined that a medical consultant would not be required to review the case.

Cause:

The details of the prescribed dosages were not properly communicated to the technologist who prepared the two syringes, the details were not independently confirmed by other licensee personnel, and the written procedure for preparing the dosages did not specify multiple syringe volumes.

Licensee Action:

The licensee now requires the prescribing physician to establish a standard activity and volume for each treatment site, and the injecting physician to verbally repeat this information and ask the technologist to verbally confirm it prior to the administration.

NRC Action:

NRC conducted a special inspection and issued a Notice of Violation for deficiencies in the Quality Management Program.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

Appendix A (see Event Type 5[b]) of this report notes that administering a therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent, and the actual dose is less than 0.5 times the prescribed dose, can be considered a significant AO.

ITEM #:	960163	AO #:	AS 96-01	EVENT DATE:	03/05/1996
TITLE:	Stolen Cobalt-60 Radiography Cameras				
NAME:	Larpen of Texas	CITY:	Houston	STATE:	TX

Nature and Probable Consequences:

Larpen of Texas (Larpen) was a radiography company that owned two cobalt-60 (Co-60) radiography cameras. The Co-60 sources in the cameras had activities of 1.31 terabecquerel (TBq) (35.3 curie [Ci]) and 0.32 TBq (8.6 Ci) respectively. Larpen provided radiography services to a steel-manufacturing company at the company's 37-acre site.

When the steel-manufacturing company went bankrupt, the Texas Department of Health Bureau of Radiation Control (TDH/BRC) issued orders to Larpen in October 1992 to stop operating, and ordered all of its radioactive sources to be impounded in place. Larpen subsequently filed for bankruptcy and its name was consequently changed to Many Diversified Interests, Inc. (MDI), in compliance with the law. Upon learning of the MDI bankruptcy, TDH/BRC verified that the Co-60 radiography cameras were secured in a building on the site.

TDH/BRC wrote to the bankruptcy court on June 24, 1994, and to the trustee for bankrupt MDI on July 11, 1994, to request that Co-60 radiography cameras be properly disposed of, but no actions were taken. On July 29, 1994, TDH/BRC formally notified the bankruptcy court, through the Texas Attorney General's Office, that it was a creditor and party of interest in the bankruptcy of MDI. TDH/BRC then ensured that the Co-60 radiography cameras were secure in an on-site building and that the metal door to the building was welded shut.

During the period of March 1995 to January 1996, all structures on the site were demolished and all salvageable equipment was sold, with the exception of the building containing the Co-60 radiography cameras. When the salvage company vacated the site the site had no security and people removed anything of value that could be sold as scrap. TDH/BRC consequently notified the bankruptcy court of its concern about the security of the Co-60 radiography cameras.

On February 27, 1996, three thieves broke into the building containing the Co-60 radiography cameras by removing the metal door that had been welded shut, stole the cameras, and sold them to a scrap yard. The scrap yard then sold them to an intermediary dealer who sent them to a recycling facility. The recycling facility refused to accept the cameras because they were radioactive, and the intermediary dealer consequently returned them to the scrap yard by truck. When the cameras arrived at the scrap yard the 1.31 TBq (35.3 Ci) Co-60 source, which was accidentally unshielded while in transit, was thrown to the ground by the delivery man and forgotten. The scrap yard resold the cameras to other scrap yards. However, no one at the scrap yard knew that the unshielded Co-60 source was lying on the ground. The unshielded source lay on the ground for 100.5 hours until it was located by TDH/BRC on March 5, 1996. TDH/BRC also located the other camera on the same day. Both cameras and their Co-60 sources were then secured at an authorized disposal company. After the sources were recovered and secured, the trustee for bankrupt MDI had to obtain permission from the bankruptcy court for the disposal company to dispose of the cameras.

The unshielded Co-60 source irradiated scrap yard workers and the scrap-yard manager's two small children. The delivery man who touched the source received radiation burns to the thumb and middle finger of his right hand. Five police officers who investigated the theft of the cameras were also irradiated by the source. Two TDH/BRC personnel who located and secured the source received doses of 1.5 millisievert (mSv) (150 millirem [mrem]) and 5.2 mSv (520 mrem) respectively.

TDH/BRC estimated the possible radiation doses that were received by the individuals who were exposed to the unshielded Co-60 source. Since the estimates indicated that the doses may have been as high as 600 mSv (60 rem), the scrap yard workers, the children, the policemen, and the thieves had their blood tested to determine their doses. Cytogenetic studies by the Department of Energy's Radiation Emergency Assistance Center/Training Site in Oak Ridge, Tennessee, determined that their doses were less than 100 mSv (10 rem). Also, the doses to the general public conducting business at the scrap yard were determined to be less than 5.0 mSv (500 mrem).

The three thieves were arrested for stealing the cameras and the owner, manager, and manager's wife of the scrap yard were arrested for receiving stolen goods.

Cause:

The devices were stolen from a facility where they were being stored by TDH/BRC after a licensee went bankrupt. TDH/BRC has severely limited jurisdiction over radiography sources in cases where a licensee declares bankruptcy and any action must be taken through the bankruptcy court.

Licensee Action:

The licensee is in bankruptcy and is no longer a viable company. All assets of the company are handled by a trustee appointed by the bankruptcy court. The cameras and sources are being disposed of by the trustee.

NRC Action:

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Other Agency Action:

TDH/BRC is trying to determine if there are requirements and controls that can be placed on the trustees of bankrupt companies possessing radioactive materials. TDH/BRC is also participating in a working group composed of representatives from the Nuclear Regulatory Commission and other Agreement States to review the loss of control of radioactive sources, with emphasis on bankruptcy situations.

This event is closed for the purpose of this report.

Criteria:

Appendix A (see For All Licensees, Example 6) of this report notes that a substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility should be considered an AO.

ITEM #: 951155 AO #: AS 96-02 EVENT DATE: 09/15/1995
TITLE: Rupture of a Source Owned by Little Bit Wireline
NAME: Little Bit Wireline CITY: Winnie STATE: TX

Nature and Probable Consequences:

An 111,000 megabecquerel (MBq) (3 curie [Ci]) americium-241/beryllium source owned by Little Bit Wireline was found to be leaking after it was recovered from an oil well near Winnie, Texas, where it had been stuck. The Texas Department of Health, Bureau of Radiation Control (BRC), was notified of the event. BRC subsequently found that the radiation level of the leaking source was 10 microsievert per hour (1 millirem per hour), and that the well site and associated equipment were contaminated.

BRC reported the event to NRC, and asked for assistance from the Department of Energy (DOE). DOE subsequently transported the leaking source to Los Alamos National Laboratory where it was determined that the remaining source activity was approximately 37,000 MBq (1 Ci).

DOE was also asked to evaluate 10 individuals, including the licensee, for internal contamination. The individuals were sent to the Oak Ridge Institute for Science and Education (ORISE) for whole body scans and urinalysis. ORISE determined that the whole body scans and urinalysis for the individuals were negative, and that there was no reason to believe that anyone had received a significant internal exposure.

Cause:

It is believed that there are two ways in which the source may have been ruptured. The first is that it was ruptured by a milling tool which was used to recover it. The second is that it was lodged between the oil well casing and another assembly known as a "screen and liner" which had also become stuck, and was ruptured during operations to recover the "screen and liner."

Licensee Action:

The licensee's facility was contaminated by the ruptured source and access to it has been restricted. The licensee is no longer performing well logging.

NRC Action:

Other Agency Action:

BRC ordered the licensee and affected companies to restrict access to the contaminated equipment and land, to characterize the contamination, and to decontaminate the equipment and land. Further enforcement action is pending.

This event is closed for the purpose of this report.

Criteria:

Appendix A (see For All Licensees, Example 10) of this report notes that a major deficiency in design, construction, or operation having safety implications requiring immediate remedial action should be considered an AO.

ITEM #: 951169 AO #: AS 96-03 EVENT DATE: 10/03/1995

TITLE: Release of Radioactive Material in Lemont, Illinois, from a Package that Was Accidentally Destroyed While Being Transported by Associated Couriers of Maryland Heights, Missouri

NAME: Associated Couriers CITY: Lemont STATE: IL

Nature and Probable Consequences:

A spent nuclear medicine generator containing approximately 666 megabecquerel (18 millicurie) of molybdenum-99/technetium-99m fell from a moving delivery van operated by Associated Couriers of Maryland Heights, Missouri. It was then struck by an unidentified vehicle and destroyed. The contamination that was released was spread on both lanes of the roadway by a sudden and the spray from moving vehicles.

A Radiological Assessment Team from Argonne National Laboratory was the first to arrive at the scene of the accident. The team transferred control of the scene to representatives of the Illinois Department of Nuclear Safety (IDNS) when they arrived, but remained at the scene to assist the IDNS representatives. The roadway was decontaminated to a near surface dose rate of 3 microsievert per hour (0.3 millirem per hour), at which time it was reopened. Since no contamination migrated from the roadway doses to members of the public were negligible. Doses to emergency workers were significantly below regulatory limits. (It should be noted that even though the licensee [Medi-Physics, Inc.] was not responsible for the event, its personnel were at the scene to collect all debris and decontamination materials for transport to its facility.)

Cause:

The event was caused by the failure of the driver of the delivery van to secure the rear door of the van. The package fell out of the van when the door opened.

Licensee Action:

The licensee for the spent nuclear medicine generator was not responsible for the accident, and consequently was not required to take corrective action. It is not known if the carrier, Associated Couriers, took any corrective action.

NRC Action:

Other Agency Action:

Since this was a violation by a moving vehicle on a public roadway, enforcement action was brought against the carrier by the Illinois Department of Transportation (IDOT), based on information supplied by IDNS. IDOT assessed a civil penalty of \$2,700 and received full payment of the penalty on December 14, 1995.

Since this was the first violation on record by this carrier, no further action was taken. An order may be issued in the future for recovery of response costs, but no further punitive penalty is anticipated.

This event is closed for the purpose of this report.

Criteria:

Appendix A (see For All Licensees, Example 11) of this report notes that serious deficiency in management or procedural control in major areas should be considered an AO.

ITEM #: 960069 AO #: AS 96-04 EVENT DATE: 01/31/1996
TITLE: Lost Source at Deseret Generation and Transmission Cooperative's Bonanza Power Plant
NAME: Deseret Generation and Transmission Cooperative CITY: Vernal STATE: UT

Nature and Probable Consequences:

A 370 megabecquerel (10 millicurie) cesium-137 source was found to be missing from its housing. The source was part of a KayRay/Sensall Model 7062 BP fixed density gauge which was mounted to a fly ash chute. The gauge had been in service since October 18, 1984.

False signals from the gauge started to appear on January 9, 1996, the day after a vibrator was attached to the fly ash chute. Several attempts were made to identify and correct the problem from January 9 until January 31, 1996, when it was discovered the source-housing shutter mechanism was broken and the source was missing.

Several people tried unsuccessfully to find the source by systematically searching the plant site using radiation detection survey instruments. Consequently, five persons may have received an exposure to radiation. However, it is highly improbable that any received a measurable level of exposure.

Cause:

The licensee believes that the vibrator which was attached to the fly ash chute on January 8, 1996, was probably responsible for destroying the source-housing shutter mechanism and precipitating the loss of the source.

Licensee Action:

To prevent recurrence, the licensee modified its radiation protection program to require that a semi-annual check be made to verify that the source is in its housing; that vibration isolators be used to mount the source housing; and that the source housing be positioned so that the opened shutter block lays on the bottom of the housing.

NRC Action:

Other Agency Action:

The Utah Division of Radiation Control notified the Illinois Radiation Control Program of the event involving KayRay/Sensall, a gauge manufacturer, licensed in the State of Illinois. The Illinois Radiation Control Program is taking action with its licensee (KayRay/Sensall) regarding the possibility of any generic issues. The State of Utah is continuing its investigation and plans to follow-up at the next inspection of its licensee (Deseret Generation and Transmission Cooperative's Bonanza Power Plant), which was advanced because of this event.

This event is closed for the purpose of this report.

Criteria:

Appendix A (see For All Licensees, Example 10) of this report notes that a major deficiency in design, construction, or operation having safety implications requiring immediate remedial action should be considered an AO.

ITEM #: 960171 AO #: AS 96-05 EVENT DATE: 03/12/1996
TITLE: Brachytherapy Misadministration at Duke University Medical Center
NAME: Duke University Medical Center CITY: Durham STATE: NC

Nature and Probable Consequences:

A patient was prescribed a dose of 650 centigray (cGy) (650 rad) to the bronchus using an Omnitron 2000 high dose rate (HDR) remote afterloading brachytherapy unit having an iridium-192 source. The HDR unit was to be used with a catheter that was 150.25 centimeter (cm) (59.15 inch) long. However, during patient setup, the wrong catheter-length value of 125.25 cm (49.31 inch) was entered into the HDR's computer treatment planning software.

Upon completion of the treatment, the attending physician recognized the misadministration and notified the radiation oncologist the error. The patient and the referring physician were then notified by the radiation oncologist.

Since the catheter length entered into the HDR's computer treatment planning software was 125.25 cm (49.31 inch), and a 150. cm (59.15 inch) long catheter was attached to the HDR, the source did not completely traverse the length necessary to treat the bronchus with 650 cGy (650 rad). As a result, the wrong treatment sites received unplanned exposure; the right cheek received to 130 cGy (90 to 130 rad) and the right eye received 35 to 50 cGy (35 to 50 rad). The radiation oncologist anticipates no short long term health effects from the misadministration.

Cause:

The misadministration was caused by human error. The wrong catheter length was entered into the HDR's computer treatment planning software.

Licensee Action:

To prevent recurrence, the licensee added redundancy to its internal checklists to verify that the correct catheter length is entered into the HDR's computer treatment software.

NRC Action:

Other Agency Action:

The State Agency agrees with the licensee's action to prevent recurrence.
This event is closed for the purpose of this report.

Criteria:

Appendix A (see Event Type 1 in Table A-1) of this report notes that a therapeutic exposure which results in any part of the body receiving unscheduled radiation should be considered an AO.

ITEM #:		AO #:	NRC 88-09	EVENT DATE:	02/26/1988
TITLE:	SIGNIFICANT WIDESPREAD BREAKDOWN IN RADIATION SAFETY PROGRAM AT CASE WESTERN RESERVE UNIVERSITY RESEARCH LABORATORIES				
NAME:	Case Western Reserve University	CITY:	Cleveland	STATE:	OH

Nature and Probable Consequences:

This occurrence addresses licensee performance over a period of time until February 26, 1988, when the NRC proposed impose a \$10,000 fine on Case Western Reserve University, Cleveland, Ohio.

The proposed fine was for numerous violations of NRC requirements in the licensee's radiation safety program for its research laboratories, indicating a significant breakdown in its management control program (Ref. 20). The violations were in the licensee's research programs, not medical care and treatment of patients. The circumstances associated with the enforcement action are follows:

On November 8, 1987, the NRC Region III office received a news media inquiry concerning the radioactive contamination of a research laboratory at Rainbow Babies and Children's Hospital in Cleveland, Ohio. The laboratory, although located at the hospital, was under the NRC license of Case Western Reserve University. Telephone discussions on November 9, 1987 with the licensee determined that a licensee consultant had identified tritium and carbon-14 contamination in the laboratory (Diabetes Laboratory) that it was being decontaminated.

It was learned later, through subsequent telephone conversations with the licensee, that the contamination in the laboratory was more widespread than initially found. On November 17, 1987, the NRC began an inspection to review the circumstances of the contamination and to determine if the problems associated with the laboratory were indicative of additional problems at other licensee laboratories.

The initial and subsequent NRC inspections during November and December 1987 identified about 20 violations of NRC requirements, involving the training of laboratory personnel, radiation safety practices, and control and oversight of the laboratory using radioactive materials. Several of the violations (i.e., failure to calibrate radiation survey instruments, failure to perform a contamination survey, failure to perform leak tests of sealed radiation sources, and evidence of food and beverage consumption laboratories) were similar to violations identified during a May 1986 NRC inspection at the licensee's facilities. Therefore, the licensee's corrective actions, taken following the 1986 inspection, were insufficient to prevent a recurrence of the violation.

Based on the inspection findings, it appeared that the University was unable to keep track of the number of laboratories engaged in licensed activities, was not controlling the required training of workers handling radioactive materials, and was unable, through its radiation safety committee, to assure compliance with NRC requirements and license commitments. The latter became evident when the University found it necessary to contract with an outside consultant to perform required radiation surveys and audits which the University radiation staff could not complete in a timely manner. (It was a survey performed by the consultant which initially identified the contamination of the Diabetes Laboratory.)

In regard to the Diabetes Laboratory, the inspection indicated that no single incident appeared to have contributed to the contamination; rather the widespread, low-level contamination in the laboratory was caused by inadequate handling procedures (technicians had not been adequately trained) and a lack of contamination surveys. There is no evidence that any workers or members of the public received a significant radiation exposure as a result of the contamination incident or of the violations of the licensee's radiation safety program. Bioassay tests on the two Diabetes Laboratory technicians showed no detectable indication of ingestion or inhalation of radioactive material.

Cause:

The failure to adequately correct past violations identified in a May 1986 inspection, as well as the numerous violations identified during the November-December 1987 inspections, demonstrated a serious, widespread breakdown in the management of the licensee's radiation safety program.

Licensee Action:

The licensee conformed to the various NRC actions described below. Following suspension of all NRC licensed work (which affected about 350 laboratories), the licensee retained an interim Radiation Safety Officer, provided training to laboratory workers and expanded the work of its consultant to review all laboratories for compliance with University and NRC requirements.

Extensive programmatic changes were made to the licensee's radiation safety program. Based on these changes, on December 1987, the NRC authorized the gradual lifting of the suspension as each laboratory was checked and found to comply with NRC requirements. By mid-February 1988, work had been permitted to resume in all laboratories, except for the Diabetes Laboratory. The latter laboratory required final decontamination work before its suspension could be lifted.

During March 1988, the licensee hired a new Radiation Safety Officer to oversee NRC licensed activities.

NRC Action:

When the initial inspection revealed violations of NRC requirements, NRC Region III issued a Confirmatory Action Letter on November 20, 1987, documenting the University's agreement to accelerate its radiation survey program and to direct each laboratory supervisor to assure that the requirements were being followed (Ref. 21).

Based on further inspection findings, a second Confirmatory Action Letter was issued on November 25, 1987, confirming the suspension of NRC licensed work (Ref. 22).

At the time work was authorized to resume on December 8, 1987, the NRC issued a license amendment to include the modifications and improvements to the radiation safety program adopted by the licensee.

On February 26, 1988, the NRC issued to the licensee a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$10,000 for the numerous violations identified during the inspections (Ref. 17). The inspection reports were also enclosed. The violations were categorized as Severity Level II (on a scale in which the most significant and least significant are categorized as Severity Levels I and V, respectively). The base value of a civil penalty for a Severity Level II violation is \$4,000. This was increased to \$10,000 because of the licensee's poor prior performance in their radiation safety program and the failure to take adequate corrective actions subsequent to the identification of violations during the most recent events. The licensee has paid the civil penalty.

The NRC will continue to monitor the licensee's performance through periodic inspections.

This item is considered closed for the purposes of this report.

Other Agency Action:**Criteria:**

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Example 11 of "For All Licensees") of this report notes that serious deficiency in management or procedural controls in major areas can be considered an abnormal occurrence. In addition, the first general criterion of Appendix A notes that a moderate release of radioactive material licensed by or otherwise regulated by the Commission can be considered an abnormal occurrence.

ITEM #:		AO #:	AS 88-01	EVENT DATE:	11/16/1987
TITLE:	RADIATION INJURY TO TWO RADIOGRAPHERS				
NAME:	North Shore X-Ray and Testing Company	CITY:	Houston	STATE:	TX

Nature and Probable Consequences:

On December 8, 1987, the licensee reported to the Texas Bureau of Radiation Control (the Agency) film badge overexposures (whole body) of 5.0 rem and 5.2 rem to a radiographer and a radiography helper, respectively. Based on subsequent follow-up with the Agency and referral of the men to a physician experienced in radiation exposures, it was determined that each man had received a radiation burn to the skin of one ankle. The exposures associated with the burns are estimated to be in the range of 1940 rem. A summary of the Agency's investigation is as follows.

On December 14, 1987, a physician called the Agency to report that the radiographer had a radiation burn to his left ankle. On December 15, 1987, the Agency began the investigation to determine when and how the radiation injury occurred.

Agency investigators interviewed both the radiographer and the radiography helper. Both men had been working as radiographer for a number of years. Neither of the individuals could recall any circumstance that would have resulted in a radiation burn. During the interview, the helper indicated he had observed a reddened area on his right ankle. He later was examined by a physician (the same physician who examined the radiographer) and was also diagnosed as having a radiation burn. Both men indicated noticeable evidence of injury around the first of December, although neither could recall an exact date.

Based on extensive interviews, review of records, and other investigations, the Agency concluded that the exposures had most likely occurred on November 16, 1987. On February 9, 1988, the Agency sent an investigator to attempt to reenact the bench work performed on November 16, 1987. The reenactment was speculative since the radiographer and the helper could not recall details of the work. Set-up times for the work could vary from a few seconds to several minutes. Assuming just a brief contact with the source tube connector, the exposures to each ankle was estimated to be in the range of 860-1940 rem.

Cause:

Evidence indicated that the radiographers were working on the same job at the time of the injuries and, based on the company records, they were working with a 125 curie iridium-192 source. Statements made by the radiographers indicate the survey meter was not in an ideal location to observe a significant radiation field. It is also possible that it was not observed after the source was returned to its shielded position each time. In any case, radiation surveys were not properly conducted after each exposure.

The only explanation for the exposures considering their location, on the right ankle of the helper and the left ankle of the radiographer, is that the source somehow came to an exposed position, probably just inside the outlet nipple, and this was occurring after each exposure or occurred once and the radiographers came in contact with the outlet nipple resulting in the radiation burns, apparently as the men stood on either side of the source tube.

Licensee Action:

The licensee discussed the incident with the individuals and with other employees performing radiography, and stressed the importance of using the survey meter each time the source is cranked out and back in. Management did not feel there was much they could do to prevent these incidents except to stress the use of detection equipment.

NRC Action:

The licensee was cited for allowing the overexposure to occur and for failure to use survey instruments. One of the radiographers passed the radiography qualification exam after the incident occurred and was issued an identification card prior to completion of the investigation. The radiographer has been notified that he may be required to show cause why the identification card should be revoked or suspended, if he violates the Agency's regulations for control of radiation in the future. The identification card is a requirement for qualification as a radiographer in Texas.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

Appendix A (see Example 1 of "For All Licensees") of this report notes that an exposure of the feet, ankles, hands, or forearms of any individual to 375 rem or more of radiation can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 88-10 EVENT DATE: 06/03/1988
TITLE: SIGNIFICANT BREAKDOWN IN MANAGEMENT AND PROCEDURAL CONTROLS IN A MEDICAL FACILITY
NAME: Riverton Memorial Hospital-Health Trust, Inc. CITY: Riverton STATE: WY

Nature and Probable Consequences:

This occurrence addressed licensee performance, leading to an Order Modifying License and Proposed Civil Penalty of \$5,000, issued June 3, 1988, Riverton Memorial Hospital-Health Trust, Inc., Riverton, Wyoming.

During a special unannounced inspection on September 30 and October 1, 1986, in response to an allegation of unauthorized individuals using radioactive materials, an NRC inspector identified nine violations of NRC requirements and substantiated the allegation. An enforcement conference was held November 4, 1986, with members of the licensee's management to discuss the findings of the inspection and the licensee's corrective actions. On January 21, 1987, a Notice of Violation and Proposed Imposition of Civil Penalties (\$2,500) was issued. The licensee requested mitigation of the civil penalties, but mitigation was denied by the NRC. On June 11, 1987, an Order Imposing Civil Monetary Penalty was issued (Ref. 1).

On March 4, 1988, a special, unannounced inspection was performed to assess the effect of the licensee's corrective actions. The NRC inspectors identified eight violations of NRC requirements, of which four were repeated from the previous inspection and three were related to previous findings. The violations involved, (1) an unauthorized use of licensed material, (2) failure to adequately instruct a worker, (3) failure of the Radiation Safety Committee to meet quarterly, (4) failure to notify the Commission within 30 days that authorized users had terminated employment, (5) failure to perform quarterly inventories of sealed sources, (6) failure to have a copy of the license on which a visiting physician was named, (7) failure to make a record of a diagnostic misadministration, and failure to provide all required information on radio-pharmaceutical administration records.

A Confirmation of Action Letter (CAL) was issued March 29, 1988, to confirm, among other things, that the hospital had established controls to preclude the conduct of therapeutic procedures involving licensed materials (Ref. 2). The licensee responded on April 7, 1988, with a copy of a memorandum distributed to all nuclear medicine personnel, which stated that no therapeutic procedures were to be performed.

Another enforcement conference was held April 15, 1988, and on June 3, 1988, the NRC issued an Order Modifying License and Notice of Violation and Proposed Imposition of Civil Penalty for \$5,000 (Ref. 3). The licensee responded, acknowledging the violations and proposing a new plan of corrective action.

Cause:

The causes are attributed to significant deficiencies in management oversight and control of the licensed program.

Licensee Action:

The licensee trained its personnel, including the Radiation Safety Officer. In a letter of May 2, 1988, the licensee committed to setting up a calendar for those parts of its radiation safety program that need to be performed on a regular schedule and committed to a review of the program by the hospital administrator on a monthly basis.

The licensee has committed to hiring a consulting company to audit the hospital's radiation protection program on a quarterly basis.

NRC Action:

The NRC modified the license by order issued June 3, 1988. The order required the licensee to (1) notify the NRC Region IV office by telephone prior to the effective date of any employment termination of any personnel directly involved in the nuclear medicine department's licensed activities, and (2) have audits of the radiation safety program performed by an independent party one year, at quarterly intervals.

The NRC reviewed the licensee's proposed corrective action and approved the use of the consultant. The licensee's program will be reinspected to confirm the implementation and effectiveness of corrective actions.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the third general criterion) of this report notes that major deficiencies in use of, or management controls for, licensed material can be considered an abnormal occurrence. In addition, Example 11 of "For All Licensees" of Appendix A notes that serious deficiency in management or procedural controls in major areas can be considered an abnormal occurrence.

ITEM #: AO #: EVENT DATE:

TITLE:

NAME: CITY: STATE:

Nature and Probable Consequences:

For a bone metabolism, a patient was administered a dose of 15 millicuries of technetium (Tc)-99m DTPA, which exceeded the prescribed dose by a factor of 1000. The misadministration was initially caused by a technologist presenting the wrong dose to resident physician for injection. The resident physician then administered the radioactive material without properly identifying the material or determining the procedure for which it was to be administered.

The licensee stated that no untoward effects on the patient are anticipated. (For comparison purposes, 20 millicuries of Tc-99m DTPA is routinely used in the United States for diagnostic renal perfusion studies.)

Cause:

The cause was due to the failure of the technician and resident physician to follow the protocol for radiopharmaceutical injection

Licensee Action:

The Chief of Service immediately conducted a review and discussion of injection procedures. All nuclear medicine staff attended the required sessions. Personnel performing injections were admonished to determine appropriateness of dose and/or procedure as specified in the Service Protocol for Radiopharmaceutical Administration.

NRC Action:

The circumstances of the misadministration were discussed with the licensee. The licensee's corrective actions were determined to be acceptable.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	AS 88-02	EVENT DATE:	01/27/1988
TITLE:	RADIOACTIVE MATERIAL RELEASED DURING A TRANSPORTATION ACCIDENT				
NAME:	Houston Inspection Laboratories, Inc. (HILI)	CITY:	Houston	STATE:	TX

Nature and Probable Consequences:

A Model SPEC 2T radiographic exposure device (camera) [NRC Certification of Compliance No. 9056] fell from the back of a HI truck onto a roadway. The camera was struck by another vehicle and dragged for a considerable distance along the roadway. At some point in the accident, the 48 curie iridium-192 radioactive source became separated from the camera. The details of the event, as determined by the investigation by the Texas Bureau of Radiation Control (Agency), as follows.

At 7:15 a.m., a radiographic crew returned to the HILI office. The crew failed to remove the camera from the darkroom on the truck and to place it in the storage vault, or to notify anyone that the camera was still on the truck. The radiography crew arrived at the licensee's facility before the office staff and, as the facility was locked and they did not have keys, could not enter the portion of the facility where the storage vault is located.

The licensee reported that sometime after 7:00 p.m., an employee used the truck to run an errand, not knowing that the camera was still in the darkroom. As the truck rounded a corner, the camera fell from a shelf in the darkroom and struck the darkroom door. The lock hinge plate on the door broke free, the camera fell onto the roadway and was immediately struck by a privately owned auto. The impact caused the oil and transmission pans to be ripped from the bottom of the car and the camera to become wedged under the front of the car.

The car coasted to a stop about 1 block and a half from the impact site and the driver called for a wrecker. When the wrecker driver raised the front of the car he noticed the radiation warning labeling on the camera. At this time the Houston Police Department and the Houston Fire Department were notified and a Hazardous Material (Hazmat) Response Unit was sent to the scene by the fire department. A survey of the camera performed by the Hazmat Unit detected a maximum radiation level of 2 millirem per hour.

At about the same time the camera was recovered, the licensee's radiation safety office (RSO) discovered that it was not in the storage vault or the darkroom. The RSO followed the route the truck had taken, but failed to locate the camera. A friend of the RSO informed him the Hazmat Unit had found a box with radiation labels. The RSO notified the licensee's consultant that a camera was missing and that a Hazmat Unit from the Houston Fire Department had recovered a box with radiation labels.

The Hazmat Unit returned to its station with the camera and was in the process of determining who the camera belonged to when the RSO contacted them. When notified by the fire department that the radiation level was only 2 millirem per hour, the RSO felt that the fire department had misread their survey instrument. When the RSO and consultant arrived at the fire department, they found that the source was not in the camera.

The RSO immediately returned to HILI and picked up a survey instrument. At 12:04 a.m. on January 28, 1988, the RSO found the source in the north bound traffic lane close to the median. HILI's consultant and the City of Houston Health Department were notified that the source had been recovered.

A greenish powder, believed to be depleted uranium, was found on the roadway at two locations: where the car came to a stop where it is believed the lock box came loose from the camera, either from the fall from the truck or when it was struck by the car. Surveys at these locations detected radiation levels above background. The consultant and the city health department employee traveled to where the car was taken and found contamination at one location on the axle. The contamination on the car was removed by the consultant at this time. The consultant also decontaminated the roadway the same day.

Calculations performed by the Agency have determined that a passing motorist would have received an exposure of less than 1 millirem from the source lying in the roadway.

Cause:

It is the conclusion of the Agency that the camera was not properly secured for transportation in the transport vehicle and that the radiography crew did not follow the licensee's operating procedures that required the camera be returned to storage upon arrival at the licensee's facility.

Licensee Action:

The licensee has discussed with their employees the importance of returning cameras to storage upon arrival at the licensee's facility. They are also planning to modify their security to allow the radiography crews admission to the storage vault when the office staff is not present. Cameras will be transported in lockable lead-lined wooden transport boxes that have been placed in each of the licensee's darkrooms. Each box is secured to the vehicle by bolts that are attached to the bed of the pickup.

NRC Action:

The State Agency notified the NRC of the incident on March 14, 1988. The NRC was concerned that the radioactive source had separated from its container during the accident. Therefore, the NRC and DOT reviewed the accident as well as the design and use of the container.

Several issues of concern were identified. Therefore, on May 27, 1988, the NRC issued Information Notice No. 88-33 ("Recent Problems Involving the Model SPEC 2-T Radiographic Exposure Device") to all Agreement States and NRC licensees authorize to manufacture, distribute, or operate radiographic exposure devices and source changers (Ref. 4). The SPEC 2-T radiographic exposure device is manufactured by Source Production and Equipment Company, Kenner, Louisiana.

Based on further inspection and review, on June 14, 1988, the NRC issued Bulletin No. 88-06 ("Actions to be Taken for the Transportation of Model no. SPEC 2-T Radiographic Exposure Device") to all NRC licensees authorized to manufacture, distribute or operate radiographic exposure devices or source changers (Ref.5). The Bulletin requires the licensees to be aware of the changes involving certain transportation and NRC notification requirements that were made on June 8, 1988, for the NRC Certificate of Compliance No. 9056 for the device.

This items is considered closed for the purposes of this report.

Other Agency Action:

The Agency cited the licensee for not following procedures required by the licensee's Operating and Emergency Procedures Manual. These include the failure to secure the camera in a locked transport container that is permanently attached to the vehicle and the failure to place the camera in the storage vault upon return of the radiographic crew to the licensee's office. An administrative penalty of \$10,000 has been proposed by the Agency.

Criteria:

Appendix A (see the third general criterion) of this report notes that major deficiencies in use of licensed material can be considered an abnormal occurrence. In addition, Example 5 of "For All Licensees" of Appendix A notes that any loss of licensed material in such quantities and under such circumstances that substantial hazard may result to persons in unrestricted areas can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 88-12	EVENT DATE:	04/06/1988
TITLE:	MULTIPLE MEDICAL THERAPY MISADMINISTRATIONS				
NAME:	Marquette General Hospital	CITY:	Marquette	STATE:	MI

Nature and Probable Consequences:

Twenty-one medical therapy misadministrations during 1985 and 1986, reported to the NRC on April 6, and May 5, 1988; Marquette General Hospital, Marquette, Michigan.

On April 6, 1988, a medical physicist discovered that the doses given to two patients undergoing irradiation of the breast in November of 1985 and March of 1986 were about 85% of the prescribed doses. On the same day, the licensee notified NRC Region III of the misadministration.

The licensee was using a proprietary computer program to calculate dose profiles in patients; however, there was an error in the procedure used to calculate the beam-on time using information generated by the treatment planning computer. The medical physicist who discovered the error in the two patient charts was conducting a quality assurance review of the treatment records.

Upon notification, the NRC requested the licensee to review its patient files to identify any additional patients who may have been treated using the erroneous computer program. On May 5, 1988, the licensee reported that 19 additional cases from September 1985 to October 1986 had been identified in which the actual doses were only about 85% of the prescribed doses. (The licensee stated that the procedure was no longer used after October 1986.) In regard to possible health effects, the licensee stated, "The radiation dose given is less than the prescribed dose. Radiobiologically, it is not harmful to the patient and no medical damage done. The average given dose was about 15% less, however, patients received boost doses to the breast via electron or interstitial implants to localized areas."

Nevertheless, the event is of concern since a single error resulted in so many people receiving therapeutic doses other than were prescribed.

Cause:

The cause was due to an error in the manual calculations that were performed on the treatment planning computer output. The licensee failed to detect the error before the procedure was used.

Licensee Action:

The particular procedure involved has not been used since October 1986. In order to prevent a recurrence of the type of event, licensee committed to take the following actions:

- (1) All current dose calibration procedures will be reviewed and documented by the physicist and the radiation oncologist to check for correctness.
- (2) Before any new calculation procedures are initiated, they will be thoroughly discussed between the radiation oncologist and the physicist.
- (3) If there are any questions brought up during these reviews, a physicist from an outside institution will be contacted for consultation.

The licensee submitted a quality assurance program to prevent recurrence of this type of event. The program has been incorporated into the licensee's license.

NRC Action:

The incident, and the licensee's corrective actions, will be reviewed during the next NRC inspection at the hospital.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on the public health or safety can be considered an abnormal occurrence.

ITEM #: AO #: EVENT DATE:
TITLE:
NAME: CITY: STATE:

Nature and Probable Consequences:

A patient was administered 2.7 millicuries of I-131 MIBG rather than the intended dose of 500 microcuries of I-131 MIBG.

I-131 MIBG is currently an Investigational New Drug and is used in a relatively new and rarely ordered diagnostic study performed at the hospital. Prior to the administration, the technologist involved, who was unfamiliar with the correct amount to administer, checked both the literature which accompanied the shipment and the department's procedure manual. However, even though the correct dose was listed in the procedure manual, the technologist missed it and assumed that the entire vial of 2.7 millicuries was to be administered.

The misadministration resulted in an estimated adrenal medullae dose of 268.4 rads, as calculated in accordance with literature supplied by the United States Food and Drug Administration. The thyroid burden should be negligible because the thyroid had been blocked with Lugols prior to the administration of the I-131 MIBG, as prescribed in the protocol.

The licensee stated the patient exhibited no adverse health effects.

Cause:

The cause is attributed to the technologist's error in overlooking the proper dosage as listed in the department's procedure manual.

Licensee Action:

The technologist was admonished and retrained.

NRC Action:

NRC Region II telephoned the hospital for additional details on the incident. The incident will be reviewed during the next NRC inspection at the hospital.

This item is considered closed for the purposes of this report.

Other Agency Action:

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	AS 88-03	EVENT DATE:	05/17/1988
TITLE:	MEDICAL DIAGNOSTIC MISADMINISTRATION				
NAME:	West Houston Medical Center	CITY:	Houston	STATE:	TX

Nature and Probable Consequences:

A patient was scheduled to be administered 30 microcuries of iodine-131 in capsule form for a diagnostic scan of her thyroid. Instead she was administered 30 millicuries of iodine-131 in capsule form. This resulted in an estimated dose to the thyroid of c 30,000 rads; such a dose would be expected to destroy the thyroid's function. The event was investigated by the Texas Department of Health, Bureau of Radiation Control (the "Agency").

After the patient's doctor ordered a diagnostic thyroid scan, the technologist mistakenly ordered a dose of 30 millicuries of iodine 131 on Sunday May 15, leaving the order on an answering machine. The pharmacist on duty the next day took the order but co not fill it because therapy doses are ordered from the manufacturer individually. He called the technologist to explain, and she agreed to postpone until the next day, May 17. When the dose arrived, she placed it in the dose calibrator and was perplexed b the high count rate she obtained, but administered the dose and told the patient to come back the next morning for her scan. Tt technologist mentioned the high count rate to the doctor, who apparently didn't get enough information to realize the potential problem and told her the count rate was relative.

On Monday May 16, she had ordered 30 millicuries doses for two other patients to be administered on May 18 and was informed was too late to change the delivery but that there would still be 27.5 millicuries (quantity reduction due to radioactive decay) on t 19th when the dose was to be administered. When she checked with the doctor, informing him of the 27.5 millicuries dose, he corrected her saying she meant microcuries. She still didn't realize her mistake. Later, on the evening of May 17th, she orderec 30-microcurie dose and was told it could be delivered right away. She asked why she had to wait for the others and was remind that they had been 30 millicuries. She then realized her mistake and notified another physician on the hospital staff, who after consulting with the patient's physician, called the patient back to the hospital and administered a blocking agent about 12 hours after the original dose was administered. However, the blocking agent was felt to have little effect.

The hospital's estimate of the dose to the thyroid was 30,000 rads. The Agency's calculations indicated a thyroid dose of approximately 34,000 rads. The hospital is performing follow-up examinations of the patient. No prognosis for the patient was available at the time of the Agency's report to the NRC.

Cause:

The Agency's investigation indicated several contributing factors to the misadministration. The hospital performs relatively few thyroid scans and they are all performed using microcurie quantities of iodine. Scans using other radionuclides require millicurie quantities.

The technologist placing the order was not as experienced as the technologist who normally performed the scans. She had alre performed several scans using millicurie quantities of other radionuclides and when the thyroid scan was ordered, went to her procedures manual for the quantity to be ordered. When she placed the order, she apparently didn't realize she was saying millicuries and continued to confuse millicuries with microcuries until after the dose was administered.

Licensee Action:

The licensee is rewriting its protocol for nuclear medicine scans to list each procedure with the activity and form of the material t be used. In addition, the licensee is instructing any firm supplying therapy doses of radiopharmaceuticals that they are to be prepared only when the order is accompanied by a written prescription signed by the physician user authorizing the procedure o verbal, personal authorization is obtained by the pharmacist from the physician-user.

NRC Action:

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Other Agency Action:

At the time of the Agency's report to the NRC, the Agency was still reviewing the incident to determine the appropriate enforcem action.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public h or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	NRC 88-14	EVENT DATE:	11/17/1988
TITLE:	MEDICAL THERAPY MISADMINISTRATION				
NAME:	Wilkes-Barre General Hospital	CITY:	Wilkes-Barre	STATE:	PA

Nature and Probable Consequences:

On November 18, 1988, the licensee notified NRC Region I by telephone that a therapeutic misadministration had occurred involving a patient receiving treatment for an endo-bronchial tumor.

A radiotherapy physician had prescribed a therapeutic dose of 750 rads to the right bronchus at a distance of 0.5 centimeters from an iridium-192 source in a remote afterloading brachytherapy device. However the staff radiotherapy physicist mistakenly developed a treatment plan that delivered 750 rads at 1.0 centimeter from the source. This resulted in a dose of 1800 rads at 1.0 centimeters from the source, rather than the prescribed 750 rads.

The licensee stated that the dose received by the endo-bronchial tumor is within standard treatment protocols for that type of tumor and that no adverse effects are anticipated as a result of the misadministration.

However, the event was of concern because of the large magnitude of the error. NRC Region I conducted a special inspection of the licensee on November 29, 1988, to review the circumstances associated with the event and the corrective actions planned by the licensee to prevent recurrence. In addition, NRC Region I requested an NRC medical consultant to review the event.

Cause:

The cause was attributed to human error. The licensee's staff radiotherapy physicist used the wrong table of the manual used to develop a treatment plan.

Licensee Action:

Corrective actions include independent verification of treatment calculations (one by a dosimetrist and one by a radiotherapist), providing additional training on the therapy equipment, and providing an additional chart for determining maximum treatment time for each treatment plan.

NRC Action:

On December 16, 1988, NRC Region I sent a Confirmatory Action Letter to the licensee confirming the licensee's corrective action plans (Ref. 1). The NRC's consultant confirmed the licensee's statement that the dose received was within standard treatment protocols and that no adverse effects on the patient were anticipated. The report for the November 28, 1988 NRC inspection was issued on February 8, 1989 (Ref. 2). NRC Region I has scheduled a management meeting with the licensee to review the licensee's corrective actions.

This item is considered closed for the purposes of this report.

Other Agency Action:

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Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #:		AO #:	AS 88-04	EVENT DATE:	08/23/1996
TITLE:	MULTIPLE MEDICAL THERAPY MISADMINISTRATION				
NAME:	Rochester General Hospital	CITY:	Monroe County	STATE:	NY

Nature and Probable Consequences:

On August 23, 1988, the New York State Department of Health, Bureau of Environmental Radiation Protection (State Agency), was notified of a series of cobalt teletherapy misadministrations at the hospital. The hospital was using a computer program in treatment planning for cobalt teletherapy patients. The procedure in use by the physics staff was to enter fractional wedge factors into a utility file in the computer, which then used the factors to normalize isodose curves to the values they would have in an "open plan (without wedges). The wedge factors were applied in a subsequent manual calculation to arrive at the correct treatment time.

It appears that in April 1988, someone altered the data in the wedge file so that the computer now applied the wedge factors. These factors were applied again in the subsequent treatment time calculations resulting in substantial errors in the treatment times calculated for wedged fields. The licensee believes the data was changed when a software upgrade was loaded, and originally believed that loading the software altered the wedge factors. The software manufacturer, however, asserted that this was impossible and that it would have required deliberate action to access and change the data.

Fourteen patients received doses that exceeded the prescribed total doses by greater than 10 percent. In addition, five patients received fractional doses that exceeded the prescribed dose per fraction by greater than fifty percent, although their treatments were terminated before the total error exceeded 10 percent. The largest total overdose was 81 percent, and the largest fractional overdose was 119 percent.

On August 25, 1988, a consultant physicist retained by the State Agency visited the hospital to assess the extent of the problem. He found two additional problems: (1) output calibrations performed by a previous assistant physicist omitted two necessary correction factors, which fortunately cancelled each other numerically, and (2) incorrect data on the physical dimensions and composition of one wedge had been entered into the computer in January 1988. The senior physicist had measured the wedge transmission with a dosimeter and was aware that his measured factor differed substantially from the factor calculated by the computer using the input on physical dimensions and compositions. However, he did not attempt to resolve the discrepancy and used the measured factor to calculate treatment times.

During the period January to April 1988, use of the incorrect data entered in the wedge file in January resulted in dose distribution patterns that differed from those seen and approved by the prescribing physician. After the wedge file data was changed in April the incorrect data actually helped to reduce the percent of error by "splitting the difference."

All patients were notified of the errors and an outside radiation oncologist was brought in to evaluate any possible impact on the affected patients and make recommendations.

Cause:

The person who is alleged to have made the changes in the wedge data files had advanced degrees and work experience in applied physics. However, he had no training and experience in medical physics prior to his employment at the Rochester General Hospital, beginning in August 1987, under the supervision of an experienced medical physicist. Although in January 1988, the supervising physicist had decided that the individual was competent to work independently, it appears that he did not understand the significance of the changes he apparently made and should have been more closely supervised.

The supervising physicist had also failed to observe the errors in calibration reports by a previous assistant physicist and had not acted to resolve a discrepancy between a computer wedge factor and the measured factor.

No one made any quality assurance tests after the software upgrade was loaded, or routinely ran test plans to check the operation of the treatment planning system.

The causes of this series of misadministrations appear to have been lack of supervision, inadequate quality assurance, and an inadequate program to identify and eliminate errors.

Licensee Action:

The licensee proposed a corrective action plan which included recruitment of a second certified medical physicist. The State Agency has asked the licensee to provide a better description of the supervisory responsibilities of the senior physicist and of actions to ensure a specified level of accuracy in dose delivery.

NRC Action:

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Other Agency Action:

The Agency has taken enforcement action against the licensee and has amended all teletherapy licenses to require quality assurance, reporting of misadministrations, and a medical physicist with specified qualifications for each license. Code amendments are in preparation.

This item is considered closed for the purposes of this report.

UPDATE: This abnormal occurrence was originally reported in NUREG-0090, Vol. 11, No. 4, "Report to Congress on Abnormal Occurrences," October-December 1988 and closed out at that time. It was reported that 19 patients received cobalt teletherapy misadministrations at Rochester General Hospital in Monroe County, New York, between January 1988 and August 1988.

This abnormal occurrence was reopened because the following new significant information concerning enforcement action and status of the affected patients became available.

Enforcement action was initiated by the New York State Department of Health which included provisions that the hospital take the following actions: commit to comprehensive quality assurance reviews for radiation therapy, submit quarterly progress reports for each component of the stipulation, order of the enforcement action, implement quality assurance reviews, mandatory periodic in-service training, testing of physics staff, and perform a periodic follow-up of the affected patients for 1 year.

Reports of the patient follow-up were submitted to the State of New York, Department of Health. As of December 1990, the reported status of the patients' condition involved in the misadministration is as follows: two patients had laryngectomies; one patient had necrosis of the larynx; three patients had discomfort in the treatment area; one patient had a rib fracture; four patients had skin changes; three patients had atrophy in the breast; one patient had a radiation ulcer, one patient had radiation proctitis, nine patients died from complications not related to the misadministration.

The State radiation control regulations have been revised to include requirements of Quality Assurance programs, audits of their programs, misadministration reporting and training, and experience requirements for therapy physicists.

The item is considered closed for the purposes of this report.

Criteria:

Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: AO #: AS 88-05 EVENT DATE: 08/29/1988
TITLE: MEDICAL THERAPY MISADMINISTRATION
NAME: Sacred Heart Hospital CITY: Cumberland STATE: MD

Nature and Probable Consequences:

On September 2, 1988, Maryland's Center for Radiological Health (State Agency) was notified by the licensee that an 81 year old patient had received a therapeutic dose of 1400 rads to a part of the body which was not scheduled for radiation therapy.

The patient was scheduled to receive radiation therapy exposures for a total of 3,000 rads to the right maxillary sinus from a cobalt-60 teletherapy machine. The total exposure was to be administered in increments over a period of time. Two ports of the teletherapy device unit were used during these treatments; however, one port was improperly aligned toward the base of the brain rather than toward the right maxillary sinus. Seven incremental exposures between August 8 and August 26, 1988, were administered before the oncologist discovered the error on August 29, 1988, and halted the treatments. As a result, the base of the brain received a total of 1,400 rads. The oncologist stated that the misadministration did not cause any medical side effects. On later dates, the patient received additional exposures to the right maxillary sinus to conclude the 3,000 rads prescribed dose.

Cause:

The oncologist improperly aligned the teletherapy unit's lateral port to the patient's skull.

Licensee Action:

In the report to the State Agency, the oncologist stated that she would exercise increased vigilance and alertness in performing work.

NRC Action:

UPDATE: These abnormal occurrences were originally reported in NUREG-0090, Vol. 11, No. 4, "Report to Congress on Abnormal Occurrences," October-December 1988. The abnormal occurrences are updated as follows:

NRC is continuing to work with the State of Maryland to obtain more information regarding these occurrences.

Other Agency Action:

During the subsequent investigation at the hospital, the State Agency's investigator and the oncologist discussed additional methods to prevent recurrence, such as conducting the resimulation of the port areas earlier than two weeks into a patient's treatment program and establishing a film method for using the cobalt-60 source in producing a patient image to determine port locations.

This item is considered closed for the purposes of this report.

Criteria:

Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: 960236 AO #: AS 88-06 EVENT DATE: 10/27/1988
TITLE: MULTIPLE MEDICAL THERAPY MISADMINISTRATIONS
NAME: Sacred Heart Hospital CITY: Cumberland STATE: MD

Nature and Probable Consequences:

On October 27, 1988, Maryland's Center for Radiological Health (State Agency) was notified by the hospital's Vice President that over the past 13 months, 33 patients undergoing brain cancer treatments had received therapeutic radiation exposures from a cobalt-60 teletherapy machine that exceeded 10% of the prescribed dose in each case.

All 33 patients had been diagnosed as terminally ill prior to the initiation of their treatments. The hospital consulting physicist later determined that each patient had received a radiation exposure that was 75% greater than the prescribed dose. At the time of notification to the State Agency, 20 patients had died, either during the course of their treatment or after the conclusion of treatment. The Vice President believed that none of the deaths were attributed to the excessive radiation doses.

The hospital's therapy staff had observed severe skin erythemas on several patients during the 13-month span and expressed their concerns to the hospital oncologist, who determined the erythemas to be normal during treatment. Finally, after a skin erythema was again observed on a patient undergoing treatment, the hospital physicist was notified. The physicist determined that a computer program file used for the treatment of brain cancer and identified for use "with trimmer bars" was not updated in March 1987 when the therapy department replaced a depleted cobalt-60 source. Other program files had been updated to reflect the current cobalt-60 source, but the aforementioned file had not been updated because, as the oncologist stated to the consulting physicist during the March 1987 source calibration, "trimmer bars" were not used to treat patients requiring whole brain irradiation. However, in September 1987, the oncologist initiated brain treatments using the "trimmer bar" computer file with the data reflecting the prior source, thereby causing the actual doses to be 75% greater than the prescribed doses.

Once the file was identified, it was removed and stored under lock and key. The physicist reviewed all computer files for their accuracy and proper identification and measured the output of the cobalt-60 source. No changes were needed in the remaining files. The hospital suspended the oncologist pending the investigation and removed this individual as radiation safety officer and Chairman of the Medical Isotopes Committee.

The hospital retained the services of an oncologist from the University of Virginia Medical Center to perform an independent review of the patient records to determine if the radiation doses contributed to and enhanced patients' deaths.

In addition, the State Agency retained the services of a medical physicist representing Radiation Physics Associates of Louisville, Kentucky, and an oncologist from the Johns Hopkins Medical Institutions of Baltimore, Maryland. Investigation activities by these doctors included measuring the radiation output of the cobalt-60 unit, reviewing the computer program files, and reviewing the medical charts of those patients who incurred misadministrations.

Cause:

The error which resulted in the misadministration was due to the hospital oncologist's use of a computer program file that was not updated to reflect the current cobalt-60 source information. Also, the oncologist failed to perform manual calculations to cross-check the computer chart calculations that would have identified this problem earlier.

Licensee Action:

The hospital oncologist who was responsible for the misadministrations has resigned. During the time of this investigation the hospital has hired two interim oncologists. According to the hospital administrator, the hospital is actively pursuing the hiring of a full-time oncologist. Also, the hospital's consulting physicist has made weekly visits to the hospital to ensure that the therapy program's operations are smooth, efficient, and safe for both the hospital's patients and the therapy staff.

NRC Action:

On December 2, 1988, the NRC issued Information Notice No. 88-93 ("Teletherapy Events") to all NRC medical licensees to emphasize the importance of the correct use of computerized treatment planning (Ref. 3). The Notice described the above events as well as therapy misadministrations due to errors in computerized treatment planning that occurred at hospitals in the Agreement State of New York. The latter events were described in Agreement State abnormal occurrence No. AS87-5 in NUREG-0090, Vol. 10, No. 3 ("Report to Congress on Abnormal Occurrences: July-September 1987").

This item is considered closed for the purposes of this report.

UPDATE: These abnormal occurrences were originally reported in NUREG-0090, Vol. 11, No. 4, "Report to Congress on Abnormal Occurrences," October-December 1988. The abnormal occurrences are updated as follows:

NRC is continuing to work with the State of Maryland to obtain more information regarding these occurrences.

Other Agency Action:

The Agency is waiting for all written reports to be sent from those individuals hired to conduct independent evaluations of this incident. After all reports are reviewed and evaluated, the Agency will then decide upon and proceed with the proper compliance action against the licensee.

Criteria:

Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

ITEM #: [] AO #: NRC 86-03 EVENT DATE: 01/04/1986
TITLE: RUPTURE OF A URANIUM HEXAFLUORIDE CYLINDER AND RELEASE OF GASES
NAME: Sequoyah Fuels Corporation CITY: Gore STATE: OK

Nature and Probable Consequences:

At 11:30 a.m. on January 4, 1986, a cylinder filled with uranium hexafluoride (UF6) ruptured while it was being heated in a steam chest at the Sequoyah Fuels Corporation's Sequoyah Facility near Gore, Oklahoma. One worker died from pulmonary edema caused by the inhalation of hydrofluoric acid, a reaction product of UF6 and airborne moisture. Much of the facility complex and some offsite areas to the south were contaminated with hydrofluoric acid, and a second reaction product, uranyl fluoride. The interval of release was approximately 40 minutes.

The licensee experienced another incident involving an overfilled uranium hexafluoride cylinder on March 12, 1986; however, in incident the overfilled cylinder was not heated and no damage to the cylinder occurred.

Some other events involving overfilled uranium hexafluoride cylinders at Allied Chemical Company, Metropolis, Illinois, are discussed in the Annex to this abnormal occurrence. Allied Chemical Company is a division of Allied-Signal Corporation of Morristown, New Jersey.

NATURE AND PROBABLE CONSEQUENCES: At approximately 10:00 a.m. on January 3, 1986, the filling of a 14-ton capacity cylinder with UF6 was commenced. This operation continued during the following work shifts. During the early morning of January 4, a chemical operator was unable to add further material into the cylinder, even though the targeted load of 27,500 pounds had been achieved. The cylinder and its attendant cart had been placed on a scale during the filling process in order to monitor the weight of the cylinder. At this time, the scale indicated that the cylinder contained 26,400 pounds of product.

The chemical operator inspected the cylinder and observed that the cart on which it sat had not been fully moved onto the scale platform. This condition occurred because the cylinder, being the largest design filled at the facility, was not properly positioned the cart so as to allow clearance at the front end of the cylinder when the cart was moved onto the scale platform. When the cart and cylinder were repositioned onto the scale platform, the scale dial indicator registered its maximum possible reading of approximately 29,500 pounds. The cylinder had been filled with a quantity of UF6 in excess of the amount measurable with the scale and in excess of the maximum shipping weight specification of the cylinder which is 27,560 pounds.

At approximately 6:15 a.m. the chemical operator began to evacuate UF6 from the cylinder back into plant process vessels. He was relieved by the day shift chemical operator at 8:00 a.m., and the evacuation process continued until the material began to solidify in the cylinder. The operator consulted with the assistant shift supervisor, who is the ranking production manager on site and who instructed the operator to move the cylinder to a steam chest located outside the process building. The steam chest was to be used to heat the cylinder to approximately 210 degrees F, thus liquifying the contained UF6. Although some material had been removed from the cylinder, the scale indicator still registered approximately 29,500 pounds before the cylinder was removed. Heating an overfilled cylinder was later noted to be contrary to company procedures.

At approximately 11:30 a.m., the cylinder ruptured in the steam chest. The cylinder ruptured while it was being heated because the expansion of uranium hexafluoride as it changed from the solid to the liquid phase. Liquid UF6 flowed from the 4-foot lengthwise rupture and rapidly reacted with moisture in the air to form uranyl fluoride and hydrofluoric acid. The resulting vapor cloud was carried south the southeast by a winds gusting to 25 mph.

The cloud enveloped the process building, and the acidic vapor fatally injured the chemical operator located within a structure approximately 70 feet southwest of the cylinder. Most of the approximately 40 workers at the site were in the plant lunch room and quickly evacuated the building. The airborne release continued for about 40 minutes crossing an interstate highway one mile to south and private residences beyond.

The licensee immediately notified various local, state, and federal officials. Four injured workers were transported to a local hospital. A private physician arrived at the site within one hour of the accident and examined plant workers. During the afternoon downwind residents were personally notified to go to nearby hospitals and clinics for examinations.

The NRC Region IV Duty Officer was notified of the incident by the NRC-HQ Operations Officer by pager at approximately 12:25 p.m. The Region IV Incident Response Center was staffed and communication links with NRC Headquarters and the licensee began at 12:55 p.m. Six NRC personnel were immediately dispatched and began arriving at the site at 6:00 p.m. Additional NRC personnel were dispatched to the site during the following days to oversee bioassay of workers and residents, evaluation of offsite effluents, and decontamination of the plant complex. An NRC Augmented Investigation Team was formed to investigate the incident. Their findings were reported in NUREG-1179, Vol. 1, published during February 1986 (Ref. 14). An assessment of the public health impact of the accident was published during March 1986 as NUREG-1189 (Ref. 15).

After the January accident, the licensee planned to drain UF6 remaining in plant vessels into 10-ton shipping cylinders in order to enable modification of facilities and equipment at the plant. A procedure for the work was reviewed by NRC and the work commenced on March 12, 1986. The procedure limited the filling of the cylinders to 20,000 pounds each. The maximum shipping weight specification of the cylinders was 21,030 pounds. During the draining process on March 13, 1986, a scale malfunctioned which caused UF6 to be drained into a cylinder in excess of both of the above limits. The final net weight of the cylinder was 26,017 pounds. Most of the excess material was immediately evacuated from the cylinder before the UF6 solidified. The final net

weight of the cylinder was 21, 203 pounds.

The root cause of this second incident was identified as inadvertent damage to a scale apparently when it was decontaminated the first incident. Results of the NRC investigation of this overfilling event, together with a report of a detailed metallurgical examination performed on the cylinder damaged on January 4, 1986, were reported in NUREG-1179, Vol. 2, published during January 1986 (Ref. 16).

Cause:

The NRC Augmented Investigation Team (AIT) which investigated both incidents reported the following causes in NUREG-1179 Vol. 1 and Vol. 2, respectively.

January 4, 1986 Incident:

1. The cylinder was overfilled because it was not placed fully on the scales. Plant facilities were not designed to accommodate 14-ton cylinders, and associated equipment were not designed to prevent improper positioning of cylinders on the scales.
2. The time required for filling the cylinder was long enough to allow partial solidification of the UF₆, which inhibited product removal from the cylinder.
3. The precise weight of the cylinder was not readily determinable after it was overfilled.
4. There was no secondary or alternative way to measure the quantity of material in a cylinder being filled.
5. Employees violated company procedures when they heated an overfilled cylinder. Workers, including line management personnel, had not been sufficiently trained in regard to company procedures. Procedural controls such as checklists or approval points were not used.
6. Equipment for monitoring or automatically venting cylinders that are being heated was not used.

In summary, the factors can be aggregated into the following causes of the accident:

- The physical equipment and facilities used for filling and weighing UF₆ cylinders were inappropriate for safe use with 14-ton cylinders.
- The training of workers in operating procedures and ensuring the implementation of the procedures were not carried out effectively.

March 13, 1986 Incident:

1. The scale used for weighing the cylinder being filled malfunctioned.
2. The procedures for draining did not include any provisions for ensuring proper scale function.
3. The supervisor in charge of the operation did not recognize early indications of malfunction. (An operator advised his management of peculiar scale behavior during the filling of the cylinder.)

Both the NRC and licensee actions to prevent recurrence are currently in progress. The following summarizes actions as of March 1986.

Licensee Action:

The licensee has committed to keep the plant shut down until equipment modifications are made, plant personnel are retrained, plant procedures are rewritten, organization changes have been implemented, and NRC approves plant restart.

NRC Action:

A Lesson Learned Task Group reviewed regulatory practices in regard to such fuel facilities in general. The Group interviewed appropriate members of the NRC staff, licensee, State, and local authorities. A Lesson Learned Report was completed in May 1986. A request to restart the facility was received by NRC in May 1986 and is under review. NRC is monitoring licensee plant modification work. Enforcement actions are pending.

The staff is also compiling a list of followup items that need to be considered and addressed. Additional items are anticipated from the Lessons Learned Task Group and other sources. Upon completion of the list, action items will be grouped into categories and priorities assigned. Tasks will be undertaken based on priorities and resource requirements.

In the meantime, the staff is moving ahead on a number of near-term follow-on actions, such as: (1) verification by NRC of existing emergency phone numbers; (2) requiring licensees to verify quarterly emergency numbers and availability of emergency response assistance; (3) informing DOE and other licensees, who are conducting operations involving UF₆, of the accident and providing

relevant reports; and (4) conducting an independent review of the material licensing and inspection programs by a study group.

To assure that licensees have an updated list of telephone numbers to the NRC Operations Center and Regional Offices, the NRC Office of Inspection and Enforcement issued Information Notice No. 86-28 on April 24, 1986 (Ref. 17).

The event remains under review by the NRC, and future reports will be made as appropriate.

Other Agency Action:

ANNEX: During the publicity associated with the Sequoyah Fuels Accident, NRC Region III (Chicago) received an inquiry from a newspaper reporter about an incident on December 7, 1984 at Allied Chemical Company, Metropolis, Illinois, involving overfilling and subsequent damage to a uranium hexafluoride cylinder. The licensee was asked about the incident and provided the following information. (The incident had not been previously reported to NRC. The licensee stated that it had considered reporting it, but concluded that it did not meet any NRC reporting requirements.)

On December 7, 1984, an overfill incident occurred in which a cylinder was overfilled and the cylinder subsequently damaged during heating of the cylinder to remove the excess uranium hexafluoride. There was no release of any uranium hexafluoride to environment associated with the incident, and there were no injuries. In the incident, a 48-inch diameter cylinder, with a maximum capacity of 26,560 pounds, was filled with 33,000 pounds of uranium hexafluoride. The weight recording device was apparently faulty and showed an incorrect weight during the filling operation. Based on the length of time the filling had been underway, licensee personnel suspected that it had been overfilled and moved it to another scale to be weighed. The second scale showed to contain 33,000 pounds.

The cylinder was returned to the filling position and about 500 pounds of UF₆ was drawn off before the cylinder cooled and the UF₆ solidified. The cylinder was then moved to another fill location where a steam chest was placed over it to heat the cylinder. A line was attached to the cylinder to draw off the UF₆ as the cylinder was heated, but the line was blocked. Plant personnel were unable to clear the line, and so the cylinder was heated for about 2-1/2 hours with the cylinder valve closed. The steam chest was then removed, and the cylinder was moved to the weighing location to draw off the UF₆.

At that time, plant personnel noted that the three stiffening rings which surround the cylinder were cracked at a welded joint. A portion of the UF₆ was then drawn off at the scale location, and then the cylinder was moved to another fill location where the remainder of the UF₆ was drawn off, while applying heat in a steam chest. It was later observed that the cylinder was slightly deformed--placing a straight edge along the cylinder wall showed a deformation of approximately 1/2 inch.

The licensee later provided information to the NRC on overfill incidents at the Metropolis facility for the time period 1981 through 1985. During the five-year period, there were 41 overfills--of which three were greater than 1,000 pounds. The three were 1,183 pounds in 1981, 5,448 in 1984 (described above), and 2,140 in 1985. With the exception of the December 7, 1984 event, none of the other overfill incidents involved damage to the cylinders. No releases of UF₆ occurred in any of the incidents.

Another overfill incident occurred on March 23, 1986, when a cylinder was filled with 28,207 pounds (an overfill of 1,367 pounds). The excess was successfully removed without applying additional heat. This incident was attributed to the failure of an operator "zero out" the scale to account for the empty weight of the cylinder combined with the erroneous calculation by another operator of the time required to fill the cylinder.

Subsequent to the December 1984 incident, the licensee installed new load cells (scales) at each fill location to provide clearer, more reliable weight measurements in the control room. A scale was also added to the overhead crane used to lift the cylinders to allow weighing of the cylinders without transporting them more than 50 feet to another weighing location.

After the January 1986 Sequoyah Fuels accident, licensee installed a flow totalizer which measures the flow rate of the liquid UF₆ and has an alarm and automatic shutdown function based on total flow and data from the load scale. The licensee has also initiated improvements in its training and retraining programs, procedures, and level of supervision for cylinder filling activities.

In response to the January 1986 accident at Sequoyah Fuels, NRC Region III conducted a special inspection at the Metropolis facility on January 14-15, 1986 to observe the Allied Chemical Company cylinder handling procedures. Additional inspections were conducted to examine the circumstances of the December 7, 1984, incident, and the licensee's actions to preclude the occurrence of significant overfills (Ref. 18).

Region III issued a Confirmatory Action Letter to the licensee on January 10, 1986 (Ref. 19), documenting the licensee's agreement that no overfilled cylinders would be heated without the review and concurrence of Region III. A second Confirmatory Action Letter was issued on March 24, 1986 (Ref. 20), documenting the licensee's planned actions in response to the March 23, 1986 overfill incident. These corrective measures include increased supervision of filling activities, prohibiting cylinder filling unless two independent methods are available to determine the amount of UF₆ in a cylinder, and completion of the installation of the new load cell flow readout and alarm functions by April 15, 1986.

A special NRC inspection, by a seven member team, was conducted in mid-April 1986 to extensively review the licensee's activities. The team identified two violations of NRC requirements: radiation survey instruments did not have the required sensitivity; and a procedure concerning the handling of overfilled cylinders did not have all the proper internal approvals (Ref. 21).

An emergency planning inspection was conducted March 31-April 14, 1986, and the inspectors determined that while the licensee

had an on-site emergency contingency plan, off-site emergency response capability for the area surrounding the plant was poor coordinated. The inspectors also found that training of off-site emergency response personnel to respond to emergencies at the plant was inadequate (Ref. 22). These items will be reviewed during a future inspection. In addition, the NRC is currently reviewing its requirements for emergency planning at fuel facilities.

Although no regulations exist for off-site emergency response, the licensee has taken the initiative to work with the appropriate site groups to establish a coordinated capability.

On June 27, 1986, the NRC forwarded to the Allied-Signal Corporation (parent company of Allied Chemical Company) a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$25,000 (Ref. 23). The violations included the failing to report the December 7, 1984 incident to the NRC and for three instances of failing to follow procedures during the March 23, 1986 over incident.

Criteria:

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see the general criterion) of this report notes that a major reduction in the degree of protection of the public health or safety can be considered an abnormal occurrence. In addition, Example 11 (of "For All Licensees") of Appendix A notes that serious deficiencies in management or procedural controls in major areas can be considered an abnormal occurrence.

ITEM #:	960060	AO #:	NRC 96-03	EVENT DATE:	10/10/1995
TITLE:	Brachytherapy Misadministrations by Jose L. Fernandez, M.D., in Mayagüez, Puerto Rico				
NAME:	José L. Fernández, M.D.	CITY:	Mayagüez	STATE:	PR

Nature and Probable Consequences:

On January 14, 1994, Dr. Fernández acquired an eye applicator device, which contained a strontium-90 (Sr-90) source of approximately 3219 megabecquerel (87 millicurie) activity, from the estate of a deceased licensee in Mayagüez, Puerto Rico. (Eye applicator devices are used for the supplemental treatment of non-malignant growths on the eye after surgery is performed.) NF knew that Dr. Fernández acquired the Sr-90 source because the estate was acting under a Confirmatory Action Letter (CAL) to maintain control of the Sr-90 source and to either dispose of it or transfer control of it to an authorized recipient. Since Dr. Fernández was already an NRC licensee for another Sr-90 source in San Juan, Puerto Rico, his license was amended so that he was an authorized recipient when the transfer took place. (After the transfer took place, Dr. Fernández was licensed to have two sources.) NRC did not require Dr. Fernández to receive additional training in the use of the Sr-90 source after he acquired it from the estate because he was already an authorized user for a Sr-90 eye applicator as defined by 10 CFR 35.

When Dr. Fernández took possession of the eye applicator device, it was in the manufacturer's carrying case. A label attached to the carrying case contained the following hand written information: (1) the dose rate for the device, which was calibrated as 24 centigray (cGy) per second (24 rad per second); (2) the instrument used to calibrate the dose rate; (3) the date when the dose rate was calibrated; and (4) the name of the individual who performed the calibration. Dr. Fernández assumed that the hand written information on the label attached to the manufacturer's carrying case was correct and proceeded to treat patients.

On October 18, 1995, during a routine inspection, an NRC inspector questioned the labeled dose rate on the eye applicator device and the resultant administered doses. Dr. Fernández was unable to provide documentation to answer the questions. He then voluntarily ceased the administration of radiation doses and requested a calibration of the device by the manufacturer. The actual dose rate was found by the manufacturer to be 53 cGy per second (53 rad per second); i.e., more than twice the assumed dose rate.

Dr. Fernández and NRC reviewed the computer sorted records of all administrations using the eye applicator device and determined that between October 24, 1994, and October 10, 1995, 87 patients had received radiation doses which were approximately twice the prescribed dose. However, the computer sort was not complete, since Dr. Fernández later discovered additional 17 cases which occurred between January 1994 and October 1995. Dr. Fernández notified the patients about the misadministrations. NRC contracted a medical consultant to review the medical aspects of the misadministrations.

The NRC medical consultant, who reviewed patient records for the 87 patients initially identified, determined that 25 of the patients were at higher risk for complications. These 25 patients were initially prescribed treatment doses of 1500 to 2880 cGy (1500 to 2880 rad), but received doses of 3312 to 6360 cGy (3312 to 6360 rad) instead. Of these 25 patients, 12 were then prescribed second treatment doses of 1000 to 2160 cGy (1000 to 2160 rad), but received doses of 2208 to 4770 cGy (2208 to 4770 rad) instead. Additionally, two of these 25 patients were prescribed third treatment doses of 1500 to 3000 cGy (1500 to 3000 rad), but received doses of 3313 to 6625 cGy (3313 to 6625 rad) instead. The highest total dose received by a patient was 13,603 cGy (13,603 rad) to the surface of the eye, with an estimated 544 cGy (544 rad) to the lens of the eye.

The NRC medical consultant believes that the long-term consequences of the misadministrations to the 25 highest dose patients could include: (1) increased risk of cataracts; and (2) increased risk of infections, due to severe thinning or ulceration of the sclera which could cause blindness if not detected early and aggressively treated. No adverse health effects were reported during a reexamination of seven of these 25 patients by Dr. Fernández. However, the NRC medical consultant indicated that the possible adverse consequences to these patients may not appear for a period of up to 10 years after irradiation.

The AO report is updated as follows:

The consultant hired by Dr. Fernández identified that 202 of the patients treated were involved in the misadministration.

In addition, NRC reviewed the records of administrations done by Dr. Luis A. Vázquez after September 1990 and identified 559 dose administrations in which 41 resulted in overdoses that met the definition of a misadministration. Dr. Fernández and the clinic in possession of Dr. Vázquez' patient records, made all reasonable efforts to notify the patients involved in these misadministrations according to the requirements of 10 CFR 35.33; however, 24 patients were not notified because of inaccurate information on the record, such as a wrong address or telephone number.

NRC compiled information on patients who received a misadministration (overdoses) by Dr. Fernández and Dr. Vázquez and sent the information to the Commonwealth of Puerto Rico, Department of Health, which is considering follow-up actions, including reminding the patients annually about the need to receive periodic eye exams by specialized physicians. On June 11, 1997, NRC issued a Notice of Violation and Proposed Imposition of a Civil Penalty to Dr. Fernández for the violations identified during NRC inspections that represented a significant lack of program oversight and careless disregard of regulatory requirements. Dr. Fernández paid the \$8000 Civil Penalty, and on July 17, 1997, filed an NRC Form 134, "Certificate, Disposition of Materials" requesting the termination of his license. Since Dr. Fernández disposed of the licensed material in his possession, the NRC terminated his license on September 5, 1997.

Cause:

Dr. Fernández used an incorrect dose rate for the Sr-90 source, as calibrated by a medical physics consultant employed by the deceased former licensee, to develop treatment plans.

The incorrect dose rate calibration occurred when the former licensee had a medical physics consultant calibrate the Sr-90 source after the original calibration certificate was lost. The medical physics consultant used an inappropriate measurement instrument for the calibration, which gave an erroneous dose rate calibration of 24 cGy per second (24 rad per second). (The label attached to the carrying case of the eye applicator device indicated that the medical physics consultant calibrated the Sr-90 source in September 1990.)

Also, Dr. Fernández had no Quality Management Program (QMP) as required by 10 CFR 35.32, which could have helped in detecting the calibration error. Medical use licensees, as required under 10 CFR 35.32, must establish a QMP to provide high confidence that radiation will be administered as directed by the authorized user.

Licensee Action:

Dr. Fernández initially ceased operations until the eye applicator device was properly calibrated; reliable dosimetric data was available to perform the dose administrations; and a QMP was developed and submitted to NRC for review. Dr. Fernández subsequently decided to cease using the Sr-90 source and to terminate his license. (The QMP was never implemented.)

NRC Action:

A CAL was issued to confirm that Dr. Fernández would submit a QMP for use of the eye applicator device, and that he would cease operations until approval was received from NRC to resume operations. A second CAL was issued confirming that Dr. Fernández would perform an in-depth review of his records to identify the misadministrations and to notify the patients.

After Dr. Fernández requested termination of his license, NRC issued an order, which required him to maintain the Sr-90 source in locked, safe storage until the sources were transferred to an authorized recipient, to transfer the Sr-90 source within 90 days, identify and notify any additional patients who may have received misadministrations, to obtain the services of an independent medical physics consultant with expertise in therapy dosimetry calculations, and to perform several other tasks specified in the order. Dr. Fernández currently has a possession only license until his sources are properly transferred and his request for termination has been granted by the NRC. In addition, NRC is requesting that the Puerto Rico Health Department perform a long term follow-up of these patients.

NRC also issued Information Notice 96-66, "Recent Misadministrations Caused by Incorrect Calibrations of Strontium-90 Eye Applicators," on December 13, 1996, to alert all medical use licensees authorized to use Sr-90 eye applicators of misadministrations caused by incorrect source strength determinations of Sr-90 eye applicators.

Dr. Fernández purchased the medical practice and the Sr-90 source from the estate of the deceased former licensee, Dr. Luis A Vázquez of Mayagüez, Puerto Rico. Consequently, Dr. Fernández has the records of all of the administrations that were made using the Sr-90 source while it was licensed to Dr. Vázquez. In a letter to Dr. Fernández dated October 28, 1996, NRC confirmed with Dr. Fernández that he would preserve the patient records of the former licensee and perform a computer search to identify patients who were treated with the eye applicator. NRC is considering options for the review of these records to determine how many additional misadministrations occurred when the incorrectly calibrated Sr-90 source was in the possession of the former licensee.

Other Agency Action:

Criteria:

Appendix A (see Event Type 5[a],[d]) of this report notes that administering therapeutic radiation such that the actual dose is greater than 1.5 times the prescribed dose, or the event (regardless of any health effects) affects two or more patients at the same facility, should be considered an AO.

ITEM #: 960096 AO #: NRC 96-04 EVENT DATE: 11/16/1995
TITLE: Brachytherapy Misadministrations by Phillip J. W. Lee, M.D.
NAME: Phillip J. W. Lee, M.D. CITY: Honolulu STATE: HA

Nature and Probable Consequences:

During an NRC inspection, it was determined that the licensee had incorrectly performed calculations for the decayed activity of strontium-90 (Sr-90) source in an eye applicator. Consequently, the licensee had the Sr-90 eye applicator calibrated by the National Institute of Standards and Technology (NIST). Based on calibration data provided by NIST, NRC and the licensee determined that 17 misadministrations involving 16 patients had occurred between May 6 and November 16, 1995. (Two of the misadministrations involved one patient who was treated on both eyes.) The delivered doses were from 21.1 to 22.7 percent greater than the prescribed total dose of 4000 centigray (cGy) (4000 rad). (The total dose was to be delivered in four fractions of 1000 cGy [1000 rad] each.)

The licensee and referring physicians did not observe any adverse consequences to the patients. The licensee noted that the misadministered doses were within the ranges recommended for this type of treatment. NRC contracted a medical consultant to review the cases and make an independent assessment of the potential health effects to the patients. As of the date of this report the reviews of the NRC and its consultant were ongoing.

The licensee notified the patients of the misadministration.

Cause:

The licensee did not know how to calculate the decay of the Sr-90 source, and used a linear function rather than a logarithmic function. In addition, the licensee used an incorrect half-life for Sr-90; however, this error was less significant.

Licensee Action:

The licensee had the Sr-90 eye applicator calibrated at NIST and learned how to calculate the decay of the Sr-90 source.

NRC Action:

NRC requested that the licensee have the Sr-90 eye applicator calibrated at NIST and taught the licensee how to calculate the decay of the Sr-90 source. NRC is conducting an inspection, which will remain open until the NRC medical consultant finishes reviewing the cases and provides an assessment of the potential health effects to the patients. Enforcement action may be taken in the future if necessary.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

Appendix A (see Event Type 5[d]) of this report notes that administering a therapeutic dose from a sealed source such that the errors in source calibration and time of exposure result in a calculated total treatment dose differing from the prescribed treatment dose by more than 10 percent, and the event (regardless of any health effects) affects two or more patients at the same facility, be considered an AO.

ITEM #: 951291 AO #: NRC 96-05 EVENT DATE: 11/24/1995

TITLE: Brachytherapy Misadministration at Harper Hospital

NAME: Harper Hospital CITY: Detroit STATE: MI

Nature and Probable Consequences:

A patient was being treated with a strontium-90 eye applicator for pterygium (a growth over the eye which causes gradual blindness). The patient was prescribed three 800-centigray (800 rad) treatments lasting 30 seconds each. Each of the treatments was to be administered to the medial side of the left eye. However, the second treatment was mistakenly administered to the lateral side of the left eye. The physician realized the error and immediately treated the correct side with the prescribed dose.

The patient was notified of the misadministration and given a written report. The patient's referring physician was notified. An NRC medical consultant evaluated the effects of the misadministration and concurred with the licensee that the patient was not expected to suffer any adverse health effects.

Cause:

The patient's chart was upside down and the treating physician incorrectly interpreted the sketch of the left eye on the diagram that specified the treatment site. (The diagram was part of the written directive for treatment using the strontium-90 eye applicator; however, it did not show the nose, top of the page, or bottom of the page.) Also, the second treatment was administered by a different physician and physicist than the first treatment.

Licensee Action:

The licensee revised the diagram so that it shows the nose, thereby making it obvious which is the left eye and which is the right eye.

NRC Action:

NRC conducted a special safety inspection. A Notice of Violation was issued for failing to ensure that the administration was in accordance with the written directive. Since the inspection showed that actions had been taken to correct the violation and to prevent recurrence, no reply to the violation was required.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

ITEM #: 951015 AO #: NRC 96-06 EVENT DATE: 11/10/1993
TITLE: Brachytherapy Misadministration at New England Medical Center
NAME: New England Medical Center CITY: Boston STATE: MA

Nature and Probable Consequences:

A patient with carcinoma of the cervix metastatic to the brain was being treated with an intercavity implant using cesium-137 sources in a gynecological applicator. During treatment a source became dislodged and delivered radiation to the patient's thigh which was an unprescribed treatment site.

The licensee subsequently calculated that the consequent dose to the patient's thigh was 71 centigray (cGy) (71 rad), as compared to 65 cGy (65 rad) which would have been delivered to the thigh at 20 centimeters (7.87 inches) distance from the applicator during the total procedure if performed as prescribed.

During a routine NRC inspection conducted on April 10-12, 1995, the NRC inspector noted the incident report and brought it to the attention of NRC management. NRC subsequently determined that the event was a misadministration and notified the licensee. The licensee consequently submitted the required notifications to NRC, and notified the patient in writing of the misadministration.

Cause:

A malfunction of the aging gynecological applicator and a possible lack of attention to details by the personnel involved in loading the applicator caused the misadministration.

Licensee Action:

The licensee replaced the malfunctioning gynecological applicator. In addition, the licensee now requires that two persons perform loading of the gynecological applicator to insure that the sources are in and that the ovoids are taped to insure that the sources do not come out inadvertently.

NRC Action:

The NRC again reviewed the information provided by the licensee and determined that a violation of the licensee's Quality Management Plan had occurred. An NRC medical consultant reviewed the circumstances of the misadministration, determined that the licensee had used an inaccurate source-to-thigh distance in its dose calculation, and determined that the patient received a dose of 864 cGy (864 rad) to the thigh instead of 71 cGy (71 rad) as calculated by the licensee. The medical consultant stated that the patient experienced no ill effects.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

ITEM #: 960177 AO #: NRC 96-07 EVENT DATE: 03/19/1996
TITLE: Brachytherapy Misadministration at William Beaumont Hospital
NAME: William Beaumont Hospital CITY: Royal Oak STATE: MI

Nature and Probable Consequences:

A patient with cancer of the vagina was prescribed treatment with a high dose rate (HDR) remote afterloader brachytherapy unit having an iridium-192 source. The treatment plan specified a step size of 2.5 millimeters (mm) (0.098 inches). A wrong step size of 5.0 mm (0.197 inches) was entered into the HDR unit's computer control program. Therefore, a part of the body not schedule to receive radiation was exposed.

The licensee calculated that the skin of the patient's thighs, which was the wrong treatment site, received a maximum unintended dose of 500 centigray (500 rad) because of the misadministration. An NRC medical consultant determined that the patient should have no side effects as a consequence of the misadministration. The patient and the referring physician were notified of the misadministration.

Cause:

The wrong step size was entered into the HDR remote afterloader brachytherapy unit's computer control program.

Licensee Action:

The licensee revised its "physics worksheet" to include the step length as an additional entry; developed a checklist for the physicist/dosimetrist to verify the treatment plan parameters, and posted it on the treatment console; and instituted a policy that treatment plan parameters must be verified, and the verification recorded, prior to each treatment.

NRC Action:

NRC conducted a special safety inspection, where one apparent violation was noted. This was the failure of the licensee's Quality Management Program to provide assurance of correct administration of the prescribed dose in compliance with the physician's written directive.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not schedule to receive radiation can be considered an AO.

ITEM #: 960478

AO #: NRC 96-08

EVENT DATE: 08/16/1996

TITLE: Brachytherapy Misadministration at Community Hospitals

NAME: Community Hospitals of Indiana

CITY: Indianapolis

STATE: IN

Nature and Probable Consequences:

A patient was prescribed a 500 centigray (cGy) (500 rad) treatment for an esophageal tumor using a high dose rate remote afterloader unit having an iridium-192 source. Because of a treatment planning error, a non-prescribed treatment area approximately 27 millimeters (mm) (1.06 inches [in]) below the tumor volume received a maximum dose of 465 cGy (465 rad) instead of the estimated dose of 50 to 100 cGy (50 to 100 rad).

The patient was notified of the misadministration. The licensee expects no adverse health effects to the patient. A NRC medical consultant was retained to review the case.

Cause:

Because of a treatment planning error, the source was placed approximately 27 mm (1.05 in) below the tumor volume.

Licensee Action:

A table of offset distances for the various sources and catheter lengths used by the licensee was placed in the licensee's quality control manual.

NRC Action:

NRC conducted a special safety inspection.

This item is closed for the purpose of this report.

Other Agency Action:

Criteria:

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

ITEM #: 960313 AO #: NRC 96-09 EVENT DATE: 12/31/1995
TITLE: Brachytherapy Misadministrations at EquiMed
NAME: EquiMed, Inc. CITY: Lehighton STATE: PA

Nature and Probable Consequences:

Two patients were prescribed vaginal treatment with a high dose rate (HDR) remote afterloader brachytherapy unit having an iridium-192 source. The prescribed total dose for each patient was between 2000 and 2200 centigray (cGy) (2000 and 2200 rad) and was to be delivered in five fractional doses over a period of several weeks. Each fractional dose was to be between 400 and 500 cGy (400 and 500 rad).

For one of the treatment fractions, 500 cGy (500 rad) was to be delivered to each patient over a treatment length of 5 centimeter (cm) (1.97 inches [in]) using a step size of 5 millimeters (mm) (0.197 in). However, a wrong step size of 10 mm (0.394 in) was entered into the HDR unit's control console, and a length of 10 cm (3.94 in) was treated instead of the prescribed length of 5 cm (1.97 in). Therefore, radiation was delivered to the wrong treatment site for each patient.

The licensee concluded that each patient received 312 cGy (312 rad) instead of the prescribed dose of 500 cGy (500 rad) (an underdose of 37.6 percent), and an additional length of 5 cm (1.97 in) received an unintended dose of 312 cGy (312 rad).

The licensee did inform the patients of the misadministrations, and does not expect the patients to have any adverse effects from the misadministrations.

Cause:

A wrong step size was entered into the HDR unit's control console because the licensee did not follow its Quality Management Procedures (QMP). The QMP requires that treatment planning information be checked by the person entering the data in the control console, and then verified by the authorized user.

Licensee Action:

The licensee's authorized user and the HDR physicist will extract the pre-treatment printout of the input parameters from the HDR treatment console, review the input data for accuracy, and compare it with the written directive. Both the authorized user and the HDR physicist will then initial the printout before the HDR treatment is initiated.

NRC Action:

NRC determined that the incidents occurred because the licensee did not follow its QMP. NRC contracted a medical consultant to evaluate the health effects on the patients from the misadministrations. Subsequently, the consultant determined no probable deterministic effects of the radiation exposure to the unintended site were expected.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

ITEM #: 951186 AO #: NRC 96-10 EVENT DATE: 10/19/1995
TITLE: Brachytherapy Misadministration at the University of Wisconsin
NAME: University of Wisconsin CITY: Madison STATE: WI

Nature and Probable Consequences:

A patient had two separate lung tumors, one in the lower section of the right lung and one in the middle section of the left lung. The patient was prescribed a total treatment dose of 1600 centigray (cGy) (1600 rad), with each tumor to receive a total dose of 800 cGy (800 rad). The total treatment dose was to be administered in four fractions of 400 cGy (400 rad) each over 2 days using a high dose rate (HDR) remote afterloader unit having an iridium-192 source. Each fraction was to be administered in two parts; a 200 cGy (200 rad) dose to the lower section of the right lung followed by a 200 cGy (200 rad) dose to the middle section of the left lung. Catheters of appropriate length were inserted into each lung to guide the source during treatment; i.e., a long catheter was inserted into the right lung and a short catheter was inserted into the left lung.

While the HDR controller was inserting the source into the left lung during the first treatment fraction, the source stopped moving when it touched the bottom of the short catheter in the left lung even though the HDR controller was attempting to move it further into the left lung. Because the intended treatment sites had been reversed during treatment planning and were subsequently programmed into the HDR controller, the controller had positioned the source in the middle of the right lung during the first part of the first treatment fraction and was attempting to position the source in the lower part of the left lung during the second part of the first treatment fraction. Consequently, the middle of the right lung had received an unintended dose of 200 cGy (200 rad) during the first part of the first treatment fraction.

After the error was discovered, the correct treatments were delivered. The patient was notified of the misadministration both verbally and in writing. The referring physician was also notified.

An NRC medical consultant evaluated the misadministration and concluded that the patient would not have organ damage or long term biological effects.

Cause:

When planning the treatment, the treating physician deviated from standard protocol and used different dummy sources to obtain clearer opaque x-ray markers for source location. Upon recording the data, the planned source locations for each treatment fraction were reversed. An independent verification of the treatment plan by a second physicist did not include a review of the x-rays for proper source location, so the error was not immediately discovered.

Licensee Action:

The licensee revised its Quality Management Program to include an independent review of the x-rays for source location by a second physicist. Also, when there is a deviation from the protocol, the results must be documented and reviewed by a second physicist.

NRC Action:

NRC conducted a special safety inspection in conjunction with a routine inspection. A Notice of Violation was issued for failing to establish adequate procedures to ensure that final treatment plans were in accordance with the written directive. The licensee responded in writing and no additional actions were required.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

ITEM #: 951061 AO #: NRC 96-11 EVENT DATE: 08/14/1995
TITLE: Brachytherapy Misadministration at Thomas Jefferson University Hospital
NAME: Thomas Jefferson University Hospital CITY: Philadelphia STATE: PA

Nature and Probable Consequences:

A patient was undergoing brachytherapy treatment of the palate; i.e., the roof of the mouth. A total of 64 iridium-192 seeds, having a total activity of 1102.6 megabecquerel (29.8 millicurie), were inserted into six catheters. Four of the catheters were sutured in the mouth, and two were placed in the nostrils.

While making a routine visit to the patient, the prescribing physician noticed that two catheters were outside of the patient's mouth and had been taped to the patient's right cheek. Also, one of the two catheters remaining in the mouth was loose and its suture was removed. Because the catheters were not properly positioned, the physician terminated the treatment.

The radioactive seeds were subsequently removed. The patient was informed both verbally and in writing that the sources had become dislodged and had consequently delivered radiation to the wrong treatment site. It was determined that the patient's cheek received a dose of 70 centigray (70 rad).

Cause:

While responding to a call from the patient, a nurse noticed that two of the catheters were loose and subsequently taped them to the patient's cheek. The nurse had not been trained to recognize that the radioactive seeds were moved from their intended positions.

Licensee Action:

Refresher in-service training was given to the nurses who care for brachytherapy patients. Emphasis was placed on identifying radioactive sources and handling them properly under normal and emergency conditions. Also, the nurses will be briefed on the details of a planned treatment at the time the sources are implanted with emphasis on radiation safety issues. Finally, physician will visit implant patients at least twice daily during treatment.

NRC Action:

After conducting an investigation, NRC determined that the event was a misadministration. An NRC medical consultant concluded that no significant injury would be expected. A Notice of Violation was issued with one Severity Level IV violation.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

ITEM #: 960165 AO #: NRC 96-12 EVENT DATE: 03/11/1996
TITLE: Brachytherapy Misadministration at Macombe Hospital Center
NAME: Macombe Hospital Center CITY: Warren STATE: MI

Nature and Probable Consequences:

A patient was undergoing a cervical boost brachytherapy treatment with a manually afterloaded standard gynecological applicator using cesium-137 sources. Approximately 100 minutes after the treatment was started, a nurse found one of the sources from the applicator lying on the sheet between the patient's legs. The dislodged source contained 1.29 gigabecquerel (34.8 millicurie) of cesium-137 and was intended for the right ovoid of the applicator. The nurse placed the source into the portable shielding that was available in the room and notified the radiation safety officer. The radiation safety officer immediately returned to the patient's room with the physician, who inserted the source into the right ovoid for the remainder of the prescribed 48 hours of treatment.

The licensee calculated that the unintended skin dose to the patient's upper inner thighs was 5 centigray (cGy) (5 rad). NRC concurred with the licensee's calculation and did not obtain a medical consultant. The dose of 5 cGy (5 rad) is within the occupational exposure limit and is not expected to result in deleterious effects to the patient. The patient and physician were notified of the misadministration.

Cause:

When the radiation oncologist manually afterloaded the sources from the right and left carriers into the ovoids, difficulty was encountered in identifying the correct carrier for the right ovoid. Also, the hinge on the correct carrier for the right ovoid was tight. The radiation oncologist believed that the sealed source dislodged from the carrier bucket when the problem with the hinge was encountered.

Licensee Action:

To prevent recurrence, the licensee will: (1) ensure that the carrier bucket hinges are working properly prior to loading the source into the bucket; (2) inscribe the handles of the ovoid carriers, with "R" for right ovoid and "L" for left ovoid, so that they can be readily identified without difficulty; (3) require the physicist to observe the radiation oncologist during the afterloading procedure in order to detect a dislodged source; and (4) require that the radiation oncologist complete a visual check of the bed sheets and immediate area before leaving the room.

NRC Action:

NRC conducted a special safety inspection. NRC issued a Notice of Violation for failing to meet the objective that each administration is in accordance with a written directive. The inspection showed that actions had been taken to correct the violation and to prevent recurrence.

Other Agency Action:

Criteria:

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

ITEM #: 960483 AO #: NRC 96-13 EVENT DATE: 08/19/1996
TITLE: Brachytherapy Misadministration at Unity Hospital
NAME: Unity Hospital CITY: Fridley STATE: MN

Nature and Probable Consequences:

A patient was prescribed a dose of 2500 centigray (cGy) (2500 rad) for a gynecological brachytherapy procedure, using a gynecological applicator containing cesium-137 sources in two ovoids. Because 3-centimeter (cm) diameter caps had been used on the ovoids of the gynecological applicator, instead of the intended 2-cm diameter caps, the patient received a dose of 1186 cGy (1186 rad) to the vaginal surface.

With the addition of the external beam therapy that the patient had received prior to this treatment, the total administered dose was 5680 cGy (5680 rad). The treating physician determined that the total administered dose was within the medically accepted range of treatment, and that no negative effects to the patient were expected. The treating physician did not plan to administer any further radiation treatments to the patient to compensate for the underdose.

The patient was notified of the misadministration both verbally and in writing. The referring physician was also notified.

Cause:

There was poor communication between the treating physician and the dosimetrist who prepared the treatment plan regarding the size of the ovoid caps to be used for the treatment. (The treating physician may select 2-cm diameter caps, 3-cm diameter caps, or no caps at all from an applicator kit, depending on the anatomy of the patient.) In addition, licensee personnel may have become desensitized to the possibility that an ovoid cap size different than 2-cm in diameter could be used; the treating physician failed to follow-up on earlier instructions to the dosimetrist to verify the correct cap size used; and the applicator kit was not returned immediately to the radiation oncology department following the implant of the applicator device.

Licensee Action:

The licensee revised its written-directive form to require the treating physician to enter the cap size when ovoids are used, and for a second person to verify that the information was entered. If the entry on the form is not made, the person confirming the information must independently verify which size ovoid caps were used.

NRC Action:

NRC conducted a special safety inspection on September 9, 1996. No violations of NRC requirements were identified during the course of this inspection.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

Appendix A (see Event Type 5[b]) of this report notes that administering a therapeutic dose such that the actual dose is less than 0.5 times the prescribed dose should be considered an AO.

ITEM #: 960294 AO #: NRC 96-14 EVENT DATE: 03/18/1996
TITLE: Radiopharmaceutical Misadministration at Universal Imaging
NAME: Universal Imaging, Inc. CITY: Taylor STATE: MI

Nature and Probable Consequences:

A patient was prescribed a 7.4 megabecquerel (MBq) (200 microcurie [μCi]) dosage of iodide-123 (I-123) for a thyroid scan, but was administered 7.4 MBq (200 μCi) of iodide-131 (I-131) instead.

The referring physician's directive stated that I-123 was to be used. (This is the only isotope of iodine used at the facility.) A technologist then accidentally ordered the I-131 from the nuclear pharmacy. A second technologist recognized that the I-131 was different from the I-123 routinely used, but assumed that it was prescribed and administered it anyway.

The licensee estimated that the dose to the patient's thyroid was 104 centigray (104 rad).

The referring physician was notified of the misadministration. The referring physician decided not to notify the patient because the information would be harmful to the patient.

An NRC medical consultant reviewed the event and determined that the impact of the misadministration on the status of the patient's health was very low, and that no specific medical follow-up care was necessary.

Cause:

The misadministration was apparently caused by a lack of sufficient oversight of licensed activities, inadequate training, and failure to establish a written protocol for ordering and verifying radiopharmaceuticals.

Licensee Action:

The licensee implemented the following corrective actions: (1) all technologists were informed not to use any radiopharmaceutical that was not listed in the licensee's "Prescribed Dosage List"; (2) orders must be sent to the nuclear pharmacy via facsimile, rather than over the telephone; (3) the nuclear pharmacy was instructed not to deliver I-131, I-125, or any other therapeutic radiopharmaceutical to the licensee; (4) all technologists were informed in writing not to proceed if they were unsure of any procedure; and (5) copies of radiopharmaceutical orders and their activities were to be checked against receipts.

The licensee is not required to have written directives to follow. This is because it does not perform therapy of any kind, does not use I-125 or I-131 in quantities greater than 1.11 MBq (30 μCi), and has no Quality Management Program.

NRC Action:

NRC conducted an inspection. Based on the results of the inspection, eight apparent violations were identified and are being considered for escalated enforcement action. A predecisional enforcement conference was held to discuss the apparent violations and any potential enforcement action is pending.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

Appendix A (see Event Type 1 in Table A-1) of this report notes that administering a radiopharmaceutical other than the one intended, where the actual dose is greater than five times the prescribed dose, can be considered an AO.

ITEM #: 951165 AO #: NRC 96-15 EVENT DATE: 09/21/1995
TITLE: Radiopharmaceutical Misadministration at Miami Valley Hospital
NAME: Miami Valley Hospital CITY: Dayton STATE: OH

Nature and Probable Consequences:

A patient was administered a 2.8 megabecquerel (MBq) (77 microcurie [μ Ci]) dosage of iodine-131 (I-131) for a thyroid uptake study, rather than the prescribed dosage range of 0.19 to 0.37 MBq (5 to 10 μ Ci) of I-131. The licensee determined that the dose to the patient's thyroid was 80.85 centigray (80.85 rad).

The patient was informed of the misadministration in writing. The patient's referring physician was also notified.

An NRC medical consultant determined that no adverse health effects are expected from the additional dosage.

Cause:

A nuclear medicine technologist inadvertently picked-up the wrong capsule, and in accordance with the licensee's practice did not calibrate the dosage in the dose calibrator prior to administration. The licensee's staff did not believe there was a requirement to assay dosages below 1.11 MBq (30 μ Ci).

Licensee Action:

The licensee implemented procedures to require that all dosages must be assayed regardless of their activity, and to review the assay of dosages on a quarterly basis.

NRC Action:

NRC conducted a special safety inspection. NRC issued a Notice of Violation for failing to measure dosages containing less than 1.11 MBq (30 μ Ci) before they were administered to patients for medical use. The licensee responded in writing and no additional actions are required.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

Appendix A (see Event Type 4 in Table A-1) of this report notes that if an actual diagnostic dose of a radiopharmaceutical is greater than five times the prescribed dose it can be considered an AO.

ITEM #: 960280 AO #: NRC 96-16 EVENT DATE: 04/09/1996
TITLE: Radiopharmaceutical Misadministration at St. Joseph Mercy Hospital
NAME: St. Joseph Mercy Hospital CITY: Ann Arbor STATE: MI

Nature and Probable Consequences:

A patient was administered a 596 megabecquerel (MBq) (16.1 millicurie [mCi]) dosage of iodine-131 rather than the prescribed MBq (3.3 mCi) dosage of I-131 for a diagnostic study of the neck and chest.

The misadministration was discovered after a vial, intended for another patient, was assayed and found to contain 122 MBq (3.3 mCi) instead of the expected 633 MBq (17.1 mCi). The patient was notified of the misadministration. The patient's referring physician was also notified.

The patient's thyroid gland had been removed previously and therefore the licensee anticipated minimal medical consequences. NRC contracted with the Oak Ridge Institute for Science and Education to conduct an assessment of the I-131 dose to the patient. The assessment concluded that since the patient had no thyroid, the maximum dose was misadministered to the patient's bladder wall and was equal to 48.3 centigray (48.3 rad).

Cause:

The technologist, when administering the dosage, mistakenly picked up a wrong radiopharmaceutical vial.

Licensee Action:

Licensee personnel failed to completely follow the written Quality Management Program.

NRC Action:

NRC conducted a special safety inspection. NRC issued a Notice of Violation for failure of the supervised user (technologist) to follow instructions in accordance with the written directive.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

Appendix A (see Event Type 4 in Table A-1) of this report notes that if an actual diagnostic dose of a radiopharmaceutical is greater than five times the prescribed dose it can be considered an AO.

ITEM #: 960010 AO #: NRC 96-17 EVENT DATE: 01/09/1996
TITLE: Radiopharmaceutical Misadministration at the Veteran Affairs Medical Center
NAME: Veteran Affairs Medical Center CITY: Charleston STATE: SC

Nature and Probable Consequences:

An outpatient was administered 277.5 megabecquerel (MBq) (7.5 millicurie [mCi]) of a prescribed 573.5 MBq (15.5 mCi) dosage iodine-131 (I-131) in liquid form. The error was discovered when the licensee rechecked the prescription vial with a dose calibrator after the administration to verify that the patient had received all of the prescribed dose. The licensee discovered that approximately 296 MBq (8 mCi) of the prescribed dosage had been retained in the vial cap, and consequently was not administered to the patient. The patient was informed of the event and was subsequently administered an additional 296 MBq (8 mCi) to make up for the underdosage. The licensee also notified the referring physician of the misadministration. The licensee expects no adverse effects to the patient from the misadministration.

Cause:

The root cause for the misadministration was a pronounced reaction of the I-131 with the vial cap, thereby allowing a significant portion of the radioactive material to bind itself to the cap.

Licensee Action:

The licensee's Radiation Safety Officer investigated the incident. Bioassays were conducted on the individuals who handled and administered the I-131 dose, and all were found to be negative. The licensee also revised its policy and procedures to require that only I-131 in capsule form be used in the future.

NRC Action:

NRC conducted a special inspection to review the circumstances surrounding the misadministration, and identified no violations of NRC requirements.

The State Agency is working with the nuclear pharmacy that filled the prescription and the intermediate processor of the I-131, both South Carolina state licensees, to determine the cause of event. The nuclear pharmacy informed its customers of the event.

This event is closed for the purpose of this report.

Other Agency Action:

Criteria:

Appendix A (see Event Type 5[b]) of this report notes that administering a therapeutic dose such that the actual dose is less than 0.5 times the prescribed dose should be considered an AO.

ITEM #: 040342 AO #: AS 04-03 EVENT DATE: 03/31/2004
TITLE: High Dose Rate Afterloader Medical Event at New Orleans Cancer Institute at Memorial Medical Center, Louisiana
NAME: New Orleans Cancer Institute CITY: New Orleans STATE: LA

Nature and Probable Consequences:

A cancer patient undergoing therapeutic radiation treatment for prostate cancer received 18 Gy (1,800 rads) to the wrong treatment site. This error occurred using a high dose rate (HDR) afterloader device with a radioactive source containing 270.7 GBq (7.32 Ci) of Ir-192. The event occurred after the dosimetrist made an error while inputting data into the afterloader's dosimetry software program. Although the dosimetrist appropriately clicked the "catheter tip" selection, the dosimetrist did not highlight and choose "catheter tip." Therefore, the computer cursor stayed on the "connector end" selection. This resulted in a 2-cm positioning error, which caused the source to stop short of the target so that the total prescribed dose was not delivered. The patient was informed of the event, and the remaining dose was delivered by external beam therapy. According to the Radiation Oncologist, no detriment effects are expected. The patient was self-referred for the therapeutic treatment.

Cause:

This event was attributed to operator error.

Licensee Action:

Actions taken to prevent recurrence include implementing procedures to add a visual check and documentation that the treatment plan was administered with the source position calculated from the tip end of the catheter or needle. This procedure will be added to the pre-treatment checklist, which is performed and signed by the radiation oncologist, physicist, and dosimetrist. The checklist will be performed prior to initial treatment and at treatment plan changes, and will be part of the patients' permanent records. Also, the licensee contacted the device's manufacturer regarding the confusion associated with the default orientation in the software program, and requested an adjustment to the program. The manufacturer stated that this could not be done at this time, but is discussing the issue. The manufacturer offered additional training to the licensee's employees, and the licensee is sending its employees to the training.

NRC Action:

Other Agency Action:

The State accepted the licensee's implementation of new procedures and its corrective actions as appropriate.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 040610 AO #: AS 04-04 EVENT DATE: 08/10/2004
TITLE: Diagnostic Medical Event at Northeast Alabama Regional Medical Center, Alabama
NAME: Northeast Alabama Regional Medical Center CITY: Montgomery STATE: AL

Nature and Probable Consequences:

A patient received 111 MBq (3,000 uCi) of I-131 instead of the prescribed dose of 0.93 MBq (25 uCi). The licensee discovered the event on August 12, 2004, when the patient returned for the whole body scan 48 hours later. The referring physician had requested a diagnostic I-131 scan to assess a thyroid nodule, which requires 0.93 MBq (25 uCi). The technologist misunderstood the order assuming that the referring physician wanted a whole body scan to assess thyroid cancer, and administered 111 MBq (3,000 uCi) of I-131 without requesting clarification or approval from the authorized users.

Two authorized users determined that the patient could become hypothyroid. Therefore, patient followup assessments included thyroid profiles and thyroid uptakes to determine thyroid function. The patient and the referring physician were informed of the event.

Cause:

This event was attributed to human error. The technologist misunderstood the treatment ordered by the referring physician and failed to verify the written directive.

Licensee Action:

The licensee implemented corrective measures to ensure that authorized users approve all procedures involving the administration of radiopharmaceuticals and re-instructed nuclear medicine personnel.

NRC Action:

Other Agency Action:

The State conducted an inspection.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 040222 AO #: AS 04-05 EVENT DATE: 03/17/2004
TITLE: Occupational Exposure at Palmetto Health and Baptist Hospital in Columbia, South Carolina
NAME: Palmetto Health and Baptist Hospital CITY: Columbia STATE: SC

Nature and Probable Consequences:

The licensee reported that a pharmacist trainee received an extremity exposure resulting in a shallow dose equivalent to the hand of 7.420 mSv (742 rem), a deep dose equivalent to the hand of 70 mSv (7.02 rem), and a thyroid dose of 0.9 mSv (0.09 rem). The exposures occurred when a spill took place while compounding I-131 from a vial. The pharmacist trainee cleaned up the area, decontaminated his skin, and reported the spill to the imaging manager the following day. The imaging manager conducted a second survey of the area, which showed that no contamination remained from the spill. The pharmacist trainee completed a spill report but did not reveal his contamination in the report. The pharmacist trainee left for vacation and 11 days later, after his return, informed the Radiation Safety Officer (RSO) that his forearm had been contaminated during the I-131 spill. Immediate actions were taken to determine whether any contamination still remained on his arm. Elevated levels were discovered on his right forearm and left fingertips. The appropriate hospital/nuclear medicine personnel were notified. The pharmacist trainee was suspended from all and all duties involving radioactive material.

Cause:

This event occurred as a result of human error and failure to follow established procedures. An initial crimp failure on the vial may also have contributed to the spill.

Licensee Action:

The licensee retrained all staff in spill procedures, emphasizing proper notification of supervisors. Additionally, at the prompting of the licensee, the vial supplier reevaluated the process of ensuring that each crimp is acceptable for shipment, although the supplier believed it was more likely an isolated incident.

NRC Action:

Other Agency Action:

The State agency conducted inspections and cited the licensee for violations of regulations for controlling radiation.

Criteria:

Criterion I.A.1, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report states, in part, that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent of 250 mSv (25 rem) or more or an annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) be considered for reporting as an AO.

ITEM #: 040125 AO #: AS 04-06 EVENT DATE: 01/24/2003
TITLE: Gamma Stereotactic Radiosurgery (Gamma Knife) Medical Event at Radiosurgical Center of Memphis in Memphis Tennessee
NAME: Radiosurgical Center of Memphis CITY: Memphis STATE: TN

Nature and Probable Consequences:

The licensee reported that a patient received 27 Gy (2,700 rads) to a brain metastasis instead of the intended 18 Gy (1,800 rads) during gamma knife treatment. The physicist did not determine that an error had occurred until the treatment was complete. The RSO determined that one of the four brain metastases received greater than the prescribed dose. The other three brain metastases received the prescribed dose. The tumor that received the incorrect dose was at the periphery of the brain next to the skull in a critical area so that much of the extra dose was delivered to the space between the brain and the skull. The cause of the incident was that a 14-millimeter (mm) (.55-inch) collimator helmet was used instead of the prescribed 8-mm (.31 inch) collimator helmet. The personnel setting up the treatment neglected to change the helmet. The tumor that received the unintended dose was located at the periphery of the brain, adjacent to the skull. Because most of the unintended dose was delivered to a non-critical space, between the brain and skull, the additional radiation exposure should have no significant effect on the patient.

The referring physician was notified of the event and informed the patient's family of the unintended dose.

Cause:

The cause was human error, in that the event resulted from use of the wrong collimator helmet.

Licensee Action:

The licensee established a new procedure to require the physician, physicist, and nurse to sign off on the treatment time, helmet size, and position before each shot. Also, new labels identifying the size of the helmet were attached to each of the four helmets. These labels can be seen by personnel via the TV monitor located at the control panel outside the treatment room. The physician will verify the correct size before the control panel button is pushed to start the treatment.

NRC Action:

Other Agency Action:

The State reviewed and approved the licensee's new procedures.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 040213

AO #: AS 04-07

EVENT DATE: 03/25/2004

TITLE: Strontium-90 Eye Applicator Brachytherapy Medical Event at St. Francis Hospital in Memphis, Tennessee

NAME: St. Francis Hospital

CITY: Memphis

STATE: TN

Nature and Probable Consequences:

A 79-year-old patient was prescribed radiation treatment for pterygium (an eye abnormality). The patient was to receive 20 Gy (2,000 rads), but instead received 70 Gy (7,059 rads). The prescribed dose was to be administered via a Sr-90 radioactive source with an activity of 3.7 GBq (100 mCi) for a duration of 42.5 seconds. However, the manual timer was incapable of being set for fractions of a second and interpreted the entry to be 4 minutes and 25 seconds. During the treatment, the physician questioned treatment time and terminated the treatment after 2 minutes and 30 seconds. The Radiation Oncologist concluded that the maximum possible dose delivered to the sclera was well below the sclera tolerance dose and that the optic nerve and retina did receive any meaningful dose. The patient and the referring physician were notified of the event.

Cause:

The wrong treatment time was programmed for the patient's eye treatment.

Licensee Action:

The licensee updated its procedures, which require use of an additional person to operate a second timer during brachytherapy treatment.

NRC Action:

Other Agency Action:

The Tennessee Department of Radiological Health conducted an onsite inspection on March 29, 2004. The State investigated, reviewed, and approved the licensee's new procedures.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 960264 AO #: AS 96-06 EVENT DATE: 05/23/1996
TITLE: Brachytherapy Misadministrations at the University of Mississippi Medical Center
NAME: University of Mississippi Medical Center CITY: Jackson STATE: MS

Nature and Probable Consequences:

Two patients were prescribed manual gynecological brachytherapy procedures using cesium-137 (Cs-137) sealed sources loaded in a gynecological applicator.

Patient A was prescribed a total dose of 4000 centigray (cGy) (4000 rad) in two fractional treatments of 2000 cGy (2000 rad) each. Patient B was prescribed a total dose of 2275 cGy (2275 rad) in one treatment. However, the medical physicist noticed while removing the sources from Patient A that the Cs-137 sources for the two patients were switched. The medical physicist immediately went to Patient B's room and removed the sources from Patient B.

As a result of the error, the administered second fractional treatment dose for Patient A was 1342 cGy (1342 rad), for an underdose of 33 percent. Also, Patient B was administered a treatment dose of 2698 cGy (2698 rad), for an overdose of 19 percent.

The licensee notified the referring physician and the patient's relatives of the misadministrations.

Cause:

The licensee stated that this event occurred because of human error. The medical physicist prepared three source configurations for three patients at the same time. The loads were color-coded for each patient to prevent mix-ups. On removal of the sources the medical physicist discovered that Patient A's and Patient B's loads were switched, even though the color-codes were correct for the patients. Patient C was not affected. The medical physicist stated that he must have switched the loads prior to color-coding the loads for the patients.

Licensee Action:

The licensee immediately implemented new procedures for loading brachytherapy sources into patients, which require the medical physicist to only prepare and load sources for one patient at a time.

NRC Action:

Other Agency Action:

The State Agency conducted an investigation. The State Agency concurred with the licensee's evaluation of the event and the corrective action implemented by the licensee. No violations were cited.

This event is closed for the purpose of this report.

Criteria:

Appendix A (see Event Type 5[d] in Table A-1) of this report notes that administering a therapeutic dose from a sealed source such that the treatment dose differs from the prescribed dose by more than 10 percent and the event affects two or more patients at the same facility can be considered an AO.

ITEM #: 960149 AO #: AS 96-07 EVENT DATE: 01/08/1996
TITLE: Radiopharmaceutical Misadministration at Baptist Medical Center Princeton
NAME: Baptist Medical Center Princeton CITY: Birmingham STATE: AL

Nature and Probable Consequences:

A 67-year-old male patient suspected of having Graves disease was prescribed 0.37 megabecquerel (MBq) (10 microcurie [μCi] iodine-131 (I-131) for a thyroid uptake study. The nuclear pharmacy delivered 3.7 MBq (100 μCi) by mistake, and a nuclear medicine technician subsequently administered the 3.7 MBq (100 μCi) to the patient. The administered diagnostic dose exceeded the prescribed diagnostic dose by a factor of 10; i.e., the diagnostic dose to the thyroid was approximately 350 centigray (cGy) (35 rad) instead of 35 cGy (35 rad).

The results of the thyroid uptake test confirmed that the patient had Graves disease and the patient was therapeutically treated with 555 MBq (15 millicurie) of I-131 the next day. Because the patient was treated with a therapeutic dose of I-131, there was no consequence or adverse health effect to the patient as a result of the diagnostic misadministration. The patient's attending physician decided that there was no need to notify the patient of the diagnostic misadministration.

Cause:

The misadministration was caused by two errors.

The first error occurred at the nuclear pharmacy, Syncor of Birmingham, Alabama, where the wrong date was entered into a computer. As a result, a 3.7 MBq (100 μCi) I-131 capsule was incorrectly identified as being the lowest activity capsule in inventory. Consequently, a 3.7 MBq (100 μCi) I-131 capsule was sent to Baptist Medical Center Princeton instead of the prescribed 0.37 MBq (10 μCi) I-131 capsule.

The second error occurred at Baptist Medical Center Princeton, where a technician failed to recognize that the activity of the capsule received from the nuclear pharmacy did not match the written directive for the prescribed activity.

Licensee Action:

Baptist Medical Center Princeton posted a copy of its written directives for each routine diagnostic procedure in the nuclear medicine department and confirmed that the nuclear pharmacy had a copy on file.

NRC Action:

Other Agency Action:

The State Agency discussed the misadministration with both the nuclear pharmacy and Baptist Medical Center Princeton and determined that a special inspection was not warranted. The State Agency sent an information notice to the State nuclear medicine licensees and nuclear pharmacies requesting that each verify with the other the values of activity utilized on any written directive that they may use in ordering or dispensing radiopharmaceuticals.

This event is closed for the purpose of this report.

Criteria:

Appendix A (see Event Type 4[a] in Table A-1) of this report notes that administering a diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent, and the actual dose is greater than five times the prescribed dose, should be considered an AO.

ITEM #: 970434 AO #: NRC 97-02 EVENT DATE: 05/14/1997
TITLE: Overexposure of a Worker at Mallinckrodt, Inc., in Maryland Heights, Missouri
NAME: Mallinckrodt, Inc. CITY: Maryland Heights STATE: MO

Nature and Probable Consequences:

On May 14, 1997, an employee was removing radioactive waste from the hot cell where rhenium-186 (Re-186) was used. The employee was performing this task manually, using gloves, instead of remotely. When he left the area, he attempted to perform personal contamination survey but the survey meter immediately went off the scale. He assumed that the high count rate was due to background radiation from an adjacent radioactive material transport cart and, subsequently, forgot to resurvey himself in a low background area before he left the facility that evening. Upon arrival at work the next day, he was told that his urine sample, which he had submitted before going home the previous night, indicated iodine-131 (I-131) radiation contamination and that he was restricted from working with radioactive material. At that time, he performed a personal contamination survey and detected significant levels of contamination on his left thumb which subsequently was identified as Re-186. The I-131 contamination level did not exceed the AO criteria for exposure to radiation from licensed material.

The licensee estimates that the individual received a shallow-dose equivalent of 6090 millisievert (609 rem) to an area of about 10 square centimeters (0.12 square inches) on the palm side of the thumb of his left hand. Lower levels of contamination were found on the back of his right hand and fingers. On May 15, 1997, the employee had undergone decontamination to the extent that only approximately 4 percent of the activity remained.

The licensee surveyed the offsite locations where the employee had been after leaving work on May 14, 1997. Low levels of Re-186 contamination were found on three locations inside the employee's vehicle and on various items in the bathroom and kitchen at his home. The employee's vehicle and home were decontaminated. The employee was examined by a physician who identified no immediate health effects. However, according to a report from an NRC consultant, a small possibility exists for skin cancer to develop in the exposed area of the thumb.

Cause:

The cause of the event was a procedural deficiency in handling waste from the Re-186 hot cell. Normally, radioactive waste in other hot cells at the facility was handled with remote tools. However, in this case, procedural controls did not require remote handling of the waste. Once the employee completed the work, poor radiation work practices were exhibited as he cross-contaminated his hands when he removed his gloves. In addition, the worker did not investigate the detection of high count rate during his first attempt to perform a contamination survey.

Licensee Action:

The staff was instructed on the importance of conducting proper personal contamination surveys and the proper use of protective clothing. The use of Re-186 was suspended until improvements to existing waste disposal procedures could be evaluated and implemented. Plans were made (1) to compile all existing contamination protection procedures into one contamination protection procedure, (2) to evaluate the use of a portal type monitoring system, and (3) to post personal-monitoring reminder signs at all laboratory exits.

NRC Action:

NRC conducted a special safety inspection, proposed a \$55,000 civil penalty on December 17, 1997, and the licensee paid the penalty on January 20, 1998.

Other Agency Action:

Criteria:

Appendix A (see Criterion I.A. 1, "For All Licensees") of this report states that any unintended radiation exposure to an adult (an individual 18 years of age or older) resulting in an annual shallow-dose equivalent to the skin or extremities of 2500 mSv (250 rem) or more will be considered for reporting as an AO.

ITEM #: 960008 AO #: AS 97-01 EVENT DATE: 12/31/1995
TITLE: Multiple Transuranic Overexposures to a Worker at Isotope Products Laboratories in Burbank, California
NAME: Isotope Products Laboratories CITY: Burbank STATE: CA

Nature and Probable Consequences:

A radiochemist was assigned to make transuranic and other types of sources. The transuranics utilized included the isotopes of plutonium-238 (Pu-238), Pu-239, Pu-240, americium-241 (Am-241), and curium-244 (Cm-244). During January 1995, while making a Cm-244 source, it was discovered that the exhaust fan of the fume hood where the source was being fabricated was not working. An analysis of room air samples confirmed the loss of Cm-244 into the working area.

Bioassay results disclosed that the fecal and urine samples provided by the radiochemist contained Cm-244 and Am-241. The licensee hired dosimetry and radiation protection consultants as directed by the State Agency. Careful analysis of the bioassay data by these consultants, which included dose summation and retrospective time correction for various intakes, suggested that during 1995 the radiochemist received a TEDE of 383.20 mSv (38.32 rem) and a CDE of 6900 mSv (690 rem) to the bone surfaces. The specific exposures were as follows: (1) committed effective dose equivalent (CEDE) of 271.8 mSv (27.18 rem) from Cm-244, (2) CEDE of 80 mSv (8 rem) from Am-241, (3) CEDE of 4.4 mSv (0.44 rem) from Pu-238, Pu-239, and Pu-240, and (4) DDE of 27.0 mSv (2.70 rem) from external radiation.

The State Agency discovered this incident during a routine inspection on December 5, 1995, and was initially reported to NRC in January 1996. During a follow-up inspection, the State Agency learned that another Cm-244 incident took place and was significant. The State Agency also learned of other exposure incidents that indicated the licensee had a deficient contamination control program, an inability to conduct internal dose assessments, and inadequate management oversight. The State provided additional information on these events to NRC in 1997.

Cause:

The licensee's radiation protection program was inadequate and lacked important elements needed to ensure the radiation safety of its workers. Some of these inadequacies were the lack of (1) work permits, (2) glove boxes for certain types of work, and (3) radiation procedural controls.

Licensee Action:

After the licensee's consultants conducted their review and comprehensive audit of the existing radiation protection program, the licensee made recommendations to ensure future compliance with the license and regulations. The licensee hired a competent radiation safety officer, and the radiochemist was assigned duties that did not involve the handling or processing of radioactive materials.

NRC Action:

Other Agency Action:

The State Agency completed its investigation and is committed to closely tracking the licensee's radiation protection program to ensure continued compliance.

Criteria:

Appendix A (see Criterion I.A.1, "For All Licensees") of this report states that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more; or an annual sum of the deep dose equivalent (DDE) (external dose) and committed dose equivalent (CDE) (intake of radioactive material) to any individual organ or tissue other than the lens of the eye, bone marrow, and the gonads of 2500 mSv (250 rem) or more will be considered for reporting as an AO. In addition, Appendix A (see Criterion I.D.3, "Other Events") of this report states that a serious deficiency in management or procedural controls in major areas will be considered for reporting as a AO.

ITEM #: 960327 AO #: AS 97-02 EVENT DATE: 07/01/1996
TITLE: Overexposure of a Radiographer and an Untrained Technician at Wolf Creek Mine in Walker County, Alabama
NAME: Wolf Creek Mine CITY: Walker County STATE: AL

Nature and Probable Consequences:

A radiographer, employed by Certified Testing and Inspection of Cottondale, Alabama, and a technician, employed by Ultron, Inc. of Mt. Vernon, Illinois, were performing industrial radiography at the Wolf Creek Mine in Walker County, Alabama, when they became so distracted by problems with excessively exposed film that they forgot they had an exposure in progress and entered high radiation area without making a survey and changed the film with the source in the unshielded exposed position. The radiographer had received prior radiation safety training, however, the technician, an employee of Ultron, Inc., had not received radiation safety training. The radiography film and the device used to support the source and the film during exposures were supplied to the radiographer by Ultron, Inc.

Consequently, both individuals received unintended radiation exposure. The State Agency estimated that the radiographer received a dose of 530 millisievert (mSv) (53 rem) to his head and 48 mSv (4.8 rem) to the center of his body and the Ultron, Inc., technician received a dose of 110 mSv (11 rem) to his head and 28 mSv (2.8 rem) to the center of his body. Neither individual reported an acute radiation symptoms.

The radiography film supplied by Ultron, Inc., had faster and different exposure characteristics than the film usually used by Certified Testing and thus was being overexposed during processing in the darkroom. The darkroom, which was supplied by Certified Testing, utilized a homemade "safe light," which had been made a safe light by the application of red spray paint. The radiographer did not realize beforehand that the light would not be "safe" for the film supplied by Ultron, Inc.

Cause:

The radiographer entered a designated high radiation area with his alarm ratemeter turned off and without following his normal practice of cranking in the source and surveying the guide tube and camera. The radiographer interpreted the silence from the alarm ratemeter as an indication of safe conditions. Unfortunately, when turned off, the alarm ratemeter gives the same indication as it does when indicating safe conditions. In addition, the radiographer did not utilize a collimator to reduce the exposure to himself and the Ultron, Inc., technician.

Licensee Action:

The licensee stated that the radiographer did not develop any symptom of acute radiation exposure and that its personnel were reinstructed in the importance of performing surveys and using a collimator. The licensee committed to the State Agency to verify the training of all technicians, including those of the company that hires the licensee to perform radiography.

NRC Action:

Other Agency Action:

The State Agency cited the Licensee for the following four violations: (1) excessive exposure to a radiation worker, (2) excessive exposure to a member of the public (the Ultron, Inc., technician representative), (3) failure to prevent unauthorized entry into the High Radiation Area, and (4) failure to exercise ALARA by using a collimator. A civil penalty was considered but not imposed. The State Agency recommended that both individuals contact the State and seek medical attention if any symptoms of acute exposure should appear.

Criteria:

Appendix A (see Criterion I.A.1, "For All Licensees") of this report states that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more; or an annual sum of the deep dose equivalent (DDE) (external dose) and committed dose equivalent (CDE) (intake of radioactive material) to any individual organ or tissue other than the lens of the eye, bone marrow, and the gonads of 2500 mSv (250 rem) or more will be considered for reporting as an AO. In addition, Appendix A (see Criterion I.D.3, "Other Events") of this report states that a serious deficiency in management or procedural controls in major areas will be considered for reporting as a AO.

ITEM #: 970220 AO #: AS 97-03 EVENT DATE: 02/28/1996
TITLE: Radiopharmaceutical Misadministration at Mad River Community Hospital in Arcata, California
NAME: Mad River Community Hospital CITY: Arcata STATE: CA

Nature and Probable Consequences:

A patient was prescribed a dosage of 3.7 megabecquerel (MBq) (0.1 millicurie [mCi]) of iodine-131 (I-131) for a thyroid scan and uptake procedure. However, the patient was administered a dosage of 262.7 MBq (7.1 mCi) of I-131. As a result, the patient's thyroid received a dose of about 9100 centigray (cGy) (9100 rad), instead of the prescribed dose of 130 cGy (130 rad).

The licensee stated that such a dose may induce a hypothyroid state requiring the patient to take thyroid hormone.

Cause:

The wrong dosage was administered on the assumption that the patient was prescribed a whole body thyroid scan for a cancer metastatic disease evaluation.

Licensee Action:

Procedures for scheduling a whole body scan for thyroid cancer metastases were revised to include a detailed patient preparation and history. The revised procedures required that the approving radiologist sign the I-131 administration policy before ordering radiopharmaceutical. In addition, the nuclear medicine technologist attended a continuing education program at San Francisco General Hospital, which included a segment on the effects of studies involving therapy dosages.

NRC Action:

Other Agency Action:

The State Agency conducted numerous follow-up inspections to ensure that the licensee's actions taken to prevent recurrence have been implemented.

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") of this report states that a medical misadministration that results in a dose that is equal to or greater than 10 gray (Gy) (1000 rad) to any organ (other than a major portion of the bone marrow, to the lens of the eye, or to the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 970155 AO #: AS 97-04 EVENT DATE: 12/11/1996
TITLE: Radiopharmaceutical Misadministration at Tuomey Regional Medical Center in Sumter, South Carolina
NAME: Tuomey Regional Medical Center CITY: Sumter STATE: SC

Nature and Probable Consequences:

A patient was prescribed a dosage of 74 megabecquerel (MBq) (2.0 millicurie [mCi]) of iodine-131 (I-131) for a treatment of Grave disease. However, the patient was administered a 388.5 MBq (10.5 mCi) dosage of I-131. As a result, the patient's thyroid received a dose of 40,400 centigray (cGy) (40,400 rad) instead of the prescribed dose of 7700 cGy (7700 rad).

The licensee stated that the administered dose of I-131 to the patient's thyroid is not expected to have major health effects.

Cause:

The wrong dosage was administered to the patient because the written order for the I-131 procedure was misread by the administering technologist.

Licensee Action:

The licensee will have the written order on hand before ordering radiopharmaceuticals from the pharmacy and will have a second person verify the dosage before administration to the patient.

NRC Action:

Other Agency Action:

The State Agency accepted the licensee's report and corrective action as appropriate. No further action was requested.

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") of this report states that a medical misadministration that results in a dose that is equal to or greater than 10 gray (Gy) (1000 rad) to any organ (other than a major portion of the bone marrow, to the lens of the eye, or to the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 980005 AO #: NRC 98-02 EVENT DATE: 04/27/1995
TITLE: Multiple Medical Brachytherapy Misadministrations by José N. De León, M.D., in Rio Piedras, Puerto Rico
NAME: José N. De León, M.D. CITY: Rio Piedras STATE: PR

Nature and Probable Consequences:

Between April 27, 1995, and June 26, 1996, nine patients were treated after surgery for non-malignant eye growths with a strontium-90 (Sr-90) eye applicator, at Dr. De León's private medical office. Each of the nine patients received a dose of 4000 centigray (cGy) (4000 rad) instead of the intended dose of 2000 cGy (2000 rad). The NRC staff identified this event during Fiscal Year 1996.

On June 1, 1994, Dr. De León submitted to NRC a Quality Management Program (QMP) indicating that his 4.625 gigabecquerel (125 millicurie) Sr-90 eye applicator device would deliver to a patient a dose of 2000 cGy (2000 rad) in 26 seconds. In April 1995, Dr. De León hired a health physics consultant to calculate a decay correction for the surface dose rate of the Sr-90 eye applicator. In April 1995, Dr. De León submitted a revised QMP to the NRC, incorporating the surface dose rate corrections performed by the consultant, stating that the Sr-90 eye applicator device would deliver a 2000 cGy (2000 rad) dose in 60 seconds.

On December 11, 1997, the NRC conducted a special inspection of Dr. De León's licensed activities. During this inspection, the NRC determined that in April 1995, Dr. De León's consultant had made a calculation error. Without verifying the consultant's calculations, Dr. De León had adjusted the treatment time from 26 seconds to 60 seconds.

When Dr. De León became aware of this error, he indicated that (1) all patients or next of kin were notified, (2) a free examination was offered to all patients, which was declined, and (3) there were no problems or complications reported by patients associated with the misadministrations. Dr. De León also indicated that it is unlikely for patients to develop any harmful effects as a result of the misadministration.

The NRC hired a medical consultant to review the medical aspects of the misadministration. The NRC's medical consultant reviewed the information obtained from the NRC, Dr. De León, and Ryder Memorial Hospital, and concluded that (1) the range of single fraction for eye radiation treatments, recommended by the medical community using a Sr-90 applicator, is about 1800 - 3000 cGy (1800 - 3000 rad), (2) the highest single dose, using a Sr-90 applicator, recommended in published medical reports, is 3000 cGy (3000 rad), and (3) the patients treated by Dr. De León are at a higher risk for harmful effects because of the high doses given in single fractions.

Cause:

Dr. De León's consultant made a calculation error in correcting the surface dose rate of the Sr-90 applicator for radioactive decay and Dr. De León failed to verify or question the consultant's calculation before using the revised surface dose rate in patient treatments.

Licensee Action:

Dr. De León has retired; he has properly transferred the Sr-90 eye applicator to a foreign user and he has obtained from NRC a termination of his license.

NRC Action:

The NRC's Advisory Committee on the Medical Use of Isotopes will be recommending courses of action to the NRC. NRC will perform additional inspections of NRC licensees authorized to possess and use Sr-90 eye applicators to confirm the use of proper decay corrections and source calibrations. In addition, the NRC staff will review this case with the Secretary of Health of the Commonwealth of Puerto Rico for possible action.

Other Agency Action:

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states that a medical misadministration that results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or the gonads; or (2) equal to or greater than 10 Gy (1000 rad) to any other organ and that represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 980140 AO #: NRC 98-03 EVENT DATE: 04/22/1995
TITLE: Multiple Medical Brachytherapy Misadministrations at Ryder Memorial Hospital, in Humacao, Puerto Rico
NAME: Ryder Memorial Hospital CITY: Humacao STATE: PR

Nature and Probable Consequences:

Between April 22, 1995, and February 21, 1996, twelve patients treated with a strontium-90 (Sr-90) eye applicator at the Ryder Memorial Hospital received a dose of 4000 cGy (4000 rad) instead of the intended dose of 2000 cGy (2000 rad). Two patients received a second treatment dose of 4000 cGy (4000 rad) to the same eye. These treatments were performed by Dr. José De León, who, in addition to his private practice in Rio Piedras in Puerto Rico, was authorized by NRC to practice at the Ryder Memorial Hospital in Humacao, Puerto Rico. The NRC staff identified this event during Fiscal Year 1998.

On June 28, 1994, Ryder Memorial Hospital notified the NRC that it had canceled the authorization given to the ophthalmologist named on their license to use Sr-90 at its facility, and a Quality Management Program was not needed for this activity. However, during a routine inspection of Ryder Memorial Hospital, conducted between November 17 and December 11, 1997, the NRC staff learned that Dr. De León had used his Sr-90 eye applicator at the Ryder Memorial Hospital without authorization from the hospital. NRC was unable to determine whether Dr. De León had been told by Ryder Memorial Hospital that his authority was canceled for the use of the Sr-90 eye applicator.

On December 11, 1997, the NRC conducted a special inspection of Dr. De León's licensed activities. During this inspection, the NRC determined that in April 1995, Dr. De León's consultant had made a calculation error. Without verifying the consultant's calculations, Dr. De León adjusted the treatment time from 26 seconds to 60 seconds.

Ryder Memorial Hospital representatives and Dr. De León notified the patients or next of kin of the misadministrations. The information presented by Ryder Memorial Hospital describing the effects on patients from the misadministrations was based on information submitted by Dr. De León. Specifically, Dr. De León indicated that the delivered dose of 4000 cGy (4000 rad) falls within the dose range used by the medical community to prescribe these treatments and no adverse effects were expected.

The NRC medical consultant reviewed the information obtained from the NRC, Dr. De León, and Ryder Memorial Hospital, and concluded that (1) the range for a single fraction for eye radiation treatments, recommended by the medical community using a Sr-90 applicator, is about 1800 - 3000 cGy (1800 - 3000 rad), (2) the highest single dose, using a Sr-90 applicator, recommended in published medical reports, is 3000 cGy (3000 rad), and (3) the patients treated by Dr. De León are at a higher risk for harmful effects because of the high doses given in single fractions.

Cause:

Dr. De León's consultant made an error in calculating the surface dose rate of the Sr-90 applicator, and Dr. De León failed to verify the consultant's calculation before incorporating the revised surface dose rate in patient treatments. In addition, Dr. De León performed ophthalmic brachytherapy using his Sr-90 eye applicator device at Ryder Memorial Hospital under Ryder Memorial Hospital's NRC license, without the hospital's authorization.

Licensee Action:

Ryder Memorial Hospital reiterated its withdrawal of Dr. De León's authority to use the Sr-90 eye applicator device at Ryder Memorial Hospital and does not intend to authorize future use of the Sr-90 eye applicator for ophthalmic brachytherapy. In addition, Dr. De León has retired; he has properly transferred the Sr-90 eye applicator to a foreign user and he has obtained from NRC a termination of his license.

NRC Action:

The NRC's Advisory Committee on the Medical Use of Isotopes will be recommending courses of action to the NRC. NRC will perform additional inspections of NRC licensees authorized to possess and use Sr-90 eye applicators to confirm the use of proper decay corrections and source calibrations. In addition, the NRC staff will review this case with the Secretary of Health of the Commonwealth of Puerto Rico for possible action.

Other Agency Action:

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states that a medical misadministration that results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or the gonads; or (2) equal to or greater than 10 Gy (1000 rad) to any other organ and that represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 971111 AO #: NRC 98-04 EVENT DATE: 11/21/1997
TITLE: Iodine-131 Medical Misadministration at Virginia Beach General Hospital, in Virginia Beach, Virginia
NAME: Virginia Beach General Hospital CITY: Virginia Beach STATE: VA

Nature and Probable Consequences:

A patient was administered a dosage of 199.8 megabecquerel (MBq) (5.4 millicurie [mCi]) of iodine-131 (I-131) for a thyroid procedure instead of an 11.1 MBq (0.300 mCi) dosage of iodine-123 (I-123). As a result, the patient's thyroid received a dose of 4000 centigray (cGy) (4000 rad), instead of the intended dose of 2.0 cGy (2.0 rad).

On November 20, 1997, the referring physician prescribed a thyroid function procedure, which, at Virginia Beach General Hospital required the administration of about 11.1 MBq (0.300 mCi) of I-123. Due to poor communication between the referring physician and her staff (a staff nurse), the patient was scheduled for a whole-body thyroid scan, which required the administration of approximately 185 MBq (5 mCi) of I-131. On November 21, 1997, the technologist who was to perform the procedure attempted contact the referring physician to ask questions about the requested procedure. However, the referring physician was not available and the staff nurse who had originally taken the request from the referring physician and scheduled the procedure confirmed that the physician wanted an I-131 scan. The technologist, without a written directive, decided to proceed with the procedure and administered the dosage of 199.8 MBq (5.4 mCi) of I-131 to the patient. The misadministration was identified on November 24, 1997, when the patient returned for a 72-hour whole-body scan.

The licensee stated that no adverse health effects are expected from the misadministration. The NRC's medical consultant determined that the impact of the misadministration on the patient's health should be negligible, with no expected long-term disability.

Cause:

This event was caused by the licensee's failure to prepare a written directive before the administration of the I-131 dosage and inadequate followup by the technologist involved in the I-131 procedure.

Licensee Action:

New procedures were initiated that required all I-131 procedures to be scheduled through the Nuclear Medicine Department, and additional quality management measures were implemented. The licensee also initiated changes to the computerized scheduling system and provided retraining of the staff.

NRC Action:

An inspection was conducted to review the circumstances of the misadministration. A Notice of Violation was issued for failure of the licensee to prepare a written directive before the administration of I-131.

Other Agency Action:

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states that a medical misadministration that results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or the gonads; or (2) equal to or greater than 10 Gy (1000 rad) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 970972 AO #: AS 98-01 EVENT DATE: 09/23/1997
TITLE: Medical Brachytherapy Misadministration at Tuomey Regional Medical Center in Sumter, South Carolina
NAME: Tuomey Regional Medical Center CITY: Sumter STATE: SC

Nature and Probable Consequences:

On September 23, 1997, a patient was scheduled by a referring physician (urologist) for a palladium-103 (Pd-103) permanent prostate seed implant via transrectal ultrasound guidance. However, the referring physician had two patients with identical names and the wrong individual got the orders for the Pd-103 treatment. The patient was identified at the Medical Center by verbal means (asking the patient's name) and by the chart stating he was at the hospital for seed implant for treatment of prostate cancer. The patient received 67 seeds of Pd-103 at 37 megabecquerel (MBq) (1 millicurie [mCi]) per seed, thus a total implant activity of 247 MBq (67 mCi). On the basis of pre-implant dosimetry, the periphery of the prostate was to receive a maximum dose of 9000 centigray (cGy) (9000 rad). The posterior wall of the bladder and anterior wall of the rectum would receive approximately 4000 (4000 rad) and the whole-body dose would be less than 1 cGy (1 rad). The procedure was performed without complication.

On September 25, 1997, the referring physician notified Tuomey Regional Medical Center that he had two patients with identical names and that the wrong individual had received the implant. On September 29, 1997, the authorized user met with the individual who had received the Pd-103 treatment and discussed the potential early and late side effects, and all necessary precautions.

The licensee stated that the early consequences from this type of implant usually are dysuria and possible hematuria, which, if they occur, resolve in several days. Late consequences could be an approximately 25 percent chance of impotence. Damage to the bladder and rectum occurs in fewer than 1 percent of patients.

Cause:

The referring physician had two patients with identical names. The wrong individual arrived at Tuomey Regional Medical Center with orders from the referring physician for the Pd-103 seed implant. The patient who should have had these orders had been to Tuomey Regional Medical Center for a pre-operative interview. When the wrong individual presented for treatment at Tuomey Regional Medical Center with orders for the Pd-103 seed implant, the registration process failed to note that he was not the same individual who had undergone the pre-operative interview.

Licensee Action:

The licensee performed a comprehensive review of the patient identification process once the incident occurred. As a result, the patient identification system was revised on a hospital-wide basis in order to prevent recurrence of this type of event.

NRC Action:

Other Agency Action:

The State agency investigated the event and a Notice of Violation and Enforcement Conference was held on February 10, 1998. Notice of Noncompliance was issued for failure to meet the objective that each administration is done in accordance with a written directive. The licensee responded in writing and no additional actions were required.

Criteria:

Appendix A (see Criterion I.A.1, "For All Licensees") to this report states that any unintended radiation exposure to an adult (an individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to any individual organ or tissue other than the lens of the eye, bone marrow, and the gonads of 2500 mSv (250 rem) or more will be considered for reporting as an AO.

ITEM #: 000186 **AO #:** NRC 98-01 **EVENT DATE:** 02/18/1998
TITLE: Seismic Risk from Liquid Uranium Hexafluoride at the Withdrawal Facilities at the Paducah Gaseous Diffusion Plant, Paducah, Kentucky
NAME: Paducah Gaseous Diffusion Plant **CITY:** Paducah **STATE:** KY

Nature and Probable Consequences:

On October 31, 1997, USEC submitted a certificate amendment request that provided an updated Safety Analysis Report, containing a new accident analysis, for Paducah. The seismic accident analysis stated that equipment (piping, condensers, and accumulators) in the withdrawal facilities containing liquid uranium hexafluoride (UF6) could fail at a 70-year return earthquake [0.05 gravitational acceleration (g) peak ground acceleration (pga)] rather than at the 250-year return design basis earthquake (0.1 g pga). However, the consequences of the accident analysis were noted as minimal because of the assumptions made in the accident analysis. The NRC's request for additional information (RAI) dated February 5, 1998, raised concerns about the conservative nature of assumptions for the seismic accident analysis. In response to the RAI, USEC confirmed that the seismic accident analysis assumption of no liquid UF6 in the withdrawal facilities' accumulators underestimated the potential source term for the seismic accident analysis.

The accumulators are normally empty and serve only as a reservoir for liquid UF6 when cylinders are changed after being filled, during periods of equipment problems or surveillances. However, with no operational restrictions on the amount of liquid UF6 in accumulators, a seismic event could occur with the accumulators full. Consequences from a 0.05 g pga earthquake with full accumulators in the withdrawal facilities could involve onsite fatalities and significant offsite injuries from exposure to the release of UF6 and reaction products.

Cause:

The cause of this event was an inadequate seismic design for the facility and an inadequate accident analysis that failed to consider the full range of allowable operations of the withdrawal facilities.

Licensee Action:

Immediate corrective actions included restricting operations in the withdrawal facilities to limit the amount of liquid UF6 available for release. Long-term corrective actions were to install seismic modifications that will allow the withdrawal facilities' equipment to withstand a design-basis earthquake. The modifications have been completed as directed by the NRC.

NRC Action:

An immediately effective "confirmatory order modifying certificate" to incorporate the immediate and long-term corrective actions was issued on April 22, 1998.

Other Agency Action:

Criteria:

Appendix A (see Part III, "For Fuel Cycle Facilities") to this report states that a major condition or significant event not considered in the license/certificate that requires immediate remedial action will be considered for reporting as an AO.

ITEM #: 981204 AO #: NRC 99-01 EVENT DATE: 12/09/1998
TITLE: Fire Breaches Containment and Requires Shutdown of a Portion of the Cascade at the Portsmouth Gaseous Diffusion Plant in Piketon, Ohio
NAME: Portsmouth Gaseous Diffusion Plant CITY: Piketon STATE: OH

Nature and Probable Consequences:

On December 9, 1998, the certificate holder's operations staff observed a series of abnormal conditions associated with the side purge cascade, Cell 25-7-2. The staff's immediate response to the abnormal conditions was not successful in restoring normal operations and an exothermic reaction was either started or propagated within the cascade. The exothermic reaction continued until sufficient heat was generated to cause a failure of the Cell 25-7-2 cooling system, initiating a second exothermic reaction. Subsequent heat and pressure increases within the side purge cascade resulted in (1) the creation of holes within the process gas cascade boundary of Cell 25-7-2, (2) an automatic shutdown of the side purge cascade caused by the motor load overcurrent protection system which provides "Defense in Depth," (3) the activation of a portion of the Building X-326 automatic fire suppression sprinkler system, (4) an emergency response and approximately 2 hours of firefighting activities by the onsite fire department, and (5) challenges to the continued operation of the remainder of the process gas cascade.

There were no measurable radiological consequences or chemical consequences to the plant staff or the general public from the release of radioactivity during this event. The holes created in the side purge cascade equipment and piping created a credible pathway for water to accumulate in unsafe geometry sections of the cascade. This led to the need to revise the criticality safety basis for this portion of the side purge cascade.

Cause:

The extensive fire damage experienced by Cell 25-7-2 equipment has made it difficult to determine the root cause. Much of the equipment has been damaged to such an extent that evidence needed to determine the root cause was destroyed. The investigation by the certificate holder identified two possible initiating events: a physical failure of the compressor impeller or a chemical deposit caused by wet air leakage into the equipment. In either event, mechanical friction within the process gas cascade equipment generated a sufficient amount of sustained heat to begin an exothermic reaction between the aluminum compressor components and the process gas (uranium hexafluoride). On the basis of a review of some of the Cell 25-7-2 components removed since the fire, the exothermic reaction was believed to have been initiated in the Stage 2 compressor and propagated through the cell equipment to the Stage 4 compressor. In the Stage 4 compressor, the reaction was thought to have been intensified by the input gases, received from the remainder of the cascade, resulting in increasing internal process gas cascade temperatures until there was a failure in the freon coolant system boundary. Elevated pressure, caused by the introduction of freon from the coolant system and a second exothermic reaction between the hot metal and freon, was thought to be the final event that occurred before the holes were burned in the process gas cascade boundary.

Licensee Action:

Initial compensatory and corrective measures implemented by the plant staff as a result of the fire included: (1) administrative controls to preclude a restart of the side purge cascade and some other plant operations pending the completion of a root cause evaluation of the fire, (2) immediate manual vibration monitoring of other centrifugal compressors to search for other unstable equipment, (3) covering of openings created in the process gas piping and equipment of Cell 25-7-2 as a result of the fire, (4) development of a revised nuclear criticality safety basis for Cell 25-7-2, (5) interim training of cascade operators and managers on the lessons learned about operations from the event, and (6) interim training of firefighters and management on the safety risks and the proper fire fighting techniques for a fire concurrent with holes in the process gas cascade equipment. The long-term corrective actions include the following "Defense in Depth" features and administrative actions: (1) adding process gas temperature monitoring to detect high temperature reactions in a timely manner, (2) adding alarm and automatic shutdown systems on the side purge compressors for compressor high-process gas temperature to protect against the propagation of high temperature accidents by detecting hot spots in a timely manner, (3) improving the process for evaluating and responding to cascade component vibrations to improve the identification of precursors to a hot metal reaction, and (4) completing procedures for improving operator response to other precursors to hot metal reactions. These corrective actions will be instituted prior to re-introducing process gas into the side purge cascade.

NRC Action:

An augmented inspection team was sent to the site on December 9, 1998. The team documented its findings in an inspection report issued on February 19, 1999. A follow-up inspection was conducted in March 1999 to evaluate the effectiveness of the certificate holder's corrective actions. Although the follow-up inspection team found the certificate holder's corrective actions adequate, several procedural and reporting violations were identified during the follow-up inspections. One violation was that the event met the criteria for an "Alert" declaration and that the certificate holder failed to identify and declare the Alert. Since many credible accidents postulated for the Portsmouth Gaseous Diffusion Plant can occur suddenly and last a short duration, it is important for the certificate holder to make proper and timely emergency declarations that would lead to timely notifications to the appropriate regulatory agencies. Therefore, even though, in this case, there were no significant radiological releases to the environment, the NRC staff considered the certificate holder's failure to declare an Alert, which is the lowest level emergency category, a serious violation (Level III) that carried a \$55,000 civil penalty. The certificate holder acknowledged the violation and paid the civil penalty.

Other Agency Action:

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Criteria:

Appendix A (see Criteria III.A and III.C, "For Fuel Cycle Facilities") to this report states, in part, that an event will be considered AO if it represents a shutdown of a portion of the plant resulting from a significant event or a significant event that seriously compromises the ability of a safety system to perform its designated function that requires immediate remedial action to prevent radiological or chemical process hazard.

ITEM #: 981106 AO #: NRC 99-02 EVENT DATE: 10/06/1998
TITLE: Medical Event Involving the Administration of Iodine-131 to a Pregnant Patient at St. Joseph Health Center in Kansas City, Missouri
NAME: St. Joseph Health Center CITY: Kansas City STATE: MO

Nature and Probable Consequences:

After a patient was administered a 5.75 gigabecquerel (155.2 millicurie) dosage of iodine-131 (I-131) for ablation of residual thyroid tissue and for the treatment of metastatic thyroid cancer, the patient was determined to be pregnant.

Preceding the administration of the I-131 therapy dosage, the licensee's nuclear medicine technologist and the authorized user, following internal policies and procedures to determine the pregnancy status of a patient, repeatedly questioned the patient regarding the possibility of a pregnancy and whether she was breast-feeding. The patient stated that she was not breast-feeding and there was no possibility of pregnancy. Approximately 3.5 hours after the I-131 administration, the licensee received positive results of a pregnancy test previously ordered by the patient's referring physician. The licensee had not been aware that the referring physician had ordered the pregnancy test.

Upon notification of the pregnancy, the licensee told the patient she was pregnant and attempted to minimize the potential exposure to the fetus by having the patient increase fluid intake in order to flush the free iodine from her system. The licensee also notified the patient's referring physician of the event. Ultrasound performed following identification of the pregnancy confirmed that the patient had been approximately 13.5 weeks pregnant with twins at the time of the procedure.

The licensee does not expect the patient to experience any ill effects. The dose equivalent to each fetus was estimated to be at 0.38 sievert (Sv) (38 rem) and the dose equivalent to each fetal thyroid was estimated to be in excess of 2,000 Sv (200,000 rem). The licensee expected that such a dose would result in the following likely effects to the fetuses: (1) thyroid ablation, (2) a 30 percent increase in the likelihood of microcephaly (small head size), (3) a 20 to 50 percent increase in the probability of childhood cancer, and (4) an increased probability of mental retardation. On the basis of this information, the patient elected to terminate her pregnancy.

Cause:

This medical event appears to have been caused by the licensee's reliance on the patient's statements preceding the administration of I-131 that she was not pregnant. The patient's referring physician had ordered a pregnancy test for the patient preceding the administration of I-131; however, neither the patient nor the referring physician had informed the licensee. The referring physician believed that the pregnancy test was standard practice preceding all radiopharmaceutical therapy treatments.

Licensee Action:

The licensee modified its internal procedures for the administration of therapeutic radiopharmaceuticals, including diagnostic quantities of I-131 in excess of 74 megabecquerel (MBq) (200 microcurie [uCi]). All such procedures will include a statement that female patients between the ages of 10 and 55 years, without exception, prescribed to receive I-131 dosages equal to or greater than 7.4 MBq (200 uCi) shall obtain a "beta serum pregnancy test" within 24 hours preceding administration.

NRC Action:

The NRC staff reviewed the licensee's revised procedures and determined that they were adequate to address the cause of this medical event and to preclude similar events. Because the licensee made a reasonable effort to obtain a confirmation from the patient that she was not pregnant before the I-131 administration, no NRC requirements were violated.

The corrective actions taken by the licensee were voluntary and were not required by NRC regulations.

Other Agency Action:

Criteria:

Appendix A (see Criterion I.A.3, "For All Licensees") to this report states, in part, that any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician will be considered AO.

ITEM #: 981083 **AO #:** NRC 99-03 **EVENT DATE:** 09/01/1998
TITLE: Medical Event Involving the Administration of Iodine-131 to a Pregnant Patient at Camden-Clark Memorial Hospital, Parkersburg, West Virginia
NAME: Camden-Clark Memorial Hospital **CITY:** Parkersburg **STATE:** WV

Nature and Probable Consequences:

A patient was administered 340 megabecquerel (MBq) (9.2 millicurie [mCi]) of sodium iodide-131 (I-131) in accordance with licensee procedures for the treatment of hyperthyroidism. However, after the procedure was performed, the licensee learned that the patient was pregnant.

On July 15, 1998, the patient was scheduled for a thyroid uptake and scan involving the administration of 7.62 MBq (0.206 mCi) iodine-123 (I-123). Before performing the procedure, the licensee's nuclear medicine technologist asked the patient if she was pregnant. The patient indicated that she was not pregnant and the technologist administered the dosage of I-123. On August 4, 1998, the patient was examined by one of the licensee's authorized users. As part of the examination, the patient was asked about her pregnancy status and she again stated that she was not pregnant. The licensee confirmed with the patient's referring physician a negative pregnancy test, performed on May 5, 1998. The authorized user determined that the patient was a good candidate for I-131 therapy based on the results of the thyroid scan and other tests and prepared a written directive for the administration of 33 MBq (9 mCi) of I-131. The authorized user informed the patient about the effects of I-131 to the fetus if it is administered to a pregnant woman. The patient signed a form acknowledging the risks associated with the procedure, as explained by the authorized user, and stated that she would not become pregnant for 1 year after the I-131 procedure.

The patient returned to the licensee's facility on September 1, 1998, and was administered 340 MBq (9.2 mCi) of I-131 in accordance with the written directive and other licensee procedures regarding the administration of radiopharmaceuticals. On October 5, 1998, the patient informed the licensee about recent information she received indicating that she was about 5 months pregnant. Subsequently, it was determined that the patient had been 14 weeks pregnant at the time of the administration.

The licensee personnel contacted a pediatric endocrinologist for assistance in calculating the thyroid and the whole-body doses to the fetus. Using the information supplied by the licensee, the dose equivalent to the fetus was estimated to be about 0.023 sievert (Sv) (2.3 rem) and the dose equivalent to the fetal thyroid to be about 88 Sv (8,800 rem). The fetus received intra-amniotic thyroid hormone therapy from high-risk pregnancy specialists at a major university hospital.

On October 8, 1998, the licensee notified the patient's referring physician of the event and potential consequences. On October 20, 1998, the licensee notified the NRC of the event. The NRC staff engaged a medical consultant to evaluate the incident. The consultant concluded that (1) the hypothyroidism developed in the fetal thyroid is expected to be permanent, (2) there is no increase in the risk of thyroid carcinoma, (3) a radiation-induced severe mental retardation is unlikely, and (4) the risk of leukemia and other childhood cancers is slightly higher than normal. At the time of the evaluation of this event, the patient had decided to continue pregnancy.

Cause:

The cause of this event was the licensee's assumption that the patient was not pregnant at the time the radiopharmaceutical was administered based on the verbal and written statements made by the patient to the licensee staff.

Licensee Action:

The licensee is considering professional standards such as the 1996 American College of Radiology's "Standard for the Performance of Therapy with Unsealed Radioactive Sources," which specifies acceptable methods for ruling out pregnancy preceding the administration of therapeutic doses of radiopharmaceuticals. These include a pregnancy test obtained within 48 hours preceding administration of the radiopharmaceutical; or documented hysterectomy or tubal ligation; or post-menopausal condition.

NRC Action:

An inspection was conducted to review the circumstances of the event. Because the licensee made a reasonable effort to obtain confirmation from the patient that she was not pregnant before the I-131 administration, no NRC requirements were violated.

The corrective actions taken by the licensee were voluntary and were not required by NRC regulations.

Other Agency Action:

Criteria:

Appendix A (see Criterion I.A.3, "For All Licensees") to this report states, in part, that any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician will be considered an AO.

ITEM #: 990631 **AO #:** NRC 99-04 **EVENT DATE:** 09/14/1999
TITLE: Sodium Iodide Radiopharmaceutical Misadministration at Holy Redeemer Hospital and Medical Center in Meadowbrook, Pennsylvania
NAME: Holy Redeemer Hospital and Medical Center **CITY:** Meadowbrook **STATE:** PA

Nature and Probable Consequences:

A patient's referring physician intended for the patient to receive a thyroid uptake and scan. The licensee routinely performed the procedure using iodine-123 (I-123). However, because of an error, the patient was administered iodine-131 (I-131).

The authorized user intended to administer 11.1 megabecquerel (MBq) (0.300 millicurie [mCi]) of I-123 to a patient for the evaluation of hyperthyroidism. However, no one prepared a written directive to indicate the type of thyroid procedure to administer. The patient was mistakenly listed on the licensee's schedule for a whole-body imaging as part of an evaluation for thyroid cancer therapy. The licensee routinely performs this type of procedure using I-131. Therefore, the licensee's technologist administered 196.1 MBq (5.3 mCi) dosage of I-131 without obtaining a written directive. As a result of this error, the licensee's medical physicist determined that the patient's thyroid received an unintended dose of about 41.9 gray (4,190 rad) based on a 65 percent uptake.

The NRC's consultant stated that the impact of the misadministration on the status of the patient's health should be negligible, with no expected long-term disability. The licensee believes that no harm was done to the patient because the patient's condition required additional thyroid treatment using I-131. The patient was notified of the misadministration on September 16, 1999, and a written report was prepared. The patient's referring physician was also notified.

Cause:

The technologist performed a thyroid procedure using I-131 without a written directive from an authorized user. The licensee's authorized user was not involved in the process of administration of I-131 to clarify what type of thyroid evaluation was needed for the patient.

Licensee Action:

The licensee counseled the technologist on the importance of implementing the NRC regulations.

NRC Action:

The NRC staff conducted a special safety inspection on September 17, 1999, and is evaluating enforcement options.

Other Agency Action:

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results in a dose to the patient equal to or greater than 10 gray (1,000 rad) to an organ (other than a major portion of the bone marrow, liver, the eye, or gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered an AO.

ITEM #: 990302 AO #: AS 99-01 EVENT DATE: 05/07/1999
TITLE: Medical Event Involving the Administration of Iodine-131 to a Pregnant Patient at Via Christi Regional Medical Center in Wichita, Kansas
NAME: Via Christi Regional Medical Center CITY: Wichita STATE: KS

Nature and Probable Consequences:

A pregnant patient was administered a 436.6 megabecquerel (MBq) (11.8 millicurie [mCi]) dosage of I-131 for a thyroid treatment. Before the treatment, the technologist and the authorized user interviewed the patient regarding her pregnancy status and the patient certified that she was not pregnant and signed a consent form for the treatment. The patient then was administered the dosage of 436.6 MBq (11.8 mCi) of I-131. Approximately one week after the I-131 administration during a routine gynecological exam the patient learned that she was between 18 and 20 weeks pregnant.

A telephone report was made to the State of Kansas Radiation Control Program on May 12, 1999, and the State staff conducted on-site investigation on May 13, 1999. They contacted the Department of Energy's Radiation Emergency Assistance Center/Training Site (REACTS) in Oak Ridge, Tennessee for assistance. REACTS provided initial medical guidance and dosimetry calculations and agreed to act as consultant to the attending physician.

The dose equivalent to the fetus was estimated to be about 0.03 sievert (Sv) (3 rem) and the dose equivalent to the fetal thyroid about 253 Sv (25,300 rem). The fetal thyroid dose was considered to be ablative. The authorized user notified the patient and her husband about the fetal exposure and the possible consequences. The patient continued her pregnancy to full term.

Cause:

The cause of the event was the licensee's assumption that the patient was not pregnant at the time the radiopharmaceutical was administered based on the verbal and written statements made by the patient to the licensee staff.

Licensee Action:

The licensee's radiation safety officer conducted an investigation and determined that the licensee's procedures and policies had been followed and that a reasonable effort had been made to determine the pregnancy status of the patient preceding the administration of I-131. The licensee indicated a revision of its policy to require that all females of child-bearing age be tested for pregnancy preceding administration of therapeutic doses of radioactive material.

NRC Action:

Other Agency Action:

The State staff conducted an investigation and agreed with the licensee's findings and believes that the licensee's proposal is adequate to prevent recurrence.

The corrective actions taken by the licensee were voluntary and were not required by the State Agency.

Criteria:

Appendix A (see Criterion I.A.3, "For All Licensees") to this report states, in part, that any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician will be considered an AO.

ITEM #: 990040 AO #: AS 99-02 EVENT DATE: 12/31/1998
TITLE: Industrial Radiography Occupational Overexposure at Global X-ray and Testing Corporation in Aransas Pass, Texas
NAME: Global X-ray and Testing Corporation CITY: Aransas Pass STATE: TX

Nature and Probable Consequences:

A radiography trainee failed to retract a 4.6 terabecquerel (123 curie) source of iridium-192 into the shielded position after taking radiograph (exposure). As a result, the trainee received an estimated TEDE of about 100 mSv (10 rem) and an extremity annual shallow-dose equivalent of about 30,000 to 50,000 mSv (3,000 to 5,000 rem).

On December 31, 1998, a radiographer and a radiography trainee were working at a job site. At about 6:00 p.m., the radiograph trainee thought that the radiography work was completed and removed a tool belt with a dosimeter and an alarming ratemeter and placed it in the truck. However, the radiographer asked the trainee for assistance to obtain additional radiographs. The trainee to take an additional radiograph but the source would not crank and the trainee realized that the source was not retracted into the shielded position after the previous exposure. During this process, the trainee stood at the end of the guide tube for approximately 4 minutes at a distance of about 61 centimeters (2 feet) and touched the end of the guide tube where the source was located three of four times for about 2 or 3 seconds each time.

On January 10, 1999, signs of a radiation injury, including redness, dry skin, and slight swelling accompanied by aching pain, appeared in the index finger of the trainee's right hand. On January 27, 1999, the finger developed a callous. On follow-up of the symptoms, it was indicated that the trainee received an extremity annual shallow-dose equivalent of about 30,000 to 50,000 mSv (3,000 to 5,000 rem).

Cause:

The company's president told the office manager that the radiographer could act as a trainer because the paperwork requesting name the individual radiographer as a trainer had been mailed to the State's Bureau of Radiation Control. Therefore, the radiographer was sent with the trainee to the job site. However, the radiation safety officer later told the office manager and the president of the company that Global X-ray and Testing Corporation had not yet received a license amendment naming the radiographer as a trainer.

The radiographer had been a trainer for several other radiography companies and was familiar with the requirements for a trainee working with a trainee. However, the radiographer was new with the company, was not familiar with this trainee, and was not aware that the trainee was not a radiographer. Therefore, the trainee was not appropriately supervised.

The trainee thought that the work for the day was completed and took the belt off and put it in the truck. The dosimeter and alarming rate meter were on the tool belt and were not used during the additional exposures. An operating survey meter was available, but the trainee did not use it during the radiographs.

Licensee Action:

The licensee met with all radiography personnel to discuss the incident and make a presentation on radiation safety. Trainees were told to verify they were assigned to work with a trainer before leaving for a job site and radiographers were told to verify whether not they were assigned to work with trainees. A memorandum stating these requirements was added to the licensee's safety training program. The office manager was given a written reprimand, which stated that another violation of any radiation regulation or safety policy would result in immediate termination of employment. The radiographer and the radiographer trainee had their employment terminated.

NRC Action:

Other Agency Action:

The licensee was cited for violations of the radiation safety program and an escalated enforcement conference was conducted. As a result, inspection of the licensee's program and the radiographers' audit frequency was increased. A "Preliminary Report for Assessment of Administrative Penalties" was compiled and the licensee requested a settlement conference with the State agency.

Criteria:

Appendix A (see Criterion I.A.1, "For All Licensees") to this report states, in part, that any unintended radiation exposure to an individual (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more or an annual shallow-dose equivalent to the skin or extremities of 2500 mSv (250 rem) or more will be considered a violation of the Act.

ITEM #:	981231	AO #:	AS 99-03	EVENT DATE:	12/16/1998
TITLE:	Industrial Radiography Overexposure to a Member of the Public at Professional Service Industries, Inc. in Seattle, Washington				
NAME:	Professional Service Industries, Inc.	CITY:	Seattle	STATE:	WA

Nature and Probable Consequences:

The Washington State Department of Health was notified by Professional Service Industries, Inc. (PSI), that on December 16, 1998, a contractor's employee (member of the public) had accidentally handled a source guide tube containing a 2.22 terabecqu (60 curie) iridium-192 radiography source at a temporary job site in Seattle, Washington.

A radiographer and a radiographer's assistant working for PSI were performing radiography at a large parking garage of an office building. The building entrances and the place where radiographs (exposures) were taken were properly posted. Two of the contractor's employees were allowed inside the parking garage along with the radiographer in order to mark locations for future radiographs. The radiographer was talking with the contractor's employees while a radiograph was in progress. One of the contractor's employees needed a ladder and approached the ladder in the garage that was being used to support the radiograph source collimator. The radiography source collimator was positioned on the top of the ladder. The contract employee's actions dislodged the collimator from the source guide tube. The radiographer's assistant, who was monitoring the floor above the parking garage, came back to the garage and saw the contractor's employee trying to reassemble the collimator and the guide tube. The radiographer's assistant immediately shouted a warning and the radiographer, being alerted, ran to crank in the source to a safe position.

PSI's radiation safety officer (RSO) at the Seattle office and the corporate RSO were notified and PSI began an immediate investigation, including a re-enactment. Preliminary shallow-dose equivalent estimates for the extremities ranged from 6 to 17 sievert (Sv) (600 to 1700 rem). The Washington State Department of Health's Radiation Control Program was notified approximately 4 hours after the incident occurred and an investigation team was dispatched the next morning. The Washington Radiation Control Program estimated that the individual received a shallow-dose equivalent of (1) 6.8 Sv (680 rem) to the right thumb, (2) 1 Sv (100 rem) to the right index finger, and (3) 1.7 Sv (170 rem) to the palm of the left hand. The TEDE was estimated to be less than 0.05 Sv (5 rem). A cytogenetic study by the Department of Energy's Radiation Emergency Assistance Center/Training Site in Oak Ridge, Tennessee, determined that the TEDE was in the range of 0.01 to 0.15 Sv (1 to 15 rem).

No physical signs of radiation damage to the contractor's hands were observed by the primary physician during the weeks follow the incident. The exposed individual and his physician were kept informed of the findings of the investigation.

Cause:

The cause of the incident was attributed primarily to the radiographer's failure to (1) maintain direct surveillance of a radiography operation and (2) warn individuals in the area that an exposure was underway.

Licensee Action:

PSI has complied with the corrective actions recommended by the State by (1) completing a 2-day training for the Seattle PSI radiography personnel based on the incident, (2) accelerating the schedule of field audits of the PSI Seattle radiography person and (3) performing a cytogenetic study for the contractor's employee.

NRC Action:

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Other Agency Action:

PSI was cited for violations that resulted in the overexposure of a member of the public and for failure to maintain direct surveillance of the radiography operation by allowing a member of the public to enter a high-radiation area.

Criteria:

Appendix A (see Criterion I.A.1, "For All Licensees") to this report states, in part, that any unintended radiation exposure to an a (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (2 rem) or more or an annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more will be considered AO.

ITEM #: 981221 **AO #:** AS 99-04 **EVENT DATE:** 12/16/1997
TITLE: Gamma Stereotactic Radiosurgery (Gamma Knife) Misadministration at University of Maryland Medical Systems in Baltimore, Maryland
NAME: University of Maryland Medical Systems **CITY:** Baltimore **STATE:** MA

Nature and Probable Consequences:

A patient was prescribed a radiation therapy treatment using a gamma knife device for a brain metastasis involving three lesions. The patient was prescribed 1,600 centigray (cGy) (1,600 rad) to the first lesion. However, because of an error in the treatment plan, the first lesion received 2,600 cGy (2,600 rad).

The neurosurgeon prepared the treatment plan for the first lesion. While treating the first lesion, the neurosurgeon prepared the treatment plans for the second and third lesions. However, the treatment plan for the second lesion unintentionally included the settings for a treatment of a focal point of the first lesion. The neurosurgeon and the oncologist reviewed the treatment plans but failed to identify any deviation from the prescribed dose. After the three lesions had been treated, the medical physicist who reviewed the dose calculations determined that an error occurred that resulted in an overdose to the first lesion. The licensee's oncologist determined that the administered overdose was within the range of acceptable prescribed dose for intra-cranial lesion. It was not anticipated that any complications would occur in addition to those normally seen with this type of therapy treatment.

The neurosurgeon notified the patient and the referring physician of the event on December 17, 1997. A letter confirming the discussion of the event was also sent to the patient on January 8, 1998. The patient died on January 20, 1998, of lung cancer.

Cause:

This misadministration was caused by human error in preparing the treatment plans. The neurosurgeon and the oncologist did not follow procedures describing the team approach in treatment planning. Furthermore, the treatment planning procedure did not accurately reflect the role and responsibilities of each type of authorized user. Finally, the neurosurgeon and the oncologist reviewed and signed the treatment plan without identifying the unintended dose.

Licensee Action:

The licensee immediately implemented measures to ensure that treatment will only be carried out after planning for all treatment sites is completed. The medical physicist will participate in the entire treatment planning process and will review the treatment plan before the plan is executed. The neurosurgeon and the oncologist will collaborate at critical points in the process, such as dose selection, approval of the written plan, and initiation of the treatment.

NRC Action:

Other Agency Action:

The licensee was cited for violations that included training deficiencies, failure of the radiation safety committee and the radiation safety officer to assume their duties and responsibilities, failure to apply for and receive license amendments before changing procedures, and failure to comply with notification requirements. Enforcement action is pending.

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results in a dose that is equal to or greater than 10 gray (Gy) (1,000 rad) to an organ (other than a major portion of the bone marrow, lens of the eye, or gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive shall be considered an AO.

ITEM #: 981080 **AO #:** AS 99-05 **EVENT DATE:** 10/15/1998
TITLE: Gamma Stereotactic Radiosurgery (Gamma Knife) Misadministration at Good Samaritan Hospital in Los Angeles, California
NAME: Good Samaritan Hospital **CITY:** Los Angeles **STATE:** CA

Nature and Probable Consequences:

A patient was prescribed treatment of 9,000 centigray (cGy) (9,000 rad) to the left trigeminal nerve. However, the treatment was administered to the patient's right trigeminal nerve.

The licensee's medical physicist prepared a treatment plan for the wrong treatment site (right trigeminal nerve). The radiation oncologist, who was an authorized user on the license, signed the treatment plan without verifying the neurosurgeon's request, which listed the correct treatment site (left trigeminal nerve). Because the head restraint was positioned correctly on the patient, medical physicist experienced difficulty positioning the patient in the gamma knife for the incorrect treatment site. In response to questions from the medical physicist, both the patient and the nurse informed him that the correct treatment site was the left trigeminal nerve. Inexplicably, this did not lead the medical physicist to recognize that he was about to treat the wrong trigeminal nerve. The error was discovered after the procedure was completed. As a result, the patient received a dose of 9,000 cGy (9,000 rad) to the wrong treatment site. During this procedure, the medical physicist was training another medical physicist on how to use the facility's gamma knife equipment. The patient's neurosurgeon was not present during this procedure because of a scheduling conflict, even though it was the licensee's standard practice for the neurosurgeon to be present.

Treatment of the intended left trigeminal nerve was postponed pending evaluation of the medical outcome of the treatment of the wrong trigeminal nerve. The patient's physician stated that the patient might experience increasing numbness on the affected side of the face within 1 to 18 months. If the numbness occurs, it may affect the plan for treating the prescribed left side.

Cause:

The misadministration occurred because (1) the medical physicist prepared a treatment plan for the wrong treatment site, (2) the radiation oncologist signed the treatment plan without properly verifying it, and (3) the neurosurgeon was not present during the procedure, which differed from standard licensee practice. The radiation oncologist had not conferred with the patient before the treatment, which may have contributed to the incorrect site treatment. Although it is possible that his training of the other medical physicist distracted the medical physicist, this could not be determined as a contributing cause.

Licensee Action:

The licensee revised the gamma knife treatment procedure to require that (1) the treatment plan be verified before each procedure by the neurosurgeon, the radiation oncologist, and the medical physicist, (2) two of the three individuals (the neurosurgeon, the radiation oncologist, and the medical physicist) verify that the treatment program coordinates are correctly set, (3) either the neurosurgeon or the radiation oncologist verify the prescribed treatment site after the patient is positioned, and (4) the neurosurgeon and either the radiation physicist or the radiation oncologist be physically present during the treatment. Also, the radiation oncologist shall examine the patient before the treatment and verify the treatment site.

NRC Action:

Other Agency Action:

The State cited the licensee for failure to report the therapeutic misadministration within 24 hours as required. The licensee was also cited for failure of the authorized user to verify the dosimetry plan and the treatment programming.

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results in a dose that is equal to or greater than 10 gray (Gy) (1,000 rad) to an organ (other than a major portion of the bone marrow, lens of the eye, or gonads) and represents a dose or dosage that is delivered to the wrong treatment site will be considered an AO.

ITEM #: 990549 AO #: AS 99-06 EVENT DATE: 08/04/1999
TITLE: Therapeutic Radiopharmaceutical Misadministration of Iodine-131 to the Wrong Individual at Hermann Hospital in Houston, Texas
NAME: Hermann Hospital CITY: Houston STATE: TX

Nature and Probable Consequences:

A patient was scheduled to receive a 1010 megabecquerel (MBq) (27.3 millicurie [mCi]) dosage of iodine-131 (I-131) for a thyroid treatment. However, because of an identification error, the wrong individual was administered the I-131.

Two middle-aged female Asian patients were at the licensee's nuclear medicine department for different procedures. The patient who was scheduled to receive the I-131 dosage left the waiting room. The licensee's technologist approached the other patient to verify her name and date of birth by stating the name and date of birth of the patient who was to receive the I-131 treatment. The patient responded with "yes," although she did not understand the questions. She also indicated she understood the instruction previously given to her about the I-131 treatment. Therefore, she was administered the dosage of I-131. Later it was found that I-131 was administered to the wrong individual. The licensee ordered another dosage of I-131, which was administered to the correct patient as prescribed.

The licensee estimated that (1) the dose to the patient's thyroid as a result of the misadministration was about 220 gray (22,000 rad), (2) the patient has about an 85 percent chance of losing thyroid function, and (3) replacement thyroid hormone will be required indefinitely. The patient's attending physician was contacted and remedial action was taken.

Cause:

The patient who received the misadministration spoke English as a second language. She was asked identification questions that could be answered "yes" or "no" without her actually understanding the meaning of the questions. No further verification of the patient's identification was performed.

Licensee Action:

The licensee has changed procedures for all outpatient therapy treatments that involve radioactive materials. The format of questions for patient identification will be revised to read "What is your name?" and "What is your date of birth?" instead of "Is your name...?" or "Is your date of birth...?" Outpatients will also be asked to show a picture form of identification. In the case of pediatric patients, the child's parent or guardian must confirm the patient's identification.

NRC Action:

Other Agency Action:

The licensee was cited for administering a therapeutic dosage of I-131 to the wrong individual, who had a normally functioning thyroid, and for the authorizing physician user not being present when therapy procedures were being performed. Enforcement action is pending.

Criteria:

Appendix A (see Criterion I.A.1, "For All Licensees") to this report states, in part, that any unintended radiation exposure to an individual (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to any individual organ or tissue other than the lens of the eye, bone marrow, and the gonads of 2,500 mSv (250 rem) or more will be considered an AO.

ITEM #: 990158 AO #: AS 99-07 EVENT DATE: 07/31/1998
TITLE: Therapeutic Radiopharmaceutical Misadministration of Iodine-131 to the Wrong Individual at Milton Hospital in Milton Massachusetts
NAME: Milton Hospital CITY: Milton STATE: MA

Nature and Probable Consequences:

A patient was prescribed a diagnostic dosage of 270.1 megabecquerel (MBq) (7.3 millicurie [mCi]) of technetium-99m (Tc-99m) a thyroid scan. However, the patient was erroneously administered a therapeutic dosage of 318.2 MBq (8.6 mCi) of iodine-131.

The licensee's technologist administered the patient the diagnostic dosage of 270.1 MBq (7.3 mCi) of Tc-99m. After this procedure was finished, the patient was asked to remain in the waiting room while the thyroid scan was processed. Because of identification error, the patient was taken again into the treatment area by the authorized user and was administered the therapeutic dosage of I-131. This dosage was intended for another patient who was still in the waiting room. The patient was informed of the error.

The licensee believes that no harm was done because the patient's condition required additional thyroid treatment using I-131.

Cause:

The authorized user, who also was the primary care physician for both patients, was aware that both patients were to have I-131 treatment. However, on the day of the incident, the patient should have received only the Tc-99m dosage. Since the authorized user failed to follow the established Quality Management Program (QMP) procedures requiring verification of the patient's identity by more than one method before administering radioactive material, the wrong individual was administered the I-131.

Licensee Action:

The licensee modified its procedures as follows: (1) the authorized user will review the chart for each therapy patient, (2) each chart will contain a photograph of the patient, (3) each patient will be identified by checking the photograph in the chart, (4) preceding administration of radiopharmaceuticals, a band will be placed on the wrist of the identified therapy patient, and (5) the authorized user and the technologist will be present during the radiopharmaceutical administration. The written directive form for iodine therapy dosages was modified to include the changes made in the procedures.

NRC Action:

Other Agency Action:

The State investigated this event on September 10 and 11, 1998, and the licensee was issued a Notice of Violation on September 14, 1998, for not following its submitted procedures for radiopharmaceutical therapy as outlined in the QMP. The State acknowledged the action taken by the licensee to prevent recurrence of this incident.

Criteria:

Appendix A (see Criterion I.A.1, "For All Licensees") to this report states, in part, that any unintended radiation exposure to an individual (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more or an annual sum of the deep dose equivalent and committed dose equivalent to any individual organ or tissue other than the lens of the eye, bone marrow, and the gonads of 2,500 mSv (250 rem) or more will be considered an AO.

ITEM #: 990479 AO #: AS 99-08 EVENT DATE: 05/06/1999
TITLE: Therapeutic Radiopharmaceutical Misadministration of Samarium-153 at Merle West Medical Center in Klamath Falls, Oregon
NAME: Merle West Medical Center CITY: Klamath Falls STATE: OR

Nature and Probable Consequences:

A patient with metastatic prostate cancer was prescribed a dosage of 2,294 megabecquerel (MBq) (62 millicurie [mCi]) of samarium-153 (Sm-153) to palliate bone pain. However, because of an error, the patient was administered a dosage of 3,589 MBq (97 mCi) of Sm-153. The recommended dosage for the Sm-153 procedure is "1 mCi per kg of body weight" (37 MBq per kilogram [kg]) (1 mCi per 2.2 pounds [lb]).

The misadministration resulted in an additional dose of 200 centigray (cGy) (200 rad) to the bone marrow. The patient's other organs received additional doses that were below 1,000 cGy (1,000 rad). The hospital checked with the manufacturer, DuPont Merck Pharmaceutical Company, concerning possible side effects of the misadministration. The pharmaceutical company indicated that other studies have been done using 74 to 92.5 MBq per kg (2.0 to 2.5 mCi per 2.2 lb) of Sm-153 with no significant side effects.

Both the attending physician and the patient's family were notified of the misadministration.

Cause:

This event was caused by a human error. The licensee indicated that the dosage was calculated using the patient's weight in pounds instead of kilograms.

Licensee Action:

The incident was discussed with the Radiation Safety Committee (RSC). The licensee revised its Quality Management Program (QMP) for the use of Sm-153 and strontium-89 therapy to require the prescribing physician to calculate and personally order the dosage. The RSC approved the changes to the QMP. The technologist involved in the procedure was counseled concerning therapy procedures, dosage administrations, and the importance of rechecking calculations.

NRC Action:

Other Agency Action:

The State cited the licensee for failure to report the misadministration within the required time.

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results a dose that is equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or the gonads will be considered an AO.

ITEM #: 981182 **AO #:** AS 99-09 **EVENT DATE:** 12/07/1998
TITLE: Sodium Iodide Radiopharmaceutical Misadministration at St. Edward Mercy Medical Center in Fort Smith, Arkansas
NAME: St. Edward Mercy Medical Center **CITY:** Fort Smith **STATE:** AR

Nature and Probable Consequences:

A patient was prescribed a thyroid scan using 222 megabecquerel (MBq) (6 millicurie [mCi]) dosage of technetium-99m (Tc-99m) pertechnetate. However, the patient was administered about a 148 MBq (4 mCi) dosage of iodine-131 (I-131).

The medical center routinely received unit dosages from a nuclear pharmacy packaged in appropriately sized syringes ready for injection to patients. However, in this case, instead of being in a syringe, the dosage was in a glass vial within a large lead container. The shipping package also contained two dispensing straws. The shipping container, the lead "pig," and the vial were labeled by the nuclear pharmacy as 222 MBq (6 mCi) of Tc-99m. The licensee's staff surveyed the incoming package but saw nothing unusual. The licensee's staff attributed the change in the appearance of the package (a glass vial instead of a syringe and the presence of the dispensing straws) to a mistake made by the nuclear pharmacy. Therefore, the oral solution of the I-131 dosage, mislabeled as Tc-99m, was drawn into a syringe and was injected into the patient.

The licensee's medical physicist determined that the dose to the patient's thyroid based on the radiopharmaceutical manufacturer package insert was about 48 gray (4,800 rad). The patient was notified of the misadministration by the licensee's radiation safety officer (RSO). The patient's attending physician was also notified of the circumstances and possible complications. The RSO advised the patient to continue long-term follow-up with the primary care physician.

Cause:

This event was caused by the nuclear pharmacy mislabeling a radiopharmaceutical dosage. Also, it appears that the medical center's nuclear medicine staff did not question or address the unusual package upon receipt.

Licensee Action:

The licensee reported this event to the Arkansas Department of Health on December 7, 1998, and submitted a written report on December 8, 1998. The center's management revised the policy and procedure for the receipt of radiopharmaceuticals from the nuclear pharmacy. The revision states that only I-131 radioactive dosages will be accepted in glass vials. Any suspect or other labeled isotope received in glass vials will be questioned or returned to the pharmacy for isotope verification. The nuclear pharmacy indicated that policies and procedures for dispensing radiopharmaceutical therapy products have been revised to prevent recurrence of similar incidents.

NRC Action:

Other Agency Action:

The State staff performed an on-site investigation at the medical center and the nuclear pharmacy on December 8, 1998.

The investigation discovered violations associated with license conditions and regulations for activities conducted at the nuclear pharmacy.

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results a dose that is equal to or greater than 10 gray (Gy) (1,000 rad) to an organ (other than a major portion of the bone marrow, lens of the eye, or gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive be considered an AO.

ITEM #: 000269 AO #: NRC 00-02 EVENT DATE: 12/31/1995
TITLE: Overexposures at Mallinckrodt, Inc., in Maryland Heights, Missouri
NAME: Mallinckrodt, Inc. CITY: Maryland Heights STATE: MO

Nature and Probable Consequences:

On March 31, 2000, a contract employee who was providing services for Mallinckrodt, Inc., was attempting to correct flow problem with a 703,000 megabecquerel (19 curie) molybdenum-99/technetium-99m generator. The employee performed the operation in a glove box. The employee's initial attempts to correct the generator problem were not successful. The employee then removed the generator column containing the radioactive material from its shield and determined that the inlet line was not connected and the outlet line was bent at an angle. Holding the unshielded column in his right hand, the employee corrected the problems with the inlet and outlet lines. This process took between 10 and 20 seconds to complete. Dose rates at the location of the column held by the employee were calculated to be approximately 510 mSv (51 rem) per second. As a result the employee's thumb and index finger of the right hand received a dose ranging from 5,100 mSv (510 rem) to 11,200 mSv (1,120 rem) shallow-dose equivalent. The NRC annual dose limit to the skin or any extremity is 500 mSv (50 rem) shallow-dose equivalent. The employee believed that the gloves he wore provided him adequate protection from radiation.

On April 5, 2000, Mallinckrodt determined that the radiation monitor worn on the employee's right hand recorded a dose of 57 mSv (5.7 rem) shallow-dose equivalent in excess of its administrative weekly limit which was 20 mSv (2 rem). Mallinckrodt's investigation of the exposure determined that the employee had directly handled the generator column and reported the event to NRC on April 13, 2000. The employee was examined by a physician, who identified no immediate health effects. Due to the inability of either the NRC or the licensee to precisely estimate the likely exposure to the employee's finger and thumb, long-term health effects could not be predicted.

During its investigation of the March 31, 2000 event, Mallinckrodt identified other employee overexposures that occurred in the preceding 5 years during the performance of two routine operations. As a result of the first routine operation, 11 employees involved in the hand-labeling of vials containing millicurie quantities of indium-111 (In-111) (a State-regulated, non-NRC licensee material) received extremity doses ranging from 500 mSv (50 rem) to 3,200 mSv (320 rem) shallow-dose equivalent. In addition to these doses from In-111, the 11 employees had also received doses from NRC-regulated material, typically less than 5 percent their total extremity doses.

The second operation involved the handling of unshielded and partially shielded vials and syringes containing radioactive material (State- and NRC-regulated material) in a sterility testing laboratory. As a result of this operation Mallinckrodt identified four employees who received extremity doses ranging from 680 mSv (68 rem) to 960 mSv (96 rem) shallow-dose equivalent.

Cause:

The causes of the March 31, 2000 event were insufficient training to ensure that the employee understood the difference between radioactive contamination and radiation and inadequate oversight of the laboratory. The written, approved procedure on the employee's assigned duties did not allow the removal of the generator column during manufacturing. However, an ad hoc procedure had been developed by the staff of the laboratory, that was not known to or approved by the management outside the laboratory. The ad hoc procedure allowed the removal of the generator column from the shield using remote handling tools. On March 31, 2000, the employee was using the ad hoc procedure but the tools that were used to remove the generator column from the shield had fallen to the bottom of the glove box and were out of the employee's reach. The employee decided on his own to remove the column and to perform repairs without using tools.

With regard to the other operations that resulted in significant doses, Mallinckrodt personnel believed, erroneously, that the dose recorded by the personnel monitoring devices worn by its employees reflected the actual exposures received. However, the actual doses were, in some instances, 100 times greater than those recorded by the monitors. This was due to the distance between the monitors, which are normally worn like a ring at the base of the finger, and the fingertips, where the exposures were received.

Licensee Action:

The licensee staff was instructed in the proper handling of unshielded containers of radioactive material. The licensee increased its radiation safety and supervisory oversight in the generator manufacturing laboratory. In addition, the licensee initiated and implemented managerial changes to its operations and agreed to: (1) retain an independent organization to assess the radiation safety program and the radiation safety aspects of its radioactive material manufacturing processes; (2) provide assurance that workers have received training and understand procedures and practices to maintain radiation exposures as low as is reasonably achievable (ALARA); (3) develop a plan to review operations for the last five years to determine if additional workers have received exposures in excess of regulatory limits; and (4) request an amendment to incorporate a corrective action program into its license. NRC confirmed the licensee's agreement in a Confirmatory Order Modifying license issued on June 22, 2000.

NRC Action:

The NRC conducted an Augmented Inspection Team (AIT) inspection on May 4 through May 26, 2000, and a follow up inspection on July 17 through August 4, 2000. As a result of the AIT inspection, NRC issued the June 22, 2000, Confirmatory Order Modifying License to Mallinckrodt. On December 21, 2000, NRC issued a Notice of Violation and Proposed Imposition of a \$125,000 Civil Penalty.

Other Agency Action:

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Criteria:

Appendix A (see Criterion I.A.1, "For Medical Licensees") to this report states, in part, that any unintended radiation exposure to adult (any individual 18 years of age or older) resulting in an annual shallow-dose equivalent to the skin or extremities of 2,500 r (250 rem) or more will be considered for reporting as an AO.

ITEM #: 000739 AO #: NRC 00-03 EVENT DATE: 09/15/2000
TITLE: Brachytherapy Misadministration at Sibley Memorial Hospital in Washington, District of Columbia
NAME: Sibley Memorial Hospital CITY: Washington STATE: DC

Nature and Probable Consequences:

Two patients were prescribed doses of 70 Gy (7,000 rad) each for eye treatment. The first patient received a dose of 108.7 Gy (10,870 rad) and the second patient received a dose of 114.70 Gy (11,470 rad).

The two patients were prescribed iodine-125 (1-125) eye plaques for treatment of ocular melanomas. These treatments were performed in an attempt to preserve the patients' eyes, which otherwise would have been surgically removed. The licensee's treatment planning system uses air-kerma, and the supplier of the 1-125 seeds uses millicurie units. The licensee made an error converting air-kerma to millicurie units. Consequently, orders were placed for a higher source strength of 1-125 seeds, which was subsequently administered to the patients, resulting in the overdoses.

The error was identified by the licensee during a review of the patients' charts on September 22, 2000, after the physicist noted the dosimetrist was ordering 1-125 seeds for an upcoming study with higher than expected source strength.

The patients were informed of the misadministrations. Prior to the start of the treatments, the patients were informed of the substantial risk of vision loss, the possibility of cataract formation, and a 10 to 15 percent possibility that removal of the eye might be required due to tumor progression or eye pain.

Cause:

The principal cause of the misadministrations was a human error in converting source strength of the 1-125 seeds from air-kerma to millicurie units. A secondary cause was the failure of the authorized user and medical physicist to recheck the conversion factor equations before the treatment was completed (a requirement of the licensee's Quality Management Plan).

Licensee Action:

The licensee suspended all procedures involving the eye plaques until corrective actions were developed and the staff was trained in the corrective actions. Written procedures were established to ensure the accuracy of the treatment calculations. The licensee has submitted to the NRC its planned corrective actions to prevent potential errors in the future.

NRC Action:

An inspection was conducted by the NRC's Region I office on September 28 and 29, 2000, to examine the circumstances of the misadministration and the licensee's corrective and preventive actions. In accordance with the NRC's Medical Event Assessment Program, the NRC has retained a medical consultant to assess the misadministrations and their potential consequences. Enforcement action is pending.

Other Agency Action:

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 000336 AO #: AS 00-01 EVENT DATE: 04/12/2000
TITLE: Gamma Stereotactic Radiosurgery Misadministration at Healthsouth Medical Center in Birmingham, Alabama
NAME: Healthsouth Medical Center CITY: Birmingham STATE: AL

Nature and Probable Consequences:

Patient A was prescribed a dose of 80 Gy (8,000 rad) to the left trigeminal nerve using a gamma Stereotactic radiosurgery (GSF device). However, because of an error, a dose of about 0.2 Gy (20 rad) was delivered to the intended treatment site and a dose 80 Gy (8,000 rad) was delivered to a wrong treatment site.

On the same day that patient A was scheduled for a GSR treatment, patient B was also admitted for a similar treatment using the same device. During the approval process of the treatment plan, the dose delivery sheet of patient B was inadvertently switched with that of patient A. As a result, patient A was treated with the radiosurgery parameters intended for patient B, and a dose of 80 Gy (8,000 rad) was delivered at the wrong treatment site within the patient's skull. The misadministration was discovered immediately following the delivery of the dose by the patient's radiation oncologist. The identification of this misadministration prevented a related misadministration for patient B. The licensee notified the State agency of this misadministration on April 12, 2000. The patient returned to the Medical Center on April 20, 2000, and was treated as prescribed.

The licensee stated that the misadministration resulted in no observable acute effects to the patient. The patient was notified verbally within 24 hours by the referring physician and the neurosurgeon and will be closely monitored by the neurosurgeon.

Cause:

This misadministration was caused by mixing patient treatment protocol documentation during approval of the treatment plans for the two different patients that were prescribed similar treatments.

Licensee Action:

The licensee took immediate action to prevent the mixing of patient treatment protocol documentation. As a result, each page of treatment protocol contains a unique name and time stamp, which the radiation oncologist or medical physicist will in the future check before delivering the radiosurgery treatment.

NRC Action:

Other Agency Action:

The Alabama Department of Public Health, Office of Radiation Control was satisfied with the licensee's corrective actions. The licensee's corrective measures will be reviewed during the agency's next routine inspection of the licensee's activities.

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 000615 AO #: AS 00-02 EVENT DATE: 09/11/1998
TITLE: Gamma Stereotactic Radiosurgery Misadministration at University of California in San Francisco, California
NAME: University of California CITY: San Francisco STATE: CA

Nature and Probable Consequences:

The California Department of Health Services, Radiologic Health Branch was notified of the misadministration on September 17, 1998. The NRC staff was informed of this event in July 2000. The State of California indicated that the delay in reporting this event to the NRC resulted from a computer error.

A patient was prescribed a radiation therapy treatment of two metastatic lesions of the brain using a gamma Stereotactic radiosurgery (GSR) device. One of the brain lesions was prescribed a dose of 16 Gy (1,600 rad). However, because of an error the wrong site of the brain received more than 10 Gy (1,000 rad).

The patient was treated for two metastatic brain lesions, one in the left thalamus and the other in the right parietal regions of the brain. A treatment plan was developed for the lesion in the left thalamus to deliver a single dose of 16 Gy (1600 rad), at the 60% isodose line. However, one of the seven parameter settings of the GSR, the "left Y" coordinate, was erroneously set at 111 mm (4.37 in.) instead of 101 mm (3.98 in.) resulting in a 5 mm (0.20 in.) translocation of the treatment volume. This error resulted in under-dose of a portion of the intended treatment volume and an unintended dose of more than 10 Gy (1,000 rad) to brain tissue outside of the prescribed treatment volume. The misadministration was discovered when the licensee performed a quality control verification of the GSR parameters after the radiation treatment.

The licensee reported that the patient experienced no acute side effects from this misadministration. The physician who was involved in this treatment notified the patient of this misadministration. The physician explained the necessity of another treatment because of the under-dose to a portion of the tumor site. An additional treatment was added to the treatment plan to complete the prescribed dose to the intended treatment volume of the left thalamus, and the treatment was completed. The patient died as a direct result of the metastatic condition on March 3, 1999.

Cause:

The misadministration was caused by a human error. One member of the treatment team set a wrong coordinate and another member of the treatment team failed to independently verify the coordinate setting.

Licensee Action:

The initial corrective actions by the licensee included decreasing distractions to the treatment team by limiting telephone calls in treatment control area and restricting conversations in the treatment room to conversations required for the treatment of the patient. The licensee was requested by the State to contact other GSR facilities to review their methods of operation. The licensee found that another GSR facility had performed a study comparing the frequency of incorrect coordinate settings by licensees who did independent verification and licensees who did not. The licensee used this study as a guide and has adopted the procedure of performing two independent checks of the coordinate settings before each treatment and retaining the follow-up check of the coordinate settings after each treatment to determine if an error was made.

NRC Action:

Other Agency Action:

The findings of the on-site investigation by the State staff agreed with the findings of the licensee's quality assurance review. The State also shared the finding of the study performed by the licensee with other Agreement States and with the NRC because of the study's generic implications. The State was satisfied with the licensee's corrective actions and believes they should be adequate to prevent recurrence. No enforcement actions were taken by the State for this misadministration.

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 000104 AO #: AS 00-03 EVENT DATE: 01/25/2000
TITLE: Gamma Stereotactic Radiosurgery Misadministration at Healthsouth Doctor's Hospital in Coral Gables, Florida
NAME: Healthsouth Doctor's Hospital CITY: Coral Gables STATE: FL

Nature and Probable Consequences:

A patient was prescribed a gamma Stereotactic radiosurgery (GSR) treatment for 80 brain lesions. Each brain lesion site was prescribed 12 Gy (1,200 rad). However, a lesion site was treated twice because of an error.

The patient's treatments were based on computer-generated magnetic resonance imaging (MRI) slices taken in the Z direction. Prior to each treatment, the lesion site coordinates were printed out as part of the written directive and they were checked manually and initialed by the authorized user and the medical physicist. For the fourth treatment, the licensee intended to deliver 12 Gy (1,200 rad) to lesion site 47. However, prior to the treatment the wrong MRI slice was displayed in the computer showing lesion 16 (Z=70.7 mm [2.78 in.]) instead of lesion site 47 (Z= 65.0 mm [2.56 in.]). Thus, the treatment plan was calculated at lesion site 16, which had already been treated. The written directive was prepared and signed by the authorized user and the radiation safety officer (RSO) indicating a dose of 12 Gy (1,200 rad) to Z=70.7 mm (2.78 in.). The treatment was administered as indicated in the directive. As a result, lesion site 16 was treated twice. The RSO discovered the error on January 28, 2000, during a routine quality assurance review of the treatment plan. The licensee indicated that the retreatment of site 16 did not result in harmful effects for the patient. The patient was rescheduled for treatment of lesion site 47 and treatment of additional untreated sites.

The misadministration was reported to the Florida Bureau of Radiation Control, the authorized user, and the patient on January 2000.

Cause:

The licensee determined that this misadministration was caused by human error.

Licensee Action:

No action was taken by the licensee. The licensee has not identified any quality management procedures that need to be changed to prevent this type of human error. In addition, the licensee believes that this type of error was detected because of its aggressive quality assurance program.

NRC Action:

Other Agency Action:

The Bureau of Radiation Control performed an onsite investigation on February 2, 2000. The investigation found no apparent violations of the licensee's license or the regulations. During the investigation the licensee indicated that it has performed in excess of 2,000 GSR procedures and a quality assurance review of each procedure. Of the 2,000 procedures the licensee has estimated that over 600 procedures involved the treatment of 20 or more lesion sites and that this was the only time a lesion site was treated twice.

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 000277 AO #: AS 00-04 EVENT DATE: 04/20/2000
TITLE: Gamma Stereotactic Radiosurgery Misadministration at University of Maryland Medical Systems in Baltimore, Maryland
NAME: University of Maryland Medical Systems CITY: Baltimore STATE: MD

Nature and Probable Consequences:

A patient was prescribed a radiation therapy treatment for pituitary adenoma using a gamma stereotactic radiosurgery (GSR) device. The licensee's therapy treatment team planned to deliver a maximum dose of 18 Gy (1,800 rad) to the 50% isodose line given in six administrations. However, because of the incorrect settings of the Y and Z coordinates, a dose of 12.5 Gy (1,250 rad) was administered to the wrong treatment site.

The licensee's therapy treatment team consisted of a neurosurgeon, an oncologist, and a medical physicist. The treatment plan was developed, reviewed, and signed by each member of the treatment team prior to the administration of the first dose. When the medical physicist briefly left the GSR facility, the neurosurgeon and the oncologist inadvertently reversed the Y and the Z coordinates while adjusting the position of the patient's stereotactic frame (moving the patient's head to the incorrect position). When the medical physicist returned, each member of the treatment team incorrectly verified the position of the patient's frame assembly. All team members signed the quality assurance checklist to indicate that they conducted this check and that the patient's frame was positioned in accordance with the written directive. As a result, the patient's base of the frontal lobe received the unintended dose. The medical physicist identified the incorrect settings of the Y and Z coordinates while preparing to adjust the frame assembly for the second administration. Upon discovery of the misadministration, the treatment team revised the treatment plan to accommodate for the error and to complete the therapy procedure. The State agency was notified of this misadministration on April 21, 2000, and performed an onsite investigation on April 26-28, 2000.

The neurosurgeon notified the patient, provided an estimate of the unintended dose delivered, and explained that no adverse health effects were expected to result from this event.

Cause:

This misadministration was determined to be a sequence of human errors made by the neurosurgeon, oncologist, and medical physicist during patient positioning. However, while the root cause of the event appears to be human errors during the setting of the patient positioning parameters, other factors may have contributed to the event. For example, to position the patient, the treatment team used an internal procedure which was not documented in writing. This procedure was not sent to the licensee's Radiation Safety Committee or the State Agency for approval. The radiation safety officer (RSO) was a contract employee of the UMMS. Furthermore, he had not received any specialized training, e.g., equivalent to the authorized user training. Interaction between the RSO and the authorized users was rare. Finally, the RSO failed to complete and document the annual reviews of the GSR radiation protection program content and implementation for the previous 3 years (1997 through 2000).

Licensee Action:

The licensee held a management conference with key members of management, radiation safety, radiation oncology, neurosurgery, patient care services, and clinical effectiveness. As a result of this meeting, the licensee implemented a written protocol regarding patient positioning.

NRC Action:

Other Agency Action:

The onsite investigation by the State determined that the licensee failed to implement approved written procedures regarding treatment planning, patient positioning, and administration of doses. Furthermore, the licensee failed to complete and document the annual reviews of the GSR radiation protection program content and implementation for the previous 3 years. A Department Letter/Notice of Violation was issued on June 21, 2000. An enforcement action is pending.

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 970358 AO #: AS 00-05 EVENT DATE: 10/16/1996
TITLE: Teletherapy Misadministration at Western Baptist Hospital in Paducah, Kentucky
NAME: Western Baptist Hospital CITY: Paducah STATE: KY

Nature and Probable Consequences:

This misadministration was discovered by the hospital on January 8, 1997. The State was informed of the misadministration on January 8, 1997 and was reported to NRC on March 5, 1997. However, it was identified as an AO during discussions of the event at an Integrated Materials Performance Evaluation Program review of the State of Kentucky in July 2000.

A patient was prescribed a radiation therapy treatment using cobalt-60 teletherapy equipment. The patient was prescribed a dose of 39 Gy (3900 rad). However, the dose was administered to the wrong treatment site because of an error.

The patient was treated for bone pain associated with renal cell carcinoma with metastases to the right iliac bone. The prescribed treatment was 5 treatments per week for a total of 13 treatments. The prescribed dose to the right iliac bone was 39 Gy (3900 rad). When the patient returned for evaluation of the right iliac bone pain, the physician determined that the dose of 39 Gy (3900 rad) was administered to the left iliac bone.

The licensee stated that the misadministration had no effect on the patient's life-span and did not result in any permanent impairment or dysfunction.

Cause:

The causes of this misadministration were that (1) markers were not used on the patient's x-ray film to distinguish the supine/prone positions, 2) a second x-ray film was incorrectly labeled as to left/right, 3) the physician did not perform a visual inspection to determine that the correct area had been marked on the patient, and 4) the prescribing physician and simulator therapists failed to correctly orient left/right on fluoroscopy.

Licensee Action:

The licensee established a requirement to label the x-ray films in order to distinguish left/right and supine/prone positions. One of the radiation physicists will review the treatment plans of patients that are not responding clinically as expected. The physicists have been retrained to check all information in the patient's chart regarding calculations and setup. The physicians and therapists have been reminded of the importance of accurately determining patient orientation.

NRC Action:

Other Agency Action:

The State agency reviewed the written directive and no problems were noted. A telephone conference was held with the radiation safety officer, the attending physician, and the Director of Safety Management. The inspection frequency for the facility was increased. An inspection in March 1998 found no violations.

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #:	000843	AO #:	AS 00-06	EVENT DATE:	08/22/2000
TITLE:	Brachytherapy Misadministration at Aultman Hospital in Canton, Ohio				
NAME:	Aultman Hospital	CITY:	Canton	STATE:	OH

Nature and Probable Consequences:

As a result of a common error, four patients that were prescribed manual brachytherapy gynecological procedures were administered doses higher than those prescribed.

The first patient was prescribed a total dose of 92.9 Gy (9,290 rad). This dose included brachytherapy treatments of 20 Gy (2,000 rad) and 22.5 Gy (2,250 rad) using Ir-192 sources and a dose of 50.4 Gy (5,040 rad) from an external beam linear accelerator. On September 18, 2000, the patient was administered a brachytherapy dose of 33.3 Gy (3,330 rad) Ir-192 instead of the prescribed dose of 20 Gy (2,000 rad). On October 9, 2000, the same patient was administered a brachytherapy dose of 35 Gy (3,500 rad) Ir-192 instead of the prescribed dose of 22.5 Gy (2,250 rad) Ir-192. The patient was also administered the prescribed dose of 50.4 Gy (5,040 rad) from an external beam linear accelerator.

The second patient was prescribed a total dose of 90.7 Gy (9,070 rad). This dose included brachytherapy treatments of 19.8 Gy (1,980 rad) using Ir-192 sources and of 20.5 Gy (2,050 rad) using a combination of Ir-192 and radium-226 (Ra-226) sources and a dose of 50.4 Gy (5,040 rad) from an external beam linear accelerator. On August 22, 2000, the patient was administered a brachytherapy dose of 35.2 Gy (3,520 rad) Ir-192 instead of the prescribed dose of 19.8 Gy (1,980 rad) Ir-192. On September 5, 2000, the same patient was administered the prescribed dose of 20.5 Gy (2,050 rad) using a combination of Ir-192 and Ra-226 implant sources. The patient was also administered the prescribed dose of 50.4 Gy (5,040 rad) from an external beam linear accelerator.

The third patient was prescribed a total dose of 63.9 Gy (6,390 rad). This dose included a brachytherapy treatment of 18.9 Gy (1,890 rad) using Ir-192 sources and a dose of 45 Gy (4,500 rad) from an external beam linear accelerator. On October 30, 2000 the patient was administered a brachytherapy dose of 32.4 Gy (3,240 rad) Ir-192 instead of the prescribed dose of 18.9 Gy (1,890 rad) Ir-192. The patient was also administered the prescribed dose of 45 Gy (4,500 rad) from an external beam linear accelerator.

The fourth patient was prescribed a total dose of 79.3 Gy (7,925 rad). This dose included brachytherapy treatments of 20.3 Gy (2,025 rad) and 14 Gy (1,400 rad) using Ir-192 sources and a dose of 45 Gy (4,500 rad) from an external beam linear accelerator. On October 23, 2000, the patient was administered a brachytherapy dose of 31.5 Gy (3,150 rad) Ir-192 instead of the prescribed dose of 20.3 Gy (2,025 rad) Ir-192. On November 6, 2000, the same patient was administered the prescribed brachytherapy dose of 14 Gy (1,400 rad) Ir-192. The patient was also administered the prescribed dose of 45 Gy (4,500 rad) from an external beam linear accelerator.

The misadministrations were discovered on November 3, 2000, and November 13, 2000, during an internal audit of the licensee Quality Management Program (QMP) by the Radiation Safety Officer (RSO) and the Radiation Protection Staff. A telephone report by the licensee's RSO was made to the Ohio Department of Health, Bureau of Radiation Protection, on November 4, 2000, and November 13, 2000.

The first, second, and fourth patients were notified of the misadministrations. The notification of the third patient is pending because the patient was hospitalized for an unrelated infection. The licensee stated that the clinical treatment of these patients not been affected by the misadministrations.

Cause:

The licensee indicated that this event was primarily caused by an operator error in the data entry of the source strength in the treatment planning computer. The facility obtained a new computer in August 2000, and the operator made a mistake and enter the source strengths in milligram-radium-equivalent instead of millicurie. Also, the quality assurance of the treatment planning was inadequate, and the second checks of treatment plans, to which the licensee committed in its QMP were inadequate.

Licensee Action:

As soon as the licensee's management determined that a reportable event had occurred, the licensee took action to provide additional training to the staff involved in brachytherapy procedures. The licensee submitted a written report to the Ohio Department of Health, Bureau of Radiation Protection, within 15 days of discovering the misadministrations.

NRC Action:

Other Agency Action:

The Ohio Department of Health, Bureau of Radiation Protection, performed an onsite investigation on November 21 and 22, 2000 to review the procedures and the findings of the licensee's quality management review and to confirm that the licensee's correct action proposal is adequate to prevent recurrence. Enforcement actions or penalties, if any, will be determined at a later date.

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 000455 AO #: NRC 01-01 EVENT DATE: 06/13/2000
TITLE: Occupational Overexposure at Southeast Missouri State University in Cape Girardeau, Missouri
NAME: Southeast Missouri State University CITY: Cape Girardeau STATE: MO

Nature and Probable Consequences:

In 1970, the university was licensed by the Atomic Energy Commission, NRC's predecessor, to possess and use up to 185 megabecquerel (MBq) [5 millicurie (5 mCi)] of americium-241 (Am-241) in unsealed form. The authorized user of the Am-241 died in 1980. In 1991, the university requested and received an amendment to its NRC license to remove authorization to possess or use certain radionuclides, including Am-241. The university disposed of some radionuclides in its possession but inadvertently kept the unsealed Am-241.

On February 16, 2000, a routine NRC inspection at the university found that the radiation program had deteriorated significantly. Specifically, since August 1, 1999, the university had been without a radiation safety officer (RSO), and the university officials were not sure whether they had radioactive materials in their possession or what materials they were authorized to possess. They did not know the general terms and conditions of their license. During the inspection, the licensee and an NRC inspector found an apparently empty vial labeled as containing 185 MBq (5 mCi) of Am-241 in a safe, located in the basement of the university, along with additional unauthorized material.

After the discovery of the unauthorized material, the university hired a consultant to characterize the material in the safe, and assess contamination in and around the area. On April 19, 2000, the consultant inventoried the contents of the safe and found elevated radiation levels in the room where the safe was located. On June 13, 2000, the consultant began to perform surveys and decontamination activities and identified loose Am-241 contamination. Inadequate radiological surveys and poor handling techniques used by the consultant resulted in contamination in a number of areas in the basement.

On June 21, 2000, the NRC initiated a special inspection in response to a report from the university on loose Am-241 contamination. NRC surveys independently confirmed the Am-241 contamination.

The licensee restricted access to all contaminated areas, interrupted the decontamination process, and performed internal dose assessments of individuals potentially exposed to Am-241 contamination. These assessments indicated that the consultant received a calculated committed dose equivalent to the bone surface of 2630 millisievert (263 rem). The consultant has seen a doctor, had one therapeutic medical treatment, and no adverse health effects are expected. The licensee hired a second consultant to complete the decontamination process.

Cause:

The licensee possessed radioactive material not authorized by the NRC license and failed to perform adequate radiation survey including air sampling to measure airborne radioactivity present during the inventory and decontamination activities. The survey instruments were incapable of detecting alpha activity which is needed to identify the presence of Am-241. In addition, from August 1, 1999, to July 10, 2000, the licensee had no RSO to oversee and ensure implementation of an effective radiation protection program.

Licensee Action:

The licensee appointed a new RSO and revised its radiation safety program, with an emphasis on inventory control. Specifically, the university implemented new property control and surplus inventory policies and procedures that included: (1) review and approval by the RSO of property transfers of potentially contaminated equipment, (2) surveys of surplus equipment for contamination control, and (3) training of personnel in the correct procedures for surplus equipment containing radioactive material.

NRC Action:

On September 13, 2001, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty against the university for the violation associated with the June 2000 radiation overexposure to the consultant. The fine was \$11,000. The NRC also issued Information Notice 2001-01 to emphasize the importance of accurate inventory controls to prevent unauthorized possession of radioactive material.

Other Agency Action:

Criteria:

Criterion I.A.1 of Appendix A to this report states that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual sum of the deep dose equivalent (external dose) and the committed dose equivalent (intake of radioactive material) to any individual organ or tissue, other than the lens of the eye, the bone marrow, and the gonads, of 2500 millisievert (mSv) (250 rem) or more will be considered for reporting as an AO.

ITEM #: 010155 AO #: AS 01-01 EVENT DATE: 02/16/2001
TITLE: Industrial Radiography Occupational Overexposure at Quality Inspection Services, Inc., in Jacksonville, Florida
NAME: Quality Inspection Services, Inc. CITY: Jacksonville STATE: FL

Nature and Probable Consequences:

Based on discussions with the involved individuals, it was determined that a radiographer retracted a 2.15 terabecquerel (58 curie) iridium-192 source into what was thought to be a locked, shielded, and fully retracted position inside the radiography camera. In setting up for the next shot, the radiographers noticed that the source had not been secured in the off position after the previous shot and that their survey meters and their pocket dosimeters were off scale. The radiographers immediately retracted the source to its fully shielded position and exited the working area. Film badges belonging to the radiographers indicated exposures of 29 mSv (2.9 rem) and 392 mSv (39.2 rem). For the radiographer with the highest exposure, blood tests were normal and he declined further testing. No adverse health effects are expected.

Cause:

The radiographers failed to perform an adequate survey of the radiography camera after performing radiographic operations. In addition, the alarming ratemeter worn by one of the radiographers was not turned on during radiography. The alarming ratemeter for the second radiographer had a low battery and did not produce an audible alarm.

Licensee Action:

The licensee conducted a reenactment of the event and, based on lessons learned, the training procedures were revised to prevent future incidents.

NRC Action:

Other Agency Action:

The State of Florida Bureau of Radiation Control determined that the radiographer failed to follow procedures and took enforcement action against the licensee. The State reviewed and accepted the licensee's corrective actions, which included refresher training.

Criteria:

Criterion I.A.1 of Appendix A to this report states that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent of 250 millisievert (mSv) (25 rem) or more will be considered for reporting as an AO.

ITEM #: 010662 AO #: NRC 02-02 EVENT DATE: 07/10/2001
TITLE: Gamma Stereotactic Radiosurgery (Gamma Knife) Misadministration at St. Luke's Medical Center in Milwaukee, Wisconsin
NAME: St. Luke's Medical Center CITY: Milwaukee STATE: WI

Nature and Probable Consequences:

A patient undergoing Gamma Stereotactic Radiosurgery (Gamma Knife) was prescribed treatment of 20 Gy (2,000 rad) to a portion of the brain. During the treatment, the licensee completed three of eight treatment fractions and approximately one-half of the fourth fraction when the medical physicist and radiation therapist realized that the administered treatment utilized the treatment parameters for another patient, resulting in a dose of 12.8 Gy (1,280 rad) to an unintended portion of the brain (i.e., wrong treatment site).

For treatment, the licensee's medical physics staff prepared treatment plans for two patients, to be treated on the same day. The treatment plan for Patient A consisted of a prescribed dose of 18 Gy (1,800 rad). Prior to initiating treatment of Patient A, someone on the licensee's staff handed the plan of treatment for Patient B to the licensee's radiation therapist; later, the therapist could not recall who had handed her the plan. Using Patient B's treatment plan, the treatment team set up and delivered the first three fractions to Patient A and began delivery of the fourth fraction. The error was discovered by the medical physicist during delivery of the fourth fraction. Once notified of the error, the radiation oncologist terminated the treatment.

The medical physicist determined that the treatment delivered a dose of 12.8 Gy (1,280 rad) to an unintended region of the patient's brain. The radiation oncologist determined that the location of the unintended site was far enough away from the intended site to proceed with the intended treatment. The licensee subsequently administered the intended treatment without incident. The radiation oncologist did not anticipate any immediate adverse effects to the patient because of the treatment to the wrong site. He was not certain of the potential for any long-term effects as a result of the misadministration.

The NRC contracted with a medical consultant to evaluate the medical data associated with the July 10, 2001, misadministration and assess any probable deterministic effects to the exposed patient. The consultant agreed with the licensee's assessment. With regard to long-term effects, the NRC's consultant concluded that the misadministration may be at the threshold of late central nervous system injury and may produce symptoms. The consultant further opined that long-term follow up was indicated for the patient and that the patient was eligible for inclusion in the Department of Energy's Office of Epidemiology and Health Surveillance voluntary life-time morbidity study. The licensee conducted medical follow up of the patient to identify and respond to potential adverse medical consequences resulting from the misadministration in December of 2001. However, during an attempt to follow up on the patient in June 2002, the licensee lost contact with the patient.

The licensee notified the patient's referring physician, who was also the attending neurosurgeon, immediately after the event. The radiation oncologist informed the patient of the event the following day and subsequently provided a copy of the report submitted to the NRC.

Cause:

This misadministration was caused by human error, in that the licensee staff failed to verify that the treatment plan used was for the patient being treated. Contributing factors included: (1) the patient's name was not on each page of the computer-generated treatment plan; (2) the clipboard obscured the patient's name on the first page of the treatment plan; and (3) the licensee treated two patients with similar treatment plans.

Licensee Action:

Based on the cause and contributing factors of the misadministration, the licensee immediately implemented measures to ensure that patient-specific parameters are confirmed and verified prior to initiation of treatment. The measures included: (1) independent verification of the treatment plan to ensure that it corresponds to the couch on the Gamma Knife unit; (2) labeling each page of the computer treatment plan with the patient's name; (3) placing the treatment plan in the standard pink-colored patient-specific binder; (4) ensuring that the outside of patient-specific binders have large lettering indicating the patient's name; (5) ensuring that all patient-specific binders contain all medical information for the patient; (6) use of clipboards to hold verification forms that do not cover up the patient's name at the top of the forms; and (7) training of applicable staff regarding the cause and contributing factors of the misadministration and the measures to ensure that patient-specific parameters are confirmed and verified prior to initiation of treatment.

NRC Action:

The licensee was cited for violations that included failure to verify that the treatment parameters implemented were for the patient being treated.

Other Agency Action:

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results a dose that is (1) equal to or greater than 1Gy (100 rad) to a major portion of the bone marrow, to the lens of the eye, or the gon or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and is delivered to the wrong treatment site, will be consider for reporting as an AO.

ITEM #: 020313 AO #: NRC 02-03 EVENT DATE: 03/26/2002
TITLE: Extremity Exposure in Excess of Regulatory Limits at Pacific Radiopharmacy, Limited, in Honolulu, Hawaii
NAME: Pacific Radiopharmacy, Limited CITY: Honolulu STATE: HI

Nature and Probable Consequences:

During a routine, unannounced inspection conducted by the NRC on March 6, 2002, an inspector observed a radiopharmacist drawing 3700 megabecquerels (MBq) [100 millicurie (mCi)] bulk doses of technetium-99m (Tc-99m) utilizing a vial shield without shielded top. The inspector observed that the radiopharmacist used his left index finger to hold the vial containing the Tc-99m in shield when he inverted the vial to draw a dose. After questioning the individual, the inspector determined that this was the individual's routine practice. The inspector then informed the licensee that this practice may contribute to unnecessary exposure the individual's finger and that the licensee should perform an evaluation to determine if the individual's extremity monitor (finger badge) was indicative of the actual dose received as a result of this handling practice. Following the inspection, a licensee consultant calculated the exposure to the individual's left index finger to be 7000 mSv (700 rem) for calendar year 2001. The exposure was reported to the NRC Operations Center on March 26, 2002. In addition, the licensee's consultant calculated the exposure to the individual's left index finger to be 1400 mSv (140 rem) from January 1, 2002 through March 13, 2002. The exposure was reported to the NRC Operations center as a thirty day report on March 28, 2002. The radiopharmacist's extremity exposure was chronic and not acute, occurring over the entire calendar year. The inspector viewed the individual's left index finger and did not identify any visible skin reddening.

Cause:

Licensee management and the Radiation Safety Officer failed to effectively train Pacific Radiopharmacy employees on NRC requirements for the safe handling of radionuclides and failed to provide effective oversight of its radiation safety program.

Licensee Action:

The licensee has obtained additional vial shields with shielded tops, placed them at the second drawing station, and has require the radiopharmacist to use them. The licensee also reviewed the adequacy of the radiation safety officer's oversight of the radiation safety program, determined it to be inadequate, and has replaced the radiation safety officer with another individual. The new radiation safety officer conducts unannounced inspections of the radiopharmacy to ensure compliance with their procedures requiring the use of vial shields with shielded tops during dose drawing procedures.

On March 29, 2002, the NRC issued Confirmatory Action Letter (CAL) 4-02-003 to the licensee associated with the extremity exposure in excess of regulatory limits. On April 8, 2002, the licensee responded to the CAL with corrective actions which include (1) removing the radiopharmacist from working with radioactive materials throughout the remainder of calendar year 2002; (2) contracting with a local consultant to provide safety training, conduct random unannounced audits, and provide Radiation Safety Officer (RSO) services; and (3) replacing its current RSO with the new consultant and requiring the RSO to attend quarterly board meetings to provide safety reports to the board.

NRC Action:

In addition to issuance of CAL 4-02-003, NRC staff also met with licensee representatives in a Predecisional Enforcement Conference on October 10, 2002, to discuss the inspection findings. Enforcement action is currently pending.

Other Agency Action:

Criteria:

Appendix A (see Criterion I.A.1, "Human Exposure to Radiation from Licensed Material") to this report states, in part, that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more, will be considered for reporting as an AO.

ITEM #: 020017 AO #: AS 02-01 EVENT DATE: 01/02/2002
TITLE: Loss of Package Integrity and Elevated Radiation Levels Measured at Federal Express Facility in Kenner, Louisiana
NAME: Source Production and Equipment Company CITY: Kenner STATE: LA

Nature and Probable Consequences:

A package containing iridium-192 (Ir-192) with elevated surface radiation levels was discovered at the Federal Express facility located at the New Orleans airport. The package was identified as a routine shipment for Source Production and Equipment Company (SPEC), located in St. Rose, Louisiana. After being notified by Federal Express authorities, a representative of SPEC picked up the package from the Federal Express facility. While loading the package, known as the SAFKEG, onto his truck, the individual noticed that his survey meter was offscale and his pocket dosimeter showed a reading of 1.6 mSv (160 mrem). The SAFKEG was transported back to SPEC facilities and entombed in high-density concrete bricks in its secured warehouse. The individual's total exposure during these activities was later determined to be 3.45 mSv (345 mrem).

The SAFKEG was shipped from a Swedish Company, Studsvik AB, and contained three vials loaded with a total of 1078 Ir-192 discs. The total activity was 366 terabecquerels (TBq) [9893 curies (Ci)]. Shipping papers accompanying the package indicated that the Ir-192 was solid metal, in a Type B(U) package with a yellow radioactive III label, and a transportation index of 2 [radiation levels of 0.02 mSv/hr (2 mrem/hr) at one meter from the surface]. Photographs taken by SPEC personnel, in St Rose, Louisiana prior to the SAFKEG entombment confirmed that the appropriate U. S. Department of Transportation (DOT) labeling was affixed to the package. Surveys conducted at about the same time at 15 feet from the cask revealed measured radiation levels of 10 mSv, (1 rem/hr). The package remained entombed until a hot cell capable of remote inspection was constructed. After the SAFKEG's contents were removed, in the hot cell, and before its shipment from the St. Rose facility, surveys for radiation levels and leak tests conducted for removable contamination showed no removable contamination.

The SAFKEG was originally shipped by Federal Express. A Health Physicist/Consultant to Federal Express performed dose estimate calculations for personnel exposed to the package during its transit. Personnel monitoring devices were worn by the flight crews for both the flights; specifically, from Sweden to Paris and from Paris to Memphis. The First Officer for the Paris to Memphis flight received 0.05 mSv (5 mrem) for the January-February 2002 monitoring period and 0.39 mSv (39 mrem) for the November-December 2001 period. The consultant concluded that there were no excessive radiation levels from the SAFKEG on either flight. The consultant's calculations estimated the highest dose to any Federal Express employee at 20 mSv (2 rem). The French and Swedish regulatory agencies evaluated the portions of the event that occurred within their jurisdictions.

Cause:

On February 7, 2002, after construction of the hot cell, appropriate SPEC personnel opened the SAFKEG utilizing robotics. The tamper seal was intact; after it was broken, it was sealed in plastic and put aside. The interior shielded pot was removed and placed into a small lead shield. The shielding pot lid is normally secured with six allen head screws; however, one of the six screws was found loose. The plug assembly accessing the cavity containing the three vials of Ir-192 disks was removed, revealing that two of the three vials were open. The screw tops for the vials and a large number of Ir-192 disks were visible along the lip of the inner cavity. It is presumed the screw tops became unscrewed during transportation, resulting in the elevated external radiation levels.

Licensee Action:

The licensees involved in this occurrence are the package shipper, Studsvik AB, the package manufacturer, Croft, and the U.S. recipient, SPEC. The shipper and package manufacturer are pursuing corrective actions, but these have not been formalized as of the date of this report. The inner-shielded pot of the package remained in the hot cell of the SPEC facility at the time of this report. SPEC had no plans to attempt further decontamination of the pot.

NRC Action:

Other Agency Action:

DOT — DOT issued a revision to the certificate of compliance (COC) requiring the type of radioactive material transported in the SAFKEG be contained in special form source capsules. This revision prohibits the use of the screw-top type vials that were used during this incident. The revised COC should prevent this type of occurrence in the future. DOT has discussed possible enforcement action as a result of this event.

State Agency — The State of Louisiana had the lead role in the investigation of this event and has concluded its investigation.

Criteria:

Appendix A (see Criterion I.B.2.a, "Discharge or Dispersal of Radioactive Material from its Intended Place of Confinement") to the report states that radiation levels in excess of the design values for a package, or the loss of confinement of radioactive material resulting in a radiation dose rate of 10 millisievert (mSv) (1 rem) per hour or more at 1 meter (3.28 feet) from the accessible external surface of a package containing radioactive material will be considered for reporting as an AO.

ITEM #: 020473 AO #: AS 02-02 EVENT DATE: 06/01/2000
TITLE: Industrial Radiography Occupational Overexposure at Longview Inspection in Channahon, Illinois
NAME: Longview Inspection CITY: Channahon STATE: IL

Nature and Probable Consequences:

The Illinois Department of Nuclear Safety (the Department) was notified on January 15, 2002, by the licensee's RSO, that in June 2000, a radiographer experienced an overexposure and subsequent injury at a temporary job site near Channahon, Illinois.

On January 15, 2002, the licensee reported a potential overexposure to a radiographer and a subsequent injury that could have resulted from the overexposure. The overexposure occurred in June 2000, and involved a 3.0 TBq (81.2 Ci), Ir-192 source at a temporary job site near Channahon, Illinois. The radiographer, believing that the source was secured following the radiographic exposure, approached the guide tube area and knelt down without looking at his survey meter. The radiographer's alarming rate meter was inoperable because of a low battery. After changing the radiography film for the next shot and unhooking the guide tube he noticed the source drive cable was still in the guide tube and his survey meter showed an off-scale reading. He immediately cranked the source back into the shielded position. His self-reading pocket dosimeter was off-scale. The radiographer did not inform the licensee of the incident. Approximately 2 weeks after the incident, the radiographer noticed skin redness in a 2-centimeter sized area of his left calf. Over the next year, the wound became ulcerated and would not heal. A physician examined the individual and concluded that it could have resulted from radiation. In January 2002, the licensee's RSO became aware of the condition and reported it to the Department. Prior to commencing an extensive investigation, the Department recommended that licensee seek immediate assistance from Oak Ridge Radiation Emergency Assistance Center/Training Site (REAC/TS). The REAC/TS concluded that the injury could have resulted from the overexposure in June 2000. The Department performed interviews and extensive time-motion studies and concluded that the incident could have occurred as described by the radiographer. The estimated dose to the individual was 15,000 mSv (1,500 rem) to the extremity. The licensee's radiation monitoring program revealed a whole body dose of 9.1 mSv (0.910 rem) assigned to the radiographer for the month of June 2000. The reading was within the normal range for this individual, based on licensee records.

The radiographer underwent skin grafting on February 26, 2002. Based on the results of the medical treatment, no long-term adverse health effects are expected.

Cause:

The cause was identified as a failure to conduct a lockout survey of the camera after the source was retracted, the failure to conduct radiation surveys and the failure to utilize an operable alarming rate meter due to a low battery.

Licensee Action:

The licensee terminated the radiographer's employment and incorporated the event into the annual refresher training at all thirty Longview Inspection offices.

NRC Action:

Other Agency Action:

State Agency — The Department conducted an investigation and concluded that the subsequent injury could have resulted from the overexposure. The Department imposed a suspension of the radiographer's certification for one year.

Criteria:

Appendix A (see Criterion I.A.1, "Human Exposure to Radiation from Licensed Material") to this report states, in part, that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in a shallow-dose equivalent to the skin or extremities of 2500 mSv (250 rem) or an annual total effective dose equivalent of 250 mSv (25 rem) or more will be considered for reporting as an AO.

ITEM #: 010893 AO #: AS 02-03 EVENT DATE: 09/25/2001
TITLE: Industrial Radiography Occupational Overexposure at McShane Industries in Baltimore, Maryland
NAME: Accurate Technologies, Incorporated CITY: Baltimore STATE: MA

Nature and Probable Consequences:

The NRC was informed of this event in September 2001; however, this event was not documented as an AO in the "Report to Congress on Abnormal Occurrences, Fiscal Year 2001" because of its investigation at that time.

On September 25, 2001, a radiographer employed by Accurate Technologies Incorporated (ATI) of Tinton Falls, New Jersey, was overexposed while conducting industrial radiography in Baltimore, Maryland. (On December 20, 2001, the licensee changed its name to United Evaluation Services Incorporated.) The radiographer was using an Amersham 660A radiography exposure device (camera) when the sealed source containing 2.16 TBq (58.4 Ci) of Ir-192 failed to retract into the shielded position inside the camera following the previous radiographic exposure. The radiographer thought that the source was completely retracted into the shielded position when he relocated the camera, crank, guide tube and its extension tube in preparation for next exposure. The radiographer did not use a survey meter and was not wearing a pocket dosimeter, a whole body badge, or an alarming rate meter. The radiographer changed the film and identification, then secured the tip of the guide tube on to a different pipe weld for the next exposure. While attempting to unlock the camera for the next exposure, the radiographer noticed that the self-locking device on camera was not in the locked position. Using the crank, the radiographer retracted the source into the shielded and secured position inside the camera. On September 29, 2001, the radiographer experienced burning and itching sensations in his fingers. On October 1, 2001, the radiographer notified the RSO and visited a physician. The physician reported that, on October 1, 2001 the radiographer had erythema on his fingers and palms. On October 5, 2001, State Inspectors observed radiation burns and blisters on the radiographer's hands. At the request of the State of Maryland, the United States Department of Defense, Armed Forces Radiobiology Research Institute, analyzed a 30 milliliter blood sample obtained from the radiographer, using cytogenetic biological dosimetry techniques, and reported a mean whole body dose estimation of approximately 2,670 mGy (267 rad). The assistant radiographer on site during this incident was not exposed.

Cause:

The root cause of this radiation injury was identified as a failure by the radiographer to follow licensed radiation safety procedure to comply with Maryland Regulations regarding radiation safety requirements for industrial radiographic operations, and to properly use required radiation detection and measurement devices. Specifically, the radiographer failed to wear an audible alarming rate meter or any type of dosimetry. He also failed to use a radiation survey meter. He inadvertently entered a very high radiation area caused by the Ir-192 sealed source that did not retract into the shielded position inside the camera. Finally, he failed to ensure that the source was secured in the shielded position prior to relocating the equipment from one location to another.

Licensee Action:

On October 4, 2001, the licensee agreed to discontinue all licensed activities until the completion of the Departmental Investigation.

NRC Action:

Other Agency Action:

State Agency — The licensee was cited for violations of Maryland Regulations for Control of Radiation. Specifically, the licensee was cited for exceeding occupational exposure limits; failure to conduct radiation surveys; failure to secure the device after the exposure; failure to wear and properly use a pocket dosimeter, alarming rate meter and film badge; failure to notify the Agency of overexposure; failure to maintain a utilization log; failure to report a bankruptcy to the Agency; failure to notify the Agency before vacating premises; failure to authorize the RSO on the license; and several other associated violations. On October 25, 2001, the Agency issued a Cease and Desist Order to the licensee, prohibiting all industrial radiography activities in Maryland. ATI's Maryland radioactive materials license expired on December 31, 2001, and was terminated. The incident has been referred for escalated enforcement.

Criteria:

Appendix A (see Criterion I.A.1, "Human Exposure to Radiation from Licensed Material") to this report states, in part, that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in a shallow-dose equivalent to the torso or extremities of 2500 mSv (250 rem) or an annual total effective dose equivalent of 250 mSv (25 rem) or more will be considered for reporting as an AO.

ITEM #: 020221 AO #: AS 02-04 EVENT DATE: 01/28/2002
TITLE: Intra Vascular Brachytherapy Misadministration (IVB) at Rhode Island Hospital, Providence, Rhode Island
NAME: Rhode Island Hospital CITY: Providence STATE: RI

Nature and Probable Consequences:

A patient was prescribed a dose of 8 Gy (800 rad) to the coronary artery during a Cordis Checkmate IVB procedure using 10 Ir-192 seeds, 8991 MBq (243 mCi). On January 31, 2002, during a review of dosimetry and physician records, the licensee discovered that the diameter of the artery was used in the treatment plan calculation instead of the radius. This error resulted because the physicians (authorized users) using the CORDIS device were more familiar with the procedures for a NOVOSTE device also in use at this institution. The Novoste device uses the diameter of the artery in the dosimetry calculations whereas the Cordis device uses the radius. The authorized user provided the wrong dimension (diameter instead of radius) which led to an incorrect dose being calculated. As a result the patient received an actual dose of 14.6 Gy (1,460 rad) to the outer coronary artery site instead of the prescribed 8 Gy (800 rad). The licensee indicated that there will probably be no adverse health effect to the patient.

Cause:

As stated, the misadministration occurred due to human error in the use of the diameter of the artery instead of the radius of the vessel as required when using the Cordis system. The physicians' (authorized users) familiarity with the procedures for a Novoste device was a contributing factor.

Licensee Action:

The licensee informed the State of Rhode Island the next day by telephone of the potential misadministration and provided a written report of the incident on February 14, 2002. In-service training has been conducted concerning the misadministration. In addition the prescription form has been modified to indicate if the radius or the diameter of the vessel is being used for the treatment plan.

NRC Action:

Other Agency Action:

State Agency — The Agency has been in contact with the licensee concerning this matter and the effectiveness of the corrective measures implemented. The licensee indicated that there will probably be no adverse health effects to the patient. To date there has been no recurrence of the problem.

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 020032 AO #: AS 02-05 EVENT DATE: 01/04/2002
TITLE: Strontium-90 Eye Applicator Brachytherapy at South Broward Hospital District in Hollywood, Florida
NAME: South Broward Hospital District CITY: Hollywood STATE: FL

Nature and Probable Consequences:

A patient was prescribed radiation treatment for pterygium in his left eye. The patient was to receive a total dose of 30 Gy (3,000 rad) in three 10 Gy (1,000 rad) fractions spaced approximately a week apart. Due to human error, the third and final fraction, given on January 4, 2002, was 24.84 Gy (2,484 rad) instead of the prescribed 10 Gy (1,000 rad). The prescribed dose was to be administered via a 3M Company Model 6D1A eye applicator using a 973 MBq (26.3 mCi) strontium-90 (Sr-90) source. The written directive called for each fraction to consist of a treatment duration of 44 seconds to deliver a 10 Gy (1,000 rad) dose. The correct fractionated dose was administered as planned on December 20, 2001, and December 28, 2001. A routine administration of the eye applicator required one person to time the event with a stopwatch while the authorized user administered the dose. The nurse and the authorized user became distracted in conversing with the patient and lost track of the time. The stopwatch used was the style that simply counted time up and the nurse lost focus in trying to make the patient more comfortable and at ease. The authorized user had to remind the patient to gaze in a certain direction to treat the affected area. As a result, the third fractionated treatment time was 109 seconds instead of the prescribed 44 seconds resulting in a dose of 24.84 Gy (2,484 rad).

The patient was counseled about the slight increase in late effects including cataract formation and scleral scar tissue formation.

Cause:

The State found and the licensee agreed that the misadministration occurred due to human error and the failure of staff to attend to details as required in licensee's procedures.

Licensee Action:

The licensee has identified and made changes in their procedures for use of the Sr-90 ophthalmic applicator. The facility purchased a digital stopwatch that has a large display, counts time down and not up, audibilizes the time in the last 10 seconds, alarms at the end of treatment. In addition, the nurse has been counseled and all personnel have received training in the revised procedures using the new stopwatch.

NRC Action:

Other Agency Action:

State Agency — The Florida Bureau of Radiation Control performed an on-site investigation on February 7, 2002, to review the licensee's corrective actions, which were found adequate by the State. The State also determined that while the patient was informed verbally of the misadministration, the licensee did not inform the patient in writing as required. The licensee was cited for failure to notify the patient in writing within 15 days.

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that a medical misadministration that results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive, will be considered for reporting as an AO.

ITEM #: 020377 **AO #:** AS 02-06 **EVENT DATE:** 04/10/2002
TITLE: Industrial Radiography Occupational Overexposure at Technical Welding Laboratory, Inc. in Houston, Texas
NAME: Technical Welding Laboratory, Inc. **CITY:** Houston **STATE:** TX

Nature and Probable Consequences:

On April 10, 2002, a radiographer received an overexposure calculated at 0.70 Sv (70 rem) due to handling his radiographic equipment with the source in an unshielded condition.

The exposure occurred while conducting radiography using an Amersham 660 radiography exposure device (camera) containing 1.30 TBq (35 Ci) cobalt-60 (Co-60) radiography source. At the conclusion of a radiograph, the radiographer cranked the source to the shielded position without conducting a survey and then repositioned the source guide tube for the next radiograph. When he attempted to crank out the source for the next radiograph, the radiographer realized the source had not been retracted to its fully shielded position and was contained at the end of the guide tube. The radiographer notified the Radiation Safety Officer and returned to the office. The licensee then notified the State of Texas. While being interviewed for the event, the radiographer stated that although the camera's automatic locking mechanism was inoperable while performing radiography, he did not stop work and proceeded to complete the job. Subsequently, the licensee hired a consultant to check the equipment's operability and found no problem. The equipment was placed back in service with no repair necessary.

The radiographer was sent to a doctor, underwent blood tests and participated in a chromosome aberration study. Although the blood tests results were negative, the chromosome aberration study indicated a radiation exposure ranging from 0.70 Sv (70 rem) to 1.52 Sv (152 rem) with a 95-percent confidence level. In addition, due to the radiographer's difficulty in performing a good reenactment, a dose calculation of the exposure was difficult, however a consultant determined that an exposure of 0.70 Sv (70 rem) did occur. Although the radiographer stated that he could have possibly touched the end of the guide tube where the source was located, no erythema or blistering of the hand, as expected with an incident of this type was seen. A second consultant conducted calculations for a possible extremity exposure which resulted, in a possible 2.01 Sv (201 rem) exposure to the right h

Cause:

It was determined that the cause of the overexposure involved the radiographer's failure to: (1) wear his alarming rate meter; and (2) wear a personnel monitoring device.

Licensee Action:

The licensee terminated the radiographer's employment and reviewed the incident with other radiographers employed by the company. A licensee consultant evaluation of the equipment determined that the camera was functioning properly.

NRC Action:

Other Agency Action:

State Agency — The licensee and radiographer were cited for not performing a lockout survey after a radiographic exposure, not using an alarming rate meter during radiographic operations; not using a collimator during radiographic operations and not using individual monitoring device during radiographic operations. The licensee was also cited for allowing an individual to receive an exposure in excess of regulatory limits.

The licensee has since terminated its license and the radiographer no longer works in the industrial radiography industry.

Criteria:

Appendix A (see Criterion I.A.1, "Human Exposure to Radiation from Licensed Material") to this report states, in part, that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in a shallow-dose equivalent to the head or extremities of 2500 mSv (250 rem) or an annual total effective dose equivalent of 250 millisievert (mSv) (25 rem) or more will be considered for reporting as an AO.

ITEM #: 020666 AO #: AS 02-07 EVENT DATE: 05/29/2002
TITLE: Diagnostic Misadministration at Cedars-Sinai Medical Center in Los Angeles, California
NAME: Cedars-Sinai Medical Center CITY: Los Angeles STATE: CA

Nature and Probable Consequences:

A patient was erroneously administered 111 MBq (3 mCi) of iodine-131 (I-131) for a neck scan instead of receiving a diagnostic uptake scan of 7.4 MBq (0.2 mCi) of iodine-123 (I-123). This resulted in a dose of 30.8 Gy (3,087 rad) from the I-131 to the patient's remaining thyroid tissue, rather than 0.07 Gy (7 rad) that would have resulted from the prescribed I-123.

The elderly patient was from another country, had some language difficulties, and had no medical records. The patient had a scar on her neck, and answered affirmatively when the referring physician (who was not an endocrinologist) asked if she had a thyroidectomy. Because there were no medical records, and because she had symptoms indicating a potential thyroid dysfunction, the referring physician ordered a "thyroid scan", and in the referral noted that the patient had a thyroidectomy. A temporary scheduling clerk at the administering hospital noted the thyroidectomy information and, after conferring with a nuclear medicine technologist (NMT), scheduled a dosage of 111 MBq (3 mCi) of I-131 for the patient. When the patient arrived at the licensee's facility, the NMT received confirmation from the patient that a scar on the patient's neck was the result of a thyroidectomy, the NMT proceeded to administer the scheduled neck scan with I-131. Neither the temporary scheduling clerk nor the NMT consulted with the authorized user or the referring physician to confirm their use of 111 MBq (3 mCi) of I-131 instead of 7.4 MBq (0.2 mCi) of I-123. It was determined later that the patient had only a partial thyroidectomy, with approximately 50 percent of her thyroid mass remaining. The dose to the patient's remaining thyroid tissue 30.87 Gy (3,087 rad) from the I-131, instead of 0.07 Gy (7 rad) had I-123 been administered. Because of a possible reduction of thyroid function, the patient's physician will follow her medical needs.

Cause:

The misadministration occurred due to human errors and inadequate procedures. The patient had language barriers that impeded clear communication with medical providers and licensee staff failed to consult the authorized user to obtain clarification from the referring physician. Finally, training and written instructions were not adequate to have prompted the temporary scheduling clerk the NMT to seek appropriate assistance to resolve the dosage scheduled and administered.

Licensee Action:

Corrective actions taken to prevent recurrence included modifying the Nuclear Medicine Department procedures and ensuring that scheduling for all I-131 administrations, no matter what the activity, are performed by the Thyroid Treatment Coordinator or by the Chief, NMT.

NRC Action:

Other Agency Action:

State Agency — The California Department of Health Services has reviewed and approved the licensee's corrective actions. The State is considering enforcement actions.

Criteria:

Appendix A (see Criterion IV, "For Medical Licensees") to this report states, in part, that (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive or (2) a prescribed dose or dosage that (i) is the wrong radiopharmaceutical, or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) delivered by the wrong treatment mode, or (v) is from a leaking source(s), will be considered for reporting as an AO.

ITEM #: 020937 AO #: NRC 03-01 EVENT DATE: 10/09/2002
TITLE: Intravascular Brachytherapy (IVB) Medical Event at the Queen's Medical Center in Honolulu, Hawaii
NAME: The Queen's Medical Center CITY: Honolulu STATE: HI

Nature and Probable Consequences:

A patient undergoing IVB treatment for cardiac stenosis received an underdose to the intended treatment site, but a dose above the AO criterion to an unintended site. This medical event occurred because the strontium-90 (Sr-90) source contained in the device's source train (catheter) did not reach the intended treatment site. The patient undergoing IVB was prescribed treatment of 18.4 Gray (Gy) (1,840 rads) to the left anterior descending (LAD) artery to prevent scar tissue blockage. Sixteen Sr-90 seeds with a total activity of 2.224 gigabecquerel (GBq) (60.11 millicuries [mCi]) were positioned in the patient using fluoroscopy. Because the radiation oncologist and cardiologist believed that they could see the proximal and distal markers of the source train on the fluoroscopy monitor, the physicist did not perform a survey to ensure that the source train was in the patient's chest. After the end of the treatment, the radiation oncologist was unable to retrieve all of the Sr-90 radioactive sources. After a second attempt to retrieve the sources failed, the oncologist pulled the treatment catheter from the patient and placed it in the bailout box. The bailout box is an acrylic box approximately 12 inches (in) by 10 in by 6 in with a hinged acrylic lid. Acrylic is used because of its shielding properties to attenuate the beta radiation from the catheter system. While inspecting the catheter, the oncologist discovered a kink at the location wherein the distal seed and marker became lodged. The kink was attributed to the patient's anatomy (small curve in the blood vessel, branching off the aorta where the catheter was inserted). A review of the cinematography images revealed that only one Sr-90 seed reached the intended treatment site while 5 seeds were positioned in the beginning LAD and 10 seeds were positioned outside the cinematography field of view. Instead of receiving the intended 18.4 Gy (1,840 rads), the LAD received approximately 1.25 Gy (125 rads). The remaining dose was delivered to an unintended section of the LAD and aorta. No adverse effects due to this medical event are expected.

Cause:

This medical event was caused by human error as the licensee did not perform a survey to verify that the radioactive sources were in the proper location. The patient's anatomy was a contributing factor in that there were curves in a small blood vessel branching off the aorta.

Licensee Action:

Based on the cause and contributing factors of the medical event, the licensee modified its procedures to require additional documented verification of the position of the markers by the radiological technologist and medical physicist in addition to the required verification by the radiation oncologist and cardiologist.

NRC Action:

On November 13, 2002, the NRC issued a Notice of Violation to the licensee for the failure to follow the manufacturer's operating procedures for the IVB device as specified in its license.

Other Agency Action:

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 030675 AO #: NRC 03-02 EVENT DATE: 08/08/2003
TITLE: Dose to Fetus at Community Hospital of Anderson in Anderson, Indiana
NAME: Community Hospital CITY: Anderson STATE: IN

Nature and Probable Consequences:

On August 8, 2003, the Community Hospital of Anderson reported that a 35-year-old female patient was administered 1.1 GBq (29.8 mCi) of sodium iodide-131 (1-131) for the treatment of hyperthyroidism. At the time of the therapy, the patient was unaware that she was pregnant and, as a result, an unintentional dose to her embryo/fetus was delivered. On August 25, 2003, the patient's gynecologist informed the hospital and the patient that she had been approximately 15 weeks pregnant at the time of the therapy.

The NRC staff contracted with a medical consultant to review the possible deterministic effects of the dose to the embryo/fetus as a result of the event. The medical report indicated that the total effective dose equivalent (whole body) to the embryo/fetus was approximately 0.074 Gy (7.4 rads) and the committed dose equivalent to the embryo/fetal thyroid was approximately 278 Gy (27 rads). The licensee anticipated that the fetal thyroid would be ablated. The NRC medical consultant, contracted to review this event, also anticipated that the fetal thyroid would be ablated.

Cause:

The event appeared to be an isolated occurrence. The root cause of the event was determined to be human error. Although the authorized physician user and the chief technologist asked the patient on several occasions, prior to the administration of the 1-131 dosage, if she were pregnant or believed that she could possibly be pregnant, the patient denied the possibility of pregnancy. Due to other preexisting medical conditions and consultations by other physicians informing the patient that she was unable to conceive, the patient believed that she could not become pregnant and declined taking a pregnancy test prior to the 1-131 therapy. Further, the hospital staff, knowing that the patient was also a physician on staff at the hospital, did not pursue a pregnancy test because they believed that the patient was aware of her pregnancy status.

Licensee Action:

The licensee conducted a thorough investigation of the event, including identification of the root cause. The root cause of the event was identified as human error by the patient. The event appeared to be an isolated occurrence. No further actions were deemed necessary to prevent recurrence.

NRC Action:

The NRC conducted an inspection on August 26 and 27, 2003, with continued in-office review through September 30, 2003. The inspectors determined that the licensee made the required notifications to the patient, referring physician, and the NRC. No violations of NRC requirements were identified.

Other Agency Action:

Criteria:

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report states, in part, that a medical event that results in any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent (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 will be considered for reporting as an AO; and,

Criterion I.A.3, "Human Exposure to Radiation from Licensed Material," states that any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician will be considered for reporting as an AO.

ITEM #: 030385 AO #: NRC 03-03 EVENT DATE: 05/06/2003
TITLE: IVB Medical Event at Washington Hospital Center in Washington, D.C.
NAME: Washington Hospital Center CITY: Washington STATE: DC

Nature and Probable Consequences:

A patient undergoing IVB treatment of two areas within the right coronary artery for the treatment of restenosis was prescribed a dose of 23 Gy (2,300 rads) to each treatment site. Some difficulty was experienced in inserting the catheter to the first treatment site, but in the judgment of the treatment team, the catheter appeared to be inserted properly. Fluoroscopy was used to guide insertion and to position the source train. Upon completion of the first treatment, the catheter was moved to the second treatment position, as planned. When the source train was sent out for the second treatment, resistance was met and this time the catheter was replaced. The second treatment was successfully given.

In documenting the treatment, the licensee reviewed the films taken during the treatment and printed a copy of the films for the patient's record. During this documentation, the medical physicist noted that the source markers were not in the right position and suspected that the treatment area was not covered for the first treatment given. The radiation oncologist and interventional cardiologist reviewed the films and determined that the source train was approximately 40 millimeters (mm) (1.6 in) away from the intended treatment site. Therefore, the 23 Gy (2,300 rads) dose was delivered to an unintended treatment site.

The NRC contracted a medical consultant to review the medical event and assess the probable deterministic effects of the treatment to the wrong area of the patient's coronary artery. The medical consultant concluded that the dose to the normal segment of the right coronary artery reported in this case was well below the tolerance dose for coronary arteries and no effect was expected other than fibrosis of the right coronary artery vessel wall.

Cause:

This medical event was caused by human error, in that the licensee did not properly visualize the placement of the source train in part, to a lapse in time in the fluoroscopy performed during the treatment and the inherent inability to differentiate between the proximal and distal markers of the source train. In addition, a kink in the catheter may have prevented the source train from traversing to the correct area of the right coronary artery.

Licensee Action:

The licensee immediately implemented measures to further enhance source positioning verification prior to initiation of future treatments. The measures included verification of fluoroscope calibration and reinstruction of the treatment team to fully appreciate the movement of both ends of the source train at the site prior to treatment. Further, the licensee recommended to the device manufacturer that they redesign the proximal and distal markers to make them more radiographically distinct from each other and from the guiding catheter marker.

NRC Action:

No violations of NRC requirements were identified. The NRC issued Information Notice 2003-09 describing medical events resulting from source positioning errors and is in the process of reviewing all events related to IVB since inception of this technology.

Other Agency Action:

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 030502 AO #: NRC 03-04 EVENT DATE: 05/24/2001
TITLE: Iodine-125 (1-125) Brachytherapy Seed Medical Event at Guthrie Healthcare System in Sayre, Pennsylvania
NAME: Robert Packer Hospital CITY: Sayre STATE: PA

Nature and Probable Consequences:

In 2001, a patient received a permanent brachytherapy implant using 1-125 seeds as treatment for prostate carcinoma. The authorized user prescribed a dose of 144 Gy (14,400 rads) to the prostate. The implant was performed under ultrasound guidance using 18 needles and 50 radioactive sources, as prescribed in the written directive. In June 2003, the patient returned for consultation regarding additional treatment after a diagnostic test indicated that the prostate cancer may have returned. A computerized tomography (CT) scan taken May 27, 2003, revealed that many of the seeds were not in the prostate but in adjacent tissue where they would have been ineffective in the treatment. The CT scan showed the array of seeds approximately 3 centimeters from the prostate. A review was then conducted of the May 2001 CT scan performed shortly after the initial implant procedure. This CT scan showed the array of 1-125 seeds in the same location as in the May 2003 CT scan. The seed configuration resulted in a negligible dose to the prostate and a dose of 60 to 80 Gy (6,000 to 8,000 rads) to an adjacent structure, the penile bulb. The probable deterministic effects to the patient are being determined by NRC medical consultants. The patient and the patient's referring physician were notified of the event.

Cause:

The cause of this event is under investigation by the licensee.

Licensee Action:

This event occurred in 2001 and involved an entirely different radiation oncology team than is currently employed by the licensee. The current radiation oncology team uses a different prostate implant protocol than was used in 2001. Reviews of the licensee's current prostate implant program by both the NRC and an independent physics consultant indicate that treatments performed since October 2002 have been accurate.

NRC Action:

The NRC staff conducted a special safety inspection on June 19, 2003. Subsequent to this inspection, the licensee (Guthrie Healthcare System) began to audit other prostate implants performed in 2001 and identified additional cases of possible treatment errors. On July 28, 2003, the NRC issued a Confirmatory Action Letter (CAL) specifying actions the licensee agreed to perform, including evaluation of the root cause of the events and performance of an audit of past and current prostate implants. The NRC conducted a second special inspection on August 14, 2003. As of the date of this report, the licensee has reported a total of 21 possible medical events and is continuing the actions required by the CAL. It appears that the treatment errors may have been less extreme for the additional 20 cases reported by the licensee. An NRC medical consultant is currently evaluating these cases. NRC staff will consider enforcement options upon the completion of the licensee's and NRC's investigations.

Other Agency Action:

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 030274 AO #: NRC 03-05 EVENT DATE: 03/28/2003
TITLE: Diagnostic Medical Event at Deaconess Hospital, Evansville, Indiana
NAME: Deaconess Hospita CITY: Evansville STATE: IN

Nature and Probable Consequences:

A nine-year-old patient, who had been prescribed a dosage of 0.148 MBq (4 uCi) in an 1-131 capsule for a thyroid uptake study, instead received 15.6 MBq (421 uCi) of 1-131 in liquid form. Because the patient was unable to swallow the capsule, the technologist placed a telephone request to a local commercial radiopharmacy for liquid 1-131; however, the technologist erroneously ordered 15.6 MBq (421 uCi) of 1-131 for the patient. The licensee identified the error while reviewing related papers on April 2, 2003. The referring physician, the patient, and the patient's family were informed of this event on April 3, 2003. The intended thyroid dose was approximately 0.13 Gy (13 rads), but the NRC's contracted medical consultant estimated that the patient received a thyroid dose of 13.7 Gy (1,370 rads) and an effective dose equivalent of 0.42 Gy (42 rads). According to the medical consultant, no acute radiation effects were anticipated to any organ, since no organ (except the thyroid) received more than 0.07 Gy (7.0 rad). The 13.7 Gy (1,370 rads) dose will not cause radiation thyroiditis. The medical consultant also stated that there was insufficient data on juveniles to be reassured that a radiation dose in excess of 13.7 Gy (1,370 rads) to the thyroid would have no long-term consequences, given the increased radiosensitivity of the thyroid glands of children.

Cause:

This medical event was caused by human error in ordering the correct dosage.

Licensee Action:

Corrective actions include (1) develop and use a standardized order form for liquid 1-131 that will be faxed to the local nuclear pharmacy as written confirmation of the dosage ordered; (2) modify the computerized unit dose manager system to prevent an inappropriate dosage of 1-131 from being entered into the computer system; (3) provide the local nuclear pharmacy with typical dosage ranges used by the licensee, which will be put into the nuclear pharmacy's computer and used as a secondary check to verify that the dosage ordered is appropriate for the study or treatment to be performed; and (4) provide in-service training to the nuclear medicine technicians regarding the medical event.

NRC Action:

On August 29, 2003, a Notice of Violation was issued for a violation that included the failure to order the correct quantity of 1-131 as directed by the authorized user, to have a written directive dated and signed by an authorized user prior to the administration of the 15.6 MBq (421 uCi) 1-131 dosage, and to administer a dosage within 20% of the prescribed dosage range for a thyroid uptake study using 1-131.

Other Agency Action:

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 030429 AO #: AS 03-01 EVENT DATE: 05/22/2003
TITLE: IVB Medical Event at Union Memorial Hospital in Baltimore, Maryland
NAME: Union Memorial Hospital CITY: Baltimore STATE: MD

Nature and Probable Consequences:

During a cardiac brachytherapy procedure conducted at the licensee's facility, a malfunction of the drive mechanism occurred with an IVB device containing a phosphorous-32 source with an activity of 3.48 GBq (94 mCi). The malfunction occurred during the treatment of the third of three patients. The first two treatments were completed without incident. The treatment of the third patient was initiated with the dummy source successfully reaching the proper dwell position (confirmed visually via fluoroscopy) and returning to the cartridge. The active source was then advanced into the catheter, but when the source movement light continued to blink well after the anticipated transit time, the licensee initiated a fluoroscopic view of the treatment site. The source was not observed in the fluoroscopic field of view, so the licensee assumed a machine malfunction had occurred and initiated emergency procedures. Radiation surveys were performed, which confirmed that the source had stopped inside the patient. The indicator light on the console continued to indicate that the source was in transit even after the licensee confirmed the source was in the patient and not at the treatment site. The licensee was unable to retract the source to its shielded position using the machine interrupt, the system stop button, or the handwheel. At that point, the attending physician removed the catheter and source from the patient and accidentally dropped them on the operating room floor. After the power cord was removed from the wall receptacle, the source retracted into its shielded position. The licensee stated that it took approximately 45 to 60 seconds to remove the source from the patient. The manufacturer's representative present during the treatment indicated that this period was 60 to 90 seconds. The licensee estimated a worst case dose to the wall of the patient's artery as approximately 10.38 Gy (1,038 rads) based on a 60-second exposure time. The source delivery unit was taken to the licensee's "hot" laboratory after the event and the daily quality assurance (QA) checks were performed in the physics and clinical modes. The unit passed both QA checks. The manufacturer's representative present during the procedure immediately notified the manufacturer's technical center. The device was returned to the manufacturer for evaluation and a new device was provided to the licensee.

Cause:

This medical event was caused by equipment malfunction. The manufacturer was able to simulate a similar type of failure on two occasions and is focusing on a timer chip as the possible cause of the malfunction. The manufacturer believes that a hardware problem and not the device's software caused the failure. The State of Maryland ruled out human error as the cause of the drive mechanism malfunction.

Licensee Action:

Corrective actions included the implementation of revised procedures regarding dosimetry, emergency response, and notification incidents. Training for the revised procedures was completed on November 12, 2003. The licensee also revised its annual Radiation Safety Training Program to ensure compliance with pertinent State regulations and revised procedures.

NRC Action:

Other Agency Action:

The State of Maryland conducted an investigation, and the State concurs with the licensee corrective actions that included implementation of revised procedures and an annual emergency exercise.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 030500 AO #: AS 03-04 EVENT DATE: 06/09/2003
TITLE: High Dose-Rate Afterloader (HDR) Medical Event at Saint Joseph's Hospital in Houston, Texas
NAME: Saint Joseph's Hospital CITY: Houston STATE: TX

Nature and Probable Consequences:

A cancer patient undergoing therapeutic radiation treatment for breast cancer received a superficial skin dose of 70 Gy (7,000 rads) to a circular area approximately 10 mm (0.4 in) in diameter. This error occurred using an HDR device. Deeper absorbed doses of 34 Gy (3,400 rads), 15 Gy (1,500 rads), and 10 Gy (1,000 rads) have been estimated at depths of 10 mm (0.4 in), 20 mm (0.8 in) and 30 mm (1.2 in), respectively. These deeper doses were absorbed by the subcutaneous fat and muscle of the lower left chest wall. The patient had a slight erythema of the skin which measured 5 to 10 mm (0.2 to 0.4 in) in diameter approximately 2 weeks after the radiation therapy injury.

The incorrect placement of the source in the catheter was detected on June 11, 2003, between treatment fractions 5 and 6. The patient and referring physician were notified of the treatment error and the facts involved with this treatment. The patient elected continue treatment with a modified treatment plan after the source location was corrected. A new plan was generated representing a composite of the unintended dose to the skin of the lower left chest wall and the intentional dose prescribed in the original treatment plan.

The attending physician, who was present during treatment, followed the patient's progress for any needed medical intervention to exposure to the HDR source. The patient's erythema of the skin failed to heal and developed into an ulceration. The ulceration was surgically excised by the referring physician. After excision, the area fully healed within a period of approximately two months. The patient continues to be monitored by the referring physician.

Cause:

During the setup of the HDR unit with the approved treatment plan, the source was instructed to stop at the 20th position from the catheter tip. The 20th stop resulted in the source stopping at 20 cm (7.9 in) from the catheter tip instead of the planned 20 mm (0.8 in) from the catheter tip. This was due to failure to correct the default value step size from 10 mm to 1 mm (0.4 in. to 0.04 in) as specified in the treatment plan. This failure was a human error in the copying of the treatment plan into the device's control console after the initial QA test. After the QA test the physician requested that the plan instruction be copied into a new plan, after the initial QA films had been approved. This procedure is required as the device manufacturer does not have a separate QA mode that allows QA without recording the QA tests as a fractional treatment.

Licensee Action:

The facility instituted a policy of comparing the console instructions to the approved QA record prior to each treatment fraction. In addition the medical physicist has made two suggestions for product improvement (1) the addition of a physics QA mode to allow the physicist to test a treatment plan without having it recorded as a treatment fraction to the patient; and (2) the placement of a display on the operator's console that graphically displays the actual position of the source within the catheter. Presently, the source position must be deduced by multiplying the current dwell stop by the step size.

NRC Action:

Other Agency Action:

The licensee's comments and suggested product improvements were forwarded to the manufacturer's regulatory affairs office. The licensee was cited for failure to verify that the specific details of the administration were in accordance with the treatment plan at the written directive. Escalated enforcement actions were taken against the licensee.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 030565 AO #: AS 03-05 EVENT DATE: 06/28/2003
TITLE: Overexposure at Monsanto Chemical Plant in Luling, Louisiana
NAME: Monsanto Chemical Plant CITY: Luling STATE: LA

Nature and Probable Consequences:

The licensee notified the Louisiana Office of Environmental Services on July 10, 2003, that a radiation overexposure had occurred to members of the public due to a loss of control of a 37 GBq (1 Ci) cesium-137 (Cs-137) source that became dislodged from a damaged fixed gauge. The licensee stated that on June 29, 2003, a Monsanto maintenance technician noticed that the gauge's handle mechanism had broken off and fallen to the floor. The technician picked up the broken pieces and placed them on the Monsanto Planner's desk. The Planner was not present. The Planner returned to work on July 1, 2003, but did not discover the pieces until July 10, 2003. The Planner thought the parts were the gauge's locking mechanism and went to the area where the gauge had been mounted and realized that the gauge's source was missing. After realizing that the parts contained the unshielded Cs-137 source, the licensee evacuated the building and secured the area. On July 11, 2003, a representative from a consulting company arrived on-site to perform an area survey, retrieve the source from the Planner's desk, and place the source in a secure storage area. The licensee requested that the manufacturer evaluate the failed gauge and conduct an assessment of the repair gauges. On July 19, 2003, a representative from the device manufacturer removed the source from the Monsanto plant.

It was determined that the Planner occupied the desk for approximately 50 to 60 hours and received a whole body dose of approximately 400 mSv (40 rem). This determination was based on an analysis of the Planner's schedule and work habits together with the radiation dose rate of the source. The technician who carried the source to the Planner's desk received an extremity dose of approximately 18,000 mSv (1,800 rem) to the hand. Reenactments were performed to estimate the exposures to 100 individuals employed by the plant. The estimates were determined by the time spent and proximity to the source. The highest exposure was estimated to be 740 mSv (74 rem) and the next highest exposure 180 mSv (18 rem). Altogether, 42 nonradiation workers exceeded the 1 mSv (0.1 rem) exposure limit to members of the general public. The workers are considered to be members of the public, not radiation workers, because they are not exposed to radiation from licensed radioactive material as a normal part of their work. Others may have also been exposed at lower levels. Blood tests were performed for seven individuals, but revealed no cell changes. No one has shown signs of sickness or erythema.

The licensee contacted the Radiological Emergency Assistance Center/Training Site (REAC/TS) in Oak Ridge, Tennessee, and requested its assistance in having a cytogenetic blood study performed for the Planner. The licensee reported that it appears the vibration of the gauge caused the source holder and the attached source to fall. Surveys of the relevant areas and wipe tests on source did not reveal any source leakage.

Cause:

Monsanto believes the cause of the incident was corrosion of the epoxy that holds the source in place. However, the end plate was held in place by one tack weld and the vibration of the gauge could have contributed to the gauge becoming dislodged.

Licensee Action:

The decision has been made to take this type of device out of service and replace it with a newer model. Until the devices are removed from service, weekly visual inspections on the devices will be performed. The Planner and Monsanto engineers/technicians were trained only to recognize the radiation posting on the device. Now the safety training includes pictures of the device, its components, and the radioactive capsule.

NRC Action:

Other Agency Action:

The licensee was cited for two violations. One violation was for the exposure of a nonradiation worker in excess of 1 mSv (0.1 rem) in a year, and the other was for creating a radiation area in an unrestricted area that exceeded 0.02 mSv (0.002 rem) in any one hour. The event was referred to the State of Louisiana's Enforcement Section.

Criteria:

Criterion I.A.1, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report states, in part, that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or an annual total effective dose equivalent of 250 mSv (25 rem) or more will be considered for reporting as an AO.

ITEM #: 030411 AO #: AS 03-06 EVENT DATE: 05/13/2003
TITLE: Brachytherapy Medical Event at University Hospitals of Cleveland in Cleveland, Ohio
NAME: University Hospitals of Cleveland CITY: Cleveland STATE: OH

Nature and Probable Consequences:

On May 22, 2003, the Ohio Department of Health notified the NRC Operations Center of an apparent brachytherapy medical event at University Hospitals of Cleveland. The licensee reported a radiation treatment to the wrong target area during a brachytherapy prostate procedure using 59 1-125 seeds, each containing 13 MBq (0.351 mCi) for a total activity of 765 MBq (20.71 mCi). The treatment resulted in a distribution of seeds in areas other than prescribed.

An unintended area of the prostate gland received approximately 1.4 Gy (140 rads) due to seeds implanted outside of the intended cancer cell site. The licensee determined that 31% of the bladder received 72 Gy (7,200 rads) and 3% of the rectum received 72 Gy (7,200 rads).

Cause:

Unusual anatomical aspects of the seminal/prostate vesicle under ultrasound hampered the physician's ability to correctly place seeds fully within the intended preplan margins. In addition, seed visualization on fluoroscopy was suboptimal.

Licensee Action:

Faculty and staff will increase efforts to identify unusual prostate anatomical features during the preplanning process; specifically they will continue to cross-check and verify seed position in relation to underlying anatomy. Corrective actions taken by the licensee include (1) the introduction of stabilization needles to assist in keeping the prostate fixed relative to the base plate, the ultrasound probe, and surrounding tissues during the localization and the seed deposition process and (2) the use of a more radio-opaque seed to facilitate positive location during procedures viewed under fluoroscopy. The patient and referring physician were notified of the medical event.

NRC Action:

Other Agency Action:

The Ohio Department of Health performed an investigation of the event.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 030505

AO #: AS 03-07

EVENT DATE: 06/11/2003

TITLE: Diagnostic Medical Event at Christus Santa Rosa in San Antonio, Texas

NAME: Christus Santa Rosa

CITY: San Antonio

STATE: TX

Nature and Probable Consequences:

A patient received 85.1 MBq (2.3 mCi) of 1-131 instead of the prescribed dosage of 11.1 MBq (0.3 mCi) of 1-131. The licensee discovered the error when the patient returned after 48 hours for a scan. The physician's written order requesting a thyroid scan thyroiditis was misunderstood by the technologist as a request for a "whole body image" instead of a "thyroid up-take and scan". a result, the technologist ordered the wrong dose for the prescribed procedure. Both the referring physician and the patient have been informed of the error.

Cause:

The medical event was caused by human error. The wrong dosage was administered to the patient because the written order for the 1-131 procedure was misread by the administering technologist.

Licensee Action:

The licensee implemented revised procedures mandating that a physician review all prescriptions requiring the use of 1-131 and concur on the correct dosage.

NRC Action:

Other Agency Action:

The State accepted the licensee's report and corrective actions as appropriate.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 020489 AO #: AS 03-08 EVENT DATE: 04/25/2002
TITLE: Therapy Medical Event at Marian Medical Center in Santa Maria, California
NAME: Marian Medical Center CITY: Santa Maria STATE: CA

Nature and Probable Consequences:

A patient was prescribed a therapeutic dose to the thyroid of 1-131 with an activity of 296 MBq (8 mCi) but was erroneously administered 3,700 MBq (100 mCi) of 1-131 instead. The error was discovered immediately and was reported to the RSO and the referring physician. After consultation, the RSO and referring physician prescribed suppressive and hydration therapy to the patient immediately in order to minimize the patient's absorbed dose. The suppressive therapy blocked the thyroid from absorbing the dose and the hydration therapy was given to accelerate the excretion of the radioactivity from the body.

The dose to the patient was calculated to be 0.03 Gy (3 rads) to the whole body and 38.7 Gy (3,870 rads) to the thyroid. No adverse health effects are expected.

Cause:

The State found that the medical event occurred due to human error. Two 1-131 capsules had been delivered that day for two patients who were to receive iodine therapy. The capsule containing 3.7 GBq (100 mCi) was given to the first patient. The error was recognized before the second patient was treated; therefore, the second 1-131 capsule was never administered. The technologist failed to check the labeling and did not verify the dose using a dose calibrator.

Licensee Action:

Corrective actions included (1) counseling the technologist to review the labels on the vial and to check the dose in the dose calibrator before administration, (2) providing in-service training to technologists on proper procedures, (3) implementing new procedures requiring the doctor to check the label to ensure the patient will be administered the correct dose, and (4) administer 1-131 to no more than one patient daily.

NRC Action:

Other Agency Action:

The State has reviewed and accepted the licensee's corrective actions.

Criteria:

Criterion IV to Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 (1,000 rads) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 021005 AO #: AS 03-09 EVENT DATE: 08/26/2002
TITLE: Gamma Stereotactic Radiosurgery Device Medical Event at Bayfront Medical Center, Inc., in St. Petersburg, Florida
NAME: Bayfront Medical Center, Inc. CITY: St. Petersburg STATE: FL

Nature and Probable Consequences:

On October 31, 2002, the Florida Bureau of Radiation Control was notified that 10 patients undergoing Gamma Stereotactic Radiosurgery (gamma knife) had received a dose or doses at least 50% greater than prescribed. The prescribed treatments ran from 12.2 to 24 Gy (1,220 to 2,400 rads) at the 50% isodose curve; however, the delivered doses to the patients ranged between 19.2 and 38.4 Gy (1,920 and 3,840 rads) at the 50% isodose curve, which is 60% greater than the treatment prescribed. The patients were diagnosed with a variety of brain disorders (vascular diseases, tumors, and functional targets such as selected nerves). A treatment plan was developed and reviewed by the physicist, and the doses were administered using a gamma knife device. On October 30, 2002, while performing a routine QA, the RSO discovered that the physics parameters in the treatment planning file had an incorrect calibration factor. Further investigation identified that the system had an older calibration date which resulted in the incorrect information that the sources had 60% less activity. The medical events were discovered during a review all patient files.

The medical events were reported to two authorized users and three referring physicians. Notification of the medical event was provided to nine of the patients or patients' responsible guardians and they were subsequently provided a copy of the report pertinent to that patient. The authorized user does not anticipate any change in the patient's condition from the additional exposure. The licensee's authorized users noted that these doses are still within the published literature. During the notifications it was discovered that one of the patients had died as a result of the patient's disease. The licensee's authorized users stated that this patient was given palliative treatment for four metastatic lesions that were not close to any critical structure. The patient died approximately 2 months after the treatment, which was the typical period of life expectancy for a patient with this type and stage disease.

Cause:

The State was not able to identify how the calibration date was changed in the treatment planning software physics protocol file. However, it is the licensee's responsibility, through an effective quality management program, to ensure that the treatment is administered with high confidence as directed by the authorized user.

Licensee Action:

The licensee has revised its quality management program to include additional daily checks to verify that the expected dose rate agrees with the dose rate shown on the treatment planning software physics protocol output to within 1%. The gamma knife manufacturer issued a notice dated November 4, 2002, to all customers utilizing the treatment planning system specific to the gamma knife used to treat these patients. The notice requested customers to check the physics protocol and to run tests to verify dose calibration factors after any treatment planning system service or software reinstallation.

NRC Action:

Other Agency Action:

The State conducted an onsite investigation that included interviews with licensee personnel involved and a representative from device's manufacturer on November 12-13, 2002. In the licensee's medical event report, the licensee indicated the device manufacturer installed a peripheral printer on August 26, 2002. The licensee's report also indicated that on this date the source calibration information was changed. During the investigation the manufacturer stated that it was unable to recreate the occurrence. Telephone interviews were conducted with service personnel from the device manufacturer. The State also consulted with an independently contracted physicist with experience specific to the gamma knife and its treatment planning system to determine the state of the equipment. It was determined that the licensee's quality management program did not routinely verify calibration information as compared to treatment planning dose rates. State actions for this case are still pending.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 021063 AO #: AS 03-02 EVENT DATE: 10/18/2002
TITLE: Industrial Radiography Occupational Overexposure at a Temporary Jobsite in Ghent, Kentucky
NAME: Huntington Testing and Technology CITY: Ghent STATE: KY

Nature and Probable Consequences:

The licensee reported an overexposure to a radiographer of 314 mSv (31.4 rem). A 3.81 terabecquerel (TBq) (103 Ci) Ir-192 source was being retracted after an exposure. The radiographer who had entered the area was in the area for approximately 3 minutes before realizing the source was not fully retracted. Upon realizing that the source was not fully retracted, the radiographer immediately left the area, extended the source, and then retracted it to the housed position. The radiographer's dosimetry was used for processing and results indicated a whole body exposure of only 48.6 mSv (4.86 rem). However, the licensee, with assistance from the source manufacturer's Radiation Safety Officer (RSO), completed a reconstruction of the whole body exposure to the radiographer. The final result indicated an exposure of 300 mSv (30 rem) whole body from the event. This exposure was added to the radiographer's year-to-date exposure of 14 mSv (1.4 rem), for a total yearly whole body exposure of 314 mSv (31.4 rem). Discussions with the Kentucky Radiation Health & Toxic Agents (KRHTA) Branch, along with independent calculations, confirm the 300 mSv (30 rem) event exposure. The licensee stated that the thermoluminescent dosimeter (TLD) and operating ratemeter were in the radiographer's pocket, an area that did not reflect true whole body exposure, and the alarm ratemeter was never heard in an alarming condition.

Cause:

This event was caused by inadequate operating procedures for the exposure device, improper placement of the TLD in the radiographer's pocket (rather than on his body), improper storage of the alarm ratemeter in his pocket (rather than on his body), failure to survey the exposure device upon completion of the radiograph.

Licensee Action:

The licensee's corrective actions included revision of the operating procedure for retracting the source into the exposure device, personnel training on the revised procedure and proper wearing of dosimetry devices, and annual refresher training on proper operation and responses of survey instrumentation. Additionally, the radiographer involved will receive an additional 40 hours of radiation safety training prior to returning to work in radiography, and will be evaluated at least once a month for the next year.

NRC Action:

Other Agency Action:

The KRHTA Branch conducted an onsite investigation and concurred with the licensee's dose assessment and identification of causes of the event. The licensee was issued a Notice of Violation and has provided corrective actions to the Commonwealth of Kentucky.

Criteria:

Criterion I.A.1, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report states, in part, that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or an annual total effective dose equivalent of 250 mSv (25 rem) or more will be considered for reporting as an AO.

ITEM #:	030624	AO #:	AS 03-03	EVENT DATE:	07/28/2003
TITLE:	Diagnostic Medical Event at Rush Copley Medical Center in Aurora, Illinois				
NAME:	Rush Copley Medical Center	CITY:	Aurora	STATE:	IL

Nature and Probable Consequences:

The Illinois Emergency Management Agency received a call on July 29, 2003, from a nuclear medicine technician at Rush Copley Medical Center in Aurora, Illinois. The technician reported that a patient who was to receive 148 MBq (4 mCi) of thallium-201 (TI 201) for a heart test instead received 148 MBq (4 mCi) of 1-131 on July 28, 2003. The patient had been admitted the day before event with an order for a treadmill heart stress test to be performed. The patient remained hospitalized at the facility until discharge after July 30, 2003.

The circumstances of the event, as reported by the technician, are that both the exterior lead container and the syringe were labeled as containing a diagnostic unit dose of TI-201. Although the injection occurred the previous day, it was not determined that 1-131 was involved until the morning of July 29, 2003. Service engineers were called to the site on both days to inspect the gamma cameras used after attempts to image the patient failed. The reason became evident when a gamma camera flood source that had been made from what was thought to be the remaining TI-201 material in the syringe from July 29 showed peaks consistent with 131, rather than the expected TI-201. The syringe had been assayed by the medical center before injection. The assay results showed the dose to be within the prescribed range for a typical 148 MBq (4 mCi) TI-201 diagnostic administration.

On Friday, July 25, 2003, the nuclear pharmacy received an order for five unit dose syringes of 1-131 for the Veterinary Service Center (VSC) and two unit dose syringes of TI-201 for Rush Copley Medical Center. When the computer generated orders and associated labels were segregated, one of the prescriptions for the TI-201 was mistakenly substituted for 1-131. The pharmacist did not realize the error and the 1-131 dose (syringe) and its container were labeled with one of the TI-201 labels generated for the original order. On Monday, July 28, 2003, the pharmacy facility manager noted that only four 1-131 prescriptions had been filled at VSC. Assuming the 1-131 dose had not been filled with the others the previous Friday, July 25, 2003, he filled an additional syringe with 1-131 to complete the order for VSC.

The medical center estimates that a small amount of residual activity remained adhered to the walls of the syringe. Therefore, it estimates the amount of injected 1-131 to be 148 MBq (4 mCi). Based on the package insert information for this material and assuming that an injected sodium iodide solution of 1-131 results in a radiation absorbed dose similar to oral administration and the patient had normal thyroid function (25% uptake), the dose to the patient's thyroid is approximately 51.95 Gy (5,195 rads).

The medical center technician indicated that the patient involved had been contacted by the referring physician, onsite oncologist and the medical center's administrator and lawyer and was informed as to what had happened at the initial time of discovery of the event. Later, a copy of the medical center's report to the agency was also provided to the patient. The medical center offered to perform routine blood analysis throughout the year to monitor any changes in thyroid activity. The patient had been advised as to potential health effects of the medical event during that time and the need for routine followup testing. The patient has not returned to the medical center for any additional testing, diagnosis, or consultation.

The medical center's oncologist indicated that it is very unlikely that any medical changes will be noted in the patient because the dose administered is only slightly larger than that typically ordered for whole body scans using 1-131. Blood tests were taken immediately following the discovery of the event. Those tests suggest that the patient was hypothyroid as a preexisting condition at admittance.

Cause:

The medical event was caused by the mislabeling of the 1-131 unit dose syringe. Other factors that led to the medical event included improper segregation of the prescriptions at the pharmacy and lack of a second means of verifying proper completion of the order.

Licensee Action:

The pharmacy ceased dispensing therapeutic quantities of 1-131 in unit dose syringes. Therapeutic doses of 1-131 will only be dispensed in capsule form. This will preclude the possibility of a unit dose of diagnostic material being mistakenly filled with a quantity of therapeutic material. Additional corrective actions included (1) retraining of pharmacists, (2) implementation of a dual verification system for all prescriptions received, (3) implementation of a triple check system for dispensing compounds, and (4) testing a new bar code system for tracking all prescriptions.

NRC Action:

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Other Agency Action:

On July 30, 2003, the State agency sent an investigator to the medical center and the nuclear pharmacy to observe licensed activities and to review the circumstances of the event. During those onsite visits, preliminary information reported by the medical center and pharmacy was confirmed. The pharmacy was cited for failure to properly fill the prescription as ordered by the physician. The State agency is holding this action item open pending enforcement action and will include a review of the corrective actions.

taken during the next routine inspection. The agency does not expect any additional significant information to be received or other notable action to be taken outside of the enforcement process.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is the wrong radiopharmaceutical will be considered for reporting as an AO.

ITEM #: 000666 AO #: NRC 00-02 EVENT DATE: 12/31/1995
TITLE: Overexposures at Mallinckrodt, Inc., in Maryland Heights, Missouri
NAME: Mallinckrodt, Inc. CITY: Maryland Heights STATE: MO

Nature and Probable Consequences:

On March 31, 2000, a contract employee who was providing services for Mallinckrodt, Inc., was attempting to correct flow problem with a 703,000 megabecquerel (19 curie) molybdenum-99/technetium-99m generator. The employee performed the operation in a glove box. The employee's initial attempts to correct the generator problem were not successful. The employee then removed the generator column containing the radioactive material from its shield and determined that the inlet line was not connected and the outlet line was bent at an angle. Holding the unshielded column in his right hand, the employee corrected the problems with the inlet and outlet lines. This process took between 10 and 20 seconds to complete. Dose rates at the location of the column held by the employee were calculated to be approximately 510 mSv (51 rem) per second. As a result the employee's thumb and index finger of the right hand received a dose ranging from 5,100 mSv (510 rem) to 11,200 mSv (1,120 rem) shallow-dose equivalent. The NRC annual dose limit to the skin or any extremity is 500 mSv (50 rem) shallow-dose equivalent. The employee believed that the gloves he wore provided him adequate protection from radiation.

On April 5, 2000, Mallinckrodt determined that the radiation monitor worn on the employee's right hand recorded a dose of 57 mSv (5.7 rem) shallow-dose equivalent in excess of its administrative weekly limit which was 20 mSv (2 rem). Mallinckrodt's investigation of the exposure determined that the employee had directly handled the generator column and reported the event to NRC on April 13, 2000. The employee was examined by a physician, who identified no immediate health effects. Due to the inability of either the NRC or the licensee to precisely estimate the likely exposure to the employee's finger and thumb, long-term health effects could not be predicted.

During its investigation of the March 31, 2000 event, Mallinckrodt identified other employee overexposures that occurred in the preceding 5 years during the performance of two routine operations. As a result of the first routine operation, 11 employees involved in the hand-labeling of vials containing millicurie quantities of indium-111 (In-111) (a State-regulated, non-NRC licensee material) received extremity doses ranging from 500 mSv (50 rem) to 3,200 mSv (320 rem) shallow-dose equivalent. In addition to these doses from In-111, the 11 employees had also received doses from NRC-regulated material, typically less than 5 percent of their total extremity doses.

The second operation involved the handling of unshielded and partially shielded vials and syringes containing radioactive material (State- and NRC-regulated material) in a sterility testing laboratory. As a result of this operation Mallinckrodt identified four employees who received extremity doses ranging from 680 mSv (68 rem) to 960 mSv (96 rem) shallow-dose equivalent.

Cause:

The causes of the March 31, 2000 event were insufficient training to ensure that the employee understood the difference between radioactive contamination and radiation and inadequate oversight of the laboratory. The written, approved procedure on the employee's assigned duties did not allow the removal of the generator column during manufacturing. However, an ad hoc procedure had been developed by the staff of the laboratory, that was not known to or approved by the management outside the laboratory. The ad hoc procedure allowed the removal of the generator column from the shield using remote handling tools. On March 31, 2000, the employee was using the ad hoc procedure but the tools that were used to remove the generator column from the shield had fallen to the bottom of the glove box and were out of the employee's reach. The employee decided on his own to remove the column and to perform repairs without using tools.

With regard to the other operations that resulted in significant doses, Mallinckrodt personnel believed, erroneously, that the dose recorded by the personnel monitoring devices worn by its employees reflected the actual exposures received. However, the actual doses were, in some instances, 100 times greater than those recorded by the monitors. This was due to the distance between the monitors, which are normally worn like a ring at the base of the finger, and the fingertips, where the exposures were received.

Licensee Action:

The licensee staff was instructed in the proper handling of unshielded containers of radioactive material. The licensee increased its radiation safety and supervisory oversight in the generator manufacturing laboratory. In addition, the licensee initiated and implemented managerial changes to its operations and agreed to: (1) retain an independent organization to assess the radiation safety program and the radiation safety aspects of its radioactive material manufacturing processes; (2) provide assurance that workers have received training and understand procedures and practices to maintain radiation exposures as low as is reasonably achievable (ALARA); (3) develop a plan to review operations for the last five years to determine if additional workers have received exposures in excess of regulatory limits; and (4) request an amendment to incorporate a corrective action program into its license. NRC confirmed the licensee's agreement in a Confirmatory Order Modifying license issued on June 22, 2000.

NRC Action:

The NRC conducted an Augmented Inspection Team (AIT) inspection on May 4 through May 26, 2000, and a follow up inspection on July 17 through August 4, 2000. As a result of the AIT inspection, NRC issued the June 22, 2000, Confirmatory Order Modifying License to Mallinckrodt. On December 21, 2000, NRC issued a Notice of Violation and Proposed Imposition of a \$125,000 Civil Penalty.

Other Agency Action:

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Criteria:

Appendix A (see Criterion I.A.1, "For Medical Licensees") to this report states, in part, that any unintended radiation exposure to adult (any individual 18 years of age or older) resulting in an annual shallow-dose equivalent to the skin or extremities of 2,500 r (250 rem) or more will be considered for reporting as an AO.

ITEM #: 031001 AO #: NRC 04-01 EVENT DATE: 12/22/2003
TITLE: Uranium Hexafluoride Release at Honeywell Specialty Chemicals, Inc. in Metropolis, Illinois
NAME: Honeywell International, Inc CITY: Metropolis STATE: IL

Nature and Probable Consequences:

On December 22, 2003, a uranium hexafluoride (UF6) release occurred from one of the plant's chemical process lines. The release occurred due to improper valve alignment which caused inadvertent pressurization of the system. The licensee did not have a written procedure for a process that was performed infrequently and relied on the operator's memory to perform the required actions. The release lasted approximately 40 minutes. The licensee observed a visible cloud crossing the site boundary and declared a site area emergency, which was terminated approximately 4 hours later. Approximately 25 members of the public were temporarily evacuated from their homes, and approximately 75 persons remained sheltered in their homes for a time. Four members of the public went to the hospital. Three of the four were examined and released, while the fourth was held for observation and released the next day. This individual showed skin reddening on portions of his face and part of one arm, which indicated a hydrogen fluoride (HF) acid burn. Honeywell's initial estimate of a release of 7 pounds of UF6 was later refined to be approximately 70 pounds. Honeywell shut the plant down and agreed to discuss corrective actions with the NRC before restarting operations to determine whether the NRC had any objection to restarting specific operations.

Cause:

An NRC Augmented Inspection Team (AIT) and Honeywell's Root Cause Investigation Team identified similar root and contributing causes. The Honeywell Root Cause Investigation Team provided its findings to the NRC in a meeting on February 11, 2004.

Key causes were as follows:

- The licensee failed to have a written procedure for an infrequent evolution and, thus, relied on the operator's memory to perform the required actions.
- The licensee's corrective action program had not adequately corrected a previously identified lack of procedures for certain activities, the licensee had not adequately aligned staff to the need for procedures for activities.
- The licensee did not have an alarm to warn operators that the system was becoming pressurized. The licensee did not have procedures or measures to respond to abnormal conditions during operations. The licensee did not have procedures or process for documenting when equipment was not in proper working order.

In addition, the AIT and Honeywell Root Cause Investigation Team identified problems in implementing the emergency plan once the licensee identified the release, including problems in communication with State and local authorities.

Licensee Action:

In addition to the Root Cause Investigation Team, Honeywell chartered a Plant Engineering Team, a "Triangle of Prevention" Team and a Corporate "Deep Dive" Team to review the facility and operations. These teams reviewed certain UF6 safety and environmental improvements, management processes, change management, mechanical integrity, and the emergency plan. As a result of these reviews, Honeywell developed a list of corrective and improvement actions to be completed before restarting operations. On March 4, 2004, Honeywell submitted a list of the actions to be taken for each phase of the restart. Honeywell has also worked with State and local authorities to improve emergency response, and the company conducted an emergency drill with local agencies on March 11, 2004. That drill identified items that needed to be improved, including use of the dedicated phone for communicating with off site authorities. Honeywell plans to improve this communication method. In addition, Honeywell is in the process of implementing other corrective and improvement actions.

NRC Action:

The NRC developed a Restart Readiness Oversight Plan to review Honeywell's actions, including safety and emergency preparedness improvements. The NRC has reviewed actions the licensee planned to prevent recurrence. In addition, the NRC observed an emergency drill of the revised Emergency Plan and procedures.

The NRC held two public meetings in Metropolis, Illinois (on March 18 and April 21, 2004) during the restart phase to inform the public of the licensee's plans and progress and to describe the NRC's oversight activities and results. In addition, the NRC completed inspections of the licensee's corrective actions before the restart of licensed operations. On May 10, 2004, the NRC issued a Notice of Violation for two significant violations identified during the AIT inspection. Specifically, those violations involve (1) reconfiguration of the fluorination system without detailed instructions (which allowed a UF6 leak to occur), and (2) failure to maintain and execute various response measures in the emergency response plan.

The NRC performed followup inspections specifically focused on Honeywell's implementation of its corrective actions on June 1 and August 13, 2004. The areas inspected included plant operations, chemical safety, emergency preparedness, maintenance and surveillance, management organization and controls, and operator training. The June inspection did not identify any violations, but the August inspection identified two Severity Level IV violations. Those cited violations concerned the conduct of operations that were not adequately described in written operating procedures and an inadequate evaluation of the radiological conditions associated with storage of bed material and filter fines.

On September 30, 2004, the NRC held a public meeting with Honeywell to discuss the company's progress in implementing long-term corrective actions that will ensure sustained performance improvements. Honeywell's long-term efforts were primarily directed

at procedures and training, plant material conditions, and emergency preparedness. The NRC also described the additional inspections completed since the restart of licensed operations at the site and the agency's plan to continue increased oversight.

The NRC performed an additional inspection in December 2004, and identified a violation that involved the failure of the license operations personnel to properly perform pre-fill inspections of UF6 cylinders. This failure resulted in Honeywell's shipment of 14 cylinders with prohibited Hunt valves attached. Based upon the results of this inspection, together with those of the previous inspections, the NRC has determined that the heightened oversight of licensed activities performed at the Honeywell facilities will continue.

Other Agency Action:

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Criteria:

Criterion III.A., "For Fuel Facilities," of Appendix A to this report states that a shutdown of the plant or portion of the plant resulting from a significant event and/or violation of a law, regulation, or a license/certificate condition will be considered for reporting as a AO.

ITEM #: 040169 AO #: NRC 04-02 EVENT DATE: 03/05/2004
TITLE: Incinerator Event at Westinghouse Columbia Fuel Fabrication Facility in Columbia, South Carolina
NAME: Westinghouse Columbia Fuel Fabrication Facility CITY: Columbia STATE: SC

Nature and Probable Consequences:

The licensee uses a standard industrial incinerator to reduce uranium-contaminated process waste volume and facilitate uranium recovery from the waste. During a technical review of a proposed procedure change, the licensee determined that its incinerator gas system was being operated outside the approved safety basis. Samples of ash deposited at various locations in the incinerator exceeded the assumed uranium concentration for incinerator ash. The licensee immediately stopped incinerator operations and performed a complete incinerator clean-out. The licensee determined that approximately 271 kilograms of ash at a maximum uranium concentration of approximately 30 wt% had accumulated in the incinerator's secondary combustion chamber. The licensee had performed a criticality analysis that concluded no ash would accumulate in the secondary combustion chamber, and the maximum uranium concentration of ash in the incinerator system could not exceed 21.6 wt%. No criticality safety controls were in place to prevent the accumulation of fly-ash containing excessive uranium concentrations.

Cause:

The licensee's criticality safety staff failed to recognize that fly-ash could accumulate in the incinerator's secondary combustion chamber, and ash uranium concentrations could exceed 21.6 wt%. Contributing factors were the failure to control incinerator operations that allowed the increased uranium concentration in the fly-ash, and failure to recognize excessive material accumulation or uranium concentration increases.

Licensee Action:

The licensee immediately stopped incinerator operations and initiated a project to prevent future material accumulations. The licensee also initiated a program to upgrade criticality safety at the plant, including assigning additional staff to the nuclear criticality safety program, improving ownership of criticality safety by production and engineering staff, improving management and ownership of change, performing a comprehensive review of existing criticality safety analyses, using the integrated safety analysis process to prioritize changes to administrative criticality safety controls, and implementing a comprehensive program throughout the plant to ensure procedure compliance.

NRC Action:

On May 13, 2004, the NRC issued Inspection Report 70-1151/2004-001, which described the event. On July 19, 2004, the NRC issued an Information Notice to fuel cycle licensees concerning the use of less-than-optimal bounding assumptions in criticality safety analyses at fuel cycle facilities. On July 28, 2004, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$24,000 to the licensee for failure to establish and maintain double-contingency protection in the incinerator and failure of management controls to detect the accumulation of a critical mass of fissile material in an unsafe geometry vessel. Although the normal civil penalty assessment process would have fully mitigated the civil penalty, the NRC exercised enforcement discretion in accordance with Section VII.A.1 of the Enforcement Policy and proposed a base civil penalty to reflect the safety significance of the issue, which resulted in a substantial increase in the likelihood of a nuclear criticality event. On October 21, 2004, the NRC conducted a management meeting with the licensee to discuss the incinerator event and its proposed corrective actions. The NRC will follow the corrective actions through the agency's inspection and oversight programs.

Other Agency Action:

Criteria:

Criterion III.A., "For Fuel Cycle Facilities," of Appendix A to this report states that a shutdown of the plant or portion of the plant resulting from a significant event and/or violation of a law, regulation, or a license/certificate condition will be considered for reporting as an AO.

ITEM #: 030947 **AO #:** NRC 04-03 **EVENT DATE:** 10/16/2003
TITLE: Iodine-125 Brachytherapy Seed Medical Event at Albert Einstein HealthCare Network in Philadelphia, Pennsylvania
NAME: Albert Einstein HealthCare Network **CITY:** Philadelphia **STATE:** PA

Nature and Probable Consequences:

A patient received a permanent brachytherapy implant using iodine-125 (I-125) seeds as treatment for prostate carcinoma on October 16, 2003. The authorized user prescribed a dose of 145 Gy (14,500 rads) to the prostate gland. The implant was performed under ultrasound guidance, and 89 sources were implanted as prescribed in the written directive. On November 17, 2003, the patient returned for a routine postoperative computerized tomography (CT) scan. On November 20, 2003, a review of scan revealed that many of the seeds were not located in the prostate as intended, but were in adjacent tissue where they were ineffective during treatment. As a result, the prostate gland received an inadequate dose of 18.6 Gy (1,860 rads), while the adjacent tissue received a dose of approximately 115 Gy (11,500 rads). An NRC medical consultant determined that the probable consequences to the patient would be comparable to the effects of external beam radiation treatment for prostate cancer and would not cause further damage to the patient. The patient and the patient's referring physician were notified of the event.

Cause:

The licensee determined that this medical event was caused by human error, the most likely being the misidentification of the prostate gland on the intra-operative ultrasound. Other possible causes include shifting of the needle grid in the patient on the operating room table or the suction of the seeds into the needle tract after the removal of the individual needles from the patient.

Licensee Action:

The licensee's corrective actions for future prostate brachytherapy treatments include new requirements that an outside radiation oncologist with expertise in prostate brachytherapy will monitor authorized users, and an experienced prostate brachytherapist will observe authorized users as they perform prostate implant procedures. In addition, the licensee implemented revised procedure including performing a pre-operative CT scan; reviewing pre-planned ultrasound studies prior to, during, and after the procedure and reviewing postoperative pelvic x-rays within 1 day of the procedure. Furthermore, the Radiation Safety Committee will review forms, documents, education, and oversight associated with the permanent prostate implant program, and will make recommendations or amendments, as necessary, to reflect programmatic changes.

NRC Action:

The NRC staff conducted a special safety inspection on December 5, 2003, and did not identify any violations associated with the licensee's actions. The NRC also reviewed the licensee's current prostate implant program, and concluded that 12 other I-125 prostate implants had been completed without incident.

Other Agency Action:

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 gray (Gy) (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 040415 AO #: NRC 04-04 EVENT DATE: 06/08/2004
TITLE: Diagnostic Medical Event at William Beaumont Hospital in Royal Oak, Michigan
NAME: William Beaumont Hospital CITY: Royal Oak STATE: MI

Nature and Probable Consequences:

The licensee reported that a patient was prescribed a dose of 0.37 megabecquerels (MBq) [10 microcuries (uCi)] of I-131 for a thyroid uptake procedure, but instead received 33.86 MBq (915 uCi) of I-131. The pipette used to prepare I-131 therapy dosage earlier in the day was inadvertently used to draw the 0.37 MBq (10 uCi) I-131 uptake dosage. The technician properly disposed the I-131 uptake dosage after identifying the error.

The technician then obtained the "uptake" pipette and prepared a second dosage from the I-131 bulk uptake solution. However, "uptake" pipette had inadvertently been switched with the "therapy" pipette used earlier. This may have occurred because both the thyroid "uptake" pipette and the "therapy" pipette had illegible labels. As a result, the second dosage contained 0.074 MBq (2 uCi) I-131 remaining from the earlier therapy administrations and the newly drawn I-131 prepared for the thyroid uptake. The total activity for the second dosage measured 33.86 MBq (915 uCi). The technician focused on drawing the calculated volume required to obtain the prescribed activity, rather than the radioactive activity measured in the dose calibrator and interpreted the "0.915 millicuries (mCi)" displayed on the dose calibrator as "9.15 uCi." The technician electronically transferred the dosage measurement from the dose calibrator to a dosage label. A second technician administered the dosage to the patient. Assuming a 55% uptake the absorbed dose to the patient's thyroid was 26.75 Gy (2,675 rads) with an effective dose equivalent of 0.81 Gy (81 rads). The patient and referring physician were notified of the medical event on June 9, 2004. The licensee indicated that the additional dose administered to the patient would not result in any increased risk or biological effect to the patient.

Cause:

This event was caused by human error. The nuclear medicine technologist who drew the dose misinterpreted the reading on the dose calibrator, and the technician who administered the dose did not verify the dose before administration.

Licensee Action:

The licensee implemented a requirement to use a new pipette each time an I-131 uptake dose is prepared, reprogrammed the computer to accept uptake dose activity rather than volume and stopped the computer from printing a dose label when the activity not within the established range. The licensee also trained the radiopharmacy staff not to override the computer's failsafe mechanisms, and retrained the nuclear medicine technologist in the process for dose verification prior to administration.

NRC Action:

The NRC staff conducted a special safety inspection on June 10, 2004. Then, on September 14, 2004, the NRC issued a Notice of Violation for a significant violation involving the administration of a dosage of liquid I-131 to a patient for a thyroid uptake study that was approximately 90 times larger than the 10-uCi dosage prescribed by the authorized user physician.

Other Agency Action:

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 040001 AO #: AS 04-01 EVENT DATE: 12/04/2003
TITLE: I-125 Brachytherapy Seed Medical Event at Central Arkansas Radiation Therapy Institute in Conway, Arkansas
NAME: Central Arkansas Radiation Therapy Institute CITY: Conway STATE: AR

Nature and Probable Consequences:

The licensee reported that a patient received a radiation dose to an unintended area during an I-125 prostate-seed implant procedure. The patient was prescribed treatment with 122 I-125 seeds, with each seed containing an activity of 13.3 MBq (0.36 mCi). During the patient's post-implant CT scan on December 18, 2003, the licensee discovered that the seeds had been implanted 2 centimeters (cm) too low and missed treating the upper portion of the prostate gland. As a result, 68 cc of adjacent tissue received the prescribed dose of 144 Gy (14,400 rads). The licensee reported that the adjacent tissue should not be affected adversely by the dose delivered by the seeds. The licensee administered additional treatment to deliver the intended dose to the upper 2 cm of the prostate gland. The licensee notified the patient and the patient's referring physician of the event.

Cause:

This event was attributed to human error in that the treatment site was not verified.

Licensee Action:

The licensee wrote a new procedure to implement the use of fluoroscopic guidance to ensure the correct placement of seeds.

NRC Action:

Other Agency Action:

The State has reviewed and accepted the licensee's corrective actions.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 040057 AO #: AS 04-02 EVENT DATE: 11/20/2003
TITLE: Dose to Fetus at Hillcrest Hospital of Mayfield Heights, Ohio
NAME: Hillcrest Hospital CITY: Mayfield Heights STATE: OH

Nature and Probable Consequences:

The Ohio Bureau of Radiation Protection reported that a 19-year-old female patient was administered 5.18 gigabequerels (GBq) (140 mCi) of I-131 as prescribed for thyroid carcinoma. At the time, the patient was unaware that she was pregnant and she completed the required forms indicating that she was not pregnant. However, on December 5, 8, and 11, 2003, quantitative tests confirmed that the patient was pregnant. The licensee provided the results to the patient's endocrinologist, who recommended performing a fetal dose calculation. The licensee was notified and its consultant informed the endocrinologist that the fetus would have received a whole body dose of 0.19 Gy (19.8 rads). The endocrinologist sent the results to the Center for Human Genetics at the University Hospital in Cleveland, Ohio, where an assessment determined that the pregnancy could safely continue.

Cause:

This event was caused by human error. At the time of the administration, the patient was unaware of her pregnancy status and completed forms indicating that she was not pregnant.

Licensee Action:

The licensee has implemented pregnancy testing for patients of child bearing age, who receive radiation therapy.

NRC Action:

Other Agency Action:

The Ohio Bureau of Radiation Protection was notified of this event on January 16, 2004, and performed a special inspection on January 22, 2004. The State found the licensee's corrective actions adequate to prevent recurrence.

Criteria:

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report states, in part, that a medical event that results in any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent (TEDE) of 50 millisievert (mSv) (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more will be considered for reporting as an AO.

ITEM #: 020585 AO #: AS 04-12 EVENT DATE: 06/07/2002
TITLE: Therapeutic Medical Event at University of California at Los Angeles Harbor Medical Center in Torrance, California
NAME: UCLA Harbor Medical Center CITY: Torrance STATE: CA

Nature and Probable Consequences:

A patient receiving treatment for thyroid ablation was administered a dose of 4.74 GBq (128 mCi) of I-131 instead of the prescribed dose of 1.18 GBq (32 mCi) of I-131.

On June 7, 2002, five patients were scheduled to be treated with I-131. Five vials containing I-131 arrived from the radiopharmacy and were properly labeled with the patients' names. The nuclear medicine technologist incorrectly thought that the name on the 4.74 GBq (128mCi) vial did not match any of the patient's names scheduled for treatment that day. Assuming that this vial was incorrectly labeled, the 4.74 GBq (128 mCi) dosage was administered to the patient for whom the technologist thought the dose was intended. However, the technologist failed to verify whether any of the remaining four dosages were labeled for that patient. In fact, a vial was correctly labeled as prepared for that patient.

The authorized user was present during the administration to supervise the administration of the radiopharmaceutical, and to verify that the correct radiopharmaceutical and dosage were administered. The authorized user did not perform an independent verification, but instead assumed that the nuclear medicine technologist had verified that the dosage was correct. The error was discovered about 5 hours later, when the patient scheduled to receive the 4.74 GBq (128 mCi) dosage arrived at the medical center for treatment. The patient and the referring physician were notified. The authorized user went to the home of the patient who received the inadvertent administration and verified that appropriate radiation safety precautions were in place. The patient's treatment plans were modified to accommodate the larger dosage. The authorized user stated that the dosage was intended to ablate the thyroid and render the patient hypothyroid, and that was accomplished with the larger dose. He further stated that the patient is doing well, with no complications.

Cause:

This medical event was caused by human error which resulted in the licensee's failure to follow proper policies and procedures to verify the prescribed dosage for a specific patient.

Licensee Action:

The licensee re-instructed all nuclear medicine personnel on the importance of following the division's policies and procedures and the use of a third party to check the prescription dose and patient identification before administration. Additionally, the RSO will review all I-131 therapy documents and administrations.

NRC Action:

Other Agency Action:

The State cited the licensee for failure to provide written notification to the referring physician and the patient within 15 days after the occurrence of the medical event. The State has reviewed and approved the licensee's corrective actions.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 040352 AO #: AS 04-13 EVENT DATE: 05/10/2004
TITLE: Diagnostic Medical Event at University Hospital in Cincinnati, Ohio
NAME: University Hospital CITY: Cincinnati STATE: OH

Nature and Probable Consequences:

The licensee reported that a patient was given 74 MBq (2,000 uCi) of I-131 for a thyroid cancer work-up instead of the prescribed dose of 7.4 MBq (200 uCi) of I-123 for a thyroid uptake scan. The patient scheduled to receive the I-123 dose responded affirmatively to being the patient that was to receive the I-131 dose. The technologist did not follow procedures regarding proper identification of the patient, which requires two separate methods for verifying patient identification. A follow-up scan revealed the patient does have hypothyroidism, and as a result, the 74 MBq (2,000 uCi) of I-131 would have been prescribed based on the scan results. The referring physician and patient were notified. No adverse health effects are expected.

Cause:

The technologist failed to follow established procedures.

Licensee Action:

The licensee disciplined the technologist in accordance with hospital policy and reiterated to all technologists the need to thoroughly check patient identification using two approved methods. Additionally, the Radiation Safety Committee modified the Quality Management Program to require a photo as one method of verifying patient identification.

NRC Action:

Other Agency Action:

The Ohio Department of Health conducted an investigation of the event on May 11, 2004, and reviewed the licensee's corrective actions. The State found the licensee's corrective actions adequate to prevent a recurrence of the event.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 050065 AO #: NRC 05-01 EVENT DATE: 01/24/2005
TITLE: Medical Event at the University of Minnesota in Minneapolis, Minnesota
NAME: University of Minnesota CITY: Minneapolis STATE: MN

Nature and Probable Consequences:

The licensee reported that a patient being treated for cervical cancer received an incorrect dose distribution. One area of the cervix received 8.21 Gy (821 rads) instead of the intended 16.43 Gy (1,643 rads). Another area of the cervix received 3.72 Gy (372 rads) instead of the intended 4.65 Gy (465 rads). Additionally, other locations received higher than intended doses. The intended dose to the bladder and the rectum were 11.47 Gy (1,147 rads) each, but they received 14.48 Gy (1,448 rads) and 20.12 Gy (2,012 rads), respectively. The treatment involved an applicator with an insert which contained low-dose radiotherapy sources. The licensee cut the insert 6 centimeters (cm) too short so that when the applicator was positioned in the patient's cervix, the three cesium-137 (Cs-137) sources were not extended the proper distance. The referring physician and patient were informed of this event. The licensee does not believe that this event will have any adverse health effects on the patient. The patient subsequently received a follow-up treatment to deliver the full intended dose to the treatment sites.

Cause:

This event was caused by human error. The incorrect dose was administered to the incorrect location.

Licensee Action:

Corrective actions taken by the licensee included stopping all low dose-rate treatments until all individuals are trained, and modifying their procedures to incorporate a dual verification system.

NRC Action:

Other Agency Action:

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a prescribed dose or dosage that is delivered to a wrong treatment site will be considered for reporting as an AO.

ITEM #: 050143

AO #: NRC 05-02

EVENT DATE: 03/09/2005

TITLE: Medical Event at St. Johns Mercy Hospital in St. Louis, Missouri

NAME: St. Johns Mercy Hospital

CITY: St. Louis

STATE: MO

Nature and Probable Consequences:

The licensee reported that a 5-month old infant was prescribed 18.5 MBq (0.5 mCi) of technetium-99 metastable (Tc-99m), but instead received 414.4 MBq (11.2 mCi) of Tc-99m. Hospital personnel did not look at the dosage label to verify the dose to be administered. The whole body dose to the infant was calculated to be between 0.052 to 0.10 Sv (5.2 to 10 rem). The physician informed the infant's parents. The NRC's medical consultant determined that there were no acute or subacute effects noted in the patient, but recommended that a pediatric gastroenterologist monitor the patient for cancer for an extended period of time.

Cause:

The event was caused by human error. The hospital staff member did not look at the dosage label before administering the radiopharmaceutical.

Licensee Action:

Corrective actions taken by the licensee involved revision of their procedures to require dual verification of all dosages to be administered to children and retraining the staff on the new procedures.

NRC Action:

Other Agency Action:

Criteria:

Criterion I.A.2, "For All Licensees," of Appendix A to this report states, "Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent (TEDE) of 50 millisieverts (mSv) (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more," will be considered for reporting as an

ITEM #: 050183 AO #: NRC 05-03 EVENT DATE: 01/26/2004
TITLE: Medical Event at St. Joseph Regional Medical Center in South Bend, Indiana
NAME: St. Joseph Regional Medical Center CITY: South Bend STATE: IN

Nature and Probable Consequences:

The licensee reported in March and April 2005, that between January 26 and March 22, 2004, three patients received unintended radiation doses to the skin of their thighs from cesium-137 brachytherapy sources. The vaginal applicator used for the treatment was loaded with incorrectly sized cesium-137 sources, which migrated from the intended treatment position through the placement spring when the patient moved to a more up-right position. As a result of the sources moving, the patient's inner thighs received unintended doses of radiation. Approximately two weeks after treatment, the patients developed skin lesions on their inner thigh. The licensee determined that these patients received unintended doses to a small area of the skin on the upper thigh of approximately 2000, 1500, and 2000 cGy (rad), respectively. Based on clinical observations, the licensee determined that all patients received the respective prescribed doses to the intended treatment areas. The referring physician and patients were notified of the event. The licensee referred the patients to other institutions and care providers for specialized followup wound care to treat the recurring skin ulcerations. The NRC retained a medical consultant during the inspection associated with the event. The long-term health effects on the patients, as a result of the unintended doses, is unknown.

Cause:

The causes of these events were improper source selection, inadequate manufacturer instructions, inadequate management oversight, and inadequate procedures.

Licensee Action:

Corrective actions taken by the licensee involved modifying the applicator by using different hardware to hold the sources in place, revising their procedures, and retraining the staff on the new procedures.

NRC Action:

Other Agency Action:

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 040780 AO #: AS 05-01 EVENT DATE: 10/26/2004
TITLE: Iridium-192 Brachytherapy Seed Medical Event at LDS Hospital in Salt Lake City, Utah
NAME: LDS Hospital CITY: Salt Lake City STATE: UT

Nature and Probable Consequences:

A patient received 27.56 Gy (2,756 rads) instead of the prescribed 5 Gy (500 rads) during a high dose-rate (HDR) treatment for larynx cancer. The event involved an iridium-192 (Ir-192) source with an activity of 244.2 GBq (6.6 Ci). The error was caused by use of the diameter instead of the radius of a circular tool to mark the treatment site in a computer software program. As a result the area treated was 2 centimeters (cm) away from the intended treatment site. The error was discovered before the third fraction. The prescribing physician stopped the treatment until dosimetry information was completed. The licensee notified the patient and the patient's referring physician of the event. The licensee determined that the impact of the additional dose is probable acute radiation effects and possible late or chronic toxicities.

Cause:

This event was caused by human error. The incorrect size button corresponding to the circle tool was used, which caused the diameter instead of the radius to be used in the dosing plan. This caused the incorrect dose to be administered to the incorrect location.

Licensee Action:

The licensee suggested that the software manufacturer print the word "RADIUS" on the "size" button located adjacent to the circle tool. To date, the manufacturer has not responded to this issue. The licensee will measure the distance on the brachytherapy device's hard copy output with a ruler to confirm that the distance is entered correctly. The licensee also modified the HDR dose check program so that, in addition to confirming the doses to coordinates entered into the device's input, user specified point coordinates may be manually entered into the check program and compared to what is calculated.

NRC Action:

Other Agency Action:

The Utah Division of Radiation Control investigated the event on November 3, 2004 and approved the corrective actions that the licensee implemented to prevent the recurrence.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a prescribed dose or dosage that is delivered to the wrong treatment site, will be considered for reporting as an AO.

ITEM #: 050124 AO #: AS 05-02 EVENT DATE: 01/07/2005

TITLE: Diagnostic Medical Event at Baystate Health Systems in Springfield, Massachusetts

NAME: Baystate Health Systems CITY: Springfield STATE: MA

Nature and Probable Consequences:

The licensee reported that a patient should have received 0.63 MBq (0.017 mCi) of iodine-131 (I-131) for a thyroid uptake study but instead received 133.2 MBq (3.6 mCi) of I-131 for a total body scan. A nuclear medicine technologist incorrectly placed the order for a total body scan instead of a thyroid uptake study without looking at the diagnosis. The I-131 was administered and it was later discovered that the wrong procedure was administered. The administration resulted in a thyroid dose of 131 Gy (13,100 rads). The patient and referring physician were notified of the error. The licensee indicated there would be no negative health effects from this administration because the patient had hyperthyroidism, thus, the unintended thyroid dose will be taken into account when additional I-131 is given to the patient.

Cause:

Human error in that the procedure was erroneously posted as a total body scan when it was actually a thyroid uptake study. This caused the wrong quantity of I-131 to be administered.

Licensee Action:

Corrective actions taken by the licensee involved modifying procedures to include removing Central Booking from radioisotope ordering (the referring physician will fax the order directly to Nuclear Medicine), switching from I-131 to I-123 for thyroid uptake studies, and revising the nuclear medicine request form for thyroid procedures.

NRC Action:

Other Agency Action:

The State reviewed and approved the corrective actions taken by the licensee and will follow-up at the next inspection.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a prescribed dose or dosage that is delivered by the wrong treatment mode, will be considered for reporting as an AO.

ITEM #: 050236 AO #: AS 05-03 EVENT DATE: 01/24/2005
TITLE: High Dose-Rate Afterloader Medical Event at Saddleback Memorial Medical Center in Laguna Hills, California
NAME: Saddleback Memorial Medical Center CITY: Laguna Hills STATE: CA

Nature and Probable Consequences:

A patient undergoing therapeutic radiation treatment following a breast lumpectomy was treated with a high dose-rate (HDR) device using an iridium-192 (Ir-192) source with an activity of 277.5 GBq (7.5 Ci). The prescribed dose was 35 Gy (3,500 rads) to the inside of the breast at the site of the excised tumor, but instead the patient received 70 Gy (7,000 rads) to other portions of the breast during treatment. The unintended irradiation occurred when the HDR device was mispositioned. Re-evaluation of the treatment plan revealed that the wrong source wire travel distance was used during the treatment. The Ir-192 source was positioned 8 centimeters (cm) short of the planned location. The licensee believes the error occurred when the source wire travel distance was input to the HDR device; however, since no record was maintained of the source wire travel distance measured by the therapy technologist, this could not be verified. It is known that the incorrect distance was input to the HDR planning system. The patient and the referring physician were notified of the event. No long-term health effects are expected due to the unplanned tissue dose.

Cause:

This event was attributed to human error and an inadequate procedure.

Licensee Action:

A procedure was developed specifying the need to verify and document the verification of source wire travel distance determination and training on the correct input to the treatment planning system was performed. In addition, nominal source wire travel distances for expected types of HDR usage were added to the form utilized for recording the HDR treatment quality assurance checklist, thus providing a check on the determination of this parameter.

NRC Action:

Other Agency Action:

State inspectors investigated the medical event and issued written violations for failure to follow a license condition that required independent verification of HDR treatment data input, and for failure to report the medical event to the state within 24 hours of its discovery. The State reviewed the licensee's corrective actions and found them adequate to prevent recurrence.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 050235 AO #: AS 05-04 EVENT DATE: 04/05/2005
TITLE: Yttrium-90 Therapeutic Medical Event at University of Wisconsin in Madison, Wisconsin
NAME: University of Wisconsin in Madison CITY: Madison STATE: WI

Nature and Probable Consequences:

A patient was administered a 1.78 GBq (48 mCi) dose of yttrium-90 (Y-90), instead of the intended 1.04 GBq (28 mCi) Y-90 dose. As a result of the medical event, the patient received a dose of 1.07 to 3.20 Gy (107 to 320 rads) to the red bone marrow, with a median exposure of 2.31 Gy (231 rads) from Y-90. The error was discovered on April 7, 2005, during a licensee review of records. The patient and referring physician were notified of the event. The licensee indicated there will be no negative health effects from this administration.

Cause:

Lack of management oversight which attributed to failure to prepare a written directive prior to the administration, a poor training program, and human error.

Licensee Action:

The licensee suspended the use of Y-90 and conducted a root cause investigation of the event. The licensee's corrective action included writing new policies and procedures, implementing new training programs, and hiring new personnel.

NRC Action:

Other Agency Action:

The State of Wisconsin investigated the event on April 11, 2005 and determined that the licensee (1) failed to prepare a written directive prior to administering the Y-90, (2) failed to prevent usage of a dose that differed from the intended dosage by more than 20 percent, (3) failed to establish appropriate administrative procedures, (4) failed to ensure radiation safety activities were performed under approved procedures, and (5) failed to instruct individuals working under the supervision of an authorized user to follow the licensee's written directive procedures. A medical consultant contracted by the State of Wisconsin determined that no adverse medical effects occurred as a result of this medical event. As a result of the State's investigation, the licensee implemented the corrective actions detailed above. The State reviewed the licensee's corrective actions and found them adequate to prevent recurrence.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 050550

AO #: AS 05-05

EVENT DATE: 08/04/2005

TITLE: Therapeutic Medical Event at University of Utah in Salt Lake City, Utah

NAME: University of Utah

CITY: Salt Lake City

STATE: UT

Nature and Probable Consequences:

A patient received radiation therapy to the left bronchus using a high dose-rate (HDR) device. The HDR contained a 252 GBq (6 Ci) iridium-192 (Ir-192) source. The prescribed radiation therapy treatment plan called for three treatments to the left bronchus, each fraction to deliver a dose of 7 Gy (700 rads). The medical event, which occurred during the second treatment, was due to a centimeter (cm) error in the source wire travel distance. The source wire distance was entered incorrectly by a medical physicist. As a result, a 3 cm length of the left bronchus received approximately 6.40 to 18.60 Gy (640 to 1,860 rads) at a 0.5 cm depth and 2.54 to 6.62 Gy (254 to 662 rads) at a 1 cm depth. A 3-cm region next to the intended treatment site received up to 6 Gy (600 rads) less than the prescribed dose. The licensee notified the patient and the patient's referring physician of the event. The patient received no adverse health effects from the medical event.

Cause:

This event was attributed to human error in that the treatment site was not verified.

Licensee Action:

The licensee implemented a new procedure adding a question to verify the treatment distances during HDR treatments.

NRC Action:

Other Agency Action:

The State has reviewed and accepted the licensee's corrective actions.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a prescribed dose or dosage that is delivered to the wrong treatment site, will be considered for reporting as an AO.

ITEM #: 050066 AO #: AS 05-06 EVENT DATE: 11/16/2004
TITLE: Dose to Fetus at Riverside Methodist Hospital in Columbus, Ohio
NAME: Riverside Methodist Hospital CITY: Columbus STATE: OH

Nature and Probable Consequences:

On November 2, 2004, a patient was administered 7.59 MBq (0.205 mCi) of iodine-123 (I-123) as part of a diagnostic procedure hyperthyroidism. On November 16, 2004, the patient returned for a therapeutic treatment and was administered 469.9 MBq (12.7 mCi) of iodine-131 (I-131) as treatment. Prior to this administration, the patient was counseled regarding pregnancy and acknowledged, in writing, that she was not and could not be pregnant at that time. A pregnancy test was not performed to confirm this declaration. Later, the patient saw her physician because of abdominal pain. A radiograph of the abdomen revealed the pregnancy. A prenatal specialist determined that the fetus was 17 weeks old at the time of the I-131 administration. The dose estimate for the fetus was 0.024 Gy (2.04 rads) to the whole body and 224 G3y (22,400 rads) to the fetal thyroid from both I-123 and I-131 administrations. The perinatal specialist performed a blood test on the fetus and confirmed that the fetus had hyperthyroidism. An ultrasound test on the fetus showed no abnormalities in fetal development. The perinatal specialist will perform treatments in-utero to mitigate the effects of hyperthyroidism. The referring physician and patient were notified of the medical ev

Cause:

The cause of the event was human error. At the time of the administration, the patient was unaware of her pregnancy status and completed forms indicating that she was not pregnant.

Licensee Action:

The licensee has implemented a policy performing a serum pregnancy test and receiving the results within 80 hours of administration of therapeutic amounts of I-131. This test will be performed on all women 13 to 50 years of age, unless the women have been surgically sterilized.

NRC Action:

Other Agency Action:

The Ohio Department of Health performed an on-site investigation on January 28, 2005 and determined that the licensee followed all required procedures. The State agency will conduct periodic inspections to ensure that the licensee's actions taken to prevent recurrence were implemented.

Criteria:

Criterion I.A.2, "For All Licensees," of Appendix A to this report states, "Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent (TEDE) of 50 millisieverts (mSv) (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more," will be considered for reporting as an

ITEM #: 060319 AO #: NRC 06-02 EVENT DATE: 05/09/2006
TITLE: Medical Event at Bozeman Deaconess Hospital in Bozeman, Montana
NAME: Bozeman Deaconess Hospital CITY: Bozeman STATE: MT

Nature and Probable Consequences:

The licensee reported that a patient was prescribed a brachytherapy treatment of 145 Gy (14,500 rad) to the prostate gland for prostate cancer using 82 iodine-125 seeds, but instead received a 130 Gy (13,000 rad) dose to an unintended treatment site. The brachytherapy seeds were implanted under ultrasound guidance; however, a post-treatment computerized tomography scan confirmed that only 10 seeds were implanted in the prescribed location of the prostate, resulting in a dose of 8.6 Gy (860 rad) delivered to the intended treatment site. Concerning the 72 seeds not in the intended treatment site, the urologist was able to recover 3 seeds and determined that 69 seeds were implanted inferior to the prostate in the wrong treatment site. The referring physician and the patient were informed of this event and were advised that the patient may experience discomfort during urination. The NRC staff conducted a reactive onsite inspection on May 16, 2006. An NRC contracted medical consultant experienced in radiation oncology reviewed the case and agreed with the licensee's analysis and conclusions. An NRC inspection report has been issued.

Cause:

This medical event was caused by human error because the licensee did not verify that the sources were positioned in the proper location in the prostate. The urologist misidentified the anatomy viewed under the ultrasound guidance procedure.

Licensee Action:

The licensee revised its procedures, requiring a fluoroscopic examination early in the implant procedure to ensure that the seeds are placed in the correct location, thus resolving any questions concerning ultrasound images prior to commencing with the implant. The licensee also implemented additional staff training.

NRC Action:

Other Agency Action:

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 060494 AO #: NRC 06-03 EVENT DATE: 05/03/2006
TITLE: Dose to an Embryo/Fetus at Munson Medical Center in Traverse City, Michigan
NAME: Munson Medical Center CITY: Traverse City STATE: MI

Nature and Probable Consequences:

The licensee reported an unintended dose to an embryo/fetus. On May 3, 2006, the licensee administered a therapy dosage of 1.5 GBq (150 mCi) of I-131 to a 26-year-old female patient who had affirmed in writing that she was not pregnant. On May 22, 2006 the patient informed the licensee that she had been approximately 10 to 14 days pregnant at the time of the administration. Based on this new information, the licensee estimated that the dose to the embryo/fetus was approximately 400 mSv (40 rem). The referring physician and patient were informed of this event. The NRC-contracted medical consultant agreed with the licensee's dose estimate and concluded that this event should result in no harm to the embryo because the administration occurred during a stage of development when the thyroid does not take up iodine. The medical consultant recommended that a complete thyroid evaluation be performed after delivery.

Cause:

This medical event was caused by the patient's incorrect written statement that she was not pregnant prior to receiving the therapy dosage. The licensee did not require an independent pregnancy test for women of child-bearing age prior to administering the dosage.

Licensee Action:

The licensee implemented a procedure that requires pregnancy tests for all women of childbearing age prior to any therapy dose of radioactive material, a checklist to ensure that the pregnancy test is ordered, and staff training.

NRC Action:

Other Agency Action:

Criteria:

Criterion I.A.2, "For All Licensees," of Appendix A to this report states that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent (TEDE) of 50 millisievert (mSv) (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more will be considered for reporting as an AO.

ITEM #: 060163 AO #: AS 06-01 EVENT DATE: 03/03/2006
TITLE: Industrial Radiography Occupational Overexposure at Anvil International in North Kingston, Rhode Island
NAME: Anvil International CITY: North Kingston STATE: RI

Nature and Probable Consequences:

The licensee reported that a radiographer and a trainee received unintended radiation exposures in excess of those specified in AO criteria. The incident occurred at a permanent radiography facility and involved an iridium-192 source with an activity of 3.44 TBq (93 Ci). After performing surveys outside a dedicated radiography cell, where radiation levels confirmed that radiography was in process in the cell, the radiographer and the trainee went to an alternate location and performed equipment maintenance and training. They were joined by a third radiographer, who was performing radiography inside the cell. All three radiography personnel entered the cell to view the radiography setup and examine the guide tube for training purposes. However, they entered without a survey meter and were unaware that the source was still exposed. As a result, the first radiographer and the trainee handled the collimator and guide tube (which contained the source) for approximately 15 - 60 seconds. The first radiographer received a dose to the left hand ranging from 1.4 to 2.8 Sv (140 rem to 280 rem). The trainee received a dose to the left hand ranging from 11 Sv to 8,500 rem. The third radiographer did not receive a dose in excess of regulatory exposure limits, since he did not handle the equipment.

Cause:

This event was caused by the failure of radiography personnel to follow safety procedures and use survey meters inside the cell.

Licensee Action:

The licensee provided additional training to the personnel. The licensee also solicited the assistance of a medical physicist and source manufacturer in determining the dose to the radiographers. The licensee also committed to keep the State updated on the medical conditions of the radiographer and trainee until they are released from medical oversight.

NRC Action:

Other Agency Action:

On March 7, 2006, the State issued a suspension letter to the licensee. On March 8 and March 16, 2006, the State, accompanied by NRC Region I staff, conducted an investigation of the event. On April 13, 2006, the State issued a Notice of Violation and on November 3, 2006, terminated the license after an onsite inspection to confirm decommissioning actions.

Criteria:

Criterion I.A.1, "For All Licensees," of Appendix A to this report states, in part, that any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or an annual total effective dose equivalent of 250 mSv (25 rem) or more will be considered for reporting as an AO.

ITEM #: 060317 AO #: AS 06-02 EVENT DATE: 03/31/2006
TITLE: Medical Event at 21st Oncology, Inc., in Coral Springs, Florida
NAME: 21st Oncology, Inc. CITY: Coral Springs STATE: FL

Nature and Probable Consequences:

The licensee reported that an 80-year-old female patient received 100 Gy (10,000 rad) to an unintended area of approximately 2 (0.8 in) that was three times the prescribed dose for the mammosite brachytherapy procedure, using a high dose rate (HDR) afterloader containing an iridium-192 source with an activity of 240.5 GBq (6.5 Ci). The patient received less than 30 percent of prescribed dose to the prescribed treatment site. The source stopped 6 cm (2.4 in) short of the intended position. The patient visited the attending physician for followup on May 2, 2006. The physician discovered that the patient's skin was abnormally red. The referring physician, patient, and patient's family were notified of the incident. The patient was treated for erythema (skin reddening) and moist desquamation (skin thinning and weeping).

Cause:

This medical event was caused by human error. The authorized user entered an incorrect distance into the computer entry data.

Licensee Action:

The licensee developed new procedures requiring the authorized user to verify the source wire distances during HDR treatment and provided additional training in these procedures.

NRC Action:

Other Agency Action:

The State reviewed and accepted the licensee's corrective actions.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a prescribed dose or dosage that is delivered to a wrong treatment site will be considered for reporting as an AO.

ITEM #: 060540

AO #: AS 06-03

EVENT DATE: 06/19/2006

TITLE: Medical Event at the McKay Dee Hospital, Inc., in Ogden, Utah

NAME: McKay Dee Hospital, Inc.

CITY: Ogden

STATE: UT

Nature and Probable Consequences:

The licensee reported that a patient undergoing treatment for hyperthyroidism received 1.08 GBq (29.3 mCi) of 1-131 instead of prescribed dosage of 0.56 GBq (15 mCi). On June 19, 2006, two patients were scheduled to receive 1-131 treatments at the same time. However, the first patient was administered the second patient's prescribed dosage resulting in the patient receiving a higher than intended dose. The error was identified by the licensee prior to the administration of 1-131 to the second patient. The administration resulted in a thyroid dose of 1,066 Gy (106,600 rad). The patient and referring physician were notified of the error. No negative health effects from this administration are expected. On July 17, 2006, the licensee sent a letter to the State confirming that a medical event had occurred.

Cause:

This medical event was caused by human error. The licensee failed to verify the prescribed dosage for a specific patient.

Licensee Action:

Corrective actions taken by the licensee included revising procedures to improve patient identification techniques and not scheduling patients with similar treatments at concurrent times.

NRC Action:

Other Agency Action:

The State reviewed and accepted the licensee's corrective actions.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 060280

AO #: AS 06-04

EVENT DATE: 03/28/2006

TITLE: Medical Event at Central Arkansas Radiation Therapy Institute in Little Rock, Arkansas

NAME: Central Arkansas Radiation Therapy Institute

CITY: Little Rock

STATE: AR

Nature and Probable Consequences:

The licensee reported that a patient undergoing implant brachytherapy for prostate cancer received a radiation dose to an unintended area during an 1-125 prostate-seed implant procedure. The patient was prescribed 108 Gy (10,800 rad) to the base of the prostate gland with 84 1-125 seeds but it was delivered 4 cm (1.6 in) inferior to the intended treatment site. The post-implant dose calculation confirmed that the dose was delivered to the wrong treatment site. The patient will require further brachytherapy treatment. The patient did not incur adverse health effects as a result of the medical event. The patient and referring physician were notified of the medical event.

Cause:

This medical event was caused by human error. The urologist was not able to clearly identify the base of the prostate gland during the ultrasound used to view the target organ during the treatment.

Licensee Action:

The licensee implemented a new policy to ensure that the urologist clearly defines the base of the prostate and urethra.

NRC Action:

Other Agency Action:

The State reviewed and accepted the licensee's corrective actions.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a prescribed dose or dosage that is delivered to a wrong treatment site will be considered for reporting as an AO.

ITEM #: 060480 AO #: AS 06-05 EVENT DATE: 07/24/2006
TITLE: Medical Event at Children's Memorial Medical Center in Chicago, Illinois
NAME: Children's Memorial Medical Center CITY: Chicago STATE: IL

Nature and Probable Consequences:

The licensee reported that a patient received a higher than intended dosage of 74 MBq (2 mCi) of 1-131 instead of the prescribe dosage of 0.19 MBq (0.005 mCi). The physician did not prepare a written directive. The authorized user noted the error on July 2006. The licensee estimated a whole body dose of 0.0189 Sv (1.89 rem) and a dose to the thyroid of 41.4 Sv (4,140 rem), base on a 59.2-percent uptake. Using the same assumptions, the intended dosage of 0.19 MBq (0.005 mCi) would have given the patient a thyroid dose of 0.104 Sv (10.4 rem). The patient and referring physician were notified of the medical event. The patient incurred no adverse health effects from the medical event.

Cause:

This medical event was caused by inadequate verbal communications between the nuclear medicine technologist (NMT) and the physician and the lack of a written directive.

Licensee Action:

The licensee reviewed previous administrations of radioiodine to confirm that this event was an isolated occurrence. The license added additional procedures to ensure proper oversight by a physician during all future radioidodine administrations.

NRC Action:

Other Agency Action:

The State investigated the event and concurred with the licensee's dose estimates. The State issued a Notice of Violation to the licensee.

Criteria:

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a dose or dosage that is at least 50 percent greater than that prescribed in a written directive will be considered for reporting as an AO.

ITEM #: 060662 AO #: AS 06-06 EVENT DATE: 05/26/2006
TITLE: Dose to an Embryo/Fetus at McLeod Regional Medical Center in Florence, South Carolina
NAME: McLeod Regional Medical Center CITY: Florence STATE: SC

Nature and Probable Consequences:

The licensee reported an unintended dose to an embryo/fetus. The licensee administered 555 MBq (15 mCi) of technetium-99m on May 24, 2006, and 518 KBq (0.014 mCi) of 1-131 on May 25 as a prelude to a thyroid ablation to a patient. Prior to the administrations and following a detailed explanation provided by the physician, the patient signed an informed consent indicating that she was not pregnant. The licensee's radioactive materials license requires that a pregnancy test be done on any female of child-bearing age undergoing radiation therapy. However, the patient convinced the attending NMT that she could not possibly be pregnant. The NMT did not perform the pregnancy test and on May 26, 2006, administered 0.548 GBq (14.8 mCi) of 1-131 to the patient for a thyroid ablation. At approximately 32 - 34 weeks of pregnancy, the patient visited an obstetrician and mentioned that she had undergone a thyroid ablation procedure when she was approximately 17 weeks pregnant. The obstetrician notified the licensee on October 3, 2006. The licensee estimated that the fetus received a whole body dose of 0.0517 Gy (5.17 rad) and a thyroid dose of 139.2 Gy (13,920 rad). The child was born in November 2006. The newborn appears to have no apparent problem resulting from the radiation exposure with the exception of an underactive thyroid gland (hypothyroidism). The child is currently receiving a small amount of thyroid supplement. The referring physician and patient were notified of the event.

Cause:

This event was caused by human error. At the time of the administration, the patient indicated that she was not pregnant, and the licensee failed to perform the required pregnancy test.

Licensee Action:

The licensee provided instructions to staff emphasizing its policy to administer a pregnancy test to female patients of child-bearing age prior to undergoing radiation therapy.

NRC Action:

Other Agency Action:

The State reviewed and approved the corrective actions taken by the licensee and will followup at the next inspection. The State is in the process of issuing a Notice of Violation.

Criteria:

Criterion I.A.2, "For All Licensees," of Appendix A to this report states that 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 will be considered for reporting as an AO.

ITEM #: 070406 AO #: NRC 06-01 EVENT DATE: 03/06/2006
TITLE: Spill of High-Enriched Uranium Solution at Fuel Fabrication Facility
NAME: Nuclear Fuel Services CITY: ERWIN STATE: TN

Nature and Probable Consequences:

In a facility authorized to process high-enriched uranium (HEU), a transfer of HEU solution through a transfer line resulted in a portion of the HEU solution, approximately 35 liters, leaking into a glovebox where criticality was possible and subsequently to the floor where criticality was also possible because of the presence of an elevator pit.

Immediately before the event, the facility operator decided to move the unused filter glovebox to another location. Workers opened and drained the filters so that the filter glovebox could be moved. After draining the filters, workers failed to reseal the system tight. During the next transfer of HEU solution through the line, HEU solution leaked into the filter glovebox. On several occasions before the event, workers had reported signs of a yellowish liquid in the filter glovebox. Supervisors had failed to fully investigate the reports because they assumed the yellowish liquid was natural uranium solution which had been used to initially test the process.

Criticality was possible in the filter glovebox because of the size and shape of the glovebox and because there were no controls in the filter glovebox to prevent accumulation of solution. The solution leaked out of the filter glovebox through uncontrolled drains on the floor. Investigation of the event revealed that the floor contained an uncontrolled accumulation point, an elevator pit, where criticality was also possible. In different circumstances, the total volume of the transfer would have been more than enough for criticality to be possible in the filter glovebox or the elevator pit. If a criticality accident had occurred in the filter glovebox or the elevator pit, it is likely that at least one worker would have received an exposure high enough to cause acute health effects or death. The NRC conducted a team inspection to determine the root causes of the event and performed a series of three readiness reviews before allowing this portion of the facility to restart. The NRC issued an order to the licensee delineating specific actions designed to address this and other performance issues at the facility.

Cause:

Failure to maintain configuration control of facility equipment and failure to comply with procedures.

Licensee Action:

The operator stopped all processing of HEU in the affected processing area, removed the enclosure and associated piping, filled an uncontrolled accumulation point (the elevator pit) with concrete, and conducted an extensive review to identify any similar configuration issues.

NRC Action:

Other Agency Action:

Criteria:

Criterion III, "For Fuel Cycle Facilities," of Appendix A to this report states, in part, that a major condition or significant event that seriously compromises the ability of a safety system to perform its designated function that requires immediate remedial action to prevent a criticality, radiological, or chemical process hazard will be considered for reporting as an AO.

ITEM #: 070339 AO #: NRC 07-01 EVENT DATE: 05/29/2007
TITLE: Human Exposure to Radiation at Washington University Medical Center in St. Louis, Missouri
NAME: Washington University Medical Center CITY: St. Louis STATE: MO

Nature and Probable Consequences:

Washington University Medical Center (the licensee) reported that cancer treatment to a 22 year old patient using iodine-131 resulted in a dose to an embryo/fetus. On May 29, 2007, the treatment was conducted at Barnes Jewish Hospital, the affiliated teaching hospital of Washington University School of Medicine, using 4.64 GBq (126 mCi) of iodine-131. Prior to that treatment, the patient saw her prescribing physician on May 22, 2007, for a related consultation. In addition, because hospital procedures require a pregnancy test within 1 week before the therapy is administered, the licensee conducted a pregnancy test on the patient the same day. That test yielded a negative result and the patient was advised not to get pregnant prior to the treatment. Moreover, before treatment on May 29, 2007, the patient signed a statement that, to the best of her knowledge, she was not pregnant. However, on May 30, 2007, the patient performed a home pregnancy test, which yielded a positive result. Consequently, the licensee performed another pregnancy test the same day, and the results indicated that the patient had been pregnant for 4-5 weeks at the time of the iodine-131 administration. The patient and the referring physician were informed of this event. As an approximation for the dose equivalent received by the embryo/fetus, the licensee's staff calculated an annual total effective dose equivalent to the patient's uterus, which was estimated to be 250-340 mSv (25-34 rem).

The NRC-contracted medical consultant confirmed the licensee's dose estimate and determined that the most likely result would be the delivery of a normal infant (with regard to thyroid function) because the iodine-131 was administered at such an early stage in the pregnancy; however, the risk of childhood cancer may be slightly increased. The possible effects of the event have been discussed with the patient.

Cause:

The causes of this event were the false negative pregnancy test and the patient's lack of awareness that she might be pregnant.

Licensee Action:

Because the causes of the event were beyond the licensee's control, the licensee determined that no corrective action was necessary to prevent recurrence.

NRC Action:

There were no violations identified by the NRC.

Other Agency Action:

Criteria:

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report states that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 5 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

ITEM #: 060659 AO #: NRC 07-02 EVENT DATE: 10/23/2006
TITLE: Medical Event at St. Luke's Hospital of Kansas City, Missouri
NAME: St. Luke's Hospital of Kansas City CITY: Kansas City STATE: MO

Nature and Probable Consequences:

On October 27, 2006, St. Luke's Hospital of Kansas City (the licensee) notified the NRC of a medical event that occurred during high dose-rate (HDR) remote afterloader, using a 144 GBq (3.9 Ci) iridium-192 source, brachytherapy procedure to treat breast cancer.

The authorized user physician developed a written directive that prescribed 10 fractionated doses, to be administered to the patient's left breast using a balloon catheter technique, with each dose consisting of 3.4 Gy (340 rad), for a total dose of 34 Gy (3,400 rad). The first fractionated dose was administered to the patient on October 23, 2006. On October 26, 2006, after the seventh fraction and prior to administering the eighth fraction to the patient, the chief physicist noted a discrepancy. The investigation into the discrepancy revealed that the catheter length entered into the treatment planning computer was 93.0 cm (36.6 in), rather than 95.0 cm (37.4 in). This error resulted in delivering an unplanned dose of 100 Gy (10,000 rad), 1.0 cm (0.4 in) from the treatment site and proximal from the balloon. The area proximal from the balloon would have received an intended dose of 2 Gy (2,450 rad), had the treatment been delivered as prescribed by the authorized user physician. Moreover, because the prescribed dosage was not delivered to the correct location, the patient also received an under dosage to the distal side of the balloon. Specifically, the area intended to be treated received a dose in the range of 7 Gy to 10 Gy (700 rad to 1,000 rad) rather than the prescribed dosage of 34 Gy (3,400 rad). The patient and the referring physician were informed of this event. The authorized user physician did not expect any acute adverse medical effects to the patient as a result of the medical event, but indicated that surgery may be required in the future. The authorized user physician discontinued further treatments and plans to follow-up on the patient clinically.

The NRC-contracted medical consultant expects some necrosis to fatty tissue in the overexposed region of the breast, within 2-3 months.

Cause:

The medical event was caused by the dosimetrist's failure to enter the correct catheter length in preparing the treatment plan parameters for the HDR brachytherapy treatment. In addition, the licensee's written procedures for implementing HDR treatment plans did not require verification of the treatment plan parameters to ensure that they were correct.

Licensee Action:

The licensee initiated several immediate and long-term corrective actions to prevent recurrence. Specifically, those corrective actions included (1) revising the procedures for HDR treatments to include verification of the catheter length and input to the treatment planning computer by both the medical physicist and the authorized user physician, (2) revising the treatment plan to require that the authorized user physician and the medical physicist document the verification of the catheter length, and (3) conducting in-house training to ensure that staff are aware of the new procedural steps and to ensure that the prescribing authorized user physician and the medical physicist actively participate in the training.

NRC Action:

On March 14, 2007, the NRC issued a Notice of Violation related to this event.

Other Agency Action:

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report states in part, that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

ITEM #: 070024 AO #: NRC 07-03 EVENT DATE: 01/08/2007
TITLE: Medical Event at Hackley Hospital in Muskegon, Michigan
NAME: Hackley Hospital CITY: Muskegon STATE: MI

Nature and Probable Consequences:

On January 8, 2007, Hackley Hospital (the licensee) notified the NRC of a medical event that occurred during a brachytherapy implant procedure to treat prostate cancer. The written directive prescribed a total dose of 120 Gy (12,000 rad) to the patient's prostate using 41 iodine-125 seeds as permanent implants. According to the licensee, because the patient moved, only 7 of the prescribed 41 seeds were delivered to the prostate (the intended site), and the other 34 seeds were delivered to an unintended site located approximately 4 cm (1.6 in) inferior to the prostate. As a result, the prostate received a dose of approximately 13 Gy (1,300 rad) rather than the prescribed dose of 120 Gy (12,000 rad) (-90% less than the prescribed dose). In addition, the unintended site received a dose of approximately 110 Gy (11,000 rad) and the patient's skin around the unintended site received a dose of approximately 2.4 Gy (240 rad). The patient and the referring physician were informed of this event. The patient will require further treatment via external beam therapy in order to deliver the appropriate dose to the prostate.

The NRC-contracted medical consultant agreed with the licensee's dose estimate and concluded that the risk for impotence is somewhat increased by the additional radiation dose to the unintended site as a result of the medical event. There may also be some risk of perineal tissue fibrosis and skin irritation, although the risk may not be significant enough to cause clinical concerns.

Cause:

The licensee determined the root cause of the event was a failure to identify the patient's movement before continuing with the procedure. In addition, the NRC inspector determined that the licensee failed to develop adequate written procedures to provide high confidence that each brachytherapy administration was in accordance with the authorized user physician's written directive required by 10 CFR 35.41. Specifically, the licensee's procedures did not include appropriate steps or guidance to ensure that radioactive sources were positioned in the patient in accordance with the written directive and treatment plan.

Licensee Action:

The licensee's corrective actions to prevent recurrence included revising its written procedure to ensure that sources are positioned in the patient in accordance with the written directive, and ensuring that the staff implements those revisions.

NRC Action:

On June 20, 2007, the NRC issued a Notice of Violation related to this event.

Other Agency Action:

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

ITEM #: 060748 AO #: NRC 07-04 EVENT DATE: 10/25/2006
TITLE: Medical Event at Kennedy Memorial Hospitals in Turnersville, New Jersey
NAME: Kennedy Memorial Hospitals CITY: Turnersville STATE: NJ

Nature and Probable Consequences:

Kennedy Memorial Hospitals (the licensee) reported that a patient was prescribed a brachytherapy treatment of 145 Gy (14,500 rad) to the prostate gland for prostate cancer using 104 iodine-125 seeds, but instead received a dose of 145 Gy (14,500 rad) to unintended treatment site. The brachytherapy seeds were implanted under ultrasound guidance; however, a post-treatment computed tomography scan showed that the implanted seeds were displaced inferior to the intended position, resulting in a dose approximately 8 Gy (800 rad) delivered to the intended treatment site. The patient and the referring physician were informed of the event, and additional external beam radiation treatment was recommended.

The NRC staff conducted a reactive onsite inspection on December 12, 2006. The NRC-contracted medical consultant reviewed the case and agreed with the licensee's analysis and conclusions, stating that no significant adverse health effect to the patient expected.

Cause:

The medical event was caused by the licensee's failure to accurately identify the position of the prostate during the intraoperative ultrasound guidance procedure.

Licensee Action:

The licensee revised its procedures, including the use of a contrast medium in the Foley catheter balloon to more clearly identify bladder/prostate interface, and use of fluoroscopic imaging to confirm anatomical positioning and verify seed placement.

NRC Action:

There were no violations identified by the NRC.

Other Agency Action:

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

ITEM #: 070014 AO #: AS 07-01 EVENT DATE: 11/29/2006
TITLE: Medical Event at St. James Hospital and Health Center in Olympia Fields, Illinois
NAME: St. James Hospital and Health Center CITY: Olympia Fields STATE: IL

Nature and Probable Consequences:

St. James Hospital and Health Center (the licensee) reported that a 75-year-old female patient received a dose to an unintended area of approximately 4 cm² (0.6 in²) of 20 Gy (2,000 rad), which was prescribed to supplement surgery and external radiation treatments for cancer of the uterus. The treatment used a high dose-rate (HDR) afterloader containing an iridium-192 source with an activity of 370 GBq (10 Ci). The source stopped 20 cm (7.9 in) short of the intended position; thus, the patient received none of the prescribed dose to the correct location. The patient and the referring physician were informed of this event. Over the next 4 weeks, the patient was treated for wet desquamation on both of her inner thighs, surrounded by a halo of erythema and the licer continues to monitor the patient.

Cause:

This medical event was caused by human error. The licensee entered an incorrect initial value into the treatment system, and the treatment plan was not reviewed by an authorized medical physicist during the subsequent three weekly treatment sessions. The error was identified during a chart audit before the next similar HDR treatment was planned.

Licensee Action:

The licensee reviewed previous administrations to confirm that this event was an isolated incident. The licensee also developed new procedures requiring additional quality assurance steps, including the presence of a medical physicist during treatments. In addition, licensee personnel received additional training on the revised treatment procedures.

NRC Action:

Other Agency Action:

The State conducted an investigation on January 8, 2007, and issued a Notice of Violation. On March 8, 2007, the NRC-contract medical consultant investigated the matter for the State and supported the licensee's conclusions. The State accepted the licensee's corrective actions on April 12, 2007.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

ITEM #: 070276 AO #: AS 07-02 EVENT DATE: 01/16/2007
TITLE: Medical Event at Aroostook Medical Center of Presque Isle, Maine
NAME: Aroostook Medical Center CITY: Presque Isle STATE: ME

Nature and Probable Consequences:

Aroostook Medical Center (the licensee) reported that a patient received 148 MBq (4 mCi) of iodine-131 for a whole body scan, instead of the prescribed 5.6 MBq (0.151 mCi) for a thyroid uptake scan. On March 6, 2007 during a follow-up visit with an endocrinologist, it was recognized that the wrong scan was performed. The patient and referring physician were informed of this event. Using the methodology in NUREG-CR-6345, "Radiation Dose Estimates for Radiopharmaceuticals," the licensee estimated that the administration of 148 MBq (4 mCi) resulted in a thyroid dose of 51.22 Gy (5,122 rad) and a whole body effective dose equivalent of 1.537 Sv (153.7 rem). The licensee concluded that no significant adverse health effect to the patient is expected.

Cause:

The medical event was caused by human error. The licensee failed to verify the prescribed dosage for a specific patient directly with the referring physician. In addition, a written directive was not completed for this procedure.

Licensee Action:

Corrective actions taken by the licensee included revising procedures to improve communication with referring physicians, to all the certified nuclear medicine technologist to speak directly with the referring physician or authorized user to confirm the type of to be conducted. Also, written directives will be required for all administrations of iodine-131 in quantities greater than 1.11 MBq (uCi).

NRC Action:

Other Agency Action:

The State Radiation Control Program (RCP) performed an onsite investigation on May 24, 2007, and requested that the licensee take corrective actions to prevent recurrence. The RCP initially reviewed and accepted the licensee's proposed corrective action during this onsite investigation. The RCP issued a Notice of Violation on November 1, 2007, and awaits the licensee's response.

Criteria:

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is equal to or greater than 10 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 dose or dosage that is at least 50 percent greater than that prescribed, shall be considered for reporting as an AO.

ITEM #: 070215 AO #: AS 07-03 EVENT DATE: 03/07/2007
TITLE: Medical Event in New York
NAME: Unspecified Licensee CITY: Unspecified Facility STATE: NY

Nature and Probable Consequences:

The licensee reported a brachytherapy medical event to the New York State Department of Health. The event involved a 31-year-old female patient with a history of vaginal cancer. The treatment involved the use of both cesium-137 and iridium-192 seeds. Each ribbon contained 8 seeds with an activity of 1.855 milligram radium equivalent (118 MBq or 3.19 mCi). The patient was to be administered a total dose of 25 Gy (2,500 rad) via interstitial brachytherapy, to be delivered to the 0.5 Gy (50 rad) isodose line for a total treatment time of 50 hours.

On March 6, 2007, the iridium-192 seeds and the cesium-137 seeds were placed into the patient. Late in the morning of March 6, 2007, the medical physicist performed a manual check of the treatment plan calculations, and discovered that the hand calculation indicated a significantly higher dose rate than was generated using the treatment planning software. The ensuing investigation revealed that the original treatment plan was in error. On March 7, 2007, after 27 hours of treatment, the seeds were removed from the patient.

The patient received an estimated dose of 45.9 Gy (4,590 rad) to the treatment site, rather than the intended 25 Gy (2,500 rad). The rectal dose was 73 Gy (7,300 rad). The radiation oncologist disclosed that the patient is at risk for radiation cystitis, rectal proctitis and more importantly, fistula formation between the rectum and the vagina. The patient and the referring physician were informed of this event. The patient will be monitored closely over the next year by both her gynecologic oncologist and the radiation oncologist. The patient is being treated with broad spectrum antibiotics, along with daily treatments in a hyperbaric oxygen chamber.

Cause:

The primary cause was the use of an inappropriate Dose Rate Factor (DRF) in the treatment planning system. The value used corresponded to the DRF for air kerma, however, the seed strength entered was in milligram radium equivalent. Other causes and contributing factors included failure to check the treatment pre-plan before the seeds arrived although there was time to do so; failure to double-check the calculations either prior to the implant or shortly thereafter; use of a treatment planning system that underwent acceptance testing for cesium-137 and iodine-125, but not iridium-192; and lack of recent experience preparing a treatment plan using iridium-192. Neither the physicist nor the radiation oncologist had prepared a treatment plan using iridium-192 in 6 years.

Licensee Action:

The licensee changed its policy and procedures to require a check of calculations for any single-fraction brachytherapy treatment.

NRC Action:

Other Agency Action:

The State plans to follow-up on the licensee's implementation of their new procedures during the next scheduled inspection.

Criteria:

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any tissue or organ (other than the lens of the eye, the gonads, or major portion of the bone marrow), and represents either a dose or dosage that is at least 50 percent greater than that prescribed shall be considered for reporting as an AO.

ITEM #: 070263 AO #: AS 07-04 EVENT DATE: 04/24/2007
TITLE: Medical Event at Memorial Mission Hospital of Asheville, North Carolina
NAME: Memorial Mission Hospital CITY: Asheville STATE: NC

Nature and Probable Consequences:

Memorial Mission Hospital (the licensee) reported that a 19-year-old female patient was prescribed a dose of 1.24 MBq (33.4 uCi) of iodine-131 for a diagnostic scan to assess the health of her thyroid, however, she was administered a dose of 1235.8 MBq (33,400 uCi) on April 24, 2007. The licensee discovered the event when the patient returned the next day for her uptake scan. The licensee had the patient return for a second uptake scan on April 26, 2007. The patient was placed on a gamma camera and given a whole body scan. The spectrum was identified as iodine-131 and the uptake was concentrated in the patient's neck area, consistent with a thyroid uptake. As a result, the patient received a dose to the thyroid of approximately 287.3 Gy (28,728 rad). The patient and the referring physician were informed of this event.

The patient received an ablative quantity of radioactive iodine and initially showed classic signs of thyroiditis, including inflammation, swelling, pain, and difficulty swallowing. The patient has recently started taking a synthetic thyroid hormone.

Cause:

The radiopharmacy provided the hospital an incorrect and mislabeled dose. The hospital failed to conduct a proper and accurate receipt survey on the package when it arrived in the hospital's nuclear medicine department. The nuclear medicine technologist, who performed the package receipt survey, failed to investigate the higher-than-expected dose rate off the transport container to determine if anything unusual was present. The nuclear medicine technologist assigned to the patient failed to correctly and accurately assay the dose in the dose calibrator. A second nuclear medicine technologist who is supposed to perform a quality assurance (QA) check of the dose calibrator reading, taken by the nuclear medicine technologist assigned to the patient, failed to correctly and accurately read the dose calibrator. The nuclear medicine technologist assigned to the patient failed to recognize that the number of counts obtained from the neck phantom used for the uptake scan baseline was unusually high for the quantity of radioactive material prescribed for the patient.

Licensee Action:

The licensee ceased purchasing radiopharmaceuticals from the radiopharmacy that provided the incorrect and mislabeled dose. The licensee set aside a designated area for receiving shipments of radiopharmaceuticals and posted a list of expected dose rate per shipment (based upon contents of the shipment). The licensee redesigned the patient administration log to serve as a check for QA, instituted procedural changes to include a one-meter survey of each diagnostic capsule while it is being counted in the phantom prior to administration, and implemented updated training to acquaint all nuclear medicine technologists with these new policies.

NRC Action:

Other Agency Action:

The State radiation control agency conducted an investigation into this incident assisted by the State board of pharmacy. The licensee's actions to prevent recurrence will be inspected at their next regularly scheduled inspection.

Criteria:

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is equal to or greater than 10 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 dose or dosage that is at least 50 percent greater than that prescribed, shall be considered for reporting as an AO.

ITEM #: 060716 AO #: AS 07-05 EVENT DATE: 11/16/2006
TITLE: Medical Event at University of Washington Harborview Gamma Knife of Seattle, Washington
NAME: University of Washington Harborview Gamma Knife CITY: Seattle STATE: WA

Nature and Probable Consequences:

University of Washington Harborview Gamma Knife (the licensee) reported that a patient who was prescribed to receive 18 Gy (1,800 rad) during a gamma knife treatment actually received 28 Gy (2,800 rad). The gamma knife contained 267.7 TBq (7,236 Ci) of cobalt-60. The patient and the referring physician were informed of this event. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause:

The cause of the incident was determined to be human error. The prescribing physician prescribed 18 Gy (1,800 rad) and erroneously entered 28 Gy (2,800 rad). The physician entered the prescribed value into the computer treatment planning system rather than having the medical physicist enter the value as is the usual procedure, resulting in a failure to follow an established procedure.

Licensee Action:

Corrective actions taken by the licensee included a verification process to ensure that the prescribed treatment value is transferred from the treatment planning computer to the gamma knife computer prior to patient therapy. Also, a treatment plan signed by the treating oncologist, physicist, and neurosurgeon is now required. In addition, the treating oncologist and physicist will verify and initial the prescribed dose and isodose treatment parameters prior to patient therapy.

NRC Action:

Other Agency Action:

The State reviewed the licensee's corrective actions and determined that the procedures were adequate to ensure that this type of event should not happen in the future.

Criteria:

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is equal to or greater than 10 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 dose or dosage that is at least 50 percent greater than that prescribed, shall be considered for reporting as an AO.

ITEM #: 070547 AO #: AS 07-06 EVENT DATE: 08/22/2007
TITLE: Medical Event at Physician Reliance of Fort Worth, Texas
NAME: Physician Reliance CITY: Fort Worth STATE: TX

Nature and Probable Consequences:

Physician Reliance (the licensee, dba Texas Oncology at Klabzuba) reported that a patient who was being treated for lung cancer with a high dose-rate (HDR) afterloader and an iridium-192 source, received 2,500 cGy (2,500 rad) during the first fraction, instead of the prescribed dose of 500 cGy (500 rad). The patient was prescribed to receive five fractions with 500 cGy (500 rad) per fraction over five weeks. The incident was discovered following an independent physicist's review of the treatment plan. The patient and the referring physician were informed of this event. The patient's pulmonologist concluded that no significant adverse health effect to the patient is expected.

Cause:

The incident occurred as a result of the incorrect isodose line being chosen and entered into the treatment planning system. The oncologist signed and approved the treatment plan and the radiation safety officer performed a second calculation to check the treatment plan. The treatment planning system then normalized the calculations to the incorrect isodose line and delivered the resulting treatment. The calculation error was identified by an independent physicist prior to administration of the second fraction.

Licensee Action:

The licensee's corrective action was to change their procedure to include a second check by a licensed medical physicist of all treatment plans.

NRC Action:

Other Agency Action:

The State issued two violations related to this event: (1) a violation of 25 Texas Administrative Code (TAC) §289.256(p)(4)(A) and (B) was cited because the procedure as implemented was insufficient to ensure that a second check of the printed output of the treatment plan was performed to verify the accuracy of the planned treatment factors prior to treatment; and (2) a violation of 25 TAC §289.256(o)(1) and §289.256(p)(1) was cited because the instructions of obtaining the authorized physician's signed and dated written directive for each therapeutic administration were not followed. In addition, the State reviewed the licensee's corrective action of changing their procedures to include a second check by a licensed medical physicist of all treatment plans.

Criteria:

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is equal to or greater than 10 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 dose or dosage that is at least 50 percent greater than that prescribed, shall be considered for reporting as an AO.

ITEM #: 090130 AO #: NRC 06-01 EVENT DATE: 03/06/2006
TITLE: Spill of High-Enriched Uranium Solution at Fuel Fabrication Facility
NAME: Nuclear Fuel Services CITY: ERWIN STATE: TN

Nature and Probable Consequences:

In a facility authorized to process high-enriched uranium (HEU), a transfer of HEU solution through a transfer line resulted in a portion of the HEU solution, approximately 35 liters, leaking into a glovebox where criticality was possible and subsequently to the floor where criticality was also possible because of the presence of an elevator pit.

Immediately before the event, the facility operator decided to move the unused filter glovebox to another location. Workers opened and drained the filters so that the filter glovebox could be moved. After draining the filters, workers failed to reseal the system tight. During the next transfer of HEU solution through the line, HEU solution leaked into the filter glovebox. On several occasions before the event, workers had reported signs of a yellowish liquid in the filter glovebox. Supervisors had failed to fully investigate the reports because they assumed the yellowish liquid was natural uranium solution which had been used to initially test the process.

Criticality was possible in the filter glovebox because of the size and shape of the glovebox and because there were no controls in the filter glovebox to prevent accumulation of solution. The solution leaked out of the filter glovebox through uncontrolled drains on the floor. Investigation of the event revealed that the floor contained an uncontrolled accumulation point, an elevator pit, where criticality was also possible. In different circumstances, the total volume of the transfer would have been more than enough for criticality to be possible in the filter glovebox or the elevator pit. If a criticality accident had occurred in the filter glovebox or the elevator pit, it is likely that at least one worker would have received an exposure high enough to cause acute health effects or death. The NRC conducted a team inspection to determine the root causes of the event and performed a series of three readiness reviews before allowing this portion of the facility to restart. The NRC issued an order to the licensee delineating specific actions designed to address this and other performance issues at the facility.

Cause:

Failure to maintain configuration control of facility equipment and failure to comply with procedures.

Licensee Action:

The operator stopped all processing of HEU in the affected processing area, removed the enclosure and associated piping, filled an uncontrolled accumulation point (the elevator pit) with concrete, and conducted an extensive review to identify any similar configuration issues.

NRC Action:

Other Agency Action:

Criteria:

Criterion III, "For Fuel Cycle Facilities," of Appendix A to this report states, in part, that a major condition or significant event that seriously compromises the ability of a safety system to perform its designated function that requires immediate remedial action to prevent a criticality, radiological, or chemical process hazard will be considered for reporting as an AO.

ITEM #: 080550 AO #: AS 08-01 EVENT DATE: 04/11/2008

TITLE: Human Exposure to Radiation at St. Luke's Hospital in Bethlehem, Pennsylvania

NAME: St. Luke's Hospital CITY: Bethlehem STATE: PA

Nature and Probable Consequences:

St. Luke's Hospital (the licensee) reported that a therapeutic dose of 4,958 MBq (134 mCi) of iodine-131, for thyroid cancer treatment, resulted in a dose to an embryo/fetus of 350 mSv (35 rem). Prior to administration of iodine-131, the patient was given a pregnancy test and it yielded a negative result. Following the treatment, the patient suspected she was pregnant and returned to hospital on April 28, 2008. Subsequent testing indicated that the patient became pregnant approximately 4-6 days following her treatment. The patient and the referring physician were informed of this event.

The hospital calculated a total dose to the embryo/fetus of 350 mSv (35 rem). The hospital concluded that based on the total dose to the embryo/fetus of 350 mSv (35 rem), no immediate health effects would be experienced. On May 2, 2008, the patient met with a perinatologist and a recommendation was made to consult with a genetic counselor regarding the fetal exposure.

Cause:

The causes of this event were the negative pregnancy test and the patient not using a method of contraception, as advised, following the treatment.

Licensee Action:

The licensee is providing additional instructions to its staff to strongly emphasize to patients the risks associated with becoming pregnant following the administration of radioiodine treatments.

NRC Action:

Other Agency Action:

The State conducted a follow-up inspection on June 10, 2008, and did not take any enforcement action regarding this event.

Criteria:

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

ITEM #: 080514 AO #: NRC 08-01 EVENT DATE: 06/04/2008
TITLE: Human Exposure to Radiation at Wilford Hall Medical Center on Lackland Air Force Base in San Antonio, Texas
NAME: Wilford Hall Medical Center CITY: San Antonio STATE: TX

Nature and Probable Consequences:

Wilford Hall Medical Center, a permit holder under the United States Air Force (USAF) Master Material license, reported that a therapeutic dose of 5.55 GB (150 mCi), for post-thyroidectomy therapy to a patient, administered on June 4, 2008, resulted in a dose to an embryo/fetus of 315 mSv (31.5 rem). Two days prior to administration of the radioiodine-131, a pregnancy test was given to the patient and it yielded a negative result. Later, on June 26, 2008, the patient became aware that she was pregnant. The hospital's radiation safety staff did not become aware of the pregnancy until August 13, 2008, when the patient contacted the radiation safety staff asking about the consequences of the radioiodine ablation therapy on her embryo/fetus.

The hospital's radiation safety staff immediately conducted an investigation, in consultation with experts at the Department of Energy, and concluded that based on the total dose calculated of 315 mSv (31.5 rem) to the embryo/fetus, no immediate health effects would be experienced. The hospital estimated that the pregnancy was approximately seven days post-conception at the time of the administration and that the zygote (fertilized ovum) was in a pre-implantation state. This estimated condition is supported by the negative pregnancy test results prior to the administration. In addition, the hospital also estimated that the likelihood of childhood cancer had been increased by an estimated 1.9 percent. According to the licensee's report dated September 22, 2008, the pregnancy was progressing satisfactorily.

Cause:

Wilford Hall Medical Center believes that it followed its policies and standards of care. A pregnancy test does not typically have the capability to detect a pregnancy at such an early stage. The NRC special inspection is complete and the results are being evaluated for significance and potential regulatory action. The final report will be issued at the completion of the evaluation.

Licensee Action:

Wilford Hall Medical Center - Patients will be advised that serum pregnancy tests are not capable of detecting early stage pregnancy and therefore patients will be advised to abstain from intercourse for a period of 14 days prior to treatment or utilize an effective method of contraception for a period of 30 days prior to treatment. In addition, only quantitative serum tests will be used to detect pregnancy for patients with the physiological capacity for becoming pregnant.

Department of the Air Force - The United States Air Force (USAF) Radioisotope Committee (RIC) is performing a root-cause analysis of this event. As part of its reviews, the USAF RIC is identifying other hospitals, under its Master Materials license, and asking them to review radioiodine procedures for the past two years to determine if patients had become pregnant either before or after receiving a radioiodine procedure. The USAF RIC will also review the policies and procedures of these hospitals. In addition, the USAF RIC is arranging to send an inspector from the Air Force Inspection Agency to further assess procedures. The USAF Surgeon General issued a Notice to Airmen (NOTAM) on September 22, 2008, that outlined compliance objectives to reduce the likelihood of future occurrences. The USAF RIC is sending information to educate clinicians and support staff on the intent and implementation of the NOTAM.

NRC Action:

NRC first learned of this incident on September 5, 2008, while conducting a routine unannounced inspection at Wilford Hall Medical Center. On September 9, 2008, NRC initiated a special inspection team to review this event and obtained the services of a medical consultant. NRC's medical consultant corroborated the hospital's total dose estimate to the fetus, with an estimated total dose of 325 mSv (32.5 rem). NRC's medical consultant also concurred with the hospital's assessment of the probable health effects to the fetus.

Other Agency Action:

Criteria:

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 5 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

ITEM #: 030135 AO #: NRC 08-02 EVENT DATE: 02/03/2003
TITLE: Medical Events at the Department of Veterans Affairs in Philadelphia, Pennsylvania
NAME: Department of Veterans Affairs CITY: Philadelphia STATE: PA

Nature and Probable Consequences:

The VA Medical Center - Philadelphia reported that 92 medical events involving prostate brachytherapy occurred between February 2002 and May 2008. Each patient was prescribed 160 Gy (16,000 rad) using permanent iodine-125 seeds. The licensee determined that 57 of the 92 patients received less than 80 percent of the prescribed dose to the prostate. Thirty-five patients received excessive doses to other organs. Of these 35 patients, 25 patients received a dose in excess of 100 Gy (10,000 rad) to the rectum due to misplaced iodine-125 seeds. Each patient and the referring physicians were notified of these events. The VA Medical Center - Philadelphia is reviewing possible health effects on the patients. The circumstances for each patient are being evaluated to determine if follow-up medical care is needed.

The NRC-contracted medical consultant reviewed a selected number of the cases and agreed with the licensee's dose analysis. However, in one overdose case, the patient experienced rectal bleeding of the colon and laboratory results indicated ulcerative colitis. The NRC-contracted medical consultant and the licensee agreed that the increased dose to the colon could be a contributing factor to the rectal bleeding.

Cause:

The VA Medical Center - Philadelphia identified three root causes as a result of these events in its Report of Administrative Board of Investigation dated September 5, 2008: (1) no corrective action was taken when post-implant dosimetry was performed and incorrect doses were observed, (2) inadequate supervision by the physician/authorized users and (3) posttreatment plans were not performed on patients due to computer interface problems. In addition, two factors contributed to these events: (1) internal procedures were not followed and (2) the succession of minor technical errors that stemmed from a misperception that other team members performed safety checks.

Licensee Action:

Corrective actions taken by the VA Medical Center - Philadelphia included: (1) the prostate brachytherapy program has been suspended until a standardized brachytherapy program is established and implemented; (2) a physician and medical physics consultant, who are experts in performing prostate implants, were hired to evaluate the prostate implant program; and (3) several key staff directly involved in the prostate brachytherapy procedures are no longer employed by the VA Medical Center - Philadelphia.

NRC Action:

The NRC Region III Office conducted a reactive inspection on July 23-25, 2008. Based on the results of this inspection and the high number of medical events identified, NRC conducted a special inspection on September 9-12, 2008. On October 14, 2008, NRC issued a confirmatory action letter (CAL) to the Department of Veterans Affairs (DVA) National Health Physics Program due to the multiple medical events involving permanent prostate brachytherapy treatments. The CAL documents the commitments made by the DVA to identify and address the problems that have led to medical errors and to prevent their recurrence. NRC will verify, through inspections, that the items in the CAL have been successfully completed. Enforcement action is pending.

Other Agency Action:

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

ITEM #: 050671 AO #: NRC 08-02 EVENT DATE: 10/03/2005
TITLE: Medical Events at the Department of Veterans Affairs in Philadelphia, Pennsylvania
NAME: Department of Veterans Affairs CITY: Philadelphia STATE: PA

Nature and Probable Consequences:

The VA Medical Center - Philadelphia reported that 92 medical events involving prostate brachytherapy occurred between February 2002 and May 2008. Each patient was prescribed 160 Gy (16,000 rad) using permanent iodine-125 seeds. The licensee determined that 57 of the 92 patients received less than 80 percent of the prescribed dose to the prostate. Thirty-five patients received excessive doses to other organs. Of these 35 patients, 25 patients received a dose in excess of 100 Gy (10,000 rad) to the rectum due to misplaced iodine-125 seeds. Each patient and the referring physicians were notified of these events. The VA Medical Center - Philadelphia is reviewing possible health effects on the patients. The circumstances for each patient are being evaluated to determine if follow-up medical care is needed.

The NRC-contracted medical consultant reviewed a selected number of the cases and agreed with the licensee's dose analysis. However, in one overdose case, the patient experienced rectal bleeding of the colon and laboratory results indicated ulcerative colitis. The NRC-contracted medical consultant and the licensee agreed that the increased dose to the colon could be a contributing factor to the rectal bleeding.

Cause:

The VA Medical Center - Philadelphia identified three root causes as a result of these events in its Report of Administrative Board of Investigation dated September 5, 2008: (1) no corrective action was taken when post-implant dosimetry was performed and incorrect doses were observed, (2) inadequate supervision by the physician/authorized users and (3) posttreatment plans were not performed on patients due to computer interface problems. In addition, two factors contributed to these events: (1) internal procedures were not followed and (2) the succession of minor technical errors that stemmed from a misperception that other team members performed safety checks.

Licensee Action:

Corrective actions taken by the VA Medical Center - Philadelphia included: (1) the prostate brachytherapy program has been suspended until a standardized brachytherapy program is established and implemented; (2) a physician and medical physics consultant, who are experts in performing prostate implants, were hired to evaluate the prostate implant program; and (3) several key staff directly involved in the prostate brachytherapy procedures are no longer employed by the VA Medical Center - Philadelphia.

NRC Action:

The NRC Region III Office conducted a reactive inspection on July 23-25, 2008. Based on the results of this inspection and the high number of medical events identified, NRC conducted a special inspection on September 9-12, 2008. On October 14, 2008, NRC issued a confirmatory action letter (CAL) to the Department of Veterans Affairs (DVA) National Health Physics Program due to the multiple medical events involving permanent prostate brachytherapy treatments. The CAL documents the commitments made by the DVA to identify and address the problems that have led to medical errors and to prevent their recurrence. NRC will verify, through inspections, that the items in the CAL have been successfully completed. Enforcement action is pending.

Other Agency Action:

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

ITEM #: 080296 AO #: NRC 08-02 EVENT DATE: 02/25/2002
TITLE: Medical Events at the Department of Veterans Affairs in Philadelphia, Pennsylvania
NAME: Department of Veterans Affairs CITY: Philadelphia STATE: PA

Nature and Probable Consequences:

The VA Medical Center - Philadelphia reported that 92 medical events involving prostate brachytherapy occurred between February 2002 and May 2008. Each patient was prescribed 160 Gy (16,000 rad) using permanent iodine-125 seeds. The licensee determined that 57 of the 92 patients received less than 80 percent of the prescribed dose to the prostate. Thirty-five patients received excessive doses to other organs. Of these 35 patients, 25 patients received a dose in excess of 100 Gy (10,000 rad) to the rectum due to misplaced iodine-125 seeds. Each patient and the referring physicians were notified of these events. The VA Medical Center - Philadelphia is reviewing possible health effects on the patients. The circumstances for each patient are being evaluated to determine if follow-up medical care is needed.

The NRC-contracted medical consultant reviewed a selected number of the cases and agreed with the licensee's dose analysis. However, in one overdose case, the patient experienced rectal bleeding of the colon and laboratory results indicated ulcerative colitis. The NRC-contracted medical consultant and the licensee agreed that the increased dose to the colon could be a contributing factor to the rectal bleeding.

Cause:

The VA Medical Center - Philadelphia identified three root causes as a result of these events in its Report of Administrative Board of Investigation dated September 5, 2008: (1) no corrective action was taken when post-implant dosimetry was performed and incorrect doses were observed, (2) inadequate supervision by the physician/authorized users and (3) posttreatment plans were not performed on patients due to computer interface problems. In addition, two factors contributed to these events: (1) internal procedures were not followed and (2) the succession of minor technical errors that stemmed from a misperception that other team members performed safety checks.

Licensee Action:

Corrective actions taken by the VA Medical Center - Philadelphia included: (1) the prostate brachytherapy program has been suspended until a standardized brachytherapy program is established and implemented; (2) a physician and medical physics consultant, who are experts in performing prostate implants, were hired to evaluate the prostate implant program; and (3) several key staff directly involved in the prostate brachytherapy procedures are no longer employed by the VA Medical Center - Philadelphia.

NRC Action:

The NRC Region III Office conducted a reactive inspection on July 23-25, 2008. Based on the results of this inspection and the high number of medical events identified, NRC conducted a special inspection on September 9-12, 2008. On October 14, 2008, NRC issued a confirmatory action letter (CAL) to the Department of Veterans Affairs (DVA) National Health Physics Program due to the multiple medical events involving permanent prostate brachytherapy treatments. The CAL documents the commitments made by the DVA to identify and address the problems that have led to medical errors and to prevent their recurrence. NRC will verify, through inspections, that the items in the CAL have been successfully completed. Enforcement action is pending.

Other Agency Action:

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

ITEM #: 070672 AO #: NRC 08-03 EVENT DATE: 10/24/2007
TITLE: Medical Event at Karmanos Cancer Center in Detroit, Michigan
NAME: Karmanos Cancer Center CITY: Detroit STATE: MI

Nature and Probable Consequences:

Karmanos Cancer Center reported that a medical event occurred associated with its gamma stereotactic radiosurgery unit (gamma knife). A patient being treated for a metastatic brain tumor was scheduled to receive 18 Gy (1,800 rad) to the lesion in the right cerebella area of the brain but received 18 Gy (1,800 rad) to an unintended area adjacent to the tumor. An error in the setup of the magnetic resonance imaging (MRI) unit caused the MRI scan to be reversed (i.e., the image of the right side of the head was on the left side and vice versa). The patient and the referring physician were informed of this event.

Prior to the treatment, the medical physicist, authorized user physician, and neurosurgeon reviewed the MRI scan and treatment plan but failed to recognize the reversed MRI images. The reversed MRI images were scanned into the gamma knife treatment planning computer, and a treatment plan was generated based on the reversed MRI images. The authorized user physician and neurosurgeon reviewed and approved the treatment plan generated from the reversed MRI images, and again the reversed MRI images were not recognized.

The NRC staff conducted a reactive onsite inspection on October 29, 2007. The NRC-contracted medical consultant reviewed the case and agreed with the licensee's analysis, stating that no significant adverse health effect to the patient is expected.

Cause:

The medical event was caused by the MRI technologist who inadvertently performed the MRI scans in the "caudal" mode (from jaw to the top of the head) rather than the "cranial" mode (from the top of the head to the jaw). This change in device mode caused the MRI images to be reversed.

Licensee Action:

The licensee initiated several corrective actions to reduce the likelihood of recurrence of a similar event. Specifically, those corrective actions included (1) weekly meetings with the physics staff to discuss technical issues, focusing on the importance of good communication and (2) new written procedures and policies for the MRI staff and gamma knife facility staff that require dual verification of the various steps in the process to ensure that the correct treatment plan is generated from the MRI images.

NRC Action:

On January 10, 2008, NRC issued a Notice of Violation related to this event.

Other Agency Action:

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

ITEM #: 080230 AO #: AS 08-02 EVENT DATE: 12/12/2007
TITLE: Medical Event at University of Mississippi Medical Center in Jackson, Mississippi
NAME: University of Mississippi Medical Center CITY: Jackson STATE: MS

Nature and Probable Consequences:

University of Mississippi Medical Center (the licensee) reported that a medical event occurred during a high dose-rate (HDR) treatment for cervical cancer using an iridium-192 source with an activity of 185 GBq (5.0 Ci). The authorized user physician prescribed five fractionated doses of 600 cGy (600 rad) each to be administered using tandem and ovoid applicators. The licensee calculated that during the first, second, and third fractionated treatments, the patient received a total dose of 470 cGy (470 rad) to the treatment area and 1,300 cGy (1,300 rad) to the vaginal region inferior to the treatment area. The patient and the referring physician were informed of this event. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause:

The medical event was caused by human error due to the incorrect catheter length entered into the treatment planning system. An incorrect value of 128 cm was entered as the length instead of 120 cm, resulting in the 86 mm displacement. An HDR service technician identified the error in the treatment planning system on March 25, 2008.

Licensee Action:

The licensee committed to taking several corrective actions as a result of the medical event, including (1) verification of the length of all disposable catheters and checking the integrity of the catheters prior to treatment, (2) placing an order for and use of a single of reusable catheters for HDR cervical cancer treatments, (3) the treatment plan and catheter measurement will be independently checked prior to treatment, and (4) review and modification, if necessary, of the quality assurance plan to ensure accuracy.

NRC Action:

Other Agency Action:

The State cited the licensee with two violations for failing to verify the treatment plan.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

ITEM #: 080007 AO #: AS 08-03 EVENT DATE: 12/17/2007
TITLE: Medical Event at Southwest Volusia Healthcare Corporation in Orange City, Florida
NAME: Southwest Volusia Healthcare Corporation CITY: Orange City STATE: FL

Nature and Probable Consequences:

Southwest Volusia Healthcare Corporation (the licensee, doing business as Florida Hospital Fish Memorial) reported that a patient received 81.4 MBq (2.2 mCi) of iodine-131 for a whole body scan, instead of the intended iodine-123 for a thyroid uptake scan. Administration of 81.4MBq (2.2 mCi) of iodine-131 resulted in the patient receiving a dose of 17.6 Gy (1,760 rad) to the thyroid and a whole body effective dose equivalent of 1.034 cGy (1.034 rad). The authorized user physician ordered an iodine thyroid uptake scan procedure, but did not specify the isotope in the written directive. The licensee uses iodine-123 for thyroid uptake scan procedures and iodine-131 for whole body scan procedures. On December 17, 2007, the patient received an iodine-131 whole body scan. The patient and the referring physician were informed of this event. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause:

The licensee identified four causes of the medical event: (1) the incorrect examination was scheduled in their Radiology Information System, (2) the patient had a prescription from the ordering physician, but did not make it available for verification, (3) the isotope for the incorrect exam was ordered without verifying the prescription, and (4) the technologist involved in the administration did not recognize the error when the written directive was presented.

Licensee Action:

The licensee implemented corrective actions by providing counseling and re-training to the hospital personnel involved in the medical event and notified hospital personnel that iodine-131 and iodine-123 studies must be verified prior to scheduling patient for these types of procedures. In addition, the technologists have been instructed to visually verify the authorized user physician order on the written directive before ordering the radioisotope and the technologist and radiologist will review the written directive prior to patient administration.

NRC Action:

Other Agency Action:

The State conducted an investigation and reviewed the licensee's corrective actions and found the corrective actions to be adequate.

Criteria:

Criteria III.C.1.b and III.C.2.b(i), "For Medical Licensees," of Appendix A to this report provide in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or lens of the eye, or the gonads) and represents a prescribed dose or dosage that uses the wrong radiopharmaceutical shall be considered for reporting as an AO.

ITEM #: 080053 AO #: AS 08-04 EVENT DATE: 01/14/2008
TITLE: Medical Event at Southern Baptist Hospital of Florida in Jacksonville, Florida
NAME: Southern Baptist Hospital CITY: Jacksonville STATE: FL

Nature and Probable Consequences:

Southern Baptist Hospital of Florida (the licensee, doing business as Baptist Medical Center) reported that a patient received 17 MBq (4.7 mCi) of iodine-131 for an uptake scan, instead of the intended iodine-123 for the same procedure. The administration of 173.9 MBq (4.7 mCi) of iodine-131 resulted in the patient receiving a dose of 61 Gy (6,100 rad) to the thyroid and a whole body effective dose equivalent of 180 cGy (180 rad). An authorized user physician gave a verbal order to a nurse, who wrote the order for an iodine-123 uptake scan. The nurse incorrectly scheduled an iodine-131 uptake scan and the authorized user physician did not review the order. On January 16, 2008, the authorized user physician reviewed the results of the iodine-131 uptake scan and identified that the wrong isotope had been used in the procedure. The patient and the referring physician were informed of this event. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause:

The cause of the medical event was the authorized user physician's failure to write a written directive and failure to review the order for the procedure.

Licensee Action:

The licensee implemented corrective actions by rewriting its procedures such that all written directives will be completed and reviewed by the authorized user physician prior to the administration to patients.

NRC Action:

Other Agency Action:

The State conducted an investigation and reviewed the licensee's corrective actions and found the corrective actions to be adequate.

Criteria:

Criteria III.C.1.b and III.C.2.b(i), "For Medical Licensees," of Appendix A to this report provide in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or lens of the eye, or the gonads) and represents a prescribed dose or dosage that uses the wrong radiopharmaceutical shall be considered for reporting as an AO.

ITEM #: 080132 AO #: NRC 08-04 EVENT DATE: 02/27/2008
TITLE: Medical Event at Reid Hospital and Health Care Services in Richmond, Indiana
NAME: Reid Hospital and Health Care Services CITY: Richmond STATE: IN

Nature and Probable Consequences:

Reid Hospital and Health Care Services reported that a medical event occurred during a brachytherapy seed implant procedure treat prostate cancer. The written directive prescribed a total dose of 110 Gy (11,000 rad) to the patient's prostate using 62 iodine 125 seeds as permanent implants. The licensee calculated that the patient received less than 15 Gy (1,500 rad) to the prostate. The region of the patient's perineum, where the seeds were placed, received a dose of 55 Gy (5,500 rad). The patient and the referring physician were informed of this event.

According to the licensee, the base of the prostate was misidentified through ultrasound, causing 37 of the prescribed 62 seeds be placed approximately 1 cm to 2 cm below the prostate in the perineum. When it was recognized that the seeds were not in the prostate, the procedure was halted. The licensee physicians stated that the patient may develop possible complications, including fibrosis and necrosis of the tissue in the perineum, where the seeds were implanted.

The NRC-contracted medical consultant agreed with the licensee's dose estimate and stated it was unlikely that the patient would experience radiation-induced rectal wall necrosis or soft tissue necrosis below the prostate in the perineum area, but that it was possible to have delayed fibrosis of some areas of the genital tract. The NRC-contracted medical consultant further stated that because no tissue necrosis had occurred one month after the medical event, tissue necrosis was very unlikely to occur.

Cause:

The licensee determined the root cause of the medical event was the misidentification of the base of the prostate. Specifically, the prostate/bladder interface was not identified properly using the ultrasound due to poor image quality. As a result, the needle used to implant the seeds was not located in the prostate during the implantation.

Licensee Action:

The licensee's corrective actions to prevent recurrence included revising its procedure for prostate seed implants to require that needle location in the prostate be verified by x-ray imaging at the beginning of the procedure, prior to any seeds being implanted and halting the procedure if the location of the needle in the prostate cannot be verified with certainty.

NRC Action:

On July 11, 2008, NRC issued a Notice of Violation related to this event.

Other Agency Action:

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

ITEM #: 080337 AO #: NRC 08-05 EVENT DATE: 05/01/2008
TITLE: Medical Event at Bon Secours Virginia Health Source in Midlothian, Virginia
NAME: Bon Secours Virginia Health Source CITY: Midlothian STATE: VA

Nature and Probable Consequences:

Bon Secours Virginia Health Source reported that a medical event occurred during a high dose-rate (HDR) treatment for breast cancer using an iridium-192 source with an activity of 165.4 GBq (4.47 Ci). The authorized user physician prescribed 10 fraction of 340 cGy (340 rad) each to be administered using a balloon catheter technique. The licensee calculated that a portion of the target volume received a dose in the range of 86 cGy (86 rad). In addition, a small volume of skin, at the catheter entrance into the patient, received a dose in the range of 1,142 cGy (1,142 rad). The patient and the referring physician were informed of this event.

During the check source run for the first fraction, an HDR alarm interrupted the run. Rather than investigate the cause of the alarm, the physicist concluded that a 2 mm error had been made in the measurement of the catheter length and the alarm occurred because the check source hit the end of the catheter. The physicist adjusted the catheter length value at the treatment console from 1300 mm to 1280 mm, believing this to be a change of 2 mm, and the treatment was administered. Immediately following the first treatment, it was determined that the original catheter length measurement of 1300 mm was correct and the length change made at the treatment console was 20 mm rather than 2 mm. As a result, the source dwell positions were 20 mm from the intended locations and were closer than intended to the skin entry point of the HDR catheter.

Subsequent HDR treatment fractions were administered as intended, with adjustments to the final two treatment fractions to assure that all areas of the target volume received an adequate dose over the course of the treatment. An NRC medical consultant concluded that no significant adverse health effect to the patient is expected.

Cause:

The cause of the medical event was human error in (1) failing to investigate the cause of the HDR alarm and (2) adjusting the catheter length value at the console by 20 mm instead of the intended 2 mm.

Licensee Action:

The licensee's corrective actions taken to prevent recurrence included updating procedures to define steps that will be taken to resolve HDR device alarms.

NRC Action:

NRC performed a reactive inspection at the facility and issued a Notice of Violation for three violations of regulatory requirement on October 10, 2008.

Other Agency Action:

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide in part that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

ITEM #: 090579 AO #: AS 09-01 EVENT DATE: 03/30/2009
TITLE: Human Exposure to Radiation at Chester County Hospital in West Chester, Pennsylvania
NAME: Chester County Hospital CITY: West Chester STATE: PA

Nature and Probable Consequences:

Chester County Hospital (the licensee) reported that a therapeutic dose of 2,001.7 MBq (54.1 mCi) of iodine-131 resulted in a dose to an embryo/fetus of 119 mSv (11.9 rem). On March 30, 2009, the patient was given a pregnancy test and it yielded a negative result. Based on the negative pregnancy test, the licensee administered the iodine-131 to the patient.

On May 13, 2009, the patient informed the authorized user that she was pregnant. The administration of iodine-131 was given to the patient approximately 5 days post-conception, a time period at which the thyroid had not developed. The hospital discovered pregnancy at 9.5 weeks gestation, at which time the thyroid had developed. Due to residual iodine-131 in the patient's system, both a whole body and an organ dose exposure occurred. The hospital calculated a total whole body dose to the embryo/fetus of 119 mSv (11.9 rem) and a fetal thyroid dose of 9.7 mSv (0.97 rem). The hospital recommended that the patient consult with a genetic counselor for any potential health effects to the embryo/fetus.

Cause:

The cause of this event was the close proximity of conception, which resulted in a negative pregnancy test, to the administration of iodine-131.

Licensee Action:

The licensee is providing additional instructions to its staff to strongly emphasize to patients the risks associated with being pregnant prior to the administration of radioiodine treatments.

NRC Action:

Other Agency Action:

The State conducted a follow-up inspection and did not take any enforcement action regarding this event.

Criteria:

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provide, in part, that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

ITEM #: 090755 AO #: AS 09-02 EVENT DATE: 09/21/2009

TITLE: Human Exposure to Radiation at Loyola University Medical Center in Maywood, Illinois

NAME: Loyola University Medical Center CITY: Maywood STATE: IL

Nature and Probable Consequences:

Loyola University Medical Center (the licensee) reported that the administration of 925 MBq (25 mCi) of iodine-131 resulted in a dose to an embryo/fetus of 67 mSv (6.7 rem). Prior to the administration of iodine-131, a urinary pregnancy test was conducted the licensee on September 21, 2009, and it yielded a negative result. On September 29, 2009, the patient notified the licensee that she took a home pregnancy test and it was positive. The patient's pregnancy was confirmed by an independent clinic that administered a second pregnancy test.

The administration of iodine-131 was given to the patient at 2 to 3 weeks gestation (as determined by a consulting physician), a time period at which the thyroid had not developed. Shortly thereafter, the pregnancy ended. The licensee calculated a total whole body dose of 67 mSv (6.7 rem) to the embryo/fetus. There was no dose to the fetal thyroid since the pregnancy ended before the thyroid had developed.

Cause:

The cause of this event was the close proximity of conception, which resulted in a negative pregnancy test, to the administration of iodine-131.

Licensee Action:

The licensee reviewed its established patient selection criteria, screening methods, and testing protocols for any procedural changes. A more sensitive pregnancy test for women capable of bearing children will now be conducted no more than a few days prior to the dose administration.

NRC Action:

Other Agency Action:

After consulting an expert, the State determined that the administration occurred before the development of the thyroid. The State also performed independent calculations that verified the estimate of the fetal dose by the licensee. The State reviewed and accepted the licensee's formal report on October 14, 2009.

Criteria:

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provide, in part, that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

ITEM #: 080694 AO #: AS 09-03 EVENT DATE: 09/10/2008
TITLE: Medical Event at St. Vincent's Medical Center Inc., in Jacksonville, Florida
NAME: St. Vincent's Medical Center Inc. CITY: Jacksonville STATE: FL

Nature and Probable Consequences:

St. Vincent's Medical Center Inc., (the licensee) reported that a medical event occurred associated with a high dose-rate (HDR) mammosite treatment for breast cancer containing 199.8 GBq (5.4 Ci) of iridium-192. A patient was prescribed to receive 34 Gy (3,400 rad) to the right breast but received 34 Gy (3,400 rad) to the skin of the left breast.

On October 16, 2008, the patient notified her physician of erythema on her left breast. During a records review, the medical physicist determined that an error in programming the catheter length in the HDR device caused the source to stop 10 cm short the intended tumor site in the right breast. Due to this programming error, the dose intended for the right breast was delivered to skin of the left breast. The authorized user concluded that no chronic health effect to the patient is expected.

Cause:

The medical event was caused by human error in failing to verify that the correct catheter length was entered into the treatment planning system.

Licensee Action:

The licensee committed to taking several corrective actions as a result of the medical event that include (1) utilizing a catheter length worksheet to determine and verify the mammosite catheter length, (2) documenting the mammosite catheter length by two individuals - one physicist and either a dosimetrist, physicist, or radiation therapist - during simulation treatment set-up, (3) providing procedures for the medical physicist and authorized user on documenting the catheter length on the catheter worksheet during the review of the treatment control unit and treatment plan, and (4) conducting a second measurement of the catheter length to verify that the length agrees with the data in the treatment control unit.

NRC Action:

Other Agency Action:

The Florida Bureau of Radiation Control conducted an investigation and reviewed the licensee's corrective actions and found the corrective actions to be adequate.

Criteria:

Criterion III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provides, in part, that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site, shall be considered for reporting as an AO.

ITEM #: 090019 AO #: AS 09-04 EVENT DATE: 12/02/2008

TITLE: Medical Event at Presbyterian Hospital of Dallas in Dallas, Texas

NAME: Presbyterian Hospital of Dallas CITY: Dallas STATE: TX

Nature and Probable Consequences:

Presbyterian Hospital of Dallas (the licensee) reported that a medical event occurred associated with its gamma stereotactic radiosurgery unit (gamma knife) containing 125.8 TBq (3,400 Ci) of cobalt-60. A patient being treated for trigeminal neuralgia was prescribed to receive 80 Gy (8,000 rad) to the fifth intracranial nerve but received 14.95 Gy (1,495 rad) to the seventh intracranial nerve. The patient and the referring physician were informed of this event.

An error in entry of information into the treatment planning system caused the wrong nerve to receive treatment. The error was identified by the neurosurgeon 9 minutes into the 45-minute treatment. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause:

The medical event was caused by the misidentification of the anatomical target site listed on the written directive.

Licensee Action:

The licensee modified its written procedure to include verification of the target site, by the neuroradiologist, for each treatment. In addition, an updated written directive will document the new procedure to ensure that the correct treatment site is targeted and treated in each procedure.

NRC Action:

Other Agency Action:

The State will conduct a review of at least 20 percent of the past treatment cases to ensure that this error had not previously occurred.

Criteria:

Criterion III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site, shall be considered for reporting as an AO.

ITEM #: 090466 AO #: AS 09-05 EVENT DATE: 04/14/2009

TITLE: Medical Event at Cancer Care Northwest PET Center in Spokane, Washington

NAME: Cancer Care Northwest PET Center CITY: Spokane STATE: WA

Nature and Probable Consequences:

Cancer Care Northwest PET Center (the licensee) reported that a medical event occurred associated with a HDR brachytherapy treatment for prostate cancer containing 185 GBq (5 Ci) of iridium-192. During patient treatment, the aluminum connector to needle 13 became detached from the plastic guide tube and a dose of 12.5 Gy (1,250 rad) was delivered to a small area of the patient's inner thigh (wrong treatment site). The patient and the referring physician were informed of this event.

The source wire for needle 13 hung about 6 inches past the disconnected guide tube, which resulted in the skin dose. The licensee conducted several follow-up examinations of the patient's inner thigh and noted that no skin reddening or injury has occurred and the patient is not experiencing any pain in this area. Therefore, the licensee concluded that no significant adverse health effect to the patient is expected.

Cause:

The cause of the medical event was the source wire, for needle 13, snagged on the seam between the aluminum connector and plastic guide tube during retraction.

Licensee Action:

The licensee committed to taking several actions as a result of the medical event that include (1) requiring the staff to sign the patient quality assurance list when they check the applicators, transfer guide tubes, and aluminum connectors; (2) inspecting the guide tube catheters daily and examining the aluminum connectors prior to patient use; and (3) revising the refresher training to include new procedures for staff prior to patient treatment.

NRC Action:

Other Agency Action:

The State conducted follow-up inspection activities from April-May 2009, and reviewed the licensee's corrective actions. The State found the licensee's corrective actions adequate and did not take any enforcement action regarding this event.

Criteria:

Criterion III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site, shall be considered for reporting as an AO.

ITEM #: 090497 AO #: AS 09-06 EVENT DATE: 05/11/2009
TITLE: Medical Event at The Urology Center in Cincinnati, Ohio
NAME: The Urology Center CITY: Cincinnati STATE: OH

Nature and Probable Consequences:

The Urology Center (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed to receive a total dose of 144 Gy (14,400 rad) to the prostate using 64 iodine 125 seeds as permanent implants. Instead, the patient received an approximate dose of 76 Gy (7,600 rad) to the urethra and bulb of the penis (unintended sites). The patient and the referring physician were informed of this event.

According to the licensee, an interpretation of the ultrasound image of the patient's prostate resulted in 30 of the 64 seeds delivered to the prostate while the other 34 seeds were delivered outside the prostate. Due to the patient's prostate being smaller than normal, the prostate received 68 Gy (6,800 rad) of the prescribed dose and the urethra and bulb of the penis (unintended sites) received approximately 76 Gy (7,600 rad). Prior to the seeds being implanted, the urologist and radiation oncologist should have consulted on the ultrasound image of the patient's prostate to determine the correct seed placement. The licensee concluded that no significant adverse health effect on the patient is expected. On May 19, 2009, the patient returned for a second treatment to compensate for the original underdosing to the prostate.

Cause:

The cause of the medical event was the misinterpretation of the correct size of the patient's small prostate gland by ultrasound.

Licensee Action:

Corrective actions taken by the licensee included instituting a new policy requiring agreement by both the urologist and radiation oncologist on seed placement for all prostate glands measuring 20 cubic centimeters or less. On May 26, 2009, the licensee submitted a written report of this event to the Ohio Department of Health, Bureau of Radiation Protection (ODH BRP).

NRC Action:

Other Agency Action:

On June 12, 2009, ODH BRP conducted an inspection of this event and determined that the licensee had followed the correct procedures for administrations requiring a written directive. ODH BRP reviewed the licensee's corrective actions for this event and found the corrective actions to be adequate.

Criteria:

Criterion III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provides, in part, that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site, shall be considered for reporting as an AO.

ITEM #: 090580 AO #: NRC 09-02 EVENT DATE: 07/02/2009
TITLE: Medical Event at Gamma Knife Center of the Pacific in Honolulu, Hawaii
NAME: Gamma Knife Center of the Pacific CITY: Honolulu STATE: HI

Nature and Probable Consequences:

Gamma Knife Center of the Pacific (the licensee) reported that a medical event occurred associated with its gamma stereotactic radiosurgery unit (gamma knife) containing 104.86 TBq (2,834 Ci) of cobalt-60. A patient being treated for multiple brain metastatic sites was prescribed to receive 24 Gy (2,400 rad) to seven discrete brain sites using an 8 mm collimator. However, an 18 mm collimator was used to treat two of the discrete brain sites, resulting in a dose of 24 Gy (2,400 rad) to additional brain tissue. The patient and the referring physician were informed of this event.

The patient received treatment to the first and second discrete brain sites and after receiving treatment to the second discrete site it was discovered that an 18 mm collimator was used to deliver treatment instead of the prescribed 8 mm collimator. The larger collimator caused the volume of each of the two discrete sites to increase by 2.45 cubic centimeters, resulting in a dose of 24 Gy (2,400 rad) to additional brain tissue. After the 18 mm collimator was discovered, it was replaced with the 8 mm collimator and the patient received treatment to the five remaining discrete sites as prescribed. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause:

The cause of the medical event was human error in failing to check the collimator size prior to patient treatment.

Licensee Action:

Corrective actions taken by the licensee included (1) sending a notice to all authorized users, neurosurgeons, and medical physicists reiterating that they should each independently check the collimator size prior to patient treatment and (2) revising procedures to have a second independent verification of all treatment parameters, including the collimator size, by a treatment team member.

NRC Action:

NRC conducted an onsite inspection and hired a medical consultant to review the event. The conclusions from the onsite inspection and medical consultant's review are ongoing.

Other Agency Action:

Criteria:

Criterion III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site, shall be considered for reporting as an AO.

ITEM #: 090748 AO #: NRC 09-03 EVENT DATE: 09/21/2009
TITLE: Medical Event at the Veterans Affairs San Diego Health Care System in San Diego, California
NAME: Veterans Affairs San Diego Health Care System CITY: San Diego STATE: CA

Nature and Probable Consequences:

The Department of Veterans Affairs (the licensee), National Health Physics Program (NHPP) reported that a medical event occurred at the Veterans Affairs (VA) San Diego Health Care System associated with a therapeutic dosage of iodine-131 for the treatment of metastatic thyroid cancer. A patient was prescribed to receive 6.9 GBq (187 mCi) of iodine-131 to the metastatic site around the body but received 6.1 GBq (166 mCi) to the stomach (wrong treatment site). The patient and the referring physician were informed of this event.

On September 21, 2009, a dosage of 6.9 GBq (187 mCi) of iodine-131 was administered to the patient through an existing feeding tube. Daily radiation measurements indicated small decreases in radiation readings that were consistent with the physical decay of iodine-131, but not consistent with the biological elimination of iodine-131. On September 25, 2009, the feeding tube was replaced and a subsequent investigation revealed that the majority of the dosage, 6.1 GBq (166 mCi), was administered to the wrong orifice of the feeding tube. As a result, the dosage remained in the balloon of the feeding tube and irradiated the patient's stomach, resulting in an approximate dose of 16 Gy to 19 Gy (1,600 rad to 1,900 rad) to the stomach.

Cause:

Three root causes were identified for this medical event: (1) inadequate training of staff, (2) inadequate procedures, and (3) an inadequate procedure on the verification that administrations involving feeding tubes were being administered in accordance with written directives.

Licensee Action:

Corrective actions taken by the licensee included (1) immediate suspension of any further gastric tube administrations until the direct cause of the medical event was identified, (2) suspension of one individual's participation in administrations requiring a written directive, (3) informal training of the nuclear medicine technologists by the Radiation Safety Officer, and (4) development of draft written policies and procedures on the administration of iodine-131 through a gastric tube.

NRC Action:

The NRC Region III Office conducted a reactive inspection on November 3, 2009, and also contracted a medical consultant to review this event. Based on the results of the inspection, five apparent violations of NRC's regulations were identified. Enforcement action is pending and the medical consultant's review is on-going.

Other Agency Action:

Criteria:

Criterion III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site, shall be considered for reporting as an AO.

ITEM #: 100319 AO #: AS 10-01 EVENT DATE: 05/01/2007
TITLE: Human Exposure to Radiation at Mohamed Megahy MD, Ltd in Maryville, Illinois
NAME: Mohamed Megahy MD, Ltd CITY: Maryville STATE: IL

Nature and Probable Consequences:

Mohamed Megahy MD, Ltd (the licensee) indicated that on May 1, 2007, a patient was given 3,807 MBq (102.9 mCi) of iodine-131 as a treatment for the recurrence of thyroid cancer. On June 11, 2007, the licensee was contacted by the patient's obstetrician/gynecologist (OB/GYN) who advised them that the patient was 25-27 weeks (6 months) pregnant at the time of the iodine-131 administration. At the time of administration, the patient indicated to the licensee that she was not pregnant, and the licensee did not perform an independent test.

In June 2010, the Illinois Emergency Management Agency was contacted by the licensee and requested to make a dose estimate to a fetus as a result of administration of iodine-131 to a patient who was later found to be pregnant. When the Illinois Emergency Management Agency requested additional information to determine the appropriate parameters of the event, the licensee advised the agency that the administration had occurred 3 years earlier. The Illinois Emergency Management Agency calculated an estimated dose to the fetus of 860 mSv (86 rem) and the fetal thyroid of over 1,000,000 mSv (100,000 rem). A full-term child was subsequently born in August 2007 without a thyroid. The child was immediately placed on replacement hormone therapy and continues such treatment.

Cause:

The cause of the event was found to be a combination of miscommunication and failure of the licensee to conduct an independent confirmatory pregnancy test.

Licensee Action:

The licensee has subsequently made procedural changes to the interview process for screening patients for iodine-131 treatment. This policy includes a confirmatory negative pregnancy test. In addition, the licensee identified the significant delay in reporting the event to the Illinois Emergency Management Agency as not knowing the reporting requirement for this type of event.

NRC Action:

Other Agency Action:

The Illinois Emergency Management Agency conducted an investigation of the event and issued a Notice of Violation (NOV) for licensee's failure to report the event. The Illinois Emergency Management Agency is considering rulemaking to require the performance of testing to determine pregnancy prior to administration of iodine-131.

Criteria:

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides, in part, that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

ITEM #: 100245 AO #: AS 10-02 EVENT DATE: 03/16/2010
TITLE: Human Exposure to Radiation at Mercy Medical Center in Durango, Colorado
NAME: Mercy Medical Center CITY: Durango STATE: CO

Nature and Probable Consequences:

Mercy Medical Center (the licensee) reported that a therapeutic dose of 1,110 MBq (30 mCi) of iodine-131 for hyperthyroidism resulted in a dose to an embryo of 80 mGy (8 rem) whole body. Prior to the treatment, the patient informed the licensee's staff that she was not pregnant and the licensee's staff administered a pregnancy test as a routine precaution. The pregnancy test yielded a negative result. Based on the negative pregnancy test results and the patient's interview responses, the licensee administered iodine-131 to the patient.

On April 26, 2010, the patient performed a home pregnancy test that resulted in a positive test result. The patient's pregnancy was confirmed with a positive blood serum pregnancy test on April 27, 2010. The patient's OB/GYN estimated that conception occurred on March 13, 2010 (about 1 week pregnant at the time of administration). A consulting medical physicist reviewed the case and estimated the embryonic exposure (whole body) at 53 to 92 mGy (5.3 to 9.2 rem). The possibility of embryonic thyroid exposure was also investigated and determined to be insignificant due to the early stage of embryonic development. At this dose and administration time in relation to the embryonic development (blastogenesis), the licensee determined that no adverse impact was likely on subsequent embryonic or fetal development and that subsequent health risks were unlikely. The patient was informed of the dose estimates and potential risks and she elected to continue the pregnancy.

Cause:

The cause of this event was the close proximity of conception, which resulted in a negative pregnancy test, to the administration of iodine-131.

Licensee Action:

To help prevent recurrence, the licensee added additional questions to the screening process to help identify patients that might be pregnant even though all procedures to prevent this occurrence were followed.

NRC Action:

Other Agency Action:

The State conducted an investigation and concurs with the licensee that a reasonable standard of care was met and, consequently, no enforcement action is warranted.

Criteria:

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides, in part, that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

ITEM #: 100113 AO #: AS 10-03 EVENT DATE: 11/08/2005
TITLE: Medical Event at Mercy St. Vincent Medical Center in Toledo, Ohio
NAME: Mercy St. Vincent Medical Center CITY: Toledo STATE: OH

Nature and Probable Consequences:

Mercy St. Vincent Medical Center (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed to receive a total dose of 160 Gy (16,000 rad) to the prostate using 67 iodine-125 seeds. Instead, the patient's sigmoid colon received at least the full prescription dose of 160 Gy (16,000 rad) and a significant portion of the bladder base including the region of the urethral orifices received at least 108 Gy (10,800 rad) (wrong treatment sites). The patient and referring physician were informed of this event.

On March 3, 2010, the Ohio Department of Health (ODH) performed an inspection of the licensee and noted that the licensee had not reported this medical event to the State and the NRC. The licensee had not identified the medical event as a reportable event and did not investigate it to determine a cause. Subsequently, the licensee reported the medical event to the NRC. The licensee confirmed that 13 of the permanent iodine-125 seeds were improperly positioned in the bladder and subsequently removed from patient's bladder immediately after the procedure. A post-implant dose calculation showed that the prostate received a dose of 15.43 Gy (1,543 rad), or 9.6 percent of the prescribed dose. The patient chose to then receive an external beam treatment with a linear accelerator to treat the tumor. About 13 months after the brachytherapy procedure, the patient developed rectosigmoid bleeding that required hospitalization and argon laser coagulopathy. In August 2010, ODH ordered an independent medical expert evaluation of the event. The independent medical expert concluded that the subsequent delivery of external beam radiotherapy have contributed to the rectosigmoid damage, but the high dose from the brachytherapy procedure almost certainly was the primary cause of the damage.

Cause:

The cause of the medical event was the failure of the licensee to adequately visualize the prostate prior to the implant procedure.

Licensee Action:

Corrective actions taken by the licensee included training of the RSO, medical physicist, clinical director, and radiation oncologist on ODH regulations concerning medical events. New procedures were also developed for brachytherapy seed implant procedure.

NRC Action:

Other Agency Action:

In March 2010, ODH conducted a special inspection of the licensee and issued an NOV. The NOV required the licensee to perform a self audit of all brachytherapy cases performed since November 2004, which revealed seven additional medical events that were not reported. In June 2010, an Adjudication Order and administrative penalty of \$25,000 were issued to the licensee.

Criteria:

Criterion III.C.1.b, III.C.2.a and III.C.2.b.(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads); and represents either a dose or dosage that is at least 50 percent greater than that prescribed; or is a prescribed dose delivered to the wrong treatment site.

ITEM #: 090565 AO #: AS 10-04 EVENT DATE: 03/20/2009
TITLE: Medical Event at Hoag Memorial Hospital Presbyterian in Newport Beach, California
NAME: Hoag Memorial Hospital Presbyterian CITY: Newport Beach STATE: CA

Nature and Probable Consequences:

Hoag Memorial Hospital Presbyterian (the licensee) reported that a medical event occurred associated with its GSR unit. A patient being treated for an acoustic neuroma was scheduled to receive between 11 and 18 Gy (1,100 and 1,800 rads) to an intended neuroma volume of 0.08 cm³ but, due to an unintended shift in the treatment volume of about 2 mm, only about one-half of the neuroma received the treatment dose and an adjacent temporal bone volume of 0.04 cm³ received the treatment dose (wrong treatment site). The other half of the neuroma received between 3 and 11 Gy (300 and 1,100 rads). The patient and physician were informed of this event.

The unintended shift in treatment volume occurred due to a misaligned fiducial marker (indicator) box during a CT scan used in the treatment planning process. The misalignment occurred because one alignment pin of four on the indicator box was not fully seated in the stereotactic frame attached to the patient's head, resulting in the indicator box not being correctly aligned. The alignment pin error was not detected until the conclusion of the treatment. The additional dose to the temporal bone because of alignment error is not expected to result in any significant adverse health effect to the patient.

Cause:

The medical event is believed to have been caused by human error in not ensuring the CT indicator box was properly installed at the time of the CT scan. It is not known if the improper installation occurred when the technologist positioned the indicator box in the stereotactic frame or whether the indicator box became misaligned during patient positioning in preparation for the CT scan.

Licensee Action:

The licensee has retrained all CT technologists concerning the proper placement of the CT indicator box. Also, because use of CT imaging for GSR treatment is infrequent (normally MRI is used), the licensee now requires that a GSR qualified medical physicist verify the placement of the CT indicator box immediately prior to all CT imaging that will be used for GSR treatment planning.

NRC Action:

Other Agency Action:

On June 22, 2009, the California Department of Public Health (CDPH) issued an NOV related to this event. Subsequently, CDPI received dosimetry information which they used to interpret the event as not meeting the AO criteria; however, CDPH was not certain of this determination and asked NRC for a final determination. On July 1, 2010, after the NRC Medical Radiation Safety Team (MSRT) had performed a careful analysis of the event along with the dosimetry data, NRC determined that the event met AO criteria.

Criteria:

Criterion III.C.1.b and III.C.2.b.(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that delivered to the wrong treatment site.

ITEM #: 100357 AO #: AS 10-05 EVENT DATE: 05/01/2005
TITLE: Medical Event at Marshfield Clinic in Marshfield, Wisconsin
NAME: Marshfield Clinic CITY: Marshfield STATE: WI

Nature and Probable Consequences:

In July 2010, the Marshfield Clinic (the licensee) reviewed all prostate brachytherapy cases performed under its license in the past 7 years. The review resulted in the identification of nine medical events involving permanent implants of iodine-125 for prostate brachytherapy where the total dose delivered differed from the prescribed dose by 20 percent or more, or another organ received at least 50 percent more dose than intended. The three medical events involved planned doses to the prostate of 120 Gy (12,000 rad), 160 Gy (16,000 rad), and 160 Gy (16,000 rad). The licensee assumes an identical planned dose to the urethra. However, these treatments resulted in actual doses to the urethra of 191.6 Gy (19,160 rad), 258.1 Gy (25,810 rad), and 242.6 Gy (24,260 rad), which were overdoses of 59.7, 61.3, and 51.6 percent, respectively. The licensee notified the affected patients and referring physicians.

The authorized user physicians had previously determined that patients would not suffer significant health effects for urethral doses below 400 Gy (40,000 rad). Because the urethra penetrates through the center of the prostate and the prostate itself is a small gland, a balance exists between reducing the dose to the urethra and delivering the prescribed dose to the prostate. The doses delivered to the patients in question were well within the 400 Gy (40,000 rad) urethral tolerance dose, and the licensee considers the treatments to be clinically acceptable.

Cause:

The licensee suspects that the implants deviated from their intended tracks after insertion into the prostate, causing the seeds to be deposited closer to the urethra.

Licensee Action:

Corrective actions included developing a procedure for ensuring that treatments were delivered in accordance with the written directive, planning treatments to D90 (minimum dose received by 90 percent of CT-defined prostate volume) values of 100-110 percent, using the same written directive form at each site that performs brachytherapy, increasing ultrasound and fluoroscopy visualization during prostate implants and providing additional training to personnel.

NRC Action:

Other Agency Action:

The Wisconsin Department of Health Services determined that Marshfield Clinic did not have a procedure for evaluating whether the dose delivered in a prostate brachytherapy treatment was in accordance with the written directive. In addition, the licensee did not have criteria for identifying a medical event for prostate brachytherapy. The licensee has been cited for several items of noncompliance.

Criteria:

Criterion III.C.1.b and III.C.2.a, "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than the bone marrow, the lens of the eye, or the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed.

ITEM #: 100219 AO #: AS 10-06 EVENT DATE: 03/15/2010
TITLE: Medical Event at Mary Bird Perkins Cancer Center in Baton Rouge, Louisiana
NAME: Mary Bird Perkins Cancer Center CITY: Baton Rouge STATE: LA

Nature and Probable Consequences:

Mary Bird Perkins Cancer Center (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed a total dose of 145 Gy (14,500 rad) to the prostate using iodine-125 seeds. Instead, the patient received a dose of 39.55 Gy (3,955 rad) to the rectum, 40.94 Gy (4,094 rad) to the urethra and 6 Gy (600 rad) to the bladder (wrong treatment sites). The patient and referring physician were informed of this event.

During the review of this event, the licensee determined that a positioning error occurred and the dose was delivered about 3.0 cm away from the targeted prostate gland. The estimated dose to the prostate gland was 12.88 Gy (1,288 rad). The licensee concluded that no significant adverse health effect to the patient is expected.

Cause:

The medical event was caused by patient movement between the time the planning images were obtained and the actual implantation of the seeds.

Licensee Action:

The licensee modified its procedure to insert the needles that hold the prostate in place prior to obtaining the ultrasound images instead of immediately before the seed needles are inserted. In addition, the sagittal image will be captured at the time of planning image acquisition and confirmed periodically throughout the case, and the radiation oncologist will personally confirm the location of the reference base prior to dispensing the first seed.

NRC Action:

Other Agency Action:

The Louisiana Department of Environmental Quality conducted an investigation, reviewed the licensee's corrective actions, and found the corrective actions to be adequate.

Criteria:

Criterion III.C.1.b, and III.C.2.b.(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and is a prescribed dose delivered to the wrong treatment site.

ITEM #: 100148 AO #: AS 10-07 EVENT DATE: 03/23/2010
TITLE: Medical Event at Mayo Clinic in Rochester, Minnesota
NAME: Mayo Clinic CITY: Rochester STATE: MN

Nature and Probable Consequences:

The Mayo Clinic (the licensee) reported a medical event associated with an HDR biliary treatment for liver carcinoma containing 329 GBq (8.9 Ci) of iridium-192. A patient was prescribed to receive four fractionated doses totaling 16 Gy (1,600 rad) to the liver. The treatment to the liver should have produced an estimated dose to the duodenum (wrong treatment site) of 1.2 Gy (120 rad) as a result of the event it received a dose of about 10 Gy (1,000 rad). The patient and referring physician were informed of this event.

During the second fractionated treatment, the measurement cable was inserted into the catheter and it was noted that it extended about 17 cm beyond the programmed treatment distance used during the first fractionated treatment. It was concluded that the measurement wire on the first treatment had met with some resistance at a tight bend and that it was not at the end of the catheter. This resulted in overdosing the duodenum (wrong treatment site). Upon discovery of the treatment distance error and overdose, licensee changed the written directive to add a fifth fractionated treatment to correct for the underdose of the liver. A lesser total dose to the liver was given because of concerns regarding the dose already received by the duodenum. The authorized user concluded that no chronic health effect to the patient is expected.

Cause:

The medical event was caused by human error in failing to verify that the correct catheter length was entered into the HDR unit.

Licensee Action:

The licensee committed to taking several corrective actions including the imaging of inserted catheters prior to treatments and performing catheter length checks prior to HDR treatments.

NRC Action:

Other Agency Action:

On April 6, 2010, the Minnesota Department of Health (MDH) staff performed a reactive inspection of the licensee's HDR program. The MDH approved the licensee's corrective actions and did not take enforcement action.

Criteria:

Criterion III.C.1.b, III.C.2.a and III.C.2.b.(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads); represents either a dose or dosage that is at least 50 percent greater than that prescribed; and is a prescribed dose delivered to the wrong treatment site.

ITEM #: 100400 AO #: NRC 10-01 EVENT DATE: 06/07/2010
TITLE: Human Exposure to Radiation at Tripler Army Medical Center in Honolulu, Hawaii
NAME: Tripler Army Medical Center CITY: Honolulu STATE: HI

Nature and Probable Consequences:

Tripler Army Medical Center (TAMC) (the licensee) reported that a female patient underwent a therapeutic administration of iodine-131 for thyroid ablation therapy. Prior to the treatment, the patient informed the licensee's staff that she was not pregnant and the licensee's staff administered a pregnancy test as a routine precaution. The pregnancy test yielded a negative result. Based on the negative pregnancy test results and the patient's interview responses, the licensee administered iodine-131 to the patient.

On July 8, 2010, the patient became aware that she was pregnant and informed the licensee and her physician. On August 3, 2010, an ultrasound was performed on the patient and a determination was made that the actual date of conception was June 1, 2010 (about 1 week pregnant at time of administration). The TAMC radiation safety officer (RSO) estimated the embryonic dose to be 41.27 cGy (41.27 rad) and concluded that the exposure of the embryo in the first 2 weeks following conception is not likely to result in malformation or embryo/fetal death despite the fact that the central nervous system and the heart are beginning to develop in the third week. NRC contracted with a medical consultant to perform an independent medical evaluation of this embryo/fetal overexposure event. The consultant's report agreed with TAMC conclusions with the exception that the medical consultant did not want to rule out the chance of embryo/fetal malformation.

Cause:

The cause of this event was the close proximity of conception, which resulted in a negative pregnancy test, to the administration of iodine-131.

Licensee Action:

The patient consent form has been updated to reflect that the pregnancy test may not show a positive result until the embryo has implanted, which may not occur until 7-10 days after conception. In future consultations, the clinic plans to ask the patient to refrain from any action that may lead to pregnancy during the period immediately prior to therapeutic radioisotope administration.

NRC Action:

NRC conducted an inspection on October 13-14, 2010, and concluded there were no violations of NRC requirements associated with this event.

Other Agency Action:

Criteria:

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides, in part, that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

ITEM #: 080896 AO #: NRC 10-02 EVENT DATE: 12/16/2008
TITLE: Medical Event at Chippenham & Johnston-Willis (CJW) Medical Center in Richmond, Virginia
NAME: Chippenham & Johnston-Willis (CJW) Medical Center CITY: Richmond STATE: VA

Nature and Probable Consequences:

Chippenham & Johnston-Willis (CJW) Medical Center (the licensee) reported a medical event with its gamma stereotactic radiosurgery (GSR) unit. A patient being treated for trigeminal neuralgia (inflammation of the nerve) was prescribed a treatment 40 Gy (4,000 rad) to the right trigeminal nerve but received the treatment dose to the left trigeminal nerve (wrong treatment site). The patient and referring physician were informed of this event.

The licensee noted that on the day of the treatment, the top portion of the written directive correctly documented the prescribed treatment site; however, while the staff was preparing the daily patient treatment log, it was inadvertently annotated that the dose was to be delivered to the left trigeminal nerve. This error was carried through by the medical physicist during preparation of the patient's treatment plan and completion of the bottom part of the written directive. Upon completion of the procedure and after reviewing the patient's file, the treatment team identified the inadvertent treatment of the left trigeminal nerve. The NRC contract medical consultant concluded that although no actual consequences resulted, an unlikely injury to the brain stem was possible due to high radiation dose to a tiny volume of the brain stem tissue and an increased risk of cataract formation.

Cause:

The cause of the medical event was the licensee's failure to have adequate procedures that verify the location of treatment sites and ensure that any inconsistencies in the written directives are resolved prior to administration.

Licensee Action:

The licensee revised their GSR treatment procedures to affirm that (1) a "Physician Order" will be the primary source of documentation of the treatment site and will accompany the patient through the entire course of the treatment, (2) the radiation oncologist and the neurosurgeon will independently verify and document the treatment site, (3) the nurse and the medical physicist will confirm that the treatment site identified by the radiation oncologist in the written directive and the neurosurgeon's "physician order" both match, (4) the neurosurgeon will mark the treatment site with ink in the presence of a nurse, and (5) a "Time-Out" process involving independent verification of the final treatment plan by each of the four members of the clinical team (who are required to sign-off their presence and acceptance of time-out in the presence of the patient before moving ahead with the treatment) will be used with the patient or the patient's authorized representative to confirm the treatment site.

NRC Action:

NRC initiated an inspection on December 18, 2008. NRC completed the inspection on November 30, 2009, and issued one Severity Level III violation to the licensee on January 21, 2010.

Other Agency Action:

Criteria:

Criterion III.C.1.b and III.C.2.b.(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that delivered to the wrong treatment site.

ITEM #: 090395 **AO #:** NRC 10-03 **EVENT DATE:** 01/19/2009
TITLE: Medical Event at Virtua Health System in Marlton, New Jersey
NAME: Virtua Health System **CITY:** Marlton **STATE:** NJ

Nature and Probable Consequences:

Virtua Health System (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed to receive a total dose of 145 Gy (14,500 rad) to the prostate using 93 iodine-125 seeds. Instead, the patient received an approximate dose of 12.2 Gy (1,220 rad) to the rectum (wrong treatment site). The patient and referring physician were informed of this event.

On January 19, 2009, the urologist inserted needles in the patient's prostate gland under transrectal ultrasound guidance while the radiation oncologist left the operating room to obtain the radioactive seeds. The licensee's staff (including the authorized medical physicist [AMP]) questioned the accuracy of prostate visualization prior to implantation of the seeds but took no action to resolve the question. On February 23, 2009, following a post-implant computed tomography (CT) scan, it was noted that some mispositioning of the sources occurred and the patient was notified that additional treatment may be necessary. On March 19, 2009, the AMP reviewed the case and determined that 100 percent of the seeds were implanted outside of the prostate, which received about 1 Gy (1,000 rad). NRC contracted with a medical consultant who concluded that although the probability of long-lasting negative health effects to the patient is low, an increased risk of impotency and fibrosis was possible due to the high radiation dose.

Cause:

The cause of the medical event was failure of the medical implant team to adequately visualize and identify the prostate prior to implant.

Licensee Action:

The licensee revised its policy and procedures to require that (1) all members of the implant team be present before the patient brought to the operating room and placed under anesthesia, (2) the AMP be included in the pre-implantation ultrasound, (3) the authorized user consult with the urologist before needle insertion, (4) both the radiation oncologist and the urologist agree on the positioning and the visualizing of the target anatomy, (5) any objection or question by an implant team member is cause for stop the implant and performing a review, and (6) the implant be stopped if there are any ultrasound image questions. The licensee's staff was also trained on the revised procedures, the definition and reporting requirements of a medical event, and the communication of any CT scan abnormalities or seed misplacement to the RSO.

NRC Action:

NRC initiated an inspection on March 20, 2009. NRC completed the inspection on August 26, 2009, and issued one Severity Level III violation to the licensee on October 21, 2009.

Other Agency Action:

Criteria:

Criterion III.C.1.b and III.C.2.b.(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that delivered to the wrong treatment site.

ITEM #: 090597 AO #: NRC 10-04 EVENT DATE: 03/05/2009
TITLE: Medical Event at Nanticoke Memorial Hospital, in Seaford, Delaware
NAME: Nanticoke Memorial Hospital CITY: Seaford STATE: DE

Nature and Probable Consequences:

Nanticoke Memorial Hospital (the licensee) reported that a medical event occurred involving a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed a total dose of 145 Gy (14,500 rad) to the prostate using 61 iodine 125 seeds. Instead, the patient received an approximate prostate dose of 26 Gy (2,600 rad) (18 percent of the prescribed dose) and a dose of 139 Gy (13,900 rad) to unintended tissue (wrong treatment site). The patient and referring physician were informed of this event.

The seeds were implanted under ultrasound guidance using an axial view; however, following the implant, the urologist performed cystoscopy to remove 22 of the seeds from the bladder. When the patient returned to the hospital for a post-implant CT scan, the images revealed that 32 seeds were displaced superiorly to the prostate and 7 seeds were implanted in the prostate. NRC contracted with a medical consultant who concluded that no significant adverse health effects to the patient were expected.

Cause:

The cause of the medical event was due to a miscalculation of the prostate depth in relation to the skin surface due to possible patient movement during the procedure.

Licensee Action:

The licensee revised its prostate implant procedure to include the use of both the axial and sagittal views of an ultrasound probe to determine prostate depth. In addition, the licensee revised its medical event policy to ensure timely reporting of medical events and to clearly state the parameters under which a medical event must be reported. The licensee provided training on the revised policy and procedures to its staff.

NRC Action:

NRC initiated an inspection on July 19, 2009. NRC completed the inspection on January 6, 2010, and issued one Severity Level 2 violation to the licensee on February 2, 2010.

Other Agency Action:

Criteria:

Criterion III.C.1.b and III.C.2.b.(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that was delivered to the wrong treatment site.

ITEM #: 090659 AO #: NRC 10-05 EVENT DATE: 08/05/2009
TITLE: Medical Event at Yale New-Haven Hospital, in New Haven, Connecticut
NAME: Yale New-Haven Hospital CITY: New Haven STATE: CT

Nature and Probable Consequences:

Yale New-Haven Hospital (the licensee) reported that a medical event occurred associated with its GSR unit. A patient being treated for brain metastases was prescribed 18 Gy (1,800 rad). However, while treating a patient earlier in the day, an equipment malfunction occurred with the GSR unit that resulted in a positioning shift of the x-axis by 4.5 mm. The positioning shift in the x-axis resulted in an underdose to the treatment site and an overdose to a wrong treatment site. The patient and physician were informed of this event.

The malfunction occurred following the treatment of the first patient on August 5, 2009. The automatic positioning system (APS) malfunctioned and, after discussion with the GSR manufacturer, the position error codes were cleared by the AMP. A second patient was treated for multiple brain metastases later that day. GSR service personnel noted on August 5, 2009, that the APS positioning was off by about 5 mm. After further evaluation, the manufacturer determined that a position shift (offset) occurred with licensee personnel accepted an error message concerning position deviation. NRC contracted with a medical consultant who concluded that no clinically significant side effects from radiation damage to the wrong treatment sites would be expected.

Cause:

The cause of the medical event was failure of licensee personnel to verify that the APS coordinates were in accordance with the written directive.

Licensee Action:

The licensee issued a memorandum to all personnel involved in GSR treatments to require visual verification of the physical coordinates against the electronic coordinates before the start and at the end of each treatment run. The licensee also retrained GSR personnel on the importance of fully understanding error conditions and reviewing unexpected errors with other staff involved in the treatment (e.g., radiation oncologist, AMP, etc.) prior to clearing any unexpected error.

NRC Action:

NRC initiated an inspection on August 13, 2009. NRC completed the inspection on April 7, 2010, and issued one Severity Level violation to the licensee on May 21, 2010.

Other Agency Action:

Criteria:

Criterion III.C.1.b and III.C.2.b.(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that delivered to the wrong treatment site.

ITEM #: 090662 AO #: NRC 10-06 EVENT DATE: 07/29/2009
TITLE: Medical Event at Valley Hospital in Paramus, New Jersey
NAME: Valley Hospital CITY: Paramus STATE: NJ

Nature and Probable Consequences:

Valley Hospital (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed a total dose of 65 Gy (6,500 rad) to the prostate using 46 cesium-131 seeds. Instead, the licensee determined that an unintended volume (30.1 ml) of soft tissue received 100 percent of the prescribed prostate dose. The patient and referring physician were informed of this event.

On August 6, 2009, the patient returned to the hospital for a post-implant CT scan. The images revealed that the seeds were implanted in soft tissue 4 to 5 cm from the prostate. Post-implant dosimetry calculations indicated that none of the prostate received the prescribed dose of 6,500 cGy (6,500 rad). NRC contracted with a medical consultant who concluded that the additional dose can increase the risk of soft tissue fibrosis or increase the risk of impotency.

Cause:

The cause of the medical event was the licensee's failure to identify the position of the prostate due to the patient's unusual anatomy and obesity.

Licensee Action:

The licensee revised their prostate implant procedures to include steps to ensure that the prostate and surrounding anatomy is adequately visualized prior to implant.

NRC Action:

NRC initiated an inspection on August 13, 2009. NRC completed the inspection on October 29, 2009, and determined that no violations of NRC requirements occurred.

Other Agency Action:

Criteria:

Criterion III.C.1.b and III.C.2.b.(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that delivered to the wrong treatment site.

ITEM #: 100082 AO #: NRC 10-07 EVENT DATE: 01/18/2010
TITLE: Medical Event at Christiana Care Health Center in Wilmington, Delaware
NAME: Christiana Care Health Center CITY: Wilmington STATE: DE

Nature and Probable Consequences:

Christiana Care Health Center (the licensee) reported that a patient was prescribed a high dose-rate (HDR) mammosite (brachytherapy) multi-lumen catheter treatment of 34 Gy (3,400 rad) over a 5 day period to the left breast. The patient received an average dose of 17 Gy (1,700 rad) to 100 cm³ of unintended breast tissue; 68 Gy (6,800 rad) to 7.5 cm³ of unintended skin and underlying tissue; and 3.4 Gy (340 rad) to 35 cm³ of intended breast tissue. The patient and referring physician were informed of this event.

On February 22, 2010, during a follow-up examination, the patient complained about skin reddening on the external breast. In reviewing the treatment plan, it was discovered that the AMP performed measurements using a source position simulator (SPS) measurement tool following a CT scan to determine the treatment distance for each catheter. The catheter distances were recorded and confirmed with two manufacturer representatives that were present at the time of the treatment. However, it was noted that an incorrect measurement caused the placement of the radioactive source 10 cm proximal to the intended position. The NRC-contracted medical consultant concluded that the dose that was administered to the unintended left breast tissue is unlikely to result in any significant or unusual adverse effect. However, a significant risk exists that local tumor recurrence could occur if additional intervention is not performed.

Cause:

The cause of the medical event was human error in the failure to identify that the measurement tool was functioning improperly and to identify an incorrect measurement distance.

Licensee Action:

The licensee revised its procedures for HDR brachytherapy to require a doublecheck of all patient measurements, a daily and monthly quality assurance requirement to confirm that the SPS tool is functioning properly, and a process to ensure that all members of the treatment team agree on the specifics of the treatment. In addition, the licensee acquired a new SPS tool, developed and posted a reference table at the HDR control console, provided training on revised procedures to staff involved in the HDR program (to be repeated annually), and implemented a "New Product" committee to review all new product plans.

NRC Action:

NRC conducted an inspection on July 12, 2010, and issued one Severity Level III violation to the licensee on August 24, 2010.

Other Agency Action:

Criteria:

Criterion III.C.1.b and III.C.2.b.(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that was delivered to the wrong treatment site.

ITEM #: 100448 AO #: NRC 10-08 EVENT DATE: 08/30/2010
TITLE: Medical Event at Providence Hospital in Novi, Michigan
NAME: Providence Hospital CITY: Novi STATE: MI

Nature and Probable Consequences:

Providence Hospital (the licensee) reported that a medical event occurred associated with an anal brachytherapy treatment using 32 seeds containing iodine-125. The intended dose was 90 Gy (9,000 rad) to the tumor. Instead, the patient's seminal vesicle received 19.79 Gy (1,979 rad) more than intended and the bladder received 3.68 Gy (368 rad) more than intended. The patient and referring physician were informed of this event.

On September 1, 2010, a follow-up CT scan showed that the permanent implants had been inserted about 4 cm from the intended location. The licensee reported that the tumor near the anus and rectum received a maximum dose of 8 Gy (800 rad). The licensee calculated the dose difference to the surrounding tissue as a result of the improper permanent implant placement. The licensee concluded that no significant adverse health effect to the patient is expected.

Cause:

The licensee determined that the cause of the event was that they did not use tissue markers to confirm source placement and the insertion needle did not have a visible mark to ensure proper depth placement.

Licensee Action:

Procedures were modified to administer sources as prescribed in the written directive as follows: (1) any interstitial procedure that requires the use of fluoroscopy alone will be done with the use of tissue markers to confirm source placement, and (2) interstitial procedures that use fluoroscopy alone will have needle depth verified. The licensee completed training of licensee staff on the event and the corrective actions by October 1, 2010.

NRC Action:

Region III reviewed and concurred on the licensee's corrective actions. NRC has retained the services of an independent medical consultant to determine if any significant health effects to the patient are expected.

Other Agency Action:

Criteria:

Criterion III.C.1.b and III.C.2.b.(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that was delivered to the wrong treatment site.

ITEM #: 110073 **AO #:** NRC 11-01 **EVENT DATE:** 01/12/2011
TITLE: Human Exposure to Radiation at Portsmouth Naval Medical Center in Portsmouth, Virginia
NAME: Portsmouth Naval Medical Center **CITY:** Portsmouth **STATE:** VA

Nature and Probable Consequences:

The Department of the Navy (the licensee) reported that a female patient at the Naval Medical Center in Portsmouth, Virginia (NMCP), received 3,630 MBq (98 mCi) of iodine-131 for thyroid ablation therapy. On the day of the treatment the patient informed NMCP staff that she was not pregnant and NMCP staff administered a pregnancy test as a routine precaution. The pregnancy test yielded a negative result. Based on the negative pregnancy test results and the patient's interview responses, NMCP staff administered iodine-131 to the patient.

On January 27, 2011, the patient became aware that she was pregnant and informed the physician who had administered the treatment. An obstetrician estimated that conception had occurred somewhere around January 7-10, 2011, and that a pregnancy test administered on January 12, 2011, would not have been sensitive enough to produce a positive result. NMCP estimated the dose to the embryo to be 21.3 cGy (21.3 rem) and notified the Naval Radiation Safety Committee that the patient may have been pregnant before the therapy. NMCP staff estimated a slight increased risk of early pregnancy failure and this was discussed with the patient. NMCP staff subsequently refined the dose estimate to 24.7 cGy (24.7 rem). The NRC contracted with a medical consultant who estimated a fetal/embryo dose of 27 cGy (27 rem) and stated that embryonic tissue capable of concentrating iodine-131 is not formed until 10 to 12 weeks of gestation; therefore, the tissue had not yet formed at the time of the treatment. The medical consultant concluded that there was a low possibility of carcinogenesis or malformations.

Cause:

The cause of this event was the close proximity of conception, which resulted in a negative pregnancy test result, to the administration of the iodine-131.

Licensee Action:

NMCP revised the initial consultation procedures for the prescribing physician to stress the importance of discussing with the patient the need for sexual abstinence at least 10 days before therapeutic dose administration.

NRC Action:

The NRC conducted an inspection on February 2, 2011 through June 2, 2011, and there were no violations of NRC requirements associated with this event.

Other Agency Action:

Criteria:

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides, in part, that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

ITEM #: 110305 AO #: AS 11-01 EVENT DATE: 09/22/2006
TITLE: Human Exposure to Radiation at Montefiore Medical Center in New York City, New York
NAME: Montefiore Medical Center CITY: New York STATE: NY

Nature and Probable Consequences:

Montefiore Medical Center (the licensee) reported that a female patient received 3,519 MBq (95 mCi) of iodine-131 for thyroid ablation therapy. Before the treatment, the licensee interviewed the patient and ascertained that she was not pregnant. The licensee's staff administered a pregnancy test as a routine precaution. The pregnancy test yielded a negative result. Based on the negative pregnancy test results and the patient's interview responses, the licensee administered iodine-131 to the patient.

On December 22, 2006, the patient returned to the licensee for a followup visit. Following that visit, the nuclear medicine department staff was informed by another section of the medical center that the patient was pregnant. The licensee confirmed the pregnancy with the patient's obstetrician/gynecologist. The ultrasound performed by the patient's obstetrician/gynecologist revealed that the patient was approximately 2-3 weeks pregnant at the time of the iodine-131 treatment. The licensee estimated that the fetus received about 25 cGy (25 rem) of radiation exposure and stated that embryonic tissue capable of concentrating iodine-131 is not formed until 10 to 12 weeks of gestation; therefore, this tissue had not yet fully formed at the time of the treatment. The patient was advised to see a genetic specialist to discuss the possible consequences to the fetus from this exposure. Although the licensee claimed that it had originally reported the event to the New York City Office of Radiological Health in 2006, the office had no record of the report. The New York City Office of Radiological Health identified the missing report in April 2011, and subsequently notified the NRC on June 15, 2011.

Cause:

The cause of this event was the close proximity of conception to the iodine-131 treatment and a false negative result on a pregnancy test done before the administration of the treatment.

Licensee Action:

The licensee's corrective actions included additions to its Safety Precaution Form stressing the necessity of sexual abstinence before the treatment and recommending that patients also take precautions to avoid getting pregnant for 6 months after the treatment.

NRC Action:

Other Agency Action:

The New York City Office of Radiological Health conducted an inspection on June 16, 2011, and determined that the licensee had followed acceptable protocols before the administration of iodine-131. Consequently no civil penalties or enforcement action for event are warranted.

Criteria:

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides, in part, that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

ITEM #: 110504 AO #: AS 11-02 EVENT DATE: 09/12/2011
TITLE: Human Exposure to Radiation at Caribbean Inspection & NDT Services, Inc., in Port Lavaca, Texas
NAME: Caribbean Inspection & NDT Services, Inc. CITY: Port Lavaca STATE: TX

Nature and Probable Consequences:

Caribbean Inspection & NDT Services Inc. (the licensee) reported that a radiographer trainee received an overexposure to his right hand and was seeking medical attention. The radiographer trainee stated that on September 12, 2011, while conducting radiography operations in the field, he removed a radiography camera guide tube from the Amersham 660 D radiography camera. The radiographer trainee stated that he noticed the 2.7 TBq (73 Ci) iridium-192 source was not fully retracted and protruding from the camera about 2 inches. The radiographer trainee stated that he may have brushed the source with his hand when he removed the guide tube.

On September 19, 2011, the radiographer trainee presented himself to a Houston, Texas hospital with observable deterministic effects, which included blistering of the thumb, index and middle fingers. These types of effects correspond to an exposure range of 20 - 40 Sv (2000 to 4000 rem) to the extremities. His doctors initially conferred with the Radiation Emergency Assistance Center/Training Site in Oak Ridge, Tennessee regarding his medical treatment. The trainee is continuing his treatment at the Houston, Texas hospital as an out-patient. The licensee stated that the results of the trainee's dosimeter indicated that he received 14.1 mSv (1.41 rem) whole body exposure based on the film badge he was wearing at the time of the event.

Cause:

The State of Texas is currently investigating the cause of this event.

Licensee Action:

The licensee is conducting an investigation to determine the exact nature and cause of this event. Pending the results of this investigation the licensee will determine corrective action and inform the State of the circumstances of the event and the correct actions.

NRC Action:

Other Agency Action:

Texas Department of State Health Services, Radiation Control Program is currently investigating this incident, which includes collecting information from the physicians, the licensee, and the individuals involved in the event. Pending the results of this investigation and the depositions performed through the General Counsel, the Texas Department of State Health Services will determine the probable causes of the event and review the licensee's corrective actions and consider what, if any, civil penalties and enforcement actions to pursue.

Criteria:

Criterion I.A.1, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides, in part, that any unintended radiation exposure to an adult resulting in an annual shallow dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more shall be considered for reporting as an AO.

ITEM #: 110363 AO #: AS 11-03 EVENT DATE: 07/19/2011
TITLE: Stolen Radiography Camera at Acuren Inspection, Inc., in La Porte, Texas
NAME: Acuren Inspection, Inc. CITY: La Porte STATE: TX

Nature and Probable Consequences:

Acuren Inspections Inc. (the licensee) reported the theft of a radiography camera containing 1.25 GBq (33.7 Ci) of iridium-192. On July 19, 2011, the licensee discovered that their radiography truck had been broken into, and the radiography camera, associated equipment, and portable generator had been stolen. The alarm system on the truck was then tested and determined to be operational; however, the alarm had not been set at the time of the theft. Attempts to locate the camera included the use of portable radiation detection equipment on vehicles, Austin Police Department/6 Civil Support Team helicopter flyovers of the area, and a Department of Energy fly-over survey between the cities of Austin and San Antonio, using a fixed wing plane.

It should be noted that at the time this event was reported to the NRC, the radioactive material in the camera was at a level considered to be risk-significant. However, as of October 1, 2011, the radioactive material had decayed to a level considered to be risk-significant. The radioactive source has not been recovered at the time of this report.

Cause:

Licensee failure to use the vehicle alarm system.

Licensee Action:

The licensee conducted a company-wide review of the incident with all employees, inspected all their trucks to verify the alarm systems were operating, and required all employees to view a video that showed the proper way to lock and secure radioactive material.

NRC Action:

Other Agency Action:

The Texas Department of State Health Services conducted an inspection on July 21, 2011 and determined that radiographer had failed to activate the alarm system on the truck containing the radiography camera. The licensee and the radiographers involved were cited for the violation.

Criteria:

Criterion I.C.2, "Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach" of Appendix A to this report provides, in part, that any substantiated case of actual theft or diversion of licensed, risk-significant radioactive sources, shall be considered for reporting as an AO.

ITEM #: 090391 AO #: AS 11-04 EVENT DATE: 02/23/2009
TITLE: Medical Event at Western Pennsylvania Hospital in Allegheny, Pennsylvania
NAME: Western Pennsylvania Hospital CITY: Allegheny STATE: PA

Nature and Probable Consequences:

Western Pennsylvania Hospital (the licensee) reported that a medical event occurred associated with a high-dose-rate (HDR) mammosite treatment for breast cancer; the treatment consisted of 184.2 GBq (4.9 Ci) of iridium-192. The patient was prescribed to receive 34 Gy (3,400 rad) in 10 fractionated doses, but instead, received a dose of 50 Gy (5,000 rad) to the skin tissue around the catheter entry point (wrong treatment site). The patient's physicist notified the patient and the referring physician of this event.

Before starting the treatment on February 23, 2009, the medical staff performed a check to verify the catheter length and treatment calculations. In addition, the treatment procedure required daily CT scans to verify the treatment site. On February 27, 2009, a different therapy physicist identified a potential error in the patient's chart and contacted the patient's physicist. On March 3, 2009, the patient's physicist checked the other therapy physicist's findings and discovered there had been a 3 cm error in the placement of the source during treatment. This incorrect distance resulted in the intended site receiving only 30 percent of the intended dose and the skin tissue receiving the full dose. The patient received followup care for erythema of the skin tissue and the licensee concluded that this medical event would not have a significant medical effect on the patient.

Cause:

The medical event was caused by human error in the placement of the source during treatment.

Licensee Action:

The licensee revised all mammosite policies and procedures to strengthen the accuracy of measurement, planning, treatment, and quality control. Specifically, the licensee modified the mammosite worksheet to add the expected catheter length beside the block where the measured catheter length is recorded, and required that the catheter measurement wire be kept in place during CT simulation following catheter measurement.

NRC Action:

Other Agency Action:

The Pennsylvania Department of Environmental Protection investigated the incident on March 18, 2009 and determined that the licensee's corrective actions were adequate. No enforcement action was taken and the State forwarded the final update of the event to the NRC on November 14, 2011.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

ITEM #: 100085 **AO #:** AS 11-05 **EVENT DATE:** 01/21/2010
TITLE: Medical Event at the University of Pennsylvania in Philadelphia, Pennsylvania
NAME: University of Pennsylvania **CITY:** Philadelphia **STATE:** PA

Nature and Probable Consequences:

University of Pennsylvania (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed to receive a total dose of 145 Gy (14,500 rad) to the prostate using 65 iodine-125 seeds. Instead, the seeds were inadvertently placed outside the intended treatment site (wrong treatment site). The patient received an approximate dose of 161 Gy (16,100 rad) to the penile bulb (glans) (wrong treatment site). The patient and referring physician were informed of this event.

On January 21, 2010, the iodine-125 seeds were implanted in the patient's prostate using real time dosimetry under ultrasonic guidance. The written directive called for a therapeutic radiation dose of 145 Gy (14,500 rad) to the prostate volume, plus 5 mm margin. On February 23, 2010, the patient returned for a 30 day post implant CT scan, which revealed that the implanted seeds were "in an appropriate pattern," but outside the intended target volume, which resulted in unintended dose to the penile bulb (glans). The licensee concluded that the medical event would not have a significant medical effect on the patient.

Cause:

The medical event is presumed to have been caused by misuse of a new ultrasound unit.

Licensee Action:

The licensee's Radiation Oncology Department suspended all prostate brachytherapy treatments pending an additional quality assurance review. Upon completion of the quality assurance review, the licensee modified its prostate brachytherapy treatment procedures. As of January 2012, the licensee has not yet resumed prostate brachytherapy treatments after implementation of the modified procedures.

NRC Action:

Other Agency Action:

The Pennsylvania Department of Environmental Protection investigated the incident on April 15, 2010 and determined that the licensee's corrective actions were adequate. No enforcement action was taken and the State forwarded the final update of the event to the NRC on November 14, 2011.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

ITEM #: 100074 AO #: AS 11-06 EVENT DATE: 02/14/2010
TITLE: Medical Event at University Community Hospital in Tampa, Florida
NAME: University Community Hospital CITY: Tampa STATE: FL

Nature and Probable Consequences:

University Community Hospital (the licensee) reported that two patients were prescribed single-channel HDR brachytherapy treatments of 34 Gy (3,400 rad). An actual average dose of 17 Gy (1,700 rad) to the first patient, and 26 Gy (2,600 rad) to the second patient, were delivered to the target area of the breast, and some parts of the planned volume received greater than 700 percent (first patient) and 220 percent (second patient) of the prescribed dose. In addition, other areas of the breast not in the target region received up to 136 Gy (13,600 rad) in the first patient and 75 Gy (7,500 rad) in the second patient. The maximum skin dose was calculated to be 42.5 Gy (4,250 rad) to the first patient and 75 Gy (7,500 rad) to the second patient. The patients and their referring physicians were informed of the events.

On February 14, 2010, the licensee noted that the source within the mammosite catheter was erroneously positioned approximately 2 to 2.5 cm away from the tumor. This was the result of the operator entering the wrong dwell position into the planning system. The licensee concluded that no significant adverse health effects to the patients are expected.

Cause:

The cause of the medical events was human error involving entering the wrong position of the reference end of the catheter into the planning system.

Licensee Action:

Corrective actions included implementing various quality assurance steps to ensure that the correct treatment calculations and data are used for future treatments. Additional procedural guidance will be created with detailed instructions.

NRC Action:

Other Agency Action:

The Florida Bureau of Radiation Control initiated an inspection on February 18, 2010. The State completed the inspection on March 1, 2010, and determined that the licensee's corrective actions were adequate. No enforcement action was taken and the State forwarded the final update of the event to the NRC on February 1, 2011.

Criteria:

Criteria III.C.1.b, III.C.2.a and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads), and represents a dose or dosage that is at least 50 percent greater than that prescribed or is delivered to the wrong treatment site.

ITEM #: 100118 AO #: AS 11-07 EVENT DATE: 03/11/2010
TITLE: Medical Event at Coral Springs Clinic in Coral Springs, Florida
NAME: Coral Springs Clinic CITY: Coral Springs STATE: FL

Nature and Probable Consequences:

Coral Springs Clinic (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for basal cell carcinoma of the ear. The patient was prescribed 14 fractionated doses of 2.5 Gy (250 rad) to the ear, but instead, the patient received 22.5 Gy (2,250 rad) on the second fractionated treatment dose. The patient and referring physician were informed of this event.

While starting the treatment the radiation therapist accidentally pushed the incorrect button on the HDR device, which was the "radiography" button rather than the "treatment" button on the machine control console. This resulted in the patient receiving approximately 9 times the intended dose for that fraction of the treatment. Further treatments were canceled. The patient and doctor were notified of the incident. The licensee concluded that no significant health effects to the patient are expected as a result of the incorrect dose.

Cause:

The medical event was caused by human error in that the radiation therapist failed to push the correct button on the HDR device.

Licensee Action:

The licensee immediately disabled the autoradiograph function on the HDR and other similar devices. The licensee modified its procedures to include the use of an independent mechanical timer and provided additional training to its entire clinical staff.

NRC Action:

Other Agency Action:

The Florida Bureau of Radiation Control initiated an inspection on April 27, 2010 and determined that the licensee's corrective actions were adequate. No enforcement action was taken and the State forwarded the final update of the event to the NRC on October 10, 2011.

Criteria:

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

ITEM #: 100388 AO #: AS 11-08 EVENT DATE: 04/23/2010
TITLE: Medical Event at Rhode Island Hospital in Providence, Rhode Island
NAME: Rhode Island Hospital CITY: Providence STATE: RI

Nature and Probable Consequences:

Rhode Island Hospital (the licensee) reported that a medical event occurred during a thyroid diagnostic uptake scan. The patient was prescribed to receive 7.4 MBq (200 µCi) of iodine-123, but was administered 148 MBq (4 mCi) of iodine-131. The administration resulted in a dose of approximately 3,108 cGy (3,108 rad) to the patient's thyroid, rather than the estimated 7 cGy (rad) that would have resulted from the iodine-123 administration. The patient and referring physician were informed of this event

The patient's physician handed the patient a written prescription for the iodine-123 scan, but the physician's office faxed an incorrect order to the hospital for an iodine-131 scan. On April 23, 2010, the patient presented the correct written prescription slip for the iodine-123, to the licensee's admitting receptionist. The receptionist refused the written prescription, because she thought the hospital already had the correct prescription in its records. The patient was administered the iodine-131, and the whole body scan was performed. The nuclear medicine technologist noticed something was wrong based on the scan results. The impact of this event on the patient was not reported by the licensee.

Cause:

The cause of this medical event was human error and failure of the licensee staff to follow existing written procedures and protocols.

Licensee Action:

The licensee reviewed existing written protocols and training procedures used for the nuclear medicine technologists. The licensee's corrective actions included modifying the procedures and conducting refresher training for the nuclear medicine technologists. In addition, the licensee developed a thyroid interview and patient assessment history sheet and now requires a pathology report for all thyroid cancer patients before iodine-131 doses are administered.

NRC Action:

Other Agency Action:

The Rhode Island Department of Health, Radiation Control Program, conducted an investigation of this medical event on April 3 through May 20, 2010, and issued an NOV to the licensee. The Rhode Island Department of Health also issued a regulatory citation regarding the licensee's failure to follow established procedures and forwarded the final update of the event to the NRC September 2011.

Criteria:

Criteria III.C.1.b and III.C.2.b(i), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dose rate that uses the wrong radiopharmaceutical.

ITEM #: 100294 AO #: AS 11-09 EVENT DATE: 05/04/2010
TITLE: Medical Event at Lovelace Medical Clinic in Albuquerque, New Mexico
NAME: Lovelace Medical Clinic CITY: Albuquerque STATE: NM

Nature and Probable Consequences:

The Lovelace Medical Clinic (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for endometrial carcinoma; the treatment consisted of 129.7 GBq (3.5 Ci) of iridium-192. The patient was prescribed to receive a total dose of 21 Gy (2,100 rad) in three fractionated doses to the vaginal cuff, but instead, the skin tissue on the patient's thigh received 30.6 Gy (3,060 rad). The patient and referring physician were informed of this event.

On May 4, 2010, the patient received the third fractionated dose of 7 Gy (700 rad) and, 1 week later, noticed the appearance of somewhat painful dark spots on the skin of her thigh. On May 18, 2010 the patient notified the licensee of the appearance of the spots on her skin and was examined by the prescribing physician the next day. The prescribing physician did not diagnose the spots as radiation erythema at this time, but asked the patient to return for a followup examination approximately a week later. On May 26, 2010, the physician identified two circular areas with a diameter of approximately 1 cm, which were determined to be radiation erythema. The average skin dose to the patient's thigh was calculated to be 30.6 Gy (3,060 rad) and the thigh dose at depth of 2.5 cm was calculated to be 4.08 Gy (408 rad). The licensee concluded that no long-term medical effects are expected for the patient.

Cause:

The medical event was caused by either improper placement or workers inadvertently moving the catheter while adjusting the patient for better alignment with the treatment device.

Licensee Action:

The licensee revised its procedures to ensure that the catheter is correctly positioned before the start of the treatment. In addition, the licensee required staff training to address the procedure updates.

NRC Action:

Other Agency Action:

The New Mexico Radiation Control Bureau is conducting a long-term investigation of the event and the licensee's corrective actions and is still considering what, if any, enforcement actions to pursue.

Criteria:

Criteria III.C.1.b, and III.C.2.b(iii), "For Medical Licensees," 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 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and is a prescribed dose delivered to the wrong treatment site.

ITEM #: 100314 AO #: AS 11-10 EVENT DATE: 06/03/2010
TITLE: Medical Event at Lancaster General Hospital in Lancaster, Pennsylvania
NAME: Lancaster General Hospital CITY: Lancaster STATE: PA

Nature and Probable Consequences:

Lancaster General Hospital (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for ovarian cancer; the treatment consisted of 310.8 GBq (8.4 Ci) of iridium-192. The patient was prescribed to receive 7.2 Gy (7 rad) in five fractionated doses, but instead during one of the fractionated treatments received a dose of 19 Gy (1,900 rad) to the small bowel (wrong treatment site). The patient and referring physician were informed of this event.

On June 15, 2010, before starting the second treatment, the medical staff noted that an incorrect target area had been previously entered into the HDR device for the first treatment on June 3, 2010. The medical staff noted that the intended treatment area in written directive differed from the actual area treated by approximately 3 cm. This error in treatment area resulted in a dose of 19 Gy (1,900 rad) to the small bowel. The licensee concluded that the medical event would not have a significant medical effect on the patient.

Cause:

The medical event was caused by human error in that the licensee entered the incorrect target area into the HDR device.

Licensee Action:

The licensee implemented corrective measures including procedure modifications to discontinue using the part of the HDR software that allows for treatment offsets to occur.

NRC Action:

Other Agency Action:

The Pennsylvania Department of Environmental Protection investigated the incident on June 21, 2010 and determined that the licensee's corrective actions were adequate. No enforcement action was taken and the State forwarded the final update of the event to the NRC on November 14, 2011.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide, in part, that a medical event shall be considered for reporting as an AO if it results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or doses that is delivered to the wrong treatment site.

ITEM #: 100397 AO #: AS 11-11 EVENT DATE: 07/06/2010
TITLE: Medical Event at the Greater Baltimore Medical Center in Baltimore, Maryland
NAME: Greater Baltimore Medical Center CITY: Baltimore STATE: MD

Nature and Probable Consequences:

The Greater Baltimore Medical Center (the licensee) reported that a medical event occurred associated with a manual brachytherapy treatment for cervical cancer. The patient was prescribed to receive 35 Gy (3,500 rad) to the cervix over the course of 73 hours using 1.635 GBq (44.2 mCi) of cesium-137. While the sources were being inserted into the patient, one of the cesium-137 sources fell out of the Fletcher-Suit applicator and into the patient's hospital gown. Consequently, the skin tissue on the patient's buttocks received a dose of 10.5 Gy (1,050 rad) from the errant source. The patient and referring physician were informed of this event.

Sometime after the sources had been inserted into the patient, the patient removed the hospital gown, folded it, placed it with the trash, and donned a clean gown. On July 9, 2010, the oncologist and medical physicist removed the sources from the patient and discovered that one of the six sources was missing. The oncologist and radiation safety officer subsequently located the source wrapped in the soiled hospital gown in a bag designated for radioactive waste. The source was retrieved and transported back to the Radiation Oncology Department's source storage room. The licensee noticed no erythema of the patient's skin and concluded that no clinically significant side effects would be expected from the radiation exposure to the skin.

Cause:

The cause of the medical event was the failure of the source attachment to the applicator, coupled with failure of the licensee to establish appropriate procedures to prevent the occurrence of the medical event.

Licensee Action:

The licensee plans to discontinue the use of the Fletcher-Suit applicator used during this treatment and exclusively use the Fletcher-Suit-Delclos applicator. The licensee also plans to revise procedures for brachytherapy applicators and provide improved training to the staff.

NRC Action:

Other Agency Action:

The Maryland Department of the Environment, Radiological Health Program conducted an investigation on July 27, 2010 and August 18, 2010. On October 18, 2010, the Department issued a letter and NOV to the licensee and forwarded the final update of the event to the NRC in July 2011.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

ITEM #: 100457 **AO #:** NRC 11-03 **EVENT DATE:** 08/04/2008
TITLE: Medical Event at the G.V. (Sonny) Montgomery VA Medical Center in Jackson, Mississippi
NAME: G.V. (Sonny) Montgomery VA Medical Center **CITY:** Jackson **STATE:** MS

Nature and Probable Consequences:

The U.S. Department of Veterans Affairs (the licensee) reported that a medical event involving prostate cancer brachytherapy seed implants occurred at the G.V. (Sonny) Montgomery VA Medical Center in Jackson, Mississippi. The patient was prescribed to receive a total dose of 145 Gy (14,500 rad) to the prostate using 104 iodine-125 seeds. However, the seed placement resulted in an approximate dose of 233 Gy (23,300 rad) to the patient's rectum (wrong treatment site). The patient and referring physician were informed of this event.

In September 2010, the medical center staff completed a followup comprehensive external review and reanalysis of posttreatment dose parameters for all prostate seed implants performed at the G.V. (Sonny) Montgomery VA Medical Center for the period between February 2005 and August 2008. Upon an evaluation of the updated dose information generated by external review, medical center staff, working with the National Health Physics Program, discovered this event. No adverse effect to the patient is expected from the implant procedure, and the licensee continues to monitor the progress of the patient.

Cause:

The cause of the medical event was an anatomical anomaly of the patient. The patient had an unusually thin tissue layer between the prostate gland and rectum, which resulted in a small area of the rectum receiving a higher than expected dose.

Licensee Action:

The U.S. Department of Veterans Affairs, working with the National Health Physics Program and the medical center's staff, performed an initial review of all prostate brachytherapy seed implant procedures for the period between February 2005 and August 2008. The initial review of this program resulted in the suspension of and eventual termination of the medical center's prostate brachytherapy implant program in August 2009. The followup comprehensive external review and reanalysis of the program identified this event, which the medical center reported to the licensee and the NRC.

NRC Action:

In August 2010, the NRC issued an NOV and Proposed Imposition of Civil Penalties to the licensee, based on the results of the initial evaluation and analysis of several events associated with the licensee's prostate brachytherapy implant program. The licensee was cited for failure to have adequate written procedures and failure to verify that the administered doses were in accordance with written directives. The NRC has not taken any additional actions based on the identification of this event.

Other Agency Action:

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

ITEM #: 100506 AO #: NRC 11-04 EVENT DATE: 10/06/2010
TITLE: Medical Event at Community Hospitals of Indiana in Indianapolis, Indiana
NAME: Community Hospitals of Indiana CITY: Indianapolis STATE: IN

Nature and Probable Consequences:

Community Hospitals of Indiana (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for breast cancer; the treatment consisted of 340.4 GBq (9.2 Ci) of iridium-192. The patient was prescribed to receive total dose of 34 Gy (3,400 rad) in 10 fractionated doses to the postsurgical cavity in the left breast following excision of a cancer tumor (treatment site). It was determined that the first eight treatment fractions resulted in a portion of the treatment site receiving dose of 266 Gy (26,600 rad). In addition, a portion of the patient's skin on the left breast and the chest muscle tissue (tissue other than the treatment site) received doses of 105 Gy (10,500 rad) and 1,002 Gy (100,200 rad), respectively. The patient and referring physician were informed of this event.

On October 6, 2010, following the eighth fractionated treatment dose, an error was discovered in the treatment plan by the medical physicist who remembered that he had not changed a default entry in the treatment planning system. This error caused the source placement to be flipped 180 degrees along the applicator's long axis which resulted in a portion of the treatment site at the tip of the applicator receiving less than the prescribed dose, and a portion of the treatment site at the connector end of the applicator receiving more than the prescribed dose. The licensee concluded that no long-term medical effects are expected for the patient. The NRC contracted with a medical consultant who determined that the overall impact to the patient is minimal.

Cause:

The medical event was caused by human error in that the medical physicist failed to change a default entry in the treatment planning system as required by the licensee's procedure.

Licensee Action:

The licensee revised its written directive form to remind staff to change the default entry in the treatment planning system as applicable, added a step to its procedure for multicatheter HDR breast treatments to verify that the default was changed as applicable, and trained its staff on the revised written directive form. In addition, the licensee evaluated all of the other HDR breast treatments that were conducted in 2010 to verify that the applicators were accurately reconstructed in the treatment planning computer.

NRC Action:

The NRC conducted a reactive inspection on October 18-20, 2010, with continued inoffice review through January 18, 2011, and issued two NOVs to the licensee on March 1, 2011 and April 20, 2011 respectively.

Other Agency Action:

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

ITEM #: 100543 AO #: AS 11-12 EVENT DATE: 10/26/2010
TITLE: Medical Event at Cleveland Clinic Foundation in Cleveland, Ohio
NAME: Cleveland Clinic Foundation CITY: Cleveland STATE: OH

Nature and Probable Consequences:

The Cleveland Clinic Foundation (the licensee) reported, to the Ohio Department of Health (ODH) that a medical event occurred associated with a radioembolization brachytherapy treatment for liver cancer; the treatment consisted of 3.96 GBq (107 mCi) of yttrium-90. A postprocedure scan of the patient identified significant undesired activity in the duodenum (wrong treatment site). The licensee estimated that approximately 0.37 GBq (10 mCi) of activity was present in the duodenum, with a dose to the duodenum approximately 90 Gy (9,000 rad). The patient and physician were informed of this event.

Approximately 3 weeks before the therapy, the patient was scanned for extra hepatic shunting by injecting technetium-99m into hepatic artery. No shunting to the duodenum was identified during this procedure. On October 26, 2010, the interventional radiologist correctly inserted the catheter into the patient and its placement was confirmed by a second interventional radiologist. During the radioembolization treatment, the patient complained of pain, which resulted in the medical staff performing a postprocedure SPECT/CT scan of the patient. The SPECT/CT scan identified undesired yttrium-90 activity in the duodenum. The patient was hospitalized for observation and possible intervention as a result of the dose to the duodenum. Some ulceration of the duodenum bulb was observed, but no evidence of perforation or bleeding was detected. The licensee is continuing to monitor the patient for health effects from the radiation exposure.

Cause:

The licensee reported that the cause of the medical event was that some collateral blood vessels became dominant and blood was shunted through them to the duodenum, allowing movement of the yttrium-90 microspheres. Although the licensee has not seen this relatively uncommon occurrence in the past 3 years, it has been noted in other treatment cases.

Licensee Action:

The licensee modified its radioembolization therapy procedure to include posttreatment imaging of yttrium-90 distribution. This will allow the licensee to respond appropriately in the event of a recurrence. The licensee's rate of occurrence is approximately 10 times less than is reported in medical literature; therefore, no specific action to prevent a recurrence is proposed.

NRC Action:

Other Agency Action:

On November 3, 2010, ODH performed an onsite investigation of the event. ODH reviewed and approved the licensee's corrective actions and took no enforcement action.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

ITEM #: 110032 AO #: AS 11-13 EVENT DATE: 11/23/2010
TITLE: Medical Event at Rush University Medical Center in Chicago, Illinois
NAME: Rush University Medical Center CITY: Chicago STATE: IL

Nature and Probable Consequences:

Rush University Medical Center (the licensee) reported that a medical event occurred associated with a brachytherapy seed implantation procedure to treat prostate cancer. The patient was prescribed to receive a total dose of 145 Gy (14,500 rad) to the prostate using 102 iodine-125 seeds. Instead, the seeds were placed 4-5 cm inferior of the treatment plan (wrong treatment site). The patient received an approximate dose of 273.5 Gy (27,350 rad), 112 Gy (11,200 rad) and 183 Gy (18,300 rad) to the urethra, perineum and penile bulb (glans), respectively. The patient and referring physician were informed of this event.

During the treatment, the iodine-125 seeds were manually inserted into the prostate needle template via ultrasound imaging. Visualization of the seed placement in the postimplantation scan was problematic for the licensee's staff; however, the staff's initial estimate of seed placement was that the seeds may have been inferior to the ideal placement, but still in an acceptable location. An additional posttreatment scan at the 4-week posttreatment mark indicated that the seeds were placed 4-5 cm inferior to the plan treatment site. The licensee surmised that the geometry of the template against the patient's perineum shifted during the procedure and pulled away from the patient, perhaps due to leg movement or coughing. This placement resulted in an elevated dose to the patient's urethra, perineum and penile bulb (glans). The licensee concluded that there were no observed medical effects to the patient, and no long-term significant complications are expected.

Cause:

The cause of the medical event was the engorgement of the prostate gland and surrounding tissue, which made the visualization and placement of the seeds difficult during the implantation procedure.

Licensee Action:

The licensee has indicated that these procedures will now be conducted only where fluoroscopic imaging can be performed to provide better "real time" imaging of seed placement, in addition to transrectal ultrasound. Needle unloading procedures have been modified, and ultrasound equipment quality assurance tests have been added before each procedure.

NRC Action:

Other Agency Action:

The Illinois Emergency Management Agency (IEMA) conducted an onsite investigation. IEMA reviewed the event and other similar treatment procedures at the facility and determined that this event was an isolated incident. IEMA approved the licensee's corrective actions, and issued no citations or enforcement actions at the conclusion of the investigation.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

ITEM #: 110108 AO #: AS 11-14 EVENT DATE: 07/16/2010
TITLE: Medical Event at the University of Texas Southwestern Medical Center in Dallas, Texas
NAME: University of Texas Southwestern Medical Center CITY: Dallas STATE: TX

Nature and Probable Consequences:

The University of Texas Southwestern Medical Center (the licensee) reported the occurrence of a medical event to two young adult patients prescribed colloidal phosphorus-32 (ranging from 7.4 MBq (0.2 mCi) to 92.5 MBq (2.5 mCi) of activity) for treatment of cranial cysts. The patients were prescribed to receive a total dose of 300 Gy (30,000 rad) and 200 Gy (20,000 rad) respectively, instead the patients received an approximate dose of 565 Gy (56,500 rad) and 506 Gy (50,600 rad) to the cysts. These dosages were 88 and 153 percent greater than the prescribed dosages. The patients and referring physicians were informed of these events.

On February 15, 2011, the licensee discovered that two young adult patients were administered doses of phosphorus-32 greater than 50 percent of the prescribed doses. The incidents were discovered when the authorized user noticed an area of inflammation surrounding the cysts and along the track of the drainage catheter. The authorized user discussed these findings with the staff medical physicist who reviewed the colloidal phosphorus-32 doses supplied by the nuclear pharmacy. The licensee determined for both cases, the labels had the correct total activity, but the incorrect volume and activity per unit volume. Therefore, the doses were incorrectly labeled, and the concentration was approximately 60 percent higher than indicated on the labels. The licensee subsequently calculated the doses to the target and surrounding tissues and does not expect any patient impact or unfavorable outcomes as a result of these events.

Cause:

The cause of the medical event was that the two colloidal phosphorus-32 prescriptions provided by the vendor's nuclear pharmacy were incorrectly diluted and labeled. In addition, the licensee did not perform a verification assay of the doses before their administration.

Licensee Action:

To prevent recurrence, the licensee will obtain future doses that have been calibrated to a National Institute of Standards and Technology traceable standard. The licensee also will perform a verification assay at its facility and will assess the dose volume calculating the specific activity.

NRC Action:

Other Agency Action:

On March 1, 2011, the Texas Department of State Health Services conducted an inspection and reviewed the causes and the licensee's corrective actions. The licensee was cited for a violation for failing to perform a direct measurement of the dosage taken from a bulk quantity for medical purposes.

Criteria:

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed.

ITEM #: 110133 AO #: NRC 11-05 EVENT DATE: 03/09/2011
TITLE: Medical Event at the University of Michigan Hospital in Ann Arbor, Michigan
NAME: University of Michigan Hospital CITY: Ann Arbor STATE: MI

Nature and Probable Consequences:

The University of Michigan Hospital (the licensee) reported that a medical event occurred associated with a radioembolization brachytherapy treatment of liver cancer; the treatment consisted of 2.24 GBq (60.5 mCi) of yttrium-90. The patient was prescribed to receive a total dose of 74.4 Gy (7,440 rad) to the left lobe of the liver, but instead, the patient received an approximate dose of 159.4 Gy (15,940 rad). This dosage was in excess of 100 percent of the prescribed dosage to the patient. The patient and referring physician were informed of this event.

On March 9, 2011, before the treatment, the licensee's medical physicist calculated the activity needed for the dose to the left lobe of the liver. The medical physicist's calculations used the liver segment volumes for the right lobe and medial segment combined instead of the much smaller left lobe. As a result of the volume calculation error, the dose to the left lobe of the liver was 159.4 Gy (15,940 rad), which was in excess of 100 percent of the prescribed dose. The licensee concluded that the elevated radiation dose to the patient's liver will not result in permanent medical damage or loss of function. The NRC contracted with a medical consultant who concluded that the administered dose is unlikely to result in any significant adverse effects.

Cause:

The NRC determined that the root cause of the medical event was a lack of communication between licensee personnel which resulted in an inaccurate written directive and subsequent medical event.

Licensee Action:

The licensee modified procedures by adding reviews of treatment plans to ensure that written directives properly reflect the treatment plan.

NRC Action:

The NRC conducted an inspection on March 15 and 16, 2011, and reviewed the licensee's corrective actions. On January 6, 2011, the NRC issued an NOV for failure to possess adequate procedures resulting in the medical event.

Other Agency Action:

Criteria:

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed.

ITEM #: 110144 AO #: AS 11-15 EVENT DATE: 03/17/2011
TITLE: Medical Event at Abbott Northwestern Hospital in Minneapolis, Minnesota
NAME: Abbott Northwestern Hospital CITY: Minneapolis STATE: MN

Nature and Probable Consequences:

Abbott Northwestern Hospital (the licensee) reported that a medical event occurred associated with a radioembolization brachytherapy treatment of liver cancer; the treatment consisted of 1.11 GBq (29.97 mCi) of yttrium-90. The patient was prescribed to receive a total dose of 30.8 Gy (3,080 rad) to the liver, but instead, the patient received an approximate dose of 46.1 Gy (4,610 rad). This delivered dosage was about 150 percent of the prescribed dosage to the patient. The patient and referring physician were informed of this event.

On March 18, 2011, after reviewing the treatment procedure from the previous day, the licensee's radiation oncologist discovered that the dose delivered to the patient's liver was actually 150 percent of the prescribed dose. For further clarification, the radiation oncologist brought this error to the attention of the lead medical physicist responsible for the patient's treatment delivery. Upon investigation, it was deduced that the medical physicist had not read the patient's therapy written directive prescription correctly, resulting in a higher than intended dosage being administered to the patient's liver. The licensee's radiation oncologist and interventional radiologist concluded that this elevated dose would slightly increase the patient's risk of radiation-induced liver disease.

Cause:

The medical event is believed to have been caused by human error in failing to correctly read the therapy written directive prescription.

Licensee Action:

The licensee implemented corrective measures, including increasing the font and highlighting in a different color the final dose on the written directive. In addition, the final dose is now transferred automatically rather than manually to the spreadsheet workbook used to draw up the dose. Also, procedures now require a second individual to verify that the correct prescribed activity has been transferred to the worksheet used for drawing up the dose.

NRC Action:

Other Agency Action:

The Minnesota Department of Health (MDH) conducted an investigation on April 5, 2011. During the investigation, MDH met with the radiation safety officer, the medical physicist and both radiation oncologists involved with the incident, and several members of the licensee administrative team. In addition, MDH reviewed the corrective actions implemented by the licensee. MDH did not identify any violations or penalties associated with the event; however, MDH will evaluate the licensee's corrective actions at its next inspection.

Criteria:

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a dose or dosage that is at least 50 percent greater than that prescribed.

ITEM #: 110254 AO #: AS 11-16 EVENT DATE: 04/04/2011
TITLE: Medical Event at the University of California, Los Angeles in Los Angeles, California
NAME: University of California, Los Angeles CITY: Los Angeles STATE: CA

Nature and Probable Consequences:

The University of California, Los Angeles (UCLA) (the licensee) reported the occurrence of a medical event associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed a dose of 144 Gy (14,400 rad) to the prostate using 101 iodine-125 seeds. Instead, the iodine-125 seeds were implanted inferior to the target volume (wrong treatment site), resulting in a dose to this tissue of 144 Gy (14,400 rad). The patient and referring physician were informed of this event.

On May 3, 2011, the patient returned to the UCLA Department of Radiation Oncology for a routine postimplant CT scan to verify seed placement and final dosimetry endpoints. The routine postimplant CT scan indicated that of the 101 total seeds implanted, approximately 72 seeds had been placed inferior to the target volume. As a result of the seed misplacements, approximately 31 cm³ of normal tissue inferior to the prostate received at least 144 Gy (14,400 rad) instead of the prostate tissue receiving that dose. Rectal and bladder doses were not significantly impacted by the seed misplacements and remained within typical doses for prostate implants. The licensee concluded that there was no harm to the patient from doses to the nontargeted tissue.

Cause:

The licensee reported that the cause of the medical event was movement of the prostate gland during the implantation procedure coupled with insufficient ultrasound images needed to identify the movement of the prostate gland during the procedure.

Licensee Action:

The licensee temporarily placed the permanent prostate seed implantation program on hold pending a review of the procedures. Upon completion of the review the licensee changed the implant procedure to require the verification of the base prostate plane needle placement using both axial and sagittal plane ultrasound views. The licensee also did an internal investigation to determine if any similar incidents of seed misplacements had occurred in the past and reported that postimplant CT had been performed for at least the previous 5 to 6 years without the detection of any significant seed misplacement events.

NRC Action:

Other Agency Action:

The California Radiation Control Program investigated the event and issued violations for failing to have adequate prostate seed implantation procedures, failing to report the medical event within 24 hours of discovery, failing to provide a written report with all the required information for the medical event within 15 days, and failing to have procedures and to adequately train staff and authorized users for reporting of medical events.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

ITEM #: 110296 AO #: AS 11-17 EVENT DATE: 05/09/2011

TITLE: Medical Event at St. Vincent Hospital in Green Bay, Wisconsin

NAME: St. Vincent Hospital CITY: Green Bay STATE: WI

Nature and Probable Consequences:

St. Vincent Hospital (the licensee) reported that a medical event occurred associated with HDR brachytherapy treatment for breast cancer; the treatment consisted of 318.2 GBq (8.6 Ci) of iridium-192. The patient was prescribed to receive a total dose of 34 Gy (3,400 rad) over 10 fractionated treatments. Instead, the patient received 8.84 Gy (884 rad) to the tumor site and a dose of 67.5 Gy (6,750 rad) to unintended skin tissue. The patient and referring physician were informed of this event.

On June 6, 2011, the licensee determined that the applicator catheter lengths measured using the check ruler were incorrect due to the breast cancer treatment. The licensee ascertained that the incorrect measurement was the result of the wire being caught at the apex of the curved catheter, approximately 4.5 cm from the end of the catheter. Members of the licensee's staff assumed that this measured length was accurate because they were not aware of the nominal catheter length. The Wisconsin Department of Health Services verified that the nominal catheter length was not provided in the manufacturer's written procedure, and the manufacturer determined that the check wire used by the licensee met all design specifications. The licensee concluded that there were no observed significant adverse effects to the patient, and no long-term significant complications are expected.

Cause:

The cause of the medical event was human error in the failure to identify that the check wire was not inserted to the end of the catheter's lumen and failure to identify an incorrect measurement length.

Licensee Action:

Corrective actions include obtaining a new measurement wire that has the same flexible tip as the HDR dummy wire. The treatment protocol was changed to incorporate the manufacturer's expected applicator treatment distances. In addition, the licensee developed a new policy and procedure, which emphasizes the due diligence required by the staff before the first clinical use of HDR treatment applicators and guide tubes.

NRC Action:

Other Agency Action:

Based on its investigation conducted on June 14, 2011, the Wisconsin Department of Health Services cited the licensee for failure to develop, implement, and maintain written procedures to ensure that each administration is performed according to the provisions of the written directive.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

ITEM #: 110402 AO #: AS 11-18 EVENT DATE: 07/07/2011
TITLE: Medical Event at the University of Wisconsin—Madison in Madison, Wisconsin
NAME: University of Wisconsin—Madison CITY: Madison STATE: WI

Nature and Probable Consequences:

The University of Wisconsin—Madison (the licensee) reported that a medical event occurred associated with radioembolization brachytherapy treatment for liver cancer; the treatment consisted of 1.05 GBq (28.4 mCi) of yttrium-90. The patient was prescribed to receive a total dose of 120 Gy (12,000 rad) to the left lobe of the liver, but instead, the patient received an approximate dose of 41.8 Gy (4,180 rad) to the right lobe of the liver (wrong treatment site). The patient and referring physician were informed of this event.

On July 7, 2011, the patient was scheduled for treatment for multinodular hepatocellular carcinoma to the left lobe of the liver. The treatment plan for yttrium-90 radioembolization brachytherapy treatment was based on the volume (mass) of the left lobe. The written directive specified the treatment of the left lobe of the liver; however, the right lobe of the liver was treated in error. The licensee concluded that the dose received was not medically significant to the patient.

Cause:

The cause of the medical event was human error in not correctly following the treatment plan as documented on the written directive. The interventional radiologist forgot that he had changed the initial target of the procedure after the dose had been ordered and did not communicate that change to the rest of the staff.

Licensee Action:

Corrective actions include a series of checks developed to occur in the interventional radiology room before an administration. Checks include a verbal confirmation between the interventional radiologist and the medical physicist and confirmation of the patient name, target area, dose, and route of administration. This checklist is also compared to the written directive.

NRC Action:

Other Agency Action:

The Wisconsin Department of Health Services conducted a reactive inspection on August 12, 2011, and did not issue any violations to the licensee.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than the lens of the eye, the gonads, or a major portion of the bone marrow) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

ITEM #: 110505 AO #: AS 11-19 EVENT DATE: 09/13/2011
TITLE: Medical Event at the Swedish American Hospital in Rockford, Illinois
NAME: Swedish American Hospital CITY: Rockford STATE: IL

Nature and Probable Consequences:

The Swedish American Hospital (the licensee) reported a medical event involving brachytherapy seed implant treatment for prostate cancer. The patient was prescribed a dose of 145 Gy (14,500 rad) to the prostate using 71 iodine-125 seeds. Instead, 68 of the iodine-125 seeds were implanted in the large bowel, the small bowel, and the bladder. The licensee calculated that the dose to the prostate was less than 1 Gy (100 rad), but the unintended dose to the large bowel was 10.2 Gy (1,020 rad). The patient and referring physician were informed of this event.

On September 15, 2011, postimplant imaging of the patient revealed that only three seeds were properly located in the prostate (target site), indicating a dose significantly less than the prescribed amount in the written directive. Postimplant imaging also revealed that seven seeds were in the bladder; these seeds were immediately removed. Additional postoperative imaging indicated that a number of seeds had been placed in the bowel wall, bladder wall, and the lumen of the bowel. On October 3, 2011, surgery was performed to remove misplaced seeds. All but four seeds were removed from the patient. With the removal of the seeds that the licensee was able to remove, the licensee concluded that the medical event would not have a significant effect on the patient.

Cause:

The cause of the medical event was a deviation from protocol by not having a medical physicist present during the procedure and not using fluoroscopy during needle placement.

Licensee Action:

Corrective actions include emphasizing strict adherence to prostate brachytherapy protocols.

NRC Action:

Other Agency Action:

IEMA conducted an investigation on September 26, 2011, and verified the root cause of the event as reported by the licensee. IEMA issued an NOV to the licensee regarding this failure to implement appropriate procedures.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

ITEM #: 120198 AO #: AS 12-02 EVENT DATE: 03/24/2012
TITLE: Human Exposure to Radiation at Non-Destructive Inspection Corporation, in Pasadena, Texas
NAME: Non-Destructive Inspection Corporation CITY: Pasadena STATE: TX

Nature and Probable Consequences:

The Non-Destructive Inspection Corporation (the licensee) reported that a radiographer received a TEDE of 293.2 mSv (29.3 rem). The licensee reported that the drive cable of a radiography camera containing 2.41 terabecquerels (TBq) (65.1 curies (Ci)) of iridium-192 broke, and the source pigtail disconnected from the drive cable inside the source guide tube. The radiographer train disconnected the source guide tube from the exposure device and placed it around his neck while he climbed down the ladder on a scaffold. The source was in the guide tube at that time, but its location within the guide tube is uncertain. When the radiographer trainer reached the platform he removed the guide tube from his neck. He then noted that the other radiographer was having problems disconnecting the crank assembly from the exposure device and that the exposure device locking mechanism was still unlocked.

Radiation surveys were performed of the exposure device and source guide tube. Radiation levels revealed that the source was within the guide tube. The radiographer trainer picked up the guide tube with long tongs and the source fell out of the guide tube onto the floor. An authorized individual responded to the site and performed source retrieval. The radiographer trainer's film badge was processed and read 0.812 mSv (81.2 mrem). During event reenactment, it was determined that the source guide tube was around the radiographer trainer's neck for approximately 35 seconds. The licensee calculated and assigned an estimated TEDE dose of 293.2 mSv (29.3 rem). The event was reported as a Level 2 (incident) on the International Atomic Energy Agency's International Nuclear and Radiological Event Scale (INES).

Cause:

The cause of this event was corrosion of the drive cable and improper maintenance coupled with the failure of the operators to perform the proper radiation surveys.

Licensee Action:

The corrective action taken by the licensee included a complete cessation of operations and review of the incident with every radiographer in the company; and an inspection of all of the licensee's equipment, with replacement as needed. The radiographer trainer was retrained and re-tested. The licensee stated it will incorporate routine equipment maintenance and inspections performed by the manufacturer.

NRC Action:

Other Agency Action:

The Texas Department of State Health Services (DSHS) collected information from the licensee, including medical surveillance information, and completed its review of the event and the licensee's corrective actions. DSHS cited both the licensee and radiographer trainer with several violations associated with this event.

Criteria:

Criterion I.A.1, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides, in part, exposure to an adult (any individual 18 years of age or older) resulting in an annual TEDE of 250 mSv (25 rem) or more, shall be considered reporting as an AO.

ITEM #: 090732 AO #: AS 12-03 EVENT DATE: 09/15/2009
TITLE: Medical Event at Greenville Memorial Hospital in Greenville, South Carolina
NAME: Greenville Memorial Hospital CITY: Greenville STATE: SC

Nature and Probable Consequences:

Greenville Memorial Hospital (the licensee) reported that a medical event occurred associated with a radioembolization brachytherapy treatment for liver cancer involving 1.7 GBq (45.9 mCi) of yttrium-90. The patient was prescribed to receive a total dose of approximately 13 Gy (1,300 rad) to the liver, but instead, received a dose of approximately 26 Gy (2,600 rad) to the liver. This delivered dosage was approximately 100 percent greater than the prescribed dosage to the patient. The patient and referring physician were informed of this event.

On September 17, 2009, the licensee notified the South Carolina Department of Health and Environmental Control that following infusion of radioactive yttrium-90, a postprocedure record review revealed that the patient was administered 1.7 GBq (45.9 mCi) yttrium-90 versus the prescribed dose of 0.94 GBq (25.4 mCi). Upon investigation, it was discovered by the licensee that errors occurred both while preparing the treatment and estimating the activity from the written directive. Upon medical followup, the patient had good tumor response with no adverse medical effects.

Cause:

The cause of the medical event was human error in failing to administer the correct activity as stated on the written directive.

Licensee Action:

The licensee corrective actions included: (1) mandatory refresher training for all participants in this event, (2) implementation of requirement to confirm the prescribed dose by two nuclear medicine technologists prior to administration, (3) implementation of requirement for the written directive to be typed or printed with the dose amount highlighted, and (4) discussion of the event and corrective actions at the next meeting of the Radiation Safety Committee.

NRC Action:

Other Agency Action:

The South Carolina Department of Health and Environmental Control conducted an investigation on September 17, 2009, and determined that no items of non-compliance were noted. The delay in reporting this event is attributed to consultation and discussion with the Office of General Counsel to determine the applicability of the AO criteria to the circumstances in this event. The State forwarded the final update of this event to the NRC on October 18, 2012.

Criteria:

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," 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 equal to or greater than 10 gray (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 dose or dosage that is at least 50 percent greater than that prescribed.

ITEM #: 100554 AO #: AS 12-04 EVENT DATE: 10/22/2010
TITLE: Medical Event at the Duke University Medical Center in Durham, North Carolina
NAME: Duke University Medical Center CITY: Durham STATE: NC

Nature and Probable Consequences:

Duke University Medical Center (the licensee) reported that a medical event occurred associated with a high dose rate (HDR) endobronchial brachytherapy treatment for small cell lung cancer. The treatment involved the use of 199.8 GBq (5.4 Ci) of iridium 192 split between two treatment catheters. The patient was prescribed to receive two doses of 10 Gy (1,000 rad) for a total dose 20 Gy (2,000 rad) to the tumor site. However, the direction of the catheters was reversed during treatment, resulting in a dose of 10 Gy (2,000 rad) to the voice box (wrong treatment site). The patient and referring physician were informed of this event.

On October 22, 2010, the medical staff initially identified the locations of the two treatment catheters using computed tomograph (CT) images. During the treatment, the direction of the catheters was mistakenly reversed. This changed the starting position of HDR source and resulted in the dose being delivered to the voice box rather than targeted treatment site on the left side of the patient's airway. The patient exhibited minor swelling of the voice box, but no airway compromise, hoarseness, shortness of breath or painful swallowing. The licensee concluded that the medical event would not have a significant medical effect on the patient. The patient was subsequently given the correct total dose in a followup treatment.

Cause:

The cause of the medical event was human error in that the oncology staff failed to correctly place and verify the position of the treatment catheters. A contributing factor to the cause of the event is that the oncology staff infrequently uses two catheters to simultaneously deliver doses during HDR treatments.

Licensee Action:

The licensee's corrective actions included: (1) a root-cause analysis of the event, (2) development of a more detailed standard operational procedure for this type of treatment, (3) a revised HDR patient quality assurance form to include extra levels of verification, and (4) a new verification procedure. The licensee also provided training on the revised procedures for all radiation oncology staff approved to conduct HDR therapy.

NRC Action:

Other Agency Action:

The North Carolina Division of Radiation Protection conducted an investigation on December 14, 2010, and identified several procedural weaknesses in the licensee's HDR program. One item of noncompliance was issued and the State forwarded the final update of this event to the NRC on November 28, 2012.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 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.

ITEM #: 100604 AO #: AS 12-05 EVENT DATE: 10/03/2001
TITLE: Medical Events at Our Lady of Bellefonte Hospital in Ashland, Kentucky
NAME: Our Lady of Bellefonte Hospital CITY: Ashland STATE: KY

Nature and Probable Consequences:

The Kentucky Department of Public Health (KDPH) identified a medical event at Our Lady of Bellefonte Hospital (the licensee) associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed to receive a total dose of 132.8 Gy (13,280 rad) to the prostate using 105 palladium-103 seeds, but instead, the patient received an approximate dose of 131 Gy (13,100 rad) to the penile bulb (glans) (wrong treatment site). The patient and referring physician were not informed of the event because the licensee believed that the treatment was satisfactory. However, the patient was subsequently informed of this event during a consultation at another medical treatment facility.

The licensee was unable to perform a dose assessment of the affected tissue due to the radiation oncologist's inadequate postprocedure seed implant records. The patient sought a second opinion from a different radiation oncologist, who performed a CT scan of the treatment site. Based on the results of this CT scan, the second radiation oncologist determined that the penile bulb received the majority of the prescribed dose. On November 30, 2010, KDPH investigated this event and the licensee's entire prostate brachytherapy treatment program. KDPH discovered 34 additional cases of improper prostate seed implantation performed by the same radiation oncologist between October 3, 2001 and February 24, 2009. KDPH documented procedural violations by radiation oncologist including written directives not containing the prescribed or delivered doses, no records of postprocedure implant doses, and the lack of postprocedure CT scans. The licensee declined to comment on the possible health effects to the patient.

Cause:

The cause of the medical events was human error in the failure of the radiation oncologist to follow the licensee's procedures and the failure of the licensee to maintain oversight of its brachytherapy program.

Licensee Action:

The corrective actions taken by the licensee included providing personnel with additional training, permanently suspending the brachytherapy program, and removing the radiation oncologist who performed the implant procedures from the license.

NRC Action:

Other Agency Action:

KDPH conducted an extensive investigation from November 30, 2010 through November 2, 2012, and cited the licensee for numerous violations in the oversight of its manual brachytherapy program. Additionally, the Kentucky Medical Board investigated the radiation oncologist for infractions that resulted in rescinding the Kentucky medical license.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than the lens of the eye, the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

ITEM #: 110005 AO #: AS 12-06 EVENT DATE: 12/22/2010
TITLE: Medical Event at Banner Good Samaritan Medical Center in Phoenix, Arizona
NAME: Banner Good Samaritan Medical Center CITY: Phoenix STATE: AZ

Nature and Probable Consequences:

Banner Good Samaritan Medical Center (the licensee) reported that a medical event occurred associated with a HDR mammosi treatment for breast cancer, involving approximately 139.5 GBq (3.8 Ci) of iridium-192. The patient was prescribed to receive a total dose of 34 Gy (3,400 rad) in 10 fractionated doses to the left breast; however, on the ninth treatment, a kink in one of the catheters apparently caused the source to punch through the catheter and slide along the skin tissue of the left breast. The patient received a dose of 20 Gy (2,000 rad) to the skin of the left breast (wrong treatment site). The patient and referring physician were informed of this event.

In preparation for the seventh treatment, the licensee had difficulty in attaching the transfer tube to the HDR unit, and one catheter kinked. During attempts to straighten and re-attach the transfer tube, the catheter broke off completely. The licensee used a technique that it developed to repair the catheter and test its integrity since the manufacturer provides no specific recommendations on how to deal with damaged catheters. In addition, the licensee determined that repairing the catheter was the best option, versus risking the surgical procedure to replace the catheter. During the ninth treatment, the patient reported a sensation of electricity on her left breast during the positioning of the source in one of the catheters. The remaining catheter treatment was completed without further complaints by the patient and the sources were retracted into the normal shielded position. On January 3, 2011, the prescribing physician noted very faint erythema over the lumpectomy site and no evidence of erythema where the source had been in contact with the skin. Later ulcerations developed and healed without further complication. The licensee concluded that there do not appear to be any skin effects from the ruptured catheter, and the patient gradually improved over time.

Cause:

The cause of the medical event was a material problem with the repaired catheter and ineffective procedures for handling a damaged catheter.

Licensee Action:

Corrective actions included changes to the licensee's procedures so that the entrance site and catheters will be visible by camera and that the treatment will be interrupted upon any abnormal observation or response from the patient. In addition, the licensee's procedures were revised so that if kinking or damage to a catheter is observed and the catheter shows any signs of weakening, the device will be replaced.

NRC Action:

Other Agency Action:

The Arizona Radiation Regulatory Agency conducted an investigation and determined that the licensee's corrective actions were adequate. No enforcement action was taken, and the State forwarded the final update of the event to the NRC on May 1, 2012.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 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.

ITEM #: 110341 AO #: AS 12-07 EVENT DATE: 02/18/2008
TITLE: Medical Event at Highlands Regional Medical Center in Prestonsburg, Kentucky
NAME: Highlands Regional Medical Center CITY: Prestonsburg STATE: KY

Nature and Probable Consequences:

KDPH performed an inspection of Highlands Regional Medical Center (the licensee) manual brachytherapy program on January 14, 2011. KDPH identified one of the licensee's authorized users, a radiation oncologist, who the KDPH investigated in prostate brachytherapy seed implant AO medical events at Our Lady of Bellefonte Hospital in Ashland, Kentucky (AS12-05). The KDPH discovered that on March 17, 2009, a patient prescribed to receive 100 Gy (10,000 rad) to the prostate instead received a dose 160.8 Gy (16,080 rad). This delivered dosage was approximately 60 percent greater than the prescribed dosage to the patient. KDPH documented procedural violations by the radiation oncologist including written directives not containing the prescribed or delivered doses, no records of postprocedure implant doses, and the lack of postprocedure CT scans. The patient and referring physician were not informed of this event because the licensee believed that the treatment was satisfactory.

KDPH uncovered two additional improper prostate seed implantation events at the licensee's facility performed by the same radiation oncologist. These two additional events occurred between February 28, 2008 and April 3, 2008, and in both events the patients received less than the dose prescribed for the treatment. However, because of the radiation oncologist's inadequate postprocedure implantation records, final dose assessments of these events cannot be performed. The licensee's lack of oversight of the manual brachytherapy program caused these events to be undetected until the KDPH inspection. The licensee declined to comment on the possible health effects to the patients.

Cause:

The cause of the medical event was human error in the failure of the radiation oncologist to follow the licensee's procedures and failure of the licensee to maintain oversight of their brachytherapy program.

Licensee Action:

The licensee's corrective actions included providing personnel with additional training and removing the radiation oncologist who performed the implant procedures from the license. Additionally, the licensee's manual brachytherapy program has been suspended until the licensee can demonstrate complete regulatory oversight and compliance with Kentucky regulations.

NRC Action:

Other Agency Action:

KDPH conducted an extensive investigation from January 14, 2011 through November 28, 2012, and cited the licensee for numerous violations in the oversight of its manual brachytherapy program. Additionally, the Kentucky Medical Board investigated the radiation oncologist for infractions that resulted in rescinding his Kentucky medical license.

Criteria:

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," 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 equal to or greater than 10 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 dose or dosage that is at least 50 percent greater than that prescribed.

ITEM #: 110052 AO #: AS 12-08 EVENT DATE: 01/19/2011
TITLE: Medical Event at Eastern Regional Medical Center in Philadelphia, Pennsylvania
NAME: Eastern Regional Medical Center CITY: Philadelphia STATE: PA

Nature and Probable Consequences:

Eastern Regional Medical Center (the licensee) reported that a medical event occurred associated with a radioembolization brachytherapy treatment for liver cancer involving 1.42 GBq (38.3 mCi) of yttrium-90. The patient was prescribed to receive a total dose of 117 Gy (11,700 rad) to the left lobe of the liver, but instead, received an approximate dose of 257 Gy (25,700 rad). This delivered dosage was about 120 percent greater than the prescribed dosage. The patient and referring physician were informed of this event.

On January 19, 2011, during a formal review, the licensee noted that the activity delivered to the left lobe of the liver was different than the activity that was prescribed by the doctor. Upon investigation, it was determined that a transcription error occurred while preparing the order form. The error was not recognized upon receipt of the yttrium-90, because the received amount of yttrium-90 was compared to the amount listed on the order form rather than the amount prescribed on the written directive. The licensee concluded that this elevated dose may result in an increased risk of atrophy to the left lobe of the liver.

Cause:

The cause of the medical event was human error in failing to correctly transcribe the activity from the written directive to the order form.

Licensee Action:

The licensee's corrective actions included the generation of a computer spreadsheet that populates fields based on initial calculations, written directives and the order form. In addition, several procedure modifications were implemented to ensure the correct dosage is ordered and received.

NRC Action:

Other Agency Action:

The Pennsylvania Department of Environmental Protection (PA DEP) conducted a reactive investigation on January 25, 2011, and identified one violation. PA DEP inspectors determined that the licensee failed to implement the procedures developed to provide high confidence that each yttrium-90 microspheres treatment was in accordance with the written directive. Specifically, the licensee's staff did not verify that the activity determined with a dose calibrator was within 10 percent of the prescribed activity or the written directive, nor were the decay calculations used to check that the activity at the time of treatment was as prescribed or the written directive.

Criteria:

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," 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 equal to or greater than 10 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 dose or dosage that is at least 50 percent greater than that prescribed.

ITEM #: 110351 AO #: AS 12-09 EVENT DATE: 07/08/2011
TITLE: Medical Event at the University of Colorado Hospital in Aurora, Colorado
NAME: University of Colorado Hospital CITY: Aurora STATE: CO

Nature and Probable Consequences:

University of Colorado Hospital (the licensee) reported that a medical event occurred associated with a patient receiving treatment for Graves Disease. The patient was prescribed to receive a total dose of approximately 340 Gy (34,000 rad) to the thyroid gland using 740 MBq (20 mCi) of iodine-131, instead the patient received 3,748 MBq (101.3 mCi) of iodine-131 resulting in a dose of approximately 1,722 Gy (172,200 rad). This dosage was in excess of 400 percent greater than the prescribed dosage to the patient. The patient and referring physician were informed of this event.

On July 8, 2011, the licensee reported to the Colorado Department of Health that a patient received the wrong dose of iodine-131. The licensee stated that the authorized user (AU) reviewed the procedure with the patient and then left the written directive and associated paperwork with the technologists. The technologist who was administering the iodine-131 to the patient incorrectly assumed that the patient was receiving treatment for cancer and did not review the written directive. The technologist then decided to use a therapeutic dosage of iodine-131, which was intended and labeled for another patient. The AU discovered this error late that day, when they attempted to administer the therapeutic dosage of iodine-131 to the intended patient. On November 10, 2011 and February 8, 2012, the licensee reported that the patient's thyroid function tests indicated a normal thyroid function with a small interval change suggesting the patient is becoming hypothyroid. The difference in the incorrectly administered iodine-131 dosage expected to cause hypothyroidism in the patient and result in the patient needing replacement thyroid hormone therapy. A less likely possibility is that patient's hyperthyroidism will reoccur and will need an additional dose of iodine-131.

Cause:

The cause of the medical event was human error in that the technologist did not properly review the written directive and label of the iodine-131 dose.

Licensee Action:

The licensee's corrective actions included the immediate suspension of the technician from active duty and an investigation, followed by procedure additions—including corroboration by two individuals for therapy doses. The technician was eventually allowed to return to work, but under the direct supervision of the lead technologist or supervisor.

NRC Action:

Other Agency Action:

The Colorado Department of Public Health and Environment (CDPHE) conducted interviews of the licensee's staff and reviewed the licensee's written report in July 2011. CDPHE issued a notice of violation (NOV) on August 17, 2011 and a followup Compliance Order on Consent on June 29, 2012.

Criteria:

Criteria III.C.1.b, III.C.2.a and III.C.2.b(vi), "For Medical Licensees," 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 equal to or greater than 10 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 at least 50 percent greater than that prescribed or is delivered to the wrong individual.

ITEM #: 110625 AO #: AS 12-10 EVENT DATE: 11/16/2011
TITLE: Medical Event at the Medical Center at Bowling Green in Bowling Green, Kentucky
NAME: Medical Center at Bowling Green CITY: Bowling Green STATE: KY

Nature and Probable Consequences:

The Medical Center at Bowling Green (the licensee) reported a medical event associated with a brachytherapy seed implant procedure to treat prostate cancer. The licensee scheduled back-to-back seed implant procedures, on consecutive days, for two patients who were prescribed a dose of 145 Gy (14,500 rad) to the prostate using 79 iodine-125 seeds. The licensee planned separate seed implant procedures for each patient and used the first patient's plan to correctly implant the seeds in the first patient. However, the licensee inadvertently reused the placement procedure for the first patient while placing the seeds in the second patient. This resulted in the incorrect placement of the seeds in the second patient and a dose to the urethra (wrong treatment site) of 310 Gy (31,000 rad). The second patient and referring physician were informed of this event.

On November 17, 2011, the licensee notified KDPH that the wrong permanent prostate brachytherapy implant treatment plan was used on a patient. The radiation oncologist identified the discrepancy immediately upon completion of the seed implants on the second patient. A postprocedure CT and magnetic resonance imaging (MRI) of the patient's prostate performed one month later revealed the patient received an approximate dose of 105.9 Gy (10,590 rad) to the prostate, which was 73 percent of the prescribed dose. The radiation oncologist placed additional seeds into the patient's prostate to improve coverage and comply with the treatment plan. The licensee concluded that the medical event would not have an adverse effect on the second patient.

Cause:

The cause of the medical event was human error in that the radiation oncologist deviated from standard operating procedures by using a different printer and did not verify the information on the prostate implantation plan.

Licensee Action:

The licensee's corrective actions included providing personnel with additional training on the modified process to ensure patients are treated using the correct prostate implant plan. Specifically, an individual will be assigned for printing the prostate implant plan, verifying the patient's identity, and signing the document. Subsequently, a second assigned individual will then verify the information and sign the document for confirmation.

NRC Action:

Other Agency Action:

KDPH conducted a reactive inspection on December 7, 2011, approved the licensee's corrective actions and did not issue any violations or penalties for this event.

Criteria:

Criteria III.C.1.b, III.C.2.b(iii) and III.C.2.b(vi), "For Medical Licensees," 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 equal to or greater than 10 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 or is delivered to the wrong individual.

ITEM #: 120050 AO #: AS 12-11 EVENT DATE: 12/19/2011
TITLE: Medical Event at the University of Toledo in Toledo, Ohio
NAME: University of Toledo CITY: Toledo STATE: OH

Nature and Probable Consequences:

The University of Toledo (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment cervical cancer; involving 148.4 GBq (4 Ci) iridium-192. The patient was prescribed to receive a total dose of 16 Gy (1,600 rad) in four fractionated doses to the cervix (treatment site). It was later determined that the skin of the patient's right and left thigh (wrong treatment sites) received doses of 12.51 Gy (1,251 rad) and 12.74 Gy (1,274 rad), respectively. The patient and referring physician were informed of this event.

During a followup patient visit in January 2012, the attending physician noticed a reddening of the skin (erythema) on both the right and left upper thighs of the patient. Upon investigation, the licensee did not identify any errors with the treatment plan, but discovered a problem with the hardware used during the procedure. During the treatment, a tandem is inserted into the patient, and a catheter for the sealed source is inserted in the tandem. The vendor had recently switched to a new catheter model that was slightly larger in diameter and thicker than the original. During the procedure, the catheter got caught on a minor blockage in the tandem and was not fully inserted, and the source was approximately 9 centimeter (cm) away from the treatment site. The misplaced source resulted in a total dose of 13.94 Gy (1,394 rad) to the treatment site and excessive doses to the patient's thigh. As of March 21, 2012, the attending physician reported that the patient had fully recovered from the medical event. The patient reported no bowel or bladder problems, and the damaged skin areas had totally healed. The physician does not anticipate significant acute or long-term complications because of this medical event.

Cause:

The cause of the medical event was human error in that the licensee failed to recognize that the catheter was not fully inserted in the tandem during at least one of the fractionated doses. A contributing factor was the change in catheter construction, which allowed it to get caught on the blockage in the tandem.

Licensee Action:

The corrective action taken by the licensee includes marking the new catheters to provide a visual indication of full insertion in the tandem and inservice training for all staff involved in HDR treatments.

NRC Action:

Other Agency Action:

The Ohio Department of Health (ODH) conducted an onsite investigation and reviewed the incident causes and corrective actions. In February 2012, the ODH issued a notice to all Ohio licensees advising them to verify procedures to preclude a recurrence of this event.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 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.

ITEM #: 120054 AO #: NRC 12-02 EVENT DATE: 01/05/2012
TITLE: Medical Event at Benefis Hospital in Great Falls, Montana
NAME: Benefis Hospital CITY: Great Falls STATE: MT

Nature and Probable Consequences:

Benefis Hospital (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for esophageal cancer. The treatment involved the use of 233.1 GBq (6.3 Ci) of iridium-192 and the patient was prescribed to receive a total dose of 7 Gy (700 rad) to the esophageal region (treatment site). However, it was determined that a 4 cm length of tissue in the nasal and nasopharyngeal sinus area (wrong treatment site) received a dose of 10 Gy (1,000 rad). The patient and referring physician were informed of this event.

On January 5, 2012, while planning the treatment, the authorized medical physicist (AMP) determined the placement of the source using a radio-opaque marker wire to simulate the source with imaging software. During the treatment, a nasogastric (NG) tube is inserted into the patient through the nostril, allowing for positioning of the HDR catheter and source at the treatment site. The NG tubes also have radio-opaque markers to aid in their placement in the patient, which the AMP mistook for the radio-opaque marker on the simulation wire. This error by the AMP was compounded by the lack of CT images of the patient's anatomy where the simulation wire was positioned. When the medical staff removed the HDR catheter and NG tube at the end of the procedure, they discovered that the HDR catheter had not been fully inserted into the NG tube. The licensee performed an investigation and determined that the dose was actually delivered to a location 29 cm away from the treatment site. The licensee concluded that the medical event would not have an adverse effect on the patient.

Cause:

The cause of the medical event was human error in that the AMP failed to recognize the source's correct placement relative to the treatment site.

Licensee Action:

The corrective action taken by the licensee included procedure modification such that catheter length measurements are performed before treatment and the NG tube and HDR catheter are introduced to the patient as a unit, rather than separately. Additionally, scans will be taken to cover the entire length of the HDR catheter during all HDR procedures.

NRC Action:

The NRC conducted a special inspection on January 18, 2012, and contracted with a medical consultant to review the event. The NRC's medical consultant agreed with the hospital's analysis of this event, and the NRC issued a NOV to the licensee.

Other Agency Action:

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 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.

ITEM #: 120083 AO #: AS 12-12 EVENT DATE: 01/05/2012
TITLE: Medical Event at Presbyterian Hospital in Charlotte, North Carolina
NAME: Presbyterian Hospital CITY: Charlotte STATE: NC

Nature and Probable Consequences:

Presbyterian Hospital (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for gastric cancer; the treatment involved 185.4 GBq (5 Ci) of iridium-192. The patient was prescribed to receive three fractionated doses of 7 Gy (700 rad) to the common bile duct (treatment site). However, it was determined that a 4 cm length of tissue in the common bile duct and liver (wrong treatment sites) received a dose of 14 Gy (1,400 rad). The patient and referring physician were informed of this event.

On January 18, 2012, while conducting the third fractionated HDR brachytherapy treatment for gastric cancer, the dosimetrist noticed that incorrect dwell location was used on the previous two fractionated treatments. On the previous fractionated treatment dates, January 5, 2012, and January 12, 2012, the dwell position on the HDR was mistakenly adjusted outward rather than inward. This resulted in treating only 1 cm of the desired treatment site of the common bile duct and delivered a dose of 14 Gy (1,400 rad) to 4 cm of the proximal portion of the bile duct and surrounding liver tissue. The licensee concluded that the medical event would not have an adverse effect on the patient.

Cause:

The cause of the medical event was human error in that the oncology staff presumed that the source position had been properly adjusted by the medical physics staff and did not notice this error until the third fractionated treatment.

Licensee Action:

The corrective action taken by the licensee included a procedure modification such that any catheter dwell position adjustments greater than 5 millimeters (mm) mandate a replanning of the treatment protocol.

NRC Action:

Other Agency Action:

The North Carolina Division of Radiation Protection conducted a full inspection of the brachytherapy program (to include HDR) on February 16, 2012. There were no items of noncompliance, and the State reviewed and approved corrective actions. The State did not issue any violations or penalties for this event.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

ITEM #: 120067 AO #: NRC 12-03 EVENT DATE: 01/16/2012
TITLE: Medical Event at Avera McKennan Hospital in Sioux Falls, South Dakota
NAME: Avera McKennan Hospital CITY: Sioux Falls STATE: SD

Nature and Probable Consequences:

Avera McKennan Hospital (the licensee) reported that a medical event occurred associated with an HDR brachytherapy treatment for breast cancer. The patient was prescribed to receive 10 fractionated doses of 3.4 Gy (340 rad) for a total dose of 34 Gy (3,400 rad) to the tumor site (treatment site). However, it was determined that the skin tissue over the rib cage (wrong treatment site) received a dose of 27.2 Gy (2,720 rad). The patient and referring physician were informed of this event.

On January 16, 2012, while conducting the fractionated HDR brachytherapy treatment for breast cancer, the medical staff identified that an incorrect treatment parameter length had been entered into the HDR. The programmed length was 10 cm too short and resulted in the source traveling to a location 10 cm short of the intended treatment site (inside the breast). This caused an unintended dose to the skin over the rib cage. This error was corrected and saved as a secondary treatment plan in the HDR console, which the staff used to correctly administer the second fractionated treatment. However, after the staff delivered the third fraction the following day (January 17, 2012), it was discovered that the original incorrect treatment plan had been inadvertently selected by the console operator, resulting in a second instance where the skin over the rib cage received an unintended dose. The licensee performed an investigation and the NRC contracted with a medical consultant, who determined that the patient received approximately 27.2 Gy (2,720 rad) of unintended skin dose and concluded that the event would not have an adverse effect on the patient. The patient experienced skin erythema, or reddening, as was expected from this level of skin exposure.

Cause:

The cause of the medical event was that the licensee failed to develop and implement effective procedures to ensure that patient treatment was in accordance with the written directive.

Licensee Action:

The corrective actions taken by the licensee included extensive revisions to the HDR procedures, including the development of requirements for independent verification of treatment parameter lengths, and staff training on these changes. The hospital also made organizational and personnel changes to improve the facility's safety culture.

NRC Action:

The NRC conducted a special inspection from January 30 through February 2, 2012, and identified several procedural weaknesses in the licensee's HDR program. On October 3, 2012, the NRC issued a NOV and civil penalty to the licensee.

Other Agency Action:

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 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.

ITEM #: 120081 AO #: AS 12-13 EVENT DATE: 01/19/2012
TITLE: Medical Event at Thomas Jefferson University Hospital in Philadelphia, Pennsylvania
NAME: Thomas Jefferson University Hospital CITY: Philadelphia STATE: PA

Nature and Probable Consequences:

Thomas Jefferson University Hospital (the licensee) reported that a medical event occurred associated with a radioembolization brachytherapy treatment of liver cancer for two patients. The first patient received a dose of 0.33 GBq (8.9 mCi) of yttrium-90 to liver, but this was the dose prescribed for a second patient, which was 36 percent less than prescribed. The second patient received the dosage for the first patient, which was 0.514 GBq (13.9 mCi) or approximately 80 Gy (8,000 rad) and 64 percent greater than prescribed. The patients and referring physicians were informed of this event.

On January 20, 2012, the licensee reported that on the previous day the licensee administered the incorrect prescribed dosage yttrium-90 to two patients. The licensee stated that the two patients were scheduled to be treated on the same day, in close time proximity, and that the worksheets were switched and each patient received the other patient's dose. The licensee concluded that the medical events would not have an effect on the two patients. However, the first patient received a higher dose than planned during the next scheduled treatment to compensate for the previous lower dosage described in this event. No adverse medical conditions are expected. The clinical judgment with respect to the second patient is that even though the dosage was 35 percent above that prescribed in the written directive, the activity was within levels acceptable for this particular patient and tumor size.

Cause:

The cause of the medical event was human error in that the medical staff did not verify the written directive before commencing treatment, coupled with the erroneous transposition of the written directives in each of the patient's files.

Licensee Action:

The corrective action taken by the licensee includes developing and implementing written procedures to both minimize the chance of errors occurring in the microsphere dose preparation process and to identify and correct any such errors before administration. Independent checks by multiple individuals will be made to verify patient identity, treatment site, and prescribed dosage relative to the prepared dosage.

NRC Action:

Other Agency Action:

The PA DEP conducted a reactive investigation on January 26, 2012, and identified inadequacies in the administration procedure. The PA DEP provided assurances that each treatment is in accordance with the written directive. A NOV was issued by PA DEP; however, no order or final action was imposed because a revised dosage administration procedure was subsequently sent to PA DEP for review.

Criteria:

Criteria III.C.1.b and III.C.2.b(vi), "For Medical Licensees," 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 equal to or greater than 10 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 individual.

ITEM #: 120096 AO #: AS 12-14 EVENT DATE: 02/02/2012
TITLE: Medical Event at the Intermountain Medical Center in Murray, Utah
NAME: Intermountain Medical Center CITY: Murray STATE: UT

Nature and Probable Consequences:

The Intermountain Medical Center (the licensee) reported that a medical event occurred associated with a radioembolization brachytherapy treatment of liver cancer. The treatment plan prescribed 5.32 GBq (143.6 mCi) of yttrium-90 to deliver a total dose of 120 Gy (12,000 rad) to the right lobe of the liver. However, the patient received the dosage for a different patient. The dosage administered to the patient was 1.77 GBq (47.8 mCi) of yttrium-90, which was approximately 33 percent of the prescribed activity and 67 percent lower than the prescribed dose. The resulting dose to the patient's liver was 39.6 Gy (3,960 rads). The patient and referring physician were informed of this event.

On February 2, 2012, two patients were at the licensee's facility to receive treatment for liver cancer using yttrium-90 microspheres. The nuclear medicine technologist inadvertently selected the wrong yttrium-90 microsphere vial, and subsequently, administered the first patient the dosage that was intended for the second patient. As a consequence, the first patient received an under dose of approximately 67 percent and because the licensee identified the error prior to administering any dose to the second patient, the licensee was able to treat the second patient with the correct dose. The licensee determined that the medical event would not have an effect on the first patient.

Cause:

The cause of the medical event was human error which resulted in the licensee administering the wrong radiopharmaceutical treatment dose to the patient.

Licensee Action:

The corrective actions taken by the licensee include a requirement for two individuals to sign off on the dosage vial, with the written directive present, before administering the dosage to the patient. In addition, the licensee committed to following protocol verification: just before treatment to verify the patient's identification, site being treated, dose to be administered, and the correct identification of the dose vial.

NRC Action:

Other Agency Action:

The Utah Department of Environmental Quality, Division of Radiation Control conducted an investigation on February 6, 2012, and concluded its investigation on April 19, 2012. The State approved the licensee's corrective actions and did not issue any violations or penalties for this event.

Criteria:

Criteria III.C.1.b and III.C.2.b(vi), "For Medical Licensees," 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 equal to or greater than 10 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 individual.

ITEM #: 120103 AO #: AS 12-15 EVENT DATE: 02/02/2012
TITLE: Medical Event at Abbott Northwestern Hospital in Minneapolis, Minnesota
NAME: Abbott Northwestern Hospital CITY: Minneapolis STATE: MN

Nature and Probable Consequences:

Abbott Northwestern Hospital (the licensee) reported to the Minnesota Department of Health (MDH) that a medical event occurred associated with a SIR-Spheres (microspheres) treatment of liver cancer involving 1.55 GBq (41.9 mCi) of yttrium-90. A postprocedure scan of the patient identified a significant undesired amount of activity in the upper stomach (gastric fundus), spleen and small intestine (duodenum) (wrong treatment sites). The licensee estimated doses to these tissues of 44 Gy (4,400 rad), 35 Gy (3,500 rad), and 35 Gy (3,500 rad), respectively. The patient and referring physician were informed of this event.

On February 3, 2012, the licensee notified MDH that following an infusion of radioactive yttrium-90, a postprocedure CT scan of the patient revealed that some of the yttrium-90 was not in the liver as intended. The scan indicated that 10 to 15 percent of the yttrium-90 appeared in vessels involving the spleen and digestive track. The patient received followup diagnostic scans to determine a baseline for future treatment and the long term prognosis. On February 6, 2012, after consultation with international and domestic experts, the patient was administered the radio-protective agent amifostine. The licensee concluded that the event may result in unintended, permanent functional damage and some form of future medical intervention was likely needed. A special review group including surgeons, radiation oncologists, and interventional radiologists are managing the care of the patient on an ongoing basis.

Cause:

The licensee stated that they had not anticipated any adverse reactions to this treatment and that the treatment was correctly planned and administered. However, the licensee hypothesized that the cause may have been the result of temporary blood vessel contractions in the patient due to the passage of the microspheres.

Licensee Action:

Corrective actions were not indicated as the licensee followed appropriate therapy procedures and the treatment had no unusual implications. Additionally, based upon the large number of this type of treatment that the licensee has performed, it appears that this medical event is a rare occurrence.

NRC Action:

Other Agency Action:

On February 6, 2012, MDH performed an onsite investigation of the medical event. MDH concluded that licensee procedures were appropriately followed and no violations were issued.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 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.

ITEM #: 120341 AO #: AS 12-16 EVENT DATE: 05/29/2012
TITLE: Medical Event at Carolina East Medical Center in New Bern, North Carolina
NAME: Carolina East Medical Center CITY: New Bern STATE: NC

Nature and Probable Consequences:

Carolina East Medical Center (the licensee) reported that a medical event occurred associated with a manual brachytherapy treatment for prostate cancer. The treatment consisted of 27 needles containing 65 pre-stranded seeds of iodine-125 with each seed containing 12.6 MBq (0.34 mCi). The physician prescribed a total dose of 145 Gy (14,500 rad) to the prostate; however, it was determined during the post implant seed count that all of the seeds were implanted in the penile bulb (glans) (wrong treatment site). The resulting dose to the penile bulb was 145 Gy (14,500 rad). The patient and referring physician were informed of this event.

On May 29, 2012, after completion of the implantation procedure, the licensee performed a CT scan of the patient to verify the placement of the implanted seeds. The licensee confirmed that all of the seeds were improperly implanted in the penile bulb. The patient was informed the following day, since he had been under the effects of general anesthesia during and after the procedure. The patient and his family were counseled at length by the AU within a week of the occurrence of the medical event. The AU reported that the patient tolerated the brachytherapy procedure well, without acute toxicity. The AU reported that anticipated side effects from this event will be similar to the anticipated side effects from a typical permanent prostate brachytherapy implant. The licensee concluded that the medical event would not have a significant medical effect on the patient.

Cause:

The cause of the medical event was the incorrect identification of the prostate during ultrasound imaging resulting in the improper placement of the brachytherapy seeds.

Licensee Action:

The AU compiled a report and discussed corrective actions with the urologist and the authorized medical physicist. The licensee revised the procedures to include a mandatory "time out" period during implant procedures, and a quality assurance procedure for pre-plan ultrasounds. Additional licensee corrective actions include, using single shot fluoroscopy, in addition to ultrasound, to verify placement of the brachytherapy seed needle at the base of the prostate. Contrast and other additional enhancements may be used in conjunction with the fluoroscopy to ensure more accurate imaging results.

NRC Action:

Other Agency Action:

The North Carolina Division of Radiation Protection conducted an investigation on June 12, 2012. Two items of noncompliance were noted: (1) the licensee failed to have documented procedures to ensure that a therapy is administered in accordance with written directive, and (2) the licensee failed to have a program commensurate with licensed activities. Enforcement actions are pending the licensee's responses to the State.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 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.

ITEM #: 120432 AO #: AS 12-17 EVENT DATE: 07/15/2005
TITLE: Medical Events at Wheaton Franciscan Healthcare-All Saints in Racine, Wisconsin
NAME: Wheaton Franciscan Healthcare-All Saints CITY: Racine STATE: WI

Nature and Probable Consequences:

Wheaton Franciscan Healthcare-All Saints (the licensee) reported 15 medical events associated with prostate brachytherapy seed implant procedures, which occurred between July 2005 and May 2010. The medical events involved permanent implant seeds containing iodine-125 where the total dose delivered differed from the prescribed dose by 20 percent or more. The 15 medical events involved 13 patients, including seven patients who received a rectal (wrong treatment site) dose that exceeded the prescribed prostate dose by more than 10 Gy (1,000 rads). The patients and physicians were informed of these events.

The Wisconsin Department of Health Services (WDHS) identified the medical events during a routine inspection and followed up with a reactive inspection on July 18, 2012. WDHS inspectors determined that the licensee was not reviewing prostate brachytherapy cases against the medical event criteria. Instead, the licensee was using established dose-based criteria based on the postoperative CT scans of the events. The events involved prostate procedures where the doses were less than 80 percent greater than 130 percent of the prescribed dose, or procedures where the doses to 2 cubic centimeters (cm³) of the rectum or bladder were greater than the prescribed prostate dose. The AU's review of each of the medical events concluded that the positions of seeds were placed too close to the rectal mucosa. The licensee has evaluated all prostate implants performed since 2005. The licensee concluded that the medical events would not have an adverse effect on the patients and is monitoring their medical progress.

Cause:

The cause of the medical events was human error in that the licensee was not providing adequate oversight of the permanent implant prostate brachytherapy program.

Licensee Action:

The licensee's corrective actions include: (1) revising the prostate implant procedures to include the use of stranded seeds, (2) allowing only the AU to insert the needles into the prostate, and (3) a secondary check of the needle position prior to deploying the seeds. Additionally, the AU is now the only individual who contours the images on the postoperative CT scan, which is reviewed by the medical physicist to improve accuracy.

NRC Action:

Other Agency Action:

WDHS conducted a reactive inspection on July 18, 2012 and did not cite the licensee because of the licensee's self-identified and implemented process improvements prior to the inspection. No additional cases have met the medical event reporting criteria.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 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), represents a prescribed dose or dosage that is delivered to the wrong treatment site.

ITEM #: 120480 AO #: NRC 12-04 EVENT DATE: 08/15/2012
TITLE: Medical Event at Deaconess Hospital in Evansville, Indiana
NAME: Deaconess Hospital CITY: Evansville STATE: IN

Nature and Probable Consequences:

Deaconess Hospital (the licensee) reported that a medical event occurred associated with an HDR mammosite brachytherapy treatment for breast cancer. The patient was prescribed to receive 10 fractionated doses for a total dose of 34 Gy (3,400 rad) to breast tumor site. However, it was determined that a 4.2-cm length of skin and fatty breast tissue (wrong treatment sites) receive dose of 34 Gy (3,400 rad). The patient and referring physician were informed of this event.

Between March 5 and 9, 2012, the patient received two HDR mammosite treatments per day to the right breast for a total prescribed dose of 34 Gy (3,400 rad). During a followup appointment on June 11, 2012, it was noted that the catheter insertion site had not healed. A plastic surgeon performed surgical removal of the entire skin and breast tissue area affected by the treatment. The surgical pathology report revealed a final diagnosis of fat necrosis with granulation tissue radiation effect. Upon reviewing the pathology report, the prescribing physician requested complete review of the treatment plan by a qualified consultant. The consultant discovered that the unintended dose to the skin and fatty breast tissue was the result of the incorrect positioning of the HDR source. The possibility of long term effects are low, but nonetheless additional skin ulceration and breast tissue necrosis could occur.

Cause:

The cause of the medical event was human error in that the medical physicist was not familiar with the treatment planning system for the HDR mammosite device. A contributing factor to the cause of the event was the licensee's ineffective independent check of the treatment plan prior to commencing the procedure.

Licensee Action:

The corrective actions taken by the licensee includes the independent review, by a qualified third party, of HDR treatment plans prior to delivery for the first five plans provided by each physician or physicist. Additionally, the licensee requires the performance of an additional independent check that verifies the physical orientation of any channel (catheter) used in an HDR procedure. Finally, the licensee implemented appropriate training and continuing medical education programs for all staff participating in HDR procedures.

NRC Action:

The NRC conducted a special inspection on August 22, 2012, and contracted with a medical consultant to review the event. The NRC's medical consultant agreed with the hospital's analysis of this event. On January 31, 2013, the NRC issued a NOV to the licensee.

Other Agency Action:

Criteria:

Criterion III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 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.

ITEM #: 120548 AO #: AS 12-18 EVENT DATE: 09/10/2012
TITLE: Medical Event at the Anderson Regional Medical Center in Meridian, Mississippi
NAME: Anderson Regional Medical Center CITY: Meridian STATE: MS

Nature and Probable Consequences:

Anderson Regional Medical Center (the licensee) reported that a medical event occurred associated with an iodine-131 treatment for thyroid carcinoma. The patient was prescribed to receive a total dose of 25 Gy (2,500 rad) to the thyroid using 3.7 GBq (100 mCi) of iodine-131. Instead, the patient received 6.03 GBq (162.8 mCi) of iodine-131 for an approximate dose of 40 Gy (4,000 rad) to the thyroid, which was about 160 percent of the prescribed dosage to the patient. The patient and referring physician were informed of this event.

On September 10, 2012, the licensee reported that a patient was administered 6.03 GBq (162.8 mCi) of iodine-131, instead of the prescribed 3.7 GBq (100 mCi). An investigation performed by the licensee revealed that the nuclear medicine technologist misinterpreted the patient's admission order as a written directive. Specifically, the nuclear medicine technologist incorrectly interpreted the AU's name and 5.55 GBq (149.9 mCi) of iodine-131 activity on the patient's admission order as the written directive for the patient's treatment. The written directive for the patient's treatment was never received by the Nuclear Medicine Department. The doctor indicated that the patient was previously treated using a prescribed dose of 100 mCi, and that the thyroid would be fully saturated with iodine-131. Additionally, the doctor believes that the thyroid would not have significant uptake of the excess iodine-131 and this excess would be quickly excreted from the patient. Therefore, the licensee concluded that this elevated dose would result in any adverse health effects to the patient.

Cause:

The medical event was caused by human error coupled with a new communication process, in which written directives were not directly communicated to the Nuclear Medicine Department.

Licensee Action:

The licensee restored its previous written directive communication policy, which required the communication of written directives directly from the AU to the Nuclear Medicine Department and required written directives for iodine-131 on a specific therapy form.

NRC Action:

Other Agency Action:

The Mississippi Division of Radiological Health conducted an investigation on September 19, 2012, and cited the licensee with a violation, for its failure to follow written directive procedures. The investigation revealed this violation was an isolated incident during a two month period where the change in written directive communication policy took place.

Criteria:

Criteria III.C.1.b and III.C.2.a, "For Medical Licensees," 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 equal to or greater than 10 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 dose or dosage that is at least 50 percent greater than that prescribed.

ITEM #: 130209 AO #: AS 13-01 EVENT DATE: 02/20/2013
TITLE: Human Exposure to Radiation at Radiological Associates of Sacramento in Sacramento, California
NAME: Radiological Associates of Sacramento CITY: Sacramento STATE: CA

Nature and Probable Consequences:

Radiological Associates of Sacramento (the licensee) reported that a pregnant patient received 6.55 gigabecquerels (GBq) [176 millicuries (mCi)] of iodine-131 for thyroid ablation therapy.

On February 18, 2013, prior to the treatment, the licensee's staff administered a pregnancy test as a routine precaution. The pregnancy test yielded a negative result and the licensee administered iodine-131 to the patient.

On April 22, 2013, the patient's physician informed the patient that she was pregnant, and that she became pregnant very close the therapy time. An ultrasound evaluation determined that the embryo/fetus would have been approximately two weeks old at the time of iodine-131 administration. The dose to the embryo/fetus was determined to be 470 mSv (47 rem). The embryonic tissue capable of concentrating iodine-131 is not formed until 10 to 12 weeks of gestation; therefore, this tissue had not yet formed at the time of the treatment. However, the medical consultant concluded that, based on the National Council on Radiation Protection and Measurements Report #54, there is a risk of fetal malformation at doses greater than 15 rem. The licensee indicated that the patient will receive ongoing medical evaluations and genetic counseling.

Cause:

The cause of this event was the inability of the pregnancy test to provide a positive determination of pregnancy in close proximity to conception.

Licensee Action:

The licensee's corrective actions included adding a declaration for female patients stating that they have not had unprotected intercourse within three to four weeks prior to treatment.

NRC Action:

Other Agency Action:

The California Radiologic Health Branch conducted an inspection of Radiological Associates on May 2, 2013. A violation was issued for failing to report the medical event within 24 hours of discovery.

Criteria:

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides, in part, that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 millisieverts (mSv) [5 roentgen equivalent man (rem)] or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

ITEM #: 130192 AO #: AS 13-02 EVENT DATE: 03/26/2013
TITLE: Human Exposure to Radiation at Baptist Medical Center-Princeton in Birmingham, Alabama
NAME: Baptist Medical Center-Princeton CITY: Birmingham STATE: AL

Nature and Probable Consequences:

Baptist Medical Center-Princeton (the licensee) reported that a pregnant patient received 1.85 GBq (50 mCi) of iodine-131 for thyroid ablation therapy.

On March 1, 2013, the patient had a thyroidectomy to treat thyroid cancer. On March 6, 2013, the patient had general lab work that included a negative pregnancy test. On March 26, 2013, the patient returned for a 50 mCi iodine-131 treatment on the remaining thyroid tissue and had another pregnancy test performed prior to the dosing that yielded positive results. The second pregnancy test was ordered based on discussions between the nurse and the patient about her menstrual cycle. The administering technician was not informed of the second pregnancy test and did not speak with the floor nurse before administration of the iodine-131. An ultrasound revealed that the patient was 4 to 5 weeks pregnant at the time of the iodine-131 treatment. The licensee estimated a fetal/embryo dose of 126 mSv (12.6 rem). The patient and referring physician were informed of this event. A low possibility of carcinogenesis or malformations of the fetus is expected based on the age of the fetus at the time of the treatment.

Cause:

The cause of the medical event was determined to be inadequate communication between the floor nurse and the nuclear medicine technologist. The floor nurse did not communicate to the nuclear medicine technologist that a second pregnancy test had been ordered for the patient and was positive nor did the nuclear medicine technologist seek this information from the nurse prior to the radiopharmaceutical administration.

Licensee Action:

The licensee implemented new procedures to include improving communications between the nursing staff and nuclear medicine staff. The department developed a "Preiodine-131 Therapy" checklist that requires a signature from the nurse and technologist. The licensee conducted training on these changes for all nuclear medicine department staff.

NRC Action:

Other Agency Action:

The Alabama Department of State Health Services conducted an inspection on April 17, 2013, and focused on implementation of new procedures and communication with hospital management. Alabama found the licensee's corrective actions acceptable.

Criteria:

Criterion I.A.2, "Human Exposure to Radiation from Licensed Material," of Appendix A to this report provides, in part, that any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more, shall be considered for reporting as an AO.

ITEM #: 090415 AO #: AS 13-03 EVENT DATE: 12/29/2008

TITLE: Medical Event at an Unspecified Licensee in New York State

NAME: NR CITY: NR STATE: NY

Nature and Probable Consequences:

The unspecified licensee reported a medical event to the New York (NY) Department of Health (DOH). The DOH reported the event and provided the NRC with all of the required information for the report. The DOH does not specify the name of the licensee for medical events in accordance with a NY state law designed to protect the privacy of the patient. This event occurred during radioiodine treatment of a patient for hyperthyroidism. The patient was prescribed 11.1 MBq (300 µCi) of iodine-123, but instead was administered 72.5 MBq (1.96 mCi) of iodine-131 for a whole body scan (wrong radiopharmaceutical and wrong dose). The dose estimate to the patient's thyroid was approximately 25 Gy (2,500 rad). The patient and referring physician were informed of this event. The patient was subsequently treated with a therapeutic dose of iodine-131 in accordance with the written directive.

A referring physician requested that the patient receive an iodine-123 uptake study and scan to be followed by an iodine-131 therapy for hyperthyroidism. On December 29, 2008, the authorized user (AU) directed the secretary to schedule the uptake study using iodine-123; however, the secretary scheduled the patient for a whole body scan using iodine-131. The nuclear medicine technologist reviewed the patient's history, which included the fact that the patient still had a thyroid, but failed to seek clarification from the AU on the correct treatment. Additionally, the nuclear medicine technologist did not review the AU's written directive/approval for the treatment. The AU discovered the error after the administration of the iodine-131 and the uptake study the patient revealed hyperthyroidism. The licensee concluded that the medical event would not have a significant medical effect on the patient.

Cause:

The cause of the medical event was human error in that the secretary did not schedule the patient's treatment correctly coupled with the failure of the medical technologist to seek clarification and review the physician's order.

Licensee Action:

The corrective action taken by the licensee included revising the treatment protocols to include a requirement for verification of the prescription by two nuclear medicine technologists and a consultation with the AU if there are any questions regarding the order written directive.

NRC Action:

Other Agency Action:

The DOH reviewed the licensee's root cause analysis and performed a reactive inspection on June 8 and 15, 2009. An additional follow-up inspection was performed on December 8, 2010. The licensee's corrective actions were found to be effective.

Criteria:

Criteria III.C.1.b, III C.2.a, and III.C.2.b(i) "For Medical Licensees," 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 equal to or greater than 10 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 either a dose or dosage that is at least 50 percent greater than that prescribed, or uses the wrong radiopharmaceutical or unsealed byproduct material.

ITEM #: 120303 AO #: AS 13-04 EVENT DATE: 11/07/2011

TITLE: Medical Event at Adventist Health System/Sunbelt, Inc., in Altamonte Springs, Florida

NAME: Adventist Health System/Sunbelt, Inc. CITY: Altamonte Springs STATE: FL

Nature and Probable Consequences:

Adventist Health System/Sunbelt, Inc. (the licensee) reported that a medical event occurred associated with a high dose rate (HDR) brachytherapy treatment for uterine cancer, containing approximately 314.5 GBq (8.5 curies (Ci)) of iridium-192. The patient was prescribed a total dose of 25 Gy (2,500 rad) to the uterine area in five fractionated doses; however, the patient received a dose of approximately 60 Gy (6,000 rad) to the skin of the inner thighs (wrong treatment site). The patient and referring physician were informed of this event.

The medical event was not identified until April 2012, when the patient informed a physician at another medical institution that she exhibited signs of delayed necrosis in the thigh area. The physician determined that this injury was consistent with a radiation burn and informed the licensee about the injury. The licensee determined that the necrosis most likely occurred during the last treatment fraction.

Cause:

The cause of the medical event was not conclusively determined but was most likely due to a malfunction of the applicator that dislodged the source from the vaginal cylinder and subsequently deposited the source in the guide tube between the patient's thighs.

Licensee Action:

The licensee modified its clinical procedure to require the therapist, physicist, and radiation oncologist to verify the applicator assembly and positioning. In addition, the procedure now requires a measurement of the flex tube to verify that it extends to the exact position beyond the end of the guide tube and also requires verification that the compression screw is tight.

NRC Action:

Other Agency Action:

The State of Florida conducted an inspection during May 14, 17, and 21, 2012. Based on the results of the inspection and additional information provided by the licensee, no enforcement action was taken, and the State forwarded the final update of the event to the NRC in April 2013.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than the lens of the eye, 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.

ITEM #: 130271 AO #: AS 13-05 EVENT DATE: 08/20/2012
TITLE: Medical Event at University of Minnesota in Minneapolis, Minnesota
NAME: University of Minnesota CITY: Minneapolis STATE: MN

Nature and Probable Consequences:

The University of Minnesota (the licensee) reported that a medical event occurred associated with a high dose rate (HDR) brachytherapy unit, during a cervical cancer treatment. The HDR unit utilized a 233.1 GBq (6.3 Ci) iridium-192 source.

The patient was prescribed a total dose of 25 Gy (2,500 rad), given in five fractions, to the target area in the uterus. The uterus received 19.5 Gy (1,950 rad) and an excessive dose of 15 Gy (1500 rad) was delivered to the inner thigh (wrong treatment site).

The event was discovered on May 26, 2013, during a transfer of electronic treatment planning records to a new system. Record showed that the tips and ends of the treatment catheters had been inverted in the planning system by an auto-locate tool whose function was to automatically detect catheters. The deficiency resulted in some source dwell positions that either were below the target area or completely outside the patient. The referring physician notified the patient of the event on May 27, 2013. The patient showed significant treatment response with no evidence of residual cervical tumor; however, the patient also experienced rectal thickening, urethral stricture, and ulceration of the anterior rectal wall, as confirmed by a colonoscopy performed on June 3, 2013.

Cause:

The causes of the medical event were determined to be a deficiency in the treatment planning system equipment and human error. The auto-locate tool did not detect that the tips and ends of the catheters were inverted. During the course of treatment, the dosimetry planner and three plan checkers also failed to notice the labeling at the proximal (shallow) ends of the catheters indicating that the catheters were inverted. Because the equipment was unable to self-identify the error, a generic concern is possible; however there is no evidence supporting a generic concern as there have been no reports of similar occurrences from other facilities.

Licensee Action:

The licensee's corrective actions included ending use of the auto-locate tool, augmenting dosimetry planner and checker training, conducting an external audit of previous interstitial cases, and changing the written directive and treatment day checklist. At the time of the event, the manufacturer, Nucletron, was contacted. Nucletron investigated the incident, but did not report any related incidents.

NRC Action:

Other Agency Action:

The Minnesota Department of Health conducted an onsite inspection on June 18, 2013. The investigation focused on clarification of the conditions surrounding the error, treatment planning software and transfer to treatment control computer, and potential for additional unnoticed cases. The State accepted the licensee's analysis and corrective actions for this incident and issued no violations.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than the lens of the eye, the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site.

ITEM #: 130001 AO #: AS 13-06 EVENT DATE: 11/27/2012
TITLE: Medical Event at the University of Toledo in Toledo, Ohio
NAME: University of Toledo CITY: Toledo STATE: OH

Nature and Probable Consequences:

The University of Toledo (the licensee) reported that a medical event occurred associated with a brachytherapy seed implant procedure to treat prostate cancer. The patient was prescribed a total dose of 160 Gy (16,000 rad) to the prostate using 88 iodine 125 seeds, but instead, the patient received an approximate dose of 10 Gy (1,000 rad) to the perineum (wrong treatment site). The patient and referring physician were informed of this event.

On December 10, 2012, the licensee performed a CT scan of the patient to verify the placement of the implanted seeds. The licensee initially confirmed that 16 of the 88 seeds were improperly implanted outside the prostate in the perineum. After additional review, on December 21, 2012, the licensee determined that only six seeds were in the perineum, yielding a dose of 10 Gy (1,000 rad) to the perineum. The licensee concluded that the medical event would not have a significant medical effect on the patient. In addition to an unrelated medical condition, the licensee has discontinued any further treatment of the patient's prostate.

Cause:

The cause of the medical event was the incorrect identification of the prostate during ultrasound imaging resulting in the improper placement of the brachytherapy seeds. Also contributing to the error was an improperly supervised trainee (urology resident) and the trainee's lack of familiarity with the tensioning adjustments on the applicator.

Licensee Action:

The licensee's corrective actions include revising procedures to preclude a recurrence of the event. The revisions to the procedures included: (1) the authorized user will provide heightened oversight of trainees, and (2) additional confirmatory measurements will be performed to verify the distance the needle is withdrawn from the applicator prior to placing the seeds.

NRC Action:

Other Agency Action:

The Ohio Department of Health conducted an inspection on December 19, 2012, to review the incident and initial reports. The Department did not cite the licensee for any violations.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 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.

ITEM #: 130150 AO #: AS 13-07 EVENT DATE: 03/27/2013
TITLE: Medical Event at Rosa of North Dallas in Dallas, Texas
NAME: Rosa of North Dallas CITY: Dallas STATE: TX

Nature and Probable Consequences:

Rosa of North Dallas (the licensee) reported that a medical event occurred associated with 253.3 GBq (6.846 Ci) iridium-192 HDR brachytherapy treatment for cervical cancer. The patient was prescribed to receive a total dose of 51.39 Gy (5,139 rad) in four fractionated doses. However, the patient's urethra (wrong treatment site) received a dose of 16.07 Gy (1,607 rad) and the patient's anterior vagina (wrong treatment site) received a dose of 15.49 Gy (1,549 rad) for the four fractions. It was determined that the physicist selected the incorrect guide tube length size for treatment delivery. The event was not discovered until after the third fraction. As a result of the exposure to the unintended site, the patient experienced radiation burns. The patient has undergone medical treatment for the radiation burns and has responded well. There are a few small areas that have not healed that will be removed surgically. The physician expects these areas to heal after the surgery. The patient and referring physician were informed of this event.

Cause:

The cause of the medical event was human error in that the physician inadvertently used a 132 centimeter (cm) tube for the treatment delivery for three out of four fractions but planned the patient's procedure with the treatment length of 119.9 cm. This resulted in the source being positioned 12 cm short of the intended treatment site.

Licensee Action:

The licensee's corrective actions included suspension of all HDR treatments pending appropriate review of its process and procedures. In addition to this action, the licensee changed its operating procedures to require the measurement of the treatment guide-tube prior to a treatment. The forms used have been changed to record the type of guide tube used for each fraction. Pictures of the different guide tubes were taken and the lengths of the tube printed on them. Labels were placed on each guide tube indicating its length. A "time-out" is now required prior to each treatment to confirm that the correct size guide tube is in place for the treatment. Additional training will be provided to physicists unfamiliar with the device and its procedures.

NRC Action:

Other Agency Action:

The Texas Department of State Health Services conducted an onsite inspection on May 8, 2013. The Agency reviewed the licensee's corrective actions and confirmed that the stated changes to their program had been completed.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 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.

ITEM #: 130438 AO #: AS 13-08 EVENT DATE: 05/09/2013
TITLE: Medical Event at the Cleveland Clinic Foundation in Cleveland, Ohio
NAME: Cleveland Clinic Foundation CITY: Cleveland STATE: OH

Nature and Probable Consequences:

The Cleveland Clinic Foundation (the licensee) reported that a medical event occurred associated with an yttrium-90 (Y-90) microsphere radioembolization procedure to treat liver metastases from colorectal cancer. The licensee prescribed a dose of 129.65 Gy (12,965 rad) to the left liver lobe tumor, and 127.94 Gy (12,794 rad) to the right liver lobe tumor. However, a dose of 6 Gy (6,200 rad) was delivered to the small intestine (wrong treatment site).

The consequence of the event is the generation of an intestinal ulcer caused by the radiation. The patient is being treated for pain management of the ulcer until it heals. The prognosis of the patient will be determined by the underlying cancer and spread of the tumors. The event was identified in September 2013 while treating the patient for the ulcer symptoms. The patient and referring physician were informed of this event.

Cause:

The cause of the medical event was most likely the development of collateral vessels around the tumor between the time of the initial patient treatment planning and delivery of the Y-90 microspheres. The licensee was not able to identify the small change in vasculature during routine checks at the time of the procedure.

Licensee Action:

The licensee did not identify corrective actions to add to its current procedures to preclude a recurrence of the event.

NRC Action:

Other Agency Action:

The Ohio Department of Health conducted an inspection on October 8, 2013, to review the incident and initial reports. The department concluded that the licensee made a conservative event determination and applied due diligence in performing the medical procedure. The department did not cite the licensee for any violations.

Criteria:

Criterion III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 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.

ITEM #: 130248 AO #: AS 13-09 EVENT DATE: 05/17/2013

TITLE: Medical Event at Tufts Medical Center in Boston, Massachusetts

NAME: Tufts Medical Center CITY: Boston STATE: MA

Nature and Probable Consequences:

On May 17, 2013, Tufts Medical Center (the licensee) reported that a medical event occurred associated with 82.8 terabecquerel (TBq) (2,231 Ci) cobalt-60 gamma knife radiosurgery procedure to treat the patient's brain for intense facial pain.

On May 17, 2013, a patient was prescribed to receive 7,500 centigray (cGy) (rad) from a single fraction gamma knife treatment to the left side of the brain, but instead received the intended dose to the right side of the brain (wrong treatment site). The radiation oncologist authorized user (AU) mistakenly selected the right trigeminal nerve on an image of the patient's brain in the planning computer, which disagreed with the diagnosis. The AU then printed the written directive and signed it. The authorized medical physicist (AMP) questioned the coordinates, suggesting the number should be higher, but the AU felt it was within the proper range. The written directive was signed by the AMP and the neurosurgeon.

The nurse and radiation therapist verified the site and side of the head with the patient prior to the treatment. However, during treatment it was not obvious to the oncology nurse and radiation therapist that they were treating the wrong side of the brain and radiation dose was administered as prescribed in the written directive.

Later the same day, the AU realized the error while dictating the end-of-treatment notes. The licensee determined that the likely effect would be possible transient numbness to the right side of the patient's face. The patient and prescribing physician were informed of this event and no serious health effects to the patient are expected.

Cause:

The cause of the medical event was human error in the failure of the AU to confirm that the proper treatment site was selected in the planning computer. A contributing factor was the licensee's ineffective independent check of the planning computer treatment site coordinates prior to commencing the procedure.

Licensee Action:

The licensee corrective actions included increasing the number of "time-out" procedures, updating the Gamma Knife Safety Checklist, and training staff to identify potential erroneous coordinates.

NRC Action:

Other Agency Action:

The Commonwealth of Massachusetts conducted an inspection on June 12, 2013, approved the licensee's corrective actions, and did not issue any violations or penalties for this event.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 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.

ITEM #: 130405 AO #: AS 13-10 EVENT DATE: 09/04/2013
TITLE: Medical Event at Abbott Northwestern Hospital in Minneapolis, Minnesota
NAME: Abbott Northwestern Hospital CITY: Minneapolis STATE: MN

Nature and Probable Consequences:

Abbott Northwestern Hospital (the licensee) reported that a medical event occurred associated with an HDR brachytherapy unit. The HDR unit utilized a 237 GBq (6.4 Ci) iridium-192 source.

The patient was prescribed to receive six fractionated doses for a total dose of 24 Gy (2,400 rad) to a tumor in the prostate and bladder. Instead, the second of the six fractionated doses was 16 Gy (1,600 rad) and delivered to the small bowel near the bladder wall (wrong treatment site). The remaining fractions of the treatment were increased to compensate for the lack of tumor dose for the second fraction.

The patient and prescribing physician were informed of this event. No immediate adverse reaction to the increased dose was seen. The radiation oncologist and lead medical physicist performed a risk analysis and determined no long-term complication to the small bowel is expected.

Cause:

The cause of the medical event was due to an error in the catheter lengths entered into the treatment planning system. This was due to human error in that the medical physicists knew that the catheter lengths needed to be adjusted in the treatment plan, but not properly communicate with each other on who would do it.

Licensee Action:

The licensee's corrective actions included procedure modifications that added verification of the catheter length to the daily HDR pre/post treatment checklist and universal "time-out" protocol. The licensee also added, and posted at the console, a procedure describing the verbal communication and verification to be used by the physics team and oncologist prior to the HDR treatment.

NRC Action:

Other Agency Action:

The Minnesota Department of Health conducted an onsite inspection on September 18, 2013, and reviewed the conditions of the treatment, the cause of the event and the effect on the patient. The State accepted the licensee's analysis and corrective actions. No violations or penalties were issued.

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," 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 equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than the 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.