

Event Detail - Abnormal Occurrence

Print



ITEMNO: 950291 AO_NO: NRC 95-04 DATE: 03/14/1995
TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT THE UNIVERSITY OF VIRGINIA, IN CHARLOTTE
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).

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.

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.

Other Agency Action:

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

Criteria:

The following information pertaining to this event is also being reported 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.

ITEMNO: 950645 AO_NO: NRC 95-05 DATE: 05/09/1995
TITLE: MEDICAL THERAPEUTIC RADIOPHARMACEUTICAL MISADMINISTRATION OF IODINE-131 AT MASSACHUSETTS GENERAL HOSPITAL
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.

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

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

Other Agency Action:

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

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

ITEMNO: 950755 AO_NO: NRC 95-06 DATE: 05/09/1995
TITLE: MULTIPLE MEDICAL BRACHYTHERAPY MISADMINISTRATIONS AT MADIGAN ARMY MEDICAL CENTER
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

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

Cause:

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

Other Agency Action:**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.

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

ITEMNO 950290

AO_NO: AS 95-02

DATE: 03/14/1995

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION BY MOBILE TECHNOLOGY, INC., AT IRVINE ME

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.

NRC Action:**Cause:**

A chest x-ray showing that the HDR remote afterloading unit's positioning catheter was erroneously placed in the right lung was not reviewed by either the pulmonologist or the radiation oncologist.

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.

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

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.

ITEMNO 950451

AO_NO: AS 95-03

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

NRC Action:**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

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.

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

Criteria:

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

ITEMNO 950065

AO_NO: AS 95-04

DATE: 07/28/1994

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT SOUTHWEST TEXAS METHODIST HOSPITAL

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 a 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,

NRC Action:

Cause:

The licensee was unable to determine how the misidentification occurred.

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

Licensee Action:

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

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 (regardless of health effects) affects two or more patients at the same facility can be considered an AO.

ITEMNO 960191 **AO_NO:** AS 95-01 **DATE:** 05/23/1993

TITLE: MEDICAL TELETHERAPY MISADMINISTRATION AT AN "UNSPECIFIED LICENSEE" IN NEW YORK, NY

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-60 teletherapy equipment. During simulation, the technologist erroneously placed the preparatory tattoo marking the treatment area on the

NRC Action:

Cause:

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

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.

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

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.

ITEMNO 900051 **AO_NO:** NRC 90-02 **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 had become dislodged from its applicator while a patient was undergoing treatment for uterine cancer.

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.

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.

Other Agency Action:

Licensee Action:

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

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:

ITEMNO: 900085 AO_NO: NRC 90-03 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

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

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

Other Agency Action:**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.

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.

ITEMNO: 900100 AO_NO: NRC 90-04 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

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

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

Other Agency Action:**Licensee Action:**

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

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.

ITEMNO: 900098 AO_NO: NRC 90-05 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

NRC Action:

An NRC Region III inspector was sent to the hospital March 7-9, 1990 to review circumstances surrounding the misadministration (Ref. 6). An Enforcement Conference was held with the licensee on May 2, 1990, to review the findings of the inspection and possible enforcement

Cause:

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

Other Agency Action:**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.

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.

ITEMNO: 900048

AO_NO: NRC 90-06

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,

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

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.

Other Agency Action:**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.

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.

ITEMNO: 900164

AO_NO: NRC 90-07

DATE: 03/08/1990

TITLE: RECEIPT OF AN UNSHIELDED RADIOACTIVE SOURCE AT AMERSHAM CORPORATION IN BURLING

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

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

Cause:

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

Other Agency Action:

Licensee 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

ITEMNO: 900190 AO_NO: NRC 90-08 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

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,

Cause:

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

Other Agency Action:**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.

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.

ITEMNO: 900189 AO_NO: NRC 90-09 DATE: 03/16/1990

TITLE: MEDICAL THERAPY MISADMINISTRATION

NAME: John F. Kennedy Memorial Hospit 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

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

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

Other Agency Action:**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

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.

ITEMNO: 900194 AO_NO: NRC 90-10 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

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 the incident (Ref. 11).

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

Other Agency Action:**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

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.

ITEMNO: 900784

AO_NO: NRC 90-11

DATE: 03/28/1990

TITLE: DEFICIENCIES IN BRACHYTHERAPY PROGRAM

NAME: St. Mary Medical Center - Porter M

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 the authorized users at St. Mary Medical Center in Gary and Hobart, Indiana. The alleged contended that the authorized user did not evaluate

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

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

Other Agency Action:**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.

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.

ITEMNO: 900240

AO_NO: NRC 90-12

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 radiography device containing an

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

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

Other Agency Action:

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.

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 can be considered an abnormal occurrence.

ITEMNO: 900347 AO_NO: NRC 90-13 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.

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

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.

Other Agency Action:**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)

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.

ITEMNO: 900388 AO_NO: NRC 90-14 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

NRC Action:

An Enforcement Conference was held on August 16, 1990, and enforcement action is being considered. Future reports will be made as appropriate.

Cause:

The physician and nuclear medicine technologist failed to confirm that the patient was not breast feeding. The patient arrived at the medical center from a remote South Pacific island. Communication between the island physician and the Army physicians was poor and the

Other Agency Action:**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.

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.

ITEMNO: 900391 AO_NO: NRC 90-15 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 on 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

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 therapy

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 the brain was the area

Other Agency Action:**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

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

ITEMNO: 951030 AO_NO: AS 90-01 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

NRC Action:**Cause:**

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

did not assay the dose in the dose calibrator prior to administering it,

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

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.

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.

ITEMNO: 900176 AO_NO: NRC 90-16 DATE: 02/20/1990

TITLE: MEDICAL THERAPY MISADMINISTRATION

NAME: Muskogee Regional Medical Cent 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

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

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

Other Agency Action:

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

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.

ITEMNO: 900313 AO_NO: NRC 90-17 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

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.

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.

Other Agency Action:**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

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.

ITEMNO: 900785 AO_NO: NRC 90-18 DATE: 07/19/1990

TITLE: SIGNIFICANT BREAKDOWN IN MANAGEMENT AND PROCEDURAL CONTROLS AT A MEDICAL FACI

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 the invalid. Such an event could have potentially resulted in significant adverse health effects to patients (.e.g., a serious disease may not be

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

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.

Other Agency Action:**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.

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

ITEMNO: 900478 AO_NO: NRC 90-19 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 on September 24,

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

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.

Other Agency Action:**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.

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.

ITEMNO: 900558

AO_NO: NRC 90-20

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 8 millicurie

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

Cause:

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

Other Agency Action:**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

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.

ITEMNO: 900786

AO_NO: AS 90-02

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 surgical instrument fitted with a hollow tube) each containing 7 seeds on a ribbon. The prescribed dose was about 2000 rads. A problem was

NRC Action:**Cause:**

There were several causes for this event:

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

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.

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.

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.

ITEMNO: 900516 AO_NO: NRC 90-21 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 to be implanted in the

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,

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

Other Agency Action:**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

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.

ITEMNO: 900586 AO_NO: NRC 90-22 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 radiography device

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

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

Other Agency Action:**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.

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.

ITEMNO: 900597 AO_NO: NRC 90-23 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

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

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

Other Agency Action:**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 the radiopharmacy when the dose is assayed, or the person must personally assay

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.

ITEMNO: 900691 AO_NO: NRC 90-24 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 sustained a possible radiation overexposure to his right hand. The licensee stated that it was not informed of the incident by the radiographer until the

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

Cause:

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

Other Agency Action:**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.

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.

ITEMNO: 900787 AO_NO: NRC 90-25 DATE: 11/26/1990

TITLE: MEDICAL DIAGNOSTIC MISADMINISTRATION

NAME: Veterans Administration Medical C 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.

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

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

Other Agency Action:

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.

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.

ITEMNO: 090326 AO_NO: NRC 91-01 DATE: 11/28/1990
 TITLE: SIGNIFICANT DEGRADATION OF PLANT SAFETY AT NUCLEAR FUEL SERVICES, INC. IN ERWIN, TN
 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

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 350 grams of uranium-235 in

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

Other Agency Action:**Licensee Action:**

Corrective actions included modification of the piping system to prevent highly concentrated uranium solutions from flowing into the unfavorable geometry tanks. A review of the fuel recovery facility was initiated to identify the nuclear safety features and controls for each unfavorable geometry vessel. A Nuclear Criticality Safety

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

ITEMNO: 910181 AO_NO: NRC 91-02 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

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

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

Other Agency Action:**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

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.

ITEMNO: 910237 AO_NO: NRC 91-03 DATE: 02/01/1991
 TITLE: MEDICAL THERAPY MISADMINISTRATION AT WASHINGTON HOSPITAL CENTER IN WASHINGTON, DC
 NAME: Washington Hospital Center CITY: Washington STATE: DC

Nature and Probable Consequences:

On February 1, 1991, NRC Region I was notified by the licensee that a therapeutic misadministration involving a teletherapy unit had occurred at its facility earlier that day.

A 74-year-old patient was to have received 250 rads to

NRC Action:

The Region I staff will examine the circumstances behind the incident during the next inspection of the program at the licensee's facility.

Unless new, significant information becomes available,

Cause:

The technologist failed to follow proper identification procedures.

Other Agency Action:**Licensee Action:**

The licensee provided additional training for the technologist in the proper identification procedures for treatment plan verification.

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.

ITEMNO

951055

AO_NO:

NRC 91-04

DATE:

02/14/1991

TITLE:

MEDICAL THERAPY MISADMINISTRATION AT HAHNEMANN UNIVERSITY HOSPITAL IN PHILADELPHIA

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.

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

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.

Other Agency Action:**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.

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.

ITEMNO

910413

AO_NO:

NRC 91-05

DATE:

03/28/1991

TITLE:

MEDICAL THERAPY MISADMINISTRATION AT CLARA MAASS MEDICAL CENTER IN BELLEVILLE, NJ

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.

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

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.

Other Agency Action:

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

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.

ITEMNO: 951054 AO_NO: AS 91-01 DATE: 07/26/1989

TITLE: MEDICAL THERAPY MISADMINISTRATION AT GOOD SAMARITAN MEDICAL CENTER IN PHOENIX,

NAME: Good Samaritan Medical Center, 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.

NRC Action:**Cause:**

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

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's activities was conducted on December 22, 1989. The violation basis was centered on the Radiation Safety Committee's failure to adequately

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.

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.

All computer generated treatment plans will have point

ITEMNO: 910621 AO_NO: NRC 91-06 DATE: 05/29/1991

TITLE: POTENTIAL CRITICALITY ACCIDENT AT THE GENERAL ELECTRIC NUCLEAR FUEL AND COMPONE

NAME: GE Nuclear Fuel & Component M 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

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

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

Other Agency Action:**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;

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

ITEMNO: 910465 AO_NO: NRC 91-07 DATE: 04/12/1991

TITLE: MULTIPLE MEDICAL TELE THERAPY MISADMINISTRATIONS AT ST. JOHN'S REGIONAL MEDICAL C

NAME: St. John's Regional Medical Cente 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

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

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

Other Agency Action:**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

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.

ITEMNO

900365

AO_NO:

AS 91-02

DATE:

06/14/1990

TITLE:

OVEREXPOSURE OF A NON-RADIATION WORKER

NAME:

H & G Inspection Company, Incor

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

NRC Action:**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.

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.

Licensee Action:

The radiographers and the Exxon employee were notified of their exposures. All licensee employees were notified of the incident by 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

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

ITEMNO

900430

AO_NO:

AS 91-03

DATE:

07/10/1990

TITLE:

EXTREMITY OVEREXPOSURE OF A RADIATION WORKER

NAME:

Rosemount, Inc., Kay-Ray/Sensall

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.

NRC Action:**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.

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

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.

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.

ITEMNO: 900788 AO_NO: AS 91-04 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.

NRC Action:**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

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

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.

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.

ITEMNO: 910998 AO_NO: NRC 91-08 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

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,

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.

Other Agency Action:**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.

Criteria:

The following information pertaining to this event is also being reported in the Federal Register. 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

ITEMNO: 911011 AO_NO: NRC 91-09 DATE: 09/09/1991

TITLE: MEDICAL DIAGNOSTIC MISADMINISTRATION AT ST. JOHN'S MERCY MEDICAL CENTER IN ST. LOU

NAME: St. John's Mercy Medical Center CITY: St. Louis STATE: MO

Nature and Probable Consequences:

A bone scan diagnostic study was scheduled for September 9, 1991, for a 15-month-old male child with possible osteomyelitis (bone inflammation) of the ankle. The child was given an adult dose of technetium-99m MDP, the radioactive pharmaceutical used for a bone

NRC Action:

The NRC staff has reviewed the circumstance of the misadministration and will evaluate the licensee's corrective actions in a routine inspection to be conducted in the next several months.

Cause:

The cause is attributed to human error on the part of the radiopharmacist and the nuclear medicine technician.

Other Agency Action:**Licensee Action:**

The hospital has counseled the two employees involved in the error. Hospital management met with the nuclear medicine department staff on September 17, 1991, to review the impact of the errors in this incident, to stress the importance of checking one's own work as well as the work of others, and to point out the need to follow

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.

ITEMNO 910705

AO_NO: NRC 91-10

DATE: 06/17/1991

TITLE: MEDICAL DIAGNOSTIC MISADMINISTRATION AT I. GONZALEZ MARTINEZ ONCOLOGIC HOSPITAL I

NAME: I. Gonzalez Martinez Oncologic H

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

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.

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.

Other Agency Action:**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.

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.

ITEMNO 910985

AO_NO: NRC 91-11

DATE: 08/30/1991

TITLE: MEDICAL THERAPY MISADMINISTRATION AT WILLIAM BEAUMONT ARMY MEDICAL CENTER IN EL

NAME: William Beaumont Army Medical C

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

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

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

Other Agency Action:

Licensee Action:

The radiopharmacist and consulting nuclear medicine physician were counseled and 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

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.

ITEMNO 951059

AO_NO: NRC 91-12

DATE: 10/25/1991

TITLE: MEDICAL THERAPY MISADMINISTRATION AT ST. JOSEPH'S HOSPITAL AND MEDICAL CENTER IN

NAME: St. Joseph Hospital and Medical C

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 95.5 millicuries, had

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

Cause:

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

Other Agency Action:**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.

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.

ITEMNO 911289

AO_NO: NRC 91-13

DATE: 11/22/1991

TITLE: MEDICAL THERAPY MISADMINISTRATION AT UNIVERSITY OF PITTSBURGH PRESBYTERIAN-UNIV

NAME: University of Pittsburgh Presbyteri

CITY: Pittsburgh

STATE: PA

Nature and Probable Consequences:

On November 22, 1991, NRC Region I was notified by the licensee's Radiation Safety Officer (RSO) that a therapeutic misadministration involving a cobalt-60 teletherapy unit had occurred at their Presbyterian-University Hospital facility on November 21, 1991. The

NRC Action:

NRC Region I will examine the licensee's preventive and corrective actions at the next scheduled inspection.

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

Cause:

The cause was attributed to failure to follow the written prescription in the patient's chart.

Other Agency Action:**Licensee Action:**

Corrective actions included stressing to the radiation technologists the need to carefully read patients' charts and to recognize notations of changes in the fields to be treated. When a field is completed on a patient, the administered dose is to be written down in the patient's chart using a different color ink.

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.

ITEMNO 911306

AO_NO: NRC 91-14

DATE: 11/27/1991

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

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

NRC Action:

A special inspection was conducted on December 17, 1991, to review the circumstances surrounding the misadministration and to review the licensee's corrective actions (Ref. 4). No violations of NRC requirements were identified. The corrective actions appeared sufficient to

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.

Other Agency Action:**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

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.

ITEMNO: 951066

AO_NO: AS 91-05

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.

NRC Action:**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

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

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

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.

ITEMNO: 900789

AO_NO: AS 91-06

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 a brachytherapy implant back to the supplier, Therapeutic Nuclides, Inc., Valencia California. The sources consisted of two 50 mCi, three 25 mCi, and

NRC Action:**Cause:**

see Nature and Consequences above.

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.

Licensee Action:

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

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

ITEMNO: 910535 AO_NO: AS 91-07 DATE: 05/03/1991

TITLE: MEDICAL THERAPY MISADMINISTRATION AT NORTHRIDGE HOSPITAL MEDICAL CENTER IN NORT

NAME: Northridge Hospital Medical Cente 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

NRC Action:**Cause:**

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

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

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

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.

ITEMNO: 920048 AO_NO: NRC 92-01 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

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

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.

Other Agency Action:**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

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

ITEMNO: 920183 AO_NO: NRC 92-02 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

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

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

Other Agency Action:**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

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

ITEMNO

920202

AO_NO:

NRC 92-03

DATE:

07/01/1990

TITLE:

MULTIPLE MEDICAL THERAPY MISADMINISTRATIONS AT G. ANTHONY DOENER, M.D., FACILITY IN

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

NRC Action:

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

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

Other Agency Action:**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.

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

ITEMNO

920506

AO_NO:

NRC 92-05

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.

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

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

Other Agency Action:

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

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

ITEMNO 920288

AO_NO: NRC 92-06

DATE: 03/24/1992

TITLE: MEDCAL THERAPY MISADMINISTRATION AT HOSPITAL METROPOLITANO IN RIO PIEDRAS, PUER

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.

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

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

Other Agency Action:**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

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

ITEMNO 920488

AO_NO: NRC 92-07

DATE: 05/19/1992

TITLE: MEDICAL DIAGNOSTIC MISADMINISTRATION AT BAYSTATE MEDICAL CENTER, INCORPORATED, I

NAME: Baystate Medical Center, Incorpor

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

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

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 radioiodine doses greater

Other Agency Action:**Licensee Action:**

The licensee's corrective actions included: (1) instruction of nuclear medicine staff in the department procedures and regulatory requirements for radioiodine studies; (2) preparation, prior to the administration of a written directive by the director of endocrine (an authorized user), or a designated authorized user before any iodine study

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

ITEMNO 920525

AO_NO: NRC 92-08

DATE: 05/29/1992

TITLE: MEDICAL THERAPY MISADMINISTRATION AT THE CHRIST HOSPITAL IN CINICINNATI, 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,

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

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,

Other Agency Action:**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.

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

ITEMNO: 920085 AO_NO: NRC 92-09 DATE: 11/11/1991
 TITLE: MEDICAL THERAPY MISADMINISTRATION AT COOPER HOSPITAL/UNIVERSITY MEDICAL CENTER
 NAME: Cooper Hospital/University Medica 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

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.

Cause:

It was determined that the cause of the misadministration was an input error into the treatment planning computer. Specifically, the 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

Other Agency Action:**Licensee Action:**

The licensee's corrective action was to included 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.

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.

ITEMNO: 920662 AO_NO: NRC 92-10 DATE: 07/06/1992
 TITLE: EXTREMITY OVEREXPOSURE OF A RADIOGRAPHER AT MQS INSPECTION, INC., FIELD SITE IN TR
 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.

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

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.

Other Agency Action:

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

Criteria:

The following information pertaining to this event is also being reported 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.

ITEMNO: 920777 AO_NO: NRC 92-11 DATE: 08/11/1992
 TITLE: MEDICAL THERAPY MISADMINISTRATION AT THE MEDICAL CENTER OF DELAWARE, INCORPORATED
 NAME: The Medical Center of Delaware, Inc. 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.

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.

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.

Other Agency Action:**Licensee Action:**

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

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.

ITEMNO: 920106 AO_NO: AS 92-01 DATE: 01/20/1992
 TITLE: MEDICAL DIAGNOSTIC MISADMINISTRATION AT SOUTHWEST TEXAS METHODIST HOSPITAL IN SAN ANTONIO
 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

NRC Action:**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.

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.

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.

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.

ITEMNO: 920764 AO_NO: NRC 92-14 DATE: 08/19/1992
 TITLE: MEDICAL THERAPY MISADMINISTRATION AT MEMORIAL HOSPITAL OF LARAMIE COUNTY IN CHEYENNE
 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 sources utilized for

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

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

Other Agency Action:**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

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

ITEMNO 920930

AO_NO: NRC 92-15

DATE: 10/02/1992

TITLE: MEDICAL THERAPY MISADMINISTRATION AND UNPLANNED EXPOSURE AT ST. CLARES RIVERSI

NAME: St. Clares Riverside Medical Cent

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

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

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.

Other Agency Action:**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

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

ITEMNO 920964

AO_NO: NRC 92-16

DATE: 10/14/1992

TITLE: MEDICAL THERAPY MISADMINISTRATION AT THE LAHEY CLINIC MEDICAL CENTER IN BURLINGT

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

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

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.

Other Agency Action:

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.

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.

ITEMNO: 921058

AO_NO: NRC 92-17

DATE: 11/13/1992

TITLE: MEDICAL THERAPY MISADMINISTRATION AT INDIANA UNIVERSITY MEDICAL CENTER IN 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 a total dose of 300 rads to reduce swelling behind the patient's eye. The dosimetrist mistakenly prepared the dose calculations for 300 rads.

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.

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

Other Agency Action:**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.

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.

ITEMNO: 921064

AO_NO: NRC 92-18

DATE: 11/16/1992

TITLE: LOSS OF IRIIDIUM-192 SOURCE AND MEDICAL THERAPY MISADMINISTRATION AT INDIANA REGIONAL

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 approximately 4.3-curie sealed iridium-192 source from their high dose rate (HDR) remote afterloader unit at their Indiana Regional Cancer Center (IRCC), Indiana,

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.

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

Other Agency Action:**Licensee Action:**

Licensee actions to prevent recurrence are still undergoing NRC staff review.

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. In addition, Appendix A (see Event

ITEMNO: 921098

AO_NO: NRC 92-19

DATE: 12/02/1992

TITLE: MEDICAL THERAPY MISADMINISTRATION AND TEMPORARY LOSS OF BRACHYTHERAPY SOURCE

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 lost before

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

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

Other Agency Action:**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

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.

ITEMNO: 920467 AO_NO: NRC 93-02 DATE: 05/11/1992
 TITLE: MEDICAL "SODIUM IODIDE" MISADMINISTRATION AT INGHAM MEDICAL CENTER IN LANSING, MI
 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

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.

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.

Other Agency Action:**Licensee Action:**

The licensee has revised the procedures for thyroid cancer studies and provided training for nuclear medicine personnel in the QM Program requirements.

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.

ITEMNO: 940003 AO_NO: NRC 93-03 DATE: 01/21/1993
 TITLE: MEDICAL THERAPY MISADMINISTRATION INVOLVING THE USE OF A HIGH DOSE-RATE REMOTE
 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 Gamma Med high dose-rate remote afterloader brachytherapy device (HDR). During the first treatment on January 21, 1993, the physician mistakenly inserted

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

Cause:

The licensee did not confirm the treatment site before the treatment was given as required by its Quality Management (QM) Program.

Other Agency Action:

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 issues on April 26, 1993 (Ref. 5).

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

ITEMNO: 940005 AO_NO: NRC 93-04 DATE: 01/14/1993
 TITLE: MEDICAL THERAPY MISADMINISTRATION AT PAPA STRAVROS' ASSOCIATES MEDICAL IMAGING I
 NAME: Papastavros' Associates Medical I 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

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 not be completed, the NRC did not contact a medical consultant to review this misadministration. a Confirmatory Action

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

Other Agency Action:**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 the packing slip provided with iodine-131 therapy doses; and (3) to require

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.

ITEMNO: 940012 AO_NO: NRC 93-05 DATE: 12/09/1992
 TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT PARKVIEW MEMORIAL HOSPITAL IN FORT
 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 vaginal cancer using a high-dose-rate brachytherapy treatment device. The device uses a 296,000 megabecquerel (MBq) (8 curie [Ci] iridium-192 (Ir-

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.

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 the same error in assuming

Other Agency Action:**Licensee Action:**

The licensee has revised its procedures for preparing the treatment plans for the high-dose-rate brachytherapy procedures. It has made improvements in the calculation notebook and other related data used in preparing the treatment plans and the dose calculations.

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.

ITEMNO: 940771 AO_NO: NRC 93-06 DATE: 04/28/1993
 TITLE: INOPERABLE RESEARCH REACTOR SCRAMS AT UNIVERSITY OF VIRGINIA IN CHARLOTTESVILLE
 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

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

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

Other Agency Action:**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

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

ITEMNO 940034

AO_NO: NRC 93-07

DATE: 02/16/1993

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MERCY MEMORIAL MEDICAL CENTER IN ST

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

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.

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

Other Agency Action:**Licensee Action:**

The licensee conducted refresher training for its nurses to explain brachytherapy procedures and provided them with instructions.

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

ITEMNO 940134

AO_NO: NRC 93-08

DATE: 06/10/1993

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT KEESLER MEDICAL CENTER, KEESLER AIR

NAME: Keesler Medical Center, Keesler A

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

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

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

Other Agency Action:

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

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.

ITEMNO

AO_NO:

AS 93-01

DATE:

06/06/1988

TITLE:

CONTAMINATION OF POOL IRRADIATOR FACILITY OWNED BY RADIATION STERILIZERS, INC., IN

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

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

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

Other Agency Action:

The State of Georgia secured the services of an independent consultant to verify the results of decontamination efforts by the DOE contractor. Once it was verified that the facility met Federal and State regulatory standards for decontamination, the State

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.

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.

ITEMNO

920329

AO_NO:

AS 93-02

DATE:

04/01/1992

TITLE:

MEDICAL "SODIUM IODIDE" MISADMINISTRATION AT GRENADA LAKE MEDICAL CENTER IN GREN

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

NRC Action:**Cause:**

The misadministration occurred because the nuclear medicine technologist failed to identify the patient prior to the administration of the radiopharmaceutical.

Other Agency Action:

The state agency staff has reviewed the circumstances of the misadministration and will evaluate the licensee's corrective actions during the next inspection to be conducted in the near future.

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 procedures will no longer be included in the same schedule with patients who are

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.

ITEMNO

921049

AO_NO:

AS 93-03

DATE:

11/11/1992

TITLE:

MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MAINE MEDICAL CENTER IN PORTLAND, M

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

NRC Action:**Cause:**

See Nature and Consequences above.

Other Agency Action:

The state agency is reviewing this event to determine necessary actions.

Future reports will be made as appropriate.

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

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.

ITEMNO

940204

AO_NO:

AS 93-04

DATE:

05/07/1993

TITLE:

INDUSTRIAL RADIOGRAPHER OVEREXPOSURE EVENT AT MURPHY OIL REFINERY IN MERAUX, L

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)

NRC Action:**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

Other Agency Action:

The Louisiana Radiation Protection Division (RPD) recommended to the licensee that routine physical examinations and blood work be performed. Enforcement actions included citations for violations associated with whole body and extremity overexposures

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.

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 may result to persons in unrestricted areas should be considered an abnormal occurrence.

ITEMNO

940090

AO_NO:

NRC 93-09

DATE:

07/27/1993

TITLE:

MEDICAL SODIUM IODIDE MISADMINISTRATION AT OSTEOPATHIC HOSPITAL FOUNDERS ASSOCI

NAME:

Osteopathic Hospital Founders As

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-

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

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

Other Agency Action:

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

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

ITEMNO: 810088 AO_NO: NRC 93-10 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

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.

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.

Other Agency Action:**Licensee Action:**

NRC documents indicate that no licensee actions was warranted or taken.

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

ITEMNO: 940597 AO_NO: AS 93-05 DATE: 12/04/1987

TITLE: MEDICAL TELETHERAPY MISADMINISTRATION AT ALTA BATES MEDICAL CENTER IN BERKELEY,

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 pathological examination identified a cancer of the patient's nasopharynx. The patient was given chemotherapy and was scheduled to receive radiation

NRC Action:**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.

Other Agency Action:

As a result of the 1993 investigation, RHB recommended that the State take the following actions to minimize recurrences, and to identify similar occurrences. (These recommendations have not yet been implemented.)

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.

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

ITEMNO: 940628 AO_NO: AS 93-06 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

NRC Action:**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

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 failure of the radiographer to wear personnel monitoring. The manufacturer was questioned about the pins, which are ordinary 3.2 millimeter (1/8 inch)

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

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.

ITEMNO 920934

AO_NO: AS 93-07

DATE: 10/05/1992

TITLE: MEDICAL RADIOPHARMACEUTICAL MISADMINISTRATION BY "UNSPECIFIED LICENSEE" IN ALBAN

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

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.

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

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 State Agency's action(s).

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.

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.

ITEMNO 921116

AO_NO: AS 93-08

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

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).

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

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

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

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 the prescribed dose should be considered an abnormal occurrence.

ITEMNO: 941693 AO_NO: AS 93-09 DATE: 07/11/1992

TITLE: MEDICAL TELETHERAPY MISADMINISTRATION BY "UNSPECIFIED LICENSEE" IN NEW YORK, NEW

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

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.

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.

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

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).

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.

ITEMNO: 940958 AO_NO: NRC 93-11 DATE: 01/07/1993

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT WASHINGTON UNIVERSITY MEDICAL SCHO

NAME: Washington University Medical Sc 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

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

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

Other Agency Action:**Licensee Action:**

The licensee informed the NRC that used 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

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.

ITEMNO: 940098 AO_NO: NRC 93-12 DATE: 10/15/1993

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MERCY HOSPITAL IN SCRANTON, PENNSYLA

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

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

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.

Other Agency Action:**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

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.

ITEMNO 940616

AO_NO: NRC 93-13

DATE: 07/01/1993

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MOUNTAINSIDE HOSPITAL IN MONTCLAIR,

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

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.

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

Other Agency Action:**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.

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.

ITEMNO 941775

AO_NO: NRC 93-14

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 to the thyroid of a 9-month-old nursing infant. On December 2, 1991, a patient was administered 0.56 megabecquerel (15 microcuries) of

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

Cause:

Failure of a supervised technologist to adequately review the hospital form used to inform the hospital staff that a patient is pregnant of breast-feeding as he/she was instructed by the authorized user.

Other Agency Action:

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

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

ITEMNO: 940072 AO_NO: NRC 93-15 DATE: 11/10/1993
 TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT GOOD SAMARITAN MEDICAL CENTER IN ZA
 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

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.

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.

Other Agency Action:**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

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

ITEMNO: 940036 AO_NO: NRC 93-16 DATE: 11/17/1993
 TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MARQUETTE GENERAL HOSPITAL IN MARQ
 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

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

Cause:

The hospital routinely uses two lengths of catheters for brachytherapy treatments, a shorter catheter for vaginal procedures and a longer one for uterine procedures. The medical physicist inadvertently placed the cesium-137 sources in the shorter (vaginal) catheter instead of the

Other Agency Action:**Licensee Action:**

The hospital has revised its procedures to include added precautions for assuring the correct length catheter is used in each brachytherapy procedure.

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

ITEMNO: 940953 AO_NO: AS 93-10 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

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 had adverse effects to

Cause:

The cause of the incident was criminal theft of radioactive material from the transportation stream. The failure to detect the thefts in a timely manner was due to inadequate accountability of packages in the return process.

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,

Licensee Action:

No licensee was direction involved in this incident. The individual responsible for the occurrence died from natural causes before legal action could be taken.

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.

ITEMNO AO_NO: DATE:

TITLE:

NAME: CITY: STATE:

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.

NRC Action:**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.

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).

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).

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.

ITEMNO AO_NO: DATE:

TITLE:

NAME: CITY: STATE:

Nature and Probable Consequences:

A patient was admitted on July 8, 1993, for treatment of a longstanding arteriovenous malformation (AVM) in the left posterior dura 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

NRC Action:**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 at the hospital in which the x-

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

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

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.

ITEMNO: 940209 AO_NO: AS 93-13 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 [Ci] americium/beryllium source made by Amersham (Serial Number 7004NE) was not located and may have been lost or stolen. BPB again notified the

NRC Action:**Cause:**

The State agency investigation determined that the major contributing factor was lack of an adequate tracking system for receiving and shipping of radioactive sources. Also, a high turnover rate at the local manager/radiation safety officer position contributed to the lack of proper

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.

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.

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.

ITEMNO: 940457 AO_NO: AS 93-14 DATE: 10/06/1993

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MICHAEL REESE MEDICAL CENTER IN CHIC

NAME: Michael Reese Hospital and Medic 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

NRC Action:**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.

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.

Licensee Action:

As soon as the licensee's management determined that a reportable event had occurred, they formed a committee of professionals 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

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.

ITEMNO: 941001 AO_NO: AS 93-15 DATE: 09/28/1993

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MT. SINAI MEDICAL CENTER IN MIAMI BEAC

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

NRC Action:**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

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

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

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.

ITEMNO 920901

AO_NO: AS 93-16

DATE: 09/24/1992

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT RICHLAND MEMORIAL HOSPITAL IN COLUM

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 as a result of being

NRC Action:**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 on the staff opened the applicator out of curiosity and improperly reinserted the source in a loose manner.

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 South Carolina to provide additional information regarding the State agency's actions(s).

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.

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.

ITEMNO 940155

AO_NO: NRC 94-02

DATE: 12/11/1993

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT HOSPITAL METROPOLITANO IN RIO PIEDRA

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

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 30, 1993 (Ref. 4). The CAL

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

Other Agency Action:

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

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.

ITEMNO: 941012 AO_NO: NRC 94-03 DATE: 12/20/1993

TITLE: TELETHERAPY MISADMINISTRATION AT TRIANGLE RADIATION ONCOLOGY ASSOCIATES IN PITT

NAME: Triangle Radiation Oncology Asso 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

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.

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).

Other Agency Action:**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

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

ITEMNO: 940266 AO_NO: NRC 94-04 DATE: 09/22/1993

TITLE: LOST REFERENCE SOURCES AT BROOKS AIR FORCE BASE IN SAN ANTONIO, TEXAS

NAME: Armstrong Laboratory, Brooks Air 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 all licensed sources at Armstrong Laboratory. During this audit, the licensee identified four missing strontium-90 (Sr-90) reference

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

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,

Other Agency Action:**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.

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.

ITEMNO: 941090 AO_NO: NRC 94-05 DATE: 01/07/1994

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT THE UNIVERSITY OF CINCINNATI IN CINCIN

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,

NRC Action:

NRC dispatched two inspectors on January 16, 1994, to monitor the licensee's decontamination efforts and to obtain more details on the misadministration. NRC also obtained the services of a medical consultant to review the medical implications of the incident. A follow-up NRC

Cause:

The seed leaked after being inadvertently crushed by a surgical staple used to secure the catheters during the implant procedure.

Other Agency Action:**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.

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.

ITEMNO

941471

AO_NO:

NRC 94-06

DATE:

01/13/1994

TITLE:

MEDICAL BRACHYTHERAPY MISADMINISTRATION AT KEESLER MEDICAL CENTER AT KEESLER A

NAME:

Keesler Medical Center, Keesler A

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 afterloader system. The prescribed tumor treatment plan included 1000 centigray (cGy) (1000 rad) absorbed doses at 5 treatment positions using a 144.3

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.

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 the misadministration.

Other Agency Action:**Licensee Action:**

The licensee immediately stopped the use of the HDR device pending a complete check of the system by the manufacturer (Ref. 8, Ref. 9). The licensee also evaluated the practice of extending special needles beyond biopsy needles and the probability of patient movement causing damage, and decided to discontinue

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

ITEMNO

941470

AO_NO:

NRC 94-07

DATE:

01/27/1994

TITLE:

MEDICAL BRACHYTHERAPY MISADMINISTRATION AT ALEXANDRIA HOSPITAL IN ALEXANDRIA, VI

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,

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

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

Other Agency Action:

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

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.

ITEMNO: 940473 AO_NO: AS 94-01 DATE: 06/17/1993
 TITLE: THERAPEUTIC RADIOPHARMACEUTICAL MISADMINISTRATION AT NORTH CAROLINA BAPTIST HO
 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

NRC Action:**Cause:**

This misadministration occurred due to personnel error during a time of heavy workload.

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.

Licensee Action:

A new policy to color-code prepared dosages was implemented to more clearly and easily distinguish between therapeutic and diagnostic dosages.

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.

ITEMNO: 940876 AO_NO: NRC 94-08 DATE:
 TITLE: MULTIPLE MEDICAL BRACHYTHERAPY MISADMINISTRATIONS AT DEACONESS MEDICAL CENTER
 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

NRC Action:

An enforcement conference was held with the licensee on June 28, 1994, to discuss the apparent violations described above and to review the corrective actions taken by the licensee. NRC is continuing its deliberations regarding any proposed enforcement action.

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

Other Agency Action:**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

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

ITEMNO: 941116 AO_NO: NRC 94-09 DATE: 04/13/1992
 TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MEMORIAL HOSPITAL IN SOUTH BEND, INDI
 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) (1500 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

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

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.

Other Agency Action:**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.

Criteria:

The following information pertaining to the 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.

ITEMNO 941038

AO_NO: NRC 94-10

DATE: 04/22/1994

TITLE: TELETHERAPY MISADMINISTRATION AT JEWISH HOSPITAL, WASHINGTON UNIVERSITY MEDICAL

NAME: Jewish Hospital, Washington Univ

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

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

Cause:

Failure of the authorized physician to prepare a change in the written directive, and failure to effectively supervise the administration of the treatment.

Other Agency Action:**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 (AMP) procedures; (3) requiring that on the first day of treatment the setup is supervised by a physician; (4) modifying the written

Criteria:

The following information pertaining to the event is also being reported concurrently in the Federal Register. 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 abnormal occurrence.

ITEMNO 941084

AO_NO: NRC 94-11

DATE: 05/02/1994

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT THE QUEEN'S MEDICAL CENTER IN HONOL

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

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

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

Other Agency Action:

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

Criteria:

The following information pertaining to this event is also being reported in the Federal Register. Appendix A (see Event Type 1[a] in 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

ITEMNO: 941355 AO_NO: NRC 94-12 DATE: 05/17/1994
 TITLE: MEDICAL SODIUM IODIDE MISADMINISTRATION AT STAMFORD HOSPITAL IN STAMFORD, CONNE
 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

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

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

Other Agency Action:**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 AI/RSO or other AI's authorized to do so; (3) all

Criteria:

The following information pertaining to the 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 administering a radiopharmaceutical other than the one intended which results in any part of the body receiving unscheduled diagnostic radiation, and the

ITEMNO: 941581 AO_NO: NRC 94-13 DATE: 06/14/1994
 TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT BLODGETT MEMORIAL HOSPITAL IN EAST
 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 of three treatments to an eye surface lesion using a strontium-90 (Sr-90) eye applicator. The misadministration resulted in the patient receiving a total

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

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

Other Agency Action:**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

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 is greater than 1.5 times the prescribed dose can be considered an abnormal occurrence

ITEMNO: 941575 AO_NO: NRC 94-14 DATE: 06/21/1994
 TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT THE WILLIAM W. BACKUS HOSPITAL IN NOR
 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)

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

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

Other Agency Action:**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

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

ITEMNO

940738

AO_NO:

AS 94-02

DATE:

08/04/1993

TITLE:

MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MEMORIAL MEDICAL CENTER IN LUFKIN, T

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

NRC Action:**Cause:**

Repositioning of the patient to relieve breathing distress was the probable cause of the implant relocation.

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.

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.

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.

ITEMNO

941441

AO_NO:

AS 94-03

DATE:

02/23/1994

TITLE:

RADIATION BURN OF AN INDUSTRIAL RADIOGRAPHER AT BLAZER INSPECTION IN TEXAS CITY, T

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 1.5-meter (5-feet) deep ditch at Amoco Pipeline, using a 3552 gigabecquerel (96 curie) iridium-192 source. They had experienced difficulty with

NRC Action:**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.

Other Agency Action:

The licensee and radiographer were cited for violations of the Texas Regulations for Control of Radiation and are being called in for an escalated Enforcement Conference.

This event will be updated when additional information

Licensee Action:

Actions will be given at the Enforcement conference.

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.

ITEMNO: 941442 AO_NO: AS 94-04 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

NRC Action:**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.

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.

Licensee Action:

The licensee will address the incident at its Enforcement Conference.

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.

ITEMNO: 941371 AO_NO: AS 94-05 DATE: 05/17/1994

TITLE: MULTIPLE BRACHYTHERAPY MISADMINISTRATIONS AT CEDARS MEDICAL CENTER IN MIAMI, FL

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,

NRC Action:**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

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 on-site visit was

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 calculations methods, which includes independent hand calculations of at least one

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

ITEMNO: 941413 AO_NO: NRC 94-15 DATE: 03/09/1994

TITLE: SODIUM IODIDE EVENT AT WELBORN MEMORIAL BAPTIST HOSPITAL IN EVANSVILLE, INDIANA

NAME: Welborn Memorial Baptist Hospital 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 millicurie [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

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

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

Other Agency Action:**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

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.

ITEMNO 941675

AO_NO: NRC 94-16

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.

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

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.

Other Agency Action:**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

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.

ITEMNO 941670

AO_NO: NRC 94-17

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

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

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

Other Agency Action:

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

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

ITEMNO: 940717 AO_NO: NRC 94-18 DATE: 07/28/1994
 TITLE: MULTIPLE TELETHERAPY MISADMINISTRATIONS AT SINAI HOSPITAL IN DETROIT, MICHIGAN (ITE
 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.

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 on September 8,

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.

Other Agency Action:**Licensee Action:**

The corrective actions taken included: (1) suspending all teletherapy treatments pending an internal investigation, and identification of 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

Criteria:

The following information pertaining to this even 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.

ITEMNO: 941712 AO_NO: NRC 94-19 DATE: 07/29/1994
 TITLE: BRACHYTHERAPY MISADMINISTRATION INVOLVING THE USE OF A STRONTIUM-90 EYE APPLICA
 NAME: University of Massachusetts Medic 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

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

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

Other Agency Action:**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.

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

ITEMNO: 940303 AO_NO: AS 94-06 DATE: 04/01/1993
 TITLE: LOSS OF MANAGEMENT AND PROCEDURAL CONTROL OF A RADIOACTIVE SOURCE LICENSED B
 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 7063P fixed gauge that was presumed to be empty had been found to still contain its 7400 gigabecquerel (200 millicurie) cesium-137 sealed source. The

NRC Action:**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

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) a follow-up inspection

Licensee Action:

The fixed gauge licensee's corrective actions included hiring a consultant to assist in the resolution of the gauge incident and in its assessment of the exposures received by its personnel, and to evaluate the implement revisions to its radiation protection program to ensure compliance. A meeting was held with the gauge manufacturer's

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)

ITEMNO AO_NO: DATE:

TITLE:

NAME: CITY: STATE:

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 records of the dosages

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

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.

Other Agency Action:**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-

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

ITEMNO AO_NO: DATE:

TITLE:

NAME: CITY: STATE:

Nature and Probable Consequences:

On August 9, 1994, the licensee's radiation safety officer (RSO) notified NRC of a misadministration involving a therapeutic dose of Strontium-89 (Sr-89) (Ref. 12).
The RSO reported that a patient scheduled to receive 185

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

Cause:

The cause of the misadministration was attributed to the administering technologist's failure to verify the isotope as well as dosage (by reading the label on the syringe) prior to injection.

Other Agency Action:

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 radiopharmacy in different containers, according to

Criteria:

The following information pertaining to this event is also being reported 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.

ITEMNO: 941746 AO_NO: NRC 94-23 DATE: 08/03/1994

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT NORTH MEMORIAL MEDICAL CENTER IN R

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.

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 the licensee on

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

Other Agency Action:**Licensee Action:**

The licensee's corrective actions include: amending the nursing staff procedure so that the attending physician will be contacted if 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

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.

ITEMNO: 942062 AO_NO: AS 94-07 DATE: 04/21/1994

TITLE: MAJOR CONTAMINATION EVENT DUE TO A BREACHED SOURCE AT KAY-RAY/SENSALL, INC., IN

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

NRC Action:**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

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 for the source supplier, located in another Agreement State.

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

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.

ITEMNO: 941957 AO_NO: AS 94-08 DATE: 10/17/1994

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT ST. JOSEPH'S HOSPITAL IN ORANGE, CALIF

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

NRC Action:**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 an upward, tilting direction and

Other Agency Action:

The State agency staff has reviewed the circumstances of the misadministration and will evaluate the licensee's corrective actions during the next inspection to be conducted in the near future.

Licensee Action:

The licensee will not visually check the source after the carrier has been placed in the applicator for each source loading.

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.

ITEMNO 941975

AO_NO: AS 94-09

DATE: 12/07/1993

TITLE: BRACHYTHERAPY MISADMINISTRATION AT THE UNIVERSITY OF CALIFORNIA'S LONG HOSPITAL I

NAME: University of California's Long Hos

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.)

NRC Action:**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 licensee procedures.

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

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

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).

ITEMNO 940524

AO_NO: AS 94-10

DATE: 05/10/1993

TITLE: MEDICAL TELEETHERAPY MISADMINISTRATION BY AN "UNSPECIFIED LICENSEE" AT AN "UNSPECI

NAME: New York State DOH "Unspecified"

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

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.

Cause:

The technologist failed to follow existing procedures which require that treatment parameters be checked prior to delivering the dose.

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

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

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.

ITEMNO: 942059 AO_NO: NRC 95-01 DATE: 11/18/1994

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT WELBORN MEMORIAL BAPTIST HOSPITAL I

NAME: Welborn Memorial Baptist Hospital 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

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

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

Other Agency Action:**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

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

ITEMNO: 950842 AO_NO: NRC 95-07 DATE: 06/08/1995

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT MARSHFIELD CLINIC IN MARSHFIELD, WISC

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

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

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

Other Agency Action:**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

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

ITEMNO: 951007 AO_NO: NRC 95-08 DATE: 07/25/1995

TITLE: MEDICAL BRACHYTHERAPY MISADMINISTRATION AT PROVIDENCE HOSPITAL IN SOUTHFIELD, M

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

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.

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

Other Agency Action:**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.

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

ITEMNO

950922

AO_NO:

NRC 95-09

DATE:

06/28/1995

TITLE:

INGESTION OF RADIOACTIVE MATERIAL BY RESEARCH WORKERS AT THE NATIONAL INSTITUTE

NAME:

National Institutes of Health (NIH)

CITY:

Bethesda

STATE:

MD

Nature and Probable Consequences:

A pregnant research employee became internally contaminated with phosphorus-32 (P-32) and was sent to a local hospital for treatment.

NRC formed an Augmented Inspection Team (AIT), which

NRC Action:

In addition to forming an AIT, NRC subsequently conducted a special inspection to determine the effectiveness of NIH security over radioactive materials.

NRC also issued two Confirmatory Action Letters. The

Cause:

Because of the ongoing investigation, NRC has not reached a final conclusion as to the cause of the event.

Other Agency Action:**Licensee Action:**

The licensee continues to investigate the incident. The licensee performed bioassay sampling to identify the isotope, calculate preliminary estimates of intake, and determine the scope of the contamination. In addition, the licensee will take actions to enhance security for handling radioactive materials.

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.

ITEMNO

950033

AO_NO:

AS 95-05

DATE:

12/20/1994

TITLE:

IMPORTATION OF A PACKAGE HAVING EXCESSIVE EXTERNAL RADIATION INTO THE UNITED STA

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

NRC Action:**Cause:**

The State of Louisiana's Radiation Protection Division concluded that the reason the one package had an excessive radiation profile was that the source wire was not secured in the safe or completely shielded position. This suggests an improper preparation for shipment and

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

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

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.

ITEMNO: AO_NO: DATE:

TITLE:

NAME: CITY: STATE:

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

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

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.

Other Agency Action:**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.

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.

ITEMNO: AO_NO: DATE:

TITLE:

NAME: CITY: STATE:

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

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

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.

Other Agency Action:**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.

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.

ITEMNO: AO_NO: DATE:

TITLE:

NAME: CITY: STATE:

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

NRC Action:

An NRC inspection was conducted on February 14-15, 1989, to review the circumstances associated with the event (Ref. 5). Four minor violations of NRC requirements were identified-none relating to the misadministration. An NRC consulting physician

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

Other Agency Action:**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

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

ITEMNO

AO_NO:

NRC 89-07

DATE:

03/13/1989

TITLE:

MEDICAL THERAPY MISADMINISTRATION

NAME:

Indiana University School of Medic

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

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).

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

Other Agency Action:**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.

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

ITEMNO

AO_NO:

AS 89-01

DATE:

02/11/1989

TITLE:

INDUSTRIAL RADIOGRAPHY OVEREXPOSURES

NAME:

Technical Welding Laboratory, Inc

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 Tech. Ops Model

NRC Action:**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

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

Licensee Action:

The licensee has held several safety meetings to discuss the importance of performing proper surveys after each radiograph.

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 rems or more of radiation can be considered an abnormal occurrence.

ITEMNO

AO_NO:

NRC 89-09

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 in a radiation dose in the therapeutic range. Prior to the date of administration, the patient's physician telephoned the licensee's nuclear

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

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

Other Agency Action:**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 to submit a written prescription for the use of iodine-131. In addition, nuclear

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.

ITEMNO

AO_NO:

NRC 89-11

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

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

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

Other Agency Action:**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

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.

ITEMNO

AO_NO:

NRC 89-10

DATE:

07/24/1989

TITLE:

MEDICAL THERAPY MISADMINISTRATION

NAME:

Worcester City Hospital

CITY:

Worcester

STATE:

MA

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

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.

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

Other Agency Action:**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.

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.

ITEMNO

AO_NO:

NRC 89-12

DATE:

TITLE:

SIGNIFICANT BREAKDOWN AND CARELESS DISREGARD OF THE RADIATION SAFETY PROGRAM

NAME:

Three facilities in Ohio operated b

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

NRC Action:

As a result of the June inspection findings, the NRC issued a Confirmatory Action Letter on June 2, 1989 (Ref. 9), documenting the licensee's agreement to take prompt corrective actions to deal with the violations identified. These actions included performing radiation and

Cause:

Inadequate management attention to radiation safety provisions and past corrective actions that were not implemented or that were ineffective in resolving the problems were the cause of the existence of problems for extended periods and the repetition of problems. This

Other Agency Action:**Licensee Action:**

Subsequent to the August 1988 and June 1989 inspections, the licensee has revamped its radiation safety programs, emphasized closer supervision at Ravenna by corporate and plant management, and undertaken a major modification of the thorium handling system at the Ravenna plant. The electrode coating was

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

ITEMNO

AO_NO:

NRC 89-13

DATE:

10/18/1989

TITLE:

MEDICAL DIAGNOSTIC MISADMINISTRATION

NAME:

Mayo Foundation

CITY:

Rochester

STATE:

MN

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 a radioactive iodine compound that was 10 times the intended dose.

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,

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

Other Agency Action:

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

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

ITEMNO: [] AO_NO: NRC 89-14 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).

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.

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.

Other Agency Action:**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

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

ITEMNO: [] AO_NO: AS 89-02 DATE: 08/26/1989

TITLE: INDUSTRIAL RADIOGRAPHER OVEREXPOSURE

NAME: Mobil-Lab, Inc. (licensee)/Shell Oil 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

NRC Action:**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.

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

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

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

ITEMNO: [] AO_NO: NRC 86-04 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

NRC Action:

The licensee was inspected by an NRC Region I inspector on February 20-11, 1986. The subject event was reviewed in detail. On February 11, 1986, Region I issued a Confirmatory Action Letter documenting the licensee's commitment described above.

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.

Other Agency Action:**Licensee Action:**

The licensee voluntarily suspended patient treatment pending the results of an internal investigation, and discussion of these results with NRC Region I.

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.

Subsequently, the licensee committed to assure that an authorized physician reviews every patient chart prior to

ITEMNO

AO_NO:

NRC 86-05

DATE:

02/19/1986

TITLE:

OVEREXPOSURE TO A MEMBER OF THE PUBLIC FROM AN INDUSTRIAL GAUGE

NAME:

C-E Glass, Inc. (Div. of Combustio

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

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

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

Other Agency Action:**Licensee Action:**

The licensee is longer in business and has no other gauges in its possession.

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

ITEMNO

AO_NO:

NRC 86-06

DATE:

03/03/1986

TITLE:

BREAKDOWN OF MANAGEMENT CONTROLS AT AN IRRADIATOR FACILITY

NAME:

Radiation Technology, Incorporate

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

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

Cause:

The root cause can be attributed to a serious breakdown in the licensee's management controls.

Other Agency Action:

Licensee Action:

The actions taken by the licensee are described above.

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.

ITEMNO

AO_NO:

NRC 86-07

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 3, 1985, equivalent to a

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

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 into the laboratory rather

Other Agency Action:**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.

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.

ITEMNO

AO_NO:

AS 86-01

DATE:

04/20/1984

TITLE:

RADIATION INJURY OF AN INDUSTRIAL RADIOGRAPHER

NAME:

BF Inspection Services (of Midlan

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 Control

NRC Action:**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 Procedures or the Texas

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.

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.

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.

ITEMNO

AO_NO:

AS 86-02

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

NRC Action:**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

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.

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 all scrap steel before it is placed in the furnace.

Criteria:

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

ITEMNO

AO_NO:

AS 86-03

DATE:

08/25/1985

TITLE:

RADIATION INJURY OF AN INDUSTRIAL RADIOGRAPHER

NAME:

Boothe-Twining, Inc. (Kern River

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

NRC Action:**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

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

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

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.

ITEMNO

AO_NO:

AS 86-04

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 a radiation burn of his left hand and an estimated 129 rems whole body exposure. The licensee failed to notify the Texas Bureau of Radiation

NRC Action:**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.

Other Agency Action:

The Agency has cited the Licensee for items of non-compliance with the Texas Regulations for Control of Radiation. In addition, a complaint has been issued to the licensee, notifying him that the Agency intends to revoke the license. The investigation of this incident is

Licensee Action:

The licensee has started tighter controls on its initial training program and hiring procedures.

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.

ITEMNO

AO_NO:

NRC 86-10

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

NRC Action:

On June 17, 1986, the NRC forwarded to Mercy Hospital (1) an Order requiring the licensee to show cause why the Chief Nuclear Medicine Technician and the RSO should not be prohibited from the performance or supervision of any licensed activities, and (2) a Notice of Violation and

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.

Other Agency Action:**Licensee Action:**

The licensee, as well as another licensee in which the RSO is involved, requested an extension to respond to the NRC enforcement actions described below.

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

ITEMNO

AO_NO:

NRC 86-11

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 that intended. This resulted in an unintended dose of several hundred rads to the patient's bone marrow.

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

Cause:

The root cause was the lack of written prescriptions for ordering therapeutic doses.

Other Agency Action:**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

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.

ITEMNO

AO_NO:

NRC 86-12

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.

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

Cause:

The NRC determined that the failure to report the misadministrations was willful.

Other Agency Action:**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 as 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

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

ITEMNO

AO_NO:

NRC 86-13

DATE:

05/07/1986

TITLE:

DIAGNOSTIC MEDICAL MISADMINISTRATION

NAME:

Robert Packer Hospital/Guthrie Cli

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,

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.

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.

Other Agency Action:**Licensee Action:**

All concerned personnel have been retrained on the policy of not administering radioisotopes without a written requisition and of the requirement to obtain the specific consent of a radiologist for all cases requiring the administration of greater than 300 microcuries of iodine-131

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.

ITEMNO

AO_NO:

NRC 86-14

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

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

Cause:

This misadministration was the result of an isolated incident of misreading the consultation sheet.

Other Agency Action:

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

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

ITEMNO

AO_NO:

AS 86-05

DATE:

05/08/1985

TITLE:

UNCONTROLLED RELEASE OF KRYPTON-85 TO AN UNRESTRICTED AREA

NAME:

Micro-Rel Division, Medtronic, Inc

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.

NRC Action:**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

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

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.

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

ITEMNO

AO_NO:

AS 86-06

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

NRC Action:**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

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.

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

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.

ITEMNO

AO_NO:

NRC 86-19

DATE:

08/27/1984

TITLE:

THERAPEUTIC MEDICAL MISADMINISTRATION

NAME:

University of Cincinnati Medical C

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 rad to the patient's thyroid.

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

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

Other Agency Action:**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

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.

ITEMNO

AO_NO:

AS 86-07

DATE:

09/05/1986

TITLE:

THERAPEUTIC MEDICAL MISADMINISTRATION

NAME:

University of Iowa Hospitals and C

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.

NRC Action:**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

Other Agency Action:

No actions are planned by the State Agency.

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

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

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.

ITEMNO

AO_NO:

NRC 86-23

DATE:

09/18/1986

TITLE:

RELEASE OF AMERICIUM 241 INSIDE A WASTE STORAGE BUILDING AT WRIGHT-PATTERSON AIR

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

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

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.

Other Agency Action:

Licensee Action:

The licensee's investigation of the incident is continuing. The Radiation Safety Officer and two other individuals associated with the handling of the incident have been removed from any work involving NRC licensed radioactive materials; this was documented by a Confirmatory Action Letter issued by NRC Region III on

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.

ITEMNO: [] AO_NO: NRC 86-24 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.

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).

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

Other Agency Action:**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

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.

ITEMNO: [] AO_NO: NRC 86-25 DATE: 10/10/1986

TITLE: SUSPENSION OF LICENSE FOR SERVICING TELE THERAPY 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

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

Cause:

The cause of this event was the apparent disregard of NRC's regulations and requirements by the licensee.

Other Agency Action:**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 unit maintenance and service work.

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"

ITEMNO: [] AO_NO: NRC 86-26 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 while the intended procedure was to be a thyroid scan.

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

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

Other Agency Action:**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

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

ITEMNO

AO_NO:

NRC 86-27

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 the wrong radioactive material was administered. It is estimated that the patient's thyroid received a dose of about 6,760 rads.

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

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 the telephone

Other Agency Action:**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

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

ITEMNO

AO_NO:

NRC 86-28

DATE:

12/30/1986

TITLE:

IMMEDIATELY EFFECTIVE ORDER MODIFYING LICENSE AND ORDER TO SHOW CAUSE ISSUED T

NAME:

Met-Chem Testing Laboratories of

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. 28).

NRC Action:

The NRC Order contained the following provisions, effective immediately:

(1) License No. 43-26821-01 is amended by adding the following condition:

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

Other Agency Action:

Licensee Action:

The licensee responded to the NRC Order on January 15, 1987. The licensee stated that the employee terminated employment at 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.

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.

ITEMNO

AO_NO:

NRC 87-02

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 21, 1986, a patient received an intravenous dose of 100 millicuries of technetium-99m rather than the prescribed dose of 20 millicuries.

NRC Action:

The licensee's corrective actions were reviewed by Region I during an inspection on February 4, 1987. Region I has requested that the licensee describe and take more comprehensive and specific corrective actions.

Cause:

The cause was due to human error by the technologist.

Other Agency Action:**Licensee Action:**

The licensee concludes that a cause of the misadministration was that the technologist was rushed and doing too many duties at 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

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.

ITEMNO

AO_NO:

NRC 87-03

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.

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 actions.

Cause:

The root cause was the licensee's failure to properly check the dose label with the prescribed dose.

Other Agency Action:**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 at 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

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.

ITEMNO

AO_NO:

NRC 87-04

DATE:

02/19/1987

TITLE:

DIAGNOSTIC MEDICAL MISADMINISTRATION

NAME:

University of Massachusetts Medic

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

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

Cause:

The cause was due to human error by a nuclear medicine technologist.

Other Agency Action:**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

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

ITEMNO

AO_NO:

NRC 87-05

DATE:

03/17/1987

TITLE:

SIGNIFICANT BREAKDOWN IN MANAGEMENT OVERSIGHT AND CONTROL OF RADIATION SAFETY

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

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

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.

Other Agency Action:**Licensee Action:**

The licensee has repaired the affected equipment, revised its operating procedures, and retrained its personnel to assure compliance with the NRC regulations.

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 areas can be considered an abnormal occurrence

ITEMNO

AO_NO:

NRC 87-06

DATE:

04/01/1987

TITLE:

DIAGNOSTIC MEDICAL MISADMINISTRATION

NAME:

Veterans Administration Medical C

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, 400 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

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.

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.

Other Agency Action:

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

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.

ITEMNO

AO_NO:

NRC 87-07

DATE:

04/01/1987

TITLE:

SIGNIFICANT BREAKDOWN IN MANAGEMENT OVERSIGHT AND CONTROL OF RADIATION SAFETY

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

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

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.

Other Agency Action:**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

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.

ITEMNO

AO_NO:

NRC 87-08

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

NRC Action:

The licensee's response to the Order is still under review by the NRC staff.

Future reports will be made as appropriate.

Cause:

The root cause can be attributed to a serious breakdown in the licensee's management controls.

Other Agency Action:**Licensee Action:**

On April 27, 1986, the licensee responded to the requirements of the Order.

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.

ITEMNO

AO_NO:

AS 87-01

DATE:

02/17/1987

TITLE:

BREAKDOWN IN MANAGEMENT AND PROCEDURAL CONTROLS AT AN INDUSTRIAL RADIOGRAPH

NAME:

U.S. Testing Company/Unitech Se

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, Unitech Services Group, San Leandro, California, to cease all radiographic operations within the State of Arizona.

NRC Action:**Cause:**

The root cause was a breakdown in management and procedural controls. This was a contributing cause of the overexposures experienced.

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.

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.

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.

ITEMNO

AO_NO:

AS 87-02

DATE:

02/27/1987

TITLE:

BREAKDOWN IN MANAGEMENT AND PROCEDURAL CONTROLS AT AN INDUSTRIAL RADIOGRAPH

NAME:

Continental Testing and Inspection

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.

NRC Action:**Cause:**

The root cause was a breakdown in management and procedural controls.

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 four

Licensee Action:

As directed, the licensee ceased operations. The licensee proposed six individuals be authorized to perform radiographer.

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.

ITEMNO

AO_NO:

NRC 87-09

DATE:

01/21/1987

TITLE:

DIAGNOSTIC MEDICAL MISADMINISTRATION

NAME:

Halifax-South Boston Community

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 a thyroid scan.

The purpose of the scan was to rule out the presence of a

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.

Cause:

The misadministration was caused by the nuclear medicine technician's misinterpretation of the dose calibrator value.

Other Agency Action:

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.

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.

ITEMNO

AO_NO:

NRC 87-10

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.

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.

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;

Other Agency Action:**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 will all technologists to review the incident and internal policies; special training for the technologists involved and review of all their work; and

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.

ITEMNO

AO_NO:

NRC 87-11

DATE:

05/20/1987

TITLE:

DIAGNOSTIC MEDICAL MISADMINISTRATION

NAME:

National Institutes of Health

CITY:

Bethesda

STATE:

MD

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 120 millicuries of technetium-99m pertechnetate rather than the prescribed radiopharmaceutical, 10 millicuries of gallium-67 citrate.

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.

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.

Other Agency Action:**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.

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.

ITEMNO

AO_NO:

NRC 87-12

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

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

Cause:

The cause of these occurrences appear to be a lack of adequate management control by the licensee and a lack of integrity on the part of individual members of the licensee's staff.

Other Agency Action:**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 accord with the restriction specified by the NRC Order. The licensee is conforming to the various

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.

ITEMNO

AO_NO:

NRC 87-13

DATE:

06/17/1987

TITLE:

SIGNIFICANT BREAKDOWN IN MANAGEMENT AND PROCEDURAL CONTROLS AT AN INDUSTRIAL

NAME:

United States Testing Company, I

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

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

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

Other Agency Action:**Licensee Action:**

As discussed further below, the licensee has taken, or is taking, appropriate actions in response to the February 13, 1987 CAL, and the June 17, 1987 NRC Order.

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 areas can be considered an abnormal occurrence.

ITEMNO

AO_NO:

AS 87-03

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

NRC Action:**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 and end play and use of too

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 pigtailed for proper connection and end play.

Licensee Action:

The licensee immediately provided reinstruction to all radiographic personnel on radiation safety and operating procedures with emphasis on surveys and emergency procedures.

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 rem or more of radiation; exposure of the skin of the whole body of any individual to 150 rem or more of radiation; or exposure of the feet, ankles, hands or forearms of any individual to 375 rem or more of

ITEMNO

AO_NO:

NRC 87-16

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.

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

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.

Other Agency Action:**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.

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.

ITEMNO

AO_NO:

NRC 87-17

DATE:

08/24/1987

TITLE:

FAILURE TO REPORT DIAGNOSTIC MEDICAL MISADMINISTRATION

NAME:

Edward Hines, Jr., Veterans Admi

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

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

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.

Other Agency Action:

The NRC investigation and previous inspections at the

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.

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.

ITEMNO

AO_NO:

NRC 87-18

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 suspended the NRC license, ordered all by-product material be placed in locked storage, and ordered the licensee to show cause why the license

NRC Action:

The NRC is terminating the license.

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

Cause:

The root cause can be attributed to a serious breakdown in the licensee's management controls.

Other Agency Action:**Licensee Action:**

The licensee has requested that the license be terminated. The licensee has transferred all sealed sources to an authorized recipient.

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.

ITEMNO

AO_NO:

NRC 87-19

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

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.

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

Other Agency Action:**Licensee Action:**

The licensee has complied with the Order and has forwarded a written request for an enforcement hearing.

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.

ITEMNO

AO_NO:

AS 87-04

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 on a patient.

On the morning of June 2, an 87 year old patient at the

NRC Action:**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.

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.

Licensee Action:

The hospital has revised its procedures for preparing for radiiodine therapy treatments, and its criteria for patient selection.

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

ITEMNO: 960281 AO_NO: AS 87-05 DATE: 08/05/1987

TITLE: THERAPEUTIC MEDICAL MISADMINISTRATION

NAME: Northern Westchester Medical Ce 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.

NRC Action:**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

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

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.

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: Insufficient information is available on the

UPDATE: This abnormal occurrence was originally

ITEMNO: AO_NO: NRC 87-20 DATE: 10/30/1987

TITLE: SUSPENSION OF LICENSE OF AN OIL AND GAS WELL TRACER COMPANY

NAME: Tracer Profiles, Inc. CITY: Oklahoma City STATE: OK

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).

NRC Action:

The NRC is considering action to revoke the license.

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.

Other Agency Action:**Licensee Action:**

None.

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

ITEMNO: AO_NO: NRC 88-04 DATE: 11/23/1987

TITLE: DIAGNOSTIC MEDICAL MISADMINISTRATION

NAME: Veteran's Administration Medical CITY: Albuquerque STATE: NM

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

NRC Action:

NRC Region IV telephoned the radiation safety officer reporting this misadministration for additional details on the incident. Those details were subsequently provided by a February 1, 1988 memorandum from the licensee. The incident will be reviewed during a special NRC

Cause:

The misadministration was caused by a student technologist selecting the wrong syringe from the dosage cart.

Other Agency Action:**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.

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.

ITEMNO

AO_NO:

NRC 88-05

DATE:

01/20/1988

TITLE:

BREAKDOWN IN MANAGEMENT CONTROLS AT GEORGIA INSTITUTE OF TECHNOLOGY RESEARC

NAME:

Georgia Institute of Technology (G

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).

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

Cause:

The root cause was a lack of regard for and adherence to procedures, and a lack of management control over licensed activities.

Other Agency Action:**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

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.

ITEMNO

AO_NO:

NRC 88-06

DATE:

01/21/1988

TITLE:

RELEASE OF POLONIUM-210 FROM STATIC ELIMINATION DEVICES MANUFACTURED BY 3M COM

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

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;

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.

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,

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

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)

ITEMNO: [] AO_NO: NRC 88-07 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

NRC Action:

NRC Region IV telephoned the radiation safety officer reporting this misadministration for additional information and assurance that corrective action had been taken. The incident will be reviewed during the next NRC inspection at the medical center.

Cause:

The misadministration was caused by a miscalculation of the dose by the technician.

Other Agency Action:**Licensee Action:**

The technician administering the dose was re-instructed in the proper technique for calculating therapy doses and for reviewing the written physician orders prior to administering the doses.

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.

ITEMNO: [] AO_NO: NRC 88-08 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.

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

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

Other Agency Action:**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.

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.

ITEMNO: 040611 AO_NO: AS 04-08 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

NRC Action:**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.

Other Agency Action:

The State agency reviewed and approved the corrective actions that the licensee implemented to prevent recurrence.

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.

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 is a dose or

ITEMNO

040003

AO_NO:

AS 04-09

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

NRC Action:**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.

Other Agency Action:

The Ohio Department of Health conducted an investigation, reviewed the licensee's corrective actions, and found them adequate to prevent recurrence.

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.

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 to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a

ITEMNO

030933

AO_NO:

AS 04-10

DATE:

11/18/2003

TITLE:

Intravascular Brachytherapy Medical Event at Swedish Medical Center in Seattle, Washington

NAME:

Swedish Medical Center

CITY:

Seattle

STATE:

WA

Nature and Probable Consequences:

A patient undergoing an intravascular brachytherapy (IVB) treatment for coronary restenosis received 13.78 Gy (1,378 rads) to an unintended site (healthy tissue). The licensee reported that the source train was partially inserted into a small artery, and the routing did not follow

NRC Action:**Cause:**

It is suspected that the pressure from the small artery and the tortuous route to the site caused a contraction of a portion of the source train and resulted in the seeds becoming stuck at a particular location.

Other Agency Action:

The State reviewed and approved the corrective actions taken by the licensee and will follow-up at the next inspection.

Licensee Action:

Corrective actions included reemphasizing the importance of adhering to established procedures and protocols before administering radiopharmaceuticals, and ensuring that all staff completed refresher training.

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 to the gonads or (2) equal to or greater than 10 Gy (1 000 rads) to any other organ and represents a

ITEMNO: 040702 AO_NO: AS 04-11 DATE: 09/24/2004

TITLE: Diagnostic Medical Event at Swedish Medical Center in Seattle, Washington

NAME: Swedish Medical Center CITY: Seattle STATE: WA

Nature and Probable Consequences:

The licensee reported that a patient received 190.9 MBq (5.16 mCi) of I-131, instead of the prescribed 74 MBq (2 mCi) for a post thyroid treatment follow-up scan. The prescribing physician realized that the error occurred on September 27, 2004, when the patient underwent the

NRC Action:**Cause:**

The licensee stated that human error led to procedural checks not being performed prior to the administration.

Other Agency Action:

The State reviewed and approved the corrective actions taken by the licensee and will follow-up at the next inspection.

Licensee Action:

Corrective actions included re-emphasis on the importance of adhering to established procedures and protocols prior to the administration of radiopharmaceuticals and the completion of staff refresher training.

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 to the gonads or (2) equal to or greater than 10 Gy (1 000 rads) to any other organ and represents a

ITEMNO: 951311 AO_NO: NRC 96-18 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

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.

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

Other Agency Action:**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.

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 an AO.

ITEMNO: 960163 AO_NO: AS 96-01 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

NRC Action:**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

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

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.

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.

ITEMNO 951155

AO_NO: AS 96-02

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

NRC Action:**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"

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.

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.

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.

ITEMNO 951169

AO_NO: AS 96-03

DATE: 10/03/1995

TITLE: Release of Radioactive Material in Lemont, Illinois, from a Package that Was Accidentally Destroyed While

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

NRC Action:**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.

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

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.

Criteria:

Appendix A (see For All Licensees, Example 11) of this report notes that serious deficiency in management or procedural controls in major areas should be considered an AO.

ITEMNO: 960069 AO_NO: AS 96-04 DATE: 01/31/1996

TITLE: Lost Source at Deseret Generation and Transmission Cooperative's Bonanza Power Plant

NAME: Deseret Generation and Transmis 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.

NRC Action:**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.

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

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

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.

ITEMNO: 960171 AO_NO: AS 96-05 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)

NRC Action:**Cause:**

The misadministration was caused by human error. The wrong catheter length was entered into the HDR's computer treatment planning software.

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.

Licensee Action:

To prevent recurrence, the licensee added redundancy to its internal checklists to verify that the correct catheter length is entered in the HDR's computer treatment software.

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.

ITEMNO: AO_NO: NRC 88-09 DATE: 02/26/1988

TITLE: SIGNIFICANT WIDESPREAD BREAKDOWN IN RADIATION SAFETY PROGRAM AT CASE WESTERN

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 imposing a \$10,000 fine on Case Western Reserve University, Cleveland, Ohio.

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

Cause:

The failure to adequately correct past violations identified in a May 1986 inspection, as well as the numerous violations identified in the November-December 1987 inspections, demonstrated a serious, widespread breakdown in the management of the licensee's radiation

Other Agency Action:**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

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

ITEMNO

AO_NO:

AS 88-01

DATE:

11/16/1987

TITLE:

RADIATION INJURY TO TWO RADIOGRAPHERS

NAME:

North Shore X-Ray and Testing C

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 by the Agency and

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.

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

Other Agency Action:**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

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.

ITEMNO

AO_NO:

NRC 88-10

DATE:

06/03/1988

TITLE:

SIGNIFICANT BREAKDOWN IN MANAGEMENT AND PROCEDURAL CONTROLS IN A MEDICAL FACI

NAME:

Riverton Memorial Hospital-Health

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.

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

Cause:

The causes are attributed to significant deficiencies in management oversight and control of the licensed program.

Other Agency Action:

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.

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

ITEMNO: [] AO_NO: NRC 88-11 DATE: 06/09/1988

TITLE: MEDICAL DIAGNOSTIC MISADMINISTRATION

NAME: Veterans Administration Medical C CITY: Los Angeles STATE: CA

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 a resident.

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

Cause:

The cause was due to the failure of the technician and resident physician to follow the protocol for radiopharmaceutical injections.

Other Agency Action:**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

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.

ITEMNO: [] AO_NO: AS 88-02 DATE: 01/27/1988

TITLE: RADIOACTIVE MATERIAL RELEASED DURING A TRANSPORTATION ACCIDENT

NAME: Houston Inspection Laboratories, I 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 HILI truck onto a roadway. The camera was struck by another vehicle and dragged for a considerable distance along the roadway. At some point

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

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.

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

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

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

ITEMNO: [] AO_NO: NRC 88-12 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.

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.

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.

Other Agency Action:**Licensee Action:**

The particular procedure involved has not been used since October 1986. In order to prevent a recurrence of the type of event, the licensee committed to take the following actions:

(1) All current dose calibration procedures will be

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.

ITEMNO

AO_NO:

NRC 88-13

DATE:

06/27/1988

TITLE:

MEDICAL DIAGNOSTIC MISADMINISTRATION

NAME:

Fairfax Hospital

CITY:

Falls Church

STATE:

VA

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

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

Cause:

The cause is attributed to the technologist's error in overlooking the proper dosage as listed in the department's procedure manual.

Other Agency Action:**Licensee Action:**

The technologist was admonished and retrained.

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.

ITEMNO

AO_NO:

AS 88-03

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 over 30,000 rads;

NRC Action:**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.

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 enforcement action.

This item is considered closed for the purposes of this

Licensee Action:

The licensee is rewriting its protocol for nuclear medicine scans to list each procedure with the activity and form of the material to 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

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.

ITEMNO

AO_NO:

NRC 88-14

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.

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

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.

Other Agency Action:**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 times for each treatment plan

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

ITEMNO

AO_NO:

AS 88-04

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

NRC Action:**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,

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.

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

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.

ITEMNO

AO_NO:

AS 88-05

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.

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:

Cause:

The oncologist improperly aligned the teletherapy unit's lateral port to the patient's skull.

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

Licensee Action:

In the report to the State Agency, the oncologist stated that she would exercise increased vigilance and alertness in performing her work.

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.

ITEMNO

960236

AO_NO:

AS 88-06

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

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 event, as well as therapy

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

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 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

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.

ITEMNO

AO_NO:

NRC 86-03

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

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

Cause:

The NRC Augmented Investigation Team (AIT) which investigated both incidents reported the following causes in NUREG-1179, Vol. 1 and Vol. 2, respectively.

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

January 4, 1986 Incident:

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.

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

ITEMNO: 960060 AO_NO: NRC 96-03 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

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

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.

Other Agency Action:**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

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.

ITEMNO: 960096 AO_NO: NRC 96-04 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 a strontium-90 (Sr-90) source in an eye applicator. Consequently, the licensee had the Sr-90 eye applicator calibrated by the National Institute of

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

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.

Other Agency Action:**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.

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

ITEMNO: 951291 AO_NO: NRC 96-05 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

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

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

Other Agency Action:**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.

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.

ITEMNO AO_NO: DATE:

TITLE:

NAME: CITY: STATE:

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

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

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.

Other Agency Action:**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.

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.

ITEMNO AO_NO: DATE:

TITLE:

NAME: CITY: STATE:

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

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.

Cause:

The wrong step size was entered into the HDR remote afterloader brachytherapy unit's computer control program.

Other Agency Action:

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 all treatment plan parameters must be verified, and the verification

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.

ITEMNO: 960478 AO_NO: NRC 96-08 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

NRC Action:

NRC conducted a special safety inspection.
This item is closed for the purpose of this report.

Cause:

Because of a treatment planning error, the source was placed approximately 27 mm (1.05 in) below the tumor volume.

Other Agency Action:**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.

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.

ITEMNO: 960313 AO_NO: NRC 96-09 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

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

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

Other Agency Action:**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

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.

ITEMNO: 951186 AO_NO: NRC 96-10 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

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

Cause:

When planning the treatment, the treating physicist 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

Other Agency Action:**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.

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.

ITEMNO: 951061 AO_NO: NRC 96-11 DATE: 08/14/1995

TITLE: Brachytherapy Misadministration at Thomas Jefferson University Hospital

NAME: Thomas Jefferson University Hosp 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 inside the

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.

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

Other Agency Action:**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

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.

ITEMNO: 960165 AO_NO: NRC 96-12 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

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.

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

Other Agency Action:

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 physician to observe the

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.

ITEMNO: 960483 AO_NO: NRC 96-13 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

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.

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

Other Agency Action:**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.

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.

ITEMNO: 960294 AO_NO: NRC 96-14 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 [μ Ci]) dosage of iodide-123 (I-123) for a thyroid scan, but was administered 7.4 MBq (200 μ Ci) of iodide-131 (I-131) instead.

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

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.

Other Agency Action:**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

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.

ITEMNO: 951165 AO_NO: NRC 96-15 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

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

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

Other Agency Action:**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.

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.

ITEMNO

960280

AO_NO:

NRC 96-16

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 122 MBq (3.3 mCi) dosage of I-131 for a diagnostic study of the neck and chest.

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.

Cause:

The technologist, when administering the dosage, mistakenly picked up a wrong radiopharmaceutical vial.

Other Agency Action:**Licensee Action:**

Licensee personnel failed to completely follow the written Quality Management Program.

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.

ITEMNO

960010

AO_NO:

NRC 96-17

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 of iodine-131 (I-131) in liquid form. The error was discovered when the licensee rechecked the prescription vial with a dose calibrator after the

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

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.

Other Agency Action:

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.

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.

ITEMNO: 040342 AO_NO: AS 04-03 DATE: 03/31/2004

TITLE: High Dose Rate Afterloader Medical Event at New Orleans Cancer Institute at Memorial Medical Center, L

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-

NRC Action:**Cause:**

This event was attributed to operator error.

Other Agency Action:

The State accepted the licensee's implementation of new procedures and its corrective actions as appropriate.

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

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

ITEMNO: 040610 AO_NO: AS 04-04 DATE: 08/10/2004

TITLE: Diagnostic Medical Event at Northeast Alabama Regional Medical Center, Alabama

NAME: Northeast Alabama Regional Medi 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

NRC Action:**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.

Other Agency Action:

The State conducted an inspection.

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.

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

ITEMNO: 040222 AO_NO: AS 04-05 DATE: 03/17/2004

TITLE: Occupational Exposure at Palmetto Health and Baptist Hospital in Columbia, South Carolina

NAME: Palmetto Health and Baptist Hospi 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

NRC Action:**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.

Other Agency Action:

The State agency conducted inspections and cited the licensee for violations of regulations for controlling radiation.

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

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

ITEMNO

040125

AO_NO:

AS 04-06

DATE:

01/24/2003

TITLE:

Gamma Stereotactic Radiosurgery (Gamma Knife) Medical Event at Radiosurgical Center of Memphis in

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

NRC Action:**Cause:**

The cause was human error, in that the event resulted from use of the wrong collimator helmet.

Other Agency Action:

The State reviewed and approved the licensee's new procedures.

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

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

ITEMNO

040213

AO_NO:

AS 04-07

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

NRC Action:**Cause:**

The wrong treatment time was programmed for the patient's eye treatment.

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.

Licensee Action:

The licensee updated its procedures, which require use of an additional person to operate a second timer during brachytherapy eye treatment.

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 dose

ITEMNO: 960264 AO_NO: AS 96-06 DATE: 05/23/1996

TITLE: Brachytherapy Misadministrations at the University of Mississippi Medical Center

NAME: University of Mississippi Medical C 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

NRC Action:**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

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.

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.

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

ITEMNO: 960149 AO_NO: AS 96-07 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 [μ Ci]) of iodine-131 (I-131) for a thyroid uptake study. The nuclear pharmacy delivered 3.7 MBq (100 μ Ci) by mistake, and a nuclear medicine technician

NRC Action:**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 μ Ci)

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

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.

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

ITEMNO: 951301 AO_NO: AS 96-08 DATE: 11/27/1995

TITLE: Radiopharmaceutical Misadministration at Methodist Medical Center

NAME: Methodist Medical Center CITY: Peoria STATE: IL

Nature and Probable Consequences:

An outpatient received 177.6 megabecquerel (MBq) (4.8 millicurie [mCi]) of a prescribed 444.0 MBq (12 mCi) dosage of iodine-131. The error was later discovered when the nuclear pharmacy received two of the three capsules in a return shipment. The referring physician

NRC Action:**Cause:**

The primary cause was the failure of the technologist to verify the number of capsules delivered by the pharmacy. This was the first dosage sent by the pharmacy in multiple capsules, so the technologist was unaware of the need to check.

Other Agency Action:

The State Agency accepted the licensee's report and corrective action as appropriate. No further action was requested.

This event is closed for the purpose of this report.

Licensee Action:

The licensee's staff was made aware of the error in order to prevent recurrence. Also, the pharmacy was requested to cease the practice of distributing multiple capsules for a single prescription.

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.

ITEMNO

970434

AO_NO:

NRC 97-02

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 a personal contamination survey

NRC Action:

NRC conducted a special safety inspection, proposed a \$55,000 civil penalty on December 17, 1997, and the licensee paid the civil penalty on January 20, 1998.

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

Other Agency Action:**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

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 shallow-dose equivalent to the skin or extremities 2500 mSv (250 rem) or more will be considered for reporting as an AO.

ITEMNO

960008

AO_NO:

AS 97-01

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

NRC Action:**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

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.

Licensee Action:

After the licensee's consultants conducted their review and comprehensive audit of the existing radiation protection program, they 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

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

ITEMNO: 960327 AO_NO: AS 97-02 DATE: 07/01/1996
 TITLE: Overexposure of a Radiographer and an Untrained Technician at Wolf Creek Mine in Walker County, Alab
 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

NRC Action:**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

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,

Licensee Action:

The licensee stated that the radiographer did not develop any symptom of acute radiation exposure and that its personnel were re-instructed 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

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

ITEMNO: 970220 AO_NO: AS 97-03 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

NRC Action:**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.

Other Agency Action:

The State Agency conducted numerous follow-up inspections to ensure that the licensee's actions taken to prevent recurrence had been implemented.

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 a radiopharmaceutical. In addition, the nuclear medicine

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

ITEMNO: 970155 AO_NO: AS 97-04 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 Graves 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

NRC Action:**Cause:**

The wrong dosage was administered to the patient because the written order for the I-131 procedure was misread by the administering technologist.

Other Agency Action:

The State Agency accepted the licensee's report and corrective action as appropriate. No further action was requested.

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.

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

ITEMNO

980005

AO_NO:

NRC 98-02

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)

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

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.

Other Agency Action:**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.

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

ITEMNO

980140

AO_NO:

NRC 98-03

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

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

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

Other Agency Action:

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

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

ITEMNO: 971111 AO_NO: NRC 98-04 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)

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.

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.

Other Agency Action:**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

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

ITEMNO: 980859 AO_NO: NRC 98-05 DATE: 07/28/1998

TITLE: Exposure to a Minor from a Radiopharmaceutical Therapy Event at Western Pennsylvania Hospital in Pitts

NAME: Western Pennsylvania Hospital CITY: Pittsburgh STATE: PA

Nature and Probable Consequences:

A female patient was prescribed a whole-body iodine-131 (I-131) thyroid scan following a thyroidectomy. The technologist asked the patient if she was breast-feeding but she did not reply and was administered a dosage of 111 megabecquerel (3 millicurie) of I-131. Two days

NRC Action:

NRC sent a letter to the licensee requiring it to prepare a plan describing how to prevent similar events. The licensee responded on October 8 and 12, 1998, listing adequate actions to prevent recurrence of similar events.

Cause:

The patient failed to answer the technologist's question regarding breast-feeding and the hospital failed to receive an answer to the question before dose administration.

Other Agency Action:**Licensee Action:**

The licensee developed a new response form for women aged between 10 and 50 years for (1) asking them if they are nursing, (2) informing them of the harm to a child if they are breast-feeding after I-131 administration, and (3) obtaining a signed statement before administering them radioactive material

Criteria:

Appendix A (see Criterion I.A.2, "For All Licensees") 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 mSv (5 rem) or more will be considered for reporting as an AO

ITEMNO: 970972 AO_NO: AS 98-01 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

NRC Action:**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

Other Agency Action:

The State agency investigated the event and a Notice of Violation and Enforcement Conference was held on February 10, 1998. A Notice of Noncompliance was issued for failure to meet the objective that each administration is done in accordance with a written

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.

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

ITEMNO 000186

AO_NO: NRC 98-01

DATE: 02/18/1998

TITLE: Seismic Risk from Liquid Uranium Hexafluoride at the Withdrawal Facilities at the Paducah Gaseous Diffus

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

NRC Action:

An immediately effective "confirmatory order modifying certificate" to incorporate the immediate and long-term corrective actions was issued on April 22, 1998.

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.

Other Agency Action:**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

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.

ITEMNO 981204

AO_NO: NRC 99-01

DATE: 12/09/1998

TITLE: Fire Breaches Containment and Requires Shutdown of a Portion of the Cascade at the Portsmouth Gaseo

NAME: Portsmouth Gaseous Diffusion Pla

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

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

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

Other Agency Action:

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

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 an 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

ITEMNO: 981106 AO_NO: NRC 99-02 DATE: 10/06/1998

TITLE: Medical Event Involving the Administration of Iodine-131 to a Pregnant Patient at St. Joseph Health Center

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.

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

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;

Other Agency Action:**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

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.

ITEMNO: 981083 AO_NO: NRC 99-03 DATE: 09/01/1998

TITLE: Medical Event Involving the Administration of Iodine-131 to a Pregnant Patient at Camden-Clark Memorial

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

NRC Action:

An inspection was conducted to review the circumstances of the event. 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.

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.

Other Agency Action:**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

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.

ITEMNO: 990631 AO_NO: NRC 99-04 DATE: 09/14/1999

TITLE: Sodium Iodide Radiopharmaceutical Misadministration at Holy Redeemer Hospital and Medical Center in

NAME: Holy Redeemer Hospital and Medi 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 this procedure using iodine-123 (I-123). However, because of an error, the patient was administered iodine-131 (I-131).

NRC Action:

The NRC staff conducted a special safety inspection on September 17, 1999, and is evaluating enforcement options.

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.

Other Agency Action:**Licensee Action:**

The licensee counseled the technologist on the importance of implementing the NRC regulations.

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, lens of the eye, or gonads) and represents a dose or dosage that is at least 50

ITEMNO

990302

AO_NO:

AS 99-01

DATE:

05/07/1999

TITLE:

Medical Event Involving the Administration of Iodine-131 to a Pregnant Patient at Via Christi Regional Medi

NAME:

Via Christi Regional Medical Cent

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

NRC Action:**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.

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

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

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.

ITEMNO

990040

AO_NO:

AS 99-02

DATE:

12/31/1998

TITLE:

Industrial Radiography Occupational Overexposure at Global X-ray and Testing Corporation in Aransas Pa

NAME:

Global X-ray and Testing Corporat

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 a radiograph (exposure). As a result, the trainee received an estimated TEDE of about 100 mSv (10 rem) and an extremity annual shallow-dose

NRC Action:**Cause:**

The company's president told the office manager that the radiographer could act as a trainer because the paperwork requesting to name the individual radiographer as a trainer had been mailed to the State's Bureau of Radiation Control. Therefore, the radiographer was sent

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

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 or not they were assigned to work with trainees. A memorandum stating

Criteria:

Appendix A (see Criterion I.A.1, "For All Licensees") 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 (TEDE) of 250 millisievert (mSv) (25 rem) or more or an annual shallow-dose equivalent to the skin or

ITEMNO: 981231 AO_NO: AS 99-03 DATE: 12/16/1998

TITLE: Industrial Radiography Overexposure to a Member of the Public at Professional Service Industries, Inc. in

NAME: Professional Service Industries, In 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 terabecquerel (60 curie) iridium-192

NRC Action:**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.

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.

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 personnel, and (3) performing a cytogenetic study for the contractor's

Criteria:

Appendix A (see Criterion I.A.1, "For All Licensees") 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 (TEDE) of 250 millisievert (mSv) (25 rem) or more or an annual shallow-dose equivalent to the skin or

ITEMNO: 981221 AO_NO: AS 99-04 DATE: 12/16/1997

TITLE: Gamma Stereotactic Radiosurgery (Gamma Knife) Misadministration at University of Maryland Medical Sy

NAME: University of Maryland Medical Sy 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

NRC Action:**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

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

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

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

ITEMNO: 981080 AO_NO: AS 99-05 DATE: 10/15/1998

TITLE: Gamma Stereotactic Radiosurgery (Gamma Knife) Misadministration at Good Samaritan Hospital in Los A

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.

NRC Action:**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,

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.

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

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

ITEMNO 990549

AO_NO: AS 99-06

DATE: 08/04/1999

TITLE: Therapeutic Radiopharmaceutical Misadministration of Iodine-131 to the Wrong Individual at Hermann Hos

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.

NRC Action:**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

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

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

Criteria:

Appendix A (see Criterion I.A.1, "For All Licensees") 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 (TEDE) of 250 millisievert (mSv) (25 rem) or more or an annual sum of the deep dose equivalent and

ITEMNO 990158

AO_NO: AS 99-07

DATE: 07/31/1998

TITLE: Therapeutic Radiopharmaceutical Misadministration of Iodine-131 to the Wrong Individual at Milton Hospit

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) for a thyroid scan. However, the patient was erroneously administered a therapeutic dosage of 318.2 MBq (8.6 mCi) of iodine-131.

NRC Action:**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

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

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 the administration of radiopharmaceuticals, a hand will be placed on the

Criteria:

Appendix A (see Criterion I.A.1, "For All Licensees") 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 (TEDE) of 250 millisievert (mSv) (25 rem) or more or an annual sum of the deep dose equivalent and

ITEMNO: 990479 AO_NO: AS 99-08 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-

NRC Action:**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.

Other Agency Action:

The State cited the licensee for failure to report the misadministration within the required time.

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

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 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.

ITEMNO: 981182 AO_NO: AS 99-09 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).

NRC Action:**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.

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

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

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

ITEMNO: 000269 AO_NO: NRC 00-02 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 problems with a 703,000 megabecquerel (19 curie) molybdenum-99/technetium-99m generator. The employee performed the operation in a glove box. The

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

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

Other Agency Action:**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)

Criteria:

Appendix A (see Criterion I.A.1, "For Medical Licensees") 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

ITEMNO: 000739

AO_NO: NRC 00-03

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).

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

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

Other Agency Action:**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

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 the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ

ITEMNO: 000336

AO_NO: AS 00-01

DATE: 04/12/2000

TITLE: Gamma Stereotactic Radiosurgery Misadministration at Healthsouth Medical Center in Birmingham, Alaba

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 (GSR) 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 of 80 Gy (8,000

NRC Action:**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.

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.

Licensee Action:

The licensee took immediate action to prevent the mixing of patient treatment protocol documentation. As a result, each page of the 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

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 the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ

ITEMNO: 000615 AO_NO: AS 00-02 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

NRC Action:**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.

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

Licensee Action:

The initial corrective actions by the licensee included decreasing distractions to the treatment team by limiting telephone calls in the 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

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 the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ

ITEMNO: 000104 AO_NO: AS 00-03 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.

NRC Action:**Cause:**

The licensee determined that this misadministration was caused by human error.

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

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

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 the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ

ITEMNO: 000277 AO_NO: AS 00-04 DATE: 04/20/2000

TITLE: Gamma Stereotactic Radiosurgery Misadministration at University of Maryland Medical Systems in Baltimore

NAME: University of Maryland Medical Sy 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

NRC Action:**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

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

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

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 the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ

ITEMNO 970358

AO_NO: AS 00-05

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

NRC Action:**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

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

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

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 the gonads, or (2) equal to or greater than 10 Gy (1,000 rad) to any other organ

ITEMNO 000843

AO_NO: AS 00-06

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.

NRC Action:**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 entered the source

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 corrective action

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

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 the gonads, or (2) equal to or greater than 10 Gy (1 000 rad) to any other organ

ITEMNO: 000455 AO_NO: NRC 01-01 DATE: 06/13/2000

TITLE: Occupational Overexposure at Southeast Missouri State University in Cape Girardeau, Missouri

NAME: Southeast Missouri State Universit 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

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

Cause:

The licensee possessed radioactive material not authorized by the NRC license and failed to perform adequate radiation surveys, including air sampling to measure airborne radioactivity present during the inventory and decontamination activities. The survey

Other Agency Action:**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

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

ITEMNO: 010155 AO_NO: AS 01-01 DATE: 02/16/2001

TITLE: Industrial Radiography Occupational Overexposure at Quality Inspection Services, Inc., in Jacksonville, Flo

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

NRC Action:**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

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

Licensee Action:

The licensee conducted a reenactment of the event and, based on lessons learned, the training procedures were revised to prevent future incidents.

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.

ITEMNO: 010662 AO_NO: NRC 02-02 DATE: 07/10/2001

TITLE: Gamma Stereotactic Radiosurgery (Gamma Knife) Misadministration at St. Luke's Medical Center in Milwa

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

NRC Action:

The licensee was cited for violations that included failure to verify that the treatment parameters implemented were for the patient being treated.

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

Other Agency Action:**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

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 1Gy (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 (1,000 rad) to any other organ and is

ITEMNO

020313

AO_NO:

NRC 02-03

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 a shielded top. The

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.

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.

Other Agency Action:**Licensee Action:**

The licensee has obtained additional vial shields with shielded tops, placed them at the second drawing station, and has required 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

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

ITEMNO

020017

AO_NO:

AS 02-01

DATE:

01/02/2002

TITLE:

Loss of Package Integrity and Elevated Radiation Levels Measured at Federal Express Facility in Kenner,

NAME:

Source Production and Equipment

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

NRC Action:**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

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

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

Criteria:

Appendix A (see Criterion I.B.2.a, "Discharge or Dispersal of Radioactive Material from its Intended Place of Confinement") to this 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

ITEMNO: 020473 AO_NO: AS 02-02 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.

NRC Action:**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.

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.

Licensee Action:

The licensee terminated the radiographer's employment and incorporated the event into the annual refresher training at all thirty-one Longview Inspection offices.

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

ITEMNO: 010893 AO_NO: AS 02-03 DATE: 09/25/2001

TITLE: Industrial Radiography Occupational Overexposure at McShane Industries in Baltimore, Maryland

NAME: Accurate Technologies, Incorporat 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.

NRC Action:**Cause:**

The root cause of this radiation injury was identified as a failure by the radiographer to follow licensed radiation safety procedures, to comply with Maryland Regulations regarding radiation safety requirements for industrial radiographic operations, and to properly use required

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;

Licensee Action:

On October 4, 2001, the licensee agreed to discontinue all licensed activities until the completion of the Departmental Investigation.

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

ITEMNO: 020221 AO_NO: AS 02-04 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

NRC Action:**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

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

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

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 the gonads, or (2) equal to or greater than 10 Gy (1 000 rad) to any other organ

ITEMNO

020032

AO_NO:

AS 02-05

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

NRC Action:**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.

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

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, and alarms at the end of treatment. In addition, the nurse has been counseled and

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 the gonads, or (2) equal to or greater than 10 Gy (1 000 rad) to any other organ

ITEMNO

020377

AO_NO:

AS 02-06

DATE:

04/10/2002

TITLE:

Industrial Radiography Occupational Overexposure at Technical Welding Laboratory, Inc. in Houston, Tex

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.

NRC Action:**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.

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 an individual

Licensee Action:

The licensee terminated the radiographers 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.

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

ITEMNO: 020666 AO_NO: AS 02-07 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,

NRC Action:**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

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.

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.

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

ITEMNO: 020937 AO_NO: NRC 03-01 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 restenosis 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)

NRC Action:

On November 13, 2002, the NRC issued a Notice of Violation to the licensee for the failure to follow the manufacturer's operation procedures for the IVB device as specified in its license.

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

Other Agency Action:**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

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 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

ITEMNO: 030675 AO_NO: NRC 03-02 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

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

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

Other Agency Action:**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

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 year of age) resulting in an annual total effective dose equivalent (TEDE) of 50 mSv (5 rem) or more, or to an

ITEMNO: 030385 AO_NO: NRC 03-03 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

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.

Cause:

This medical event was caused by human error, in that the licensee did not properly visualize the placement of the source train due, in part, to a lapse in time in the fluoroscopy performed during the treatment and the inherent inability to differentiate between the proximal and

Other Agency Action:**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

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 to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a

ITEMNO: 030502 AO_NO: NRC 03-04 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

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,

Cause:

The cause of this event is under investigation by the licensee.

Other Agency Action:

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

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 to the gonads or (2) equal to or greater than 10 Gy (1 000 rads) to any other organ and represents a

ITEMNO: 030274 AO_NO: NRC 03-05 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

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

Cause:

This medical event was caused by human error in ordering the correct dosage.

Other Agency Action:**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)

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 to the gonads or (2) equal to or greater than 10 Gy (1 000 rads) to any other organ and represents a

ITEMNO: 030429 AO_NO: AS 03-01 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

NRC Action:**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

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.

Licensee Action:

Corrective actions included the implementation of revised procedures regarding dosimetry, emergency response, and notification of 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

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 to the gonads or (2) equal to or greater than 10 Gy (1 000 rads) to any other organ and represents a

ITEMNO: 030500 AO_NO: AS 03-04 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

NRC Action:**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

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 and the written

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

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 to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a

ITEMNO: 030565 AO_NO: AS 03-05 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

NRC Action:**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.

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

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

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

ITEMNO: 030411 AO_NO: AS 03-06 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

NRC Action:**Cause:**

Unusual anatomical aspects of the seminal/prostate vesicle under ultrasound hampered the physician's ability to correctly place the seeds fully within the intended preplan margins. In addition, seed visualization on fluoroscopy was suboptimal.

Other Agency Action:

The Ohio Department of Health performed an investigation of the event.

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

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 to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a

ITEMNO: 030505 AO_NO: AS 03-07 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 for thyroiditis was

NRC Action:**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.

Other Agency Action:

The State accepted the licensee's report and corrective actions as appropriate.

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.

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 to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a

ITEMNO: 020489 AO_NO: AS 03-08 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

NRC Action:**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

Other Agency Action:

The State has reviewed and accepted the licensee's corrective actions.

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

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 Gy (1,000 rads) to any other organ and represents a dose or dosage that is at

ITEMNO: 021005 AO_NO: AS 03-09 DATE: 08/26/2002

TITLE: Gamma Stereotactic Radiosurgery Device Medical Event at Bayfront Medical Center, Inc., in St. Petersburg

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 ranged from 12.2 to 24 Gy (1,220

NRC Action:**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

Other Agency Action:

The State conducted an onsite investigation that included interviews with licensee personnel involved and a representative from the device's manufacturer on November 12-13, 2002. In the licensee's medical event report, the licensee indicated the device manufacturer

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

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 to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a

ITEMNO: 021063

AO_NO: AS 03-02

DATE: 10/18/2002

TITLE: Industrial Radiography Occupational Overexposure at a Temporary Jobsite in Ghent, Kentucky

NAME: Huntington Testing and Technolog

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

NRC Action:**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), and failure to survey the

Other Agency Action:

The KRHTA Branch conducted an onsite investigation and concurred with the licensee's dose assessment and identification of the causes of the event. The licensee was issued a Notice of Violation and has provided corrective actions to the Commonwealth of Kentucky.

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

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

ITEMNO: 030624

AO_NO: AS 03-03

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

NRC Action:**Cause:**

The medical event was caused by the mislabeling of the 1-131 unit dose syringe. Other factors that led to the medical event include improper segregation of the prescriptions at the pharmacy and lack of a second means of verifying proper completion of the order.

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

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

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 to the gonads or (2) equal to or greater than 10 Gy (1 000 rads) to any other organ and represents a

ITEMNO: 000666 AO_NO: NRC 00-02 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 problems with a 703,000 megabecquerel (19 curie) molybdenum-99/technetium-99m generator. The employee performed the operation in a glove box. The

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

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

Other Agency Action:**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)

Criteria:

Appendix A (see Criterion I.A.1, "For Medical Licensees") 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

ITEMNO: 031001 AO_NO: NRC 04-01 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

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

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.

Other Agency Action:**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

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 an AO.

ITEMNO: 040169 AO_NO: NRC 04-02 DATE: 03/05/2004

TITLE: Incinerator Event at Westinghouse Columbia Fuel Fabrication Facility in Columbia, South Carolina

NAME: Westinghouse Columbia Fuel Fabr 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 off-gas system

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

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

Other Agency Action:**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

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.

ITEMNO

030947

AO_NO:

NRC 04-03

DATE:

10/16/2003

TITLE:

Iodine-125 Brachytherapy Seed Medical Event at Albert Einstein HealthCare Network in Philadelphia, Pen

NAME:

Albert Einstein HealthCare Networ

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

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

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

Other Agency Action:**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

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 gray (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

ITEMNO

040415

AO_NO:

NRC 04-04

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 dosages earlier in the day was

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

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.

Other Agency Action:

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 is not within the established range. The licensee also trained the

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 dose

ITEMNO: 040001 AO_NO: AS 04-01 DATE: 12/04/2003

TITLE: I-125 Brachytherapy Seed Medical Event at Central Arkansas Radiation Therapy Institute in Conway, Arka

NAME: Central Arkansas Radiation Thera 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-

NRC Action:**Cause:**

This event was attributed to human error in that the treatment site was not verified.

Other Agency Action:

The State has reviewed and accepted the licensee's corrective actions.

Licensee Action:

The licensee wrote a new procedure to implement the use of fluoroscopic guidance to ensure the correct placement of seeds.

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

ITEMNO: 040057 AO_NO: AS 04-02 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 gigabecquerels (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

NRC Action:**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.

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.

Licensee Action:

The licensee has implemented pregnancy testing for patients of child bearing age, who receive radiation therapy.

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

ITEMNO: 020585 AO_NO: AS 04-12 DATE: 06/07/2002

TITLE: Therapeutic Medical Event at University of California at Los Angeles Harbor Medical Center in Torrance, C

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.

NRC Action:**Cause:**

This medical event was caused by human error which resulted in the licensee's failure to follow proper policies and procedures and verify the prescribed dosage for a specific patient.

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.

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.

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 to the gonads, or (2) equal to or greater than 10 Gy (1 000 rads) to any other organ and represents a

ITEMNO: 040352 AO_NO: AS 04-13 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.

NRC Action:**Cause:**

The technologist failed to follow established procedures.

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.

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

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 to the gonads, or (2) equal to or greater than 10 Gy (1 000 rads) to any other organ and represents a

ITEMNO: 050065 AO_NO: NRC 05-01 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

NRC Action:**Cause:**

This event was caused by human error. The incorrect dose was administered to the incorrect location.

Other Agency Action:

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.

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 to the gonads or (2) equal to or greater than 10 Gy (1 000 rads) to any other organ; and represents a

ITEMNO 050143

AO_NO: NRC 05-02

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.

NRC Action:**Cause:**

The event was caused by human error. The hospital staff member did not look at the dosage label before administering the radiopharmaceutical.

Other Agency Action:**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.

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."

ITEMNO 050183

AO_NO: NRC 05-03

DATE: 01/26/2004

TITLE: Medical Event at St. Joseph Regional Medical Center in South Bend, Indiana

NAME: St. Joseph Regional Medical Cent

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 treatments was loaded

NRC Action:**Cause:**

The causes of these events were improper source selection, inadequate manufacturer instructions, inadequate management oversight, and inadequate procedures.

Other Agency Action:**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.

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 to the gonads or (2) equal to or greater than 10 Gy (1 000 rads) to any other organ; and represents a

ITEMNO 040780

AO_NO: AS 05-01

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 the use of the diameter instead

NRC Action:**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.

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.

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

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

ITEMNO

050124

AO_NO:

AS 05-02

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

NRC Action:**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.

Other Agency Action:

The State reviewed and approved the corrective actions taken by the licensee and will follow-up at the next inspection.

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

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

ITEMNO

050236

AO_NO:

AS 05-03

DATE:

01/24/2005

TITLE:

High Dose-Rate Afterloader Medical Event at Saddleback Memorial Medical Center in Laguna Hills, Califor

NAME:

Saddleback Memorial Medical Ce

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

NRC Action:**Cause:**

This event was attributed to human error and an inadequate procedure.

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

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

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

ITEMNO: 050235 AO_NO: AS 05-04 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

NRC Action:**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.

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

Licensee Action:

The licensee suspended the use of Y-90 and conducted a root cause investigation of the event. The licensee's corrective actions included writing new policies and procedures, implementing new training programs, and hiring new personnel.

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

ITEMNO: 050550 AO_NO: AS 05-05 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 (6.81 Ci) iridium-192 (Ir-192) source. The prescribed radiation therapy treatment plan called for three treatments to the left bronchus, each fraction to

NRC Action:**Cause:**

This event was attributed to human error in that the treatment site was not verified.

Other Agency Action:

The State has reviewed and accepted the licensee's corrective actions.

Licensee Action:

The licensee implemented a new procedure adding a question to verify the treatment distances during HDR treatments.

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

ITEMNO: 050066 AO_NO: AS 05-06 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 for hyperthyroidism. On November 16, 2004, the patient returned for a therapeutic treatment and was administered 469.9 MBq (12.7 mCi) of iodine-

NRC Action:**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.

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

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.

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."

ITEMNO

060319

AO_NO:

NRC 06-02

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

NRC Action:**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.

Other Agency Action:**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

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 to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a

ITEMNO

060494

AO_NO:

NRC 06-03

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 5.55 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

NRC Action:**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.

Other Agency Action:

Licensee Action:

The licensee implemented a procedure that requires pregnancy tests for all women of childbearing age prior to any therapy dosage of radioactive material, a checklist to ensure that the pregnancy test is ordered, and staff training.

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

ITEMNO: 060163 AO_NO: AS 06-01 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 the 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).

NRC Action:**Cause:**

This event was caused by the failure of radiography personnel to follow safety procedures and use survey meters inside the cell.

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,

Licensee Action:

The licensee provided additional training to the personnel. The licensee also solicited the assistance of a medical physicist and the 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

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

ITEMNO: 060317 AO_NO: AS 06-02 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 cm (0.8 in) that was three times the prescribed dose for the mammosite brachytherapy procedure, using a high dose rate (HDR) afterloader

NRC Action:**Cause:**

This medical event was caused by human error. The authorized user entered an incorrect distance into the computer entry data.

Other Agency Action:

The State reviewed and accepted the licensee's corrective actions.

Licensee Action:

The licensee developed new procedures requiring the authorized user to verify the source wire distances during HDR treatments and provided additional training in these 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 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 Gy (1,000 rads) to any other organ; and represents a

ITEMNO: 060540 AO_NO: AS 06-03 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 the 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

NRC Action:**Cause:**

This medical event was caused by human error. The licensee failed to verify the prescribed dosage for a specific patient.

Other Agency Action:

The State reviewed and accepted the licensee's corrective actions.

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.

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 to the gonads or (2) equal to or greater than 10 Gy (1 000 rads) to any other organ; and represents a

ITEMNO

060280

AO_NO:

AS 06-04

DATE:

03/28/2006

TITLE:

Medical Event at Central Arkansas Radiation Therapy Institute in Little Rock, Arkansas

NAME:

Central Arkansas Radiation Thera

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

NRC Action:**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.

Other Agency Action:

The State reviewed and accepted the licensee's corrective actions.

Licensee Action:

The licensee implemented a new policy to ensure that the urologist clearly defines the base of the prostate and urethra.

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 to the gonads or (2) equal to or greater than 10 Gy (1 000 rads) to any other organ; and represents a

ITEMNO

060480

AO_NO:

AS 06-05

DATE:

07/24/2006

TITLE:

Medical Event at Children's Memorial Medical Center in Chicago, Illinois

NAME:

Children's Memorial Medical Cent

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 prescribed dosage of 0.19 MBq (0.005 mCi). The physician did not prepare a written directive. The authorized user noted the error on July 25, 2006. The

NRC Action:**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.

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.

Licensee Action:

The licensee reviewed previous administrations of radioiodine to confirm that this event was an isolated occurrence. The licensee added additional procedures to ensure proper oversight by a physician during all future radioiodine administrations.

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 to the gonads or (2) equal to or greater than 10 Gy (1 000 rads) to any other organ; and represents a

ITEMNO: 060662 AO_NO: AS 06-06 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

NRC Action:**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.

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.

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.

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

ITEMNO: 070406 AO_NO: NRC 06-01 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

NRC Action:**Cause:**

Failure to maintain configuration control of facility equipment and failure to comply with procedures.

Other Agency Action:**Licensee Action:**

The operator stopped all processing of HEU in the affected processing area, removed the enclosure and associated piping, filled in an uncontrolled accumulation point (the elevator pit) with concrete, and conducted an extensive review to identify any similar configuration issues.

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

ITEMNO: 070339 AO_NO: NRC 07-01 DATE: 05/29/2007

TITLE: Human Exposure to Radiation at Washington University Medical Center in St. Louis, Missouri

NAME: Washington University Medical Ce 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

NRC Action:

There were no violations identified by the NRC.

Cause:

The causes of this event were the false negative pregnancy test and the patient's lack of awareness that she might be pregnant.

Other Agency Action:**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.

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 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose

ITEMNO: 060659

AO_NO: NRC 07-02

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 a high dose-rate (HDR) remote afterloader, using a 144 GBq (3.9 Ci) iridium-192 source, brachytherapy procedure to treat breast cancer.

NRC Action:

On March 14, 2007, the NRC issued a Notice of Violation related to this event.

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

Other Agency Action:**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

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

ITEMNO: 070024

AO_NO: NRC 07-03

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 seed 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

NRC Action:

On June 20, 2007, the NRC issued a Notice of Violation related to this event.

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

Other Agency Action:

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.

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

ITEMNO: 060748 AO_NO: NRC 07-04 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 an unintended treatment

NRC Action:

There were no violations identified by the NRC.

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.

Other Agency Action:**Licensee Action:**

The licensee revised its procedures, including the use of a contrast medium in the Foley catheter balloon to more clearly identify the bladder/prostate interface, and use of fluoroscopic imaging to confirm anatomical positioning and verify seed placement.

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

ITEMNO: 070074 AO_NO: NRC 07-05 DATE: 02/02/2007

TITLE: Medical Event at the University of Virginia at Charlottesville, Virginia

NAME: University of Virginia CITY: Charlottesville STATE: VA

Nature and Probable Consequences:

University of Virginia at Charlottesville (the licensee) reported that a patient was prescribed a brachytherapy treatment of 30 Gy (3,000 rad) for treatment of cancer of the cervix using cesium-137 sources. Instead, the patient received 7.7 Gy (770 rad) to the cervix and small volumes

NRC Action:

On May 7, 2007, the NRC issued a Notice of Violation related to this event.

Cause:

The medical event was caused by the licensee's failure to ensure that the insert was of the correct length before preloading the cesium-137 sources.

Other Agency Action:**Licensee Action:**

The licensee revised its procedures, including measuring the length of the insert before loading the source, and limiting the supply of inserts in the source loading room to inserts of the length used for standard applicator treatments. The licensee also implemented additional staff training

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

ITEMNO: 070014 AO_NO: AS 07-01 DATE: 11/29/2006

TITLE: Medical Event at St. James Hospital and Health Center in Olympia Fields, Illinois

NAME: St. James Hospital and Health Ce 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

NRC Action:**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

Other Agency Action:

The State conducted an investigation on January 8, 2007, and issued a Notice of Violation. On March 8, 2007, the NRC-contracted medical consultant investigated the matter for the State and supported the licensee's conclusions. The State accepted the licensee's corrective

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

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

ITEMNO 070276

AO_NO: AS 07-02

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

NRC Action:**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.

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 actions during this onsite

Licensee Action:

Corrective actions taken by the licensee included revising procedures to improve communication with referring physicians, to allow the certified nuclear medicine technologist to speak directly with the referring physician or authorized user to confirm the type of test to be conducted. Also, written directives will be required for all

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, or the lens of the eye, or the gonads) and represents a dose or dosage that is at

ITEMNO 070215

AO_NO: AS 07-03

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

NRC Action:**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

Other Agency Action:

The State plans to follow-up on the licensee's implementation of their new procedures during the next scheduled inspection.

Licensee Action:

The licensee changed its policy and procedures to require a check of calculations for any single-fraction brachytherapy treatment.

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 a major portion of the bone marrow) and represents either a dose or dosage that is

ITEMNO: 070263 AO_NO: AS 07-04 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

NRC Action:**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

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.

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 rates per shipment (based upon contents of the shipment). The licensee redesigned

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, or the lens of the eye, or the gonads) and represents a dose or dosage that is at

ITEMNO: 060716 AO_NO: AS 07-05 DATE: 11/16/2006

TITLE: Medical Event at University of Washington Harborview Gamma Knife of Seattle, Washington

NAME: University of Washington Harborvi 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-

NRC Action:**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

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.

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

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, or the lens of the eye, or the gonads) and represents a dose or dosage that is at

ITEMNO: 070547 AO_NO: AS 07-06 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

NRC Action:**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

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

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.

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, or the lens of the eye, or the gonads) and represents a dose or dosage that is at

ITEMNO: 090130 AO_NO: NRC 06-01 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

NRC Action:**Cause:**

Failure to maintain configuration control of facility equipment and failure to comply with procedures.

Other Agency Action:**Licensee Action:**

The operator stopped all processing of HEU in the affected processing area, removed the enclosure and associated piping, filled in an uncontrolled accumulation point (the elevator pit) with concrete, and conducted an extensive review to identify any similar configuration issues.

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

ITEMNO: 080550 AO_NO: AS 08-01 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

NRC Action:**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.

Other Agency Action:

The State conducted a follow-up inspection on June 10, 2008, and did not take any enforcement action regarding this event.

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.

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 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose

ITEMNO: 080514

AO_NO: NRC 08-01

DATE: 06/04/2008

TITLE: Human Exposure to Radiation at Wilford Hall Medical Center on Lackland Air Force Base in San Antonio,

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

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

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

Other Agency Action:**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

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 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose

ITEMNO: 030135

AO_NO: NRC 08-02

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

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

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 low doses were

Other Agency Action:**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

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

ITEMNO: 050671

AO_NO: NRC 08-02

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

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

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 low doses were

Other Agency Action:**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

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

ITEMNO

080296

AO_NO:

NRC 08-02

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

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

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 low doses were

Other Agency Action:**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

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

ITEMNO

070672

AO_NO:

NRC 08-03

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

NRC Action:

On January 10, 2008, NRC issued a Notice of Violation related to this event.

Cause:

The medical event was caused by the MRI technologist who inadvertently performed the MRI scans in the "caudal" mode (from the 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

Other Agency Action:

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

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

ITEMNO: 080230 AO_NO: AS 08-02 DATE: 12/12/2007

TITLE: Medical Event at University of Mississippi Medical Center in Jackson, Mississippi

NAME: University of Mississippi Medical C 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

NRC Action:**Cause:**

The medical event was caused by human error due to the incorrect catheter length entered into the treatment planning system. The incorrect value of 128 cm was entered as the length instead of 120 cm, resulting in the 86 mm displacement. An HDR service technician

Other Agency Action:

The State cited the licensee with two violations for failing to verify the treatment plan.

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 disposal catheters and checking the integrity of the catheters prior to treatment, (2) placing an order for and use of a single set of reusable catheters for HDR cervical cancer treatments, (3) the

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

ITEMNO: 080007 AO_NO: AS 08-03 DATE: 12/17/2007

TITLE: Medical Event at Southwest Volusia Healthcare Corporation in Orange City, Florida

NAME: Southwest Volusia Healthcare Cor 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. The administration

NRC Action:**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

Other Agency Action:

The State conducted an investigation and reviewed the licensee's corrective actions and found the corrective actions to be adequate.

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 patients for these types of procedures. In addition, the technologists have been

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

ITEMNO: 080053 AO_NO: AS 08-04 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 173.9 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

NRC Action:**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.

Other Agency Action:

The State conducted an investigation and reviewed the licensee's corrective actions and found the corrective actions to be adequate.

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.

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

ITEMNO

080132

AO_NO:

NRC 08-04

DATE:

02/27/2008

TITLE:

Medical Event at Reid Hospital and Health Care Services in Richmond, Indiana

NAME:

Reid Hospital and Health Care Ser

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 to 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

NRC Action:

On July 11, 2008, NRC issued a Notice of Violation related to this event.

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

Other Agency Action:**Licensee Action:**

The licensee's corrective actions to prevent recurrence included revising its procedure for prostate seed implants to require that the 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

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

ITEMNO

080337

AO_NO:

NRC 08-05

DATE:

05/01/2008

TITLE:

Medical Event at Bon Secours Virginia Health Source in Midlothian, Virginia

NAME:

Bon Secours Virginia Health Sourc

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 fractions of 340 cGy (340

NRC Action:

NRC performed a reactive inspection at the facility and issued a Notice of Violation for three violations of regulatory requirements on October 10, 2008.

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.

Other Agency Action:

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.

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

ITEMNO: 080555 AO_NO: AS 08-05 DATE: 07/17/2008

TITLE: Medical Event at Lehigh Valley Hospital in Allentown, Pennsylvania

NAME: Lehigh Valley Hospital CITY: Allentown STATE: PA

Nature and Probable Consequences:

Lehigh Valley Hospital (the licensee) reported that a patient was prescribed a dose of 740 MBq (20 mCi) of iodine-131, for treatment of a thyroid condition, but instead was administered 2,775 MBq (75 mCi). The licensee discovered the event within an hour of the

NRC Action:**Cause:**

The cause of the medical event was human error because the technologist accidentally switched the doses between two patients.

Other Agency Action:

The State conducted a follow-up inspection on August 21, 2008, to ensure that the licensee's actions taken to prevent recurrence had been implemented and issued a Notice of Violation.

Licensee Action:

The licensee implemented corrective measures by modifying current procedures involving the administration of radiopharmaceuticals.

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 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 dose or dosage that is at

ITEMNO: 090579 AO_NO: AS 09-01 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

NRC Action:**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.

Other Agency Action:

The State conducted a follow-up inspection and did not take any enforcement action regarding this event.

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.

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

ITEMNO: 090755 AO_NO: AS 09-02 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 by the licensee on

NRC Action:**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.

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 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.

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

ITEMNO

080694

AO_NO:

AS 09-03

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

NRC Action:**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.

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.

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

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

ITEMNO

080707

AO_NO:

NRC 09-01

DATE:

10/15/2008

TITLE:

Medical Event at Saint Mary's Medical Center in Huntington, West Virginia

NAME:

Saint Mary's Medical Center

CITY:

Huntington

STATE:

WV

Nature and Probable Consequences:

Saint Mary's Medical Center (the licensee) reported that a medical event occurred associated with the administration of a 5.55 GBq (150 mCi) iodine-131 capsule for thyroid cancer. A patient was prescribed to receive 10.12 Gy (1,012 rad) to the esophagus but received 18 Gy (1,800

NRC Action:

NRC contracted a medical consultant to review this event, its effect on the patient, and the licensee's corrective actions taken to prevent recurrence of similar events. The medical consultant concluded that no significant adverse health effect to the patient is expected. The NRC

Cause:

The cause of the medical event was human error in failing to recognize that the esophageal obstruction might interfere with the patient's ability to swallow the iodine-131 capsule.

Other Agency Action:

Licensee Action:

The licensee modified its procedure to include a pre-therapy esophageal dilation for patients known to have difficulty swallowing. In addition, patients known to have this difficulty may be administered liquid iodine-131 for treatment.

Criteria:

Criterion III.C.1.b and III.C.2.a, "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 either a

ITEMNO: 090019 AO_NO: AS 09-04 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

NRC Action:**Cause:**

The medical event was caused by the misidentification of the anatomical target site listed on the written directive.

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.

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.

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

ITEMNO: 090466 AO_NO: AS 09-05 DATE: 04/14/2009

TITLE: Medical Event at Cancer Care Northwest PET Center in Spokane, Washington

NAME: Cancer Care Northwest PET Cent 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

NRC Action:**Cause:**

The cause of the medical event was the source wire, for needle 13, snagged on the seam between the aluminum connector and the plastic guide tube during retraction.

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.

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

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

ITEMNO: 090497 AO_NO: AS 09-06 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

NRC Action:**Cause:**

The cause of the medical event was the misinterpretation of the correct size of the patient's small prostate gland by ultrasound.

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

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

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

ITEMNO: 090580

AO_NO: NRC 09-02

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

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.

Cause:

The cause of the medical event was human error in failing to check the collimator size prior to patient treatment.

Other Agency Action:**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

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

ITEMNO: 090748

AO_NO: NRC 09-03

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

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

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

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 a written

Other Agency Action:

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

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

ITEMNO: 100319 AO_NO: AS 10-01 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

NRC Action:**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.

Other Agency Action:

The Illinois Emergency Management Agency conducted an investigation of the event and issued a Notice of Violation (NOV) for the licensee's failure to report the event. The Illinois Emergency Management Agency is considering rulemaking to require the performance of

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

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

ITEMNO: 100245 AO_NO: AS 10-02 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

NRC Action:**Cause:**

The cause of this event was the close proximity of conception, which resulted in a negative pregnancy test, to the administration of the iodine-131.

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.

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.

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

ITEMNO: 100113 AO_NO: AS 10-03 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-

NRC Action:**Cause:**

The cause of the medical event was the failure of the licensee to adequately visualize the prostate prior to the implant procedure.

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

Licensee Action:

Corrective actions taken by the licensee included training of the RSO, medical physicist, clinical director, and radiation oncologists on ODH regulations concerning medical events. New procedures were also developed for brachytherapy seed implant procedures.

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

ITEMNO

090565

AO_NO:

AS 10-04

DATE:

03/20/2009

TITLE:

Medical Event at Hoag Memorial Hospital Presbyterian in Newport Beach, California

NAME:

Hoag Memorial Hospital Presbyter

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

NRC Action:**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

Other Agency Action:

On June 22, 2009, the California Department of Public Health (CDPH) issued an NOV related to this event. Subsequently, CDPH received dosimetry information which they used to interpret the event as not meeting the AO criteria; however, CDPH was not certain of this

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

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

ITEMNO

100357

AO_NO:

AS 10-05

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

NRC Action:**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.

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

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

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 a major portion of the bone marrow, or the lens of the eye, or the gonads).

ITEMNO: 100219 AO_NO: AS 10-06 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.

NRC Action:**Cause:**

The medical event was caused by patient movement between the time the planning images were obtained and the actual implantation of the seeds.

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.

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

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

ITEMNO: 100148 AO_NO: AS 10-07 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

NRC Action:**Cause:**

The medical event was caused by human error in failing to verify that the correct catheter length was entered into the HDR unit.

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.

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.

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

ITEMNO: 100400 AO_NO: NRC 10-01 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

NRC Action:

NRC conducted an inspection on October 13-14, 2010, and concluded there were no violations of NRC requirements associated with this event.

Cause:

The cause of this event was the close proximity of conception, which resulted in a negative pregnancy test, to the administration of the iodine-131.

Other Agency Action:**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

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

ITEMNO: 080896 AO_NO: NRC 10-02 DATE: 12/16/2008

TITLE: Medical Event at Chippenham & Johnston-Willis (CJW) Medical Center in Richmond, Virginia

NAME: Chippenham & Johnston-Willis (C) 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 of 40 Gy (4,000 rad) to

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.

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.

Other Agency Action:**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

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

ITEMNO: 090395 AO_NO: NRC 10-03 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.

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.

Cause:

The cause of the medical event was failure of the medical implant team to adequately visualize and identify the prostate prior to the implant.

Other Agency Action:

Licensee Action:

The licensee revised its policy and procedures to require that (1) all members of the implant team be present before the patient is 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

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

ITEMNO: 090597 AO_NO: NRC 10-04 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

NRC Action:

NRC initiated an inspection on July 19, 2009. NRC completed the inspection on January 6, 2010, and issued one Severity Level III violation to the licensee on February 2, 2010.

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.

Other Agency Action:**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

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

ITEMNO: 090659 AO_NO: NRC 10-05 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

NRC Action:

NRC initiated an inspection on August 13, 2009. NRC completed the inspection on April 7, 2010, and issued one Severity Level III violation to the licensee on May 21, 2010.

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.

Other Agency Action:**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 all GSR personnel on the importance of fully understanding error

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

ITEMNO: 090662 AO_NO: NRC 10-06 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

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.

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.

Other Agency Action:**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.

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

ITEMNO

100082

AO_NO:

NRC 10-07

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

NRC Action:

NRC conducted an inspection on July 12, 2010, and issued one Severity Level III violation to the licensee on August 24, 2010.

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.

Other Agency Action:**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

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

ITEMNO

100448

AO_NO:

NRC 10-08

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

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.

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.

Other Agency Action:

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

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

ITEMNO: 110073 AO_NO: NRC 11-01 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

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.

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.

Other Agency Action:**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.

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

ITEMNO: 110305 AO_NO: AS 11-01 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

NRC Action:**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.

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

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.

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

ITEMNO: 110504 AO_NO: AS 11-02 DATE: 09/12/2011

TITLE: Human Exposure to Radiation at Caribbean Inspection & NDT Services, Inc., in Port Lavaca, Texas

NAME: Caribbean Inspection & NDT Servi 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

NRC Action:**Cause:**

The State of Texas is currently investigating the cause of this event.

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

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 corrective actions.

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

ITEMNO

110363

AO_NO:

AS 11-03

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

NRC Action:**Cause:**

Licensee failure to use the vehicle alarm system.

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

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.

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

ITEMNO

090391

AO_NO:

AS 11-04

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

NRC Action:**Cause:**

The medical event was caused by human error in the placement of the source during treatment.

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

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

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).

ITEMNO: 100085 AO_NO: AS 11-05 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.

NRC Action:**Cause:**

The medical event is presumed to have been caused by misuse of a new ultrasound unit.

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

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

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).

ITEMNO: 100074 AO_NO: AS 11-06 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

NRC Action:**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.

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

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.

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

ITEMNO: 100118 AO_NO: AS 11-07 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

NRC Action:**Cause:**

The medical event was caused by human error in that the radiation therapist failed to push the correct button on the HDR device.

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,

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.

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

ITEMNO: 100388 AO_NO: AS 11-08 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

NRC Action:**Cause:**

The cause of this medical event was human error and failure of the licensee staff to follow existing written procedures and protocols.

Other Agency Action:

The Rhode Island Department of Health, Radiation Control Program, conducted an investigation of this medical event on April 30 through May 20, 2010, and issued an NOV to the licensee. The Rhode Island Department of Health also issued a regulatory citation

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

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

ITEMNO: 100294 AO_NO: AS 11-09 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

NRC Action:**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.

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.

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.

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,

ITEMNO: 100314 AO_NO: AS 11-10 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 (720 rad) in five

NRC Action:**Cause:**

The medical event was caused by human error in that the licensee entered the incorrect target area into the HDR device.

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

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.

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

ITEMNO: 100397 AO_NO: AS 11-11 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

NRC Action:**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.

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

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.

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)

ITEMNO: 100457 AO_NO: NRC 11-03 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 Med 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

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

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.

Other Agency Action:**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

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).

ITEMNO

100506

AO_NO:

NRC 11-04

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 a total dose of 34 Gy

NRC Action:

The NRC conducted a reactive inspection on October 18-20, 2010, with continued inoffice review through January 18, 2011, and issued two NOV's to the licensee on March 1, 2011 and April 20, 2011 respectively.

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.

Other Agency Action:**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

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).

ITEMNO

100543

AO_NO:

AS 11-12

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

NRC Action:**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

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.

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

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).

ITEMNO: 110032 AO_NO: AS 11-13 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 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 102 iodine-

NRC Action:**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.

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.

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

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).

ITEMNO: 110108 AO_NO: AS 11-14 DATE: 07/16/2010

TITLE: Medical Event at the University of Texas Southwestern Medical Center in Dallas, Texas

NAME: University of Texas Southwestern 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.

NRC Action:**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.

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

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 for calculating the specific activity.

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).

ITEMNO: 110133 AO_NO: NRC 11-05 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

NRC Action:

The NRC conducted an inspection on March 15 and 16, 2011, and reviewed the licensee's corrective actions. On January 6, 2012, NRC issued an NOV for failure to possess adequate procedures resulting in the medical event.

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.

Other Agency Action:**Licensee Action:**

The licensee modified procedures by adding reviews of treatment plans to ensure that written directives properly reflect the treatment plan.

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).

ITEMNO

110144

AO_NO:

AS 11-15

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

NRC Action:**Cause:**

The medical event is believed to have been caused by human error in failing to correctly read the therapy written directive prescription.

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

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

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).

ITEMNO

110254

AO_NO:

AS 11-16

DATE:

04/04/2011

TITLE:

Medical Event at the University of California, Los Angeles in Los Angeles, California

NAME:

University of California, Los Angel

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

NRC Action:**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.

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 of the required information

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 and needle placement using both axial and sagittal plane ultrasound

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).

ITEMNO: 110296 AO_NO: AS 11-17 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)

NRC Action:**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.

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

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

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).

ITEMNO: 110402 AO_NO: AS 11-18 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

NRC Action:**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

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.

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

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).

ITEMNO: 110505 AO_NO: AS 11-19 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

NRC Action:**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.

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.

Licensee Action:

Corrective actions include emphasizing strict adherence to prostate brachytherapy protocols.

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).

ITEMNO

110566

AO_NO:

AS 12-01

DATE:

10/06/2011

TITLE:

Embryo/Fetus Exposure to Radiation at Lankenau Hospital in Wynnewood, Pennsylvania

NAME:

Lankenau Hospital

CITY:

Wynnewood

STATE:

PA

Nature and Probable Consequences:

Lankenau Hospital (the licensee) reported that a patient received 2.7 gigabecquerel (GBq) (73.7 millicuries (mCi)) of iodine-131 for thyroid ablation therapy. Before the treatment, the patient informed the licensee that she was not pregnant, and was administered a pregnancy test as

NRC Action:**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.

Other Agency Action:

The Pennsylvania Department of Environmental Protection (PA DEP) conducted a followup inspection to review this incident and collect information from the medical consultant and the licensee to complete this review. PA DEP has no further action planned for this

Licensee Action:

The licensee assessed the event and determined that it is following best practices by ordering a pregnancy test and relying on its results.

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 (TEDE) of 50 millisieverts (mSv) [5 roentgen equivalent man (rem)] or

ITEMNO

120198

AO_NO:

AS 12-02

DATE:

03/24/2012

TITLE:

Human Exposure to Radiation at Non-Destructive Inspection Corporation, in Pasadena, Texas

NAME:

Non-Destructive Inspection Corpor

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

NRC Action:**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.

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

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

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 for reporting as an AO.

ITEMNO: 090732 AO_NO: AS 12-03 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

NRC Action:**Cause:**

The cause of the medical event was human error in failing to administer the correct activity as stated on the written directive.

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

Licensee Action:

The licensee corrective actions included: (1) mandatory refresher training for all participants in this event, (2) implementation of a requirement to confirm the prescribed dose by two nuclear medicine technologists prior to administration, (3) implementation of a requirement for the written directive to be typed or printed with the dose

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

ITEMNO: 100554 AO_NO: AS 12-04 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

NRC Action:**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 two treatment catheters. A contributing factor to the cause of the event is that the oncology staff infrequently uses two catheters to simultaneously deliver

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

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

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

ITEMNO: 100604 AO_NO: AS 12-05 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

NRC Action:**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.

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

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.

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

ITEMNO: 110005 AO_NO: AS 12-06 DATE: 12/22/2010

TITLE: Medical Event at Banner Good Samaritan Medical Center in Phoenix, Arizona

NAME: Banner Good Samaritan Medical 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 mammosite 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

NRC Action:**Cause:**

The cause of the medical event was a material problem with the repaired catheter and ineffective procedures for handling a damaged catheter.

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.

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 procedures were revised so that if kinking or damage to a catheter is

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

ITEMNO: 110341 AO_NO: AS 12-07 DATE: 02/18/2008

TITLE: Medical Event at Highlands Regional Medical Center in Prestonsburg, Kentucky

NAME: Highlands Regional Medical Cente 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

NRC Action:**Cause:**

The cause of the medical event 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 their brachytherapy program.

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

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

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

ITEMNO: 110052 AO_NO: AS 12-08 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

NRC Action:**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.

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

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

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

ITEMNO: 110351 AO_NO: AS 12-09 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

NRC Action:**Cause:**

The cause of the medical event was human error in that the technologist did not properly review the written directive and label on the iodine-131 dose.

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

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

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

ITEMNO: 110625 AO_NO: AS 12-10 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

NRC Action:**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.

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.

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.

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

ITEMNO: 120050

AO_NO: AS 12-11

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 for 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

NRC Action:**Cause:**

The cause of the medical event was human error in that the licensee failed to recognize that the catheter was not fully inserted into 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

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.

Licensee Action:

The corrective action taken by the licensee includes marking the new catheters to provide a visual indication of full insertion into the tandem and inservice training for all staff involved in HDR treatments.

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

ITEMNO: 120054

AO_NO: NRC 12-02

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

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.

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.

Other Agency Action:

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, CT scans will be taken to cover the entire length of the HDR

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

ITEMNO: 120083 AO_NO: AS 12-12 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

NRC Action:**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.

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

Licensee Action:

The corrective action taken by the licensee included a procedure modification such that any catheter dwell position adjustments of greater than 5 millimeters (mm) mandate a replanning of the treatment protocol.

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

ITEMNO: 120067 AO_NO: NRC 12-03 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

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.

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.

Other Agency Action:**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

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

ITEMNO: 120081 AO_NO: AS 12-13 DATE: 01/19/2012

TITLE: Medical Event at Thomas Jefferson University Hospital in Philadelphia, Pennsylvania

NAME: Thomas Jefferson University Hosp 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 the liver, but this was the

NRC Action:**Cause:**

The cause of the medical event was human error in that the medical staff did not verify the written directive before commencing the treatment, coupled with the erroneous transposition of the written directives in each of the patient's files.

Other Agency Action:

The PA DEP conducted a reactive investigation on January 26, 2012, and identified inadequacies in the administration procedure to provide assurances that each treatment is in accordance with the written directive. A NOV was issued by PA DEP; however, no order or final

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

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

ITEMNO: 120096 AO_NO: AS 12-14 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

NRC Action:**Cause:**

The cause of the medical event was human error which resulted in the licensee administering the wrong radiopharmaceutical treatment dose to the patient.

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

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

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

ITEMNO: 120103 AO_NO: AS 12-15 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

NRC Action:**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

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.

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.

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

ITEMNO: 120341 AO_NO: AS 12-16 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

NRC Action:**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.

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 the written directive, and

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

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

ITEMNO: 120432 AO_NO: AS 12-17 DATE: 07/15/2005

TITLE: Medical Events at Wheaton Franciscan Healthcare-All Saints in Racine, Wisconsin

NAME: Wheaton Franciscan Healthcare-A 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 of iodine-125 where

NRC Action:**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.

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.

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

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

ITEMNO: 120480 AO_NO: NRC 12-04 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 the breast

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.

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

Other Agency Action:**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

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

ITEMNO

120548

AO_NO:

AS 12-18

DATE:

09/10/2012

TITLE:

Medical Event at the Anderson Regional Medical Center in Meridian, Mississippi

NAME:

Anderson Regional Medical Cente

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.

NRC Action:**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.

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

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.

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

ITEMNO

130209

AO_NO:

AS 13-01

DATE:

02/20/2013

TITLE:

Human Exposure to Radiation at Radiological Associates of Sacramento in Sacramento, California

NAME:

Radiological Associates of Sacram

CITY:

Sacramento

STATE:

CA

Nature and Probable Consequences:

Radiological Associates of Sacramento (the licensee) reported that a pregnant patient received 6.55 gigabecquerels (GBq) [176.9 millicuries (mCi)] of iodine-131 for thyroid ablation therapy.

NRC Action:**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.

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.

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.

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

ITEMNO: 130192 AO_NO: AS 13-02 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

NRC Action:**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

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.

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

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

ITEMNO: 090415 AO_NO: AS 13-03 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

NRC Action:**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.

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.

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 ordered written directive.

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

ITEMNO: 120303 AO_NO: AS 13-04 DATE: 11/07/2011

TITLE: Medical Event at Adventist Health System/Sunbelt, Inc., in Altamonte Springs, Florida

NAME: Adventist Health System/Sunbelt, I 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

NRC Action:**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.

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

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

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

ITEMNO: 130271 AO_NO: AS 13-05 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.

NRC Action:**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

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

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

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

ITEMNO: 130001 AO_NO: AS 13-06 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

NRC Action:**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

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.

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

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

ITEMNO: 130150 AO_NO: AS 13-07 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.

NRC Action:**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

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.

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

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

ITEMNO: 130438 AO_NO: AS 13-08 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

NRC Action:**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 of vasculature during

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

Licensee Action:

The licensee did not identify corrective actions to add to its current procedures to preclude a recurrence of the 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 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

ITEMNO: 130248 AO_NO: AS 13-09 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 terabecquerels (TBq) (2,231 Ci) cobalt-60 gamma knife radiosurgery procedure to treat the patient's brain for intense facial pain.

NRC Action:**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

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.

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.

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

ITEMNO

130405

AO_NO:

AS 13-10

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.

NRC Action:**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 did not properly

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

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

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