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

CHAIRMAN

April 25, 1997

The Honorable Albert J. Gore, Jr.
President of the United States Senate
Washington, D.C. 20510

Dear Mr. President:

I am forwarding the Nuclear Regulatory Commission (NRC) "Report to Congress on Abnormal Occurrences, Fiscal Year 1996," for events at licensed nuclear facilities. These reports are required by Section 208 of the Energy Reorganization Act of 1974 (PL 93-438). In the context of the Act, an abnormal occurrence (AO) is an unscheduled incident or event that the Commission determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (PL 104-66) requires that AOs be reported to Congress on an annual basis.

This report addresses eighteen AOs at NRC-licensed facilities. Two involved events at nuclear power plants, eleven involved medical brachytherapy misadministrations, and five involved radiopharmaceutical misadministrations. Eight AOs submitted by the Agreement States are included. One involved stolen radiography cameras, one involved a ruptured source, one involved release of radioactive material while being transported, one involved a lost source, two involved medical brachytherapy misadministrations, and two involved radiopharmaceutical misadministrations. Four updates of previously reported AOs are included in this report. Three "Other Events of Interest" events are being reported, and one previously reported "Other Events of Interest" event is being updated.

Sincerely,

Shirley Ann Jackson

Enclosure: As stated

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

CHAIRMAN

April 25, 1997

The Honorable Newt Gingrich
Speaker of the United States
House of Representatives
Washington, D.C. 20515

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Enclosure: As stated

NUREG–0090
Vol. 19

# Report to Congress on Abnormal Occurrences

## Fiscal Year 1996

**U.S. Nuclear Regulatory Commission**

**Office for Analysis and Evaluation of Operational Data**

## AVAILABILITY NOTICE

Availability of Reference Materials Cited in NRC Publications

Most documents cited in NRC publications will be available from one of the following sources:

1. The NRC Public Document Room, 2120 L Street, NW., Lower Level, Washington, DC 20555-0001
2. The Superintendent of Documents, U.S. Government Printing Office, P. O. Box 37082, Washington, DC 20402-9328
3. The National Technical Information Service, Springfield, VA 22161-0002

Although the listing that follows represents the majority of documents cited in NRC publications, it is not intended to be exhaustive.

Referenced documents available for inspection and copying for a fee from the NRC Public Document Room include NRC correspondence and internal NRC memoranda; NRC bulletins, circulars, information notices, inspection and investigation notices; licensee event reports; vendor reports and correspondence; Commission papers; and applicant and licensee documents and correspondence.

The following documents in the NUREG series are available for purchase from the Government Printing Office: formal NRC staff and contractor reports, NRC-sponsored conference proceedings, international agreement reports, grantee reports, and NRC booklets and brochures. Also available are regulatory guides, NRC regulations in the *Code of Federal Regulations*, and *Nuclear Regulatory Commission Issuances*.

Documents available from the National Technical Information Service include NUREG-series reports and technical reports prepared by other Federal agencies and reports prepared by the Atomic Energy Commission, forerunner agency to the Nuclear Regulatory Commission.

Documents available from public and special technical libraries include all open literature items, such as books, journal articles, and transactions. *Federal Register* notices, Federal and State legislation, and congressional reports can usually be obtained from these libraries.

Documents such as theses, dissertations, foreign reports and translations, and non-NRC conference proceedings are available for purchase from the organization sponsoring the publication cited.

Single copies of NRC draft reports are available free, to the extent of supply, upon written request to the Office of Administration, Distribution and Mail Services Section, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001.

Copies of industry codes and standards used in a substantive manner in the NRC regulatory process are maintained at the NRC Library, Two White Flint North,11545 Rockville Pike, Rockville, MD 20852-2738, for use by the public. Codes and standards are usually copyrighted and may be purchased from the originating organization or, if they are American National Standards, from the American National Standards Institute, 1430 Broadway, New York, NY 10018-3308.

NUREG–0090
Vol. 19

# Report to Congress on Abnormal Occurrences

## Fiscal Year 1996

Date Published: April 1997

**Office for Analysis and Evaluation of Operational Data**
**U.S. Nuclear Regulatory Commission**
**Washington, DC 20555–0001**

## Previous Reports in Series

NUREG 75/090 (January–June 1975), published October 1975.

NUREG–0090–1 through 10 (July–September 1975 through October–December 1977), published March 1976 through March 1978.

NUREG–0090, Vols. 1 through 18, No. 3 (January–March 1978 through July–September 1995), published June 1978 through February 1996. No Vol. 18, No. 4, was published because annual reporting on a fiscal-year basis started with publication of the report for fiscal year 1996.

# ABSTRACT

Section 208 of the Energy Reorganization Act of 1974 (PL 93–438) identifies an abnormal occurrence (AO) as an unscheduled incident or event that the Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (PL 104–66) requires that AOs be reported to Congress on an annual basis. This report includes those events that NRC determined to be AOs during fiscal year 1996.

This report addresses eighteen AOs at NRC–licensed facilities. Two involved events at nuclear power plants, eleven involved medical brachytherapy misadministrations, and five involved radiopharmaceutical misadministrations. Eight AOs submitted by the Agreement States are included. One involved stolen radiography cameras, one involved a ruptured source, one involved release of radioactive material while being transported, one involved a lost source, two involved medical brachytherapy misadministrations, and two involved radiopharmaceutical misadministrations. Four updates of previously reported AOs are included in this report. Three "Other Events of Interest" events are being reported, and one previously reported "Other Events of Interest" event is being updated.

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# PREFACE

## Introduction

Section 208 of the Energy Reorganization Act of 1974 (PL 93–438) identifies an abnormal occurrence (AO) as an unscheduled incident or event that the Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (PL 104–66) requires that AOs be reported to Congress on an annual basis. This report includes those events that NRC determined to be AOs during fiscal year 1996.

NRC identifies an AO for the purpose of this report using the criteria in Appendix A. The criteria were initially promulgated in an NRC policy statement that was published in the *Federal Register* on February 24, 1977 (Vol. 42, No. 37, pages 10950–10952).

This policy statement was published before medical licensees were required to report misadministrations to NRC and few of the examples in the policy statement were applicable to medical misadministrations. Therefore, in 1984, NRC adopted additional guidance for AO reporting of medical misadministrations. These guidelines augment the NRC policy statement examples and are summarized in Table A–1 in Appendix A.

The events included in this report were determined to be potential AOs using the reporting criteria which were in effect during fiscal year (FY) 1996. The Commission recently approved new AO reporting criteria which it had directed the NRC staff to develop, and which will be published in the *Federal Register*. These new criteria will be used starting in FY 1997.

In order to provide wide dissemination of information to the public, a *Federal Register* notice is issued on NRC licensee AOs. Copies of the notice are distributed to the NRC Public Document Room and all Local Public Document Rooms. At a minimum, each notice must contain the date and place of the occurrence and a description of its nature and probable consequences.

NRC has determined that, of the incidents and events reviewed for this reporting period, only those that are described in this report meet the criteria for reporting as AOs. Information reported on each AO includes date and place, nature and probable consequences, cause or causes, and actions taken to prevent recurrence.

Appendix B contains updated information on previously reported AOs.

Appendix C contains information on incidents that can be perceived as significant but do not involve a major reduction in the level of protection provided for public health and safety. These events are not reportable as AOs but are provided as "Other Events of Interest."

## The Regulatory System

The system of licensing and regulation by which NRC carries out its responsibilities is implemented through the rules and regulations in Title 10 of the *Code of Federal Regulations*. This includes public participation as an element. To accomplish its objectives, NRC regularly conducts licensing proceedings, inspection and enforcement activities, evaluation of operating experience, and confirmatory research, while maintaining programs for establishing standards and issuing technical reviews and studies.

In licensing and regulating nuclear power plants and the uses of byproduct nuclear materials, NRC follows the philosophy that the health and safety of the public are best ensured by establishing multiple levels of protection. These levels can be achieved and maintained through regulations specifying requirements that will ensure the safe use of nuclear materials. The regulations include design and quality assurance criteria appropriate for the various activities licensed by NRC. An inspection and enforcement program helps ensure compliance with the regulations.

## Reportable Occurrences

Operating experience is an essential input to the regulatory process for assuring that licensed activities are conducted safely. Licensees are required to report certain incidents or events to NRC. This reporting helps to identify deficiencies and to ensure that corrective actions are taken to prevent recurrence.

For nuclear power plants, dedicated groups have been formed, both by NRC and the nuclear power industry, for the detailed review of operating experience to help identify safety concerns early; to improve dissemination of such information; and to feedback the experience into licensing, regulations, and operations. In addition, NRC and the nuclear power industry have ongoing efforts to improve the operational data systems, which include not only the type and quality of reports required to be submitted, but also the methods used to analyze data. In order to more effectively collect, collate, store, retrieve, and evaluate operational data, the information is maintained in computer–based data files.

Three primary sources of operational data are Licensee Event Reports (LERs) submitted pursuant to 10 CFR 50.73, immediate notifications submitted pursuant to 10 CFR 50.72, and medical misadministration reports submitted pursuant to 10 CFR 35.33.

Except for records exempt from public disclosure by statute and/or regulation, information concerning reportable occurrences at facilities licensed or otherwise regulated by NRC is routinely disseminated by NRC to the nuclear industry, the public, and other interested groups as these events occur.

Dissemination includes special notifications to licensees and other affected or interested groups, and public announcements. In addition, information on reportable events is routinely sent to the NRC's Local Public Document Rooms throughout the United States and to the NRC Public Document Room in Washington, D.C. Congress is routinely kept informed of reportable events occurring in licensed facilities.

## Agreement States

Section 274 of the Atomic Energy Act, as amended, authorizes the Commission to enter into agreements with States whereby the Commission relinquishes and the States assume regulatory authority over byproduct, source, and special nuclear materials (in quantities not capable of sustaining a chain reaction). Agreement State programs must be comparable to and compatible with the Commission's program for such material.

Presently, information on reportable occurrences for Agreement State licensed activities is publicly available at the State level. For the purpose of developing a nationwide database, Agreement States are encouraged to provide information to NRC on reportable events.

In early 1977, the Commission determined that AOs happening at Agreement State licensed facilities should be included in the periodic reports to Congress. The AO criteria included in Appendix A are applied uniformly to incidents and events that occur at NRC and Agreement State licensed facilities. Procedures have been developed and implemented, and AOs reported by the Agreement States to NRC are included in the periodic reports to Congress.

## Foreign Information

NRC participates in an exchange of information with various foreign governments that have nuclear facilities. This foreign information is reviewed and considered in the NRC's assessment of operating experience and in its research and regulatory activities. Reference to foreign information may occasionally be made in the AO reports to Congress; however, only domestic AOs are reported.

## Reopening of Closed Abnormal Occurrences

NRC reopens previously closed AOs if significant new information becomes available. Similiarly, previously reported "Other Events of Interest" are updated if significant new information becomes available.

# REPORT TO CONGRESS ON ABNORMAL OCCURRENCES FISCAL YEAR 1996

## NUCLEAR POWER PLANTS

Using the criteria and guidelines in Appendix A of this report, the following events which occurred at nuclear power plants during this reporting period were determined to be significant enough to be reported as an AO.

### 96–1 Plant Trip With Multiple Complications at Wolf Creek Nuclear Generating Station

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see General Criteria No.3) of this report notes that major deficiencies in design, construction, use of, or management controls for licensed facilities or material can be considered an AO.

**Date and Place** – January 30–31, 1996; Wolf Creek Nuclear Generating Station, a Westinghouse–designed pressurized water reactor nuclear power plant, operated by the Wolf Creek Nuclear Operating Corporation and located about 5.63 kilometers (3.5 miles) northeast of Burlington, Kansas.

**Nature and Probable Consequences** – One train of the essential service water system (ESWS) was inoperable due frazil[1] ice blockage of the intake trash racks, and the second train was degraded. The ESWS removes heat from plant components which require cooling for safe shutdown of the reactor or following a design basis accident. The ESWS consists of two redundant trains, provides emergency makeup to the spent fuel pool and component cooling water systems, and is the safety related water supply to the auxiliary feedwater system. Freeze protection for the ESWS is a design provision, and is provided by a warming line from each ESWS train which discharges directly in front of the train's trash rack.

At approximately 2:00 a.m. on January 30, 1996, operators at Wolf Creek received alarms indicating that the traveling screens for the circulating water (CW) system were becoming blocked. The site watch reported that the traveling screens for Bays 1 and 3 were frozen and that water levels in these bays were approximately 2.44 meter[illegible] feet) below normal. The ESWS was started with the intent to separate the ESWS from the service water (SW) system. However, the ESWS was incorrectly aligned, which reduced warming flow to the ESWS suction bays (the lineup was corrected approximately 6 hours later). At approximately 3:30 a.m., operators received a service water low pressure alarm (CW system bays were subsequently determined to be at 3.66 meters [12 feet] below normal) and an electric fire pump started. The shift supervisor then directed a manual reactor/turbine trip. Following the scram, five control rods failed to fully insert (from 12 to 30 steps out). The event was further complicated because the turbine driven auxiliary feedwater pump developed a packing leak and was declared inoperable. The loss of CW system bay level was subsequently determined to be caused by ice blockage of the traveling screens, which was caused by freezing water from the spray wash system.

Train "A" ESWS pump was tripped and declared inoperable at 7:47 a.m. due to low discharge pressure and high strainer differential pressure. At about 5:45 p.m. the operators declared Train "A" operable based on an engineering evaluation. However, the pump was stopped 1–1/2 hours later at approximately 7:30 p.m. when the pump exhibited further oscillations in flow and pressure. At approximately 8:00 p.m., operators noted that ESWS Train "B" suction bay level was 4.57 meters (15 feet) below normal and decreasing slowly. Operators placed additional heat loads on Train "B" and the suction bay levels subsequently recovered. At 10:14 p.m., the operators again started Train "A" ESWS, but later secured it, at 10:27 p.m., due to decreasing flow and pressure. At about 9:00 a.m. on January 31, 1996, divers

[1]Minute ice crystals called frazil were formed when wind and temperature conditions caused water in the ultimate-heat-sink reservior to become supercooled (cooled to a few hundredths of a degree below the freezing point without solidification). The frazil ice crystals mixed with the supercooled water, and adhered to the objects (i.e., trash racks) with which they collided.

inspected the suction bay of Train "A" and noted complete blockage of the trash racks by frazil ice. The condition of the Train "B" trash racks was not determined because the pump was running. The ice blockage was cleared later that day using heating, and air sparging of the trash racks.

**Cause or Causes** – The root cause of this event was deficiencies in the ESWS warming line design. This problem was exacerbated by the initial incorrect alignment of the ESWS. A 1976 design calculation specified a warming line flow rate of 15,142 liter/minute (4000 gpm) to prevent frazil ice. This calculation assumed a warming line temperature of 2°C (3°F) above freezing. This assumption was never validated: The warming line temperature during the event was only approximately 0.5°C (1°F) above freezing. Additionally, due to the elevations and configuration of the warming line, portions of the line operated with partial pipe flows. Flow through the lines was estimated to have been 9464 liter/minute (2500 gpm) and, with the initial improper lineup, warming flow was estimated to be 6435 liter/minute (1700 gpm), less than half the design specification.

**Actions Taken To Prevent Recurrence**

**Licensee** – The hydraulics of the ESWS discharge to the ultimate heat sink, and the warming line to the ESWS pumphouse, have been changed to establish and distribute the proper amount of flow to the ESWS warming line. The licensee has installed back pressure orifices to establish the required flow rates. This work was completed by October 1, 1996.

**NRC** – NRC entered a monitoring phase following the Notification of an Unusual Event at 9:00 a.m. on January 30, 1996. During February 6 through February 15, 1996, NRC conducted an Augmented Inspection Team inspection at Wolf Creek as a result of this event. NRC issued a civil penalty of $300,000 because of violations as a result of this event.

This event is closed for purpose of this report.

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## 96–2 Containment–Bypass Leakage via Disconnected Hydrogen–Monitor Lines at Braidwood Units 1 and 2

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see General Criteria No. 2) of this report notes that a major reduction in the degree of protection to public health and safety from a major degradation of essential safety–related equipment can be considered an AO.

**Date and Place** – February 15, 1995; Braidwood Unit 2, a Westinghouse–designed pressurized water nuclear reactor plant, operated by Commonwealth Edison Company and located about 38.6 kilometers (24 miles) south southwest of Joliet, Illinois.

**Nature and Probable Consequences** – On November 9, 1994, the licensee completed a containment integrated leak rate test (ILRT). For this test, the 6.35–millimeter (0.25–inch) containment penetration hydrogen sensing lines for trains "A" and "B" were disconnected and a balloon placed on the end to identify any leakage. The procedure did not specify whether to disconnect the sensing line inside the hydrogen monitor cabinet or outside. The operators who lined up the test disconnected the lines inside the cabinet. The licensee's investigation concluded that when other operators restored the system from the test, they observed the exterior sensing lines and assumed that the lines were reconnected. Therefore, the sensing lines remained disconnected inside the cabinet.

On January 31, 1995, the operations department wrote a problem identification report to identify a growing difference in the hydrogen readings on the "A" and "B" trains which are taken during each shift. On February 15, 1995, during troubleshooting, the "A" train lines were found to be disconnected, approximately 3 months after being disconnected. Surveillance tests performed on December 11, 1994, and January 25, 1995, provided opportunities to detect the deficiency with the "A" train but were missed. It could not be conclusively determined when the "B" train was restored. Two maintenance workers had a recollection of discovering balloons on the sensing lines in a hydrogen monitoring cabinet in late 1994. Maintenance records indicate these individuals worked on the "B" train on

December20, 1994. However, computer and operator logs for the "B" train appear to have been accurately reading containment hydrogen following the ILRT.

The hydrogen monitors are normally isolated. However, during a loss of coolant accident, the Emergency Operating Procedures direct the operators to put them into service to monitor containment hydrogen concentration. This would create an unfiltered release path from the containment to the auxiliary building. The licensee calculated that, under worst case conditions using guidance from NUREG–1465, "Accident Source Terms for Light–Water Nuclear Power Plants," regulatory dose limits could be exceeded within approximately 3 hours. NRC review found the licensees calculations to be conservative. There are area radiation monitors near the hydrogen monitors. These area radiation monitors alarm in the control room and the alarm response procedures call for notification of Radiation Protection personnel to survey the area. Additionally, there are radiation monitors in the auxiliary building exhaust that would assist the operators in identifying the leak. The containment bypass flow path could be isolated remotely from the control room and it appears credible that the leak could be isolated prior to exceeding regulatory limits.

**Cause or Causes** – The cause of this event was a procedural deficiency in that the ILRT procedure did not provide adequate guidance on where the containment penetration hydrogen sensing lines should be disconnected. Additionally, the operator tasked with reconnecting the containment penetration hydrogen sensing lines, after the ILRT was completed, did not display a questioning attitude when he found that the lines appeared to be reconnected.

**Actions Taken To Prevent Recurrence**

**Licensee** – Corrective actions included revision of ILRT line up and restoration sheets to provide adequate guidance on where disconnections and connections are to be performed. Additionally, a General Information Notice was issued to all site personnel highlighting the human performance problems identified from this event.

**NRC** – Escalated enforcement was exercised on this issue and the licensee was assessed a $100,000 civil penalty. Information Notice 96–13, "Potential Containment Leak Paths Through Hydrogen Analyzers," was issued to alert other licensees to this event.

This event is closed for the purpose of this report.

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## FUEL CYCLE FACILITIES
## (Other than Nuclear Power Plants)

Using the criteria and guidelines in Appendix A of this report, no events which occurred at fuel cycle facilities during this reporting period were determined to be significant enough to be reported as an AO.

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## OTHER NRC LICENSEES
## (Industrial Radiographers, Medical Institutions, Industrial Users, etc.)

Using the criteria and guidelines in Appendix A of this report, the following events which occurred at other NRC licensees during this reporting period were determined to be significant enough to be reported as an AO.

## 96–3 Medical Brachytherapy Misadministrations by José L. Fernández, M.D., in Mayagüez, Puerto Rico

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

**Date and Place** – Between January 14, 1994, and October 10, 1995; José L. Fernández, M.D.; Mayagüez, Puerto Rico.

**Nature and Probable Consequences** – On January 14, 1994, Dr. Fernández acquired an eye applicator device, which contained a strontium–90 (Sr–90) source of approximately 3219 megabecquerel (87 millicurie) activity, from the estate of a deceased licensee in Mayagüez, Puerto Rico. (Eye applicator devices are used for the supplemental treatment of non–malignant growths on the eye after surgery is performed.) NRC knew that Dr. Fernández acquired the Sr–90 source because the estate was acting under a Confirmatory Action Letter (CAL) to maintain control of the Sr–90 source and to either dispose of it or transfer control of it to an authorized recipient. Since Dr. Fernández was already an NRC licensee for another Sr–90 source in San Juan, Puerto Rico, his license was amended so that he was an authorized recipient when the transfer took place. (After the transfer took place, Dr. Fernández was licensed to have two sources.) NRC did not require Dr. Fernández to receive additional training in the use of the Sr–90 source after he acquired it from the estate because he was already an authorized user for a Sr–90 eye applicator as defined by 10 CFR 35.

When Dr. Fernández took possession of the eye applicator device, it was in the manufacturer's carrying case. A label attached to the carrying case contained the following hand written information: (1) the dose rate for the device, which was calibrated as 24 centigray (cGy) per second (24 rad per second); (2) the instrument used to calibrate the dose rate; (3) the date when the dose rate was calibrated; and (4) the name of the individual who performed the calibration. Dr. Fernández assumed that the hand written information on the label attached to the manufacturer's carrying case was correct and proceeded to treat patients.

On October 18, 1995, during a routine inspection, an NRC inspector questioned the labeled dose rate on the eye applicator device and the resultant administered doses. Dr. Fernández was unable to provide documentation to answer the questions. He then voluntarily ceased the administration of radiation doses and requested a calibration of the device by the manufacturer. The actual dose rate was found by the manufacturer to be 53 cGy per second (53 rad per second); i.e., more than twice the assumed dose rate.

Dr. Fernández and NRC reviewed the computer sorted records of all administrations using the eye applicator device and determined that between October 24, 1994, and October 10, 1995, 87 patients had received radiation doses which were approximately twice the prescribed dose. However, the computer sort was not complete, since Dr. Fernández later discovered an additional 17 cases which occurred between January 1994 and October 1995. Dr. Fernández notified the patients about the misadministrations. NRC contracted a medical consultant to review the medical aspects of the misadministrations.

The NRC medical consultant, who reviewed patient records for the 87 patients initially identified, determined that 25 of the patients were at higher risk for complications. These 25 patients were initially prescribed treatment doses of 1500 to 2880 cGy (1500 to 2880 rad), but received doses of 3312 to 6360 cGy (3312 to 6360 rad) instead. Of these 25 patients, 12 were then prescribed second treatment doses of 1000 to 2160 cGy (1000 to 2160 rad), but received doses of 2208 to 4770 cGy (2208 to 4770 rad) instead. Additionally, two of these 25 patients were prescribed third treatment doses of 1500 to 3000 cGy (1500 to 3000 rad), but received doses of 3313 to 6625 cGy (3313 to 6625 rad) instead. The highest total dose received by a patient was 13,603 cGy (13,603 rad) to the surface of the eye, with an estimated 544 cGy (544 rad) to the lens of the eye.

The NRC medical consultant believes that the long–term consequences of the misadministrations to the 25 highest dose patients could include: (1) increased risk of cataracts; and (2) increased risk of infections, due to severe thinning or ulceration of the sclera, which could cause blindness if not

detected early and aggressively treated. No adverse health effects were reported during a reexamination of seven of these 25 patients by Dr. Fernández. However, the NRC medical consultant indicated that the possible adverse consequences to these patients may not appear for a period of up to 10 years after irradiation.

**Cause or Causes** – Dr. Fernández used an incorrect dose rate for the Sr–90 source, as calibrated by a medical physics consultant employed by the deceased former licensee, to develop treatment plans.

The incorrect dose rate calibration occurred when the former licensee had a medical physics consultant calibrate the Sr–90 source, after the original calibration certificate was lost. The medical physics consultant used an inappropriate measurement instrument for the calibration, which gave an erroneous dose rate calibration of 24 cGy per second (24 rad per second). (The label attached to the carrying case of the eye applicator device indicated that the medical physics consultant calibrated the Sr–90 source in September 1990.)

Also, Dr. Fernández had no Quality Management Program (QMP) as required by 10 CFR 35.32, which could have helped in detecting the calibration error. Medical use licensees, as required under 10 CFR 35.32, must establish a QMP to provide high confidence that radiation will be administered as directed by the authorized user.

**Actions Taken To Prevent Recurrence**

**Licensee** – Dr. Fernández initially ceased operations until the eye applicator device was properly calibrated; reliable dosimetric data was available to perform the dose administrations; and a QMP was developed and submitted to NRC for review. Dr. Fernández subsequently decided to cease using the Sr–90 source and to terminate his license. (The QMP was never implemented.)

**NRC** – A CAL was issued to confirm that Dr. Fernández would submit a QMP for use of the eye applicator device, and that he would cease operations until approval was received from NRC to resume operations. A second CAL was issued confirming that Dr. Fernández would perform an in–depth review of his records to identify the misadministrations and to notify the patients.

After Dr. Fernández requested termination of his license, NRC issued an order, which required him to maintain the Sr–90 sources in locked, safe storage until the sources were transferred to an authorized recipient, to transfer the Sr–90 source within 90 days, to identify and notify any additional patients who may have received misadministrations, to obtain the services of an independent medical physics consultant with expertise in therapy dosimetry calculations, and to perform several other tasks specified in the order. Dr. Fernández currently has a possession only license until his sources are properly transferred and his request for termination has been granted by the NRC. In addition, NRC is requesting that the Puerto Rico Health Department perform along–term follow–up of these patients.

NRC also issued Information Notice 96–66, "Recent Misadministrations Caused by Incorrect Calibrations of Strontium–90 Eye Applicators," on December 13, 1996, to alert all medical use licensees authorized to use Sr–90 eye applicators of misadministrations caused by incorrect source strength determinations of Sr–90 eye applicators.

Dr. Fernández purchased the medical practice and the Sr–90 source from the estate of the deceased former licensee, Dr. Luis A. Vázquez of Mayagüez, Puerto Rico. Consequently, Dr. Fernández has the records of all of the administrations that were made using the Sr–90 source while it was licensed to Dr. Vázquez. In a letter to Dr. Fernández dated October 28, 1996, NRC confirmed with Dr. Fernández that he would preserve the patient records of the former licensee and perform a computer search to identify the patients who were treated with the eye applicator. NRC is considering options for the review of these records to determine how many additional misadministrations occurred when the incorrectly calibrated Sr–90 source was in the possession of the former licensee.

This event is not closed for the purpose of this report.

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## 96–4 Medical Brachytherapy Misadministrations by Phillip J. W. Lee, M.D., in Honolulu, Hawaii

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 5[d]) of this report notes that administering a therapeutic dose from a sealed source such that the errors in source calibration and time of exposure result in a calculated total treatment dose differing from the prescribed treatment dose by more than 10 percent, and the event (regardless of any health effects) affects two or more patients at the same facility, can be considered an AO.

**Date and Place** – May 6, 1995, through November 16, 1995; Phillip J. W. Lee, M.D.; Honolulu, Hawaii.

**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 Standards and Technology (NIST). Based on calibration data provided by NIST, NRC and the licensee determined that 17 misadministrations involving 16 patients had occurred between May 6 and November 16, 1995. (Two of the misadministrations involved one patient who was treated on both eyes.) The delivered doses were from 21.1 to 22.7 percent greater than the prescribed total dose of 4000 centigray (cGy) (4000 rad). (The total dose was to be delivered in four fractions of 1000 cGy [1000 rad] each.)

The licensee and referring physicians did not observe any adverse consequences to the patients. The licensee noted that the misadministered doses were within the ranges recommended for this type of treatment. NRC contracted a medical consultant to review the cases and make an independent assessment of the potential health effects to the patients. As of the date of this report, the reviews of the NRC and its consultant were ongoing.

The licensee notified the patients of the misadministration.

**Cause or Causes** – 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.

**Actions Taken To Prevent Recurrence**

**Licensee** – The licensee had the Sr–90 eye applicator calibrated at NIST and learned how to calculate the decay of the Sr–90 source.

**NRC** – NRC requested that the licensee have the Sr–90 eye applicator calibrated at NIST and taught the licensee how to calculate the decay of the Sr–90 source. NRC is conducting an inspection, which will remain open until the NRC medical consultant finishes reviewing the cases and provides an assessment of the potential health effects to the patients. Enforcement action may be taken in the future if necessary.

This event is closed for the purpose of this report.

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## 96–5 Medical Brachytherapy Misadministration at Harper Hospital in Detroit, Michigan

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

**Date and Place** – November 24, 1995; Harper Hospital; Detroit, Michigan.

**Nature and Probable Consequences** – A patient was being treated with a strontium–90 eye applicator for pterygium (a growth over the eye which causes gradual blindness). The patient was prescribed three 800–centigray (800 rad) treatments lasting 30 seconds each. Each of the treatments was to be administered to the medial side of the left eye. However, the second treatment was mistakenly administered to the lateral side of the left eye. The physician realized the error and immediately treated the correct side with the prescribed dose.

The patient was notified of the misadministration and given a written report. The patient's referring

physician was notified. An NRC medical consultant evaluated the effects of the misadministration and concurred with the licensee that the patient was not expected to suffer any adverse health effects.

**Cause or Causes** – The patient's chart was upside down and the treating physician incorrectly interpreted the sketch of the left eye on the diagram that specified the treatment site. (The diagram was part of the written directive for treatment using the strontium-90 eye applicator; however, it did not show the nose, top of the page, or bottom of the page.) Also, the second treatment was administered by a different physician and physicist than the first treatment.

**Actions Taken To Prevent Recurrence**

**Licensee** – The licensee revised the diagram so that it shows the nose, thereby making it obvious which is the left eye and which is the right eye.

**NRC** – NRC conducted a special safety inspection. A Notice of Violation was issued for failing to ensure that the administration was in accordance with the written directive. Since the inspection showed that actions had been taken to correct the violation and to prevent recurrence, no reply to the violation was required.

This event is closed for the purpose of this report.

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## 96–6 Medical Brachytherapy Misadministration at New England Medical Center in Boston, Massachusetts

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

**Date and Place** – November 10, 1993; New England Medical Center; Boston, Massachusetts.

**Nature and Probable Consequences** – A patient with carcinoma of the cervix metastatic to the brain was being treated with an intercavity implant using cesium–137 sources in a gynecological applicator. During treatment a source became dislodged and delivered radiation to the patient's thigh, which was an unprescribed treatment site.

The licensee subsequently calculated that the consequent dose to the patient's thigh was 71 centigray (cGy) (71 rad), as compared to 65 cGy (65 rad) which would have been delivered to the thigh at 20 centimeters (7.87 inches) distance from the applicator during the total procedure if performed as prescribed.

During a routine NRC inspection conducted on April 10–12, 1995, the NRC inspector noted the incident report and brought it to the attention of NRC management. NRC subsequently determined that the event was a misadministration and notified the licensee. The licensee consequently submitted the required notifications to NRC, and notified the patient in writing of the misadministration.

**Cause or Causes** – 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.

**Actions Taken To Prevent Recurrence**

**Licensee** – The licensee replaced the malfunctioning gynecological applicator. In addition, the licensee now requires that two persons perform loading of the gynecological applicator to insure that the sources are in and that the ovoids are taped to insure that the sources do not come out inadvertently.

**NRC** – The NRC again reviewed the information provided by the licensee and determined that violation of the licensee's Quality Management Plan had occurred. An NRC medical consultant reviewed the circumstances of the misadministration, determined that the licensee had used an inaccurate source-to-thigh distance in its dose calculation, and determined that the patient received a dose of 864 cGy (864 rad) to the thigh instead of 71 cGy (71 rad) as calculated by the licensee. The medical consultant stated that the patient experienced no ill effects.

This event is closed for the purpose of this report.

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## 96–7 Medical Brachytherapy Misadministration at William Beaumont Hospital in Royal Oak, Michigan

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

**Date and Place** – March 19, 1996; William Beaumont Hospital; Royal Oak, Michigan.

**Nature and Probable Consequences** – A patient with cancer of the vagina was prescribed treatment with a high dose rate (HDR) remote afterloader brachytherapy unit having an iridium–192 source. The treatment plan specified a step size of 2.5 millimeters (mm) (0.098 inches). A wrong step size of 5.0 mm (0.197 inches) was entered into the HDR unit's computer control program. Therefore, a part of the body not scheduled to receive radiation was exposed.

The licensee calculated that the skin of the patient's thighs, which was the wrong treatment site, received a maximum unintended dose of 500 centigray (500 rad) because of the misadministration. An NRC medical consultant determined that the patient should have no side effects as a consequence of the misadministration. The patient and the referring physician were notified of the misadministration.

**Cause or Causes** – The wrong step size was entered into the HDR remote afterloader brachytherapy unit's computer control program.

**Actions Taken To Prevent Recurrence**

**Licensee** – 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 recorded, prior to each treatment.

**NRC** – NRC conducted a special safety inspection, where one apparent violation was noted. This was the failure of the licensee's Quality Management Program to provide assurance of correct administration of the prescribed dose in compliance with the physician's written directive.

This event is closed for the purpose of this report.

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## 96–8 Medical Brachytherapy Misadministration at Community Hospitals of Indiana in Indianapolis, Indiana

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

**Date and Place** – August 16, 1996; Community Hospitals of Indiana; Indianapolis, Indiana.

**Nature and Probable Consequences** – A patient was prescribed a 500 centigray (cGy) (500 rad) treatment for an esophageal tumor using a high dose rate remote afterloader unit having an iridium–192 source. Because of a treatment planning error, a non–prescribed treatment area approximately 27 millimeters (mm) (1.06 inches [in]) below the tumor volume received a maximum dose of 465 cGy (465 rad) instead of the estimated dose of 50 to 100 cGy (50 to 100 rad).

The patient was notified of the misadministration. The licensee expects no adverse health effects to the patient. A NRC medical consultant was retained to review the case.

**Cause or Causes** – Because of a treatment planning error, the source was placed approximately 27 mm (1.05 in) below the tumor volume

**Actions Taken To Prevent Recurrence**

**Licensee** – A table of offset distances for the various sources and catheter lengths used by the licensee was placed in the licensee's quality control manual.

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

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## 96–9 Medical Brachytherapy Misadministrations at EquiMed, Inc., in Lehighton, Pennsylvania

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

**Date and Place** – December 31, 1995; EquiMed, Inc.; Lehighton, Pennsylvania.

**Nature and Probable Consequences** – Two patients were prescribed vaginal treatment with a high dose rate (HDR) remote afterloader brachytherapy unit having an iridium–192 source. The prescribed total dose for each patient was between 2000 and 2200 centigray (cGy) (2000 and 2200 rad), and was to be delivered in five fractional doses over a period of several weeks. Each fractional dose was to be between 400 and 500 cGy (400 and 500 rad).

For one of the treatment fractions, 500 cGy (500 rad) was to be delivered to each patient over a treatment length of 5 centimeters (cm) (1.97 inches [in]) using a step size of 5 millimeters (mm) (0.197 in). However, a wrong step size of 10 mm (0.394 in) was entered into the HDR unit's control console, and a length of 10 cm (3.94 in) was treated instead of the prescribed length of 5 cm (1.97 in). Therefore, radiation was delivered to the wrong treatment site for each patient.

The licensee concluded that each patient received 312 cGy (312 rad) instead of the prescribed dose of 500 cGy (500 rad) (an underdose of 37.6 percent), and an additional length of 5 cm (1.97 in) received an unintended dose of 312 cGy (312 rad).

The licensee did inform the patients of the misadministrations, and does not expect the patients to have any adverse effects from the misadministrations.

**Cause or Causes** – A wrong step size was entered into the HDR unit's control console because the licensee did not follow its Quality Management Procedures (QMP). The QMP requires that treatment planning information be checked by the person entering the data in the control console, and then verified by the authorized user.

**Actions Taken To Prevent Recurrence**

**Licensee** – The licensee's authorized user and the HDR physicist will extract the pre–treatment printout of the input parameters from the HDR treatment console, review the input data for accuracy, and compare it with the written directive. Both the authorized user and the HDR physicist will then initial the printout before the HDR treatment is initiated.

**NRC** – NRC determined that the incidents occurred because the licensee did not follow its QMP. NRC contracted a medical consultant to evaluate the health effects on the patients from the misadministrations. Subsequently, the consultant determined no probable deterministic effects of the radiation exposure to the unintended site were expected.

This event is closed for the purpose of this report.

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## 96–10 Medical Brachytherapy Misadministration at the University of Wisconsin in Madison, Wisconsin

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

**Date and Place** – October 19, 1995; University of Wisconsin; Madison, Wisconsin.

**Nature and Probable Consequences** – A patient had two separate lung tumors, one in the lower section of the right lung and one in the middle section of the left lung. The patient was prescribed a total treatment dose of 1600 centigray (cGy) (1600 rad), with each tumor to receive a total dose of 800 cGy (800 rad). The total treatment dose was to be administered in four fractions of 400 cGy (400 rad) each over 2 days using a high dose rate (HDR) remote afterloader unit having an iridium–192 source. Each fraction was to be administered in two parts; a 200 cGy (200 rad) dose to the lower section of the right lung followed by a 200 cGy (200 rad) dose to the middle section of the left lung. Catheters of appropriate length were inserted into each lung to guide the source during treatment;

i.e., a long catheter was inserted into the right lung and a short catheter was inserted into the left lung.

While the HDR controller was inserting the source into the left lung during the first treatment fraction, the source stopped moving when it touched the bottom of the short catheter in the left lung even though the HDR controller was attempting to move it further into the left lung. Because the intended treatment sites had been reversed during treatment planning and were subsequently programmed into the HDR controller, the controller had positioned the source in the middle of the right lung during the first part of the first treatment fraction and was attempting to position the source in the lower part of the left lung during the second part of the first treatment fraction. Consequently, the middle of the right lung had received an unintended dose of 200 cGy (200 rad) during the first part of the first treatment fraction.

After the error was discovered, the correct treatments were delivered. The patient was notified of the misadministration both verbally and in writing. The referring physician was also notified.

An NRC medical consultant evaluated the misadministration and concluded that the patient would not have organ damage or long term biological effects.

**Cause or Causes** – 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 reversed. An independent verification of the treatment plan by a second physicist did not include a review of the x–rays for proper source location, so the error was not immediately discovered.

**Actions Taken To Prevent Recurrence**

**Licensee** – The licensee revised its Quality Management Program to include an independent review of the x–rays for source location by a second physicist. Also, when there is a deviation from the protocol, the results must be documented and reviewed by a second physicist.

**NRC** – NRC conducted a special safety inspection in conjunction with a routine inspection. A Notice of Violation was issued for failing to establish adequate procedures to ensure that final treatment plans were in accordance with the written directive. The licensee responded in writing and no additional actions were required.

This event is closed for the purpose of this report.

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## 96–11 Medical Brachytherapy Misadministration at Thomas Jefferson University Hospital in Philadelphia, Pennsylvania

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

**Date and Place** – August 14, 1995; Thomas Jefferson University Hospital; Philadelphia, Pennsylvania.

**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 mouth, and two were placed in the nostrils.

While making a routine visit to the patient, the prescribing physician noticed that two catheters were outside of the patient's mouth and had been taped to the patient's right cheek. Also, one of the two catheters remaining in the mouth was loose and its sutures were removed. Because the catheters were not properly positioned, the physician terminated the treatment.

The radioactive seeds were subsequently removed. The patient was informed both verbally and in writing that the sources had become dislodged and had consequently delivered radiation to the wrong treatment site. It was determined that the patient's cheek received a dose of 70 centigray (70 rad).

**Cause or Causes** – While responding to a call from the patient, a nurse noticed that two of the

catheters were loose and subsequently taped them to the patient's cheek. The nurse had not been trained to recognize that the radioactive seeds were moved from their intended positions.

**Actions Taken To Prevent Recurrence**

**Licensee** – Refresher in–service training was given to the nurses who care for brachytherapy patients. Emphasis was placed on identifying radioactive sources and handling them properly under normal and emergency conditions. Also, the nurses will be briefed on the details of a planned treatment at the time the sources are implanted with emphasis on radiation safety issues. Finally, physicians will visit implant patients at least twice daily during treatment.

**NRC** – After conducting an investigation, NRC determined that the event was a misadministration. An NRC medical consultant concluded that no significant injury would be expected. A Notice of Violation was issued with one Severity Level IV violation.

This event is closed for the purpose of this report.

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## 96–12 Medical Brachytherapy Misadministration at Macombe Hospital Center in Warren, Michigan

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

**Date and Place** – March 11, 1996; Macombe Hospital Center; Warren, Michigan.

**Nature and Probable Consequences** – A patient was undergoing a cervical boost brachytherapy treatment with a manually afterloaded standard gynecological applicator using cesium–137 sources. Approximately 100 minutes after the treatment was started, a nurse found one of the sources from the applicator lying on the sheet between the patient's legs. The dislodged source contained 1.29 gigabecquerel (34.8 millicurie) of cesium–137 and was intended for the right ovoid of the applicator. The nurse placed the source into the portable shielding that was available in the room and notified the radiation safety officer. The radiation safety officer immediately returned to the patient's room with the physician, who inserted the source into the right ovoid for the remainder of the prescribed 48 hours of treatment.

The licensee calculated that the unintended skin dose to the patient's upper inner thighs was 5 centigray (cGy) (5 rad). NRC concurred with the licensee's calculation and did not obtain a medical consultant. The dose of 5 cGy (5 rad) is within the occupational exposure limit and is not expected to result in deleterious effects to the patient. The patient and physician were notified of the misadministration.

**Cause or Causes** – 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 radiationoncologist believed that the sealed source dislodged from the carrier bucket when the problem with the hinge was encountered.

**Actions Taken To Prevent Recurrence**

**Licensee** – To prevent recurrence, the licensee will: (1) ensure that the carrier bucket hinges are working properly prior to loading the source into the bucket; (2) inscribe the handles of the ovoid carriers, with "R" for right ovoid and "L" for left ovoid, so that they can be readily identified without difficulty; (3) require the physicist to observe the radiation oncologist during the afterloading procedure in order to detect a dislodged source; and (4) require that the radiation oncologist complete a visual check of the bed sheets and immediate area before leaving the room.

**NRC** – 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.

This event is closed for the purpose of this report.

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## 96–13 Medical Brachytherapy Misadministration at Unity Hospital in Fridley, Minnesota

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

**Date and Place** – August 19–20, 1996; Unity Hospital; Fridley, Minnesota.

**Nature and Probable Consequences** – A patient was prescribed a dose of 2500 centigray (cGy) (2500 rad) for a gynecological brachytherapy procedure, using a gynecological applicator containing cesium–137 sources in two ovoids. Because 3–centimeter (cm) diameter caps had been used on the ovoids of the gynecological applicator, instead of the intended 2–cm diameter caps, the patient received a dose of 1186 cGy (1186 rad) to the vaginal surface.

With the addition of the external beam therapy that the patient had received prior to this treatment, the total administered dose was 5680 cGy (5680 rad). The treating physician determined that the total administered dose was within the medically accepted range of treatment, and that no negative effects to the patient were expected. The treating physician did not plan to administer any further radiation treatments to the patient to compensate for the underdose.

The patient was notified of the misadministration both verbally and in writing. The referring physician was also notified.

**Cause or Causes** – There was poor communication between the treating physician and the dosimetrist who prepared the treatment plan regarding the size of the ovoid caps to be used for the treatment. (The treating physician may select 2–cm diameter caps, 3–cm diameter caps, or no caps at all from an applicator kit, depending on the anatomy of the patient.) In addition, licensee personnel may have become desensitized to the possibility that an ovoid cap size different than 2–cm in diameter could be used; the treating physician failed to follow–up on earlier instructions to the dosimetrist to verify the correct cap size used; and the applicator kit was not returned immediately to the radiation oncology department following the implant of the applicator device.

**Actions Taken To Prevent Recurrence**

**Licensee** – The licensee revised its written–directive form to require the treating physician to enter the cap size when ovoids are used, and for a second person to verify that the information was entered. If the entry on the form is not made, the person confirming the information must independently verify which size ovoid caps were used.

**NRC** – 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.

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## 96–14 Radiopharmaceutical Misadministration at Universal Imaging in Taylor, Michigan

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 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.

**Date and Place** – March 18, 1996; Universal Imaging, Inc.; Taylor, Michigan.

**Nature and Probable Consequences** – A patient was prescribed a 7.4 megabecquerel (MBq) (200 microcurie [μCi]) dosage of iodide–123 (I–123) for a thyroid scan, but was administered 7.4 MBq (200 μCi) of iodide–131 (I–131) instead.

The referring physician's directive stated that I–123 was to be used. (This is the only isotope of iodine used at the facility.) A technologist then accidently ordered the I–131 from the nuclear pharmacy. A second technologist recognized that the I–131 was different from the I–123 routinely used, but assumed that it was prescribed and administered it anyway.

The licensee estimated that the dose to the patient's thyroid was 104 centigray (104 rad).

The referring physician was notified of the misadministration. The referring physician

decided not to notify the patient because the information would be harmful to the patient.

An NRC medical consultant reviewed the event and determined that the impact of the misadministration on the status of the patient's health was very low, and that no specific medical follow-up care was necessary.

**Cause or Causes** – 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.

**Actions Taken To Prevent Recurrence**

**Licensee** – The licensee implemented the following corrective actions: (1) all technologists were informed not to use any radiopharmaceutical that was not listed in the licensee's "Prescribed Dosage List"; (2) orders must be sent to the nuclear pharmacy via facsimile, rather than over the telephone; (3) the nuclear pharmacy was instructed not to deliver I-131, I-125, or any other therapeutic radiopharmaceutical to the licensee; (4) all technologists were informed in writing not to proceed if they were unsure of any procedure; and (5) copies of radiopharmaceutical orders and their activities were to be checked against receipts.

The licensee is not required to have written directives to follow. This is because it does not perform therapy of any kind, does not use I-125 or I-131 in quantities greater than 1.11 MBq (30 μCi), and has no Quality Management Program.

**NRC** – NRC conducted an inspection. Based on the results of the inspection, eight apparent violations were identified and are being considered for escalated enforcement action. A predecisional enforcement conference was held to discuss the apparent violations and any potential enforcement action is pending.

This event is closed for the purpose of this report.

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## 96-15 Radiopharmaceutical Misadministration at Miami Valley Hospital in Dayton, Ohio

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 if an actual diagnostic dose of a radiopharmaceutical is greater than five times the prescribed dose it can be considered an AO.

**Date and Place** – September 21, 1995; Miami Valley Hospital; Dayton, Ohio.

**Nature and Probable Consequences** – A patient was administered a 2.8 megabecquerel (MBq) (77 microcurie [μCi]) 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 μCi) of I-131. The licensee determined that the dose to the patient's thyroid was 80.85 centigray (80.85 rad).

The patient was informed of the misadministration in writing. The patient's referring physician was also notified.

An NRC medical consultant determined that no adverse health effects are expected from the additional dosage.

**Cause or Causes** – A nuclear medicine technologist inadvertently picked-up the wrong capsule, and in accordance with the licensee's practice did not calibrate the dosage in the dose calibrator prior to administration. The licensee's staff did not believe there was a requirement to assay dosages below 1.11 MBq (30 μCi).

**Actions Taken To Prevent Recurrence**

**Licensee** – The licensee implemented procedures to require that all dosages must be assayed regardless of their activity, and to review the assay of dosages on a quarterly basis.

**NRC** – NRC conducted a special safety inspection. NRC issued a Notice of Violation for failing to measure dosages containing less than 1.11 MBq (30μCi) before they were administered to patients for medical use. The licensee responded in writing and no additional actions are required.

This event is closed for the purpose of this report.

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## 96–16 Radiopharmaceutical Misadministration at St. Joseph Mercy Hospital in Ann Arbor, Michigan

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 if an actual diagnostic dose of a radiopharmaceutical is greater than five times the prescribed dose it can be considered an AO.

**Date and Place** – April 9, 1996; St. Joseph Mercy Hospital; Ann Arbor, Michigan.

**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.

The misadministration was discovered after a vial, intended for another patient, was assayed and found to contain 122 MBq (3.3 mCi) instead of the expected 633 MBq (17.1 mCi). The patient was notified of the misadministration. The patient's referring physician was also notified.

The patient's thyroid gland had been removed previously and therefore the licensee anticipated minimal medical consequences. NRC contracted with the Oak Ridge Institute for Science and Education to conduct an assessment of the I–131 dose to the patient. The assessment concluded that since the patient had no thyroid, the maximum dose was misadministered to the patient's bladder wall and was equal to 48.3 centigray (48.3 rad).

**Cause or Causes** – The technologist, when administering the dosage, mistakenly picked up a wrong radiopharmaceutical vial.

**Actions Taken To Prevent Recurrence**

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

**NRC** – NRC conducted a special safety inspection. NRC issued a Notice of Violation for failure of the supervised user (technologist) to follow instructions in accordance with the written directive.

This event is closed for the purpose of this report.

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## 96–17 Radiopharmaceutical Misadministration at the Veteran Affairs Medical Center in Charleston, South Carolina

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

**Date and Place** – January 9, 1996; Veteran Affairs Medical Center; Charleston, South Carolina.

**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 administration to verify that the patient had received all of the prescribed dose. The licensee discovered that approximately 296 MBq (8 mCi) of the prescribed dosage had been retained in the vial cap, and consequently was not administered to the patient. The patient was informed of the event and was subsequently administered an additional 296 MBq (8 mCi) to make up for the underdosage. The licensee also notified the referring physician of the misadministration. The licensee expects no adverse effects to the patient from the misadministration.

**Cause or Causes** – 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.

**Actions Taken to Prevent Recurrence**

**Licensee** – The licensee's Radiation Safety Officer investigated the incident. Bioassays were conducted on the individuals who handled and administered the I–131 dose, and all were found

to be negative. The licensee also revised its policy and procedures to require that only I–131 in capsule form be used in the future.

**NRC** – NRC conducted a special inspection to review the circumstances surrounding the misadministration, and identified no violations of NRC requirements.

The State Agency is working with the nuclear pharmacy that filled the prescription and the intermediate processor of the I–131, both South Carolina state licensees, to determine the cause of the event. The nuclear pharmacy informed its customers of the event.

This event is closed for the purpose of this report.

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## 96–18 Radiopharmaceutical Misadministration at Queen's Medical Center in Honolulu, Hawaii

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

**Date and Place** – December 8, 1995; Queen's Medical Center; Honolulu, Hawaii.

**Nature and Probable Consequences** – A patient was prescribed a dosage of 18.5 megabecquerel (MBq) (0.5 millicurie [mCi]) of phosphorus–32 (P–32) to be administered to the wrist for treatment of symptoms related to rheumatoid arthritis, but was administered 6.179 MBq (0.167 mCi) instead. The dosage was administered via a saline solution.

Prior to treatment, the volume of the patient's wrist–joint space was to be determined using fluoroscopy so that the proper volume of liquid would be injected. Also, two syringes were to be prepared. One was to contain 18.5 MBq (0.5 mCi) of P–32 in a 0.25 milliliter (ml) volume, and the other was to contain 18.5 MBq (0.5 mCi) of P–32 in a 0.5 ml volume. The appropriate syringe was to be chosen based upon the results of the fluoroscopy.

Because of poor communication, a technologist erroneously prepared one syringe containing 6.179 MBq (0.167 mCi) in a 0.25 ml volume and another syringe containing 12.32 MBq (0.333 mCi) in a 0.5 ml volume. The syringes were not labeled.

Based upon the results of the fluoroscopy, the administering physician chose the syringe with the 0.25 ml volume, believing that it contained 18.5 MBq (0.5 mCi) of P–32. However, the 0.25 ml volume contained only 6.179 MBq (0.167 mCi), which was one–third of the intended dosage. After the administration, the technologist who prepared the dosages asked why both syringes had not been used and explained how they were prepared.

The patient was notified of the misadministration in writing.

The two physicians involved with the misadministration have not observed any adverse health effects to the patient, and do not expect any. NRC determined that a medical consultant would not be required to review the case.

**Cause or Causes** – The details of the prescribed dosages were not properly communicated to the technologist who prepared the two syringes, the details were not independently confirmed by other licensee personnel, and the written procedure for preparing the dosages did not specify multiple syringe volumes.

**Actions Taken To Prevent Recurrence**

**Licensee** – The licensee now requires the prescribing physician to establish a standard activity and volume for each treatment site, and the injecting physician to verbally repeat this information and ask the technologist to verbally confirm it prior to the administration.

**NRC** – 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.

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# AGREEMENT STATE LICENSEES

Using the criteria and guidelines in Appendix A of this report, the following events which occurred at Agreement State licensees during this reporting period were determined to be significant enough to be reported as an AO.

## AS 96–1 Stolen Cobalt–60 Radiography Cameras

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.

**Date and Place** – February 27 to March 5, 1996; Houston, Texas.

**Nature and Probable Consequences** – Larpen of Texas (Larpen) was a radiography company that owned two cobalt–60 (Co–60) radiography cameras. The Co–60 sources in the cameras had activities of 1.31 terabecquerel (TBq) (35.3 curie [Ci]) and 0.32 TBq (8.6 Ci) respectively. Larpen provided radiography services to a steel–manufacturing company at the company's 37–acre site.

When the steel–manufacturing company went bankrupt, the Texas Department of Health Bureau of Radiation Control (TDH/BRC) issued orders to Larpen in October 1992 to stop operating, and ordered all of its radioactive sources to be impounded in place. Larpen subsequently filed for bankruptcy and its name was consequently changed to Many Diversified Interests, Inc. (MDI), in compliance with the law. Upon learning of the MDI bankruptcy, TDH/BRC verified that the Co–60 radiography cameras were secured in a building on the site.

TDH/BRC wrote to the bankruptcy court on June 24, 1994, and to the trustee for bankrupt MDI on July 11, 1994, to request that the Co–60 radiography cameras be properly disposed of, but no actions were taken. On July 29, 1994, TDH/BRC formally notified the bankruptcy court, through the Texas Attorney General's Office, that it was a creditor and party of interest in the bankruptcy of MDI. TDH/BRC then ensured that the Co–60 radiography cameras were secure in an on–site building and that the metal door to the building was welded shut.

During the period of March 1995 to January 1996, all structures on the site were demolished and all salvageable equipment was sold, with the exception of the building containing the Co–60 radiography cameras. When the salvage company vacated the site, the site had no security and people removed anything of value that could be sold as scrap. TDH/BRC consequently notified the bankruptcy court of its concern about the security of the Co–60 radiography cameras.

On February 27, 1996, three thieves broke into the building containing the Co–60 radiography cameras by removing the metal door that had been welded shut, stole the cameras, and sold them to a scrap yard. The scrap yard then sold them to an intermediary dealer who sent them to a recycling facility. The recycling facility refused to accept the cameras because they were radioactive, and the intermediary dealer consequently returned them to the scrap yard by truck. When the cameras arrived at the scrap yard, the 1.31 TBq (35.3 Ci) Co–60 source, which was accidentally unshielded while in transit, was thrown to the ground by the delivery man and forgotten. The scrap yard resold the cameras to other scrap yards. However, no one at the scrap yard knew that the unshielded Co–60 source was laying on the ground. The unshielded source lay on the ground for 100.5 hours until it was located by TDH/BRC on March 5, 1996. TDH/BRC also located the other camera on the same day. Both cameras and their Co–60 sources were then secured at an authorized disposal company. After the sources were recovered and secured, the trustee for bankrupt MDI had to obtain permission from the bankruptcy court for the disposal company to dispose of the cameras.

The unshielded Co–60 source irradiated scrap yard workers and the scrap–yard manager's two small children. The delivery man who touched the source received radiation burns to the thumb and middle finger of his right hand. Five police officers who investigated the theft of the cameras were also irradiated by the source. Two TDH/BRC personnel who located and secured the source received doses of 1.5 millisievert (mSv)

(150 millirem [mrem]) and 5.2 mSv (520 mrem) respectively.

TDH/BRC estimated the possible radiation doses that were received by the individuals who were exposed to the unshielded Co-60 source. Since the estimates indicated that the doses may have been as high as 600 mSv (60 rem), the scrap yard workers, the children, the policemen, and the thieves had their blood tested to determine their doses. Cytogenetic studies by the Department of Energy's Radiation Emergency Assistance Center/Training Site in Oak Ridge, Tennessee, determined that their doses were less than 100 mSv (10 rem). Also, the doses to the general public conducting business at the scrap yard were determined to be less than 5.0 mSv (500 mrem).

The three thieves were arrested for stealing the cameras and the owner, manager, and manager's wife of the scrap yard were arrested for receiving stolen goods.

**Cause or Causes** – The devices were stolen from a facility where they were being stored by TDH/BRC after a licensee went bankrupt. TDH/BRC has severely limited jurisdiction over radiography sources in cases where a licensee declares bankruptcy and any action must be taken through the bankruptcy court.

**Actions Taken To Prevent Recurrence**

**Licensee** – 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.

**State Agency** – TDH/BRC is trying to determine if there are requirements and controls that can be placed on the trustees of bankrupt companies possessing radioactive materials. TDH/BRC is also participating in a working group composed of representatives from the Nuclear Regulatory Commission and other Agreement States to review the loss of control of radioactive sources, with emphasis on bankruptcy situations.

This event is closed for the purpose of this report.

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## AS 96–2 Rupture of a Source Owned by Little Bit Wireline at an Oil Well near Winnie, Texas

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.

**Date and Place** – September 15, 1995; Winnie, Texas.

**Nature and Probable Consequences** – An 111,000 megabecquerel (MBq) (3 curie [Ci]) americium-241/beryllium source owned by Little Bit Wireline was found to be leaking after it was recovered from an oil well near Winnie, Texas, where it had been stuck. The Texas Department of Health, Bureau of Radiation Control (BRC), was notified of the event. BRC subsequently found that the radiation level of the leaking source was 10 microsievert per hour (1 millirem per hour), and that the well site and associated equipment were contaminated.

BRC reported the event to NRC, and asked for assistance from the Department of Energy (DOE). DOE subsequently transported the leaking source to Los Alamos National Laboratory where it was determined that the remaining source activity was approximately 37,000 MBq (1 Ci).

DOE was also asked to evaluate 10 individuals, including the licensee, for internal contamination. The individuals were sent to the Oak Ridge Institute for Science and Education (ORISE) for whole body scans and urinalysis. ORISE determined that the whole body scans and urinalysis for the individuals were negative, and that there was no reason to believe that anyone had received a significant internal exposure.

**Cause or Causes** – It is believed that there are two ways in which the source may have been ruptured. The first is that it was ruptured by a milling tool which was used to recover it. The second is that it was lodged between the oil well casing and another assembly known as a "screen and liner" which had also become stuck, and was ruptured during operations to recover the "screen and liner."

**Actions Taken To Prevent Recurrence**

**Licensee** – 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.

**State Agency** – BRC ordered the licensee and affected companies to restrict access to the contaminated equipment and land, to characterize the contamination, and to decontaminate the equipment and land. Further enforcement action is pending.

This event is closed for the purpose of this report.

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## AS 96–3 Release of Radioactive Material in Lemont, Illinois, From a Package That Was Accidently Destroyed While Being Transported by Associated Couriers of Maryland Heights, Missouri

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.

**Date and Place** – October 3, 1995; Lemont, Illinois.

**Nature and Probable Consequences** – A spent nuclear medicine generator containing approximately 666 megabecquerel (18 millicurie) of molybdenum–99/technetium–99m fell from a moving delivery van operated by Associated Couriers of Maryland Heights, Missouri. It was then struck by an unidentified vehicle and destroyed. The contamination that was released was spread on both lanes of the roadway by a sudden rain and the spray from moving vehicles.

A Radiological Assessment Team from Argonne National Laboratory was the first to arrive at the scene of the accident. The team transferred control of the scene to representatives of the Illinois Department of Nuclear Safety (IDNS) when they arrived, but remained at the scene to assist the IDNS representatives. The roadway was decontaminated to a near surface dose rate of 3 microsievert per hour (0.3 millirem per hour), at which time it was reopened. Since no contamination migrated from the roadway, doses to members of the public were negligible. Doses to emergency workers were significantly below regulatory limits. (It should be noted that even though the licensee [Medi–Physics, Inc.] was not responsible for the event, its personnel were at the scene to collect all debris and decontamination materials for transport to its facility.)

**Cause or Causes** – 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.

**Actions Taken To Prevent Recurrence**

**Licensee** – 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.

**State Agency** – Since this was a violation by a moving vehicle on a public roadway, enforcement action was brought against the carrier by the Illinois Department of Transportation (IDOT), based on information supplied by IDNS. IDOT assessed a civil penalty of $2,700 and received full payment of the penalty on December 14, 1995.

Since this was the first violation on record by this carrier, no further action was taken. An order may be issued in the future for recovery of response costs, but no further punitive penalty is anticipated.

This event is closed for the purpose of this report.

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## AS 96–4 Lost Source at Deseret Generation and Transmission Cooperative's Bonanza Power Plant in Vernal, Utah

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.

**Date and Place** – January 31, 1996; Deseret Generation and Transmission Cooperative's Bonanza Power Plant; Vernal, Utah.

**Nature and Probable Consequences** – A 370 megabecquerel (10 millicurie) cesium–137 source was found to be missing from its housing. The

source was part of a KayRay/Sensall Model 7062 BP fixed density gauge which was mounted to a fly ash chute. The gauge had been in service since October 18, 1984.

False signals from the gauge started to appear on January 9, 1996, the day after a vibrator was attached to the fly ash chute. Several attempts were made to identify and correct the problem from January 9 until January 31, 1996, when it was discovered that the source–housing shutter mechanism was broken and the source was missing.

Several people tried unsuccessfully to find the source by systematically searching the plant site using radiation detection survey instruments. Consequently, five persons may have received an exposure to radiation. However, it is highly improbable that anyone received a measurable level of exposure.

**Cause or Causes** – 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.

**Actions Taken To Prevent Recurrence**

**Licensee** – 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.

**State Agency** – The Utah Division of Radiation Control notified the Illinois Radiation Control Program of the event involving KayRay/Sensall, a gauge manufacturer, licensed in the State of Illinois. The Illinois Radiation Control Program is taking action with its licensee (KayRay/Sensall) regarding the possibility of any generic issues. The State of Utah is continuing its investigation and plans to follow–up at the next inspection of its licensee (Deseret Generation and Transmission Cooperative's Bonanza Power Plant), which was advanced because of this event.

This event is closed for the purpose of this report.

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## AS 96–5 Medical Brachytherapy Misadministration at Duke University Medical Center in Durham, North Carolina

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.

**Date and Place** – March 12, 1996; Duke University Medical Center; Durham, North Carolina.

**Nature and Probable Consequences** – A patient was prescribed a dose of 650 centigray (cGy) (650 rad) to the bronchus using an Omnitron 2000 high dose rate (HDR) remote afterloading brachytherapy unit having an iridium–192 source. The HDR unit was to be used with a catheter that was 150.25 centimeter (cm) (59.15 inch) long. However, during patient setup, the wrong catheter–length value of 125.25 cm (49.31 inch) was entered into the HDR's computer treatment planning software.

Upon completion of the treatment, the attending physician recognized the misadministration and notified the radiation oncologist of the error. The patient and the referring physician were then notified by the radiation oncologist.

Since the catheter length entered into the HDR's computer treatment planning software was 125.25 cm (49.31 inch), and a 150.25 cm (59.15 inch) long catheter was attached to the HDR, the source did not completely traverse the length necessary to treat the bronchus with 650 cGy (650 rad). As a result, the wrong treatment sites received unplanned exposure; the right cheek received 90 to 130 cGy (90 to 130 rad) and the right eye received 35 to 50 cGy (35 to 50 rad). The radiation oncologist anticipates no short or long term health effects from the misadministration.

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

**Actions Taken To Prevent Future Recurrence**

**Licensee** – 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.

**State Agency** – The State Agency agrees with the licensee's action to prevent recurrence.

This event is closed for the purpose of this report.

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## AS 96–6 Medical Brachytherapy Misadministrations at the University of Mississippi Medical Center in Jackson, Mississippi

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 treatmentdose 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.

**Date and Place** – May 21, 1996, through May 23, 1996; University of Mississippi Medical Center; Jackson, Mississippi.

**Nature and Probable Consequences** – Two patients were prescribed manual gynecological brachytherapy procedures using cesium–137 (Cs–137) sealed sources loaded in a gynecological applicator.

Patient A was prescribed a total dose of 4000 centigray (cGy) (4000 rad) in two fractional treatments of 2000 cGy (2000 rad) each. Patient B was prescribed a total dose of 2275 cGy (2275 rad) in one treatment. However, the medical physicist noticed while removing the sources from Patient A that the Cs–137 sources for the two patients were switched. The medical physicist immediately went to Patient B's room and removed the sources from Patient B.

As a result of the error, the administered second fractional treatment dose for Patient A was 1342 cGy (1342 rad), for an underdose of 33 percent. Also, Patient B was administered a treatment dose of 2698 cGy (2698 rad), for an overdose of 19 percent.

The licensee notified the referring physician and the patient's relatives of the misadministrations.

**Cause or Causes** – The licensee stated that this event occurred because of human error. The medical physicist prepared three source configurations for three patients at the same time. The loads were color–coded for each patient to prevent mix–ups. On removal of the sources, the medical physicist discovered that Patient A's and Patient B's loads were switched, even though the color–codes were correct for the patients. Patient C was not affected. The medical physicist stated that he must have switched the loads prior to color–coding the loads for the patients.

**Actions Taken To Prevent Recurrence**

**Licensee** – 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.

**State Agency** – The State Agency conducted an investigation. The State Agency concurred with the licensee's evaluation of the event and the corrective action implemented by the licensee. No violations were cited.

This event is closed for the purpose of this report.

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## AS 96–7 Radiopharmaceutical Misadministration at Baptist Medical Center Princeton in Birmingham, Alabama

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.

**Date and Place** – January 8, 1996; Baptist Medical Center Princeton; Birmingham, Alabama.

**Nature and Probable Consequences** – A 67–year–old male patient suspected of having Graves disease was prescribed 0.37 megabecquerel (MBq) (10 microcurie [μCi]) of iodine–131 (I–131) for a thyroid uptake study. The nuclear pharmacy delivered 3.7 MBq (100 μCi) by mistake, and a nuclear medicine technician subsequently administered the 3.7 MBq (100 μCi) to the patient. The administered diagnostic dose exceeded the prescribed diagnostic dose by a factor of 10; i.e., the diagnostic dose to the thyroid was approximately 350 centigray (cGy) (350 rad) instead of 35 cGy (35 rad).

The results of the thyroid uptake test confirmed that the patient had Graves disease and the patient was therapeutically treated with 555 MBq (15 millicurie) of I–131 the next day. Because the patient was treated with a therapeutic dose of I–131, there was no consequence or adverse health effect to the patient as a result of the diagnostic misadministration. The patient's attending physician decided that there was no need to notify the patient of the diagnostic misadministration.

**Cause or Causes** – The misadministration was caused by two errors.

The first error occurred at the nuclear pharmacy, Syncor of Birmingham, Alabama, where the wrong date was entered into a computer. As a result, a 3.7 MBq (100 μCi) I–131 capsule was incorrectly identified as being the lowest activity capsule in inventory. Consequently, a 3.7 MBq (100 μCi) I–131 capsule was sent to Baptist Medical Center Princeton instead of the prescribed 0.37 MBq (10 μCi) I–131 capsule.

The second error occurred at Baptist Medical Center Princeton, where a technician failed to recognize that the activity of the capsule received from the nuclear pharmacy did not match the written directive for the prescribed activity.

**Actions Taken To Prevent Recurrence**

**Licensee** – 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.

**State Agency** – The State Agency discussed the misadministration with both the nuclear pharmacy and Baptist Medical Center Princeton and determined that a special inspection was not warranted. The State Agency sent an information notice to the State nuclear medicine licensees and nuclear pharmacies requesting that each verify with the other the values of activity utilized on any written directives that they may use in ordering or dispensing radiopharmaceuticals.

This event is closed for the purpose of this report.

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## AS 96–8 Radiopharmaceutical Misadministration at Methodist Medical Center in Peoria, Illinois

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.

**Date and Place** – November 27, 1995; Methodist Medical Center; Peoria, Illinois.

**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 and the patient were informed of the misadministration. The patient was then administered an additional dosage of 370 MBq (10 mCi) to make up for the underdose. The radiologist reported no harmful effects to the patient from the misadministration.

**Cause or Causes** – 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.

**Actions Taken To Prevent Recurrence**

**Licensee** – 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.

**State Agency** – 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.

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# APPENDIX A

## ABNORMAL OCCURRENCE CRITERIA[1]

The following criteria used to determine an abnormal occurrence (AO) were set forth in an NRC policy statement published in the *Federal Register* on February 24, 1977, (Vol. 42, No. 37, pages 10950–10952).

An event will be considered an AO if it involves a major reduction in the degree of protection of the public health or safety. Such an event would involve a moderate or more severe impact on the public health or safety and could include but need not be limited to:

1. Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission;
2. Major degradation of essential safety–related equipment; or
3. Major deficiencies in design, construction, use of, or management controls for licensed facilities or material.

Examples of the types of events that are evaluated in detail using these criteria are:

**For All Licensees**

1. 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 radiation [10 CFR 20.403(a)(1)], or equivalent exposures from internal sources.
2. An exposure to an individual in an unrestricted area such that the whole body dose received exceeds 0.5 rem in one calendar year [10 CFR 20.105(a)].
3. The release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceed 50 times the regulatory limit of Appendix B, Table II, 10 CFR Part 20 [CFR 20.403(b)(2)].
4. Radiation or contamination levels in excess of design values on packages, or loss of confinement of radioactive material such as (a) a radiation dose rate of 1000 mrem per hour three feet from the surface of a package containing the radioactive material, or (b) release of radioactive material from a package in amounts greater than the regulatory limit.
5. Any loss of licensed material in such quantities and under such circumstances that substantial hazard may result to persons in unrestricted areas.
6. A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.
7. Any substantiated loss of special nuclear material or any substantiated inventory discrepancy that is judged to be significant relative to normally expected performance and that is judged to be caused by theft or diversion or by substantial breakdown of the accountability system.
8. Any substantial breakdown of physical security or material control (i.e., access control, containment, or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.
9. An accidental criticality [10 CFR 70.52(a)].
10. A major deficiency in design, construction, or operation having safety implications requiring immediate remedial action.
11. Serious deficiency in management or procedural controls in major areas.
12. 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.

[1]The events included in this report were determined to be potential AOs using the reporting criteria which were in effect during fiscal year (FY) 1996. The Commission recently approved new AO reporting criteria which it had directed the NRC staff to develop, and which will be published in the *Federal Register*. These new criteria will be used starting in FY 1997.

**For Commercial Nuclear Power Plants**

1. Exceeding a safety limit of license Technical Specifications [10 CFR 50.36(c)].

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

3. Loss of plant capability to perform essential safety functions such that a potential release of radioactivity in excess of 10 CFR Part 100 guidelines could result from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

4. Discovery of a major condition not specifically considered in the Safety Analysis Report (SAR) or Technical Specifications that requires immediate remedial action.

5. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions such that a potential release of radioactivity in excess of 10 CFR Part 100 guidelines could result from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

**For Fuel Cycle Licensees**

1. A safety limit of license Technical Specifications is exceeded and a plant shutdown is required [10 CFR 50.36(c)].

2. A major condition not specifically considered in the safety analysis report or Technical Specifications that requires immediate remedial action.

3. An event that seriously compromised the ability of a confinement system to perform its designated function.

**Medical Misadministrations**

As discussed in the Preface to this report, the NRC policy statement on AOs was published before licensees were required to report medical misadministrations to the NRC. Therefore, during 1984, NRC developed guidelines for selecting such events for AO reporting. These guidelines, which are summarized in Table A–1, augment the NRC policy statement.

As noted in the Preface, revised guidelines have been developed because new medical misadministration definitions became effective on January 27, 1992.

**Table A–1 NRC Guidelines for Selecting Medical Misadministration Events for Abnormal Occurrence (AO) Reporting**

| Event Type | AO Reporting Threshold | |
|---|---|---|
| | Diagnostic Exposure | Therapeutic Exposure |
| (1) Administering a radiopharmaceutical or radiation from a sealed source other than the one intended. | If the improper administration results in any part of the body receiving unscheduled radiation, an AO report should be proposed if: | If the improper administration results in any part of the body receiving unscheduled radiation, an AO report should be proposed for any such event. |
| | (a) the actual dose to the wrong body part is greater than five times the upper limit of the normal range of exposures prescribed for diagnostic procedures involving that body part, **or** | If the parts of the body receiving radiation improperly would have received radiation anyway, had the proper administration been used, an AO report should be proposed if: |
| | (b) there are clinical indications of **any** adverse health effects to the wrong body part. | (a) the actual dose is greater than 1.5 times that intended to the above described body parts, **or**, |
| | If the parts of the body receiving radiation improperly would have received radiation anyway, had the proper administration been used, an AO report should be proposed if: | (b) the actual dose is less than 0.5 times that intended to the above described body parts, **or**, |
| | | (c) the above described bodyparts show signs of adverse health effects greater than expected had the proper administration been used, **or** |
| | (a) the actual dose is greater than five times that intended to the above described body parts, **or**, | (d) the event (regardless of any health effects) affects two or more patients at the same facility. |
| | (b) the above described body parts show signs of adverse health effects greater than expected had the proper administration been used. | |
| (2) Administering a radiopharmaceutical or radiation to the wrong patient. or | An AO report should be proposed if: | An AO report should be proposed for any such event. |
| | (a) the actual dose to the wrong patient exceeds five times the prescribed dose for the intended patient, **or** | |
| | (b) the event results in **any** adverse health effects. | |
| (3) Administering a radiopharmaceutical or radiation by a | Same guidelines as for Event Type 1. | Same guidelines as for Event Type 1. |

**Table A-1 (Continued)**

| Event Type | AO Reporting Threshold | |
|---|---|---|
| | **Diagnostic Exposure** | **Therapeutic Exposure** |
| route of administration other than that intended by the prescribing physician. | | |
| (4) Administering a diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent. | An AO report should be proposed if:<br>(a) the actual dose is greater than five times the prescribed dose, **or**,<br>(b) the event results in adverse health effects worse than expected for the normal range of exposures prescribed for the diagnostic procedure. | Not applicable. |
| (5) Administering a therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent; or administering a therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose from the final prescribed total treatment dose by more than 10 percent. | Not applicable. | An AO report should be proposed if:<br>(a) the actual dose is greater than 1.5 times the prescribed dose, **or**,<br>(b) the actual dose is less than 0.5 times the prescribed dose, **or**<br>(c) the event results in adverse health effects worse than would be expected for the normal range of exposures prescribed for the therapeutic procedure, **or**,<br>(d) the event (regardless of any health effects) affects two or more patients at the same facility. |
| (6) Recurring or series of events (regardless of the number of patients or facilities involved). | For either diagnostic or therapeutic exposures, an AO report should be proposed for recurring events or a series of events (in which each individual misadministration is not of major importance) that create a significant public health or safety concern. | |
| (7) Generic events. | For either diagnostic or therapeutic exposures, an AO report should be proposed for misadministrations with generic implications that create a significant public health or safety concern. | |

# APPENDIX B

## UPDATE OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During this reporting period, the following updates of previously reported AOs were received.

## OTHER NRC LICENSEES

### 94–23 Medical Brachytherapy Misadministration at North Memorial Medical Center in Robbinsdale, Minnesota

This AO was previously reported in NUREG–0090, Vol. 17, No. 4, "Report to Congress on Abnormal Occurrences" October–December 1994.

The AO criterion used was Event Type 1 in Table A–1 of Appendix A, a therapeutic exposure that results in any part of the body receiving unscheduled radiation. (Because of typographical error, the report incorrectly stated that the criterion was listed under Event Type 5.)

At the time it was reported that a patient received 1380 centigray (1380 rad) to a wrong treatment site during brachytherapy treatment for metastatic lung cancer.

The AO report is updated as follows:

NRC conducted a special inspection, conducted an investigation, and held a predecisional enforcement conference. Consequently, NRC issued a letter informing the licensee that information regarding the misadministration and actions taken to prevent recurrence are adequately addressed in the NRC docketed reports and in the transcript of the conference. Therefore, NRC will not take any enforcement action regarding the misadministration.

This event is closed for the purpose of this report.

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## AGREEMENT STATE LICENSEES

### AS 88–5 Medical Teletherapy Misadministration at Sacred Heart Hospital in Cumberland, Maryland

This AO was originally reported in NUREG–0090, Vol. 11, No. 4, "Report to Congress on Abnormal Occurrences," October–December 1988, under the title "Medical Therapy Misadministration."

The AO criterion used was a moderate or more severe impact on public health or safety, as stated in the second paragraph of the General Criteria.

At the time it was reported that an 81–year–old patient had received a therapeutic dose of 1400 centigray (1400 rad) at the base of the brain, instead of the prescribed right maxillary sinus, because the oncologist had improperly aligned one port of the teletherapy unit.

The AO report is updated as follows:

It was determined that no additional follow–up action was necessary.

This event is closed for the purpose of this report.

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### AS 88–6 Multiple Medical Teletherapy Misadministrations at Sacred Heart Hospital in Cumberland, Maryland

This AO was originally reported in NUREG–0090, Vol. 11, No. 4, "Report to Congress on Abnormal Occurrences," October–December 1988, under the title "Multiple Medical Therapy Misadministrations."

At that time it was initially reported that over a 13–month period 33 patients undergoing radiat on

therapy to the brain had received radiation exposures from a cobalt–60 (Co–60) teletherapy machine that exceeded the prescribed dose by more than 75 percent. Before the licensee notified the State Agency of the misadministrations, 20 patients had died either during the course of their treatment or after the conclusion of treatment.

This AO was originally closed out in the October–December 1988 AO report (NUREG–0090, Vol. 11, No. 4). It was subsequently reopened when NRC and the State of Maryland initiated a joint review of the series of misadministrations in response to issues that were raised during NRC testimony at an August 1993 Congressional hearing.

The AO report is updated as follows:

In response to issues that were raised during NRC testimony before a Congressional hearing of the House of Representatives Subcommittee on Environment, Energy, and Natural Resources in August 1993, a review of the misadministrations was jointly conducted by NRC and the State of Maryland. The purpose of the joint review was to: (1) determine the facts of the misadministrations, and if Sacred Heart Hospital (SHH) complied with Maryland regulations; (2) determine the adequacy of the State's handling of the case; and (3) evaluate NRC's involvement in the State's review and oversight of the Maryland Agreement State program.

The results of the joint review are summarized below:

(1) The direct cause of the misadministrations was the use of an incorrect computer file associated with the Co–60 teletherapy machine. This computer file had not been updated to reflect actual Co–60 source activity. There were many contributing factors to why the computer file was not updated before its use and why it took so long to detect the error. These factors included inadequate communications, change over in consultant services, inadequate verification of treatment procedures and dosimetric calculations, and failure to recognize the significance of longer treatment times. The direct cause and the contributing factors led the joint review team to conclude that the overall root cause of the misadministrations was lack of management oversight of the SHH radiation safety program. The diagnoses and planned treatments were appropriate. However, SHH did not provide all the notifications to the referring physicians and patients as required by Maryland law.

(2) The State did not resolve conflicting information that it obtained from interviews and consultant's reports and the State did not adequately follow–up on information the State received on concerns about whether patients' relatives or guardians were informed of the misadministrations. Before the joint review was conducted, the State Attorney General had concluded that the State staff's action in 1989 to limit public access to the State's investigation records was inappropriate.

(3) The NRC staff provided timely support to the State at the time of the misadministrations and accurately reported information received. However, NRC did not adequately follow–up on allegations received on the SHH misadministrations, did not follow–up with the State on the results of its investigation, and did not review the State's actions in Agreement State reviews before 1993.

Subsequent to the completion of this joint review, NRC and the State of Maryland committed to implement corrective actions to address the report's findings and recommendations.

The results of the joint review are documented in a report entitled, "Report On NRC/State Of Maryland Joint Review Of The Sacred Heart Hospital Misadministrations In 1987–1988." NRC forwarded the report to Congressional oversight committees and Senate and Congressional representatives for the State of Maryland.

This event is closed for the purpose of this report.

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## AS 93–13 Lost or Stolen Radiation Source at BPB Instruments, Inc., in Midland, Texas

This AO was previously reported in NUREG–0090, Vol. 16, No. 4, "Report to

Congress on Abnormal Occurrences" October–December 1993.

The AO criterion used was Example 5 of "For All Licensees" of Appendix A, a loss of licensed material in such quantities and under such circumstances that a substantial hazard may result.

At the time it was reported that a 555 gigabecquerel (15 curie) americium/beryllium source was not located and may have been lost or stolen.

The AO report is updated as follows:

The State of Texas cannot determine whether or not the source was stolen or lost. The State discussed the loss of the source with licensee personnel, and it could not be determined if it was lost or stolen.

This event is closed for the purpose of this report.

# APPENDIX C

## OTHER EVENTS OF INTEREST

"Other Events of Interest" are reported because they can be perceived as being significant but have been determined not to involve a major reduction in the level of protection provided for public health or safety; therefore they are not reportable as AOs. During this reporting period, the following events are being reported as "Other Events of Interest."

### 1. Problems at Millstone Units 1, 2, and 3, and Haddam Neck

Millstone Unit 1 is a General Electric–designed boiling water reactor nuclear power plant (NPP), Millstone Unit 2 is a Combustion Engineering–designed pressurized water reactor (PWR) NPP, and Millstone Unit 3 is a Westinghouse–designed PWR NPP. All three NPPs are operated by Northeast Utilities, and are located about 5.15 kilometers (3.2 miles) west–southwest of New London, Connecticut. Haddam Neck is a Westinghouse–designed PWR NPP, operated by Northeast Utilities and located about 20.9 kilometers (13 miles) east of Meriden, Connecticut.

Problems were found at Millstone Units 1, 2, and 3, and Haddam Neck during follow–up of issues raised in a 10 CFR 2.206 petition to NRC dated August 21, 1995.

The petition requested that NRC shut down Millstone Unit 1 and take enforcement action based on alleged violations of licensed activities related to operation of spent fuel pool cooling systems and refueling practices. Follow–up of the issues raised in the 10 CFR 2.206 petition, including the findings from investigations conducted by the Office of the Inspector General, found that certain activities at Millstone Unit 1 may have been conducted in violation of license requirements and that refueling activities may not have been conducted consistent with the Updated Final Safety Analysis Report (UFSAR). Northeast Utilities (NU) was required to report on actions that it will take to ensure that future operation of Millstone Unit 1 would be conducted in accordance with the terms and conditions of its operating license, NRC regulations which include 10 CFR 50.59, and the Millstone Unit 1 UFSAR.

NU established an Event Response Team (ERT) to determine the causes for the inaccuracies contained in the Millstone Unit 1 UFSAR. The ERT issued a report of its findings which stated that:

- The original 1986/1987 UFSAR contained errors and omissions;
- Administrative control programs such as Design Control, Corrective Action, and Commitment Tracking did not fully address regulatory requirements;
- NU did not fully implement the administrative control programs, and NU did not see the UFSAR as a document that was required to be accurate;
- NU internal correspondence, and events involving the design basis from 1985 through 1996, showed that information was communicated to NU management which identified weaknesses and risks associated with the UFSAR and design bases; that NU management made commitments to correct these deficiencies; and that the commitments to correct these deficiencies were ineffective, partially implemented, or not done; and
- NU oversight did not identify the information which was communicated to NU management, its significance, or the effectiveness of the corrective actions taken to prevent recurrence.

The ERT report also stated that similar configuration management conditions may exist at NU–licensed Millstone Units 2 and 3, and Haddam Neck.

Because of the number of operational and design concerns involving Millstone Unit 2, NRC requested that NU provide information on the actions that it took to ensure that future operation of Millstone Unit 2 would be conducted in accordance with the license, NRC regulations, and the UFSAR. NRC also requested that NU provide information regarding its corrective

actions at Millstone Unit 3 and Haddam Neck, as well as its future corrective action plans.

During an NRC special inspection at Millstone Units 2 and 3 and Haddam Neck, NRC found deficiencies at each of these units that were similar to those found at Millstone Unit 1. Millstone Unit 3 was shut down after it was determined that containment isolation valves for the auxiliary feedwater turbine–driven pump were inoperable and were not in compliance with NRC regulations, and because additional design and configuration problems were identified. NRC then requested that NU provide information on the actions that it took to ensure that future operation of Millstone Unit 3 would be conducted in accordance with the license, NRC regulations, and the UFSAR. Haddam Neck was shutdown when it was determined that the containment air recirculation system may not operate as required under certain accident scenarios.

The NRC special inspection team issued two separate reports, one for Millstone Units 2 and 3 and another for Haddam Neck that presented its findings and conclusions. One conclusion was that the concerns identified at Millstone Units 1, 2, and 3, and Haddam Neck reflect a lack of understanding of, and respect for, the preservation of the design and licensing bases for the units. This resulted in lack of attention to detail, thoroughness, and appropriate rigor in engineering efforts and management oversight. There was also a failure to adequately track identified deficiencies and associated corrective actions.

To alert other licensees to what may be a generic deficiency, NRC issued Information Notice (IN) 96–17, "Reactor Operation Inconsistent with the Updated Final Safety Analysis Report." IN 96–17 transmitted the executive summary of the NU ERT report, as well as one of the letters that NRC sent to NU which expressed its concerns about the operational problems that were found at Millstone Units 1, 2, and 3, and Haddam Neck. As a result of the substantial number of design and licensing bases issues at Millstone Station and Haddam Neck and the concern that similar problems could exist at other nuclear facilities, the NRC issued letters in October 1996 to all licensees requesting information pursuant to 10 CFR 50.54(f) regarding the adequacy and availability of design bases information. The purpose of these letters was to obtain information that will provide the NRC with added confidence and assurance that facilities are operated and maintained within the design bases, and any deviations are reconciled in a timely manner.

This event does not meet the abnormal occurrence reporting criteria because even though there were a number of deficiencies identified, it has been determined that these deficiencies did not result in a major reduction in the level of protection provided for public health and safety.

This event is closed for the purpose of this report.

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**2. Emergency Core Cooling System Analyses Deficiencies at Maine Yankee**

Maine Yankee is a Combustion Engineering–designed pressurized water reactor nuclear power plant, operated by Maine Yankee Atomic Power Company and located about 16.1 kilometers (10 miles) north of Bath, Maine.

In December 1995, NRC received information asserting that inadequate analyses were knowingly performed to support license amendments to increase the rated thermal power at which Maine Yankee may operate. It was also asserted that these inadequate analyses were misrepresented to NRC in seeking the license amendments, which were subsequently granted by NRC.

As a result of this information, NRC conducted a technical review and evaluation of the circumstances and records surrounding these applications to increase the maximum rated thermal power at Maine Yankee. Based upon the NRC staff's review, NRC determined that the computer code RELAP5YA, which the licensee for Maine Yankee proposed for use for Cycle 15 small–break loss–of–coolant accident (SBLOCA) analyses to demonstrate compliance with the emergency core cooling system (ECCS) requirements specified at 10 CFR 50.46(a), has not been applied in a manner conforming to the requirements of 10 CFR 50, Appendix K; nor has it been applied in a manner conforming to the conditions specified in the staff's safety evaluation (SE) dated January 30, 1989, as necessary for NRC acceptance of the use of RELAP5YA for SBLOCA analyses for Maine Yankee. Specifically, the licensee has not demonstrated that the code will reliably calculate the peak fuel cladding temperature for all break sizes in the

SBLOCA spectrum for Maine Yankee; nor has the licensee submitted the justification for the code options selected, in accordance with condition 7 of the staff's SE; nor has the licensee submitted other justifications and sensitivity studies to satisfy conditions 4, 8, 9, and 12 of the January 30, 1989 SE.

In addition, as a result of the NRC staff's review of the containment analysis, the staff finds that many conservatisms have been removed from the original analyses. Although the revised method gives results within design limits, the revised analysis is not an analysis of record.

On January 3, 1996, NRC issued a confirmatory order and demand for information to the licensee for Maine Yankee to restrict the power level for restart, and to stipulate the requirements for return to operation at the previous licensed maximum power of 2700 megawatt thermal (MWt). The requirements are as follows:

1. Maine Yankee is limited to operation at 2440 MWt (90.37 percent of the previous licensed power).

2. The licensee is required to submit a SBLOCA analysis that does not rely on RELAP5YA for Maine Yankee operation at power up to 2700 MWt. The analysis must meet the requirements of 10 CFR 50.46, "Acceptance criteria for emergency core cooling systems for light water nuclear power reactors"; NUREG–0737, "Clarification of TMI Action Plan Requirements," Items II.K.3.30 and 31, "SBLOCA Methods" and "Plant–specific Analysis," respectively; and NUREG–0737 Item II.K.3.5, "Automatic Trip of Reactor Coolant Pumps During LOCA."

3. The licensee is required to submit an integrated containment analysis accounting for relevant changes to the facility. This analysis must demonstrate that the maximum calculated design basis accident containment pressure meets the design basis pressure for Maine Yankee (379.2 kPa gauge [55 psi gauge]).

The NRR staff is reviewing the required SBLOCA analyses; waiting for the licensee's response to the staff's review questions on the required SBLOCA analysis performed by Siemens; and waiting for the required integrated containment analysis to be submitted.

This event is closed for purpose of this report.

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### 3. Ingestion of Phosphorus–32 at the Massachusetts Institute of Technology in Cambridge, Massachusetts

On August 19, 1995, a researcher at the Massachusetts Institute of Technology (MIT) Center for Cancer Research in Cambridge, Massachusetts, reported that he had discovered that he was internally contaminated with radioactive material during a routine survey. MIT subsequently determined that the researcher had ingested phosphorus–32 (P–32). On October 12, 1995, MIT informed the researcher that its final estimate of his intake was 21 megabecquerel (MBq) (579 microcurie [μCi]), which was just under the regulatory limit of 22 MBq (600 μCi). MIT's estimate was based on urine sample and whole–body counting data. On October 16, 1995, MIT reported the event to NRC.

On October 17, NRC established an Incident Investigation Team (IIT) to investigate the event. The IIT concluded that the licensee's final intake and dose estimates were in accordance with accepted scientific references and NRC guidance. However, recognizing the uncertainties involved in the use of models to simulate human characteristics, the IIT determined that the intake was probably within the range of 19–28 MBq (500–750 μCi). An NRC medical consultant concluded that no symptoms or acute effects should be observed from an intake of this level. The IIT also found that there was inadequate storage and control of licensed radioactive material at the MIT Center for Cancer research.

The IIT concluded that the ingestion of P–32 was possibly the result of a deliberate act by a knowledgeable individual. However, it was not determined how the ingestion occurred. Consequently, a root cause could not be determined.

The IIT's report, "Ingestion of Phosphorus–32 at Massachusetts Institute of Technology, Cambridge, Massachusetts, Identified on August 19, 1995" (NUREG–1535) was published in November 1995. NRC issued a Confirmatory Action Letter (CAL) which documented MIT's

agreement to immediately increase physical security procedures, audits, and barriers for licensed materials; to provide immediate training in these measures, and to develop a long range plan for improving procedures for the control of access to areas where licensed materials are used. NRC subsequently determined via an on–site inspection that MIT was taking the actions required by the CAL.

This event does not meet the abnormal occurrence reporting criteria because the exposure is much less than 0.25 sievert (25 rem) dose threshold involving an occupational worker in a controlled area.

This event is closed for the purpose of this report.

# APPENDIX D

## UPDATE OF PREVIOUSLY REPORTED OTHER EVENTS OF INTEREST

During this reporting period, the following update of a previously reported "Other Events of Interest" event was received.

### 1. Safety Relief Valve Inoperability at Millstone Unit 1

This "Other Events of Interest" item was previously reported in NUREG–0090, Vol. 17, No. 4, "Report to Congress on Abnormal Occurrences," October–December 1994.

At the time it was reported that during scheduled surveillance associated with a 1994 outage at Millstone Unit 1, a plant condition was found that involved multiple failures of the safety/relief valves (SRVs) to operate at intended pressures due to set–point drift. Millstone Unit 1 is a General Electric boiling water reactor (BWR–3) located near New London, Connecticut. It is operated by Northeast Utilities.

The cause of the set–point pressure drift was attributed to oxide bonding of the seat disk in the pilot valve of the SRVs. SRV set–point drift is a problem that was experienced previously at Millstone Unit 1 and at other facilities with two–stage valves manufactured by Target–Rock. The licensee addressed this problem by replacing three of the pilot valves with valves having their disk made of platinum stellite alloy, as recommended by the Boiling Water Reactor Owner's Group (BWROG).

This "Other Events of Interest" event is updated as follows:

Based on review of operating experience of the pilot valves having the new disk material, the licensee concluded that another solution for the set–point drift problem was needed. While the valves with the new disks were being evaluated, the BWROG had submitted a topical report to NRC for the design of pressure sensing actuation switches which would actuate the SRVs with external power when the reactor pressure reached the set–point value. NRC approved the topical report, and the licensee is implementing the pressure switch modification at Millstone Unit 1 during the current refueling outage.

This event is closed for the purpose of this report.

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10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

Section 208 of the Energy Reorganization Act of 1974 (PL 93-438) identifies an abnormal occurrence (AO) as an unscheduled incident or event that the Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (PL 104-66) requires that AOs be reported to Congress on an annual basis. This report includes those events that NRC determined to be AOs during fiscal year 1996.

This report addresses eighteen AOs at NRC-licensed facilities. Two involved events at nuclear power plants, eleven involved medical brachytherapy misadministrations, and five involved radiopharmaceutical misadministrations. Eight AOs submitted by the Agreement States are included. One involved stolen radiography cameras, one involved a ruptured source, one involved release of radioactive material while being transported, one involved a lost source, two involved medical brachytherapy misadministrations, and two involved radiopharmaceutical misadminisrations. Four updates of previously reported AOs are included in this report. Three "Other Events of Interest" events are being reported, and one previously reported "Other Events of Interest" event is being updated.

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)

Nuclear Power Plants; Wolf Creek; Braidwood; Medical; Misadministration; Brachytherapy; Radiopharmaceutical; Stolen Radiography Cameras; Rupture Source; Release of Radioactive Material From Package Destroyed While Being Transported; Lost Source

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