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Report to Congress on Abnormal Occurrences

October – December 1994

U.S. Nuclear Regulatory Commission

Office for Analysis and Evaluation of Operational Data

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ABSTRACT

Section 208 of the Energy Reorganization Act of 1974 identifies an abnormal occurrence (AO) as an unscheduled incident or event that the Nuclear Regulatory Commission determines to be significant from the standpoint of public health or safety and requires a quarterly report of such occurrences to be made to Congress. This report provides a description of those incidents and events that have been determined to be AOs during the period of October 1 through December 31, 1994.

This report addresses four AOs at NRC-licensed facilities. These occurrences involved the following: a generic concern relating to core shroud cracking in boiling water reactors; recurring incidents of administering higher doses than procedurally allowed for diagnostic imaging at a single facility; one medical teletherapy misadministration; and one medical brachytherapy misadministration. Agreement States submitted four AO reports. These four occurrences involved the following: one major contamination at a commercial facility; two medical brachytherapy misadministrations; and one medical teletherapy misadministration. The report also contains updates of seven AOs previously reported by NRC licensees and four AOs previously reported by the Agreement States. Two "Other Events of Interest" are also being reported. These occurrences involved the operability of safety relief valves at a nuclear power plant, and an error in the installation process of a Leksell Gamma KnifeR teletherapy unit that resulted in an operational failure.

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PREFACE

Introduction

The Nuclear Regulatory Commission (NRC) reports to Congress each quarter, under provisions of Section 208 of the Energy Reorganization Act of 1974, any abnormal occurrences (AOs) involving facilities and activities regulated by NRC. An AO is defined in Section 208 as an unscheduled incident or event that the Commission determines to be significant from the standpoint of public health or safety.

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.

On January 27, 1992, new medical misadministration requirements became effective. As directed by the Commission, the staff is currently developing a new policy statement for reporting incidents and events to Congress. The policy statement will be published for public comment in the Federal Register prior to final Commission approval for use in developing future AO reports.

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. This report covers the period from October 1 through December 31, 1994. 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 more than 100 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, under the Exchange Information provisions of each Agreement, each Agreement State voluntarily provides NRC information on reportable events.

In early 1977, the Commission determined that AOs happening at Agreement State licensed facilities should be included in the quarterly 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 quarterly 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 these quarterly 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. Similarly, previously reported "Other Events of Interest" are updated if significant new information becomes available.

REPORT TO CONGRESS ON ABNORMAL OCCURRENCES OCTOBER-DECEMBER, 1994

Nuclear Power Plants

There are 109 operating nuclear power plants in the United States (U.S.). NRC has reviewed all incident and event reports received from these licensees through the fourth quarter of 1994. Using the criteria and guidelines in Appendix A of this report, one recurring incident was determined to be significant enough to be reported as an abnormal occurrence (AO).

94-20 Core Shroud Cracking in Boiling Water Reactors

The following information pertaining to these events is also being reported concurrently in the Federal Register. Appendix A, For All Licensees, Example 10 of this report notes that a major deficiency in design, construction, or operation having safety implications requiring immediate attention; and Appendix A, For All Licensees, Example 12 of this report also notes recurring incidents and incidents with implications for similar facilities (generic incidents) that create a major safety concern can be considered an AO.

Date and Place – From October 1993 through the present, General Electricdesigned boiling water reactors (refer to Table 1 for dates and specific sites).

Nature and Probable Consequences – Intergranular stress corrosion cracking (IGSCC) of General Electric (GE)-designed boiling water reactors (BWR) reactor vessel internals has been identified as a technical issue of concern by both NRC and the industry. Core shroud cracking as a result of IGSCC was initially discovered overseas and later identified in operating BWR plants within the United States. Although no adverse consequences are expected at currently observed levels of shroud cracking, it has been postulated that a 360-degree through-wall core shroud crack in concert with a loss-of-coolant accident has the potential to lead to core damage.

NRC has been meeting every year since 1988 with the BWR Owners Group (BWROG) and GE to review the generic safety implications of potential failure of reactor internals, with IGSCC as one of the failure mechanisms of concern.

Cracking of BWR core shrouds was first observed in an overseas BWR in 1990. It was located in the heat affected zone of a circumferential weld in the beltline elevation of the shroud, and was reported by GE via Rapid Information Communication Services Information Letter (RICSIL) 054. The core shroud is a stainless steel cylinder which performs the following functions: (1) separates feedwater in the reactor vessel's downcomer annulus from cooling water flowing through the reactor core, (2) maintains core geometry, and (3) provides a refloodable volume under postulated accident conditions. The potential loss of a refloodable volume under accident conditions has the potential of resulting in core damage making BWR core shroud cracking the most significant concern related to potential failures of reactor internals reported during 1993 and 1994.

In response to this concern, several actions were taken by NRC. In a meeting with the BWROG in January 1992, the staff emphasized that a comprehensive program should be developed to address internals cracking and that the utilities should adopt an enhanced inspection program. In September 1993, Information Notice (IN) 93-79 (Ref. 1) was issued in response to the discovery of significant circumferential cracking of the core shroud welds at Brunswick Unit 1. (This event was also included in NRC's "Report to Congress on Abnormal Occurrences, October-December 1993." [NUREG-0090, Vol. 16, No. 4]). Following the additional discovery of significant core shroud cracks at Dresden Unit 3 and Quad Cities Unit 1 in May and June 1994, respectively, NRC issued IN 94-42 (Ref. 2), IN 94-42 Supplement 1 (Ref. 2), and Generic Letter (GL) 94-03 (Ref. 3).

GL 94-03 requested that BWR licensees inspect their core shrouds at the next refueling outage, and perform a safety analysis to support continued operation of their facilities until corrective actions were implemented. During the same period of time, the BWROG initiated the BWR Vessels and Internals Project (BWRVIP)] to

facilitate industry response to the core shroud and internals cracking issues. Licensee responses to GL 94-03 were received during August and September 1994, and several BWR licensees began outages in September 1994.

Cause or Causes - IGSCC of BWR vessel internals is a time dependent material degradation process which is accelerated by the presence of crevices, residual stresses, material sensitization, irradiation, cold work and corrosive environments.

Actions Taken To Prevent Recurrence

Licensees - Several domestic BWR licensees performed visual examinations of their core shrouds in accordance with the recommendations of GE RICSIL 054 or GE Services Information Letter (SIL) 572, which was issued in late 1993 and incorporates domestic experience. A summary of the inspection results through 1994 is provided in Table 1.

NRC - Because of the extent of cracking observed, NRC evaluated safety concerns associated with the possibility of a 360-degree circumferential separation of the shroud following a pipe break. Such separation might either prevent full insertion of the control rods, or open a gap in the shroud large enough so that the resulting leakage would limit adequate core cooling by the emergency core cooling system. The accident scenarios of primary concern are the main steam line break and the recirculation line break, which are normally referred to as loss-of-coolant accidents.

The most serious event associated with cracks in the upper shroud welds is the steam line break, since the lifting forces generated may be sufficient to elevate the top guide and potentially effect the ability to insert rods. The most serious event associated with cracks in the lower elevations of the core shroud is the recirculation line break. A recirculation line break concurrent with a 360-degree through-wall weld failure could cause a lateral displacement of the shroud or opening of a crack, which would allow enough leakage through the shroud and out of the break effecting the ability to adequately cool the core.

NRC performed a probabilistic risk assessment of the consequences of shroud separation at the lower elevation for Dresden Unit 3 and Quad Cities Unit 1. The assessment estimated the potential contribution to core damage frequency from a cracked shroud. Assuming that severe shroud cracking (360-degree through-wall cracking) did exist, a large rupture of either a steam or recirculation line would have to occur to generate sufficiently large loads to move the shroud. No events involving a large rupture of a steam line or recirculation line have ever occurred, and probabilistic risk assessments have shown that such ruptures have a low probability of occurring. Furthermore, for welds in the upper portion of the shroud, such extensive degradation in and of itself can be detected during normal operation by a power/flow mismatch condition.

From the above evaluations, NRC made conservative estimates of the risk contribution to core damage from shroud cracking and concluded that immediate corrective actions are not necessary. Although immediate plant shutdowns to implement corrective actions are not necessary, degradation of the core shroud does have the potential to impact plant safety. The core shroud provides the important functions of properly directing coolant flow through the core, maintaining core geometry, and providing a refloodable volume under postulated accident conditions. NRC therefore considers that 360-degree cracking of the shroud is a safety concern for the long term based on: (1) the potential to exceed the ASME Code's structural margins, if the cracks are sufficiently deep and continue to propagate through the subsequent operating cycle; and (2) the potential effects on the ability to protect against core damage.

Even though licensees have justified (through engineering evaluations) continued operation with significant cracks existing in core shrouds, BWRs with core shroud materials susceptible to IGSCC will eventually have to be repaired or modified to inhibit cracking and thereby assure structural integrity of the shrouds in the long term.

Table 1 – Summary of Domestic Shroud Cracking Experience

Plant Summary	Type		Date of Commercial Operation	Last Inspection
Brunswick 1	MK 1 BWR-4	3/18/77	10/93	Inspection found extensive cracking. Repairs have been implemented.
Brunswick 2	MK 1 BWR-4	11/3/75	5/94	Inspection found extensive cracking. Repairs have been implemented.
Peach Bottom 2	MK1 BWR/4	7/5/74	9/94	Moderate cracking found without significant degradation of shroud structural integrity.
Peach Bottom 3	MK 1 BWR-4	12/23/74	11/93	Minor circumferential and axial cracking found.
Nine Mile Pt 2	MK 2 BWR-5	3/11/88	11/93	Inspection found no cracking.
Vermont Yankee	MK 1 BWR-4	11/30/72	10/93	Inspection found no cracking.
Millstone 1	MK 1 BWR-3	3/01/71	1/94	Minor circumferential cracking found.
Hatch 2	MK 1 BWR-4	12/31/75	4/94	Inspection found moderate cracking.
Oyster Creek	MK-1 BWR-2	12/1/69	10/94	Inspection found extensive cracking. Repairs have been implemented.
Dresden 3	MK 1 BWR-3	11/16/71	4/94	Inspection found extensive cracking. A safety evaluation justified continued operation for 15 months without repair.
Quad Cities 1	MK 1 BWR-3	2/18/73	4/94	Inspection results similar to Dresden 3. The The Dresden 3 safety evaluation covered Quad Cities continued operation for 15 monther.
Fermi 2	MK-1 BWR-4.	1/23/88	6/94	Inspection found minor axial cracking.
Monticello	MK-1 BWR-3 .	6/30/71	10/94	Inspection found minor circumferential cracking.
Duane Arnold	MK-1	2/01/75	9/93	Inspection found no cracking.
Hope Creek	MK-1 BWR-4.	12/20/86	3/94	Limited inspection found no cracking.
Lasalle 1	MK-2 BWR-5	1/01/84	5/94	Inspection found no cracking.
Perry 1	MK 3 BWR-6	11/18/87	5/94	Inspection found no cracking.
Susquehanna 1	MK 2 BWR-4	2/12/85	12/93	Inspected found no cracking.
WNP-2	MK-2 BWR-5	12/13/84	6/94	Limited inspection found no cracking.

Due to the location and the extent of the cracking recently found, NRC and the BWROG agreed that additional attention to this issue was warranted. BWROG met with NRC on June 28, 1994, to announce the formation of BWRVIP, which is headed by several high level utility executives to direct its efforts. BWRVIP has since submitted documents (Ref. 5 and Ref. 6) which addressed an integrated safety assessment of the issue, inspection plans for the reactor internals, and generic criteria for repairs and flaw acceptance.

NRC has reviewed these documents (Ref. 7 and Ref. 8) and concurs with the BWRVIP recommended generic repair criteria and flaw assessment methodology. Inspection scope and methodology are still under consideration.

In addition to the above actions, in order to verify compliance with the structural integrity requirements of 10 CFR 50.55a and to assure that the risk associated with core shroud cracking remains low, NRC concluded that it is appropriate for BWR licensees to implement timely inspections and/or repairs, as appropriate, at their plants. To implement this position, NRC issued GL 94-03 (July 25, 1994) which requested BWR licensees to inspect their core shrouds by the next outage and to justify continued safe operation until all appropriate corrective actions have been implemented.

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

There are 41 active licenses for the milling, processing, and fabrication of nuclear fuel in the U.S. NRC has reviewed all incident and event reports received from these licensees through the fourth quarter of 1994. Using the criteria and guidelines in Appendix A of this report, none of the occurrences reviewed for this reporting period were determined to be significant enough to be reported as an AO.

Fuel Cycle Facilities (Other than Nuclear Power Plants)

There are 41 active licenses for milling, processing, and fabrication of nuclear fuel in the U.S. NRC has reviewed all incident and event reports received from these licensees through the fourth quarter of 1994. Using criteria and guidelines in Appendix A of this report, none of the occurences reviewed for this reporting period were determined to be significant enough to be reported as an AO.

Other NRC Licensees
(Industrial Radiographers, Medical Institutions, Industrial Users, etc.)

There are approximately 22,000 active material licenses for the use of byproduct materials in industrial, medical, and academic applications in the U.S. Twenty-nine States, known as Agreement States, have entered into agreements with NRC to assume regulatory authority for approximately 15,000 of these licensees within their States. NRC is responsible for regulating approximately 7000 licensees located in the remaining 21 States, the District of Columbia, and all U.S. territories. NRC has reviewed all incident and event reports received from NRC licensees through the fourth quarter of 1994. Using the criteria and guidelines in Appendix A of this report, the following occurrences have been determined to be significant enough to be reported as AOs.

94-21 Recurring Incidents of Administering Higher Doses than Procedurally Allowed for Diagnostic Imaging at Ball Memorial Hospital in Muncie, Indiana

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 11 from Examples For All Licensees) of this report notes

that a serious deficiency in management or procedural controls in a major area can be considered an AO.

Due to the nature of this occurrence, NRC performed an extensive review requiring interviews and an historical review of licensee records. This detailed review resulted in a delay in the prompt reporting of this information.

Date and Place—October 1988 through June 1993; Ball Memorial Hospital; Muncie, Indiana.

Nature and Probable Consequences—On July 19, 1993, NRC was notified that nuclear medicine technologists employed by the licensee had increased the dosages of radiopharmaceuticals used in diagnostic studies. NRC was also informed that the technologists had falsified the required records of the dosages administered.

On July 21 through August 9, 1993, NRC conducted an inspection of the licensed facility. The inspection revealed that since 1988, nuclear medicine technologists employed by the licensee have been administering radiopharmaceutical dosages above the approved dose ranges for diagnostic image studies by as much as 40 percent. The inspection also verified that subsequent to administering high doses, the technologists entered false information in NRC-required records. The doses were increased for imaging studies of the lung, liver, bone, and gastrointestinal tract using technetium-99m and xenon-133.

NRC inspectors did not identify any medical misadministrations, as defined in 10 CFR 35.2, as a result of this practice of administering higher than approved doses for diagnostic imaging.

Cause or Causes—According to the licensee, one technologist told licensee officials that dosages were increased to minimize patient discomfort, to reduce imaging time for critically ill patients and to enhance the clarity of images for studies performed on obese patients.

Action Taken To Prevent Recurrence

Licensee—The licensee conducted an internal review. Based on the findings from this review, the licensee initially suspended two nuclear medicine technologists from all NRC-licensed activities. Subsequently, the licensee terminated one of the two individuals and the other individual was allowed to continue to perform duties that do not involve NRC-licensed activities.

The licensee also committed to a number of corrective actions. Some of the corrective actions include: assigning a pharmacist or a radiologist to verify all radioisotope dosages; implementing a unit dose system; obtaining the services of an assistant radiation safety officer; and conducting monthly and quarterly audits of the Nuclear Medicine Section for at least one year.

NRC—A special safety inspection was conducted by NRC from July 21 to August 9, 1993. Subsequent to that inspection, NRC conducted a followup review .

NRC issued a Confirmatory Action Letter (Ref. 9) on July 26, 1993, and Confirmatory Order Modifying License (Ref. 10) on October 20, 1993. These documented specific procedures and verifications to prevent any further unauthorized increases in patient doses.

On May 23, 1994, NRC issued an Order against a former nuclear medicine technologist of the licensee. The Order required the following: (1) prohibited the technologist from involvement in NRC-licensed activities for a period of one year; (2) required the technologist to provide a copy of the Order to any prospective employer who engages in NRC-licensed activities for a three-year period; and (3) required the technologist to notify NRC within 20 days of accepting employment involving NRC-licensed activities.

On May 27, 1994, the technologist requested a hearing and on September 26, 1994, a settlement agreement was reached. The settlement was reviewed and approved by the Atomic Safety and Licensing Board on October 3, 1994 (Ref. 11). The agreement resulted in the withdrawal of the requirement for the technologist to provide a copy of the Order to any prospective employer who engages in NRC-licensed activities. The settlement retained provisions (1) and (3) of the Order.

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

94-22 Medical Therapy Misadministration at Veterans Affairs Medical Center in Long Beach, California

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

Date and Place—August 9, 1994; Veterans Affairs Medical Center; Long Beach, California.

Nature and Probable Consequence—On August 9, 1994, the licensee's radiation safety officer (RSO) notified NRC of a misadministration involving a therapeutic dose of strontium-89 (Sr-89) (Ref. 12).

The RSO reported that a patient scheduled to receive 185 megabecquerel (MBq) (5 millicurie [mCi]) of thallium-201 (a radiopharmaceutical not regulated by NRC) for a myocardial perfusion study was mistakenly administered 148 MBq (4 mCi) of Sr-89 (which is regulated by NRC). Based on the misadministration of the Sr-89, the licensee estimated that the patient received 250 centigray (250 rads) to the surface of the bone. The RSO reported that no action was taken to mitigate the consequences of the dose (i.e., administration of calcium as a blocking agent) because the patient had a preexisting heart condition which could have been exacerbated by administering calcium. The licensee also stated that medical experts were contacted to assist in an assessment of potential health effects to the patient. In addition, the licensee reported that with the exception of emergency procedures, it had voluntarily suspended all nuclear medicine procedures involving the intravenous administration of radiopharmaceuticals and had initiated an internal review of the misadministration.

On August 10, 1994, NRC issued a Confirmatory Action Letter (Ref. 13) to confirm the licensee's actions as stated above.

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

Actions Taken To Prevent Recurrence

Licensee—Corrective actions initially proposed by the licensee included the following: (1) physically separating diagnostic unit dosages from therapeutic radiopharmaceutical dosages in the licensee's hot lab; (2) packaging unit dosages received from a local radiopharmacy in different containers, according to isotopes; and (3) retraining technologists in requirements for identifying radiopharmaceuticals prior to injection.

NRC - Two NRC inspectors conducted a special safety inspection on August 10-12 and 17-19, 1994, to review the circumstances associated with the misadministration and to review the licensee's corrective actions (Ref. 14). In addition, NRC contracted a medical physician consultant to assist in its evaluation of the potential consequences of the patient's radiation exposure. The consultant stated that there were no adverse health effects to the patient.

An Enforcement Conference was held with the licensee on November 30, 1994, to discuss an apparent violation involving the failure of an individual working under the supervision of an authorized user physician to follow the licensee's written radiation safety procedures. Additional concerns discussed during the conference included the licensee's use of an informal labeling system for unit radiopharmaceuticals which was identified as a potential programmatic weakness. The licensee presented information during the conference which supported its view that the error which led to the August 9, 1994, misadministration was an isolated failure rather than a programmatic problem.

Based on its review of information developed during the inspection and information provided during the Enforcement Conference, NRC concluded that the misadministration was the result of an isolated failure. A Notice of Violation (Ref. 15) was issued on December 29, 1994, for a violation involving the failure of an individual working under the supervision of a physician authorized user to follow the licensee's written

procedures for verifying a radiopharmaceutical dose prior to administration to a patient. The violation was categorized as a Severity level IV violation.

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

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

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 5 in Table A-1) of this report indicates that a therapeutic exposure to any part of a body not scheduled to receive radiation can be considered an AO.

Date and Place—August 3, 1994; North Memorial Medical Center; Robbinsdale, Minnesota.

Nature and Probable Consequences—On August 15, 1994, a licensee informed NRC that a patient received 1380 centigray (cGy) (1380 rads) to a wrong treatment site during a brachytherapy treatment for metastatic lung cancer.

On August 3, 1994, a catheter was inserted into the patient's bronchus and a ribbon containing 20 seeds of iridium-192 having a total activity of 673.4 megabecquerel (18.2 millicuries) was then inserted into the catheter and moved to the proper treatment location. The treatment plan was intended to deliver a prescribed dose of 2000 cGy (2000 rads) to the intended target. The treatment began at 11:15 a.m. on August 3, 1994, and continued until its scheduled completion at 10:15 a.m. on August 4, 1994.

At about 7:00 p.m. on August 3, 1994, a nurse informed the physician that the visible portion of the catheter appeared to be protruding approximately 25.4 to 30.5 centimeters (10 to 12 inches) from the patient's nose. This was a significantly greater protrusion than previously observed, indicating that the catheter had moved from its initial placement. The nurse secured the catheter in place with additional tape. The physician stated that, based on the information available to him at that time, he determined that the catheter and ribbon had moved; but that the tumor was receiving some radiation dose and therefore he continued the treatment. The iridium-192 seeds were removed on August 4 as planned. On August 4, 1994, a staff radiologist read the portable x-ray film taken on August 3, 1994, and indicated that the iridium implant was not seen.

Due to catheter displacement, the tumor dose was significantly reduced and estimated to be 620 cGy (620 rads) or 31 percent of the intended dose. The remaining dose of 1380 cGy (1380 rads) was delivered to an unintended site.

The patient was notified of the event by the treating physician on August 4, 1994, and again by another physician on August 17, 1994. The referring physician was informed by the treating physician on August 4, 1994.

An NRC medical consultant was retained to perform a clinical assessment of this misadministration. The medical consultant concluded that it is improbable that the patient will experience any long term consequences as a result of the exposure to the unintended treatment site.

Cause or Causes—The licensee has determined that the catheter movement caused a misadministration of the intended dose. Two possible explanations for the catheter movement could be the following: (1) failure to properly secure the catheter in place with tape; or (2) nasal discharge decreasing the adhesive capability of the tape.

Action Taken To Prevent Recurrence

Licensee--The licensee's corrective actions include: amending the nursing staff procedure so that the attending physician will be contacted if there are further questions; directing nurses to follow the standing protocol for obtaining an administrative consult; providing additional inservice training; documenting the final length of the catheter in the patient chart; and documenting the catheter position on each visit to the patient's room.

NRC - NRC conducted a safety inspection from August 15 through September 7, 1994 (Ref. 16), to review the circumstances of the misadministration. One apparent violation and one area of concern were identified. An Enforcement Conference was held with the licensee on October 11, 1994. Enforcement action is pending. NRC is continuing its review.

This report will be updated when additional information becomes available.

Agreement State Licensees

The 29 Agreement States have approximately 15,000 active material licenses for the use of byproduct materials in industrial, medical, and academic applications. Procedures have been developed for Agreement States to screen incidents and events using the same criteria and guidelines as NRC, and to report those occurrences that have been determined to be significant enough to be considered as AOs. Using the criteria and guidelines in Appendix A of this report, the following occurrences have been determined to be significant enough to be reported as AOs.

AS 94-07 Major Contamination Event due to a Breached Source at KayRay/Sensall, Inc., in Mt. Prospect, Illinois

Appendix A (see Event Example 10, For All Licensees) of this report indicates that a major deficiency in design, construction, or operation having safety implications requiring immediate remedial action can be considered an AO.

Date and Place—April 21, 1994; Kay-Ray/Sensall, Inc.; Mount Prospect, Illinois.

Nature and Probable Consequences—A sealed source containing 74,000 megabecqueeel (2 curies) of cesium-137 in a fixed gauge was breached on Thursday, April 21, 1994, as the manufacturer of the measuring system tried to remove the source with a steel rod and hammer from its housing. The source rupture was not detected by the licensee until the day after the breach occurred. During this time, personnel, facilities, homes, and vehicles, including the radiological consultant's (who was on-site when the breach occurred) vehicle, facility, and his employees' homes and vehicles became contaminated with unsealed radioactive material.

A total of 102 vehicles and 18 homes in Illinois and Wisconsin were surveyed by the State of Illinois. All contamination found was reduced to background levels, or the items or areas were removed or excised for disposal. The highest off-site contamination level was found in a rental truck used by the consultant on the day of the breach. The vehicle was decontaminated and returned to its owner. The State spent approximately 100 person-days in April and May characterizing the extent of the contamination and monitoring the effectiveness of the decontamination. The licensee's facility returned to full operation on April 26, with shoe covers required for production personnel.

One individual was found, through in vivo and in vitro measurements, to have an intake of 44.4 kilobecquerel (1.2 microcurie) or 0.74 percent of the annual limit intake. This resulted in a commitment effective dose equivalent (CEDE) of 0.4 millisievert (mSv) (40 millierem [mrem]). Of the seven other individuals who submitted urine samples, CEDE was estimated at 0.01 mSv (1 mrem) for one individual and 0.002 mSv (0.20 mrem) for another. No intake was detected for the other five individuals. Since the annual limit for occupational exposure is 50 mSv (5000 mrem), no long term health effect is expected for any individual involved in the incident.

Cause or Causes—Because of the possibility of generic corrosion problems in their application environments, testing was performed by an NRC contractor on a source similar to the one breached in this incident to determine if any inherent defect contributed to the consequences. The contractor concluded that the capsule had no generic construction or materials defect and that it failed because a hammer and steel rod were used to remove it from its holder. The source had apparently been used in a corrosive environment, causing it to become stuck in the holder. Staff concluded that the primary cause of the widespread contamination was failure to perform adequate surveys and failure to analyze the leak test sample until the day after it was collected. Another contributor was the method used to remove the source from the source holder. The licensee used a steel rod and a hammer to remove the source. The source had apparently been used in a corrosive environment, causing it to become stuck in the holder.

Actions Taken To Prevent Recurrence

Licensee—In the licensee's written report of the incident, they proposed that they would no longer unload source capsules from returned source heads. Their customers would be directed to send returned source heads to a third party for source removal. The licensee also proposed that hand and foot surveys would be required after handling a source head, whether at the licensee's facility, a customer site, or a third party licensed facility. Weekly surveys are to be performed on an interim basis in the production area of the Mt. Prospect plant. A complete shutdown of all plant operations and personnel movement in the production area would occur if any contamination was found.

State Agency—The results of the testing by the NRC contractor will be reviewed to determine if further action is warranted for this licensee and for the source supplier, located in another Agreement State.

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

AS 94-08 Medical Brachytherapy Misadministration at St. Joseph's Hospital in Orange, California

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 17, 1994; St. Joseph's Hospital; Orange, California.

Nature and Probable Cause—The State was notified on October 19, 1994, that a brachytherapy overexposure had occurred at St. Joseph's Hospital in Orange, California. The overexposure involved a 1110 megabecquerel (30 millicurie) cesium-137 source. The intended dose to the patient was 1400 centigray (cGy) (1400 rads), of which 1268 cGy (1268 rads) was to be administered 0.25 centimeters (0.1 inches) below the surface. The source fell out of the applicator as the radiation oncologist was attempting to load the source into an intracavity applicator. This was not observed by the physician. Approximately seven hours later the patient's nurse found the source on the bed while she was attending the patient. The nurse removed the source from the bed with long forceps and placed it in the lead pig provided in the room. When the radiation oncologist later checked with the nurse, she was informed of the incident and confirmed that the source was not in the applicator.

After consulting with the radiation safety officer (RSO), the radiation oncologist proceeded to reinsert the source into the applicator. The treatment time was rechecked to give the full, originally, prescribed dose. The treatment was completed without further complications. The patient and the referring physician were both notified.

The source was present on the bed, next to the skin of the patient for seven hours. The legs, back, and pelvic area of the patient were immediately checked for acute radiation exposure of the skin. No effects were identified. The patient was also examined at two and three weeks post incident and remains symptom free.

Using National Council on Radiation Protection and Measurements Commentary No. 40 and reenacting the event, the licensee calculated a dose of 7000 cGy (7000 rads) to the skin of this patient. The dose estimate was verified by the State for the Radiological Emergency Assistance Center/Training Site (REAC/TS). No other consultants were contacted for this incident.

Cause or Causes—After a review of the incident by the radiation oncologist and the RSO, it was determined that the source fell out of the source carrier during initial insertion because of the location and position of the applicator. Insertion required the carrier to be placed in an upward, tilting direction and this, coupled with the twisting of the carrier to position it in the applicator, caused the source to drop out.

Actions Taken To Prevent Recurrence

Licensee—The licensee will now visually check the source after the carrier has been placed in the applicator for each source loading.

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

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

AS94-09 Brachytherapy Misadministration at the University of California's Long Hospital in San Francisco, California

Appendix A (see Event Type 5 in Table A-1) of this report notes that administering a therapeutic dose that is greater than 1.5 times the prescribed dose can be considered an AO). Appendix A (see Event Type 3 in Table A-1) of this report also notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an AO.

Date and Place—December 7, 1993; University of California's Long Hospital; San Francisco, California.

Nature and Probable Consequences--A female patient was prescribed to receive 3500 centigray (3500 rads) to treat a cervical tumor using a pulsed Selectron high-dose-rate (HDR) remote afterloader brachytherapy device. (She was also treated with external beam therapy.)

The HDR treatment plan was prepared via computer and consisted of the following: (1) 161 dwell positions of varying times, and an expected total treatment time of 535.5 seconds per pulse; and (2) a total of 58 pulses for the treatment. The computer generated times and positions were manually programmed into the HDR unit to initiate treatment. One of the dwell times was incorrectly entered as 52.9 seconds, instead of the computer-calculated 2.9 seconds. Six other positions required the same dwell-time, so the programming for the first dwell-time entry was stored and recalled for the others. This resulted in seven positions being programmed for 52.9 seconds instead of the correct value of 2.9 seconds.

The consequence of the seven dwell-time errors was a total treatment time of 885.5 seconds per pulse, or 1.65 times the correct total treatment time. The data entry error probably occurred because the physicist entering the data on the keyboard accidently hit the number 5 and number 2 keys at the same time, which resulted in a programmed time of 52.9 seconds.

Further procedures required that the total radiation time be hand-calculated and entered on the treatment planning sheet prior to programming the HDR unit. The machine-printed tape displaying total radiation time programmed into the HDR must be compared with the hand-calculated value to verify agreement between the two values. This verification was not performed contributing to the misadministration.

The misadministration occurred on December 7, 1993. Because the hand- and computer-calculated time values were not compared, the mistake was not detected at the time of treatment. In June of 1994, the patient developed a recto-vaginal fistula which required admission to San Francisco General Hospital for a bypass colostomy. The family of the patient was verbally notified of the misadministration.

On July 8, 1994, a copy of the discharge summary was forwarded to the radiation oncology physician at University of California at San Francisco. The physician asked a medical physicist to recalculate the doses that were delivered during the HDR treatment in December 1993. The review was performed on July 10, 1994, and revealed the results shown in the following table.

Region	Expected Dose centigray (rads)	Delivered Dose centigray (rads)	Variation from Intended Dose (percent)
Tumor	3500 (prescribed)	3784 - 10,500	8 - 300
Bladder	2774	3000	8
Upper Rectum	2925	3200	9.4
Lower Rectum	3000	5000 - 6000	167 - 200
Lower Vagina	4000	6000 - 8000	150 - 200

The licensee determined that the combined doses from external beam therapy and the HDR misadministration could have caused a recto-vaginal fistula.

Cause or Causes—The root cause of this incident was determined to be keyboard entry errors while programming the HDR unit. A second contributing factor was the failure to verify the total time programmed with the manually calculated total time as required by licensee procedures.

Actions Taken To Prevent Recurrence

Licensee—The licensee changed its procedures to require that a physician review and sign the machine-printed tape that shows the plan details, in addition to signing the prescription in the chart. In addition, the machine programmer must write the "total radiation time" calculated by the machine on the planning sheet that contains the prior hand-calculation of this value. The two values must be checked by a second person, and both people must initial the sheet. The second person can be a physicist, dosimetrist, physician, or brachytherapy technologist. All of these actions must be completed prior to the initiation of treatment.

The licensee is also discussing possible corrective actions with the manufacturer. One option being explored is the possibility of having the computer-calculated treatment plan written to a disk, which will then be used to program the afterloader. The manufacturer has also been asked to recommend other software changes to prevent this type of event from recurring.

State Agency—The State of California reviewed the licensee's action and was satisfied that appropriate actions were taken. The State of California considers this event closed.

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

AS94-10 Medical Teletherapy Misadministration by an "Unspecified Licensee" at an "Unspecified Location" in New York

Appendix A (see Event Type 1 in Table A-1) of this report notes that a therapeutic exposure that results in any part of the body receiving unscheduled radiation can be considered an AO.

Date and Place—May 10, 1993; New York State Department of Health "Unspecified Licensee."

The name of the licensee was not provided by the State of New York. NRC has asked the State of New York to provide this information, but the State law limits its ability to report this information.

Nature and Probable Consequences—A patient, with a sarcoma on the palm of the hand, was prescribed a treatment of 100 centigray (100 rad) each to the anterior and posterior of the hand. The posterior port of a fractional treatment to the palm of the hand was administered using a larger field size (16 by 20 centimeters [cm] [6.3 by 7.8 inches]) than prescribed (11 by 14 cm [4.3 by 5.5 inches]). The prescription called for 100 centigray (100 rad) each to the anterior and posterior of the hand. The field size had been increased for the second exposure of a port film, and the technologist failed to reduce it to the proper size prior to delivering the dose for the posterior treatment. Therefore radiation was delivered to a larger field than prescribed, resulting in normal tissue outside the treatment field being irradiated. The error was detected when the set-up was being prepared for the anterior field. The patient and the referring physician were notified of the error. The treatment course was not altered as a result of the error. The licensee indicated that no adverse effect to the patient is anticipated as a result of this error.

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

Actions Taken To Prevent Recurrence

Licensee—The licensee counseled the technologist and reviewed the existing procedures. The need to check parameters before treatment was emphasized. The licensee's Quality Assurance Committee also reviewed the incident and actions taken. The licensee has procedures in place which are designed to prevent such mistakes.

State Agency—The State of New York reviewed the licensee's action and was satisfied that appropriate actions were taken. The State of New York considers this event closed.

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

REFERENCES

1. NRC Information Notice 93–79, "Cracking at the Beltline Region Welds in Boiling Water Reactors," September 30, 1993. *

2. NRC Information Notice 94–42, "Cracking in the Lower Region of the Core Shroud In Boiling Water Reactors," and Supplement 1, June 7 and July 19, 1994, respectively.*

3. NRC Generic Letter 94–03, "Intergranular Stress Corrosion Cracking of BWR Core Shrouds", July 25, 1994.*

4. Letter from John Stang, USNRC, to D. Farrar, Commonwealth Edison Company, "Resolution of Core Shroud Cracking at Dresden Unit 3 and Quad Cities Unit 1, July 20, 1994.*

5. Letter from Carl Terry, Executive Chairman of the BWRVIP Subcommittee on Assessment to USNRC, "BWR Core Shroud Inspection and Evaluation Guidelines," September 2, 1994.*

6. Letter BWRVIP–94–01 from Bruce McLeod, Technical Chairman, BWRVIP Repair Subcommittee to USNRC, "BWR Core Shroud Repair Design Criteria," August 18, 1994.*

7. Letter from Brian Sheron, Director Division of Engineering, NRR, USNRC to J.T. Beckham, Chairman, BWRVIP, "Safety Evaluation on BWR Core Shroud Repair Design Criteria," September 29, 1994. *

8. Letter from Brian Sheron, Director, Division of Engineering, NRR, USNRC, to J.T. Beckham, Chairman, BWRVIP, "Evaluation of BWR Shroud Cracking Generic Safety Assessment Revision 1, GENE–523–A107P–0794, August 5, 1994 and BWR Core Shroud Inspection and Evaluation Guidelines, GENE–523–113–0894, September 2, 1994." Letter dated December 28, 1994.*

9. Letter from Charles E. Norelius, Director, Division of Radiation Safety and Safeguards, to Mitch Carson, Vice President for Operations, Ball Memorial Hospital, forwarding Confirmatory Action Letter, License No. 13–00951–03, dated July 26, 1993.*

10. Letter from James Lieberman, Director, Office of Enforcement, to Mitchell C. Carson, Vice President of Operations, Ball Memorial Hospital, forwarding Confirmatory Order Modifying License, License No. 13–00951–03, dated October 20, 1993.*

11. Memorandum and Order from the Atomic Safety and Licensing Board, forwarding Settlement Agreement and Dismissing Proceeding, In the Matter of Kelli J. Hinds, Docket No. IA–94–012, ASLBP No. 94–697–06–EA, dated October 3, 1994.*

12. Preliminary Notification of Event or Unusual Occurrence (PNO–IV–94–043) dated August 10, 1994.*

13. Confirmatory Action Letter from L.J. Callan, Regional Administrator, NRC Region IV, to Dr. Jule Moravec, Medical Center Director, Veterans Administration Medical Center, Long Beach, California, dated August 10, 1994.*

14. Letter from Samuel J. Collins, Director, Division of Radiation Safety and Safeguards, NRC Region IV, to Mr. M. Hartford, Acting Director, Veterans Administration Medical Center, Long Beach, California, dated October 14, 1994, transmitting NRC Inspection Report 030–01215/94–01.*

15. Letter from Samuel J. Collins, Director, Division of Radiation Safety and Safeguards, NRC Region IV, to Mr. M. Hartford, Acting Medical Center Director, Veterans Administration Medical Center, Long Beach, California, dated December 29, 1994, transmitting a Notice of Violation.*

16. Letter from W.L. Axelson, Director, Division of Radiation Safety and Safeguards, to Michael W. Muenzberg, Vice President Ancillary Services, North Memorial Medical Center, forwarded Inspection Report No.

030-02228/94001, Docket No. 030-02228. License No. 22-05792-01, dated October 4, 1994.*

*A copy is available for inspection, or copying for a fee, in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC 20037.

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 500 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]On January 1, 1994, changes to Title 10 of the *Code of Federal Regulations* Part 20 were promulgated. At the Commission's directive, the staff is currently developing a policy statement revising criteria for various types of AOs. The changes pertinent to the 10 CFR 20 revision will also be included in that draft policy statement. Upon Commission's approval, the appropriate changes to this Appendix will be published.

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 are currently being 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 ,an one intended.	If the improper administration results in any part of the body receiving unscheduled radiation, an AO report should for tbe proposed if: (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** (b) there are clinical indications of **any** adverse health effects to the wrong body part. If the parts of the ,ody receiving radiation improperly would h ave received radiation a nyway, had the proper adn inistration been used, an AO ·eport should be proposed if: (a) the actual dose is greater than five times that intended to the above described body parts, **or**, (b) the above described body parts show signs of adverse health effects greater than expected had the proper administration been used.	If the improper administration results in any part of the body receiving unscheduled radiation AO report should be proposed any such event. 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: (a) the actual dose is greater than 1.5 times that intended to the above described body parts, **or**, (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** (d) the event (regardless of any health effects) affects two or more patients at the same facility.
(2) Administering a radiopharmaceutical or radiation to the wrong patient. or	An AO report should be proposed if: (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.	An AO report should be proposed for any such event.
(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: (a) the actual dose is greater than five times the prescribed dose, **or**, (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: (a) the actual dose is greater than 1.5 times the prescribed dose, **or**, (b) the actual dose is less than 0.5 times the prescribed dose, **or** (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**, (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 July through September 1994, NRC licensees, Agreement States, Agreement State licensees, and other involved parties, such as reactor vendors and architect-engineering firms, continued with the implementation of actions necessary to prevent recurrence of previously reported abnormal occurrences (AO). The AOs discussed below contain a summary of information presented in previous reports and any subsequent updated information provided during the reporting period. Those updated events which still require additional information will be discussed in future reports.

Other NRC Licensees

92-17 Medical Therapy Misadministration at Indiana University Medical Center in Indianapolis, Indiana

This AO was originally reported in NUREG-0090 Vol. 15, No.4, "Report to Congress on Abnormal Occurrences, October-December 1992."

The AO criterion used was Event Type 5 in Table A-1 of Appendix A of this report—Administering a therapeutic dose greater than 1.5 times the prescribed dose.

At the time, it was reported that a 31-month-old patient was prescribed two cobalt-60 teletherapy treatments of 150 centigray (cGy) (150 rads) each to treat a brain tumor. Due to an error by the dosimetrist, two treatments of 300 cGy (300 rads) each were delivered.

The AO report is updated and closed out as follows:

On October 7, 1993, NRC issued to the licensee a Notice of Violation and Proposed Imposition of Civil Penalty for $5,000 (Ref. 1). On January 18, 1994, an Order Imposing Civil Monetary Penalty was issued to the licensee. The licensee requested (Ref. 2) a hearing on the Order and denied that it had violated the NRC's requirements as stated in the Order.

On September 29, 1994, a settlement agreement between the NRC and the licensee was approved by the Atomic Safety and Licensing Board. The settlement agreement provisions included: payment of $2,500 by the licensee to NRC; submission by NRC to the licensee of a list of deficiencies in the licensee's written Quality Management Program; resolution by the licensee of the deficiencies; and retention by the licensee of an independent contractor to audit the implementation of its Quality Management Program.

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

94-07 Medical Brachytherapy Misadministration at Alexandria Hospital in Alexandria, Virginia

This AO was originally reported in NUREG-0090, Vol. 17, No. 1, "Report to Congress on Abnormal Occurrences, January-March 1994."

The AO criterion used was Event Type 3 in Table A-1 of Appendix A of this report — A therapeutic exposure to a part of the body not scheduled to receive radiation.

At the time, it was reported that a patient was scheduled to receive a 500 centigray (cGy) (500 rads) brachytherapy treatment to the trachea using a Nucletron high-dose-rate (HDR) remote afterloader system. Because the HDR was not properly programmed for the correct treatment site, the prescribed 500 cGy (500 rads) dose was delivered to the left lung instead of the trachea target site.

The AO report is updated and closed out as follows:

NRC held an Enforcement Conference on July 21, 1994, to discuss the inspection findings with the

licensee. A Notice of Violation was issued to the licensee for failure to follow NRC requirements.

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

94-08 Multiple Brachytherapy Misadministrations at Deaconess Medical Center in Billings, Montana

This AO was originally reported in NUREG-0090, Vol. 17, No. 2, "Report to Congress on Abnormal Occurrences, April-June 1994."

The AO criterion used was Event Type 5(d) in Table A-1 of Appendix A of this report -- A therapeutic exposure which affects two or more patients at the same facility (regardless of any health effects).

At the time, it was reported that multiple brachytherapy misadministrations had occurred because of erroneous data in treatment-planning computer software.

The AO report is updated and closed out as follows:

On June 28, 1994, an Enforcement Conference was conducted with Deaconess Medical Center of Billings, Montana, to discuss several apparent violations relating to the licensee's Quality Management Program (QMP). Some of the apparent violations were associated with two brachytherapy misadministrations which occurred at the licensee's facility in March 1994.

NRC issued a Notice of Violation and Proposed Imposition of Civil Penalties in the amount of $7,500 and a Demand For Information to the licensee on August 23, 1994 (Ref. 3). The Notice of Violation described one violation, with several examples, associated with the misadministrations which was assessed a $2,500 civil penalty. A second violation, which included multiple examples of failures to comply with the licensee's QMP and NRC's Quality Management Rule, was assessed a $5,000 civil penalty. Four other violations were cited although no civil penalty was associated with them.

The licensee responded to the Notice of Violation and Proposed Imposition of Civil Penalties and Demand For Information by letter dated September 12, 1994 (Ref. 4, Ref. 5). The licensee paid the civil penalties in full, acknowledged each of the violations, and provided a description of the corrective actions taken. The licensee also responded to the Demand For Information by describing actions taken to ensure that certain authorized users were aware of the requirement to complete written directives for brachytherapy treatments and of the licensee's QMP. NRC acknowledged the licensee's response and no further information was requested.

NRC had previously issued a Confirmatory Action Letter (CAL) on May 3, 1994 (Ref. 6). This documented the licensee's commitments to temporarily suspend brachytherapy treatments at its facility until certain reviews and evaluations for its computerized treatment planning systems, and treatment planning programs used by its contractors, could be completed. The licensee responded, in part, to the CAL in a letter dated June 17, 1994 (Ref. 7), wherein the licensee described the results of tests and evaluations for one of three treatment planning systems used by its contractors. NRC reviewed the licensee's response and acknowledged the licensee's request to resume use of a Theratronics Theraplan L treatment planning system by letter dated July 21, 1994 (Ref. 8).

The licensee provided a second response to the CAL by letter dated August 22, 1994, which documented the results of tests performed on an Applied Research System (ARS) treatment planning system used by one of the licensee's consultants (Ref. 9). In the above noted letter, the licensee stated that the third treatment planning system would no longer be used to develop brachytherapy treatment plans for treatments at the licensee's facility. In the August 22, 1994 letter, the licensee also acknowledged that one item identified in the CAL had not yet been addressed. The latter item involved re-evaluation of several patient treatments completed at the licensee's facility after January 1992. The licensee had committed to reviewing these treatments to determine whether any recordable events or misadministrations had gone unrecognized prior to NRC's inspection in March-April 1994. NRC reviewed the licensee's response and acknowledged that the licensee could resume use of the ARS treatment planning system for brachytherapy treatments by letter dated October 14, 1994 (Ref. 10).

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

94-11 Medical Brachytherapy Misadministration at the Queen's Medical Center in Honolulu, Hawaii

This AO was originally reported in NUREG-0090, Vol.17, No.2, "Report to Congress on Abnormal Occurrence, April-June 1994."

The AO criterion used was Event Type 1 in Table A-1 of Appendix A of this—Administering a therapeutic dose greater than 1.5 times the prescribed dose can be considered an AO.

At that time, it was reported that on May 2, 1994, a patient received 1778 centigray (cGy) (1778 rads) to the right eye during the second of a two-part treatment, rather than the prescribed 1000 cGy (1000 rads), because of an error in timing a strontium-90 (Sr-90) eye treatment.

The AO report is updated and closed out as follows:

An NRC inspection was conducted from May 1 to July 13, 1994. Consequently it was concluded that the licensee's Quality Management Program (QMP) lacked appropriate procedures for use of Sr-90 eye applicators, as required by Title 10 of the *Code of Federal Regulations*, Part 35.32, "Quality Management Program." However, based on additional information provided by the licensee during an Enforcement Conference on August 4, 1994, NRC concluded that the licensee's QMP, although marginal, was adequate and that the QMP was violated in this specific instance by the involved physician. Accordingly, a Severity Level IV violation with no civil penalty was issued on August 11, 1994.

The licensee responded to the violation on August 22, 1994, by identifying several corrective actions to preclude recurrence. This included additional clarification of the QMP and Sr-90 procedure, additional training of nurses and physicians, and additional independent auditing of Sr-90 procedures.

NRC accepted the licensee's response to this item in a letter dated September 16, 1994.

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

94-12 Medical Sodium Iodide Misadministration at Stamford Hospital in Stamford, Connecticut

This AO was originally reported as AO 94-12 in NUREG-0090, Vol. 17, No. 2, "Report to Congress on Abnormal Occurrences, April-June 1994."

The AO criterion used was Event Type 1 in Table A-1 of Appendix A of this report—Administering a diagnostic radiopharmaceutical other than the one prescribed that result in a wrong part of the body receiving five times the upper limit of the normal range of exposure prescribed for diagnostic procedures involving that body part can be considered an AO.

At the time, it was reported that on May 17, 1994, a patient was administered 37 megabecquerel (1 millicurie) of sodium iodide iodine-131 (I-131) for a whole body scan when no such study was prescribed. It was estimated that the patient received a whole body dose equivalent of 4.7 millisievert (470 millirems) and a thyroid absorbed dose of 800 centigray (800 rads).

The AO report is updated and closed out as follows:

In a letter (Ref. 11) dated November 17, 1994, NRC rescinded the proposed civil penalty based on a reconsideration of the licensee's good performance on previous NRC inspections.

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

94-14 Medical Brachytherapy Misadministration that Required Medical Intervention at The William W. Backus Hospital in Norwich, Connecticut

This AO was originally reported as AO 94-14 in NUREG-0090, Vol. 17, No. 2, "Report to Congress on Abnormal Occurrences, April-June 1994."

The AO criterion used was Event Type 1 in Table A-1 of Appendix A of this report -- Administering a therapeutic dose greater than 1.5 times the prescribed dose can be considered an AO.

At the time, it was reported that on June 21, 1994, a patient was implanted with 112 iodine-125 (I-125) seeds having an activity of 166 megabecquerel (MBq) (4.49 millicurie [mCi]) each, rather than the prescribed 112 I-125 seeds having an activity of between 15.9 and 17.0 MBq (0.43 and 0.46 mCi) each.

The AO report is updated and closed out as follows:

On November 7, 1994, the NRC issued a Notice of Violation (Ref. 12) and Proposed Imposition of Civil Penalty (Ref. 13) in the amount of $15,000 for the two violations indicated in the Notice. On December 6, 1994, the Licensee submitted its corrective actions for the violations cited and paid the proposed civil penalty of $15,000.

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

94-19 Medical Therapy Misadministration at University of Massachusetts Medical Center in Worcester, Massachusetts

This AO was originally reported in NUREG-0090, Vol.17, No.3, "Report to Congress on Abnormal Occurrence, July-September 1994."

The AO criteria used was Event Type 5 in Table A-1 of Appendix A of this report -- Administering a therapeutic dose that result in an actual dose less than 0.5 times the prescribed dose.

On July 29, 1994, it was reported that a physician performed an ophthalmic treatment on a patient using a strontium-90 (Sr-90) eye applicator without first removing the stainless steel mask from the source. Because of this oversight, the licensee estimated that the treatment site received 107 centigray (cGy) (107 rads) of radiation, rather than the 1250 to 2000 cGy (1250 to 2000 rads) that was intended. In addition, whereas the beta radiation from the eye applicator source only affects the surface of the eye, the bremsstrahlung radiation resulting from the interaction of the beta particles on the stainless steel mask is more penetrating.

The AO report is updated and closed out as follows:

The NRC received the medical consultant's evaluation of the clinical aspects of this misadministration on October 21, 1994. The medical consultant agreed with the licensee that the misadministration and the subsequent completion of the dose intended had no adverse effects on the patient. NRC issued a Severity Level IV violation to the licensee for failure to follow the written Quality Management Program established by the licensee in a letter dated December 27, 1994 (Ref. 14).

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

Agreement State Licensees

AS88-05 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."

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 on September 2, 1988, an 81-year-old patient received a therapeutic dose of 1400 centigray (1400 rad) to a part of the body not scheduled to receive radiation. The event was reported as an AO because it involved a moderate or more severe impact on public health or safety.

The AO report is updated as follows:

NRC is continuing to work with the State of Maryland to obtain more information regarding this incident.

AS88-06 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."

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 over a 13-month period 33 patients undergoing brain cancer treatments had received therapeutic radiation exposures from a cobalt-60 teletherapy machine that exceeded the prescribed dose by at least 10 percent in each case. The event was reported as an AO because it involved a moderate or more severe impact on public health or safety.

The AO report is updated as follows:

NRC is continuing to work with the State of Maryland to obtain more information regarding these incidences.

AS93-05 Medical Teletherapy Misadministration at Alta Bates Medical Center in Berkeley, California

This AO was originally reported in NUREG-0090, Vol. 16, No. 3, "Report to Congress on Abnormal Occurrences, July-September 1993."

The AO criterion used was Event Type 5 in Table A-1 of Appendix A of this report — Administering a therapeutic dose greater than 1.5 times the prescribed dose.

At the time, it was reported that after a 9-year-old autistic boy had a tonsillectomy at Childrens Hospital in Oakland, California, and a postsurgical pathological examination showed that he had cancer of the nasopharynx. After being given chemotherapy, he was scheduled to receive radiation therapy at Alta Bates Medical Center (ABMC) using a cobalt-60 source of 186,850 gigabecquerel (5050 curie) activity. ABMC used a consultant, West Coast Cancer Foundation (WCCF), to do treatment planning. Because of an error made by WCCF, the patient received a dose that was twice the prescribed dose on December 4, 1987. As a consequence of the overdose, the patient died on August 21, 1988.

The AO report is updated and closed out as follows:

The State of California's Radiological Health Branch (RHB) actions to prevent recurrence are as follows:

1. RHB's recommendation to require certification of specialists in the field of medical physics was addressed when RHB attempted to seek legal authority to require that these individuals become certified. The attempt involved a bill sponsored by one of the State Legislators which was introduced for consideration. The bill passed both Houses of the State Legislature and was sent to the Governor for signature in September 1993. It was vetoed by the Governor for a reason that was understood by RHB. An amended version will be introduced in the future. Certification of medical physicists cannot be required until a law is passed and signed by the Governor.

2. California's Radiation Control Regulations are consistent with respect to use of radioactive materials and/or ionizing radiation, whether the radiation is produced by x-ray machines or radioactive material. The idea that the regulations are not consistent appears to have come from a misinterpretation of RHB's ABMC incident report. The intent of the recommendation by the RHB staff was to require that all therapy misadministrations be reported within the same time frame. At present, only those misadministrations that occur when the source is a teletherapy machine or brachytherapy source are required to be reported. Misadministrations that occur when the treatment source is a linear accelerator are not required to be reported.

   Plans are still in place to amend the regulations to add a reporting requirement for a misadministration that occurs when the treatment source is a linear accelerator.

These regulations have not been finalized or adopted yet.

3. RHB recommended providing investigational techniques for RHB inspectors who might be assigned investigation duties. This specialized training was given by NRC in Walnut Creek, California, in January 1995. This training should give inspectors added insight on how to gather evidence for a criminal investigation.

4. The mechanism for NRC support in RHB investigations was established during the investigation of the ABMC incident. In the future, NRC would answer a call for assistance by RHB to aid with an investigation. There should be no further action necessary to establish this type of working relationship.

5. RHB has not made any progress toward requiring the reporting of all law suits, or malpractice suits, alleging injury from the improper use of radioactive materials or x-ray machines in the diagnosis or treatment of disease within the State of California. The State's Department of Health Services employs a staff of attorneys who prepare cases against facilities or individuals whom RHB finds have misused radioactive material or x-ray machines on patients. These attorneys review legislation reports from around the State on a regular basis, and would alert RHB if they become aware of a lawsuit involving sources of radiation. RHB has also been authorized to add an attorney to its staff who would devote full-time to the review of all legal needs of RHB.

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

AS93-13 Lost or Stolen Radiation Source at BPB Instruments, Inc., in Midland, Texas

This AO was originally reported in NUREG-0090, Vol. 16, No. 4, "Report to Congress on Abnormal Occurrences, October-December 1993."

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

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

The AO report is updated as follows:

The State of Texas Attorney General's office has been notified and the State conducted an investigation. No new information was identified and the source is still missing. The State is holding this case open and will notify NRC when it has any additional information.

This report will be updated when additional information becomes available.

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 abnormal occurrences.

During the period from September 1 through December 31, 1994, two "Other Events of Interest" were reported.

Nuclear Power Plants

1. Safety Relief Valve Inoperability at Millstone Unit 1

Millstone Unit 1 is a General Electric boiling water reactor (BWR-3) located near New London, Connecticut. It is operated by Northeast Nuclear Energy Company.

A plant condition found during scheduled surveillance associated with a 1994 outage involved multiple failures during testing of the safety/relief valves (SRVs) to operate at intended pressures. Millstone Unit 1 utilizes a total of six SRVs that serve as combination safety and relief valves. The licensee stated that of the six SRVs, two did not open at the maximum test pressure of about 1250 pounds per square inch gauge (psig) (desired set pressure is 1125 psig), and the lift pressure of each of the remaining four SRVs exceeded the technical specification tolerance of one percent. The average overpressure lift of these four valves was greater than six percent. It is not known when the set pressures "drifted," but the valves had not been required to operate during the previous operating cycle or since they were last refurbished in June 1991.

An analysis was performed to determine the potential effect of the higher than designed SRV lift pressures. The licensee concluded that the safety limit of 1375 psig for the reactor coolant system would not have been exceeded assuming (1) the "worst case" anticipated transient which has all steam isolation valves closing; (2) the four operable valves lifted at the as found lift pressure; and (3) the two valves that failed to open remained closed throughout the transient. Since the peak pressure occurs almost immediately after closure of the steam isolation valves, no consideration was given for potential operator action to utilize the manually initiated lift feature of the SRV.

The cause of the "drifting" was attributed to oxide bonding of the seat and 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. As a result of a long term effort to correct this problem, and at the recommendation of the Boiling Water Reactor Owner's Group, the licensee replaced three of the pilot valves with valves having a new disk material which was a platinum stellate alloy. This material is intended to reduce excess oxygen by the recombination of oxygen and hydrogen that collects in the pilot valve as a result of the radiolytical breakdown of the water. Operating experience of pilot valves with this new material is to be evaluated.

This report will be updated as additional information becomes available.

Agreement States Licensees

2. Leksell Gamma Knife® Teletherapy Unit Malfunction at University of Southern California, University Hospital in Los Angeles, California

A female patient was prescribed a series of 10 exposures of 3 minutes each in a Leksell Gamma Knife® teletherapy unit to remove a pituitary tumor. At the end of the sixth exposure, the treatment couch failed to retract from the treatment position, thereby not removing the patient from the treatment chamber as planned. The couch and patient remained inside the chamber while the staff attempted to withdraw the couch manually. When this failed, they physically disconnected the patient from the treatment helmet and removed her from the room. It was discovered that a solenoid valve had stuck open, continuing to force the couch into the treatment chamber, inhibiting the staff's ability to withdraw the couch manually.

Even though the treatment time for the sixth exposure was 3.8 minutes longer than the intended 3.33 minutes, the accumulated treatment time for the six exposures received was less than the total prescribed treatment time. Total dose calculations were performed and the patient was rescheduled to makeup the deficient treatment time. This incident is not a medical misadministration as defined by 10 CFR 35.2.

The members of the hospital staff were exposed to a small amount of unintended radiation during the event. If the radiation source had not been partially blocked by the treatment helmet, the unintended exposure would have been greater. The maximum exposure to the members of the rescue team was determined to be between 0.5 and 1.0 millisievert (50 and 100 millirem).

Elekta Radiosurgery, Inc., of Atlanta, Georgia, the U.S. distributor of the Leksell Gamma Knife® unit, is investigating the cause of the incident. The details are as follows:

1. It was initially postulated that a small particle of dirt or foreign matter in the hydraulic fluid could have caused a valve to stick because of the small tolerance the valves must operate under. It should be noted that there is a hydraulic fluid filter in place in the system; however, because this was a new unit, there was a chance that some debris may have gotten in the fluid during installation and had not circulated to the filter for removal before reaching the valve.

2. When the hydraulic filter port was opened and examined, several small pieces of debris were found in the filter that appeared to be bits of rubber hosing that may have broken off during the installation. Had this debris moved to one of the valves, it may have caused another failure.

3. The failed valve was examined and its spool was nicked as if it were hit by a piece of metal. The spool would not come all the way out of its cylinder as it should have.

4. The failed valve was sent back to its manufacturer for a failure analysis. The manufacture has been asked to provide a written report of its finding. This report has not yet been received.

The State of California gave a preliminary notification of the event to the NRC and subsequently submitted an AO report.

At the request of the State of Georgia (Elekta Radiosurgery, Inc., is located in Georgia), NRC, through a contract with the Idaho National Engineering Laboratory (INEL), conducted a root cause analysis of the incident. The findings of the review indicate that the valve failure was caused by metal contaminants in the hydraulic fluid system, which either became caught between the valve spool and valve body or scored the spool, thereby locking the valve in the "bed in" position. It appears that during installation several months earlier, pieces of dirt, metal, and rubber that are typically found in new hydraulic hoses were not properly cleaned from one of the hoses.

The licensee removed the unit from service until it was repaired by qualified personnel and approved

by the State of California. The service engineer arrived the following day and made the necessary repairs which were reviewed by the State agency. Emergency procedures were modified to expedite patient removal using experience gained from this incident.

Further corrective actions will be implemented upon receipt and assessment of final reports from both the manufacturer and the NRC consultants.

The INEL report (Ref. 15) provides several recommendations to further reduce the possibility of a repeat incident of the kind experienced at University Hospital including the following: (1) a modification of Elekta's current design to include installation of a 20 micron filter in a strategic location in the hydraulic fluid system; (2) a laboratory analysis of the hydraulic fluid after installation and prior to operation of each new unit and on five (of the 21 units in operation) randomly sampled Elekta Gamma Knife units currently in operation; (3) a second emergency tool used to disengage the head frame from the unit should be obtained by all Elekta Gamma Knife users; (4) a review should be performed by all gamma knife users of their emergency procedures to ensure that they include provisions for an event in which the treatment bed fails to retract; and (5) retraining for all gamma knife operating staff in emergency procedures. NRC provided the report of the findings to the States of California and Georgia, as well as to the U.S. Food and Drug Administration.

REFERENCES FOR APPENDICES

1. Letter from James Lieberman, Director, Office of Enforcement, to Gerald L. Bepko, Chancellor, Indiana University School of Medicine, forwarding Order Imposing Civil Monetary Penalty, License No. 13-02752-08, dated January 18, 1994.*

2 Memorandum from Thomas P. Gannon, Attorney for Indiana University and Robert H. Weisman, Counsel for NRC Staff, forwarding Settlement Agreement, Docket No. 030-0972, dated August 24, 1994.*

3. Letter from L. J. Callan, Regional Administrator, NRC Region IV, to Mr. Lane Basso, Chief Executive Officer, Deaconess Medical Center, Billings, Montana, dated August 23, 1994, transmitting Notice of Violation and Proposed Imposition of Civil Penalties - $7,500 and Demand For Information.*

4. Letter from Mr. Patrick Garrett, Vice President, Deaconess Medical Center, to the Director, Office of Enforcement, U.S. NRC, dated September 12, 1994, titled Reply to Notice of Violation.*

5. Letter from Mr. Patrick Garrett, Vice President, Deaconess Medical Center, to the Director, Office of Enforcement U.S. NRC, dated September 12, 1994, titled Reply to Demand For Information.*

6. Confirmatory Action Letter dated May 3, 1994, from L. J. Callan, Regional Administrator, NRC Region IV, to Mr. Lane Basso, Chief Executive Officer, Deaconess Medical Center.*

7. Letter from Mr. Patrick Garrett, Vice President, Deaconess Medical Center, to L. J. Callan, Regional Administrator, NRC Region IV, dated June 17, 1994.*

8. Letter from L. J. Callan, Regional Administrator, NRC Region IV, to Mr. Lane Basso, Chief Executive Officer, Deaconess Medical Center, dated July 21, 1994.*

9. Letter from Mr. Patrick Garrett, Vice President, Deaconess Medical Center, to L. J. Callan, Regional Administrator, NRC Region IV, dated August 22, 1994.*

10. Letter from L. J. Callan, Regional Administrator, NRC Region IV, to Mr. Lane Basso, Chief Executive Officer, Deaconess Medical Center, dated October 14, 1994.*

11. Letter from James Lieberman, Director, Office of Enforcement, USNRC, Washington, D.C. to Mr. Andrew H. Banoff, Vice President, Ambulatory Services, Stamford Hospital, Stamford, Connecticut, dated November 17, 1994, transmitting "Recision of Proposed Civil Monetary Penalty."*

12. Letter from Thomas T. Martin, Regional Administrator, NRC Region I, to Michael T. Moore, President and Chief Executive Officer, The William W. Backus Hospital, Norwich, Connecticut, dated November 7, 1994, transmitting "Notice of Violation and Proposed Imposition of Civil Penalty - $15,000," (NRC Inspection Report No. 030-01287/94-001).*

13. Letter from Brian J. Smithwick, Vice President, The William W. Backus Hospital, Norwich, Connecticut, to James Lieberman, Director, Office of Enforcement, USNRC, Washington, D.C., dated December 6, 1994, transmitting "Reply to a Notice of Violation."*

14. Letter from Mr. John R. McGrath, Acting Chief, Medical Inspection Section, NRC Region I , to Thomas Manning, Chief Operating Officer, University of Massachusetts, Worcester, Massachusetts, dated December 27, 1994.*

15. NRC/INEL Radiation Therapy Event Investigation Team Report 9501, Idaho National Engineering Laboratory, Lockheed Idaho Technologies Company, Idaho Falls, Idaho, dated January 1995.*

*A copy is available for inspection, or copying for a fee, in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

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11. ABSTRACT (200 words or less)

Section 208 of the Energy Reorganization Act of 1974 identifies an abnormal occurrence (AO) as an unscheduled incident or event that the Nuclear Regulatory Commission determines to be significant from the standpoint of public health or safety and requires a quarterly report of such occurrences to be made to Congress. This report provides a description of those incidents and events that have been determined to be AOs during the period of October 1 through December 31, 1994.

This report addresses four AOs at NRC-licensed facilities. These occurrences involved the following: a generic concern relating to core shroud cracking in boiling water reactors; recurring incidents of administering higher doses than procedurally allowed for diagnostic imaging at a single facility; one medical teletherapy misadministration and one medical brachytherapy misadministration. Agreement States submitted four AO reports. These four occurrences involved the following: one major contamination at a commercial facility; two medical brachytherapy misadministrations; and one medical teletherapy misadministration. The report also contains updates of seven AOs previously reported by the Agreement States. Two "Other Events of Interest" are also being reported. These occurrences involved the operability of safety relief valves at a nuclear power plant, and an error in the installation process of a Leksell Gamma Knife® Teletherapy unit that resulted in an operational failure.

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