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Report to Congress on Abnormal Occurrences

October – December 1993

U.S. Nuclear Regulatory Commission

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ABSTRACT

Section 208 of the Energy Reorganization Act of 1974 identifies an abnormal occurrence 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 events to be made to Congress. This report covers the period from October 1 through December 31, 1993.

This report discusses six abnormal occurrences at NRC-licensed facilities. Five involved medical brachytherapy misadministrations, and one involved an overexposure to a nursing infant. Seven abnormal occurrences that were reported by the Agreement States are also discussed, based on information provided by the Agreement States as of February 28, 1994. Of these events, three involved brachytherapy misadministrations, one involved a teletherapy misadministration, one involved a theft of radioactive material during transport and improper disposal, and two involved lost sources.

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PREFACE

Introduction

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

Events are currently identified as abnormal occurrences for this report by NRC using the criteria and accompanying examples listed in Appendix A. These criteria were promulgated in an NRC policy statement that was published in the *Federal Register* on February 24, 1977 (Vol. 42, No. 37, pages 10950–10952).

The NRC policy statement was published before licensees were required to report medical misadministrations to NRC. Few of the examples in the policy statement are applicable to medical misadministrations. Therefore, during 1984, NRC developed guidelines for selecting such events for abnormal occurrence reporting. These guidelines, which have been used by NRC since the latter part of 1984, augment the NRC policy statement examples and are summarized in Table A-1 in Appendix A. On January 27, 1992, new medical misadministration definitions became effective. Therefore, revised guidelines for identifying medical misadministrations as abnormal occurrences are currently being developed. The revised guidelines will be published for comment in the *Federal Register*.

In order to provide wide dissemination of information to the public, a *Federal Register* notice is issued on NRC licensee abnormal occurrences. 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 describe its nature and probable consequences.

NRC has determined that only those events described in this report meet the criteria for abnormal occurrence reporting. This report covers the period from October 1 through December 31, 1993. Information reported on each event 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 abnormal occurrences.

Appendix C provides descriptions of events 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 abnormal occurrences but are provided as other events of interest.

Appendix D has been added to this report which includes events submitted by Agreement States that are likely to be categorized as abnormal occurrences.

For these events, insufficient information was available in time for publication to positively identify them as abnormal occurrences.

The Regulatory System

The system of licensing and regulation by which NRC carries out its responsibilities is implemented through 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

Actual 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 early and to ensure that corrective actions are taken to prevent recurrence.

For nuclear power plants, dedicated groups have been formed both by the NRC and by 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 feed back 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 sub-

mitted, but also the methods used to analyze the 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 made pursuant to 10 CFR 50.72, and medical misadministration reports made 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. The Congress is routinely kept informed of reportable events occurring in licensed facilities.

Another source of operational data is reliability data submitted by licensees under the Nuclear Plant Reliability Data System (NPRDS). The NPRDS is a voluntary, industry-supported system maintained by the Institute of Nuclear Power Operations (INPO), a nuclear utility organization. Both engineering and failure data are submitted by nuclear power plant licensees for specified plant components and systems. The Commission considers the NPRDS to be a useful supplement to the LER system for the collection, review, and feedback of operational experience.

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

In early 1977, the Commission determined that abnormal occurrences happening at facilities of Agreement State licensees should be included in the quarterly reports to Congress. The abnormal occurrence criteria included in Appendix A are applied uniformly to events at the NRC and the Agreement State licensee facilities. Procedures have been developed and implemented, and abnormal occurrences reported by the Agreement States to NRC are included in these 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 abnormal occurrence reports to Congress; however, only domestic abnormal occurrences are reported.

Reopening of Closed Abnormal Occurrences

NRC reopens previously closed abnormal occurrences if significant new information becomes available. Similarly, previously reported Other Events of Interest items are updated if significant new information becomes available.

REPORT TO CONGRESS ON ABNORMAL OCCURRENCES OCTOBER–DECEMBER 1993

Nuclear Power Plants

NRC is reviewing events reported at the nuclear power plants licensed to operate. For this report, NRC has determined that no events were abnormal occurrences.

Fuel Cycle Facilities (Other than Nuclear Power Plants)

NRC is reviewing events reported by these licensees. For this report, NRC has determined that no events were abnormal occurrences.

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

There are currently over 7,500 NRC nuclear material licenses in effect in the United States, principally for the use of radioisotopes in the medical, industrial, and academic fields. Incidents were reported in this category by licensees such as radiographers, medical institutions, academic institutions, and byproduct material users. NRC is reviewing events reported by these licensees. For this report, using the criteria and guidelines given in Appendix A, NRC has identified the following events as abnormal occurrences. As noted in the Preface to this report, the guidelines for identifying medical misadministrations as abnormal occurrences are currently being revised.

93-11 Medical Brachytherapy Misadministration at Washington University Medical School in St. Louis, Missouri

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

Date and Place—January 7, 1993 and February 26, 1993; Washington University Medical School; St. Louis, Missouri.

Nature and Probable Consequences—On January 7, 1993, a Nucletron Micro-Selectron low-dose-rate (LDR) remote afterloader unit ejected a radioactive source without being programmed to do so and without a guide tube and applicator attached to the channel. The unguided source lay at an approximate distance of 3 centimeters (cm) (1.2 inches [in]) from the nearest skin surface for approximately 5 minutes. The licensee estimated that less than 0.1 centigray (cGy) (0.1 rad) of additional dose was delivered to the skin surface.

On February 26, 1993, a very similar incident occurred at the same facility. The incident involved a different patient and the same remote afterloader unit. The device again ejected the same strength and type of radioactive source without being programmed to do so. However, in this case, the source lay near the patient's leg for approximately 60 to 75 minutes, at an approximate distance of 5 cm (2 in) from the nearest skin surface. The licensee estimated the additional dose to the patient's leg to be approximately 3.5 cGy (3.5 rad).

In both cases, the treatment of each patient was completed on another LDR remote afterloader unit in another room of the medical center.

Cause or Causes—After the first incident on January 7, 1993, a manufacturer service engineer, who studied the device malfunction, was unable to identify the cause of the failure during his repair visit. The licensee's staff subsequently tested the device for 20 hours without discovering the cause of the failure, and concluded that the device was acceptable for use. This decision was based on the fact that they could not reproduce the malfunction. The remote afterloader was put back into service. On February 26, 1993, the device failed again when a second unprogrammed source was ejected by the afterloader. After this incident, which resulted in the second misadministration, the manufacturer provided a different

field engineer who correctly diagnosed the problem as a failure in an operational amplifier.

A previous recommendation made by the manufacturer to store unused sources in the auxiliary storage safe, instead of the remote afterloader's mobile storage container, may have contributed to the incident. The second field engineer indicated that some of the safety features which prevent sources from being erroneously ejected were not in effect or were not monitored by the device for the unprogrammed channels containing the unused sources.

Actions Taken To Prevent a Recurrence

Licensee—The licensee informed the NRC that use of the two Micro-Selectron-LDR remote afterloader units will be discontinued and a new model LDR afterloader will be installed. NRC has also asked the licensee to address the manufacturer's recommendation for storing the sources and the removal of some of the safety features, and any resulting corrective actions.

NRC—The vendor has now revised the device's operating software to monitor and generate error messages and audible alarms for unprogrammed (unused) channels. The NRC has sent a letter (Ref. 1) to the licensee identifying the two events as misadministrations and requesting that the licensee ensure the required notifications to the referring physicians and patients have been made.

During an NRC safety inspection conducted from November 15 to 18, 1993, the inspectors focused on these two incidents in addition to other inspection areas. The results of this inspection are still under review.

This report will be further evaluated when additional information becomes available.

93-12 Medical Brachytherapy Misadministration at Mercy Hospital in Scranton, Pennsylvania

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

Date and Place—October 15, 1993; Mercy Hospital; Scranton, Pennsylvania.

Nature and Probable Consequences—On October 15, 1993, Mercy Hospital in Scranton, Pennsylvania, notified NRC Region I of a therapeutic misadministration involving a Nucletron MicroSelectron high dose rate (HDR) remote afterloader which occurred at the facility on April 23, 1993. The licensee identified this misadministration during a review of the past treatment records.

A patient was scheduled to receive brachytherapy treatment to the apex of her vagina in three fractions using a Nucletron Micro Selectron HDR remote afterloader. The prescribed dose was 500 centigray (cGy) (500 rad) for each fraction and the use of a ring applicator was specified. On April 13, 1993, the patient was administered the first fractional treatment. After an examination of the patient following the first treatment, the physician revised the written directive and prescribed a change from the ring applicator to a standard vaginal cylindrical applicator for the remaining two treatments. On April 23, 1993, during the administration of the second treatment, the therapist erroneously entered the catheter length of 920 millimeter (mm) (36.2 inch) into the treatment computer instead of the intended 992 mm (39.1 inch). The physician failed to identify this error during his review of the treatment parameters prior to the initiation of the treatment.

As a result of this erroneous entry, a majority of the treatment dose was administered to an unintended region near the opening of the vagina, and the intended site received an underdose differing from the prescribed dose by more than 20 percent. The physician stated that no adverse clinical effects are expected as a result of the underdose to the target site because this treatment was intended to administer a booster radiation dose. The oncologist also stated that the patient is not expected to experience any adverse effects as a result of the 500 cGy (500 rad) overexposure to the wrong treatment site misadministration. The NRC medical consultant, in his report to Region I, also stated a similar opinion (that it is unlikely the patient will suffer any adverse effects from the misadministration).

The third fraction of the treatment was administered to the patient on April 29, 1993, as prescribed.

The referring physician and the patient have been notified. The licensee submitted a written report of the misadministration to NRC Region I on October 29, 1993.

Cause or Causes—The therapist did not enter the correct catheter length during initial setup for the second treatment. The licensee followed established procedures; however, the procedure did not require verification of all parameters at the time of the second check prior to each treatment.

Actions Taken to Prevent Occurrence

Licensee—The licensee has instituted a requirement that a medical physicist also review the final treatment plan prior to initiating the treatment. The treatment parameters for all brachytherapy (HDR) treatments will be transferred electronically to the magnetic card directly from the simulator. The output of this card will be reviewed by the medical physicist and the oncologist before the initiation of the treatment.

NRC—Region I conducted a special inspection at Mercy Hospital on October 19, 1993. Inspection Report No. 030-02983/93-001, issued November 5, 1993, identified two apparent violations: (1) failure to require supervised individual to follow written quality management procedures (QMP) 10 CFR 35.25(a)(2); (2) failure to include policies and procedures in the QMP to meet the objective that each administration is in accordance with the written directive 10 CFR 35.32(a). After receipt and review of the medical consultant's report, Region I issued a Notice of Violation to the licensee on February 9, 1994, classifying the two violations at Severity Level IV in accordance with the NRC Enforcement Policy.

An NRC medical consultant has been retained to review this misadministration. The medical consultant's report (Ref. 3) was received by Region I on February 3, 1994. The medical consultant questioned the licensee concerning its identification of a radiation oncologist as the referring physician. After discussion with the NRC's medical consultant, the licensee identified the patient's physician as the primary referring physician and then agreed to notify the physician. Following a review of the medical consultant's report, Region I confirmed in a telephone conversation that the licensee had contacted the patient's physician regarding the misadministration. The licensee stated that both referring physicians have been notified of this misadministration. The radiation oncologist had discussed the misadministration with the patient on October 21, 1993.

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

93-13 Medical Brachytherapy Misadministration at Mountainside Hospital in Montclair, New Jersey

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

Date and Place—July 1, 1993; Mountainside Hospital; Montclair, New Jersey.

Nature and Probable Consequences—On December 1, 1993, during a routine inspection, NRC identified a therapeutic misadministration involving a high-dose-rate (HDR) remote afterloader, which occurred at Mountainside Hospital in Montclair, New Jersey, on July 1, 1993. NRC identified the misadministration while reviewing the licensee's Radiation Safety Committee (RSC) meeting minutes for 1993.

On July 1, 1993, a patient was scheduled to receive the last of three brachytherapy treatments to the right mainstem bronchus. Each fraction was to deliver 750 centigray (cGy) (750 rad) to the target using a Nucletron Micro-Selectron HDR remote afterloader and a intrabronchial catheter. During the July 1, 1993 treatment, the radiation oncologist mistakenly connected the catheter to the HDR afterloader with a 750 mm (29.5 inch) transfer tube instead of a short connector. This prevented the source from entering the intrabronchial catheter, and while delivering a negligible dose to the tumor, the face, the lenses of the eyes, the thyroid, and the whole body of the patient received unscheduled exposure.

The source strength at the time of the incident was 161,000 megabecquerel (4.35 curie) of iridium-192 and the exposure time was 445.5 seconds. Following the reconstruction of the incident by the licensee, the surface dose to the lens of the left eye was determined by the licensee to be 1.97 cGy (1.97 rad), the dose to the chin (the closest surface of the body) was 4.56 cGy (4.56 rad), and the dose to the thyroid was 3.07 cGy (3.07 rad). The physician identified the error upon termination of the treatment and wrote a memorandum about the incident to the hospital's physicist and radiation safety officer (RSO).

The physician mistakenly determined that the incident was not a misadministration, and so advised the RSO. The RSO, relying on the physician's judgment, did not notify NRC and filed the report in the RSC minutes folder. The radiation oncologist decided against making up the missed third fraction of therapy.

On December 3, 1993, NRC notified the licensee by telephone that the event constituted a misadministration and the licensee notified the NRC Operations Center on the same day. The licensee's written report of the misadministration, dated December 13, 1993, was received in the NRC Region I office on December 17, 1993.

After review of the report, Region I called the licensee to determine if the referring physician and the patient were notified of the misadministration. The licensee forwarded a copy of a letter dated December 20, 1993, from the radiation oncologist to the referring physician confirming

a December 6, 1993, telephone conversation in which the referring physician was informed of the misadministration. The letter indicated that the referring physician did not feel it would be in the patient's best interest to be notified of the misadministration.

NRC contracted a medical consultant to determine the significance of the misadministration to the patient. The medical consultant's report was received by Region I on February 3, 1994. The consultant's calculations of doses to the lens of the left eye, the chin, and the thyroid of the patient agreed with the licensee's estimates, based on the strength of the source, the time of exposure and the distances of the source from the patient. The consultant concluded that the patient would not suffer any adverse effects from the misadministration. The medical consultant also determined that the oncologist failed to notify the patient of the misadministration because he did not fully understand the requirements of 10 CFR 35.33(a)(3). After discussions with the consultant, the referring physician agreed to inform the patient of the misadministration.

Cause or Causes—An error by the attending physician in connecting the catheter to the HDR remote afterloader, and the failure of the console operator to recognize the faulty connection were the direct causes of the event. Both individuals relied on the treatment computer to indicate any problems with the therapy setup. The computer on a Nucletron HDR is not designed to alert the user to an incorrect connection of a longer transfer tube.

In addition, the medical consultant's report indicates that the second individual observing the transfer tube connection during each treatment setup was a different console operator. Since the console operator in attendance during the third treatment had not been present during the prior treatments, he/she was unaware of the intended setup.

Actions Taken to Prevent Occurrence

Licensee—The licensee arranged for additional training by Nucletron on July 30, 1993. The training was attended by both HDR remote afterloader units authorized users and by three technologist-console operators.

NRC—NRC is reviewing the licensee's December 17, 1993 misadministration report (Ref. 4) and the findings of the December 1, 1993 NRC inspection. An NRC medical consultant was retained to review the misadministration.

The medical consultant's report dated February 1, 1994, was received by the NRC Region I office on February 3, 1994. In addition to the comment made in the above sections, the consultant indicated that if the licensee had required a medical physicist to be present during every setup and treatment as recommended NRC Bulletin 93-01, it is likely that this misadministration would not have occurred. In the consultant's opinion, a medical physicist would have been more likely to have noticed the human error in the set up of the third HDR treatment.

An enforcement conference has been scheduled.

This report will be further updated when additional information becomes available.

93-14 Exposure to a Nursing Infant at Queen's Hospital in Honolulu, Hawaii

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see General Criterion 1) of this report notes that a moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission can be considered an abnormal occurrence.

Date and Place—December 2, 1991; Queen's Medical Center; Honolulu, Hawaii.

Nature and Probable Consequences—On October 25, 1993, during a routine safety inspection, a Region V inspector discovered an unreported unscheduled exposure to the thyroid of a 9-month-old nursing infant. On December 2, 1991, a patient was administered 0.56 megabecquerel (15 microcuries) of iodine-131 for a diagnostic scan. Although the patient noted on a hospital form that she was breastfeeding, the technologist failed to notice this notation until the patient returned for a scan the following day. The patient was informed of the oversight by the licensee and was instructed to stop breastfeeding. The authorized user and the referring physician were also notified on December 3, 1991.

The licensee's Radiation Safety Officer calculated the infant's absorbed thyroid dose to be approximately 250 millisievert (mSv) (25 rem) based on information obtained during an uptake scan of the mother 6 hours after the administration.

The NRC retained a medical consultant to evaluate the circumstances of this misadministration. The consultant estimated the dose to the infant's thyroid to be between 160 to 650 mSv (16 to 65 rem). The medical consultant concluded that the infant is not likely to experience any adverse effects as a result of this misadministration.

Cause or Causes—Failure of a supervised technologist to adequately review the hospital form used to inform the hospital staff that a patient is pregnant or breastfeeding as he/she was instructed by the authorized user.

Actions Taken to Prevent Recurrence

Licensee—The screening procedure used to inform the hospital staff that a patient is pregnant or breastfeeding was incorporated into the clinical procedure manual. It was reviewed by each of the technologists, and it will be reviewed by all new technologists upon being hired. It will also be reviewed annually during a radiation safety training course.

NRC—NRC conducted inspections on September 28 and October 25-27, 1993. The December 2, 1991 misadministration was noted and reviewed during these inspections. A number of violations were identified as a result of these inspections and escalated enforcement actions are being considered. An NRC medical consultant was also retained to review the case.

This report will be further updated when additional information becomes available.

93-15 Medical Brachytherapy Misadministration at Good Samaritan Medical Center in Zanesville, Ohio

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

Date and Place—November 10, 1993; Good Samaritan Hospital; Zanesville, Ohio.

Nature and Probable Consequences—A patient was being treated for lung cancer. The treatment included performing an iridium192 therapeutic implant. The prescribed treatment dose was 6000 rad to the patient's lung. On November 10, 1993, a catheter was surgically implanted in the patient. Iridium-192 seeds, contained in a ribbon, were inserted into the catheter.

Following normal licensee procedure, the physicist requested that the attending nurse order a "stat" chest x-ray in order to verify source position. The "stat" radiograph was completed and two hours later upon review of the film, the seed positions could not be visualized. Two additional radiographs using different techniques were done. In the second radiograph, completed one hour later, the seeds were located in the patient's throat. The ribbon was removed and the physician successfully reinserted the ribbon to the proper location. Another radiograph was done to verify the source location. The treatment time was recalculated to deliver the total original intended dose and the treatment was completed without further difficulty.

The sources were in the improper location for about three hours, delivering an estimated dose to the larynx area of about 282 centigray (282 rad). An NRC medical consultant evaluated the medical aspects of the brachytherapy misadministration and concluded that the dose to the larynx and surrounding area is not clinically significant.

The physician verbally notified the patient of the misadministration following the successful reinsertion of the source ribbon. A written report was provided to the patient on November 15, 1993.

Cause or Causes—The immediate cause of the misadministration was an apparent crimp in the catheter which resulted in the seeds not being placed correctly. The seeds were blocked by the crimp at the level of the patient's larynx.

An inexperienced radiation therapy technician implanted the source. During interviews, the physician stated that it would be difficult for an inexperienced person to know the difference between a properly seated ribbon and when ribbon insertion was impeded by a crimp in the catheter.

Actions Taken To Prevent Recurrence

Licensee—The licensee's plan for preventing recurrence of the misadministration included: (1) formalizing the dosimetrist's "rule of practice" regarding comparison of the ribbon and catheter lengths prior to source implantation in order to ensure that the ribbon is properly seated; (2) providing training to all radiation therapy technologists and each medical physicist in the new procedure; (3) requiring that the authorized user physically implant source ribbons; (4) requiring that each radiation therapy technologist receive hands-on training and instruction in source implantation; and (5) requiring that the "stat" post-insertion radiograph be hand carried to the prescribing physician for evaluation as soon as possible to determine proper source placement.

NRC—A special safety inspection was conducted by NRC Region III on January 19, 1994 to review the circumstances surrounding this misadministration. An NRC medical consultant was also retained to review this case. Based on the results of the special inspection (Ref. 2), NRC identified an apparent violation that is being considered for escalated enforcement action.

This report will be further evaluated when additional information becomes available.

93-16 Medical Brachytherapy Misadministration at Marquette General Hospital in Marquette, Michigan

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

Date and Place—November 17-19, 1993; Marquette General Hospital; Marquette, Michigan.

Nature and Probable Consequences—On November 17, 1993, a patient was undergoing a brachytherapy procedure using cesium-137 sealed sources placed in a treatment device (catheter) inserted into the patient's uterus. When the catheter was removed on November 19, it was observed that it was too short to have been fully inserted into the uterine cavity. The three sources in the catheter had actually been in the patient's vagina instead of the uterus.

The case was evaluated by an NRC medical consultant who concluded that the lower vagina received a radiation dose of 2,700 centigray (2,700 rad) when it would not have received a significant dose if the treatment had been performed as planned. The medical consultant concluded that the radiation doses to the vagina would not be expected to cause any acute or long term effects because the vaginal tissue is extraordinarily tolerant of radiation. This placement error did not result in additional exposure to other organs.

The intended treatment area received about 50 percent of the intended dose. Subsequently, the patient received an additional dose to the uterus to complete the prescribed treatment. The licensee informed the patient of the treatment error.

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

Actions Taken to Prevent a Recurrence

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

NRC—The NRC conducted a special inspection beginning November 29, 1993, to review the circumstances surrounding the misadministration. No violations of NRC regulations were identified, but the licensee was directed to review its Quality Management Program to determine what modifications were needed to prevent similar misadministrations in the future. The NRC also retained a medical consultant to evaluate this case.

This report will be further updated when additional information becomes available.

Agreement State Licensees

Procedures have been developed for the Agreement States to screen unscheduled incidents or events using the same criteria as NRC (see Appendix A) and to report the events to NRC for inclusion in these quarterly reports to Congress. During this period, the Agreement States have identified the following events as abnormal occurrences. Information for these events provided by the Agreement States as of February 28, 1994, is included in this report to Congress.

AS 93-10 Theft of Radioactive Material During Transport and Improper Disposal

Appendix A (see Example 6 of "For All Licensees") of this report notes that a substantiated case of actual or attempted theft or diversion of licensed material should be considered as an abnormal occurrence.

Date and Place—Over several years prior to February 1993; Maryland Heights, Missouri and rural Madison and Macoupin Counties, Illinois.

Nature and Probable Consequences—This event involved the diversion of nuclear medicine generators from the transportation stream by an employee of a courier service who delivers them to hospitals and picks them up for return to the manufacturer. They were apparently stolen in order to reclaim the lead shielding as scrap metal. The generator internals were burned in an open barrel in a residential area and the ashes were often discarded in rural wooded areas. The practice had gone on for several years before authorities became aware that it was occurring. The details are as follows:

On February 7, 1993, local police in Bunker Hill, Illinois, reported the discovery in a public park of medical vials that appeared to have contained radioactive material. Investigation by the Illinois Department of Nuclear

Safety (Department) revealed that the material was partially burnt glassware and saline vials from several nuclear medicine generators. Surveys revealed that some of the items were contaminated with radioactive material.

Further investigation revealed that a resident of Bunker Hill worked for a courier service in St. Louis, Missouri, and delivered and picked up packages containing radioactive material at area hospitals. The same resident, and his landlord, had been approached by local law enforcement officials on several occasions to cease burning in a steel drum next to his residence. An examination of the grounds around his apartment building revealed other glassware similar to that found in the city park. Several attempts by Department personnel and local police to interview this individual were unsuccessful and on February 22, the Department was informed that the individual had passed away the day before from natural causes. The individual's daughter was contacted by mail and was asked to allow the Department to perform surveys for radioactive contamination in the residence she and her husband shared with her father and her small children. She did not respond to the request.

Several months before these events, a resident of the rural Alton, Illinois, area, reported to the Department the discovery of a stainless steel cylinder that bore the marking "radioactive" along with "Union Carbide, Tuxedo, NY." At the time, the purpose of the cylinder was not known, but other markings indicated that it contained depleted uranium for shielding. During March and April of 1993, several more cylinders were reported by citizens in the rural Alton area. Some of these cylinders bore the marking "Cintichem" instead of "Union Carbide," but were otherwise identical. When contacted, Cintichem personnel stated they had reported to their courier that 29 uranium-shielded generators, enroute to New York from pharmacies and hospitals throughout the country, had not arrived. All of these generators were apparently part of a weekly shipment of such generators by the same courier service in St. Louis for whom the deceased Bunker Hill resident had worked.

At this point, the Department requested the Illinois State Police to assist in the investigation. The State Police investigator interviewed the daughter and son-in-law of the deceased individual and discovered that the individual had been stealing nuclear medicine generators for several years in order to reclaim the lead and to sell it to a local metal recycler. The daughter and son-in-law said that the generators' accessories were burned in a steel drum on the grounds of the apartment building in which they lived and that the ashes were usually dumped in rural wooded areas. The individual in question had assumed that the uranium-shielded generators also contained lead shielding and had stolen an entire palette of them while they were awaiting transport back to New York.

The daughter and son-in-law also stated that the scrap yard had originally accepted the uranium shields until they discovered the "Radioactive" markings. The recycler then made the individual retrieve the shields from the facility. After taking back the shields, the deceased individual, along with his daughter and son-in-law, discarded the shields in wooded and low-lying areas along rural roads between the scrap yard and their residence in Bunker Hill. The daughter and son-in-law identified locations where they recalled discarding the shields.

On May 6 and 7, 1993, Department staff along with State Police personnel performed radiation detectors and metal detector surveys in the areas where the shields were known to have been discarded. That search, along with previous discoveries by citizens, allowed the recovery of approximately half of the 29 missing uranium shields. The shields were retrieved by the courier company for transport back to New York. The search was suspended until the water level in the creeks had dropped to a level that allowed the creek beds to be searched.

Although the risk to the general public from this prolonged diversion of radioactive material is not significant, the radiation exposure to the deceased individual could have been significant due to his direct contact with the generators. The individual apparently believed that, since the hospitals could no longer use the generators, there was not radioactive material left in them. However, no estimate of his exposure could be made without more information. The daughter and son-in-law stated that the material was never stored or processed in their apartment, so no contamination or related exposure to minor children would have occurred.

The findings of the investigation did reveal accountability problems in the current method for returning used generators. In the case of lead-shielded generators used in community hospitals, once a return authorization is issued by the manufacturers, no mechanism exists to confirm that they have arrived. In the case of the uranium-shielded generators, the inherent value of $1800 for the uranium shield caused each one to have a serial number etched on it along with the other required markings. These generators were known to be missing during the fall of 1992. The individual was able to cover up the thefts by removing the bills of lading from the shipping documents and destroying them so the courier service had no record that the packages existed.

Since the courier service operated in Missouri, the Department could not compel it to implement any corrective action. Additionally, the U.S. Nuclear Regulatory Commission apparently has no jurisdiction over these transportation activities. Jurisdiction resides with the U.S. Department of Transportation, but no violation of Title 49 of the *Code of Federal Regulations* (49 CFR) appears to have been committed by the courier

service. Legal action could not be pursued against the individual since he is deceased.

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

Actions Taken to Prevent Recurrence

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

State Agency—No violation of the Illinois Administrative Code or the *Code of Federal Regulations* had occurred. The Illinois Department of Nuclear Safety could have issued an order against the individual to cease the diversion or pursued criminal action with the cooperation of the State Police, but he died before such action could be taken. The Department could not compel a courier operating in Missouri to take corrective action when no violation of regulations could be identified on the courier's part.

NRC—No federal regulations were violated. The radiation levels involved were low and represented a very small risk to the public's health and safety. Extended and repeated exposure to low level radiation and the possible inhalation from burning the vials could have had adverse effects to those directly involved in the theft and destruction of the generator remains but there was no indication of such effects. No NRC actions were taken.

This item is considered closed for purposes of this report.

AS 93-11 Found Source at Scrap Metal Facility in Magnolia, Arkansas

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

Date and Place—March 24, 1993; Tallman Scrap Yard; Magnolia, Arkansas.

Nature and Probable Consequences—On March 24, 1993, approximately 4:15 p.m., an employee with TN Technologies notified the State by phone that a cesium-137 (Cs-137) source had been located at Tillman Scrap Yard in Magnolia, Arkansas.

The source was described as a Texas Nuclear Model 5176 source holder, Serial Number 82656, containing 148 gigabecquerel (4 curies) of Cs-137. The source was distributed under TN Technologies general license.

A TN Technologies Project Engineer traced the serial number to Elk Roofing Plant in Stevens, Arkansas. This facility has been sold to Lapry Paper Company.

Upon completion of the phone call, the State Health Physicist called Tillman Scrap Yard to ensure that the source was located in an area away from the general public and personnel working in the scrap yard. An employee with Tillman Scrap Yard informed the State that the source had been placed in a metal bin and moved to the back of the scrap yard. The scrap yard employee was instructed to keep everyone away from the source and was given assurance that the State would be responding as soon as possible.

A team was dispatched to the Tillman Scrap Yard where they immediately went to the area where the source was located. The source had been placed in a metal scrap bin for relocation to the back of the yard. The source and the detector was mounted to a piece of pipe. A swipe was taken on the surface of the source holder to determine if the sealed source had been damaged in any way. No contamination was detected.

The source was then removed from the bin. The shutter was found to be padlocked in the open position. The padlock was cut away and the shutter was secured in the closed position. The mounting bolts were also removed isolating the source from the associated equipment.

The source was packed in a 133-liter (35-gallon) drum and labeled as a Yellow-II package. The radiation readings on contact were 0.23 microcoulomb per kilogram per hour (C/kg/hr) (0.9 milliroentgen per hour [mR/hr]) and at 1 meter (3.3 feet) 0.015 C/kg/hr (0.06 mR/hr). The source was removed from the affected area. A contamination survey of the entire work area was carried out. No contamination was found. The area was released for unrestricted use.

After several discussions with the lawyers of Elk Roofing Company and Lapry Paper Company, it was decided that Elk Roofing Company would pay for the final disposal of the gauge. A representative from TN Technologies came to the department on April 26, 1993, and took final possession of the device.

Cause or Causes—Insufficient information is available to determine the cause(s) of this event. NRC has asked the State of Arkansas to provide any additional information regarding the cause(s) of this event.

Actions Taken to Prevent Recurrence

Licensee—Insufficient information is available on the action(s) taken by the licensee to prevent recurrence.

NRC has asked the State of Arkansas to identify any licensee action(s).

State Agency—Insufficient information is available on the action(s) taken by the State Agency to prevent recurrence. NRC has asked the State of Arkansas to provide additional information regarding the State Agency's action(s).

This report will be further evaluated when additional information becomes available.

AS 93-12 Medical Teletherapy Misadministration at Rocky Mountain Gamma Knife Center, Denver, Colorado

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

Date and Place—July 8, 1993; Rocky Mountain Gamma Knife Limited Liability Company; Denver, Colorado.

Nature and Probable Consequences—A patient was admitted on July 8, 1993, for treatment of a longstanding arteriovenous malformation (AVM) in the left posterior dura of the brain. The patient was taken to the special procedures room in the radiology department of the hospital where a series of lateral and posterior/anterior (P/A) angiograms were performed. These were used to identify the AVM targets. The films were given to the physicist who optically scanned them into the computer planning system. Concurrently, the patient was taken to Magnetic Resonance Imaging (MRI) where a series of scans was performed.

The physicist and neurosurgeon worked to complete the dose planning function, however, several anomalous events were noted during the process: (1) during the "definition process," the screen showed a sudden "floating point error" message. This was described as serious but the cause of the message was not known; (2) the definition program in the Leksell Gamma Plan (LGP) refused to accept on at least two occasions the "correct" orientation of the image, as viewed by the physicist and neurosurgeon. Eventually, the neurosurgeon and physicist had to instruct the LGP to accept the image they knew to be intuitively correct, but which the computer had failed to recognize. At this point, the screen images appeared correct as to orientation for diagnosis, however, the planning team did not realize that the P/A image was reversed in regard to the LGP dose-planning system.

The team then generated two separate treatment plans for the two separate targets. The radiation oncologist was consulted and concurred with the dose prescription. It was noted that the "X" coordinates for the targets indicated a right-of-midline stereotactic position, but the patient's head was tilted inside the frame, placing the midline of the brain to the left of the midline of the stereotactic system. Therefore, the coordinates were accepted as plausible. After initiating the treatment sequence for the next exposure, the physician reviewed the target points and noticed that the X coordinates indicated a definite right-side target. The physicist immediately terminated the exposure and notified the physician of a possible treatment error. It was determined that the Y and Z coordinates were accurate, but the X offset resulted in a target miss by 16 millimeters (0.63 inches).

The brainstem was stated to be the only critical structure within the 10 percent isodose contour. Reconstruction of the dose profile indicated that less than 10 cubic millimeters received no more than 2.5 gray (Gy) (250 rad). The tolerance dose for the brainstem was stated to be 10 Gy (1000 rad). The remainder of the dose within the 10 percent isodose line was stated to be of in the cerebrum and cerebellum. It was the opinion of the neurosurgeon that the dose delivered was well below the dose–volume threshold for inducing any neurological damage.

Cause or Causes—The angiographic study was done in an x-ray room with the patient supine and with the x-ray tube on the patient's left. This room was different than that previously used for gamma knife studies. The physicist had been aware of only one angiography room at the hospital in which the x-ray tube was always on the patient's right.

Although the images were "intuitively correct" to the neurosurgeon and physicist, they were perceived as incorrect by the computer software. The physicist was apparently able to override the computer rejection of the data to continue with the procedure.

The floating point error is described as an error resident in the calculation code of the software platform, and is not a part of the LGP program. The licensee was assured by the software developers that this error message would result in two outcomes if it ever happened again. The program would crash on the next command, or it would self-correct prior to the next command. None of the participants has been able to recreate this floating point error.

Actions Taken to Prevent Recurrence

Licensee—The licensee has implemented a policy that any computer error message, regardless of origin or seriousness, will require termination of the preparation for treatment. The software will not be overridden under any circumstances. A Quality Assurance (QA) Program has been instituted for angiographic images, including the

use of proximal and distal markers. The physicist will personally observe the acquisition of the angiographic images. A policy has been implemented that no treatment will be based on angiographic images alone. Confirmation will be obtained by superimposing the dose profiles over the MRI and other images obtained with the same stereotactic frame placement as the angiographic images. All treatment plans are sent to and verified by the Director of the Hospital of the Good Samaritan in Los Angeles, California. The Director, a physician, was stated to have performed several hundred gamma knife procedures and is a member of the gamma knife QA team.

State Agency—Two on-site inspections have been conducted by the State staff, to verify the adequacy of corrective actions. The information submitted to the State department has been reviewed and accepted by the Division's Medical Advisory committee as being accurate and corrective actions appropriate. The Division has required and accepted an application to name the teletherapy physicist on the license. Because no alternate teletherapy physicist has been submitted on the license, the license will allow no treatments to be performed in the absence of the primary teletherapy physicist.

No enforcement actions or penalties have been imposed on the licensee. The new procedures and policies submitted by the licensee have been reviewed by the Division and appear appropriate to prevent a recurrence.

The application to amend the license to include the teletherapy physicist, and two additional radiation oncologists is currently under review by the State.

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

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

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

Date and Place—September 2, 1993; BPB Instruments, Inc.; Midland, Texas.

Nature and Probable Consequences—BPB Instruments, Inc., notified the State of Texas agency that during a physical inventory a 555 gigabecquerel (GBq) (15 curie [Ci]) americium/beryllium source made by Amersham (Serial Number 7004NE) was not located and may have been lost or stolen. BPB again notified the State agency on September 8, 1993, that after a thorough search, the source was not found.

A State agency investigation determined that the source was documented to be present and in the control of BPB on March 31, 1992. An inventory conducted on July 7, 1992, did not indicate that the source was present. The most likely scenario is that the source was lost or stolen between the dates of March 31, 1992, and July 7, 1992. NRC has asked the State of Texas to determine why this event was not reported sooner.

BPB believes that a disgruntled employee may have taken the source to cause problems for the company. Employees and exemployees were interviewed concerning the lost source and all interviewees claimed to have no knowledge of its disappearance. The possible loss or theft was reported to the Midland County Sheriff's Department.

Surveys were performed in areas around Midland. BPB placed an ad in the Midland newspaper offering a $10,000 reward for information leading to the recovery of the source. The State agency issued a press release describing the source, warning that it should not be handled, and requesting that BPB or the State agency be contacted if the source is found. All attempts to locate the source have been unsuccessful.

According to the manufacturer, Amersham, the radiation profile for the 555 GBq (15 Ci) americium/beryllium source indicates 5.16 millicoulomb per kilogram (mC/kg) (20 roentgen) per hour gamma dose rate and 4.64 mC/kg (18 roentgen) per hour neutron dose rate at 5 centimeters (2 inches).

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

Actions Taken to Prevent Recurrence

Licensee—BPB is rewriting the job duties for the local and corporate radiation safety officers and is also reviewing and rewriting the procedures manual to aid in tracking each source of radiation.

Agency—The State agency is reviewing the incident to determine the nature and extent of enforcement action. NRC has asked the State of Texas to provide additional information on the State's action(s) upon completing their review of the incident.

This report will be further evaluated when additional information becomes available.

AS 93-14 Medical Brachytherapy Misadministration at Michael Reese Medical Center in Chicago, Illinois

Appendix A (see Event Type 5 in Table A-1) of this report notes that administering a therapeutic dose that is greater than 1.5 times the prescribed dose should be considered an abnormal occurrence.

Date and Place—October 6 through 10, 1993; Michael Reese Hospital and Medical Center; Chicago, Illinois.

Nature and Probable Consequences—A 68-year-old woman with Stage II vaginal cancer was referred to the hospital's radiation therapy department for treatment. A plan was developed to deliver a total dose of 6000 centigray (cGy) (6000 rad) by a combination of 4000 cGy (4000 rad) from an external beam (linear accelerator) and 2000 cGy (2000 rad) from vaginal implant therapy. The external beam therapy was completed on September 9, 1993. The patient was then evaluated and plans were made to complete the implantation portion of the treatment. The treatment plan for the implant therapy included calculations for the time required to deliver 6000 cGy (6000 rad). The dose already delivered by the external beam was not considered in the plan.

The attending physician reviewed the dose calculations on October 9, the fourth day of the implant, and determined that the duration of the implant treatment was likely to have been too long. He immediately removed the implants. Calculations revealed that the patient received 4000 to 4500 cGy (4000 to 4500 rad) from the brachytherapy treatment. Two days later, on Monday October 11, the attending physician verified with the physics staff that his dose calculations were correct. A telephone report was made to the Illinois Department of Nuclear Safety (IDNS) on Tuesday October 12, 1993, and an on-site investigation by IDNS staff was conducted on October 14. A written report from the licensee was submitted to IDNS on October 26. The patient had been notified of the event by the attending physician on October 20.

Cause or Causes—The reportable event was caused by a failure to account for the previously administered external beam therapy. The incident occurred due to lack of communication of the prior therapy during the planning of the brachytherapy treatment.

Actions Taken to Prevent Recurrence

Licensee—As soon as the licensee's management determined that a reportable event had occurred, they formed a committee of professionals not involved in the patient's care to conduct a quality assurance review. The committee concluded that the incident occurred due to lack of communication of the prior therapy during the planning of the brachytherapy treatment. They recommended that no brachytherapy be given without a signed, written prescription by the attending physician. The written prescription must contain information about all radiation therapy given to the patient. The medical center has adopted the committee's recommendations and has initiated training to the affected staff. This action should prevent a recurrence of a similar event.

State Agency—The results of the on-site investigation by IDNS agrees with the findings of the licensee's quality assurance review. The licensee's proposal appears to be adequate to prevent recurrence.

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

AS 93-15 Medical Brachytherapy Misadministration at Mt. Sinai Medical Center in Miami Beach, Florida

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

Date and Place—Between September 28 and November 24, 1993; Mt. Sinai Medical Center; Miami Beach, Florida.

Nature and Probable Consequences—On December 3, 1993, the State of Florida, Office of Radiation Control (ORC) was notified by phone that eight patients with a total of 22 treatments, had received therapeutic exposure to parts of the body not scheduled to receive radiation. These exposures were delivered by a Nucletron Micro-Selectron high-dose-rate (HDR) remote afterloader brachytherapy treatment unit. The device used an iridium-192 (Ir-192) sealed source of approximately 300 gigabecquerel (8.1 curie) as of December 1, 1993. All the patients were receiving gynecological booster treatments after external beam radiotherapy.

The licensee reported that the cause of the misadministrations was due to the use of a 1.5 meter (4.9 foot) Obstetrical/Gynecological (OB/Gyn) transfer tube/applicator combination length instead of a 1.0 meter (3.3 foot) length as intended. Seven of the eight patients were treated with a single transfer tube with an average exposure per treatment of 3.6 centigray (cGy) (3.6 rad). The exposures were given at approximately 51 centimeter (cm) (20 inch) from the intended site and outside of the

patients' bodies, with the source being approximately 30 to 34 cm (12 to 13 inch) from the patients' knee area. The licensee reported that no physical effects were observed or expected in these patients. One patient was treated with four catheters and one transfer tube per treatment. The transfer tube was used to treat the vaginal vault and the four shorter catheters were used to treat the interstitial tissues. Since the transfer tube was longer than the four interstitial catheters, it was looped over the patient's knee for comfort. This patient developed skin erythema in this area and a conservative estimated dose of 4000 to 6000 cGg (4000 to 6000 rad) to the knee area was calculated.

On the same day as the telephone report of the misadministration, an ORC inspector went to the licensee's facility to investigate the cause and assure immediate corrective actions were taken. The ORC inspector confirmed the two different size OB/Gyn transfer tubes and assured that immediate action was taken to segregate the tubes and assured that all transfer tubes were properly measured and marked. Since adequate actions were taken and the authorized user physician stated that it would be difficult and not advisable to switch from the HDR to other treatments for patients already undergoing HDR treatments, the licensee was allowed to complete the therapy for patients that were currently undergoing HDR treatments. These treatments have now been completed and the license has been temporarily amended to a "storage only" status.

The investigation will continue with emphasis on determining the causes of the use of incorrect length transfer tubes, and assuring the necessary corrective actions are in place prior to initiating any new HDR treatments.

Action Taken to Prevent Recurrence

Licensee—The licensee's immediate corrective actions consisted of the following: (1) removed long transfer tubes from treatment room and made inaccessible; (2) requested Nucletron to place some type of identification on transfer tubes; (3) marked all existing transfer tubes in HDR room; (4) revised the procedure and checklist used to verify equipment set-up; (5) obtained an outside consultant to assist in reviewing and modifying the Quality Assurance Program as needed; (6) scheduled retraining by Nucletron of all individuals involved in the use of the HDR; and (7) disallowed any new patient treatments on the unit.

State Agency—The State agency has placed the license on a "storage only" status and is continuing with the investigation as stated above. An independent consultant will be obtained by the State to review the incident and advise on the appropriateness of all findings, conclusions and necessary actions prior to the licensee being authorized to place the HDR unit back in service. The remainder of the investigation is expected to be completed in the next several weeks. NRC has asked the State of Florida to provide additional information regarding their follow-up of this incident.

This report will be further evaluated when additional information becomes available.

AS 93-16 Medical Brachytherapy Misadministration at Richland Memorial Hospital in Columbia, South Carolina

The following information was provided by the licensee to the State of South Carolina and presented in the 1993 third quarter "Report to Congress on Abnormal Occurrences," Appendix D, "Agreement States Events Being Considered as Abnormal Occurrences". This event has been determined to be an abnormal occurrence based on new information received since the initial report to Congress. This abnormal occurrence report is updated as follows:

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

Date and Place—September 24, 1992; Richland Memorial Hospital; Columbia, South Carolina.

Nature and Probable Consequences—A radiation oncology nurse notified the Radiation Safety Officer that she retrieved a 1.1 gigabecquerel (GBq) (30 millicurie [mCi]) cesium-137 (Cs-137) source from a female patient's bed. The patient eventually developed an ulceration beneath her right thigh as a result of being exposed to this source.

The oncology nurse stated that the attending nurse was putting the patient on a bed pan (approximately 10:00 a.m.) when she discovered the source and contacted the oncology nurse. The licensee stated that the patient was undergoing a 42-hour Cs-137 brachytherapy treatment using an applicator. The applicator contained three sources of 1.39, 0.93, and 0.93 GBq (37.5, 25, and 25 mCi) of Cs-137. Each of the two ovoids were to have one 1.39 GBq (37.5 mCi) source. However, one ovoid applicator was found empty. NRC has asked the State of South Carolina to provide clarification and additional details on the treatment plan including the sources used, the planned exposure time, the planned dose schedule, the intended dose, and the dose received up to the time of the incident.

The entire applicator system was then unloaded and returned to the brachytherapy vault where all of the

sources were accounted for. A radiation survey of the patient's room after the unloading showed no additional sources in the patient's room.

In an effort to determine the length of time that the source was out of place, several people were interviewed. The patient was asked and did not know how the source could have gotten out of the applicator. The nurse, who two days earlier loaded the Cs-137 sources into the patient's applicators, said that there was nothing unusual about that loading and that she was confident that she had loaded the applicator properly.

The patient's radiation oncologist said that he had checked the applicator after the insertion and each morning and evening of the treatment and had noticed nothing unusual or any loose sources. His most recent visit was at 8:00 a.m., on the morning of September 24, 1992. The attending nurse said that she had checked the patient and noticed nothing until the morning of September 24, 1992, when she went to help the patient with the bed pan. Upon discovery of the sources, she then contacted radiation oncology. She said that the patient had been on the bed pan several times during her treatment, and that she had checked under the patient and did not see any sources. The chief resident of gynecological services checked the patient during treatment but did not manipulate the applicator.

The licensee's radiation safety officer report stated that there were no staff overexposures as a result of this incident. The patient and family were notified. NRC has asked the State of South Carolina to identify the dose to the wrong treatment site, and to verify that the referring physician was notified of the misadministration.

Since the nurse who inserted the Cs-137 sources insisted that she inserted them properly, and that the physician had just checked the patient that morning and saw nothing, the time of source removal was estimated to be about 8:00 a.m.

This was to be the patient's first of two treatments, and the dose deficit could be made up with the subsequent treatment. However, a second treatment was not attempted because the patient was unable to cooperate enough to undergo a second treatment.

The licensee stated that this event does not meet the State's criteria for a misadministration because if the source was removed sometime after 8:00 a.m. the dose could be corrected with the subsequent treatment. However, NRC does not have sufficient information to verify this and to complete an analysis.

NRC has received additional information since the 1993 third quarter report. Although this information has allowed NRC to conclude that this misadministration is an abnormal occurrence, some concerns with the content of the information provided by the licensee have been identified. NRC has asked the State of South Carolina to investigate this event and to provide a follow-up event description.

Cause or Causes—The licensee stated that either the source fell out of the applicator as it was being inserted and it was not noticed, or a person on the staff opened the applicator out of curiosity and improperly reinserted the source in a loose manner.

Actions Taken to Prevent Recurrence

Licensee—To prevent recurrence of this event, the nursing staff was given refresher radiation safety instruction regarding the use of radioactive sources for cancer treatment.

State Agency—Insufficient information is available on the action(s) taken by the State Agency to prevent recurrence. NRC has asked the State of South Carolina to provide additional information regarding the State agency's action(s).

This event will be further evaluated when additional information becomes available.

REFERENCES

1. Letter from Roy J. Caniano, Chief, Nuclear Materials Safety Branch, NRC Region III, to Robert J. Hickok, Assistant Vice President for Medical Affairs, Washington University Medical School, forwarding inspection reports No. 030-02271/93001, 030-31205/93001, 030-15101/93001, Docket No. 030/02271, 030-31205 and 030/15101, License No. 24-00167-11, dated January 12, 1994.

2. Letter from W. L. Axelson, Director, Division of Radiation Safety and Safeguards, NRC Region III, to Dan Sylvester, Vice President for Professional Services, Good Samaritan Hospital, forwarded inspection report No.030-30954/94001, Docket No.030-30954, License No. 34-16725-02, dated February 11, 1994.

3. The medical consultant's report is filed in Docket No. 030-02983 in the Region I Materials License Docket Room. Inspection Report No. 030-02983/93-001 issued November 5, 1993, and the February 9, 1994, Notice of Violation are in the PDR.

4. The medical consultant's report will be placed in the file for Docket No. 030-02470 located in the Region I Materials License Docket Room. An inspection report will be issued to the licensee by February 18, 1994, and will be available in the PDR.

APPENDIX A

ABNORMAL OCCURRENCE CRITERIA

The following criteria used to determine 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 1,000 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.

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 one intended.	If the improper administration results in any part of the body receiving unscheduled radiation, an AO report should be 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 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 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, an AO report should be proposed for 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 body parts 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.	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 differing 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 the October through December 1993 period, 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. The referenced Abnormal Occurrence Reports below provide the initial and any subsequent updated information on the abnormal occurrences discussed. (The update provided generally covers events that took place during the report period; some updating, however, may be more current as indicated by the associated event dates.) Open items will be discussed in subsequent reports in the series.

Other NRC Licensees

92-18 Loss of Iridium-192 Source and Medical Therapy Misadministration at Indiana Regional Cancer Center in Indiana, Pennsylvania

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

On December 1, 1992, the licensee notified NRC Region I of the loss of a sealed iridium-192 source from the high dose rate remote afterloader unit at their Indiana Regional Cancer Center in Indiana, Pennsylvania. The source was left in the patient on November 16, 1992, and as a result the patient received an estimated dose at 1 centimeter (0.39 inch) of 1,600,000 centigray (cGy) (1,600,000 rad) instead of the intended dose of 1800 cGy (1800 rad). In addition, several members of the general public received radiation exposures of between 400 microsievert (40 millirem) and 220 millisievert (22 rem).

In addition to the actions described in the abnormal occurrence report for the second quarter of 1993 (NUREG-0090, Vol. 16, No. 2), NRC prepared a deficiency letter dated September 27, 1993, requesting that the licensee submit a comprehensive description of its Radiation Safety Program and Procedures, including program audits, facilities certification, personnel training and qualifications, and any other information that it may consider necessary to support safe resumption of brachytherapy operations. The licensee responded to this request in letters dated September 29, 1993, and October 21, 1993. NRC reviewed the licensee's response using Policy and Guidance Directive, FC 86-4, Revision 1, "Information Required for Licensing Remote Afterloading Devices". A deficiency letter was prepared and sent to the licensee on November 4, 1993. The licensee responded to the deficiency letter on December 7, 1993, and "requested full and permanent relaxation of its entire license." This response is currently under NRC review.

This report will be further evaluated when additional information becomes available.

92-19 Medical Therapy Misadministration and Temporary Loss of Brachytherapy Source at Yale-New Haven Hospital in New Haven, Connecticut

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

On December 3, 1992, NRC was notified by the licensee that a 39 year old female patient received a 33 percent undertreatment during a brachytherapy treatment to the cervix and an unplanned 260 centigray (260 rad) exposure to her leg. One of the prescribed sources was either never inserted or was removed from the applicator during treatment and left in her bedding.

NRC Region I conducted a special inspection on December 3 and 4, 1992. An Enforcement Conference was held on January 6, 1993. An NRC medical consultant was retained to review the misadministration. For the violations identified during the special inspection NRC Region I proposed a Civil Penalty of $2,500. On January 21, 1993, the licensee reported a second misadministration (AO 93-3). NRC elected to withhold issuance of the enforcement action for the first incident and issued one enforcement action for both incidents.

Following the staff's review of the second occurrence on April 26, 1993, NRC issued a Civil Penalty in the amount of $10,000 and Confirmatory Order Modifying License (Effective Immediately), which confirmed the licensee's proposal to have a program assessment performed by independent experts. The program assessment was completed on May 10 and 11, 1993. On August 24, 1993, the licensee submitted their Program Assessment Report and Program Improvement Plan which was formulated in response to the program assessment. On November 16, 1993, the licensee submitted the first of the required quarterly reports on the implementation of the Program Improvement Plan and stated that all actions were completed. NRC Region I has reviewed the Program Assessment Report and Program Improvement Plan and is currently preparing a response.

On June 10, 1993, the licensee responded to the Notice of Violation and Proposed Imposition of $10,000 Civil Penalty. In this response, the licensee denied one violation, took issue with the manner in which the civil penalty was determined, and requested mitigation of the civil penalty based on minimal safety significance and lack of programmatic implications. On December 27, 1993, NRC responded to the licensee's request with an Order Imposing Civil Penalties in the amount of $10,000. The licensee responded to the Order by letter dated January 26, 1994, and paid the Civil Penalty of $10,000.

A routine inspection was conducted of the licensee's program from September 28 through 30, 1993. One minor violation of regulatory requirements was identified by the inspector. This violation has since been corrected by the licensee.

This report will be updated when additional information becomes available.

93-3 Medical Therapy Misadministration Involving the Use of a High Dose-Rate Remote Afterloader Brachytherapy Device at Yale-New Haven Hospital in New Haven, Connecticut

This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 1, "Report to Congress on Abnormal Occurrences," January-March 1993. The abnormal occurrence report is updated as follows:

On January 21, 1993, NRC was notified by the licensee that a female patient received a 50 percent undertreatment during a brachytherapy procedure to the vagina and an unplanned 700 centigray (700 rad) exposure to her rectum when the physician mistakenly inserted the HDR applicator into the rectum instead of the vagina.

NRC Region I conducted a special inspection on January 26 and 27, 1993. The licensee was given the option of participating in an enforcement conference but declined. A medical consultant was retained to review the misadministration. On April 26, 1993, NRC proposed a Civil Penalty in the amount of $10,000 and Confirmatory Order Modifying License (Effective Immediately) which confirmed the licensee's proposal to have a Program Assessment performed by independent experts. The Program Assessment was completed on May 10 and 11, 1993. On August 24, 1993, the licensee submitted the report of the Program Assessment and their Program Improvement Plan which was formulated in response to the Program Assessment. On November 16, 1993, the licensee submitted the first of the required quarterly reports on the implementation of the Improvement Plan and stated that all actions were completed. NRC Region I has reviewed the Program Assessment Report and Program Improvement Plan and is currently preparing a response.

On June 10, 1993, the licensee responded to the Notice of Violation and Proposed Imposition of $10,000 Civil Penalty. In this response, the licensee denied one violation, took issue with the manner in which the civil penalty was determined, and requested mitigation of the civil penalty based on minimal safety significance and lack of programmatic implications. On December 27, 1993, NRC responded to the licensee's request with an Order Imposing Civil Penalties in the amount of $10,000. The licensee responded to the Order by letter dated January 26, 1994, and paid the Civil Penalty of $10,000.

A routine inspection was conducted of the licensee's program from September 28 through 30, 1993. One minor violation of regulatory requirements was identified by the inspector. This violation has since been corrected by the licensee.

This report will be updated when additional information becomes available.

93-10 Medical Sodium Iodide Misadministration at Osteopathic Hospital Founders Association DBA (doing business as) Tulsa Regional Medical Center in Tulsa, Oklahoma

This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 3, "Report to Congress on

Abnormal Occurrences: July-September 1993." The abnormal occurrence report is updated as follows:

In July 1993 the wrong patient was administered 0.21 gigabecquerel (GBq) (5.7 millicuries [mCi]) of iodine-131 (I-131). The misadministration occurred because the licensee failed to verify patient identity.

The NRC staff retained a medical consultant to evaluate the potential medical effects to the patient as a result of the misadministration. The consultant provided a report in October 1993, which stated that the impact of the incident on the status of the patient's health should be negligible, with no expected long-term disability as a result of this misadministration.

On January 11, 1994, the NRC issued a Notice of Violation to the licensee. The licensee was cited for failing to require individuals working under the supervision of authorized users to follow the instructions of the supervising authorized user and the written radiation safety and quality management procedures established by the licensee. Because the misadministration was the result of an isolated failure to follow the quality management procedures and was of limited consequence to the patient, no escalated enforcement action was taken by the NRC.

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

Agreement State Licensees

AS 87-5 Therapeutic Medical Misadministrations At Northern Westchester Hospital Center, Westchester County, New York

This abnormal occurrence was originally reported in NUREG-0090, Vol. 10, No. 3., "Report to Congress on Abnormal Occurrences," July-September 1987, and closed out at that time. It was reported that 22 patients received cobalt teletherapy misadministrations at Northern Westchester Hospital in Westchester County, New York, between 1982 and 1987.

This abnormal occurrence was reopened because the original report contained several incorrect statements. The following report was prepared by the State of New York to correct the errors.

Date and Place—On August 5, 1987, the New York State Department of Health Bureau of Environmental Radiation Protection was notified that mistakes in treatment planning had been discovered and that some cobalt teletherapy patients had received excess radiation at Northern Westchester Hospital Center.

Nature and Probable Consequences—The hospital had contracted with a physics consulting group (Radiological Physics Associates, Elmsford, New York) to provide physics services. A dosimetrist from the group, who normally prepared treatment plans, was not available and upon review of one plan by another physicist from the group, it was discovered that the dosimetrist had made errors in his calculations. The State Health Department was notified of the mistakes and the hospital was directed to discontinue therapy until treatment plans had been reviewed and verified as correct and the cobalt teletherapy unit recalibrated. Twenty-two patients were identified as having received incorrect treatments ranging from 50 percent underdose to approximately 100 percent overdose (total dose). All of the associated plans were prepared by the same dosimetrist.

An outside radiological physicist reviewed about 250 treatment plans including those of affected patients. The conclusion was that the dosimetrist made somewhat random mistakes, that is, plans were done with the correct methods in some cases and incorrectly at other times. Overall, the cases indicated a lack of understanding of the computer program used for treatment planning and the methods of calculation of timer settings from the computer output. Furthermore, there were no second checks performed which may have caught these mistakes.

Northern Westchester Hospital Center was directed by the State Health Department to follow-up on the affected patients for at least 1-year and to provide status reports to the department. At the time of the last report (May 1988), 11 of the 22 patients had died. Some of the deaths may have been from complications related to the misadministration in question. Other patients returned for further treatment. All treatment records for the affected patients were requested for review by the State's Radiological Health Advisory Committee. The committee did not have any comments that would counter the assertions by the hospital. The New York State Department of Health notified the NRC that the dosimetrist involved is no longer working at the hospital or any other facility in New York State. The physicist in charge of the consulting group stopped providing therapy services in New York State after the incident and only performed diagnostic x-ray and nuclear medicine consulting services.

The State requested the names of other facilities where physics services were performed by the same dosimetrist. Two other hospitals and a private office were identified

where the dosimetrist performed treatment planning. All three facilities were notified and had independent physics reviews of treatment plans. At one of the hospitals, mistakes were found in two treatments involving a wedge; however, the total dose delivered was within 10 percent of that prescribed. At that same hospital, a mistake in the calibration of an orthovoltage unit was discovered which resulted in 22 patients receiving doses in excess of 10 percent of those prescribed. That calibration was performed by the senior member of the physics consulting group. Those patients were followed up and no adverse outcomes were reported.

Cause or Causes—The dosimetrist involved lacked understanding of the computer treatment planning software and other basic methods in determining treatment times. Quality assurance of treatment planning was inadequate and no second checks of treatment plans were performed.

Actions Taken to Prevent Recurrence

Licensee—Insufficient information is available on the action(s) taken by the licensee to prevent recurrence. NRC has asked the State of New York to provide additional information regarding the licensee action(s).

State Agency—License conditions concerning the qualifications of physicists, treatment prescriptions, second checks, and misadministrations were added to all teletherapy licenses in 1988. Since that time, the State Sanitary Code has been revised to include specific requirements for quality assurance in radiation therapy for all therapy modalities. The State of New York believes that the dosimetrist involved no longer performs treatment planning in New York State. The senior physicist in the consulting group did not perform any therapy functions in New York State after the incident.

This report will be further evaluated when additional information becomes available.

AS 88-4 Multiple Medical Therapy Misadministrations by Rochester General Hospital in Monroe County, New York

This abnormal occurrence was originally reported in NUREG-0090, Vol. 11, No. 4, "Report to Congress on Abnormal Occurrences," October-December 1988 and closed out at that time. It was reported that 19 patients received cobalt teletherapy misadministrations at Rochester General Hospital in Monroe County, New York, between January 1988 and August 1988.

This abnormal occurrence was reopened because the following new significant information concerning enforcement action and the status of the affected patients became available.

Enforcement action was initiated by the New York State Department of Health which included provisions that the hospital take the following actions: commit to comprehensive quality assurance reviews for radiation therapy, submit quarterly progress reports for each component of the stipulation, order of the enforcement action, implement quality assurance reviews, mandatory periodic in-service training, testing of physics staff, and perform a periodic follow-up of the affected patients for 1-year.

Reports of the patient follow-up were submitted to the State of New York, Department of Health. As of December 1990, the reported status of the patient's condition involved in the misadministration is as follows: two patients had laryngectomies; one patient had necrosis of the larynx; three patients had discomfort in the treatment area; one patient had a rib fracture; four patients had skin changes; three patients had atrophy in the breast; one patient had a radiation ulcer, one patient had radiation proctitis, and nine patients died from complications not related to the misadministration.

The State radiation control regulations have been revised to include requirements of Quality Assurance programs, audits of therapy programs, misadministration reporting and training and experience requirements for therapy physicists.

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

AS 93-7 Medical Radiopharmaceutical Misadministration by "Unspecified Licensee" in Albany, New York

This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 3, "Report to Congress on Abnormal Occurrences," July-September 1993. The abnormal occurrence report is updated as follows:

Date and Place—October 5, 1992.

The name of the licensee has been withheld by the State of New York due to provisions in New York State Public Health law.

Nature and Probable Consequences—A patient was administered 303.4 megabecquerel (MBq) (8.2 millicurie [mCi]) of phosphorus (P-32), instead of the prescribed 185

MBq (5 mCi) of P-32, as an outpatient receiving radiation therapy treatment. The patient was discharged in stable condition. The mistake was caught when the Chief Technologist was reviewing the records of doses prescribed and comparing these to the doses administered. Immediate action was taken to follow-up on the discrepancy. The attending physician and patient were notified of the misadministration. The patient's blood count monitoring frequency was changed from monthly to bi-weekly and the patient was monitored for potential infections. Six weeks after the administration of P-32, the patient's blood count was normal except for a decrease in the platelet count, which remained within the range of safety and represented the expected therapeutic response.

Cause or Causes—The licensee's account of the cause is as follows: The stated package dose was 185 MBq (5 mCi), calibrated to a date 10 days after the date on which the technologist drew the dose. The technologist failed to take notice of the calibration date and assumed that the stated package dose of 185 MBq (5 mCi) was drawn for administration. Although the dose calibrator measurement of the prepared (drawn) dose indicated a significant discrepancy between the prescribed dose and the measured dose, the technologist failed to investigate the cause of this discrepancy and did not notify the physician in regard to the discrepancy. A dose of 303.4 MBq (8.2 mCi) was administered to the patient by the physician, a Board Certified Radiologist.

Actions Taken to Prevent Recurrence

Licensee—The corrective actions reported by the licensee included the implementation of a modified radiopharmaceutical therapy protocol for P-32 and iodine-131 administrations, and training for the technologists. In addition, a work sheet and check list, designed with several checks for technologists and physicians prior to administration of the dose were developed for P-32 therapy. The physician involved in the procedure was counselled and the technologist was suspended from administration of therapy doses for a minimum period of six months. The Chief Technologist and Nuclear Medicine Physician will evaluate the technologist prior to allowing him or her to begin administering therapeutic doses again.

State Agency—The State required the licensee to submit a plan of corrective action designed to prevent recurrence. The corrective actions reported by the facility appear to be satisfactory.

This item is considered closed for purpose of this report.

AS 93-8 Medical Sodium Iodide Misadministration at Inland Imaging in Spokane, Washington

This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 3, "Report to Congress on Abnormal Occurrences," July-September 1993. The abnormal occurrence is updated as follows:

Date and Place—December 14, 1992; Inland Imaging; Spokane, Washington.

Nature and Probable Consequences—On December 14, 1992, a patient diagnosed as hyperthyroid was referred to the licensee by the Fairchild Air Force Base Hospital for a thyroid uptake scan of .26 megabecquerel (MBq) to 3.7 MBq (7-10 microcuries) of iodine-131 (I-131). The patient was mistakenly administered a 196 MBq (5.3 millicurie) dose of I-131, sodium iodide for a whole body scan. As a result, the patient's thyroid received a dose of approximately 7950 centigray (7950 rad).

The nuclear medicine technologist misinterpreted the orally requested procedure and failed to verify the requested procedure through review of the referring physician's written requisition. The patient's physician, an endocrinologist, was notified and did inform the patient.

The licensee reported that both a whole body scan and the requested thyroid uptake study were performed three days after the misadministration "with no patient complaints or immediate side effects." The licensee has noted that the patient will most probably be hypothyroid for the rest of his life and that future litigation remains a possibility. No NRC or State medical consultant has been contracted to review this event.

Cause or Causes—This event was attributed to human error as a result of the technologist's inattentiveness and relatively short experience at this facility. Although the referring physician's written request was available at the time the dosage was prepared and administered, the technologist failed to reconcile the dose and study prescribed with the dose and study given.

Actions Taken to Prevent Recurrence

Licensee—The technologist and the lead technologist (who was not present) were counseled and reinstructed by the authorized physician user/radiation safety officer. A review by the licensee of all such administrations for the prior 6 months revealed that the technologists were inconsistent in verifying written referrals with the study given, prior to administration. The licensee stated that all iodine studies are required to be verified against the written request slips prior to any iodine administration.

State Agency—The State has accepted the licensee's determination for the cause of this event and subsequent actions taken to prevent recurrence. This will be reviewed at the time of the next routine compliance inspection. As a result of this incident, the next inspection has been scheduled for the second quarter of 1994.

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

APPENDIX C

OTHER EVENTS OF INTEREST

The following items are described because they may possibly be perceived by the public to be of health or safety significance. The items did not involve a major reduction in the level of protection provided for public health or safety; therefore, they are not reportable as abnormal occurrences.

Nuclear Power Plants

1. Cracks in the Core Shroud at Brunswick Unit 1 Nuclear Plant

In July 1993, while performing in-vessel visual inspections of the Brunswick Unit 1 reactor vessel core shroud in accordance with the recommendations contained in General Electric Company (GE) Rapid Information Communication Service Information Letter (RICSIL) No. 054, Carolina Power and Light Company discovered an approximate 360-degree circumferential crack on the inside diameter (ID) of the core support shroud at the circumferential corner weld designated H-3 weld. The core shroud is a cylindrical assembly inside the reactor vessel which provides a partition to properly distribute the flow of coolant delivered to the vessel. The core shroud is not an American Society of Mechanical Engineers (ASME) Code component; however, its safety design basis is to:

(a) provide a floodable volume in which the core can be adequately cooled in the event of a breach in the Reactor Coolant System external to the reactor vessel, and

(b) limit deflection and deformations of the reactor vessel internals to assure that the control rods and the core standby cooling systems can perform their safety functions during abnormal operational transients.

The H-3 weld is a 5.72 centimeter (cm) (2.25 inch [in]) thick corner weld which joins the top guide support ring to the shroud's 3.8 cm (1.5 in) thick mid-section which surrounds the fuel. The top guide support ring is a 7.6 cm (3 in) high x 19 cm (7.5 in) deep section of type 304 stainless steel plate, with a carbon content of about 0.06 percent, which serves as the transition between the larger diameter upper core shroud and the core shroud mid-section. The crack was located in the weld, heat-affected zone on the short transverse edge of the top guide support ring plate, and measured 2.4 cm (0.95 in) to 4.34 cm (1.71 in) in depth. The crack was unique not only because of its significant length, depth, and location above the fuel (lower neutron fluency), but because the H-3 weld was not a seam weld. The GE RICSIL had focused utility inspections on seam welds since previously observed cracking was reported adjacent to a circumferential seam weld in a core shroud of a foreign-owned GE boiling water reactor (BWR).

Analysis of boat samples (a small size material specimen) taken from the crack indicated that the cracking is primarily intergranular stress corrosion cracking (IGSCC). Crack extension is possibly assisted by neutron fluency and oxide wedging at certain locations. Susceptible material conditions, high residual stress from fabrication, and exposure to a strong oxidizing environment are sufficient to produce the cracking observed. Because these factors are not consistently present across the shroud, the location and degree of cracking varies across the shroud.

In addition to the crack in the H-3 weld, a short axial crack was also discovered during the initial visual inspection on the outside diameter (OD) of the shroud mid-section adjacent to a horizonal seam weld designated H-4.

The occurrence of the crack found at weld H-3 was analyzed and determined to be potentially safety significant because if weld H-3 failed completely and a large main steam line break was to occur, the hydrodynamic loads across the shroud are sufficient to result in the top guide core structure being lifted above the fuel assemblies. Should this happen, the lateral support to the assemblies would no longer be provided and the control rods may fail to fully insert.

The licensee performed additional visual examinations of all of the core shroud welds. These examinations revealed that the techniques required by the ASME Code were insufficient to detect the numerous tight axial and circumferential IGSCC cracks that were subsequently found at welds H-1, H-2, H-4, H-5, and H-6a. In order to detect and to determine the extent of cracking in these welds, the licensee had to enhance the examination techniques by brush cleaning the areas to be examined, using a

standard 1 mil (0.00254 cm [0.001 in]) wire as a calibration reference standard in lieu of the "0.08 cm (0.03 in) black line on a 18 percent neutral grey card" required by the ASME Code, and precisely focus the light source and camera to maximize the reflectivity of the crack. The result of these enhanced inspections revealed that the cracks associated with corner welds H-1 and H-2 were also of significant length. The largest crack discovered at a seam weld location in the shroud mid-section shell plates was a 106.7 cm (42 in) long circumferential crack at weld H-5.

The licensee evaluated the cracks in the core shroud in accordance with the screening criteria contained in GE Report No. GENE-523-123-0993, Rev. 1, "Evaluation and Screening Criteria for the Brunswick Shroud Indications." The report used a 762 cm (300 in) allowable through-wall flaw length which was derived from the limit load analysis as the basis for setting a screening criteria of 190.5 cm (75 in) for each 90-degree quadrant of the shroud. The screening criteria was considered on a "rolling" quadrant basis with the worst cracking defining the radial orientation of a quadrant. The axial and circumferential cracks at seam welds H-4, H-5, and H-6a were satisfactorily bounded by the screening criteria.

The cracks in the H-2 and H-3 welds exceeded the limits associated with the above criteria. Based on additional fracture mechanics analyses, the licensee concluded that the H-3 weld would be acceptable for continued operation without repair. Nonetheless, the licensee elected to implement a repair encompassing the H-2 and H-3 welds to justify continued operation of the shroud. The repair consisted of a series of twelve "brackets" with one installed at each 30-degree increment around the diameter of the shroud. The brackets were installed on the outside surface of the shroud with two bolts attaching the bracket to the upper shroud above weld H-2, and two bolts attaching the bracket to the mid-section below weld H-3. The cracking (from less than 0.75 cm to 1.8 cm [from less than 0.3 in to 0.7 in] in depth) in the H-1 corner weld also exceeded the GE screening criteria for length. The licensee however concluded that this cracking did not require repair based on the fracture mechanics evaluation of the H-3 weld cracking.

Based on the recommendation contained in RICSIL No. 054, the licensee had also visually examined Unit 2 during a refueling outage in July 1991. No cracks were identified at that time. The video tapes of the Unit 2 shroud in vessel visual inspection were re-examined based on the July 1993 Unit 1 findings. Utilizing a digitized enhancement process, the re-examination revealed three 2.5 cm (1 in) indications in the heat-affected zone of the weld H-2. A subsequent inspection in September revealed another 2.5 cm (1 in) long indication. The indications were assumed to be cracks (although not confirmed) and were conservatively evaluated by the licensee in an Engineering Evaluation Report (EER). The quality of the 1991 tapes however was insufficient to identify all of the types of cracks that had been confirmed on Unit 1.

The primary purpose of the above EER was to evaluate the significance of the indications observed in the Unit 1 shroud with respect to the operation of the unit for another cycle, and to evaluate the significance of postulated conditions in the Unit 2 shroud with respect to operation of the unit until the next refueling outage in March 1994.

The EER concludes that the structural integrity of the Unit 1 core shroud (without the repair that was performed) would be maintained, with full Final Safety Analysis Report (FSAR) safety margins, for a minimum of one additional fuel cycle. Based on a comparison of the fabrication histories of the shrouds, water chemistry history, operating time of the units, and similar IGSCC patterns, the licensee concluded that the conditions seen on Unit 1 also bounded Unit 2. Therefore, Unit 2 will remain within its design basis and will be operated until the spring refueling outage in 1994.

Actions taken by the licensee to prevent recurrence consisted of: (1) performing a detailed enhanced examination of the entire Unit 1 core shroud; (2) performing an evaluation of the structural integrity of the core shroud and determining that the crack at H-3 is the bounding case; and (3) implementing a permanent repair utilizing mechanical clamps which encompassed the H-2 and H-3 welds. The licensee has also held discussions with NRC and has indicated that their Inservice Inspection (ISI) Program will be augmented to include inspection of the installed repair brackets. NRC issued Information Notice 93-79 to alert other BWR Owners of the findings from the Brunswick Unit 1 core shroud inspections. GE also issued Service Information Letter (SIL) No. 572 which recommends that visual examinations be performed of accessible areas on both the ID and OD surfaces of the core shroud at the next scheduled refueling outage for all BWR plants with type 304 stainless steel shrouds with 6 or more years of power operation and for all plants with L-Grade (low carbon content) stainless steel shrouds with 8 or more years of power operation.

This SIL recommends that inspections be performed with enhanced visual testing (a VT-1 system that can

resolve a standard one mil [0.00254 cm (0.001 in)] wire on the inspection surface).

This event is included in Appendix C because the public may perceive the damage to the core shroud to be of public health and safety significance. A damaged core shroud can prevent a floodable volume from being maintained in the core during a breach in the Reactor Coolant System and inhibit the control rod and core standby cooling systems from performing the safety function. This condition was discovered during routine inservice inspection with the reactor shutdown and the reactor vessel disassembly. The licensee has taken appropriate actions to correct the existing condition and to prevent future damage to the core shroud. Generic communications have been issued by GE and NRC to alert other licensees of this potential safety concern.

2. Jet Pump Beam Failure at Grand Gulf Nuclear Plant

The Grand Gulf Nuclear Plant consists of a single General Electric boiling water reactor design six (BWR 6) located near Port Gibson, Mississippi, and operated by Entergy Operations, Inc.

On September 13, 1993, Grand Gulf had a reactor scram on high-water-level due to an unplanned high-pressure-core-spray (HPCS) initiation. The immediate cause of the HPCS initiation was found to be a reactor low-water-level signal to the HPCS circuitry. The reasons for the water level anomalies in the C and G channels could not be determined immediately. During restart from the scram, jet pump differential pressure anomalies were discovered. Upon reaching higher flows in an effort to investigate the problem, the plant experienced oscillating water level indications on some instrumentation, and instrument readings characteristic of a displaced jet pump mixer section. A decision was made to enter the plant's planned refueling outage about 3 weeks early.

After reactor shutdown and disassembly, jet pump number ten (JP10) was found to have been displaced to between JP8 and JP9. The larger piece of the jet pump beam for JP10 was found near JP6. The beam was found to have cracked and failed in an area not identified in previous BWR beam failures.

Ultrasonic testing (UT) examination of the in-service jet pump beams identified unacceptable indications on JP8 and JP21 in locations typical of previous intergranular stress corrosion cracking (IGSCC) failures. JP10 failed in the transition area between the main body of the beam and the hold down lugs. One lug failed completely, leading to the jet pump disassembly and displacement of the mixer section. The failure originated in an area in which a radius machining cut had been made in the forging. This is an area of the beam with a cross section smaller than the previously affected areas. The currently required UT beam examinations would not detect cracking in the new location, because these examinations are typically performed in the areas with a history of cracking.

Visual examination of the failed beam, conducted prior to the beam being sent offsite to a hot cell for examination, showed a crack of greater than 270 degrees of the cross section of the intact lug. The other lug had cracked in the same area and was missing.

Initial examination of the jet pump beam by General Electric Company, indicates that the probable cause of failure was an IGSCC-initiated crack that propagated through to failure. Fatigue may have contributed to crack growth prior to failure. General Electric Company recommended that the licensee of all BWRs with beams that do not have the new heat treatment should evaluate their plants with respect to mid-cycle failures of the jet pump beams. An accumulated service life of 8 years (Grand Gulf's time minus 1 year) was recommended as the benchmark for evaluation until other guidelines can be established based upon additional testing of the failed beam. Grand Gulf has replaced all of their jet pump beams with spares available onsite.

The licensee performed a review of the data available from Grand Gulf's inadvertent HPCS initiation and the water level anomalies during the recent restart. The proximity of the jet pump to the instrument nozzle of the affected instruments was considered and the most likely cause of the HPCS injection and the water level anomalies was determined to be the impact of the water jet force from the displaced jet pump mixer on the instrument nozzle.

NRC issued Information Notice 93-101, "Jet Pump Hold-down Beam Failure," to alert licensees to the new type of failure not discussed in IE Bulletin 80-07, "BWR Jet Pump Assembly Failure."

This event is included in Appendix C because it may possibly be perceived by the public to be of public health or safety significance. The displacement of the jet pump mixer will increase the time required to re-flood the core to 2/3 core height; however, for the jet pump failure to become a core cooling problem, it has been shown that as many as 10-12 jet pumps must disassemble. The reactor was automatically shutdown when the failure occurred and was

operated at low power only long enough to determine that a jet pump failure had occurred.

3. Fire at Enrico Fermi Nuclear Plant, Unit 2

The Fermi 2 Nuclear Power Plant consist of a single General Electric boiling water reactor design 4 (BWR 4) located near Monroe, Michigan. It is operated by Detroit Edison Company.

On December 25, 1993, the plant experienced a fire in the main generator and generator exciter, and a catastrophic failure of the turbine. The fire in the generator and exciter appeared to be the result of hydrogen leakage, explosion and burn. The cause of the turbine failure is still under investigation.

At the time the Fermi plant was at 93 percent power. At 1:15 p.m. a turbine trip and reactor scram occurred as a result of the turbine failure. All reactor safety systems functioned as intended, and the plant shut down as designed. The licensee declared an Alert under its Emergency Plan.

At About 1:30 p.m. an emergency response team entered the turbine building and observed heavy smoke and flowing water from a number of sources including the fire suppression system. A small fire in the exciter area was extinguished. The fire suppression system in areas of the turbine building was secured only after plant personnel determined the fire was extinguished.

The turbine failure resulted in damaged water lines in the general service water system and the turbine building closed cooling water system. About 500,000 gallons of water from the fire suppression system and the damaged water lines accumulated in the basements of the turbine building and the adjacent radioactive waste processing building. Also mixed in the water was approximately 17,000 gallons of oil from the turbine seal and lubricating oil systems.

A portion of a blade from the No. 3 low pressure turbine penetrated the turbine housing and flew about 75 feet. Other debris from the turbine was ejected into the condenser hotwell beneath the turbine, damaging condenser tubes. The tube damage resulted in circulating cooling water from the lake being pumped to the condensate storage tank and then into the reactor cooling system. Lake water is high in mineral content and contain other contaminants that are not acceptable in the reactor cooling system water.

There was no release of water containing radioactivity directly associated with the accident. Airborne radioactive releases were in the range of those during normal operations.

An Augmented Inspection Team (AIT), composed of NRC Region III (Chicago) and headquarters based personnel was sent to the Fermi 2 plant to investigate this event.

The licensee has not determined the cause of the turbine damage. Five blades of the eighth stage of the No. 3 low pressure turbine failed and were ejected. Other blades in the stage were damaged by the debris. The licensee has not determined the scope of repairs or the expected length of the outage.

The AIT concluded that with few exceptions, plant personnel and equipment responded effectively to the turbine accident and brought the reactor to a safe shut down condition.

Because of the volume of water generated by this incident, the licensee announced in February 1994 that it planned to release up to 1.5 millions gallons of slightly radioactive water. According to the licensee's announcement, any such releases would not exceed the limits of Title 10 of the *Code of Federal Regulations* (10 CFR) for effluent release of radioactive materials.

The announcement of the plans to release the water attracted considerable attention from the news media, general public, and State and local governments.

The initial plan of the licensee was to release 532,000 gallons of water contained in the Condensate Storage Tank. The licensee had been processing the water with filters and demineralizers to minimize the levels of radioactive contamination. This release would provide additional storage capacity for the water in the turbine building basement as it was processed to remove radioactivity and other contaminants.

Samples of the water in the tank were analyzed by the licensee, by NRC Region III in its mobile laboratory which was sent to the site, and by the State of Michigan Department of Public Health. The analysis from all samples taken, showed the levels of radioactivity to be a small fraction of the 10 CFR allowable effluent release limits. The radioactivity in the tank would represent a radiation dose of 0.02 millirem to the maximally exposed individual. The allowable annual radiation dose limit from Fermi 2 effluent releases is 3 millirem per year.

The contents of the Condensate Storage Tank were released February 24-25, 1994. Measurements by the NRC during the release showed no measurable

radioactivity above natural background levels at the point it was released into Lake Erie. Measurements at the Monroe, Michigan, water supply facility showed no measurable radioactivity.

Additional water releases may be made, depending on available storage capacity and water needs at the Fermi 2 site. Any such releases must meet NRC limits.

This event is included in Appendix C because it had been perceived by the public to be of public health or safety significance. The turbine damage, reactor coolant system contamination, and release of radioactive material do have financial implications but did not result in a measurable increase in radiation exposure or an increase risk to public health and safety. The reactor was brought to a safe shutdown condition and no personnel injuries occurred as a results of this event.

4. Steam Generator Boiled Dry at McGuire Nuclear Plant, Unit 2 as a Consequence of a Loss of Offsite Power

The McGuire Nuclear Station consists of two Westinghouse designed Pressurized Water Reactors (PWR) located in Huntersville, North Carolina, and operated by the Duke Power Company.

On December 27, 1993, McGuire Unit 2 was operating at 100 percent power when an electrical insulator in the 525 KV switchyard failed. This caused one of the two paths feeding the switchyard from the main generator to isolate. The main generator failed to runback as designed, and the second offsite path isolated on overcurrent, resulting in a loss of offsite power to the plant. The electrical transient caused a reactor trip and turbine trip. Both emergency diesel generators started and loaded as designed. An excessive cooldown and depressurization resulted in a low pressurizer pressure safety injection followed by a steam line low pressure safety injection and main steam isolation valve closure signal. The main steam isolation valve for the B steam generator failed to fully close, which caused continued depressurization of that steam generator. Because the plant conditions were symptomatic of a steam leak outside containment, operators properly isolated all feedwater to the B steam generator, and over the next 1-hour and 15-minutes, the steam generator boiled to a dryout condition. Primary system pressure was reduced in order to maintain a maximum of 1600 psid across the steam generator tubes by discharging through the pressurizer power operated relief valves. This led to the eventual actuation of the primary relief tank rupture disc and contributed to opening of some ice condenser doors. One source of offsite power was restored 1-hour and 15-minutes after the event initiation. The plant reached cold shutdown on December 29, 1993.

An NRC Augmented Inspection Team (AIT) was dispatched to the McGuire Nuclear Station on December 28, 1993. Based on the findings from the AIT inspection report, issued February 3, 1994, the team concluded that ineffective design controls, associated with equipment overcurrent protection schemes, led to the McGuire Unit 2 loss of offsite power event. Original design and subsequent modifications relied on the main turbine generator to runback to the half power in the event of a single fault on one offsite source. This dependence was not clearly understood by the licensee. The runback failed to function following a fault on one line, due to a misconfigured circuit card. Inadequately coordinated protective relays tripped the redundant offsite source instead of the main generator output circuit breaker resulting in a loss of offsite power.

The AIT concluded that ineffective maintenance and testing controls contributed to the failure of the B steam generator main steam isolation valve to fully close on demand. Clearance tolerances between valve components were not established and checked while at normal operating temperature as recommended by the valve vendor. The valve was also not subjected to tests which would demonstrate its ability to function at operating temperature.

The AIT also determined that corrective actions regarding excessive cooldown and depressurization, from a previous loss of offsite power event, were not effective in preventing recurrence. As a result, this event required engineered safety features to actuate. Without further actions to address this, a safety injection is highly probable following loss of offsite power event.

NRC is currently drafting an Information Notice to discuss the importance of maintenance and testing of a steam generator main steam isolation valves at normal reactor operating temperature.

This event is included in Appendix C because it may possibly be perceived by the public to be of public health or safety significance. This event did not involve a major reduction in the protection provided for public health and safety; therefore, it is not reportable as an abnormal occurrence.

Other NRC Licensees

5. Medical Brachytherapy Misadministration at the University of Minnesota in Minneapolis, Minnesota

This item was previously considered as an abnormal occurrence (AO) but was rejected because it did not meet the AO criteria of 50 percent overdose. However, it is being considered for reporting in "Other Events of Interest" of the AO report, as recommended by NRC Management Directive 8.1. A brachytherapy misadministration occurred on June 8, 1993, at the University of Minnesota in Minneapolis, Minnesota. The misadministration involved a patient receiving an absorbed dose of 3792 centigray (cGy) (3792 rad) instead of the prescribed 2592 cGy (2592 rad) for an overdose of 46 percent.

On June 8, 1993, a patient was to receive the first of two brachytherapy procedures for treatment of cervical cancer at the University of Minnesota, Minneapolis, Minnesota. The treatment involves placement of sealed radiation sources in a holding device which is surgically implanted in the patient's vagina.

The patient's physician prescribed the use of one cesium-137 source (9.1 milligram radium equivalent) and three cesium-137 sources (each 13 milligrams radium equivalent).

The medical physicist who prepared the sources took three 22.1 milligram radium equivalent sources from storage instead of the three 13 milligram sources. The four sources prepared by the medical physicist were then placed in the implant device. The implant was removed from the patient on June 10 as planned. The error in the source strengths was discovered on June 14 when the medical physicist returned the sources to the storage safe.

The use of the incorrect source strength resulted in the patient receiving a radiation dose of 3792 cGy (3792 rad) to the treatment area instead of the intended 2592 cGy (2592 rad). This represents a misadministration since the actual dose was 46 percent greater than that prescribed. The patient and the treating physician were notified of the misadministration.

Since this was the first of two brachytherapy treatments, the second treatment was modified to account for the excessive exposure in the first treatment.

NRC Region III (Chicago) retained an NRC medical consultant to evaluate the case. He concluded that the outcome of the two procedures together should be equivalent to the course of treatment originally planned. No adverse effects would be anticipated as a result of the misadministration.

APPENDIX D

AGREEMENT STATE EVENTS BEING CONSIDERED AS ABNORMAL OCCURRENCES

For this report, there are no potentially significant events with insufficient information to determine applicability for reporting as abnormal occurrences.

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11. ABSTRACT (200 words or less)

Section 208 of the Energy Reorganization Act of 1974 identifies an abnormal occurrence 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 events to be made to Congress. This report covers the period from October 1 through December 31, 1993. This report discusses six abnormal occurrences at NRC-licensed facilities. Five involved medical brachytherapy misadministrations, and one involved an overexposure to a nursing infant. Seven abnormal occurrences that were reported by the Agreement States are also discussed, based on information provided by the Agreement States as of February 28, 1994. Of these events, three involved brachytherapy misadministrations, one involved a teletherapy misadministration, one involved a theft of radioactive material during transport and improper disposal, and two involved lost sources.

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

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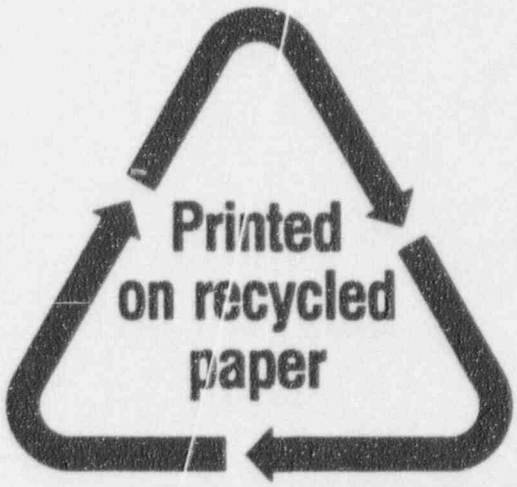

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