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

CHAIRMAN

April 7, 1994

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

Dear Mr. President:

I am forwarding the Nuclear Regulatory Commission's report on abnormal occurrences at licensed facilities for the third quarter of calendar year 1993. These quarterly reports are required by Section 208 of the Energy Reorganization Act of 1974 (PL 93-438). In the context of the Act, an abnormal occurrence is an unscheduled incident or event that the Commission determines is significant from the standpoint of public health or safety.

This report discusses two abnormal occurrences at NRC-licensed facilities. One involved a medical sodium iodide misadministration and the other involved a review of a previously reported fatal radiation exposure of a radiographer in 1981. One industrial radiographer overexposure event and four medical misadministrations that were reported by the Agreement States are also discussed, based on information provided by the Agreement States as of November 1, 1993. The report also contains information updating four previously reported abnormal occurrences at NRC-licensed facilities and three reported by the Agreement States, and includes information on two other events of interest.

Appendix D describes events submitted by Agreement States for which the information available as of November 1, 1993, was insufficient to positively identify them as abnormal occurrences. These events are likely to be characterized as abnormal occurrences after further review and analysis.

Sincerely,

Ivan Selin

Enclosure:
As stated

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

CHAIRMAN

April 7, 1994

The Honorable Thomas S. Foley
Speaker of the United States
House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

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NUREG–0090
Vol. 16, No. 3

Report to Congress on Abnormal Occurrences

July – September 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 July 1 through September 30, 1993.

This report discusses two abnormal occurrences at NRC-licensed facilities. One involved a medical sodium iodide misadministration and one involved a 1981 fatal radiation exposure of a radiographer. One industrial radiographer overexposure event and four medical misadministrations that were reported by the Agreement States are also discussed, based on information provided by the Agreement States as of November 1, 1993. The report also contains information updating four previously reported abnormal occurrences at NRC-licensed facilities and three reported by the Agreement States, and includes information on two 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 as of November 1, 1993, to positively identify them as abnormal occurrences.

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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 July 1 through September 30, 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 submitted, 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 JULY–SEPTEMBER 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.

93–9 Medical Sodium Iodide Misadministration at Osteopathic Hospital Founders Association DBA (doing business as) Tulsa Regional Medical Center in Tulsa, Oklahoma

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 1 in Table A-1) of this report notes that a diagnostic dose of a radiopharmaceutical to a part of the body receiving radiation improperly, if greater than five times the intended dose to that body part, should be considered an abnormal occurrence.[1]

Date and Place—July 27, 1993; Osteopathic Hospital Founders Association DBA (doing business as) Tulsa Regional Medical Center; Tulsa, Oklahoma.

Nature and Probable Consequences—The licensee reported that on July 27, 1993, a wrong patient was administered 0.21 gigabecquerel (GBq) (5.7 millicuries [mCi]) of iodine–131 (I–131). On July 27, 1993, diagnostic procedures were prescribed for two outpatients, patients A and B, using technetium–99m (Tc–99m) for patient A and I–131 for patient B. Prior to the administration, the technologist involved in the procedure believed that patient A was the one prescribed to receive I–131 and addressed patient A by name and requested a second form of identification. Patient A responded positively and presented a social security card as the second means of identification. The technologist copied the social security number and attached it to patient A's chart. However, the written directive was not checked for verification of the patient's name. As a result patient A was administered a 0.21 GBq (5.7 mCi) dosage of I–131 intended for patient B.

[1]The definition of a misadministration was revised in 10 CFR 35.2 and became effective on January 27, 1992. The revision defines a new type of misadministration involving sodium idodide. The existing abnormal occurrence guidelines for misadministrations do not include specific examples for these types of misadministrations but are presently under revision.

The technologist recognized the misadministration within minutes of its occurrence and immediately notified the nuclear medicine physician. The physician prescribed Ipecac to induce vomiting, which was administered within 15 minutes of the administration of I-131, and Lugol's solution (potassium iodide) as a blocking agent which was administered after emesis, approximately 45 minutes after the I-131 administration. The referring physician and patient were notified of the misadministration.

The licensee reported that the patient received a thyroid dose of about 1600 centigray (cGy) (1600 rad) as a result of the misadministration. The patient will be examined during subsequent follow-up visits to the medical center.

The NRC staff retained a medical consultant to evaluate the potential medical effects on the patient as a result of the misadministration. The medical consultant estimated that, due to the administration of Lugol's solution, the dose to the patient's thyroid is in the range of 400–700 cGy (400–700 rad). The medical consultant believes the medical consequences of the misadministration would be negligible.

Cause or Causes—10 CFR Part 35 states that individuals under the supervision of authorized users must follow the instructions of supervising authorized users and follow the written radiation safety and quality management procedures established by the licensee. The licensee's Quality Management (QM) Program states that "prior to each administration the patient's identity as the individual named in the written directive will be verified by more than one method." The licensee's program also states that "The person administering the radiopharmaceutical must verify that the type of radiopharmaceutical, the dosage, and route of administration are in accordance with the written directive and check the dosage in a dose calibrator." However, the licensee staff failed to check the written directive.

Actions Taken to Prevent Recurrence

Licensee—The licensee revised the QM procedures to prevent recurrence of similar misadministrations. The revisions include the following requirements: (1) the prescribing physician must be present at each administration of I-131 dosage for whole body scans; (2) the technologists must double check the radiopharmaceutical and patient identification against the written directive; and (3) the technologists must cross check the department's requisition with the name, the dose, and the patient's identifying documents.

NRC—NRC Region IV conducted an inspection at Tulsa Regional Medical Center on August 10–11, 1993, to review the circumstances associated with the misadministration and its probable cause(s). The NRC staff is currently reviewing the inspection results for possible violations, and enforcement action is pending (Ref. 1).

Future reports will be made as appropriate.

93–10 1981 Fatal Radiation Exposure of a Radiographer in Northeast Oklahoma

In response to a 1993 General Accounting Office report entitled "Nuclear Regulation," NRC conducted a file review of this previously reported event.

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Example 1 of "For All Licensees") of this report notes that an exposure of the whole body of an individual to 250 millisievert (25 rem) or more of radiation can be considered an abnormal occurrence.

Note—This event occurred in January 1981 in Oklahoma, and was previously reported to Congress in NUREG–0090, Vol. 4, No. 1 as an "Other Event of Interest." At that time, NRC did not identify the event as an AO because it had not been conclusively determined that the radiation exposure resulted from material subjected to licensing by NRC or by the Agreement States. NRC reevaluated the incident against the AO reporting criteria in 1993 and concluded that the event should be classified as an AO.

Date and Place—January 1981; location determined to be northeastern Oklahoma based on best available information.

Nature and Probable Consequences—On January 22, 1981, the State of Oklahoma notified NRC Region IV that an individual had been admitted to the Okmulgee Memorial Hospital, Okmulgee, Oklahoma, with serious radiation injuries to his chest and left forearm. The individual was later determined to be an unemployed radiographer living in Henryetta, Oklahoma.

On January 5, 1981, an NRC licensee (Bill Miller, Inc.) in Henryetta, Oklahoma, reported that a radiographic exposure device containing a 1221 gigabecquerel (33 curie) iridium-192 source was discovered missing following a quarterly inventory on January 2, 1981. The licensee stated that the device had been stored in a locked enclosure in a company truck while the truck was parked in the back yard of a licensee employee's residence in Henryetta. NRC investigators later noted signs of forced entry on the truck's camper shell door and determined that the theft occurred about December 30, 1980. A search for the missing source by representatives of the licensee and the State of Oklahoma Department of Public Health was unsuccessful. The licensee subsequently

reported on January 5, 1981, that the missing source had been anonymously returned intact to a licensee representative's residence.

NRC investigators interviewed the exposed individual, and he stated that he could not recall how or when he received the exposure. Medical authorities estimated his exposure occurred between December 15, 1980 and January 5, 1981. Cytogenetic studies of a sample of the patient's blood indicated that he received an equivalent whole body dose of 365 centigray (cGy) (365 rad) from iridium-192 or 405 cGy (405 rad) from cobalt-60. The individual maintained that he had last worked with a radioactive source during the first week of October 1980 and that he first noticed an irritation on his chest and arm in November 1980.

The exposed individual refused to be interviewed by NRC a second time. He directed that any further contact with him be made through his lawyer. On July 27, 1981, NRC Region IV was notified that the individual had died of his injuries. NRC conducted a second investigation, but no substantial additional facts were identified.

Cause or Causes—Based on circumstantial evidence, it appears that the death was caused by a self-inflicted exposure to the stolen source. The licensee's security measures were found to meet NRC requirements in 10 CFR 20.207 and 34.23.

Actions Taken to Prevent Recurrence

Licensee—NRC documents indicate that no licensee action was warranted or taken.

NRC—The investigation identified no violations of NRC requirements (Ref. 2, 3, and 4).

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

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 reported five events as abnormal occurrences. Information on these events that was provided by the Agreement States as of November 1, 1993, is included in this report to Congress.

AS 93-5 Medical Teletherapy Misadministration at Alta Bates Medical Center in Berkeley, California

In response to an inquiry in April 1992, from The Plain Dealer, a Cleveland, Ohio, newspaper, the Radiologic Health Branch (RHB) of the State of California investigated a fatal radiation exposure that occurred in 1987 at Alta Bates Medical Center (ABMC) in Berkeley, California. At the request of the State, NRC assisted in the investigation. The West Coast Gancer Foundation (WCCF), the medical physics consulting firm that planned the radiation therapy treatment that resulted in the fatal exposure, was not included in this investigation. The investigation was completed in 1993.

As a result of this investigation, the State determined that the event was a misadministration and sent its investigation reports to NRC. However, the State in its final report stated "(Note: Medical misadministrations involving radioactive materials used in diagnostic and therapeutic procedures, became reportable in California, as a result of amendments to the regulations effective October 5, 1989. Misadministrations of machine produced ionizing radiation are not included in this reporting requirement.) Since no requirement to report misadministrations existed at the time of the event and the regulation to report misadministrations, when it became effective, did not contain any retroactive reporting requirement, ABMC did not violate any regulatory requirements in not reporting the event. It appears that no institutional conspiracy or willful attempt to mislead the State Regulatory agency existed. Any appearance of conspiracy or willful failure to provide complete and truthful information appears to have resulted from miscommunications and misunderstandings."

After reviewing the State's reports of this event, NRC determined that this event was an abnormal occurrence. Appendix A (see event Type 5 in Table A-1) of this report notes that a therapeutic exposure that differs from the final prescribed treatment by more than 10 percent and that results in adverse effects worse than would be expected for the normal range of exposures prescribed, should be considered an abnormal occurrence.

Date and Place—December 4, 1987; Alta Bates Medical Center; Berkeley, California.

Nature and Probable Consequences—A 9-year-old autistic boy was admitted to Childrens Hospital in Oakland, California, for a tonsillectomy. Post surgical pathological examination identified a cancer of the patient's nasopharynx. The patient was given chemotherapy and was scheduled to receive radiation

therapy at ABMC using a cobalt-60 (Co-60) source of 186,850 gigabecquerel (5050 Curie). The treatment was to be performed at ABMC because Childrens Hospital did not have the capability to provide radiation therapy.

ABMC used West Coast Cancer Foundation (WCCF), a medical physics consultant organization, to do treatment planning. Based on information provided by WCCF, radiation therapy treatments began on December 4, 1987. The treatments were temporarily stopped on December 24, 1987, and were to resume in January 1988. However, when the patient returned to restart treatment, there had been anatomical changes which required treatment replanning. The replanning was done by the same dosimetrist that had done the original plan. The dosimetrist discovered that an error had been made in planning the first treatment series. The error had resulted in doubling the prescribed dose that the patient was supposed to have received during the initial treatment phase. The fact that an error had occurred was promptly communicated to the patient's physicians and by them to the patient's mother. The subsequent prognosis provided by a consultant was grave, the patient was expected to die within 2 years. The patient died at Childrens Hospital on August 21, 1988.

Cause or Causes—The cause of the misadministration was an error made by a WCCF dosimetrist in planning the first radiation therapy treatment series. The error resulted in the patient receiving double the prescribed dose during the initial treatment phase and resulted in adverse health effects.

Actions Taken to Prevent Recurrence

Licensee—The State investigation reports that were sent to NRC did not discuss the actions taken by the licensee to prevent recurrence. At the time of this event, the licensee was not required to report this event as a misadministration, therefore, this information is not available.

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

- Require certification of specialists in the fields of radiological physics and dosimetry as those fields apply to the practice of radiation therapy, or provide for State recognition of such certification by appropriate national or international bodies.
- Amend the California Radiation Control Regulations to be consistent with respect to use of radioactive materials and/or ionizing radiation, whether the radiation is produced by machine or radioactive materials.
- Provide investigational techniques for inspectors who will or might be assigned to investigational duties.
- Establish mechanisms for NRC support in RHB investigations of events of special or joint interest.
- Require all individuals and organizations subject to State regulatory control involving the use of radioactive materials, and/or ionizing radiation producing machines, to report to the State Regulatory body all lawsuits or malpractice suits alleging injury or improper use of such materials or machines.

This event will be further evaluated when the information to prevent recurrence is available.

AS 93-6 Overexposure of a Radiographer at X-Cel Group in Corpus Christi, Texas

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

Date and Place—May 22, 1993; X-Cel Group; Corpus Christi, Texas.

Nature and Probable Consequences—On May 22, 1993, an Agreement State licensee, X-Cel Group, reported a radiography event involving a camera locking mechanism that came apart from the camera. This allowed the source assembly (pigtail) and 3626 gigabecquerel (98 curie) iridium-192 source to be pulled from the camera. A radiographer is believed to have picked up the source with the thumb and index finger of his right hand resulting in an overexposure. An immediate call was made to the regional State inspector in Corpus Christi requesting an investigation of the incident.

The incident occurred after midnight on May 22, 1993. Two radiographers working in low light conditions were performing radiography using a Gamma Century Model SA camera. Approximately 30 radiographs had been performed. The radiographs were taken for development and the radiographer took off his film badge and placed it on his clipboard, thinking the radiography was completed. Several shots needed to be retaken, and the radiographer forgot to put his film badge back on.

To move the camera from the first retake location to the second retake location, the radiographer took the

crank-out cable in his left hand and lifted the camera with his right hand. He took a few steps and the cable fell from the camera to the ground. He placed the camera on a truck tailgate, thinking he had a disconnect. He picked up the crank-out approximately 122 centimeters (cm) (4 ft) from the end, and moved his hand quickly toward the connector end. He grabbed what he thought was the cable connector and brought it to within 15 cm (6 in) of his face. When he realized it was the source, he dropped it, alerted his partner, and ran from the area.

A follow-up investigation was performed on May 27, 1993. A reenactment and radiation exposure calculation indicated the radiographer received an estimated whole body exposure of 6 millisievert (mSv) (0.600 rem). A worst case extremity exposure to the fingers was estimated to be 19.25 sievert (1925 rem). At the time, no symptoms of radiation injury were noted on the fingers.

No dose to the lens of the eyes was estimated because the source was held in proximity of the face for only 1 to 2 seconds. However, the State of Texas was contacted by NRC to determine the related exposure. NRC was informed that due to the short duration of exposure, the dose to the lens of the eyes was estimated to be equal to the whole body dose (6mSv [0.600rem]).

Cause or Causes—The lock insert of the radiography camera is held in place by two roll pins. One roll pin was missing, and may have been missing for some time. The second roll pin was in the camera housing, but not inside the lock insert. This allowed the lock insert, the spring, and the movable insert to be pulled from the lock box. The drive cable was connected to the pigtail, and when the lock insert pulled from the lock box, the drive cable pulled the pigtail from the camera, thereby exposing the source. Routine maintenance had been performed on the camera, but a missing roll pin is not readily noticeable during routine maintenance. Two radiographers operated the camera immediately prior to the incident without any difficulty.

Actions Taken to Prevent Recurrence

Licensee—The radiographer who was exposed was restricted from conducting radiation work. All personnel were informed that future failure to wear a film badge would result in termination of employment. A letter was sent to sub-offices and other radiography licensees in the area describing the incident.

State Agency—A Notice of Violation was sent to the licensee and radiographer for an extremity exposure in excess of 187.5 mSv (18.75 rem) and failure of the radiographer to wear personnel monitoring. The manufacturer was questioned about the pins, which are ordinary 3.2 millimeter (1/8 inch) in diameter by 1.0 centimeter (3/8 inch) in long-length roll pins. The specific reason for inquiring about the dimensions of the roll pins and the insight(s) obtained from this information were not provided in the information provided by the State.

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

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

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 5, 1992; "Unspecified Facility;" Albany, New York.

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

NRC legal staff has reviewed the relevant New York State laws regarding disclosure of the identity of facilities in which incidents occurred warranting reporting as abnormal occurrences. The New York State Public Health Law provides that "any incident reporting requirement imposed upon diagnostic and treatment centers. . .shall be kept confidential and shall not be released. . ." (NY CLS Pub Health, Article 28, Section 2805–M.) The only exceptions provided in the law are release to the NYS Health Department or to other hospitals. Discussions with the staff and attorneys for the NYS Health Department indicate that the department will provide a description of the incident but will delete the identity of the facility and patient. The NRC Office of General Counsel advises that NRC is not itself bound by this State law so NRC could release the information if the State provided it to NRC. However, if the State refuses to provide it to the NRC, there is no conflict with Federal law because the abnormal occurrence reporting requirement, Section 208 of the Energy Reorganization Act of 1974, does not apply to Agreement State licensees nor Agreement State agencies. However, if investigation of the incident results in enforcement action, then the information provided to NRC regarding the abnormal occurrence will be updated to include the enforcement action and since that is public information, the identity of the facility would be provided at that time.

Nature and Probable Consequences—A patient was administered 303.4 megabecquerel (MBq) (8.2 millicurie [mCi]) of phosphorus-32 (P-32), instead of the prescribed 185 MBq (5 mCi) of P-32, as an outpatient receiving radiation therapy treatment. The patient was discharged in stable condition. The attending physician and the patient were notified of the misadministration.

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

As of February 3, 1994, it was known that the State of New York informed NRC that it will provide the requested information on the causes of this abnormal occurrence within 30 days.

Actions Taken to Prevent Recurrence

Licensee—The corrective actions reported by the licensee included modifying the radiopharmaceutical therapy protocol for P-32 and iodine-131 administrations, and providing training for the technologists. In addition, a work sheet was developed for P-32 therapy and the physician involved in the procedure was counselled.

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

As of February 3, 1994, it was known that the State of New York informed NRC that it will provide the requested information on the likelihood of harmful effects to the patients within 30 days.

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

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

Appendix A (see Event Type 4 in Table A-1) of this report notes that administering a diagnostic dose that is greater than 5 times the prescribed dose should be considered an abnormal occurrence.[2]

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

Nature and Probable Consequences—A patient that was prescribed a diagnostic thyroid procedure using 0.26 to 0.37 megabecquerel (MBq) (0.007 to 0.010 millicurie [mCi]) of iodine-131 (I-131) erroneously received 196.1 MBq (5.3 mCi) of I-131. As a result, the licensee stated that the patient's thyroid received a dose of approximately 7950 centigray (7950 rad). NRC has asked the State of Washington to identify if the patient had borderline hypothyroidism prior to the misadministration.

The licensee reported that both a whole body scan and the requested thyroid uptake study were performed 3 days after the misadministration "with no patient complaints or immediate side effects." No NRC or State medical consultant was retained to evaluate this event.

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

Cause or Causes—Based on information relating to the actions taken, it was determined that the nuclear medicine technologist misinterpreted the orally requested procedure and failed to review the referring physician's written directive. The licensee stated that this event was attributed to human error as a result of the technologist's inattentiveness and relatively short work experience, and that the patient will most likely develop a hypothyroidism.

Actions Taken to Prevent Recurrence

Licensee—The technologist involved in the procedure and the chief technologist were counseled and reinstructed by the physician designated as the authorized user and by the Radiation Safety Officer. In addition, the licensee stated that in the future, all sodium iodide procedures will be required to be verified against the written directive prior to administration.

State Agency—The State Agency informed NRC that it will review the cause of this event and initiate any necessary actions. NRC has asked the State of Washington to provide additional information regarding the State Agency's action(s).

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

[2]The definition of a misadministration was revised in 10 CFR 35.2 and became effective on January 27, 1992. The revision defines a new type of misadministration involving sodium idodide. The existing abnormal occurrence guidelines for misadministrations do not include specific examples for these types of misadministrations but are presently under revision.

AS 93-9 Medical Teletherapy Misadministration by "Unspecified Licensee" in New York, New York

Appendix A (see Event Type 3 in Table A-1) of this report notes that administering a therapeutic dose to a part of the body not scheduled to receive radiation should be considered an abnormal occurrence.

Date and Place—July 11, 1992; "Unspecified Facility": New York, New York.

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

NRC legal staff has reviewed the relevant New York State laws regarding disclosure of the identity of facilities in which incidents occurred warranting reporting as abnormal occurrences. The New York State Public Health Law provides that "any incident reporting requirement imposed upon diagnostic and treatment centers. . .shall be kept confidential and shall not be released. . ." (NY CLS Pub Health, Article 28, Section 2805-M.) The only exceptions provided in the law are release to the NYS Health Department or to other hospitals. Discussions with the staff and attorneys for the NYS Health Department indicate that the department will provide a description of the incident but will delete the identity of the facility and patient. The NRC Office of General Counsel advises that NRC is not itself bound by this State law so NRC could release the information if the State provided it to NRC. However, if the State refuses to provide it to the NRC, there is no conflict with Federal law because the abnormal occurrence reporting requirement, Section 208 of the Energy Reorganization Act of 1974, does not apply to Agreement State licensees nor Agreement State agencies. However, if investigation of the incident results in enforcement action, then the information provided to NRC regarding the abnormal occurrence will be updated to include the enforcement action and since that is public information, the identity of the facility would be provided at that time.

Nature and Probable Consequences—Cobalt-60 teletherapy treatments of 200 centigray (200 rad) each were to be administered to the right axilla of a patient. However, the first five treatments were given to the left axilla in error. NRC has asked the State of New York to provide additional information regarding the treatment plan and the administered doses.

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

As of February 3, 1994, it was known that the State of New York informed NRC that it will provide the requested information on the causes of this abnormal occurrence within 30 days.

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's 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 New York to provide additional information regarding the action(s) taken to prevent recurrence. The State was also asked to verify that the referring physician and patient were notified.

As of February 3, 1994, it was known that the State of New York informed NRC that it will provide the requested information on the likelihood of harmful effects to the patients within 30 days.

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

REFERENCES

1. Reports from Osteopathic Hospital Founders Association DBA (doing business as) Tulsa Regional Medical Center in Tulsa, Oklahoma (Docket No. 030-02893), submitted to NRC on July 30, 1993, and August 10, 1993, in accordance with 10 CFR 35.33.*

2. NRC Investigation Report No. 030-15283/81-01 dated April 21, 1981.**

3. Memorandum from C. L. Cain, Radiation Specialist, to Glen D. Brown, Chief, Fuel Facility and Material Safety Branch, Region IV, dated February 18, 1981.**

4. Memorandum from Karl V. Seyfrit, Director, Office of Inspection and Enforcement, NRC Region IV, to Victor Stello, Jr., Director, Office of Inspection and Enforcement, NRC Headquarters, dated August 14, 1981.**

*A copy is available for inspection, or copying for a fee, in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC 20555.

**A copy is available for inspection, or copying for a fee, in the NRC Public Document Room, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

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:	If the improper administration results in any part of the body receiving unscheduled radiation, an AO report should be proposed for any such event.
	(a) the actual dose to the wrong body part is greater than five times the upper limit of the normal range of exposures prescribed for diagnostic procedures involving that body part, **or**	If the parts of the body receiving radiation improperly would have received radiation anyway, had the proper administration been used, an AO report should be proposed if:
	(b) there are clinical indications of **any** adverse health effects to the wrong body part.	(a) the actual dose is greater than 1.5 times that intended to the above described body parts, **or**,
	If the parts of the body receiving radiation improperly would have received radiation anyway, had the proper administration been used, an AO report should be proposed if:	(b) the actual dose is less than 0.5 times that intended to the above described body parts, **or**,
	(a) the actual dose is greater than five 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**
	(b) the above described body parts show signs of adverse health effects greater than expected had the proper administration been used.	(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:	An AO report should be proposed for any such event.
	(a) the actual dose to the wrong patient exceeds five times the prescribed dose for the intended patient, **or**	
	(b) the event results in **any** adverse health effects.	
(3) Administering a radiopharmaceutical or radiation by a	Same guidelines as for Event Type 1.	Same guidelines as for Event Type 1.

Table A-1 (Continued)

Event Type	AO Reporting Threshold	
	Diagnostic Exposure	Therapeutic Exposure
route of administration other than that intended by the prescribing physician.		
(4) Administering a diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent.	An AO report should be proposed if: (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 July through September 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.

Nuclear Power Plants

86-15 Differential Pressure Switch Problem in Safety Systems at La Salle Facility

This abnormal occurrence was originally reported in NUREG-0090, Vol. 9, No. 3, "Report to Congress on Abnormal Occurrences," July-September 1986. The event involved degradation of essential safety-related switches used to initiate operation of engineered safety systems.

The initial report involved problems with reactor vessel water level switches at La Salle Unit 2. NRC issued Bulletin 86-02 on July 18, 1986, which required owners of facilities using the affected switches in safety systems to take actions to assure reliability of operation. The majority of licensees did not have the switches of concern. Acceptable actions have been implemented and verified at all other operating power reactor facilities. Status of the closeout effort for this problem is documented in NUREG/CR-5294, "Closeout of IE Bulletin 86-02: Static "O" Ring Differential Pressure Switches," published in October 1989. Closeout was complete at all facilities except Oyster Creek and Browns Ferry Nuclear Plant (BFN), Unit 1 and Unit 3.

The interim response for Oyster Creek was acceptable. This was documented in NRC Inspection Report 50-219/89-14. In a June 11, 1991, letter to NRC, the licensee stated that the setpoint drift of the static "O" ring (SOR) switches was acceptable and the switches being considered as possible replacements did not offer improved performance. SOR switch performance data training plans were reviewed by the NRC staff. Adequate instructions, guidance and compensatory actions in the event of a switch failure were provided; therefore, the staff concluded that the concerns had been adequately addressed. This is documented in Inspection Report 50-219/92-19.

BFN, Units 1 and 3 were in an extended shutdown at the time the status of IE Bulletin (IEB) 86-02 closeout was issued. These units were shutdown in March of 1985 and will continue to remain shutdown for some time to come. Prior to authorizing resumption of power operation, the staff will confirm that the Tennessee Valley Authority (TVA, the licensee) has adequately resolved staff concerns regarding the use of SOR switches. TVA's original response to IEB 86-02 was dated July 20, 1987. The staff closed out IEB 86-02 for BFN, Unit 2 in Inspection Report 50-260/88-28 dated December 9, 1988.

Since only two units are not closed out, and the projected restart dates for BFN, Units 1 and 3 are well into the future (late 1998 and September 1995, respectively), no further updates are planned. This completes the discussion regarding SOR switches and the item is considered closed for the purposes of this report.

93-1 Steam Generator Tube Rupture at Palo Verde Unit 2

This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 1, "Report to Congress on Abnormal Occurrences," January-March 1993.

As previously reported, on March 14, 1993, at 4:34 a.m., while at 98.8 percent power, the unit experienced a tube rupture in steam generator (SG) No. 2. An Augmented Inspection Team (AIT) was sent by the NRC to investigate the event. The AIT identified weaknesses in the licensee's implementation of emergency plan actions, including event classification, activation of the emergency response facilities, and promptly determining accountability for on-site personnel. Weaknesses were also found in the procedures, equipment, and training associated with responding to a SG tube rupture event. The AIT report, documented in NRC Inspection Report No. 50-529/93-14, was issued on April 16, 1993.

On July 22, 1993, NRC issued Information Notice 93-56, "Weakness in Emergency Operating Procedures Found as

documented in NRC Inspection Report No. 50-529/93-14, was issued on April 16, 1993.

On July 22, 1993, NRC issued Information Notice 93-56, "Weakness in Emergency Operating Procedures Found as Result of Steam Generator Tube Rupture," to all pressurized water reactor licensees. Enforcement action resulting from the AIT in the area of emergency preparedness was issued as Severity Level IV (Severity Levels I through V range from the most significant to the least significant, respectively) violations by NRC Inspection Report No. 50-529/93-28, dated July 1, 1993. The licensee responded by letter dated July 30, 1993, with an admission of the violations and a corrective action plan. Two Severity Level IV violations were issued in NRC Inspection Report 50-528/529/530/93-29, related to chemistry and radiation monitoring concerns following the SG tube rupture event. In addition, two Severity Level IV violations were identified in NRC Inspection Report 50-528/529/530/93-35, related to the review of SG crack growth rates and Emergency Operating Procedures inadequacies.

The licensee issued a response to the NRC Confirmatory Action Letter on July 18, 1993, providing a Unit 2 Steam Generator Tube Rupture Analysis Report, and the licensee's basis for restart of the facility. The report concluded that the damage mechanism for the steam generator tubes was inter-granular attack and inter-granular stress corrosion cracking caused by a caustic-sulfate environment, crevice formation, and residual and applied stresses. The NRC issued the Safety Evaluation Report, and a Request for Information pursuant to 10 CFR 50.54(f), to the licensee, by letter dated August 19, 1993, concluding that Unit 2 could safely resume operation for 6 months before the next steam generator tube inspection. The licensee restarted the facility on August 27, 1993, and achieved 100 percent power on September 6, 1993. The licensee has since determined that reducing power to 85 percent will minimize further tube degradation, pending further evaluation during a mid-cycle outage scheduled for January 1994. This item is considered closed for the purposes of this report.

Other NRC Licensees

91-2 Medical Diagnostic Misadministration at Hutzel Hospital in Detroit, Michigan

This abnormal occurrence was originally reported in NUREG-0090, Vol. 19, No. 1, "Report to Congress on Abnormal Occurrences," January-March 1991. The abnormal occurrence report is updated as follows:

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

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

No enforcement action was taken. This item is considered closed for the purpose of this report.

93-2 Medical Sodium Iodide Misadministration at Ingham Medical Center in Lansing, Michigan

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:

In May 1992 a patient received a whole body scan using iodine-131 (I-131) instead of a thyroid scan, which uses technetium-99m. The misadministration occurred because of an apparent misunderstanding during a telephone conversation between the referring physician's office and a technologist at Ingham Medical Center.

On September 9, 1993, NRC issued a notice of violation and proposed imposition of a fine for $11,250 to the licensee. The licensee was cited for failing to have the physician authorized to use radioactive materials prepare a written directive as required for the dosage of I-131 involved in a whole body scan and for failing to follow the hospital's written instruction that I-131 whole body scans be used only for patients who had their thyroids removed. Since the patient in this case had an intact thyroid, the whole body I-131 scan should not have been performed.

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

Agreement State Licensees

AS 88-5 and 88-6 Medical Teletherapy Misadministrations at Sacred Heart Hospital in Cumberland, Maryland

These abnormal occurrences were originally reported in NUREG-0090, Vol. 11, No.4, "Report to Congress on Abnormal Occurrences," October-December 1988. The abnormal occurrences are updated as follows:

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

AS 93-3 Medical Brachytherapy Misadministration at Maine Medical Center in Portland, Maine

This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 2, "Report to Congress on Abnormal Occurrences," April-June 1993. The abnormal occurrence is updated as follows:

The State of Maine has reviewed and approved the corrective actions taken by the licensee as a result of this misadministration. The State Agency considers this case closed.

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.

Other NRC Licensees

Medical Misadministration at Veterans Administration Medical Center in Dallas, Texas

On February 11, 1992, a misadministration occurred at the Department of Veterans Affairs, Veterans Administration Medical Center in Dallas, Texas.

The misadministration involved administration of radiation using a cobalt-60 teletherapy unit for a treatment which was initiated on February 11, 1992, for the lower extremities. The total treatment dose administered to the patient, as calculated during the NRC inspection, was 18 percent greater than the prescribed dose for the legs, and 4 to 6.5 percent less than the prescribed dose for the anterior and posterior feet. The differences between the administered total dose and the prescribed total dose for each treatment field did not meet the criteria defined in 10 CFR 35.2 for a misadministration. However, the dose administered to the lower legs during the third week of treatment was approximately 209 percent of the prescribed weekly dose (626 centigray [cGy] [626 rad] versus the prescribed 300 cGy [300 rad]). The difference between the administered dose for the legs during the third week of treatment and the prescribed weekly dose met the criteria defined in 10 CFR 35.2 for a misadministration in that the calculated weekly administered dose was more than 30 percent greater that the prescribed weekly dose.

The direct cause of the misadministration could not be determined during NRC inspection because the licensee's physicist and physician were no longer employed by the licensee and were unavailable for interview. In addition, there was insufficient information recorded in the patient's treatment chart about the physician's specific intent regarding treatment setup. One contributing factor in this case appeared to be an inconsistency in the format used for prescribing radiation treatment in the written directive. The NRC inspector noted that the written directive associated with this case differed from all other written directives completed by the licensee's authorized users in that the dose to be administered to the tumor site was apparently not specified and that the treatment was the first of this type completed by the licensee's staff. Due to the fact that key individuals involved with this case were no longer available at the licensee's facility and the licensee was unable to contact them regarding the case, the licensee was unable to contribute further information which may have assisted in determining the direct cause. During the interval between May 1992 and August 1993, the licensee developed a new Quality Management (QM) Program which was reviewed during the inspection. The new QM Program was an improvement over the program which existed at the time of the misadministration, and appeared to have incorporated policies and procedures that would be more easily implemented by the staff and which included additional controls to ensure that radiation was administered in accordance with a written directive. In addition, during this interval, the licensee experienced changes in managers, authorized users, and physicists involved with the teletherapy program and the individuals in place at the time of the inspection appeared to be more closely involved with the program.

Following the inspection, NRC requested that a medical consultant review the case to evaluate the potential consequence(s) to the patient. The consultant is currently continuing his review. NRC also conducted an enforcement conference with the licensee on September 22, 1993, to review the findings of the inspection, including a substantial failure to implement the QM program. NRC also discussed with the licensee patient notification requirements and requested that the licensee provide notification regarding this issue as requested in 10 CFR 35.33. NRC staff is still reviewing information provided by the licensee during the enforcement conference to determine the appropriate enforcement action and the status of patient notification.

Agreement State Licensees

Medical Misadministration at Roger Williams Medical Center in Providence, Rhode Island

On May 27, 1992, a patient was scheduled to receive a 0.26 gigabecquerel (GBq) (7.0 millicurie [mCi]) therapy dose of iodine-131 orally in a capsule. The order was received from a radiopharmacy on May 27, 1992, and was assayed while still in the vial as 0.26 GBq (7.0 mCi). One capsule was administered to the patient. The lead vial containing the capsule was placed in the storage area.

On July 10, while disposing of lead containers, it was discovered (by the sound of something rattling around in the container) that a capsule remained in the vial. The capsule was assayed, and by decay corrections it was determined that the prescribed dosage was originally to be delivered as two capsules, each being 0.13 GBq (3.5 mCi). The referring physician was notified.

On July 13, the hospital's Radiation Protection Office was notified of this situation by a Radiation Incident Report. The Radiation Safety Officer (RSO) investigated the event, and determined on July 29 that the event met the criteria for a misadministration. On July 29, 1992, the RSO called the State Radiation Control Agency, but was not successful in communicating with officers in that agency. On July 30, notification of this misadministration was made by telephone to the Radiation Control Agency.

This misadministration was determined to have occurred for four reasons:

a. The capsule activity ordered (0.26 GBq [7.0 mCi]) had always been delivered in one capsule in the past and it was not anticipated that there would be two capsules.

b. The vial label was not read carefully by the technologist preparing the dose. The label on the vial stated that two capsules were contained in the vial.

c. The dose calibrator check was done with the two capsules in the shipping vial before dispensing the dose.

d. Since one capsule was wedged between the vial wall and a desiccant packet, only one capsule came out when the vial was inverted.

The licensee stated that the referring physician will order a diagnostic test to determine if the dose delivered to the patient was adequate to perform the treatment desired. The licensee added that there would be no harm to the patient due to receiving only 50 percent of the prescribed dose, and the referring physician assured the Radiation Safety Office that he will continue to assess the treatment efficacy.

The authorized user instructed the Nuclear Medicine staff to a) read all labels carefully to check the dosage by volume and the number of capsules, b) label the top of the vial with the dosage and number of capsules, and c) assay the vial in the dose calibrator immediately after administration to determine if the entire dose was administered. Administering physicians were instructed to double check the labels.

The patient was not notified of this misadministration because it was felt that the dose administered would be sufficient to accomplish the planned treatment.

APPENDIX D

AGREEMENT STATE EVENTS BEING CONSIDERED AS ABNORMAL OCCURRENCES

For this report, NRC is considering two events submitted by Agreement States as abnormal occurrences. Information on these events that was provided by the Agreement States as of November 1, 1993, was insufficient to positively identify them as abnormal occurrences. When the necessary information becomes available they will be included in future reports.

PAS 93-1 Medical Brachytherapy Misadministration at Richland Memorial Hospital in Columbia, South Carolina

The necessary information to determine if a misadministration and/or an abnormal occurrence had occurred was not discussed in the event description provided by the State. NRC has asked the State of South Carolina for the necessary information to determine if this event is a misadministration and/or 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 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 2 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.

NRC has asked the State of South Carolina to determine the exposures to the attending and oncology nurses, to identify the dose to the wrong treatment site, and to verify that the referring physician and patient were 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.

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 and accurate information to verify this and to complete an analysis.

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.

PAS 93-2 Medical Misadministration at Mayo Clinic in Scottsdale, Arizona

A dose of iodine-131 (I-131) meta-iodo-benzyl-guanidine (MIBG), suspected to be at least 60 percent greater than the prescribed dose, was reported to be administered to a patient. If this dosage was administered for therapeutic purposes, it would exceed the criteria in Appendix A, Event Type 5, the administration of a therapeutic dose greater than 1.5 times the prescribed dose. NRC has asked the State of Arizona for the necessary information to determine if this event is an abnormal occurrence.

Date and Place—September 8, 1992; Mayo Clinic; Scottsdale, Arizona.

Nature and Probable Consequences—The report submitted by the State of Arizona stated that a patient was administered approximately 44.4 megabecquerel (MBq) (1.2 millicurie [mCi]) of I-131 MIBG, instead of the prescribed 18.5 MBq (0.500 mCi) dosage of I-131 MIBG. (MIBG is a radiopharmaceutical that can also be used for diagnosis.) The State also said that the amount drawn in the syringe was estimated to be 38.5 MBq (1.04 mCi). After the administration, the technologist measured the residual activity in the syringe and found it to be 3.70 MBq (0.100 mCi), which is approximately 10 percent of the reported drawn dose. In a final statement on the dose received by the patient, the State indicated that the dosage administered was estimated to be 29.75 MBq (0.804 mCi) of I-131 MIBG. NRC has asked the State of Arizona to provide a clarification on the estimated dosage administered to the patient.

The report, provided by the State, also explained that the technologist involved in the procedure assumed that the vial containing MIBG contained only the prescribed dosage and drew-up the entire volume of the vial. The patient's name and clinic number were also verified with the written directive.

The patient was administered Lugol's solution the previous day and again on the day of the procedure to minimize thyroid exposure. The patient was also instructed to complete a bowel preparation procedure to minimize exposure to the abdominal area. The lead technologist and the Radiation Safety Officer were notified of this incorrect administration. The exposure to the thyroid was not discussed. NRC has asked the State of Arizona to provide additional information regarding exposure to the thyroid. The State was also asked to verify that the referring physician and patient were notified.

Cause or Causes—The cause for administering an incorrect dose was not discussed in the description of the event provided by the Agreement State. NRC has asked the State of Arizona to provide additional information regarding the cause(s) of this event.

Actions Taken to Prevent Recurrence

Licensee—The actions taken by the licensee to prevent recurrence of a similar event as described above were not discussed in the event description provided by the Agreement State. NRC has asked the State of Arizona for this information regarding licensee's action(s).

State Agency—The actions taken by the appropriate State agency to prevent recurrence of a similar event as described above was not discussed in the event description provided by the Agreement State. NRC has asked the State of Arizona to provide additional information regarding the State agency's action(s).

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

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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 July 1 through September 30, 1993.

This report discusses two abnormal occurrences at NRC-licensed facilities. One involved a medical sodium iodide misadministration and one involved a 1981 fatal radiation exposure of a radiographer. One industrial radiographer overexposure event and four medical misadministrations that were reported by the Agreement States are also discussed, based on information provided by the Agreement States as of November 1, 1993. The report also contains information updating four previously reported abnormal occurrences at NRC-licensed facilities and three reported by the Agreement States, and includes information on two 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 as of November 1, 1993, to positively identify them as abnormal occurrences.

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

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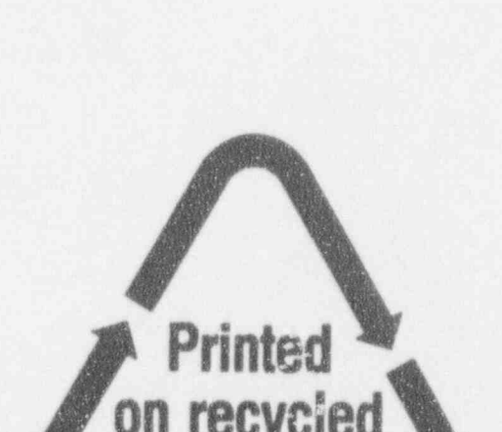

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