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Report to Congress on Abnormal Occurrences

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U.S. Nuclear Regulatory Commission

Office for Analysis and Evaluation of Operational Data



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ABSTRACT

Section 208 of the Energy Reorganization Act of 1974 identifies an abnormal occurrence 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 January 1 through March 31, 1991.

The report discusses six abnormal occurrences, none of which involved a nuclear power plant. Five of the events occurred at NRC-licensed facilities: one involved a significant degradation of plant safety at a nuclear fuel cycle facility, one involved a medical diagnostic misadministration, and three involved medical therapy misadministrations. An Agreement State (Arizona) reported one abnormal occurrence that involved medical therapy misadministrations.

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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 on any abnormal occurrences involving facilities and activities regulated by the NRC. An abnormal occurrence 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 the NRC using the criteria 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). In order to provide wide dissemination of information to the public, a *Federal Register* notice is issued on each abnormal occurrence. 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.

The NRC has determined that only those events described in this report meet the criteria for abnormal occurrence reporting. This report covers the period from January 1 through March 31, 1991. Information reported on each event includes date and place, nature and probable consequences, cause or causes, and actions taken to prevent recurrence.

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, the NRC follows the philosophy that the health and safety of the public are best ensured through the establishment of multiple levels of protection. These multiple 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 the 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 the 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, the 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.

Two primary sources of operational data are Licensee Event Reports (LERs) and immediate notifications made pursuant to 10 CFR 50.72.

Except for records exempt from public disclosure by statute and/or regulation, information concerning reportable occurrences at facilities licensed or otherwise regulated by the NRC is routinely disseminated by the 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 primary source of operational data is reports of reliability data submitted by licensees under the

Nuclear Plant Reliability Data System (NPRDS). The NPRDS is a voluntary, industry-supported system operated 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 vital adjunct to the LER system for the collection, review, and feedback of operational experience; therefore, the Commission periodically monitors the NPRDS reporting activities.

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. Certain information is also provided to the NRC under exchange of information provisions in the agreements.

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 NRC and Agreement State licensee facilities. Procedures have been developed and implemented, and abnormal occurrences reported by the Agreement States to the NRC are included in these quarterly reports to Congress.

Foreign Information

The 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.

REPORT TO CONGRESS ON ABNORMAL OCCURRENCES

JANUARY-MARCH 1991

Nuclear Power Plants

The NRC is reviewing events reported at the nuclear power plants licensed to operate. For this report, the

NRC has not determined that any events were abnormal occurrences.

Fuel Cycle Facilities (Other Than Nuclear Power Plants)

The NRC is reviewing events reported by these licensees. For this report, the NRC has determined that one event was an abnormal occurrence.

91-1 Significant Degradation of Plant Safety at Nuclear Fuel Services, Inc. in Erwin, Tennessee

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Example 10 of "For All Licensees") of this report notes that a major deficiency in design, construction, or operation having safety implications requiring immediate remedial action can be considered an abnormal occurrence.

Date and Place—Escalated enforcement action proposed on March 20, 1991, for an event occurring on November 28, 1990; Nuclear Fuel Services, Inc.; Erwin, Tennessee.

Nature and Probable Consequences—Nuclear Fuel Services, Inc. is a fuel production facility that produces nuclear fuel for the U.S. Navy. On November 30, 1990, licensee personnel discovered that on November 28, 1990, 395 grams of uranium-235, contained in liquid waste, had been processed through the waste water treatment system for collection and disposal of the uranium. This quantity was above the administrative criticality safety limit of 350 grams for the unfavorable geometry tanks used to hold the waste. (A favorable geometry tank is one having dimensions specifically designed to prevent criticality of its fissile material contents. An unfavorable geometry tank can be used, however, if the amount of fissile material is kept below that needed to achieve criticality.)

While the amount of uranium-235 was well below the amount needed for criticality, the circumstances associated with the event were particularly safety significant. Highly concentrated uranium solutions in an adjoining part of the process were available in quanti-

ties that were more than sufficient to have caused a criticality accident in the unfavorable geometry tank. The hydrostatic head associated with those highly concentrated solutions would have been sufficient to force those solutions into the unfavorable geometry tank if the set of normally closed valves were faulty or were not fully closed. The event is briefly described as follows.

Filling of storage tanks with liquid waste from the solvent extraction system in the high enriched uranium recovery process began on November 27, 1990. When the tanks were full, the contents were recirculated prior to sampling. An operator collected two samples of the liquid and submitted them for analysis. The analytical results were received on November 28, 1990, and revealed that the uranium concentration in the liquid was well below the authorized discard limit, hence, the quantity of U-235 was below the safety limit of 350 grams. The liquid waste was then pumped to another tank where it was mixed again, sampled for material accountability purposes, and then pumped to the Waste Water Treatment Facility (WWTF).

On November 30, 1990, the laboratory reported the results of the accountability sample to be above the authorized discard limit. This higher concentration was confirmed by analysis of another sample which had been obtained when the liquid was received at the WWTF. These analyses confirmed each other, and all discharges were halted as a special licensee investigation team initiated a detailed review to determine the causes and needed corrective actions. At about 4:15 p.m., the licensee reported the incident to the NRC.

The NRC issued written confirmation on November 30, 1990, that the licensee would refrain from transferring liquid waste until certain actions had been completed (Ref. 1). An NRC inspector was dispatched to the site on December 1 and two other NRC personnel arrived on December 2, 1990, to perform a special NRC team inspection (Ref. 2).

Cause or Causes—The licensee identified the probable causes of the November 28 event to be (1) less than adequate piping layout that allowed uranium solutions to flow into the unfavorable geometry tank and (2) personnel-related inadequacies in that operators had no knowledge of the potential for crossover of highly concentrated uranium solutions into unfavorable tanks as a result of open valves or other anomalies in the piping systems.

Following a review of the incident, the NRC concluded that there appeared to be other root causes in addition to those given by the licensee. These root causes include:

1. The safety basis for the plant was less than adequate because a documented safety analysis was not available.
2. As a result of the lack of a detailed safety analysis, equipment important to safety, such as valves, were not properly identified, protected, emphasized in plant control documents and training sessions, tested and maintained appropriate to their safety function, and did not possess positive closure indication.
3. The design basis of the plant was less than adequate. The system drawings lacked adequate detail.

The licensee missed an opportunity to preclude the problems several years earlier when modifications were made to the piping system. The licensee's reviews of the modifications failed to identify the significant potential for uranium solutions to flow into unfavorable geometry vessels.

Actions Taken to Prevent Recurrence

Licensee—Corrective actions included modification of the piping system to prevent highly concentrated uranium solutions from flowing into the unfavorable geometry tanks. A review of the fuel recovery facility

was initiated to identify the nuclear safety features and controls for each unfavorable geometry vessel. A Nuclear Criticality Safety Performance Improvement Program (PIP), that had been instituted prior to the incident, was accelerated and expanded to address the root causes. Training was also given to fuel recovery personnel to make them aware of the problem.

NRC—The special NRC team inspection (Ref. 2) identified two violations dealing with (1) failure to perform an adequate evaluation of equipment joined by piping for the possibility of siphoning and (2) failure to adhere to the administrative criticality safety limit of 350 grams of uranium-235 in unfavorable geometry tanks.

The NRC inspected the actions taken and, following the licensee's identification of the safety features and controls, issued a letter authorizing resumption of solution transfers on December 18, 1990 (Ref. 3). An Enforcement Conference with the licensee was held on January 18, 1991. On March 20, 1991, the NRC forwarded a Notice of Violation (for the violations identified during the special NRC team inspection) and proposed a civil penalty of \$10,000 (Ref. 4). The two violations were classified as Severity Level II on a scale in which Severity Levels I and V are the most and least significant, respectively. The licensee has paid the civil penalty.

In early 1991, the NRC prepared an action plan for the licensee's facility. This plan is updated quarterly and tracks the completion of the licensee's PIP items, quarterly NRC and licensee management meetings on the PIP status, and NRC technical reviews of PIP. Other items addressed in the plan include license renewal milestones and management meetings on decommissioning activities. A full-time resident inspector started at the facility on April 22, 1991.

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

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

There are currently over 8000 NRC nuclear material licenses in effect in the United States, principally for use of radioisotopes in the medical, industrial, and academic fields. Incidents were reported in this category from licensees such as radiographers, medical institutions, and byproduct material users. The NRC is reviewing events reported by these licensees. For this report, the NRC has determined that four events were abnormal occurrences.

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

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or

more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place—January 17, 1991; Hutzel Hospital; Detroit, Michigan.

Nature and Probable Consequences—On January 24, 1991, the licensee notified NRC Region III that a medical diagnostic misadministration had occurred at its facility on January 17, 1991, when a patient was administered a dosage of iodine-131 that was 100 times greater than prescribed. A written report was received by Region III on February 1, 1991.

On January 16, 1991, a 37-year-old female patient (who had given birth to a baby 2 days earlier) was scheduled to have a thyroid scan to determine if she had a substernal goiter (beneath the breastbone). The licensee's normal procedure for such a thyroid scan usually involves administration of a 50-microcurie dosage of iodine-131. This would typically result in a thyroid dose in the range of 50–70 rads. The prescription for the procedure was prepared by a physician's assistant at the direction of the referring physician. The nuclear medicine technologist subsequently discussed the procedure with the physician's assistant and questioned whether or not the thyroid scan was the appropriate procedure. The technologist indicated a whole body scan to identify thyroid tissue throughout the body would be the appropriate test. The physician's assistant agreed and submitted a new order for the whole body scan. The iodine-131 was administered to the patient on January 17, 1991, with the whole body scan performed on January 18, 1991. The procedure constitutes a misadministration because the referring physician had not intended to perform a whole body scan using iodine-131.

The whole body scan involved a dosage of 5 millicuries of iodine-131 instead of 50 microcuries, which would have been used for the diagnostic procedure actually prescribed by the referring physician. Although the whole body scan is a diagnostic test—intended for patients who have had their thyroid removed—the 5-millicurie dosage is in the range that may be used for treatment of thyroid disorders.

Prior to administering the iodine-131, the technologist determined that the patient was not breast-feeding her baby and did not intend to breast feed. (Breast-feeding a baby is a concern because the radioactive iodine can be passed to the baby through the milk.) Some direct radiation exposure was received by the baby due to the presence of the iodine-131 in the mother's body. This exposure, however, was minimal (estimated to be approximately 0.5 millirads) because the baby was with the mother for

only a 30-minute period because of the mother's medical problems. After the misadministration was discovered, contact between the mother and baby was restricted for two days to avoid further radiation exposure to the infant.

The NRC retained a medical consultant to evaluate the circumstances of this case. The consultant estimated that the patient received a dose of approximately 6500 rads to her thyroid. This exposure would carry a slightly increased risk of developing hypothyroidism or thyroid cancer. Because the patient was lactating, thus concentrating the radioactive iodine in the breasts, there would also be an increase in the patient's risk of breast cancer. The consultant recommended periodic monitoring of the patient for hypothyroidism and for breast and thyroid cancer.

Cause or Causes—This misadministration was caused by the modification of the intended diagnostic procedure as a result of the discussion between the physician's assistant and the nuclear medicine technologist. This modification, which involved substantially increasing the dosage of radioactive iodine-131, was not reviewed by or approved by the patient's physician. The physician, in fact, desired the thyroid scan procedure using the lower dosage.

An NRC inspection to review the circumstances of the misadministration (Ref. 5) also determined that the hospital had not provided training in the proper ordering and administration of radiopharmaceuticals to individuals working under the supervision of a physician designated on the NRC license.

Actions Taken to Prevent Recurrence

Licensee—The hospital adopted new procedures requiring specific approval by an authorized physician prior to the oral administration of more than 50 microcuries of iodine-131. This authorization is to be obtained immediately prior to the planned administration. The hospital also reaffirmed that the technologist and physician's assistants are not permitted to change an order given by an attending physician.

The hospital recommended that the patient be placed on a thyroid hormone to inhibit the growth of thyroid nodules and that she be monitored for possible development of hypothyroidism or other complications.

NRC—A special inspection was conducted February 19, 1991, to review the circumstances surrounding the misadministration (Ref. 5). The inspection identified two apparent violations associated with the incident: (1) failure to instruct supervised individuals on the principles of radiation safety, and (2) use of NRC-licensed material by unauthorized individuals. These

inspection findings remain under review by the NRC, and enforcement action is pending.

Future reports will be made as appropriate.

91-3 Medical Therapy Misadministration at Washington Hospital Center in Washington, D.C.

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place—February 1, 1991; Washington Hospital Center; Washington, D.C.

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

A 74-year-old patient was to have received 250 rads to the brain for cancer treatment. The technologist identified the patient; however, the technologist examined another chart without verifying the name on the chart or the picture of the patient on the chart. No patient treatment area markers, such as tattoos, were used. Using the wrong chart, the technologist proceeded to set up a 5.0 centimeters by 6.5 centimeters field size and initiated treatment of the patient's larynx. The thyroid of the patient was not blocked from exposure to the teletherapy beam. While the patient was undergoing treatment to the larynx, the technologist realized that the wrong organ was being treated. The technologist immediately terminated the patient treatment. It was estimated that 57 rads were delivered to the larynx, and about the same to the thyroid. The wrong chart indicated that 100 rads were to be delivered to the larynx in 1.38 minutes and the treatment was terminated after 0.79 minutes. After termination of the larynx treatment, the patient was given the proper treatment of 250 rads to the brain.

Region I contacted an NRC medical consultant to review the event. The consultant noted that there were no acute symptoms and that there should be no long term medical implications during the expected lifetime of the patient.

Cause or Causes—The technologist failed to follow proper identification procedures.

Actions Taken to Prevent Recurrence

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

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

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

91-4 Medical Therapy Misadministration at Hahnemann University Hospital in Philadelphia, Pennsylvania

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place—February 14–18, 1991; Hahnemann University Hospital; Philadelphia, Pennsylvania.

Nature and Probable Consequences—On February 22, 1991, NRC Region I was notified by the licensee that a therapeutic misadministration had occurred at its facility during the period from February 14 to 18, 1991, while a patient was undergoing radiation therapy for a tumor in the eye.

A radiotherapy physician prescribed a therapeutic dose of 30,000 rads to the base of the tumor and 14,300 rads to the apex of the tumor from an iodine-125 custom-designed eye plaque. The staff physicist who designed the eye plaque informed the radiotherapy physician that based on the eye plaque design, a dose of 30,000 rads would be delivered to the base of the tumor and 9,925 rads to the apex over 127.8 hours. This treatment plan was found acceptable and agreed upon. While the physicist was designing the eye plaque and calculating the anticipated dose, he decided to change to an eye plaque with a different radius of curvature. The physicist changed the coordinates for placement of each iodine-125 seed used in the plaque but failed to change the associated points for calculation of dose to various depths within the eye.

On February 18, 1991, the physicist suspected that an error had occurred while planning a treatment for another patient with a similar tumor. At that point, he retrieved patient data from the computer for the treatment started on February 14, 1991, reviewed the data, and confirmed that an error had been made. The patient's eye plaque was then removed. At that time, a total of 99.25 hours had elapsed since the

beginning of the treatment, resulting in a total treatment dose of about 59,000 rads to the base of the tumor and 19,500 rads to the apex of the tumor. The licensee stated that the dose received by the tumor was within acceptable medical treatment protocols for that type of tumor, and that no acute effects were observed in the patient.

NRC Region I contacted an NRC medical consultant to review the event. The consultant stated that there was an increased risk of long term adverse effects, (e.g., cataract, tissue damage).

Cause or Causes—The causes are attributed to human error on the part of the licensee's staff physicist, lack of written procedures, and lack of dual verification of dose calculations prior to administration.

Actions Taken to Prevent Recurrence

Licensee—The licensee's planned corrective actions include establishing written protocol for this procedure, including a second verification of the treatment calculations prior to administration of dosages to patients.

NRC—An NRC Region I inspector conducted a special inspection of the circumstances surrounding this misadministration on February 25, 1991. The inspection report was forwarded to the licensee on March 11, 1991 (Ref. 6). The report notes that the inspector suggested that the licensee establish a written protocol for the procedure and the licensee agreed. The report also identified one violation of NRC requirements, i.e., failure to notify the NRC of the therapy misadministration within 24 hours of discovery. A management meeting between NRC Region I and licensee management was conducted on March 21, 1991, to review the licensee's actions to prevent recurrence.

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

91-5 Medical Therapy Misadministration at Clara Maass Medical Center in Belleville, New Jersey

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place—March 28, 1991; Clara Maass Medical Center; Belleville, New Jersey.

Nature and Probable Consequences—On March 28, 1991, the licensee informed NRC Region I that a therapeutic misadministration, involving administration of iodine-131 to the wrong patient, had occurred earlier that day.

A radiotherapy physician prescribed a therapeutic dosage of 10 millicuries of iodine-131 to a patient for the treatment of hyperthyroidism. The physician that was familiar with the patient was not able to administer the therapeutic dosage and asked another physician to administer it. In the meantime, a transporter, while reviewing the patient transport requests, noted that the patient was listed in a bed that she believed was occupied by another patient. The transporter notified the nuclear medicine secretary to check into the discrepancy. The secretary referred to a patient list for the patient's name, noted the area of the hospital where the patient's room was, and changed the request form. The secretary did not know that there were two patients in the hospital with the exact same names. (The second patient was in the hospital for a lung condition.) Also, the secretary did not know the computer program that generated the patient list did not print duplicate entries. The patient's name who was to undergo treatment for hyperthyroidism was not printed on the list.

The physician who administered the dose picked up the request form and the iodine-131 dosage from the Nuclear Medicine Department and went to the nursing station on the floor of the patient with the lung problem. The physician did not inform the nursing staff that he was about to administer a therapeutic dosage to one of their patients and went to the lung patient's room. There, he asked the patient his name and verified the name on the wrist band but did not cross check the patient number on the wrist band with the patient number on the request form. The physician completed the request form and returned the patient folder to the nurses' station. Within five minutes of the administration of the radiopharmaceutical, the nurses discovered the error and informed the physician and the Radiation Safety Officer. The licensee decided to administer a thyroid blocking agent of 1000 milligrams of potassium iodide immediately, with three subsequent doses of 1000 milligrams each given at four hour intervals.

The licensee determined that the thyroid of the patient received an uptake of between 80 and 100 microcuries of iodine-131 which would give a dose of between 112 and 140 rads. An NRC medical consultant, who reviewed the event, concurred with these figures. The licensee advised the NRC that no adverse effects were anticipated during the lifetime of the patient as a result of the misadministration.

Cause or Causes—The causes were attributed to failure to follow the hospital protocol of checking the

patient identification number, and failure to inform the head nurse of the floor of the therapeutic procedure, prior to administration.

Actions Taken to Prevent Recurrence

Licensee—The licensee's planned corrective action includes establishing a check list that must be completed by individuals administering therapeutic dosages. The check list will require that the person administering the dosage to check, as a minimum, the type of radiopharmaceutical to be administered, the activity of the dosage, the name of the patient, and the patient number; it will also require notification of the nursing staff that one of their patients is undergo-

ing radiopharmaceutical therapy. Other actions include changing the computer program so that all of the information is printed out on the patient list, and reinstruction to personnel regarding patient verification procedures.

NRC—On April 1, 1991, a Region I inspector conducted a special inspection of the circumstances surrounding this misadministration. The inspection report was forwarded to the licensee on April 17, 1991 (Ref. 7). No violations of regulatory requirements were identified. The licensee's corrective actions are considered satisfactory.

This item is considered closed for the purposes 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 the NRC (see Appendix A) and report the events to the NRC for inclusion in this report. The Agreement State of Arizona reported the following event as an abnormal occurrence. The writeup is based on information provided to the NRC during late 1990.

AS91-1 Medical Therapy Misadministration at Good Samaritan Medical Center in Phoenix, Arizona

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

Date and Place—February–June 1989; Good Samaritan Medical Center; Phoenix, Arizona.

Nature and Probable Consequences—On July 26, 1989, the licensee reported to the Arizona Radiation Regulatory Agency (State Agency) a series of three misadministrations involving the use of a cobalt-60 teletherapy unit in the licensee's Radiation Oncology Department.

The three patients received exposures of approximately 14%, 11%, and 12% greater than the prescribed doses of 6200 rads, 6480 rads, and 5000 rads, respectively, from an AECL Theratron-80 unit containing 5529 curies of cobalt-60 assayed on September 16, 1988. A beam correcting wedge had been used along with a treatment planning computer. Although the computer already contained a wedge correction factor, the technologist and dosimetrist added a second wedge correction factor after checking with the

consulting physicist and being told that a wedge factor would be required.

While preparing to treat a fifth patient assigned the same treatment protocol, a point hand calculation indicated a wide discrepancy when compared to the computer generated treatment time. This discrepancy led to a comprehensive search of past cases which revealed the three overexposures out of four possible cases.

All three patients showed signs of skin erythema (reddening) and the first two patients (who had received radiation to the larynx region) reported hoarseness and pain on swallowing. The licensee stated that these symptoms are not unusual for patients undergoing radiotherapy, and in fact, these same symptoms were mentioned to the patients as possible side effects of the treatment.

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

- a. The hospital staffing level was inadequate for the patient load.
- b. There was a loss of continuity in physics services with the departure of one physicist and the hiring of another physicist.
- c. There was poor communication (documentation) regarding the use of the computer generated treatment plans.

Actions Taken to Prevent Recurrence

Licensee—The licensee has hired a full time qualified therapy physicist and a technical administrator. These individuals will not have responsibilities outside of the therapy department.

All computer generated treatment plans will have point hand calculations to verify the computer readings. Procedures for use of this computer to generate patient treatment plans have been revised.

State Agency—A civil penalty of \$3,000 was proposed on January 19, 1990, after a thorough review of the licensee's Radiation Safety Committee's activities was conducted on December 22, 1989. The violation

basis was centered on the Radiation Safety Committee's failure to adequately conduct its activities and supervise the use of therapy sources.

Litigation continues on this event and not all records have been received by the State Agency at this time. However, unless new, significant information becomes available, this item is considered closed for the purposes of this report.

REFERENCES

1. Letter from J. Philip Stohr, Director, Division of Radiation Safety and Safeguards, NRC Region II, to Charles R. Johnson, President, Nuclear Fuel Services, Inc., forwarding a Confirmation of Action Letter, Docket No. 70-143, License No. SNM-124, November 30, 1990.*
2. Letter from J. Philip Stohr, Director, Division of Radiation Safety and Safeguards, NRC Region II, to Charles R. Johnson, President, Nuclear Fuel Services, Inc., forwarding NRC Inspection Report No. 70-143/90-30, Docket No. 70-143, License No. SNM-124, January 14, 1991.*
3. Letter from Stewart D. Ebneter, Regional Administrator, NRC Region II, to Charles R. Johnson, President, Nuclear Fuel Services, Inc., forwarding a Letter of Authorization to resume operations in the Recovery Facility, Docket No. 70-143, License No. SNM-124, December 18, 1990.*
4. Letter from Stewart D. Ebneter, Regional Administrator, NRC Region II, to Charles R. Johnson, President, Nuclear Fuel Services, Inc., forwarding Notice of Violation and Proposed Imposition of Civil Penalty—\$10,000,
5. Docket No. 70-143, License No. SNM-124, March 20, 1991.*
6. Letter from John A. Grobe, Chief, Nuclear Materials Safety Branch, NRC Region III, to Susan Erickson, Vice President, Professional Services, Hutzel Hospital, forwarding Inspection Report No. 30-02024/91-001 (DRSS), Docket No. 30-02024, License No. 21-03001-01, March 13, 1991.*
7. Letter from Malcolm R. Knapp, Director, Division of Radiation Safety and Safeguards, NRC Region I, to Joseph L. Mintzer, Vice President for Clinical Services, Hahnemann University Hospital, forwarding Inspection Report No. 30-02959/91-001, Docket No. 30-02959, License No. 37-00467-34, March 11, 1991.*
7. Letter from Mohamed M. Shanbaky, Chief, Nuclear Materials Safety Section A, Division of Radiation Safety and Safeguards, NRC Region I, to Robert S. Curtis, President, Clara Maass Medical Center, forwarding Special Inspection Report No. 30-02467/91-001, Docket No. 30-02467, License No. 29-03163-03, April 17, 1991.*

*Available in NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, D.C., for public inspection and copying.

APPENDIX A

ABNORMAL OCCURRENCE CRITERIA

The following criteria for this report's abnormal occurrence determinations 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 abnormal occurrence if it involves a major reduction in the degree of protection of the public health or safety. Such an event would involve a moderate or more severe impact on the public health or safety and could include but need not be limited to:

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

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

For All Licensees

1. Exposure of the whole body of any individual to 25 rem or more of radiation; exposure of the skin of the whole body of any individual to 150 rem or more of radiation; or exposure of the feet, ankles, hands or forearms of any individual to 375 rem or more of radiation [10 CFR 20.403(a)(1)], or equivalent exposures from internal sources.
2. An exposure to an individual in an unrestricted area such that the whole body dose received exceeds 0.5 rem in one calendar year [10 CFR 20.105(a)].
3. The release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceed 500 times the regulatory limit of Appendix B, Table II, 10 CFR Part 20 [CFR 20.403(b)(2)].
4. Radiation or contamination levels in excess of design values on packages, or loss of confinement of radioactive material such as (a) a radiation dose rate of 1000 mrem per hour three feet from the surface of a package containing the radioactive material, or (b) release of ra-

dioactive 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.

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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 and safety and requires a quarterly report of such events to be made to Congress. This report covers the period January through March 1991. The report discusses six abnormal occurrences, none of which involved a nuclear power plant. Five of the events occurred at NRC-licensed facilities: one involved a significant degradation of plant safety at a nuclear fuel cycle facility, one involved a medical diagnostic misadministration, and three involved medical therapy misadministrations. An Agreement State (Arizona) reported one abnormal occurrence that involved medical therapy misadministrations.

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