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Vol. 13, No. 2

Report to Congress on Abnormal Occurrences

April – June 1990

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 April 1 through June 30, 1990.

The report discusses six abnormal occurrences, none involving a nuclear power plant. There were five abnormal occurrences at NRC licensees: (1) deficiencies in brachytherapy program; (2) a radiation overexposure of a radiographer; (3) a medical diagnostic misadministration; (4) administration of iodine-131 to a lactating female with subsequent uptake by her infant; and (5) a medical therapy misadministration. An Agreement State (Arizona) reported an abnormal occurrence involving a medical diagnostic misadministration. The report also contains information that updates a previously reported occurrence.

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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 April 1 through June 30, 1990. 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
APRIL-JUNE 1990

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.

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FUEL CYCLE FACILITIES

(Other Than Nuclear Power Plants)

The NRC is reviewing events reported by these licensees. For this report, the NRC has not determined that any events were abnormal occurrences.

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OTHER NRC LICENSEES

(Industrial Radiographers, Medical Institutions,
Industrial Users, etc.)

There are currently about 9,000 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 five events were abnormal occurrences.

90-11 Deficiencies in Brachytherapy Program

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Example 11 of "For all Licenses") of this report notes that an event involving serious deficiencies in management controls can be considered an Abnormal Occurrence.

Date and Place - On March 28, 1990, NRC Region III received allegations pertaining to brachytherapy treatments at the St. Mary Medical Center facilities in Gary and Hobart, Indiana. The NRC also conducted a special inspection at Porter Memorial Hospital, Valparaiso, Indiana. Although the original allegations did not include Porter Memorial Hospital, the NRC inspection was made because brachytherapy procedures at Porter Memorial Hospital were performed by the same physician as those at the St. Mary facilities. Following the NRC inspections at the facilities, Orders suspending the brachytherapy procedures were issued by the NRC staff to the

three hospitals. The Order to the St. Mary Medical Center facilities was issued on April 27, 1990. The Order to Porter Memorial Hospital was issued on May 2, 1990.

Nature and Probable Consequences - On March 28, 1990, NRC Region III (Chicago) received allegations pertaining to brachytherapy treatments performed by one of the authorized users at St. Mary Medical Center in Gary and Hobart, Indiana. The alleger contended that the authorized user did not evaluate patients' treatment plans prior to treatment and that the patients therefore did not receive the prescribed dose of radiation during the procedure.

Brachytherapy involves the use of small sealed capsules containing radioactive material. These capsules, which are used in the treatment of cancer, are either surgically implanted, placed in body cavities, or applied to the skin.

Assisted by a medical consultant, the NRC conducted a preliminary inquiry into the allegations on March 30 - April 19, 1990. This inspection substantiated some of the allegations, and the NRC concluded that the two St. Mary facilities were not exercising adequate management control to assure that NRC requirements were met.

Because the same authorized user performed brachytherapy treatments at Porter Memorial Hospital, the NRC performed a special inspection April 5 - April 27, 1990, at this facility. The inspection determined that adequate records had not been maintained at the hospital to evaluate whether or not the brachytherapy procedures had been administered as prescribed and planned.

On April 27, 1990, the NRC Staff issued an Order to the two St. Mary Medical Center facilities suspending brachytherapy activities (Ref. 1). The Order also directed the medical facilities to perform an independent evaluation of brachytherapy procedures performed since the brachytherapy program was started in May 1986. On May 2, 1990, the NRC Staff issued a Confirmatory Order to Porter Memorial Hospital confirming the licensee's agreement to suspend its brachytherapy program and to require an independent evaluation of previous brachytherapy procedures (Ref. 2).

Planning for these two independent evaluation programs is underway. One of the goals of the programs is to determine if any patients received radiation exposures different from those that were prescribed.

The NRC special inspection at the St. Mary facilities identified several instances where the actual therapy radiation dose may have varied from the prescribed dose by more than 10 percent. The NRC requires that a therapy radiation dose that varies from the prescribed dose by more than 10 percent be reported to the NRC and that the patient's physician be notified. Such a deviation from the prescription would be a "misadministration."

At the Porter Memorial Hospital, sufficient records were not immediately available to determine if any misadministrations occurred.

The Orders did not affect other activities performed under NRC licenses issued to the three facilities, including diagnostic tests using radiopharmaceuticals and other radiation therapy programs.

Cause or Causes - The NRC inspections determined that none of the three facilities had maintained adequate records of the treatment plans and prescriptions at the facility. The inspections also determined that licensee management at each of the facilities had not taken action to assure that established procedures were followed including maintenance of required records.

At the St. Mary facilities, hospital management was notified by a staff member as early as May 1988 that appropriate records were not being maintained nor established procedures followed, but the corrective actions taken were not effective and the inadequate recordkeeping and procedural failures continued.

Six brachytherapy procedures were performed at the Porter Memorial Hospital between 1987 and 1989. The hospital's Radiation Safety Committee and Radiation Safety Officer, however, were not aware when brachytherapy treatments were being performed or when the radioactive sources for brachytherapy were ordered.

Actions Taken to Prevent Recurrence

Licensees - The two St. Mary facilities have submitted revisions to their NRC licenses to provide quality assurance procedures for brachytherapy procedures. Porter Memorial Hospital has also submitted revisions to its NRC license providing quality assurance procedures. The proposed license amendments are under review.

The two St. Mary facilities filed a request for a hearing on the NRC Order. The authorized user, who was involved in brachytherapy treatments at the facilities, also requested a hearing and he was admitted to the proceeding as an intervenor.

The proceeding is currently pending before an Atomic Safety and Licensing Board, although settlement discussions are underway.

NRC - The NRC staff issued Orders to the three facilities, suspending brachytherapy procedures at the St. Mary facilities and confirming that Porter Memorial Hospital had ceased brachytherapy treatments. The Orders also required the licensees to undertake independent evaluation of completed brachytherapy procedures to determine if the treatments were consistent with the prescribed doses and treatment plans. The licensees were also required to submit proposed license amendments to provide quality assurance procedures should they desire to continue their brachytherapy programs. The licensees were not to resume brachytherapy procedures without NRC authorization.

Future reports will be made as appropriate.

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90-12 Radiation Overexposure of a Radiographer

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 exposure of the skin of any individual to 150 rem or more of radiation can be considered an abnormal occurrence.

Date and Place - April 6, 1990; Barnett Industrial X-Ray; Stillwater, Oklahoma; the radiation overexposure occurred at a temporary jobsite in Ardmore, Oklahoma.

Nature and Probable Consequences - On the evening of April 6, 1990, the licensee notified the NRC that an incident had occurred earlier that evening while a radiographer and his assistant were working at a temporary jobsite. The radiographic operation involved the use of a radiography device containing an approximately 80-curie iridium-192 sealed source. (A radiography device uses a radioactive sealed source to make x-ray-like images of welds and heavy metal objects. The position of the source is controlled by a drive cable which is used to crank the source out of the exposure device and retract it back to a shielded position within the device via an unshielded source guide tube.) The licensee reported that the source became disconnected from the drive cable and remained in the source guide tube. Unaware that the source remained in the tube, the assistant wrapped the source guide tube around his neck while he moved equipment at the worksite. The licensee initially estimated that the assistant received an exposure of 4000 rem to the exposed area of his neck. Two NRC Region IV inspectors were dispatched the following morning to investigate the incident. The circumstances associated with the radiation overexposure are described below.

After completing two radiographs of a pipe weld, the radiographer proceeded to develop the radiographs while the assistant disassembled the equipment to move the exposure device to another location. While doing this, he removed the source guide tube and draped it around his neck so that his hands would be free to carry the remaining equipment. He walked approximately 30-50 feet before stopping to set the equipment down. As he removed the guide tube from around his neck, he noticed that the sealed source fell from the tube to the ground. The assistant notified the radiographer who telephoned the company owner and, following his direction, successfully retrieved the source to a shielded position within the exposure device. During his conversation with the owner, the radiographer identified: (1) that he failed to conduct a radiation survey of the exposure device after each of the exposures, (2) that the assistant's pocket dosimeter had gone offscale (greater than 200 millirem), and (3) that the assistant was not wearing his film badge during these operations. Under the owner's direction, the assistant was taken for medical examination at a local hospital later that evening.

Based on interviews conducted with the radiographer and company owner together with NRC reenactments of the radiographer's actions during the event, NRC inspectors determined that he might also have received an exposure in excess of regulatory limits. When the radiographer later confirmed that his pocket dosimeter had gone offscale, his film badge was sent for immediate processing. Both the assistant and radiographer were referred for examination by a

radiation oncologist (a physician experienced in examining patients who have been treated with large doses of radiation) and blood samples were obtained for cytogenetic studies.

The cytogenetic studies revealed equivalent whole body doses of 17 rem for the radiographer and 24 rem for the assistant. The assistant developed an area of erythema on the left side of his neck, which later showed signs of more significant damage to skin tissue in an area approximately 10 centimeters in diameter. The oncologist determined that the observed effect corresponded to a local skin dose of 5000-7000 rem. As of June 1990, the skin tissue in this area had regenerated and the physician did not predict any long-term effects as a result of this exposure. The assistant remains under the physician's care, and the NRC continues to receive reports on his progress. There were no medical effects observed for the radiographer.

Cause or Causes - The radiographer and assistant failed to conduct a radiation survey of the exposure device after either of the exposures was completed to ensure that the source had been retracted to its shielded position. The radiographer was exposed to the unshielded source as he changed films between the two exposures, and the assistant received a large exposure as he carried the source tube containing the source draped around his neck. Without a radiation survey, neither individual was aware that the source had not been connected to the drive cable and remained in the guide tube.

Actions Taken to Prevent Recurrence

Licensee - The licensee's proposed corrective actions include retraining the radiographer in radiation safety procedures and continued observation of his performance. The assistant radiographer is no longer employed by the licensee.

NRC - During the investigation of this event, on April 12, 1990, an Order modifying the license was issued, prohibiting the radiographer and assistant from participating in licensed activities (Ref. 3). This Order has since been relaxed due to the licensee's implementation of corrective action. NRC Region IV conducted an enforcement conference with the licensee on May 25, 1990, to discuss the event (Ref. 4). On September 7, 1990, the NRC issued to the licensee a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $7,500 (Ref. 5). The basis for the proposed penalty were violations associated with failure to conduct the required radiation survey and the resultant overexposures. These two violations collectively were classified as Severity Level I (on a scale of Levels I through V, in which Level I is the most significant).

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

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90-13 Medical Diagnostic Misadministration

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the general 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 - June 5, 1990; Mercy Memorial Medical Center; St. Joseph, Michigan.

Nature and Probable Consequences - A 79-year-old female patient was scheduled to undergo a diagnostic evaluation to determine whether she was suffering from an enlarged thyroid gland (substernal thyroid). No prescribed dose was indicated.

The scan was scheduled for the following day. The technologist, in attempting to order the proper amount of radioactive material, noted that her standard dose chart (created by authorized users) did not list dosage for a substernal thyroid gland study.

She then referred to the department's procedures manual, which indicated that the proper dose for a substernal thyroid gland study was 3-5 millicuries of iodine-131, or 100-200 microcuries of iodine-123. The technologist then asked an authorized user which isotope to use. He instructed her to order a sufficient quantity of iodine-131 to visualize the thyroid gland. On June 5, 1990, the patient was given 4.3 millicuries of iodine-131, which conformed to the procedures manual. The dosage listed in the procedure, however, was wrong. The standard dose for a substernal thyroid scan should have been 50 to 100 microcuries of iodine-131, or approximately one-fiftieth of the amount noted in the manual. The mistake was identified by the Chief of the Nuclear Medicine Department on June 6 and reported as a misadministration to the NRC on June 8, 1990.

The licensee estimated that the misadministration resulted in a mean dose to the thyroid gland of 5,752 rads. The NRC's medical consultant investigated the case. Based on certain assumptions, the consultant estimated the dose to be 3,400 rads to the thyroid gland which, according to the consultant, would yield a 10 percent chance of hypothyroidism over five years. The licensee is monitoring the patient's condition.

Cause or Causes - The Nuclear Medicine Department's procedures manual listed the wrong iodine-131 dosage for a substernal thyroid scan. The dosage was not reviewed by an authorized user prior to its administration.

Actions Taken to Prevent Recurrence

Licensee - The license has been amended to incorporate the following changes in iodine-131 procedures: (1) Two nuclear medicine technologists will independently verify the prescribed dosage and check the dose calibrator assay; (2) A written prescription by an authorized user will be required before the procedure is carried out; and (3) Two signatures or initials will be required on all documents involving iodine-131. The licensee also

corrected the department's procedures manual to reflect the proper dosage for a substernal thyroid scan. Dosage for a substernal thyroid scan also was added to the department's Standard Dose Chart.

NRC - An NRC inspection was conducted on June 19, 1990 (Ref. 6). Seven violations of NRC requirements (unrelated to this event) were identified. The licensee's corrective actions to prevent recurrence were found to be satisfactory. The NRC notified its medical consultant who reviewed the circumstances. He made certain procedural recommendations for consideration by the licensee.

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

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90-14 Administration of Iodine-131 to a Lactating Female With Uptake by Her Infant

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the general 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 - June 19, 1990; Tripler Army Medical Center; Honolulu, Hawaii.

Nature and Probable Consequences - A nursing mother was given a 4.89 millicurie dose of iodine-131 at an NRC licensed medical facility that resulted in an unintentional radiation dose to her infant's thyroid gland estimated at 30,000 rads and a dose to the infant's whole body of 17 rads. The error was detected on June 21, 1990, when the patient returned to the medical center for a whole body scan. The scan indicated an unusually high breast uptake of iodine-131. In the opinion of the patient's physician and an NRC medical consultant, the infant's thyroid function will be completely lost. The infant will require artificial thyroid hormone medication for life to ensure normal growth and development.

Cause or Causes - The physician and nuclear medicine technologist failed to confirm that the patient was not breast feeding. The patient arrived at the medical center from a remote South Pacific island. Communication between the island physician and the Army physicians was poor and the Tripler physicians were not aware that the mother had given birth on June 1, 1990.

Actions Taken to Prevent Recurrence

Licensee - Immediately following discovery of the error the licensee began using a new questionnaire that more clearly requires the collection and documentation of information concerning patient pregnancy and breast feeding. The Commanding Officer has ordered a special investigation to define the cause and appropriate corrective actions. The licensee has contacted the patient and the patient's physician and is finalizing arrangements for long term follow-up medical care.

NRC - An Enforcement Conference was held on August 16, 1990, and enforcement action is being considered.

Future reports will be made as appropriate.

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90-15 Medical Therapy Misadministration

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the general 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 - June 22, 1990; St. Luke's Hospital; Cleveland, Ohio.

Nature and Probable Consequences - A 57-year-old woman, being treated for lung cancer, was erroneously given a 178 rem radiation dose to the left side of the head on June 22, 1990, using the licensee's cobalt-60 teletherapy unit. The patient was scheduled to receive a 200 rem radiation dose to the chest area at the time of the misadministration. The treatment was the ninth of a total of ten treatments in the series for a total of 2,000 rem to the chest. The treatment began June 11, 1990.

A technologist set the patient up for brain irradiation without looking at the treatment documents. After the left side of the head was treated, the patient asked if her chest would also be treated. At this time, the treatment staff discovered the error.

Because the misadministration involved a single treatment and because of the dosage involved, no adverse medical effects are expected. Subsequent to the misadministration, the patient received the intended 200 rem radiation dose to the chest area. The tenth treatment was administered, and the patient began a second phase of 25 radiation treatments of 150 rem each to the chest area.

Cause or Causes - This misadministration was caused by the failure of the technologist to examine the treatment documentation (the setup sheet and a treatment field picture). Although the technologist had previously treated the patient, the technologist erroneously assumed the brain was the area to be treated. (The staff determined that although lung cancers of this type often do metastasize to the brain, the irradiation of the brain in this case was a misadministration nonetheless.)

Actions Taken to Prevent Recurrence

Licensee - The licensee has revised its procedures to require the verification, when circumstances permit, of the treatment setup by a second technologist using the setup documentation. All technologists have been trained in the procedure. The NRC is requesting the licensee to amend its quality assurance procedures to include dual verification of treatment setups prior to any treatment.

NRC - The NRC conducted a special inspection on June 27-29, 1990, to review the circumstances of the misadministration and to evaluate the licensee's radiation safety and management control programs (Ref. 7). The inspection also covered an earlier therapy misadministration in which a patient received less than the intended dose. In this misadministration, a patient received a dose that was 12 per cent less than that intended during a treatment series February 15 through April 3, 1990. A Notice of Violation was issued for two instances of failure to report the misadministrations within the required time period. The inspection also identified a concern about staff shortages that may adversely affect the licensee's radiation therapy program. The NRC requested the hospital's response to this concern.

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

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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. For this period, the Agreement States determined that one of these events was an abnormal occurrence.

AS90-1 Medical Diagnostic Misadministration

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

Date and Place - November 1, 1989; Desert Samaritan Hospital; Phoenix, Arizona

Nature and Probable Consequences - On November 1, 1989, a patient scheduled for the administration of 100 microcurie capsules of iodine-123 for a diagnostic thyroid scan was mistakenly administered a therapeutic dose of 100 millicuries of iodine-131 and sent home for 24 hours until normal imaging was scheduled.

When the patient returned on November 2, the imaging camera flooded out, which indicated a large overdose. The hospital immediately notified the Arizona Radiation Regulatory Agency (ARRA). The patient was immediately hospitalized and isolated, (the standard practice for thyroid ablation patients). The patient was discharged on November 5, 1989.

The patient's family was contacted and a bioassay was performed to determine the thyroid body burden of each family member. The thyroid burdens were above the action level for radiation workers (0.4 microcurie) but the level was not considered a serious health threat to any family member.

A hospital employee and an ARRA representative surveyed and decontaminated the patient's house. Wipe tests were used to verify the efficiency of the decontamination.

Cause or Causes - There were several causes for this event. The hospital staff:

- o did not assay the dose in the dose calibrator prior to administering it,
- o did not compare the iodine-131 dose label with the physician's order, and
- o did not maintain adequate records of incoming radiopharmaceuticals.

In addition, ARRA cited the hospital for allowing a patient who had been administered a therapeutic dose of iodine-131 to go home.

Syncor International, Inc., the radiopharmacy that dispensed the dose:

- o did not record the telephone order for iodine-131 legibly so that the units for microcurie and millicurie could be differentiated, and
- o did not record the type of intended procedure (diagnostic or therapeutic).

Actions Taken to Prevent Recurrence

Agency - The ARRA placed an order on the hospital that reduced the possession limit for iodine-131 from 500 millicuries to 100 microcuries (0.1 millicurie). The ARRA also cited Syncor and imposed an order limiting them from dispensing any dose of iodine-131 in excess of 1 millicurie unless a written order from the client licensee was in the possession of the radiopharmacist dispensing the dose. Later, the ARRA sent a Notice of Violation to the licensee and imposed a civil penalty in the amount of $12,000.

Hospital - The hospital amended its Nuclear Medicine Department administrative procedures and paid the civil penalty in full. The order restricting iodine-131 possession limits to 100 microcuries was rescinded by the ARRA on March 9, 1990.

Radiopharmacy - The radiopharmacy adopted policies to be used when iodine-131 therapy orders were received and dispensed. The ARRA issued a license amendment incorporating required procedures for orders for more than 1 millicurie of iodine-131. The order limiting the amount of iodine-131 that could be dispensed was withdrawn by the ARRA on January 9, 1990.

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

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REFERENCES

1. Letter from James Lieberman, NRC Director of Enforcement, to Scott Hardtman, Vice President, Operations, St. Mary Medical Center - Hobart and St. Mary Medical Center - Gary, transmitting, "Order Suspending Brachytherapy Activities and Modifying Licenses," April 27, 1990.*

2. Letter from Hugh L. Thompson, Jr., NRC Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, to Wiley N. Carr, Administrator and Chief Executive Officer, Porter Memorial Hospital, forwarding "Confirmatory Order Suspending Brachytherapy Activities and Modifying License," May 2, 1990.*

3. Letter from Hugh L. Thompson, Jr., NRC Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, to Loyd D. Barnett, Barnett Industrial X-Ray, transmitting "Order Modifying License," Docket 030-30691, April 12, 1990.*

4. Letter from A. Bill Beach, Director, Division of Radiation Safety and Safeguards, NRC Region IV, to Loyd Barnett, Barnett Industrial X-Ray, transmitting "Enforcement Conference Summary" Docket 030-30691, June 11, 1990.*

5. Letter from Robert D. Martin, Regional Administrator, NRC Region IV, to Loyd Barnett, Barnett Industrial X-Ray, transmitting a Notice of Violation and Proposed Imposition of Civil Penalty, Docket No. 030-30691, License No. 35-26953-01, September 7, 1990.*

6. Letter from Bruce S. Mallett, Chief, Nuclear Materials Safety and Safeguards, NRC Region III to H. David Claus, Vice President of Administration, Mercy Memorial Medical Center, Inc. forwarding Inspection Report 030-02049/90001, Docket No. 030-02049, License No. 21-04177-01, July 31, 1990.*

7. Letter from Charles E. Norelius, Director, Division of Radiation Safety and Safeguards, NRC Region III, to Jeffrey Jarey, Vice President, Services, St. Luke's Hospital, forwarding Inspection Report 030-17512/90001, Docket No. 030-17512, License No. 34-00398-10, July 26, 1990.*

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* 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 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.

APPENDIX B

UPDATE OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During the April through June 1990 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 Congressional abnormal occurrence report below provides the initial and any subsequent updating information on the abnormal occurrence discussed. (The updating provided generally covers events that took place during the report period; some updating, however, is more current as indicated by the associated event dates.) Open items will be discussed in subsequent reports in the series.

OTHER NRC LICENSES

88-6 Release of Polonium-210 from Static Elimination Devices Manufactured by 3M Company.

This abnormal occurrence, involving the Minnesota Mining and Manufacturing Company (3M), was originally reported in NUREG-0090, Vol. 11, No. 1, "Report to Congress on Abnormal Occurrences: January-June 1988." It was updated and closed out in NUREG-0090 Vol. 11, No. 3. It is being reopened, and then reclosed, to report the following significant proposed enforcement action taken as a result of NRC investigations.

The Nuclear Regulatory Commission Staff proposed a $160,000 fine for willful violations of NRC requirements associated with the leakage of polonium-210 from static elimination devices manufactured and distributed by 3M (Ref. B-1). The enforcement action was based on inspections conducted by the NRC staff in 1988 and an investigation in 1988 and 1989 by the agency's Office of Investigations. The case was reviewed by the U. S. Attorney in Minneapolis, Minnesota, and that office decided not to undertake prosecution in lieu of the civil sanctions proposed by the NRC.

As a result of the contamination resulting from leakage of the devices, in 1988 the NRC staff issued a series of four Orders requiring recall of all 3M static elimination devices and prohibiting further distribution. The company was subsequently permitted to perform research and development work on the design of the device, but the prohibition of distribution remains in effect.

While there was a significant potential for unnecessary and widespread contamination, the radioactive material was in a form that made it unlikely that any person received a significant radiation exposure or that consumer products were significantly contaminated by the radioactive material.

The NRC investigation and inspection concluded that 3M personnel willfully failed to assure that customers would use the static eliminators in acceptable environments and that the company failed to determine properly the amount of

radioactive contamination on static elimination devices returned to the company by its customers. An $80,000 fine was proposed for these two violations.

A second $80,000 fine was proposed for four additional violations: the failure of 3M to identify all results of testing and evaluation of returned static eliminators classified by 3M as damaged in annual reports submitted to the NRC for 1986 (violation 1) and 1987 (violation 2); the failure of the company to notify all of its customers (violation 3) and to follow up with its customers (violation 4) the return of damaged leak detectors after it had determined that some returned static elimination devices had removable radioactive contamination on surfaces in excess of NRC limits.

No fine was assessed for a seventh violation: the failure to obtain NRC review and approval for changes in components in static elimination devices distributed between 1983 and 1988.

The NRC Office of Investigations concluded that one 3M employee: (1) willfully failed to notify 3M's customers of leaking static eliminators, and (2) willfully failed to provide information to the NRC staff. Two more employees likely failed to make accurate reports to the NRC staff and likely demonstrated a careless disregard for the agency's requirements. A fourth employee failed to become familiar with NRC reporting requirements and, as a result, also submitted inaccurate information to the NRC staff.

The enforcement action (Ref. B-1) also included a "Demand for Information" to assist in determining if there is a reasonable assurance that 3M's licensed activities would be conducted in compliance with agency requirements if these four individuals are associated with NRC-licensed activities.

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

* * * * * * * *

APPENDIX C

OTHER EVENTS OF INTEREST

The following item is described because it may possibly be perceived by the public to be of public health or safety significance. The item did not involve a major reduction in the level of protection provided for public health or safety; therefore, it is not reportable as an abnormal occurrence.

1. Reactor Operator Requalification Program Deficiencies at Several Nuclear Power Facilities

In November 1988, the NRC implemented the requalification examination program, as described in ES-601 of Revision 5 of NUREG-1021, "Operator Licensing Examiner Standards." Of the 79 power reactor facilities that the NRC evaluated against the criteria in ES-601 (Revision 5), the programs at 10 facilities exhibited deficiencies warranting an overall unsatisfactory program rating. These facilities are listed in Table C-1.

All facility licensees are required by Section 50.54(i) of Title 10 of the Code of Federal Regulations (10 CFR) to implement an operator requalification program that must, as a minimum, meet the requirements of 10 CFR 55.59. Pursuant to 10 CFR 55.57(b), an operator's license will be renewed if the Commission finds that the operator has successfully completed an approved requalification program as required by Section 55.59 and, among other things, has passed a comprehensive requalification written examination and operating test administered by the Commission during the term of his or her 6-year license.

The procedures contained in ES-601 of Revision 5 of NUREG-1021 were derived based on a Systems Approach to Training (SAT) program and rely on existing requalification program standards for guiding the development and implementation of NRC examinations. The program evaluates the effectiveness with which the facilities' requalification training programs enable licensed operators to maintain their competency and currency while providing individual operators the opportunity to satisfy their regulatory requirement to pass an NRC requalification examination before license renewal.

The NRC-administered requalification examination is composed of a comprehensive operating test and written examination developed by a team of NRC examiners and facility representatives. The two-phase operating test [crew evaluation on a dynamic simulator and individual evaluation using Job Performance Measures (JPMs)] and the two-section, open-reference written examination (static simulator and classroom) are, to the extent practical, based upon the facility's requalification program and its learning objectives.

Generic weaknesses (applicable to more than one of the facilities listed in Table C-1) found during the requalification examinations can be organized into two categories: "safety and technical" and "program." The safety and technical weaknesses included deficiencies in (1) communications within crews; (2) senior reactor operator (SRO) command and control; (3) use of emergency

Table C-1
Facilities Receiving an Overall Unsatisfactory
Requalification Program Rating

Facility (Licensee)	Plant Type*	Plant Location	Date of NRC Exam
Browns Ferry (Tennessee Valley Authority)	GE-BWR	Limestone County, Alabama	7/89
Brunswick (Carolina Power & Light)	GE-BWR	Brunswick County, North Carolina	5/90
Duane Arnold (Iowa Electric Light & Power)	GE-BWR	Linn County, Iowa	6/90
Ginna (Rochester Gas & Electric)	W-PWR	Wayne County, New York	6/89
Limerick (Philadelphia Electric)	GE-BWR	Montgomery County, Pennsylvania	1/90
Millstone 3 (Northeast Nuclear Energy)	W-PWR	New London County, Connecticut	9/89
Nine Mile Point 2 (Niagara Mohawk Power)	GE-BWR	Oswego County, New York	7/89
Point Beach (Wisconsin Electric Power)	W-PWR	Manitowoc County, Wisconsin	2/89
Turkey Point (Florida Power & Light)	W-PWR	Dade County, Florida	3/89
Zion (Commonwealth Edison)	W-PWR	Lake County, Illinois	9/89

* GE-BWR means a General Electric-designed boiling water reactor.
* W-PWR means a Westinghouse-designed pressurized water reactor.

operating procedures (EOPs); (4) technical specification interpretation and usage; (5) operation of emergency core cooling systems (ECCSs); and (6) emergency action level classification. The program weaknesses included deficiencies in (1) facility evaluator performance; (2) shift staffing and rotation; (3) reference and examination material; and (4) procedure control. The causes of the deficiencies can be generally attributed to failure to implement adequate standards for training and evaluation of the operators. In general, corrective actions consisted of licensees performing root cause analysis to identify the major weaknesses and providing remedial training of the operators.

Of the more recent examinations administered by the NRC, the most significant deficiencies were identified at the Brunswick facility. This event is discussed below to provide specifics of the deficiencies and to describe the corrective actions taken by the licensee and NRC.

Requalification examinations were administered by the NRC April 30-May 11, 1990, to 12 SROs and 8 Reactor Operators (ROs). Three SROs and 4 ROs passed these examinations. All others failed. These 20 operators consisted of 4 crews with 5 licensed operators each. Three of the 4 crews (and 13 operators) failed the dynamic simulator examinations.

Generic weaknesses were displayed by the crews during the dynamic simulator section of the examination in the areas of control and awareness of plant status, ECCS operations, EOP flow chart usage, and communication skills. Three crews (of four) failed the dynamic simulator section of the exam due in large part to their inability to maintain a proper cognizance and control of major plant parameters and systems. The command and control weaknesses identified were exacerbated by deficiencies in ECCS operations, EOP usage and communications. These deficiencies were not attributed to all of the operators, but were of a sufficient repetitive nature to be considered pervasive.

Licensee management met with the NRC on May 15, 1990, to agree on compensatory actions to correct deficiencies noted during the examinations. As a result of this meeting, the licensee agreed to place an additional Operations Supervisor (who has an operator's license) on each shift, provide remedial training to all licensed operators (while removing from shift the operators who did not pass the administered examination) and participate with the NRC in operational evaluations of the operators not previously evaluated.

Operational Evaluations on the simulator were administered to 4 crews, a total of 27 operators, on May 18-19, 1990. The NRC determined that 4 of the 4 crews evaluated, and 8 of 27 operators performed unsatisfactorily during these evaluations. As a result, the licensee placed both Brunswick units in cold shutdown to allow for crew reconstitution, training and re-evaluation prior to continued operation of the facility.

The cause of the deficiencies was failure to implement adequate standards for training and evaluation of the operators on operation of the facility's emergency systems during abnormal and emergency situations. The licensee's recovery plan involved both short and long term corrective actions. In the

short term, the licensee provided remedial training to a sufficient number of reconstituted operating crews to support restart of both units. Operational Evaluations were conducted on June 9-10, 1990, by the NRC prior to restart. The result provided the licensee with sufficient licensed operators to safely start-up and resume power operation of both units. Both units were returned to power operation as of June 11, 1990. The NRC conducted additional Operational Evaluations on July 25-26, 1990, to ensure that a sufficient number of qualified operators were available for continued power operation of both units. The licensee completed a root cause analysis to identify the major weaknesses and contributors that led to the unsuccessful operator performance on the NRC administered requalification examination. The scheduled corrective actions will result in the licensed operator requalification training program being ready for NRC re-evaluation by April 1991. Prior to conducting this reassessment, the status of the licensee's corrective actions and training program will be reviewed during an NRC training inspection.

On August 28, 1990, the NRC issued Information Notice No. 90-54, "Summary of Requalification Program Deficiencies" (Ref. C-1) to all holders of operating licenses or construction permits to alert licensees to problems identified during administration of the NRC's licensed operator requalification examination program. This notice addressed technical and program weaknesses generic to the 10 facilities listed in Table C-1.

* * * * * * * * *

REFERENCES FOR APPENDICES

B-1 Letter from Hugh L. Thompson, Jr., NRC Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support to Allen F. Jacobson, Chairman and Chief Executive Officer, Minnesota Mining and Manufacturing Company (3M), forwarding Notice of Violation and Proposed Imposition of Civil Penalty - $160,000 and Demand for Information, June 7, 1990.*

C-1 U.S. Nuclear Regulatory Commission, NRC Information Notice No. 90-54, "Summary of Requalification Program Deficiencies," August 28, 1990.*

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

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Section 208 of the Energy Reorganization Act of 1974 identifies an abnormal occurrence as an unscheduled incident or event which 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 April 1 through June 30, 1990. The report discusses six abnormal occurrences, none involving a nuclear power plant. There were five abnormal occurrences at NRC licensees: (1) deficiencies in brachytherapy program; (2) a radiation overexposure of a radiographer; (3) a medical diagnostic misadministration; (4) administration of I-131 to a lactating female with uptake by her infant; and (5) a medical therapy misadministration. An Agreement State (Arizona) reported an abnormal occurrence involving a medical diagnostic misadministration. The report also contains information that updates a previously reported abnormal occurrence.

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

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