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POLICY ISSUE

(NEGATIVE CONSENT)

SECY-92-402

December 3, 1992

For: The Commissioners

From: James M. Taylor
Executive Director
for Operations

Subject: SECTION 208 REPORT TO THE CONGRESS ON ABNORMAL OCCURRENCES
FOR JULY - SEPTEMBER 1992

Purpose: Approval of Final Draft

Discussion: Enclosure 1 is a proposed draft letter to the Speaker of the House and the President of the Senate forwarding the Section 208 report to Congress for the third quarter of CY 1992.

Enclosure 2 is a final draft of the quarterly report to Congress on abnormal occurrences (AOs). The report (draft NUREG-0090, Vol. 15, No. 3) covers the period July 1 through September 30, 1992. This draft incorporates the major comments obtained from staff review of a previous draft.

There is no proposed AO for nuclear power plants or fuel facilities. There are three proposed AOs for the other NRC licensees. An NRC Agreement State submitted one proposed AO during the period. The proposed AOs, and the criteria or guidelines for reporting, are:

Other NRC Licensees

92-9 Medical Therapy Misadministration at Cooper Hospital/University Medical Center in Camden, New Jersey - A therapeutic misadministration that affected two or more patients at the same facility.

Contact:
Marc Harper, AEOD
49-24497

NOTE: TO BE MADE PUBLICLY AVAILABLE
WHEN THE FINAL SRM IS MADE
AVAILABLE

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92-10 Extremity Overexposure of a Radiographer at MQS Inspection, Incorporated, Field Site in Trenton, Michigan - An exposure of the hand to 375 rem or more of radiation.

92-11 Medical Therapy Misadministration at the Medical Center of Delaware, Incorporated in Wilmington, Delaware - A therapeutic exposure to a part of the body not scheduled to receive radiation.

AGREEMENT STATE LICENSEES

AS92-1 Medical Diagnostic Misadministration at Southwest Texas Methodist Hospital in San Antonio, Texas - Administration of a diagnostic dose of a radiopharmaceutical that is greater than five times the prescribed dose.

There is one item for Appendix B ("Update of Previously Reported Abnormal Occurrences"). The item is:

Other NRC Licensees

90-19 Medical Diagnostic Misadministration at Copley Hospital in Morrisville, Vermont - Further information is provided and the item is closed out.

There is one item for Appendix C ("Other Events of Interest"). The item is:

Nuclear Power Plants

1. Loss-of-Coolant Event at the Fort Calhoun Station.

There is one item for Enclosure 3 (i.e., items that were candidates for inclusion as AOs, but which in the staff's judgment did not meet the criteria for AO reporting after further study) to this Commission paper. The item is:

Other NRC Licensees

1. Medical Therapy Misadministration at St. Joseph's Hospital and Medical Center in Paterson, New Jersey

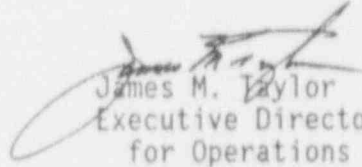
The Office of General Counsel has reviewed the draft report and has no legal objections.

Recommendations: That the Commission:

1. Approve the contents of the proposed Third Quarter 1992 Abnormal Occurrence Report to Congress, and
2. Note that upon approval and publication, forwarding letters to the Speaker of the House and the President of the Senate will be provided to the Chairman for signature. Congressional Affairs will then arrange for appropriate distribution to Congress. A Federal Register notice (describing details of the events) will be issued for the AOs at the NRC licensees. A separate Federal Register notice will be issued announcing publication of the quarterly report. No press releases are planned.

Scheduling:

It is requested that Commission action be taken within two weeks of receipt of this draft report. If no significant revisions are required, this would permit printing of the report and forwarding of the letters to Congress for the Chairman's signature about two weeks later.


James M. Taylor
Executive Director
for Operations

Enclosures:

1. Proposed letters to Congress
2. Draft of Third Quarter CY 1992
Abnormal Occurrence Report
to Congress

SECY NOTE: In the absence of instructions to the contrary, SECY will notify the staff on Friday, December 18, 1992, that the Commission, by negative consent, assents to the action proposed in this paper.

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IDENTICAL LETTERS TO:

The Honorable J. Danforth Quayle
President of the United States Senate
Washington, DC 20510

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

Dear Mr. President:

Dear Mr. Speaker:

I am forwarding the Nuclear Regulatory Commission's report on abnormal occurrences at licensed nuclear facilities for the third calendar quarter of 1992. These quarterly reports are required by Section 208 of the Energy Reorganization Act of 1974 (PL 93-438). In the context of the act, an abnormal occurrence is an unscheduled incident or event that the Commission determines is significant from the standpoint of public health or safety.

There were no abnormal occurrences at a nuclear power plant. Two abnormal occurrences involving medical misadministrations (both therapeutic) and one involving overexposure of a radiographer at NRC-licensed facilities are discussed in this report. In addition, another abnormal occurrence was reported by an NRC Agreement State. The report also contains information updating a previously reported abnormal occurrence.

The NRC will continue to disseminate information on significant events through various reports. These are routinely distributed on a timely basis to the Congress, industry, and the general public.

Sincerely,

Ivan Selin

Enclosure:
As stated

Enclosure 2

DRAFT

(Enclosure 2 to Commission Paper)

REPORT TO CONGRESS
ON
ABNORMAL OCCURRENCES
July - September 1992

Date Published: December 1992

Office for Analysis and Evaluation of Operational Data
United States Nuclear Regulatory Commission
Washington, D.C. 20555

ABSTRACT

Section 208 of the Energy Reorganization Act of 1974 identifies an abnormal occurrence as an unscheduled incident or event that the Nuclear Regulatory Commission determines to be significant from the standpoint of public health or safety and requires a quarterly report of such events to be made to Congress. This report covers the period from July 1 through September 30, 1992.

There were no abnormal occurrences at a nuclear power plant. Two abnormal occurrences involving medical misadministrations (both therapeutic) and one involving overexposure of a radiographer at NRC-licensed facilities were discussed in this report. In addition, another abnormal occurrence was reported by an NRC Agreement State. The report also contains information updating a previously reported abnormal 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 and accompanying examples listed in Appendix A. These criteria were promulgated in an NRC policy statement that was published in the Federal Register on February 24, 1977 (Vol. 42, No. 37, pages 10950-10952).

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

In order to provide wide dissemination of information to the public, a Federal Register notice is issued on 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 July 1 through September 30, 1992. 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 and the uses of byproduct nuclear materials, 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.

Three primary sources of operational data are Licensee Event Reports (LERs) and immediate notifications made pursuant to 10 CFR 50.72 and medical misadministration reports made pursuant to 10 CFR 35.33.

Except for records exempt from public disclosure by statute and/or regulation, information concerning reportable occurrences at facilities licensed or otherwise regulated by 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
JULY-SEPTEMBER 1992

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 not determined that any events were abnormal occurrences.

* * * * *

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 the following events were abnormal occurrences using the criteria and guidelines given in Appendix A. As noted in the Preface to this report, the guidelines for identifying medical misadministrations as abnormal occurrences are currently being revised.

92-9 Medical Therapy Misadministration at Cooper Hospital/University Medical Center in Camden, New Jersey

The following information pertaining to this event is also being reported concurrently in the Federal Register. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic misadministration affecting two or more patients at the same facility can be considered an abnormal occurrence.

Date and Place - November 11, 1991 to January 7, 1992; Cooper Hospital/University Medical Center; Camden, New Jersey.

Nature and Probable Consequences - On January 27, 1992, the NRC Region I office was notified by telephone that five therapeutic misadministrations involving Iridium-192 (Ir-192) wire occurred at Cooper Hospital/University Medical Center at Camden, New Jersey from November 11, 1991 to January 7, 1992. The licensee had discovered the error on January 24, 1992, after the

review of patient charts in preparation for the Quality Management Program submittal. The error caused a 12.2 percent underdosing of the patients.

Four patients received external beam therapy (Linear Accelerator) in addition to the radiation received from the Ir-192 implants. Patient A was to receive 1043 rads from an Ir-192 intracavitary bronchial implant for the treatment of lung cancer and received 916 rads on November 11, 1991. Patient A later received 5576 rads from external beam therapy. Patient B was to receive 1266 rads to the head and neck from an Ir-192 interstitial implant for the treatment of cancer and received 1112 rads on November 12, 1992. Patient B later received 4600 rads from external beam therapy. Patient C was to receive 2150 rads from an Ir-192 interstitial implant for the treatment of breast cancer and received 1888 rads on December 2, 1991. Patient C later received 5940 rads from external beam therapy. Patient D was to receive 2000 rads to the tongue for the treatment of cancer from an Ir-192 interstitial implant and received 1756 rads on January 7, 1992. Patient D later received 5940 rads from external beam therapy. The licensee has determined that the above patient's treatments were not compromised by the small decrease in the total dose received when the external beam therapy treatment is factored into the assessment.

One patient did not receive external beam therapy. On November 21, 1991, Patient E was prescribed to receive 4628 rads to the pelvis for the treatment of cancer from an Ir-192 interstitial implant and received 4063 rads. Patient E's attending physician had originally calculated a desired dose between 4000 and 4500 rads and wanted to include hyperthermia treatment. Hyperthermia treatment required insertion of interstitial microwave antennae so that heat treatment was terminated within one hour before the implants were inserted and was initiated within one hour after the implants were removed. The attending physician was informed by the licensee's staff that the implants would have to be removed at unreasonable times in order to fall within the attending physician's desired dose range. The attending physician then agreed to give 4628 rads so that the second hyperthermia treatment could be given at a more reasonable time. Since the actual delivered dose fell within the attending physician's initial range, the licensee does not foresee any adverse effects for Patient E.

Cause or Causes - It was determined that the cause of the misadministration was an input error into the treatment planning computer. Specifically, the source calibration factor was in non-Systeme Internationale (SI) units (non-metric), however, the computer was set to receive the data in SI units and the setting was not changed.

Actions Taken to Prevent Recurrence

Licensee - The licensee's corrective action was to include the calibration factor that is used during treatments in their records for Implant Source Inventory - Source Type Characteristics so that the licensee can verify that the proper factors are used.

NRC - An NRC Region I inspector conducted an inspection of the incident on August 5, 1992, to determine the circumstances associated with the misadministration. The inspector's findings were in agreement with the licensee concerning the cause of the misadministration. The inspector determined that the licensee's corrective actions were adequate to prevent recurrence. Inspection findings regarding the misadministration are documented in Inspection Field Notes approved September 9, 1992. (Ref. 1).

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

92-10 Extremity Overexposure of a Radiographer at MQS Inspection, Inc., Field Site in Trenton, Michigan

The following information pertaining to this event is also being reported in the Federal Register. Appendix A (see Example 1 of "For All Licensees") of this report notes that an exposure of the feet, ankles, hands, or forearms of any individual to 375 rem or more of radiation can be considered an abnormal occurrence.

Date and Place - July 6, 1992; a temporary radiography field site in Trenton, Michigan.

Nature and Probable Consequences - On July 6, 1992, a licensee radiographer was assigned to radiograph various pipes at a construction site. Radiography is a non-destructive testing technique which uses a sealed radiation source to make X-ray-like images of heavy metal objects.

The configuration of this job required that the radiography exposure device (camera) be suspended 20 feet above the floor. The radiation source is exposed using a remote cable to make the film image and then is retracted into the shielded camera. After an exposure, the radiographer used an aerial platform to reach the camera. He performed a radiation survey as he approached to assure that the source was in the shield. The radiographer was wearing his audible alarm radiation measuring device, but it was turned off.

The radiographer then moved the camera to reach the camera port to lock the radiation source inside. When he removed the tube which guides the source, he discovered the radiation source was exposed about 4 inches outside the camera. The source had apparently shifted into the unshielded position when the radiographer moved the camera to lock it. The source was locked into place in its exposed condition. The radiographer immediately returned to ground level, but later returned to the camera to unlock it so that the radiation source would be retracted into its shield.

The incident was subsequently reenacted by the licensee's Radiation Safety Officer and NRC inspectors to evaluate the radiation exposure received by the radiographer. The calculation by the Radiation Safety Officer, based on a series of reenactments, indicated a minimum 440 rem exposure to the individual's hand. NRC inspectors estimated that the dose was about 880 rem.

The radiation measuring device worn by the worker indicated a whole body radiation exposure of about 250 millirem.

The worker's hand was evaluated and monitored by medical radiation specialists at an area medical center. No short-term physical changes to the skin of the hand were observed.

The NRC limit for extremity exposures is 18.75 rem in a calendar quarter. Therefore, the reenactment showed that the exposure received was substantially over the limit. The whole body radiation exposure was within the NRC limit of 3 rem in a calendar quarter.

Cause or Causes - The overexposure occurred as a result of the failure of the radiographer to use an audible alarm exposure measuring device as required by NRC regulations. The locking mechanism allowed the source to be locked in place while it was still exposed.

The radiographer was wearing an audible alarm device required by the NRC for radiography work, but the device was turned off. The device had been turned off to conserve battery power while the radiographer was doing paperwork, but had not been turned back on for the remainder of the day. Use of an operable alarm device could have avoided or minimized the overexposure.

Actions Taken to Prevent Recurrence

Licensee - The licensee alerted its staff to the potential problem with the locking mechanism of this type of radiography camera. It also provided additional training on the use of the required audible alarm radiation devices and included verifying that the devices are turned on during routine internal audits of radiography activities. The radiographer was restricted indefinitely from further work with radioactive materials.

NRC - The NRC Region III conducted a special inspection of the licensee's activities on July 8-10, 1992 (Ref. 2). The inspection identified three violations of NRC requirements associated with the overexposure incident: (1) the extremity exposure in excess of the 18.75 rem limit for a calendar quarter; (2) failure of the radiographer to wear an operable audible radiation monitoring device; and (3) failure to perform an adequate radiation survey of the radiography camera in that the radiographer did not survey the full circumference of the camera. The first two violations were classified as a Severity Level I problem, and the third as a Level IV violation (on a scale in which Severity Levels I through V are the most and least significant, respectively). On October 9, 1992, a \$5,000 fine was proposed for the first two violations. No fine was proposed for the third violation (Ref. 3). On November 2, 1992, the licensee paid the civil penalty.

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

* * * * *

92-11 Medical Therapy Misadministration at the Medical Center of Delaware,
Incorporated, in Wilmington, Delaware

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

Date and Place - August 11, 1992; The Medical Center of Delaware,
Incorporated; Wilmington, Delaware.

Nature and Probable Consequence - On August 12, 1992, the NRC Region I office was notified by telephone by the licensee's radiation safety office that a therapeutic misadministration involving a cobalt-60 teletherapy unit occurred on August 11, 1992.

The physician's written directive called for 3015 rads in 15 fractions to be delivered to the central area of the pelvic region with the teletherapy machine set up in a fixed modality. During the 14th fraction, the radiation therapy technologist (RTT) did not ensure that the teletherapy machine was set in the fixed modality and started the treatment. The previous patient had received treatment in the rotational modality and the setting of the machine was not changed. The patient received a total of 160 rads to the pelvic treatment area instead of the prescribed 200 rads. In addition, the licensee estimates that the patient received an estimated dose of 80 to 110 rads to the left side of the pelvis outside of the treatment area and between 60 to 70 rads to the right side of the pelvis outside of the treatment area. The licensee has determined that the patient will not suffer any adverse effects in the areas that received an unintended radiation dose. The licensee will increase the prescribed dose for the 15th fraction to make up for the underdosing during the 14th fraction.

Cause or Causes - It was determined that the cause of the misadministration was the failure of the licensee to follow the department's Quality Management (QM) Program. The licensee's QM Program calls for two RTTs to be present when a patient is being set up to ensure that the setup is done properly. The first RTT did not ensure that the setup was done correctly and the second RTT was out of the department getting another patient.

Actions Taken to Prevent Recurrence

Licensee - The licensee's corrective action was to provide a training session to all RTTs on the requirements of the Quality Management Program.

NRC - An NRC Region I inspector conducted an inspection on November 19, 1992, to determine the circumstances associated with the misadministration. The inspection findings are still under review by the NRC, and enforcement action is under consideration.

Future reports will be made as appropriate.

* * * * *

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 these quarterly reports to Congress. For this period, the Agreement States reported the following event as an abnormal occurrence.

AS 92-1 Medical Diagnostic Misadministration at Southwest Texas Methodist Hospital in San Antonio, Texas

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

This write-up is based on information provided to the NRC in October 1992 by the Agreement State of Texas for inclusion in this report.

Date and Place - January 20, 1992; Southwest Texas Methodist Hospital; San Antonio, Texas.

Nature and Probable Consequences - On January 30, 1992, an iodine-131 thyroid scan was requested for a patient to further evaluate a suspected right paratracheal mass to determine if the mass was a substernal goiter. The technologist confused the thyroid scan requested with a whole body scan because the mass to be imaged was in the chest. As a result, the patient was administered 5 millicuries of iodine-131 for a whole body scan instead of 100 microcuries of iodine-131 for the prescribed procedure for a thyroid scan with substernal mass.

Because of the high activity in the thyroid at the time of the imaging on January 31, 1992, a doctor was asked to review the examination. He discovered the dose error. The doctor reported that based on a normal thyroid uptake of 15% for iodine-131, a dose of five millicuries would deliver exposures of 4000 rads to the thyroid and 2.35 rads to the whole body.

The misadministration was reported to the patient's referring physician, and he was advised that a radiation dose of this magnitude to the thyroid could result in development of hypothyroidism. The referring physician plans to follow the patient accordingly.

Cause or Causes - The misadministration occurred because a nuclear medicine technologist confused the requested partial body thyroid scan procedure with a whole body scan because of the location of the mass to be imaged.

Actions Taken to Prevent Recurrence

Licensee - The licensee established a policy that the administration of any dosage of iodine-131 greater than 100 microcuries must be reviewed by a staff radiologist licensed to administer radioactive materials with full knowledge of the clinical problem. The significance of the error was discussed with the technologist.

Agency - The licensee was cited by the Texas Bureau of Radiation Control for the misadministration in violation of license procedures.

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

* * * * *

REFERENCES

1. NRC Region I, Inspection Field Notes, Docket No. 030-02512, September 9, 1992; available for inspection or copying for a fee in the NRC Region I Public Document Room, 475 Allendale Road, King of Prussia, PA 19406-1415.
2. Letter from Charles E. Norelius, Director, Division of Radiation Safety and Safeguards, NRC Region III, to Hugh Doran, President, MQS Inspection, Inc., forwarding NRC Inspection Report No. 030-04041, License No. 12-00622-07, Docket No. 030-04041, July 30, 1992.*
3. Letter from A. Bert Davis, Regional Administrator, NRC Region III, to Hugh Doran, President, MQS Inspection, Inc., forwarding a Notice of Violation and Proposed Imposition of Civil Penalty, License No. 12-00622-07, Docket No. 030-04041, October 9, 1992.*

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

APPENDIX A

ABNORMAL OCCURRENCE CRITERIA

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

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

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

For All Licensees

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

6. A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.
7. Any substantiated loss of special nuclear material or any substantiated inventory discrepancy that is judged to be significant relative to normally expected performance and that is judged to be caused by theft or diversion or by substantial breakdown of the accountability system.
8. Any substantial breakdown of physical security or material control (i.e., access control, containment, or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.
9. An accidental criticality [10 CFR 70.52(a)].
10. A major deficiency in design, construction, or operation having safety implications requiring immediate remedial action.
11. Serious deficiency in management or procedural controls in major areas.
12. Series of events (where individual events are not of major importance), recurring incidents, and incidents with implications for similar facilities (generic incidents) that create major safety concern.

For Commercial Nuclear Power Plants

1. Exceeding a safety limit of license technical specifications [10 CFR 50.36(c)].
2. Major degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.
3. Loss of plant capability to perform essential safety functions such that a potential release of radioactivity in excess of 10 CFR Part 100 guidelines could result from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).
4. Discovery of a major condition not specifically considered in the safety analysis report (SAR) or technical specifications that requires immediate remedial action.
5. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions such that a potential release of radioactivity in excess of 10 CFR Part 100 guidelines could result from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

For Fuel Cycle Licensees

1. A safety limit of license technical specifications is exceeded and a plant shutdown is required [10 CFR 50.36(c)].

2. A major condition not specifically considered in the safety analysis report or technical specifications that requires immediate remedial action.
3. An event that seriously compromised the ability of a confinement system to perform its designated function.

Medical Misadministrations

As discussed in the Preface to this report, the NRC policy statement on AOs was published before licensees were required to report medical misadministrations to the NRC. Therefore, during 1984, the NRC developed guidelines for selecting such events for AO reporting. These guidelines, which are summarized in Table A-1, augment the NRC policy statement.

As noted in the Preface, revised guidelines are currently being developed because new medical misadministration definitions became effective on January 27, 1992.

Table A-1
NRC Guidelines for Selecting
Medical Misadministration Events
for Abnormal Occurrence (AO) Reporting

AO Reporting Threshold

<u>Event Type</u>	<u>Diagnostic Exposure</u>	<u>Therapeutic Exposure</u>
(1) Administering a radiopharmaceutical or radiation from a sealed source other than the one intended.	<p>If the improper administration results in any part of the body receiving unscheduled radiation, an AO report should be proposed if:</p> <p>(a) the actual dose to the wrong body part is greater than five times the upper limit of the normal range of exposures prescribed for diagnostic procedures involving that body part, <u>or</u></p> <p>(b) there are clinical indications of <u>any</u> adverse health effects to the wrong body part.</p> <p>If the parts of the body receiving radiation improperly would have received radiation anyway, had the proper administration been used, an AO report should be proposed if:</p> <p>(a) the actual dose is greater than five times that intended to the above described body parts, <u>or</u>,</p>	<p>If the improper administration results in any part of the body receiving unscheduled radiation, an AO report should be proposed for any such event.</p> <p>If the parts of the body receiving radiation improperly would have received radiation anyway, had the proper administration been used, an AO report should be proposed if:</p> <p>(a) the actual dose is greater than 1.5 times that intended to the above described body parts, <u>or</u>,</p> <p>(b) the actual dose is less than 0.5 times that intended to the above described body parts, <u>or</u>,</p> <p>(c) the above described body parts show signs of adverse health effects greater than expected had the proper administration been used, <u>or</u></p>

Table A-1 (Continued)

AO Reporting Threshold

<u>Event Type</u>	<u>Diagnostic Exposure</u>	<u>Therapeutic Exposure</u>
	(b) the above described body parts show signs of adverse health effects greater than expected had the proper administration been used.	(d) the event (regardless of any health effects) affects two or more patients at the same facility.
(2) Administering a radiopharmaceutical or radiation to the wrong patient.	An AO report should be proposed if: (a) the actual dose to the wrong patient exceeds five times the prescribed dose for the intended patient, or (b) the event results in <u>any</u> adverse health effects.	An AO report should be proposed for any such event.
(3) Administering a radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician.	Same guidelines as for Event Type 1.	Same guidelines as for Event Type 1.
(4) Administering a diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent.	An AO report should be proposed if: (a) the actual dose is greater than five times the prescribed dose, or, (b) the event results in adverse health effects worse than	Not applicable.

Table A-1 (Continued)

A0 Reporting Threshold

<u>Event Type</u>	<u>Diagnostic Exposure</u>	<u>Therapeutic Exposure</u>
	expected for the normal range of exposures prescribed for the diagnostic procedure.	
(5) Administering a therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent; or administering a therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.	Not applicable.	<p>An A0 report should be proposed if:</p> <ul style="list-style-type: none"> (a) the actual dose is greater than 1.5 times the prescribed dose, <u>or</u>, (b) the actual dose is less than 0.5 times the prescribed dose, <u>or</u> (c) the event results in adverse health effects worse than would be expected for the normal range of exposures prescribed for the therapeutic procedure, <u>or</u>, (d) the event (regardless of any health effects) affects two or more patients at the same facility.
(6) Recurring or series of events (regardless of the number of patients or facilities involved).	For either diagnostic or therapeutic exposures, an A0 report should be proposed for recurring events or a series of events (in which each individual misadministration is not of major importance) that create a significant public health or safety concern.	

Table A-1 (Continued)

A0 Reporting Threshold

<u>Event Type</u>	<u>Diagnostic Exposure</u>	<u>Therapeutic Exposure</u>
(7) Generic events.	For either diagnostic or therapeutic exposures, an A0 report should be proposed for misadministrations with generic implications that create a significant public health or safety concern.	

APPENDIX B

UPDATE OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During the July through September 1992 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 reports below provide the initial and any subsequent updating information on the abnormal occurrences discussed. (The updating provided generally covers events that took place during the report period; some updating, however, may be more current as indicated by the associated event dates.) Open items will be discussed in subsequent reports in the series.

OTHER NRC LICENSEES

90-19 Medical Diagnostic Misadministration at Copley Hospital in Morrisville, Vermont

This abnormal occurrence was originally reported in NUREG-0090, Vol. 13, No. 3, "Report to Congress on Abnormal Occurrences: July-September 1990." The abnormal occurrence is updated as follows:

As previously mentioned, on August 14, 1990, NRC Region I was notified by the licensee in writing that a diagnostic misadministration involving iodine-131 (I-131) had occurred at Copley Hospital, Morrisville, Vermont, on August 7, 1990. As a result, a patient received an estimated dose to the thyroid of 29 rads.

The NRC conducted an inspection of the licensed program on February 20 and 21, 1991. A Confirmatory Action Letter (CAL No. 1-91-005) was issued on March 1, 1991, relative to the issues identified during the inspection. The licensee committed in the CAL to take specified actions to prevent recurrence.

On April 29, 1992, an Enforcement Conference was held to review the findings of Inspection No. 030-17125/91-001, the subsequent Office of Investigation findings and the licensee's response to CAL No. 1-91-005. The licensee described its corrective and preventive actions that would be taken as a result of the items of noncompliance identified relative to the misadministration.

On July 15, 1992, the NRC issued a Notice of Violation and the Proposed Imposition of a Civil Penalty of \$2500 (Ref. B-1).

The licensee paid the civil penalty and provided their corrective and preventive actions in a letter dated August 10, 1992. The licensee admitted that the Diagnostic Misadministration Report contained inaccurate information, but stated there had been no effort on their part to deceive the NRC.

On October 7, 1992, the licensee's proposal for ensuring the safe administration of radiopharmaceuticals was approved. The procedure requires

that technologists obtain the written or verbal approval of the RSO or an authorized user prior to the administration of radiopharmaceuticals, except for those procedures covered by the Quality Management Program, which require that a written directive from an authorized user physician be obtained prior to administration of the radiopharmaceutical.

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.

NUCLEAR POWER PLANTS

1. Loss-of-Coolant Event at the Fort Calhoun Station

The Fort Calhoun Station experienced a loss-of-coolant event as a result of a stuck open pressurizer code safety valve that resulted in approximately 20,000 gallons of water spilling into the containment sump. The licensee declared an ALERT as a result of the reactor coolant system leakage that exceeded 40 gallons per minute. No radioactivity was released outside the containment building during the event.

On July 3, the licensee experienced electrical problems with an instrument inverter that supplies power to the electrohydraulic control system (EHC). This system is designed to automatically control the position of the turbine control valves, and thus, regulate steam flow to the main turbine. The problems with the instrument inverter resulted in power being lost to the EHC system. As a result, the main turbine control valves went shut and stopped all steam flow.

When steam flow to the main turbine stopped, an increase in the reactor coolant system (RCS) pressure resulted. As a result of the pressure increase, a reactor trip occurred and a pressurizer code safety valve (PCSV) opened to minimize the pressure increase. After the valve fully opened, it failed to completely shut. This resulted in a loss-of-coolant event that exceeded 40 gallons per minute. The reactor coolant passed through the PCSV and entered the quench tank. Once the quench tank was full, the disk on the tank ruptured and the coolant spilled on the floor of the containment and then flowed into the containment sump. The coolant collected in the sump and was not released outside of the containment.

The licensee's operating staff cooled down the plant, using the natural circulation mode, in a timely manner, to minimize the loss of coolant. The licensee staffed its emergency response facilities in a timely manner and provided information concerning plant status to the NRC, which had staffed the emergency response centers in Region IV and Headquarters. The information provided by the licensee was independently confirmed and assessed by the NRC resident inspectors that responded to the event.

The licensee determined that the PCSV failure was caused by a nut, which held the adjustment stem in place, that had backed out from its installed position due to inadequate torquing. Because the nut had backed out, the setpoint for the PCSV was altered and the valve chattered (i.e., opened and closed

rapidly), which caused internal valve damage. The damage to the valve was the reason the valve did not fully reseal. The licensee modified the procedure used for adjustment of the valve to specify that the nut be torqued to 400 foot-pounds. In addition, as a conservative measure, a locking device was designed and installed in the PCSV to ensure that the nut would not move from its installed position.

On August 22, the licensee experienced an event similar to the one that occurred on July 4. This event was initiated because of a failure of a power supply in the EHC control cabinet, in contrast to the failure of an external supply that occurred during the July 3-4 event. The loss of power again caused the turbine control valves to shut and resulted in a high RCS pressure reactor trip. In this event, the PCSV opened at a pressure lower than its adjusted setpoint. After the PCSV relieved the excess pressure, the valve fully shut and the plant remained stable in a hot shutdown condition. All other systems and components operated as expected during this event.

For this latter event, the licensee's investigation revealed that the PCSV lifted prematurely because of the method used in the testing laboratory to adjust the valve. The licensee determined that the temperature of the valve body was a critical parameter to be considered when adjustments to the valve were made. The licensee revised the procedure used to adjust the valve to include this critical parameter. The valve was reinstalled in the plant and power operation resumed.

The NRC is in the process of issuing an information notice to all license holders to alert other licensees of the problems related to PCSVs. As a result of the July 3-4 event, a Confirmatory Action Letter (CAL) was issued to the licensee and an Augmented Inspection Team (AIT) was dispatched to the site on July 4, 1992. The AIT noted that the response by the operating staff to the event was very good and that the health and safety of the public was protected throughout the event, because no radioactive release occurred. The CAL that was issued to the licensee specified that specific actions would be taken prior to allowing restart of the plant. The actions included determining why the inverter malfunctioned, the cause of the turbine control valves going shut, and the root cause for the failure of one of the two PCSVs to function properly. The licensee completed all the items listed in the CAL and NRC inspectors independently verified that all items had been completed prior to allowing the plant to be restarted. The details of the review performed by the AIT are documented in an NRC Inspection Report (Ref. C-1).

For the August 22 event, a special inspection team was sent to the site to review and evaluate the actions taken by the licensee to address the second occurrence of the failure of a PCSV to properly function. The team noted that the licensee performed an in-depth review of the cause of the failure and identified, through in-place testing, enhancements to the method used to adjust the setpoint of the PCSVs. The details of the results of the review are provided in an NRC Inspection Report (Ref. C-2).

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REFERENCES FOR APPENDICES

- B-1 Letter from Thomas T. Martin, Regional Administrator, NRC Region I, to Carolyn C. Roberts, President, Copley Hospital, forwarding a Notice of Violation and Proposed Imposition of Civil Penalty, License No. 44-19196-01, Docket No. 030-17125, July 15, 1992.*
- C-1 Letter from James L. Milhoan, Regional Administrator, NRC Region IV, to W. G. Gates, Division Manager, Nuclear Operations, Omaha Public Power District, forwarding NRC Inspection Report No. 50-285/92-18, Docket No. 50-285, August 6, 1992.*
- C-2 Letter from A. Bill Beach, Director, Division of Reactor Projects, NRC Region IV, to W. G. Gates, Division Manager, Nuclear Operations, Omaha Public Power District, forwarding NRC Inspection Report No. 50-285/92-21, Docket No. 050-00285, September 22, 1992.*

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

1. Medical Therapy Misadministration at St. Joseph's Hospital and Medical Center in Paterson, New Jersey

On July 16, 1992, St. Joseph's Hospital and Medical Center in Paterson, New Jersey, the licensee, informed the NRC Region I office of a possible therapeutic misadministration involving the use of iridium-192 in a Gamma Med Ili high dose rate (HDR) afterloader. Prior to insertion through the nose into the lung and adjusted to the location of the tumor. An X-ray was taken to confirm the catheter position prior to insertion of the iridium source. However, the X-ray was taken in the recovery room and the patient was transported to the treatment room approximately one and a half hours later for the HDR treatment. The planned treatment dose for the patient was 2000 rads to the upper right lobe of the lung over four fractions of 500 rads each. When the catheter was removed, it was apparent that the catheter had become dislodged, although it was not clear whether that occurred before treatment was initiated. Therefore, the actual dose to the patient was 500 rads, possibly to the wrong part of the body (to either the nasal cavity or the nasopharyngeal region). The patient has been notified of the possible misadministration and is being followed closely for any signs of adverse effects. The licensee plans to make up the treatment to the tumor site at a later date.

The licensee has concluded that the cause of the possible misadministration was human error. The X-ray was not examined by the physician immediately prior to the HDR treatment and the physician did not notice visually that the catheter was dislodged.

The licensee initiated immediate corrective action by performing an X-ray localization of the catheter in the high dose rate afterloader treatment room. The time between catheter insertion and HDR treatment was minimized to less than 15 minutes by taking the localization film in the treatment room. This will minimize the chance of a catheter becoming dislodged prior to treatment initiation. Long term corrective and preventive actions are being formulated and the Radiation Safety Committee will review and approve these actions.

A special safety inspection was conducted by the NRC on July 23, 1992, to review the circumstances associated with the event. No violations were cited.

After further consideration, NMSS concluded that there was insufficient information to determine when the catheter became dislodged and whether a medical misadministration, in fact, occurred. Therefore, this event is not being reported as an abnormal occurrence.