POLICY ISSUE

(NEGATIVE CONSENT)

December 20, 1990

SECY-90-415

For: The Commissioners

From: James M. Taylor
Executive Director
for Operations

Subject: SECTION 208 REPORT TO THE CONGRESS ON ABNORMAL OCCURRENCES FOR JULY-SEPTEMBER 1990

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 covering transmittal of the Section 208 report to Congress for the third quarter of CY 1990.

Enclosure 2 is a final draft of the quarterly report to Congress on abnormal occurrences (AOs). The report (draft NUREG-0090, Vol. 13, No. 3) covers the period July 1 through September 30, 1990. This draft incorporates the major comments obtained from staff review of a previous draft.

There are no proposed AOs for nuclear power plants. There are five proposed AOs for the other NRC licensees. The items are:

90-16 Medical Therapy Misadministration (Muskogee Regional Medical Center; Muskogee, Oklahoma).

90-17 Medical Diagnostic Misadministration (Overlook Hospital; Summit, New Jersey).

90-18 Significant Breakdown in Management/Procedural Controls at a Medical Facility (North Detroit General Hospital; Detroit, Michigan).

90-19 Medical Diagnostic Misadministration (Copley Hospital; Morrisville, Vermont).

90-20 Medical Diagnostic Misadministration (West Shore Hospital; Manistee, Michigan).

Contact:
Paul Bobe, AEOD
x24494

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

There is one proposed AO submitted by an Agreement State (Arizona) for the report. The item is:

AS90-2 Medical Therapy Misadministration (Yuma Regional Medical Center; Yuma, Arizona).

These medical events meet the guidelines for AO reporting as follows:

AO 90-16 involved a therapeutic dose administered to the incorrect part of a patient's body.

AOs 90-17, 90-19, and 90-20 involved administered doses greater than five times the prescribed diagnostic doses.

AO 90-18 involved major deficiencies in management controls.

AS90-2 involved a therapeutic dose greater than 50% of the prescribed dose.

There was no significant updating information to include in Appendix B of the draft report.

There were two events for Appendix C ("Other Events of Interest"). The items are:

1. Diagnostic Dose of Iodine-131 Administered to a Pregnant Patient (North Country Hospital and Health Center, Inc.; Newport, Vermont).

2. Contaminated Water Seepage at Sequoyah Fuels Corporation (located at Gore, Oklahoma).

There are no items for Enclosure 3 (i.e., items which were candidates for inclusion as AOs, but which in the staff's judgement did not meet the criteria for AO reporting after further study) to this Commission paper.

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 1990 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

Enclosure:
1. Proposed letter to Congress
2. Draft of Third Quarter CY 1990
   Abnormal Occurrence Report to Congress

SECY NOTE: In the absence of instructions to the contrary, SECY will notify the staff on Monday, January 7, 1991, that the Commission, by negative consent, assents to the action proposed in this paper.

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Enclosure 1

Draft

IDENTICAL LETTERS TO:

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

Dear Mr. President:

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

Dear Mr. Speaker:

I am forwarding the Nuclear Regulatory Commission's (NRC's) report on abnormal occurrences at licensed nuclear facilities for the third calendar quarter of 1990. 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.

The report discusses six abnormal occurrences, none of which involved a nuclear power plant. There were five abnormal occurrences at NRC-licensed facilities: one involved a medical therapy misadministration; three involved medical diagnostic misadministrations; and one involved a significant breakdown in management and procedural controls at a medical facility. The sixth abnormal occurrence was reported by an Agreement State (Arizona); the event involved a medical therapy misadministration.

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

Sincerely,

Kenneth M. Carr

Enclosure:
Report to Congress on
Abnormal Occurrences
(NUREG-0090, Vol. 13, No. 3)

Enclosure 2

DRAFT

REPORT TO CONGRESS

ON

ABNORMAL OCCURRENCES

July - September 1990

Date Published: January 1991

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, 1990.

The report discusses six abnormal occurrences, none of which involved a nuclear power plant. There were five abnormal occurrences at NRC-licensed facilities: one involved a medical therapy misadministration; three involved medical diagnostic misadministrations; and one involved a significant breakdown in management and procedural controls at a medical facility. The sixth abnormal occurrence was reported by an Agreement State (Arizona); the event involved a medical therapy misadministration.

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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 July 1 through September 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 re-

quired 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
JULY-SEPTEMBER 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.

90-16 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 - February 20 through March 12, 1990; Muskogee Regional Medical Center; Muskogee, Oklahoma.

Nature and Probable Consequences - On September 19, 1990, the licensee notified the NRC that a therapeutic misadministration had occurred involving a treatment administered from February 20 through March 12, 1990. The radiation oncologist had identified the treatment error on September 6, 1990, but had not immediately recognized it as a reportable misadministration. The treatment error involved administration of 2160 rads (from a cobalt-60

teletherapy unit) to the right posterior neck rather than the left posterior neck as prescribed.

The licensee reported that the oncologist had initially participated in the treatment simulation and had approved simulation radiographs prior to treatment; however, the physician failed to notice that the wrong side of the patient's neck had been the subject of the simulation. This error was attributed to the fact that the patient treatment was simulated in the prone position rather than the licensee's routine supine position. Several of the licensee's staff members, including the teletherapy physicist, therapy dosimetrist, technical staff, and oncologist, had reviewed the patient's chart and participated in treatment and followup observations although none had recognized the error. The oncologist had palpated an enlarged cervical lymph node on the patient's left side during the September 6, 1990, physical examination which prompted his subsequent review of the treatment chart and identification of the error. All treatment records indicated that the right side of the patient's neck was treated, although the prescription clearly indicated that treatment was to be given to the left side.

The licensee's radiation oncologist has advised the NRC that no adverse effects were observed during routine followup examinations, and that no adverse effects are anticipated as a result of the misadministration.

Cause or Causes - The cause is attributed to human error by the licensee's staff and failure to perform independent chart reviews in sufficient detail to detect the error. The simulation technologist had prepared a treatment simulation for, and had tattooed the right side of the patient's neck, because the oncologist had assisted in simulating the patient treatment and fluoroscoped the patient's right side. The technologist assumed that the correct treatment field had been fluoroscoped, and transcribed the treatment plan for the right posterior neck. The simulation radiographs were approved by the oncologist although they had not been labeled "right" or "left" at the time.

The treatment plan was not reviewed until seven treatment fractions had been administered, although neither the teletherapy physicist or dosimetrist recognized the error during this or subsequent reviews of the patient's chart. Additionally, the technical staff did not routinely review the physician's prescription after the patient treatment was simulated, and therefore, did not recognize that the prescription indicated treatment for the left side rather than the right.

Actions Taken To Prevent Recurrence

Licensee - The licensee's corrective actions as of October 15, 1990, included reformatting the treatment chart to include the physician's prescription in an area routinely used by the technical staff, making the prescription more readily accessible for staff review during the course of treatment. The teletherapy physicist and dosimetrist plan to provide a more detailed review of the treatment plan, including verification of treatment field rather than focusing solely on dose calculations. Further corrective actions will be

implemented pending the licensee's Radiation Safety Officer's full investigation and review.

NRC - An NRC Region IV inspector conducted a special safety inspection on October 3 and 5, 1990, of the circumstances associated with the misadministration, and identified violations of NRC requirements as well as deviations from the licensee's documented procedures (Ref. 1). A Confirmation of Action Letter (CAL) was issued on October 10, 1990, to confirm commitments made by the licensee during this inspection (Ref. 2). These commitments include conducting a retrospective review of patient treatments to determine if similar errors had been made. A decision regarding enforcement action is currently under consideration.

Future reports will be made as appropriate.

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90-17 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 - May 14, 1990; Overlook Hospital; Summit, New Jersey.

Nature and Probable Consequences - On June 1, 1990, NRC Region I was notified by the licensee in writing that a diagnostic misadministration involving iodine-131 (I-131) had occurred at the hospital.

An outpatient was scheduled for a nuclear medicine study by the referring physician's office by telephone. The nuclear medicine department understood the doctor's office to request an appointment for an iodine-131 scan. The patient brought the written prescription to the outpatient department and then proceeded to the nuclear medicine department for the scheduled study. The written prescription was not received by the nuclear medicine department until after the study was completed. When the nuclear medicine department received the written prescription, it was noted that the referring physician's written prescription requested a thyroid scan, not an iodine-131 scan. (A thyroid scan typically means a study using approximately 100-500 microcuries of iodine-123 as the imaging radionuclide. An iodine-131 scan usually refers to a whole body scan, utilizing a dose of approximately 1 to 5 millicuries.)

The patient involved in the misadministration had a benign tumor removed from a lobe of the thyroid in June 1989. Subsequent thyroid scans of the individual (an uptake study was performed in November 1989, after the thyroid lobectomy) indicated that the patient had a normally functioning thyroid.

The intended dose to the patient's thyroid was approximately 4 rads from 300 microcuries of iodine-123 The administered dose to the patient's thyroid, as a result of the misunderstanding of the physician's request, was approximately 1820 rads from 1.4 millicuries of iodine-131.

Cause or Causes - The cause of the event is attributed to inadequate procedures. The verbal request for the nuclear medicine study had not been verified by a written prescription prior to the study being performed.

Actions Taken to Prevent Recurrence

Licensee - After a telephone call on September 21, 1990, from NRC Region I staff to the licensee in regard to the incident, the licensee convened an emergency Radiation Safety Committee meeting on October 2, 1990, to review the cause of the misadministration and to determine the corrective actions required to prevent a recurrence. The licensee established a procedure requiring receipt of a written prescription by the nuclear medicine department prior to administering any iodine for studies. This information was communicated to NRC Region I by telephone on October 3, 1990.

NRC - NRC Region I inspectors will review the incident during the next routine inspection at this facility. The timeliness of the licensee's response (reviewing the cause and determining corrective actions following the May 14, 1990 incident) will also be reviewed.

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

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90-18 Significant Breakdown in Management and Procedural Controls at a Medical Facility

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the overall abnormal occurrence criterion) of this report notes that an event involving a moderate or more impact on the public health or safety can be considered an abnormal occurrence. In addition, the third general criterion in Appendix A notes that major deficiencies in management controls for licensed facilities or material can be considered an abnormal occurrence.

Date and Place - July 19-27, 1990; North Detroit General Hospital; Detroit, Michigan.

Nature and Probable Consequences - This event involved the potential use of fraudulent films from 30 diagnostic nuclear medicine studies, that rendered all but one of them invalid. Such an event could have potentially resulted in significant adverse health effects to patients (e.g., a serious disease may not be diagnosed, or a correct diagnosis could be significantly delayed). The details of the event are as follows:

On August 14, 1990, the licensee reported to NRC Region III that films from diagnostic nuclear medicine studies were apparently fraudulent. The films involved 30 studies performed on 27 patients during the time period July 19-27, 1990. (Some patients had more than one diagnostic procedure.) During this time period, the licensee's staff nuclear medicine technologist was on leave

and a replacement technologist was supplied by a temporary services contractor.

For the diagnostic procedures involved, a radioactive pharmaceutical is introduced into the patients by injection or inhalation. The movement and deposition of these radioactive pharmaceuticals is then recorded as a film image. The image is then evaluated by a physician as a diagnostic tool.

The licensee subsequently determined that the films for 29 of the 30 procedures were fraudulent and or indeterminate and were, therefore, unreliable for patient diagnosis. The remaining film is from a procedure performed by the contract technologist under the supervision of the staff technologist. It appears to be accurate. The films in question show evidence of tampering (i.e., handwritten names and dates which do not match the computer-generated display in the film, and faint underlying and overwritten labels on the films). In addition, the licensee reported that about 100 old patient films and jackets were discovered to be missing from their file location.

The fraudulent films were discovered by the staff technologist after comparison with later films after the contract technologist had left. The licensee then reviewed the films from procedures performed by the contract technologist. The licensee's investigation determined "conclusively that [the individual] had doctored and provided fraudulent nuclear medicine studies for interpretation. [The technologist] had submitted nuclear medicine studies on patients who had previously been imaged within the Department during the past 2 years and altered the names on those images and placed the names of the patients he was to have performed studies on in their place."

The licensee was unable to determine, in most cases, whether the diagnostic procedures had actually been performed and whether the patients had been administered the prescribed radiopharmaceutical for the procedures. The diagnostic procedures, with one exception, were not considered to be valid, and therefore of no use in their intended diagnostic function. The licensee offered to redo the procedures, although some patients or their physicians elected not to have the studies performed again.

In those instances where a second procedure was performed, the patient received additional radiation exposure as a result of the fraudulent films that rendered the first procedure unusable. Where the retest was refused, the patients received a radiation exposure without benefit of a valid diagnostic procedure. However, the radiation doses associated with diagnostic procedures are small.

Cause or Causes - The fraudulent films and resulting invalid studies were the result of the action by the contract technologist and the failure of the licensee to supervise and train the individual adequately.

A special NRC inspection, which reviewed the circumstances of the fraudulent films, identified 10 apparent violations of NRC requirements, some of which were directly associated with the work performed by the contract technologist.

These violations were indicative of a breakdown of management control of the licensee's nuclear medicine program.

Actions Taken to Prevent Recurrence

Licensee - As a result of this occurrence, the licensee has strengthened its screening procedures for prospective employees, both temporary and permanent. Training procedures have also been broadened and intensified. There will be more ongoing supervision and review of work by new employees.

NRC - The NRC conducted a special inspection August 15 through September 7, 1990, to review the circumstances surrounding the fraudulent films. A number of violations were identified. On October 29, 1990, the NRC issued a Notice of Violation and proposed a civil penalty of $2,500 (Ref. 3) which was paid by the licensee on November 26, 1990.

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

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90-19 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 - August 7, 1990; Copley Hospital; Morrisville, Vermont.

Nature and Probable Consequences - 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 the hospital on August 7, 1990. Further information was obtained in a follow-up phone call to the licensee on September 24, 1990. A 63-year-old woman patient, undergoing I-131 treatment for primary hypothyroidism, was administered 112 microcuries instead of a routinely prescribed 10 microcuries. The dose to the thyroid, based upon the results of an uptake scan, was calculated at 3.9% uptake, resulting in an estimated actual dose to the thyroid of 29 rads.

The hospital reported that a supply of I-131 capsules had been ordered with incorrect amounts of I-131. Instead of ordering 5 capsules with a total activity of 1.0 microcuries, the 5 capsules were ordered as 100 microcuries each. On the day of the event, the technologist measured the capsule in the dose calibrator prior to administration and incorrectly interpreted the dose calibrator reading of 112 microcuries as 11.2 microcuries. The error was identified by another technologist measuring the uptake by the patient's thyroid the following day.

Cause or Causes - The causes of the event were attributed to human errors. The wrong I-131 capsules had been ordered and the technologist incorrectly interpreted the dose calibrator reading.

Actions Taken to Prevent Recurrence

Licensee - The licensee reviewed the policies and procedures for assaying doses with all nuclear medicine technologists. In addition, the licensee's procedure was revised to require that only the technologist who orders the iodine capsules is allowed to administer them to patients.

NRC - NRC Region I inspectors will review the incident during the next routine inspection at this facility.

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

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90-20 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 than an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place - September 22, 1990; West Shore Hospital; Manistee, Michigan

Nature and Probable Consequences - On September 24, 1990, the licensee's consultant informed Region III that an 84-year-old female cancer patient received a 175 millicurie dose of a technetium-99m (Tc-99m) labeled radiopharmaceutical for an imaging scan of her gall bladder instead of the 8 millicurie dose prescribed in the Nuclear Medicine Department's procedure's manual.

The misadministration occurred on Saturday, September 22, 1990, when the patient's physician ordered a hepatobiliary (liver and gall bladder) scan. The radiopharmaceutical was prepared and administered by a part-time technician who was on weekend call. The technician had received only two weeks of training in Nuclear Medicine Department procedures the previous February and had performed only two nuclear medicine procedures since then (during one procedure, she was directly supervised by the Radiology Manager; during the other, the Radiology Manager "coached" her through the procedure by telephone). After receiving the order on September 22, the technician telephoned the Radiology Manager at home for guidance. She was told to prepare the dose according to the Department's procedures manual, which stated that an 8 millicurie (mCi) dose of Tc-99m mebrofenin was needed for hepatobiliary scans. Tc-99m mebrofenin is prepared by adding free Tc-99m to a reagent kit containing the mebrofenin.

According to the technician, she eluted 392 mCi from the molybdenum-technetium generator, and then took 4 milliliters of the eluate and injected it into the reagent kit. After mixing, she withdrew 1 milliliter of the solution, put it on a dose calibrator, which she claimed read 8 mCi, and then injected the radiopharmaceutical into the patient. When she saw a "bright spot" forming on the scanning screen where the sharp image of the gall bladder should have

been, she telephoned the Radiology Manager and informed him that something was wrong.

A reconstruction of the event by NRC and licensee consultants indicated that the dose to the patient was 175 mCi instead of the intended 8 mCi. The amount of Tc-99m mixed with the mebrofenin was probably around 440 mCi, instead of the manufacturer's maximum recommendation of 100 mCi. The NRC consultant concluded that the technician misread or misunderstood the activity reading on the dose calibrator prior to injecting the patient. The medical consultant also evaluated the medical consequences of the incident and concluded that no biological effects should be expected from the misadministration. It is estimated that the doses to the patient's bladder and upper large intestine were about 36 rads and 26 rads, respectively.

Cause or Causes - The cause of the event was the licensee's failure to properly train and supervise an inexperienced technician. The individual either misread or misunderstood instructions, and in some cases used guesswork in carrying out the procedure.

Actions Taken To Prevent Recurrence

Licensee - The licensee's corrective action includes more orientation and training of new employees; additions to the computerized quality assurance system to remind staff to hold required meetings and perform required tests; and additional oversight of the licensee's program by management and the Radiation Safety Officer. Also, the x-ray technician is no longer employed at the hospital.

NRC - NRC Region III conducted a special inspection on September 27, 1990, and identified 10 violations of NRC requirements. Seven of the 10 violations pertained to this incident, including failure to instruct the technician in NRC regulations and license requirements, and failure to prepare the reagent kit in accordance with manufacturer's instructions. The Region contacted a medical consultant who reviewed the case. On November 16, 1990, the NRC issued a Notice of Violation and proposed a civil penalty of $4,375 (Ref. 4.) The licensee has not yet responded.

Future reports will be made as appropriate.

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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.

AS90-2 Medical Therapy 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 - April 19, 1990; Yuma Regional Medical Center; Yuma, Arizona.

Nature and Probable Consequences - On April 19, 1990, a tumor was implanted with 224 iridium-192 seeds using 32 trochars*, each containing 7 seeds. The specific activity was 0.342 mg Ra eq. A problem was noted with snagging of the ribbon in one trochar; five seeds were stripped from the trochar when an attempt was being made to remove both the trochar and the seeds. The trochar had inadvertently been placed in a necrotic cavity within the tumor, permitting the seeds to 'pay out' into the cavity rather than being stopped by tissue.

An unsuccessful attempt was made to remove the five stripped seeds during removal of the other seeds. When the trochar that had contained the snagged ribbon was removed, it was discovered that the tip of the trochar had been bent, presumably by the stony hardness of the tumor. The trochar was not bent before it was inserted.

The seeds were left in the necrotic tumor center. Each of these five seeds, from the time of emplacement until total decay, will deliver 107-times the dose that it delivers during the first 24 hours. A medical consultant stated that the patient's poor prognosis outweighed any harm from additional radiation.

The Arizona Radiation Regulatory Agency (ARRA) asked for dose calculations and, in addition, asked the physician to describe the nature of the tumor hardness and to describe the incident to the Drug Product Reporting Program at the United States Pharmacopeia (USP). However, since the physician left the state, the ARRA sent a report to the USP.

Cause or Causes - There were several causes for this event:

- The trochar was inadvertently placed inside a cavity within the tumor;
- The trochar, which was flexible and bendable, was bent by the hardness of the tumor;

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* A trochar is a sharp, pointed surgical instrument fitted with a hollow tube.

- o During an attempt to remove the seeds, fluoroscopes failed because there was an inadequate power supply to the operating room; and
- o The length of the ribbons was not controlled, so that 'paying out' of the ribbons was possible.

Actions Taken to Prevent Recurrence

Licensee - The physician, no longer practicing in Arizona, stated that he would use only rigid tungsten alloy trochars and pre-measure all ribbons, limiting their length to 21 cm.

Agency - The agency notified the USP and the Arizona State Board of Medical Examiners.

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

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REFERENCES

1. Letter from A. Bill Beach, Director, Division of Radiation Safety and Safeguards, NRC Region IV, to William Kennedy, CEO, Muskogee Regional Medical Center, forwarding Inspection Report No. 30-11571/90-02, Docket No. 30-11571, License No. 35-13157-02, November 30, 1990.*

2. Confirmatory Action Letter from Robert D. Martin, Regional Administrator, NRC Region IV, to William Kennedy, CEO, Muskogee Regional Medical Center, Docket No. 30-11571, License No. 35-13157-02, October 10, 1990.*

3. Letter from A. Bert Davis, NRC Region III Regional Administrator, to Jerry Frohlich, President, North Detroit General Hospital, forwarding a Notice of Violation and Proposed Imposition of Civil Penalty ($2,500), Docket No. 030-12467, License No. 21-10578-02, October 29, 1990.*

4. Letter from A. Bert Davis, NRC Region III Regional Administrator, to Burton Parks, Administrator, West Shore Hospital, forwarding a Notice of Violation and Proposed Imposition of a Civil Penalty ($4,375), Docket No. 030-10713, License No. 21-16277-01, November 11, 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 July through September 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.

For this reporting period, there was no significant updating information to report.

APPENDIX C

OTHER EVENTS OF INTEREST

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

1. Diagnostic Dose of Iodine-131 Administered to a Pregnant Patient

On July 13, 1990, North Country Hospital and Health Center, Inc., in Newport, Vermont reported to NRC Region I that a pregnant patient had received an oral administration of 15 microcuries of iodine-131. The patient was administered the prescribed diagnostic dose on July 10, 1990, for a thyroid uptake study.

The patient, while waiting for the procedure, was carrying an infant. This led the technologist to believe that the infant belonged to the patient and, therefore, the technologist did not ask the patient whether she was pregnant before administering the iodine dose. Immediately after administering the dose, during a discussion with the technologist, the patient informed the technologist that she was pregnant in her 4th or 5th week. The technologist immediately called the referring physician, who instructed the technologist to perform a pregnancy confirmation test. The test was performed and one and half hours later, confirmed the pregnancy. The technologist informed the referring physician and, later the same day, informed the radiologist (a visiting authorized user). Neither physician recommended any medical intervention.

On July 16, 1990, the NRC performed an inspection at the licensee's facility to review the circumstances of the reported incident. As a result of the inspection, the NRC issued a Notice of Violation to the licensee for failing to instruct the technologist to ask female patients if they were pregnant, prior to administering radioactive material for nuclear medicine studies (Ref. C-1).

The licensee's Radiation Safety Officer (RSO) submitted a written account of the licensee's actions as well as an estimate of exposure to the fetus. The RSO concluded that the fetus could have received 2.25 millirad to the whole fetal body and no thyroid dose, based on a fetal age of 1.5 to 6 weeks. The NRC staff and NRC consulting physician confirmed these potential dose values to the fetus.

In the cover letter that transmitted the Notice of Violation and Inspection Report to the licensee, the NRC acknowledged the low dose to the fetus, for this specific incident, but stated that it was fortuitous. Had the fetus been more developed (greater than 12 weeks), the dose consequences would have been significantly greater.

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2. Contaminated Water Seepage at Sequoyah Fuels Corporation

On August 22, 1990, Sequoyah Fuels Corporation (SFC) in Gore, Oklahoma, reported to NRC Region IV that uranium-contaminated water had been discovered seeping into an excavation near the solvent extraction (SX) building. The uranium concentration in the seepage ranged up to 8 grams per liter, which was substantially above SFC's environmental action level of .000225 grams per liter for uranium in water. On August 23, 1990, an NRC inspector was dispatched by Region IV to the site to review the circumstances of the report. Following this review, and because of the apparent lack of awareness by SFC of the potential significance of the elevated concentrations, Region IV dispatched an Augmented Inspection Team (AIT) to the site on August 27, 1990.

During the August 27-29, 1990 inspection, the four person AIT reviewed the circumstances surrounding the contamination found in the excavation near the solvent extraction building, evaluated the licensee's actions, and determined, to the extent possible, the impact of this event on the safety and health of the workers and the public in general. The AIT reached the following findings of fact (Ref. C-2):

1. During the excavation for the vault around hexane tanks near the SX building, uranium contaminated waters and uranium salts were discovered in the pit. Measurements of water samples showed uranium levels as high as 8.1 grams per liter.

2. Surveys of personnel and equipment entering and leaving the site indicated that no contamination related to the excavation was allowed offsite.

3. Initial investigations of groundwater in the vicinity of the solvent extraction building apparently indicate that contamination has not migrated offsite or come in contact with any aquifers that may be used by members of the public.

4. Backfill around pipelines and utility lines in the vicinity of the SX building has apparently served as conduits for the migration of liquids. The licensee has effectively eliminated these pathways by construction of barriers around the lines and installation of upgradient sumps to collect any liquid.

5. Uranium contaminated water also exists in the aggregate fill under and in the vicinity of the SX building. Some of this water will probably remain relatively immobile. The remainder is probably moving at a very slow rate toward the North Ditch or the sewage lagoon.

6. The sources of the contamination were apparently solutions that had seeped over the years through the floor of the SX building, leakage from the old evaporator pad that was located adjacent to the SX building, and overflow from the solvent dump tank. These sources have been eliminated by: constructing a new floor and sump in the SX building and changing procedures to eliminate running contaminated, corrosive liquids over the floor; removing the old evaporator; constructing a new evaporator pad

and sump system; and constructing a vault with a sump to capture spillage from the solvent dump tank.

7. After August 22, upon discovery of the high levels of uranium in the water in the excavation, the licensee proceeded to survey and sample the area and require daily urinalyses of all personnel associated with the construction. Two workers, who apparently did not enter the excavation but worked above ground, did record slightly elevated levels. They were placed on work restrictions and had lowered urinalyses upon retesting.

8. The soil removed from the excavation has been partially barreled with the remainder moved to the "yellowcake pad" where it was placed on Hypalon and covered with plastic.

9. Environmental data from monitoring stations around the site were reviewed and uranium and other contaminants have been detected, although at levels below MPC. The amount that may have been contributed by the seepage is unknown at this time.

10. Licensee managers were aware of this situation as early as August 7, 1990, but no further investigation or evaluation was performed to determine the extent or severity of the problem.

11. The plans by the licensee to characterize further the extent of contamination and develop remediation actions were determined to be sufficient as an initial effort. Future, more detailed plans will be reviewed as they are available from the licensee.

During the period of the AIT follow-up and daily onsite inspections, the NRC inspectors observed licensee activities and noted that they had located and stopped process solution leakage to the ground around the solvent extraction building. The licensee drilled bore holes and monitoring wells in selected locations to characterize the soil beneath and around the building, and dug trenches in selected locations to identify leakage paths away from the building. Although there is evidence of some horizontal migration of the liquid along underground pipes and other utilities, there is no evidence to date that the liquid migrated offsite or reached the water table. The licensee will monitor the environment closely to characterize the problem.

The inspectors determined that much of the leakage probably occurred before the current licensee's ownership of the facility. The solvent extraction building was constructed in 1969 and operations began in 1970. The floor of each half of the building is sloped to a center curb, with a sump on each side of the curb. Both the floor and sumps were constructed of unprotected concrete, as was the center curb. During early operations of the building, process solutions were routinely discharged onto the floor when they did not meet specifications. These corrosive acidic solutions, which also contained uranium, traveled across the floor to the sumps. This practice resulted in extensive degradation of the concrete floor, particularly in the vicinity of the sumps.

As a result, process solutions seeped through the degraded floor and into the backfill underneath the building over a period of several years. Most of these fluids remained in the backfill because there was no significant driving force to cause them to move, particularly after the floor was replaced in 1983 and 1984. Excavation near the building in August 1990 provided a migration pathway.

Two additional sources of contamination in the vicinity of the solvent extraction building were identified. One was an antiquated evaporator located on an unprotected concrete pad adjacent to the north wall of the solvent extraction building. When the evaporator was used to increase the concentration of uranium in the solution, it routinely leaked onto the pad, degrading the unprotected concrete and allowing solutions to enter the backfill. Although the evaporator was replaced by a new one in 1980, it was used as an auxiliary unit until 1985. The degraded pad was rebuilt in 1985.

The other source of contamination was one of the two storage tanks being excavated so that a reinforced vault could be constructed to contain them. One tank is used to store hexane and the other is the solvent dump tank, used for emergency storage for all solvent extraction building solutions. Although the solution level in the solvent dump tank can be measured by a differential gauge, it is not reliable. Therefore, the level in the tank was visually checked and solution spilled out of the tank when it was overfilled. A concrete floor and curb were placed around the pipe in 1988 to contain spilled solutions.

During the period September 10-13, 1990, the AIT performed a follow-up inspection to review the findings of the AIT. In addition, the AIT reviewed the actions taken by the licensee in accordance with commitments made to the NRC in an August 30 letter as prerequisites for restart of the solvent extraction process. The inspectors determined that the licensee's actions were appropriate to satisfy those commitments, and on September 13, 1990, the licensee was given verbal concurrence by NRC to restart the solvent extraction process. At the same time, NRC initiated daily onsite inspector coverage as a result of the concerns identified by the AIT and the AIT follow-up inspection.

As indicated above, the licensee began a significant effort to identify the cause(s) of the problem and to initiate corrective actions. Actions adopted include better procedures, better training of employees, and better communication within the licensee organization and with NRC. On September 14, 1990, SFC reported by telephone the discovery of uranium-contaminated water under the main process building.

On September 20, an Order Modifying License was issued that requires Sequoyah Fuels characterize the site, take actions to prevent further releases of contaminated water, and appropriately monitor ground water (Ref. C-3). An NRC Relaxation of Order, October 23, 1990, was provided to enable the licensee to conduct proper environmental monitoring at the plant site (Ref C-4). The licensee is continuing its environmental investigation to characterize the extent of contamination at the SFC facility and its environs.

On November 9, 1990, the NRC issued a Demand for Information to determine whether the NRC should renew or modify SFC's license (Ref. C-5). Because evidence to date indicates that the contaminated water did not migrate offsite or reach the water table, there was no impact on public health and safety. Therefore, the event is below the threshold for abnormal occurrence reporting.

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REFERENCES FOR APPENDICES

C-1 Letter from Mohamed M. Shanbaky, Chief, Nuclear Materials Safety Section A, Division of Radiation Safety and Safeguards, NRC Region I, to Larry Labor, Vice President of Professional Services, North Country Hospital and Health Center, Inc., forwarding Inspection Report No. 030-17817/90-[illegible]2 and Notice of Violation, Docket No. 030-17817, License No. 44-19518-01, September 18, 1990.*

C-2 Letter from A. Bill Beach, Director, Division of Radiation Safety and Safeguards, NRC Region IV, to Reau Graves, Jr., President, Sequoyah Fuels Corporation, forwarding NRC Augmented Inspection Team (AIT) Inspection Report No. 40-8027/90-04, Docket No. 40-8027, License No. SUB-1010, October 11, 1990.* The findings may be found in paragraph 7 of the inspection report.

C-3 Letter from James M. Taylor, Executive Director for Operations, NRC, to Reau Graves, President, Sequoyah Fuels Corporation, forwarding Order Modifying License, Docket No. 40-8027, License No. SUB-1010, September 20, 1990.*

C-4 Letter from Robert D. Martin, Regional Administrator, NRC Region IV, to Reau Graves, President, Sequoyah Fuels Corporation, relaxing Order Modifying License, Docket No. 40-8027, License No. SUB-1010, October 23, 1990.*

C-5 Letter from Hugh L. Thompson, Jr., Deputy Executive Director for Nuclear Material Safety, Safeguards, and Operational Support, NRC, to Reau Graves, President, Sequoyah Fuels Corporation, transmitting Demand for Information, Docket No. 40-8027, License No. SUB-1010, November [illegible] 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.