NMSS Licensee Newsletter

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

NUREG/BR-0117
No. 92-1
March 1992

COMMISSION HAS DIRECTED STAFF TO DEVELOP AMENDMENTS TO ITS REGULATIONS FOR ONSITE STORAGE OF LOW-LEVEL RADIOACTIVE WASTE (LLW) AFTER JANUARY 1, 1996

The Nuclear Regulatory Commission (NRC) will propose to amend its regulations containing licensing requirements for reactor, material, and fuel cycle licensees, to establish a regulatory framework setting forth the procedures and criteria that will apply to onsite storage of LLW by generators beyond January 1, 1996. The Commission has determined that these changes are required because of potential health and safety concerns associated with the increased reliance upon onsite storage of LLW and to support the national disposal goals that have been established by the Low-Level Radioactive Waste Policy Amendments Act of 1985 (LLRWPAA).

On January 1, 1993, the existing LLW disposal sites are expected either to close or stop receiving LLW from outside their regional compacts. Since no new LLW disposal facilities are expected to be operational by January 1, 1993, many licensees who generate LLW will need to store their LLW onsite until disposal capacity is available, unless other arrangements for storage or disposal can be made. Nearly all the State governors have indicated that their respective States plan on interim storage by waste generators during the 1993 through 1996 period. Such storage is planned to include individual licensee facilities. Although some compacts and States are scheduled to open an LLW disposal facility before January 1, 1996, many others are expected to miss this deadline.

Although the public health and safety can be adequately protected if LLW is stored, the public health and safety will be enhanced by disposal, rather than long-term, indefinite storage of wastes. Disposal of wastes in a limited number of facilities licensed under the requirements of 10 CFR Part 61 will provide better protection of the public health and safety and environment than storage at multiple sites around the country. Permanent disposal of LLW has always been the preferred option for managing wastes, as reflected in the LLRWPAA.

In the proposed rulemaking presently being developed by staff, the Commission will restate and emphasize its position that it will not look favorably on onsite storage of LLW by generators after January 1, 1996, the final milestone of the LLRWPAA. The Commission considers onsite storage to be a last resort. Under the proposed amendments, onsite storage of LLW would not be permitted after January 1, 1996 (other than reasonable short-term storage necessary for decay or for collection or consolidation for shipment offsite), unless the licensee could document that it has exhausted other reasonable waste management options. Such options include the management of the waste by the State in which the waste generator is located. NRC will propose that the licensee request that the State take title to, and possession of, the waste, in accordance with the LLRWPAA. Another option is that the licensee contract, either directly or through the State, for the disposal of its waste. In addition, reactor licensees would have to document that onsite storage activities would be consistent with, and not compromise, the safe operation of the licensee's activities, nor decrease the level of safety provided by applicable regulatory requirements. These provisions will become standard license conditions for every license issued for reactor, materials, and fuel cycle licensees, through amendment of the regulations. The rulemaking would amend 10 CFR 30.34, 40.41, 50.54, and 70.32, which are those sections of the regulations that identify standard conditions for byproduct material, source material, production and utilization facility, and special nuclear material licenses.

Licensees would not be required to make formal submittal, to NRC, to show compliance with these conditions, but instead would be required to maintain all relevant documentation of the steps taken to satisfy the requirements and to make such documentation available for inspection by NRC. The Commission may ask for such reports as might be necessary to determine whether additional inspections or other regulatory attention would be required.

The proposed amendments would supplement, but not supersede, the existing regulatory framework applicable to storage of LLW, and the conditions in themselves would not authorize onsite storage. Onsite storage of

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LLW at reactors would continue to be subject to 10 CFR 50.59 evaluations, as well as all other regulatory requirements currently in place. Additionally, licensees would continue to use appropriate regulatory guidance for onsite storage of LLW.

The Low-Level Waste Branch of the Division of Low-Level Waste Management and Decommissioning has the lead role in developing the proposed rulemaking package. The proposed rule is scheduled for submission to the Commission by May 1, 1992, for its consideration and approval. The Commission plans to have the final rule in place by December 31, 1992.

For further information, contact: James Kennedy, Low-Level Waste Management Branch, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone 301-504-3401.

GENERAL ELECTRIC NUCLEAR FUEL PLANT URANIUM CONTAMINATION

The General Electric Company (GE) Nuclear Fuel Plant, located in Wilmington, North Carolina, manufactures fuel for commercial reactors. During examination of an eroded concrete floor in one of the manufacturing buildings, the licensee discovered a gap in the construction joint between it and an adjoining building. Core drilling in the area near the gap revealed uranium contamination in the soil beneath the floor. The area above the contamination supported tanks containing uranium nitrate. There had apparently been a spill of approximately 200 gallons of nitric acid sometime around the end of October 1991. This is not necessarily the only time acidic liquid has been

Comments, and suggestions you may have for information that is not currently being included, that might be helpful to licensees, should be sent to:

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spilled on the floor. Upon discovery of the contamination, the licensee continued the investigation, to determine the nature and extent of potential contamination. The work included more bore holes in the concrete floor of the room. Soil samples were taken and temporary well points established. No uranium contamination was discovered other than underneath the slab tank room. The licensee has employed outside experts to assist it in its recovery.

As part of its remediation actions, GE has removed sections of flooring and excavated approximately 100 m^3 of contaminated soil from the area. The final excavation was about 10 m by 4.5 m and to a depth of 2.4 m. Water was encountered in the excavation at the 2.1-m level, and a pumping/drainage system was installed. After excavation, GE measured concentrations of residual uranium activity in soil, using gamma spectrometry. Region II intensified its inspection effort and has been closely monitoring the licensee's efforts. The Office of Nuclear Material Safety and Safeguards (NMSS) has met with the licensee to discuss the issue and has supported RII with a hydrologist who accompanied the inspectors onsite and at meetings with State of North Carolina representatives.

During one of the earlier inspections, the licensee provided an inspector sample splits, to enable the Nuclear Regulatory Commission (NRC) to corroborate the licensee's analytical results. These samples were evaluated at the Environmental Survey and Site Assessment Program (ESSAP) of Oak Ridge Associated Universities (ORAU). ORAU has recently completed a more thorough onsite survey of the excavation. The magnitude of contamination reported by ORAU was similar to that reported by the licensee.

At present, the licensee, concerned that structural damage may occur if further excavation is performed, is filling in the hole (with NMSS approval). After a thorough review of the licensee's pathway analysis, and increased groundwater monitoring, etc., NMSS will stipulate a more formal and lasting solution.

NUCLEAR REGULATORY COMMISSION- (NRC-) CERTIFIED PACKAGES INVOLVED IN SPRINGFIELD, MA, TRUCK FIRE

On December 16, 1991, at approximately 3:18 a.m., a tractor-trailer truck transporting radioactive materials was involved in a head-on collision with an automobile on Interstate 91 (I-91) in Springfield, Massachusetts. The truck was carrying 12 Model RA-2 NRC-certified packages, each containing two unirradiated fuel assemblies (uranium dioxide pellets sealed within zircaloy rods). The Model RA-2 package consists of an inner metal container, 11+ inches by 18 inches by 179 inches long, positioned within an outer wooden box (30 inches by 31 inches by 207 inches long), separated by cushioning material.

The truck was traveling north on I-91, enroute from General Electric (GE) Company in Wilmington, North Carolina, to Vermont Yankee Nuclear Power Plant in Vernon, Vermont. The operator of the automobile was traveling south in the northbound lanes (and subsequently charged with driving while intoxicated). In an attempt to avoid the collision, the driver of the truck swerved his vehicle, striking the barrier on the outer edge of the highway. The truck then rebounded across the road and struck the center median before coming to rest. A fire quickly enveloped the tractor-trailer and cargo. No one was seriously injured.

The Massachusetts State Police responded to the accident within minutes. The driver of the truck immediately provided the police with the shipping papers. The Springfield Fire Department arrived at the scene shortly thereafter and took command of the emergency response. The Fire Department contacted several organizations, including GE, Vermont Yankee, and CHEMTREC, for further information about the contents of the packages. After reviewing this information, along with the information provided in the shipping papers and the Emergency Response Guide, the Fire Department decided to allow the fire to burn itself out. The outer wooden boxes on the packages were completely consumed in the fire. The packages burned until approximately 6:00 a.m. Radiation surveys were conducted by personnel for the State of Massachusetts and Vermont Yankee; no contamination was detected.

GE notified the NRC Operations Center of the event at 4:45 a.m. The Center was not activated for the accident; however, NRC Headquarters and Region I offices provided guidance to State authorities during the incident response and recovery operations. After the fire was out, the assemblies within the metal inner containers were transported to nearby Westover Air Force Base, repackaged by GE, and on December 19, 1991, shipped back to GE-Wilmington, without further incident.

NRC has contracted with Lawrence Livermore National Laboratory (LLNL) to study the severity of the accident conditions and the damage sustained by the packages involved in the accident. The packaging appear to have performed as expected. NRC is also reviewing the emergency response guidance available to on-scene responders.

NUCLEAR REGULATORY COMMISSION (NRC) DELAYS IMPLEMENTATION DATE FOR THE REVISED 10 CFR PART 20

The Commission has voted to delay the implementation date for the revised 10 CFR Part 20 (20.1001–20.2401) to January 1, 1994. This new date is consistent with the date for implementation by Agreement State licensees (the date for implementation by Agreement States has not been changed). In addition, final versions of Part 20 regulatory guides will be available to the public for 1 year before the implementation date.

A change in the implementation date is considered a major change to the rule; therefore, a delay in the implementation date must be enacted through the rulemaking process. The Commission has instructed the NRC staff to initiate this process. In addition, the Commission has instructed the staff to notify and consult with the Environmental Protection Agency (EPA) about the change.

The proposed rule to delay the implementation date will be published in the *Federal Register*, with at least a 30-day comment period. Individuals or organizations with comments on delaying the implementation date are encouraged to respond during the comment period. After the comment period has expired, the NRC staff will review the submitted comments, and the Commission will make a final decision on the delay.

RECONSTITUTION OF LIQUID RADIOACTIVE EFFLUENT

This article is intended to alert Nuclear Regulatory Commission (NRC) licensees to the potential for chemical reconstitution or reconcentration of radioactive materials released to the sanitary sewer, as liquid effluent, when processed by sewage-treatment facilities.

In June 1991, Region III was notified that two loads of incinerated sludge ash from a waste-water treatment facility were rejected from a commercial landfill because of elevated radiation readings from the ash. NRC review of the incident revealed that the ash was generated from the incineration of sewage sludge, which was also a product of the sewage-treatment process. Analysis of the rejected ash revealed detectable concentrations of several radionuclides; however, the concentrations were below those requiring a license, pursuant to 10 CFR 30.14, and posed no significant health hazard. Inspection of the originator's disposal practices, that resulted in the radioactive sludge, showed all releases during the previous 18 months to be in accordance with 10 CFR 20.303 sanitary sewer release criteria. The sewage-treatment process appeared to concentrate the radioactive material in the sewage sludge. Incineration of the sludge resulted in further concentration of the radioactive material in the ash. In this case, a total concentration factor of 10-14 was observed.

With the installation of sensitive radiation-monitoring equipment at many landfills across the country, the rejection of waste shipments because of elevated radiation readings is becoming a more common occurrence. Although release to sewers is currently allowed by 10 CFR 20.303 (20.2003 of the revised 10 CFR Part 20), licensees should be aware of potential problems associated with the release of radioactive materials, readily soluble or dispersible in water, to the sanitary sewer. After or while undergoing sewage treatment, these releases may be subject to chemical reconstitution or reconcentration.

NUREG-1324 PUBLISHED—PROPOSED IMPROVEMENTS FOR REGULATING MAJOR MATERIALS LICENSEES

In February 1992, NUREG-1324, "Report of the Materials Regulatory Review Task Force," was sent for comment to all major materials licensees. NUREG-1324 proposes improved methods for regulating major materials licensees. The NUREG was developed by a task force whose charter was to develop an ideal method of regulating major material licensees. The task force was to be unfettered by any existing regulations or regulatory guidance, concerns about backfitting, or limitations on resources of the U.S. Nuclear Regulatory Commission (NRC) or the licensees.

In the letter transmitting NUREG-1324, the NRC staff requested that comments be provided within 60 days (or about April 30, 1992) and that the following types of questions be addressed:

1. Which of the recommendations should, or should not, be accepted and why?
2. Which of the recommendations should be modified, how, and why?
3. What priority should be assigned each recommendation to be implemented, and why?

RECENT COURT DECISIONS/GENERATOR ACTIONS MAY AFFECT THE ENVIRONMENTAL PROTECTION AGENCY'S (EPA'S) REGULATION OF HAZARDOUS AND MIXED WASTE

A December 6, 1991, decision by the U.S. Court for Appeals of the District of Columbia could affect the way that EPA regulates hazardous and mixed waste. Late 1991 and early 1992 also saw increased efforts by the electric utilities to compel EPA to change the current regulations for the management of mixed waste. These efforts included petitions to both EPA and the U.S. Court of Appeals to amend or revise the Resource Conservation and Recovery Act (RCRA) regulations, as they pertain to the storage and disposal of mixed waste.

On December 6, 1991, the D.C. Court of Appeals decided that EPA had issued the "mixture" and "derived-from" rules (40 CFR 261.3 (a)(2)(iv) and (c)(2)(i)) without adequate notice and opportunity for public comment before their promulgation in 1980 (see *Shell Oil v. EPA*, No. 80-1532, *slip op.*, D.C. Cir., December 6, 1991). The "mixture" rule states that any mixture of a listed hazardous waste and a non-hazardous solid waste is a hazardous waste. The "derived-from" rule states that any waste resulting from the storage, treatment, or disposal of a listed hazardous waste is a hazardous waste. The Court's decision would vacate these two provisions in the regulations that EPA uses to define a hazardous waste. As much as 25 percent of waste that is currently regulated as hazardous

waste could be affected by the Court's decision. It is uncertain how the Court's decision will affect "mixture" and "derived-from" hazardous waste in EPA Authorized States, as the States may have already promulgated their hazardous waste regulations in accordance with applicable State procedural requirements. On March 3, 1992, EPA announced, in the *Federal Register* (57 FR 7628), that it had reinstated these rules, as interim rules, and that it would reissue the rules, as final rules, after the public was given the opportunity to comment on the proposed (reissued) rules. The effective date of the interim rules is February 18, 1992, and they will expire on April 28, 1993.

On November 27, 1991, the Edison Electric Institute (EEI), the American Public Power Association, the National Rural Electric Cooperative Association, and many individual electric utilities petitioned the U.S. Court of Appeals for the District of Columbia, to review EPA's decision on storage of mixed waste. In this decision, EPA determined that generators forced to store mixed waste, because of lack of adequate disposal capacity, are in violation of the land-disposal-restrictions prohibition on hazardous waste storage found at Section 3004 (j) of RCRA. According to the petitioners, EPA's decision forces them into immediate non-compliance, with no means to come into compliance, because adequate disposal capacity for mixed waste does not currently exist. The petitioners also requested that the Court expedite its consideration of the petition, but this has since been denied by the Court.

In addition, on January 13, 1992, the Utility Solid Waste Activities Group submitted a rulemaking petition, to EPA, requesting that EPA amend its regulations, to establish a separate exemption for small-quantity generators of mixed waste. The petitioners also requested that EPA declare that the storage of mixed waste, pending the development of adequate treatment and disposal capacity, is a legitimate practice under Section 3004 (j) of RCRA. Finally, the petitioners requested that EPA amend its regulations to allow qualified facilities to accumulate mixed waste onsite until adequate treatment and disposal capacity become available. At press time, EPA was considering both this petition for rulemaking and its response to the EEI petition, to review its determination on waste storage.

If you have any questions on these actions, please contact Nick Orlando, NRC Mixed Waste Project Manager, at 301-504-2566.

QUALITY ASSURANCE STUDY FOR GAMMA KNIVES

The Leksell Gamma Unit (LGU) or gamma knife is a relatively new (1987) radiation medical device in the United States. It is used for gamma stereotactic radiosurgery of intracranial lesions. It differs from conventional cobalt teletherapy in that its 201 cobalt-60 sources do not move but are arranged so that gamma ray beams sharply focus at a predetermined point about which the patient's lesion needs to be located. The Office of Nuclear Material Safety and Safeguards (NMSS) has contracted with the Nuclear Systems Safety Program at Lawrence Livermore National Laboratory (LLNL) to perform a research project on quality assurance for gamma knives. The objective of this project is to provide information, to the Nuclear Regulatory Commission (NRC), that will enhance the safe and reliable use of gamma knives. The project will not impact or delay license processing for facilities wishing to acquire a gamma knife.

NRC has asked LLNL to gather information on relevant quality assurance guidelines and procedures from medical associations, standard-setting organizations, the manufacturer, and gamma knife users. This information will be analyzed and compared to existing regulations and guidelines (primarily 10 CFR Part 35 and the Quality Management Rule, effective January 27, 1992). In addition, LLNL is developing a risk analysis methodology to identify and assess high-risk human-initiated actions and most likely failure modes. This project thus provides an opportunity to update regulations and develop model safety procedures grounded on a systematic and analytical risk assessment methodology. The approach being used may provide a prototypic regulatory model for a broader class of nuclear medical devices.

LLNL, working closely with NRC, has put together a research team of physicians and medical physicists with expertise in teletherapy, risk assessment experts, and scientists and engineers with extensive knowledge of quality control and regulatory compliance issues. The team has acquired quality assurance documentation from over 20 medical and standards organizations. The manufacturer's U.S. representative, Elekta Instruments, Inc., has provided the team with technical information on the gamma knife, as well as with gamma units and results of acceptance tests. LLNL has visited five gamma knife facilities, so far, to interview users about quality assurance practices and to collect information needed for the risk analysis. Since the current gamma knife community is so small, LLNL hopes to receive data for this project from all gamma knife licensees.

The NMSS project manager is Dr. Patricia A. Rathbun. She can be reached at 301-504-1407.

QUALITY ASSURANCE FOR BRACHYTHERAPY REMOTE AFTERLOADERS

The Division of Industrial and Medical Nuclear Safety (IMNS), Office of Nuclear Material Safety and Safeguards (NMSS), has contracted with Idaho National Engineering Laboratory (INEL), to identify regulations, standards, guidelines, and current practices for quality assurance in remote afterloading brachytherapy and to correlate them against existing regulations in 10 CFR Part 35 (in particular, Subparts G and I). The quality assurance areas specifically addressed by this study include:

(a) safety review and registration of remote afterloaders;

(b) acceptance testing, routine calibration, and safety checks of remote afterloaders and associated facility systems; and

(c) service and preventative maintenance of remote afterloaders.

Based on the data collected, INEL will develop a recommended model for acceptance testing, routine calibration, and safety checks of remote afterloader devices and associated safety systems. In addition, INEL will assess the risk significance associated with the use of remote afterloaders, to identify critical human actions and components that could be significant contributors to risk.

To accomplish the program's objectives, INEL has assembled a team of medical experts and scientists, including physicians and medical physicists with expertise in remote afterloading brachytherapy, and scientists with expertise in risk assessment.

Selected standard-setting bodies, medical organizations, and government agencies are being interviewed. In addition, INEL is obtaining information, relevant to quality assurance, from three manufacturers of remote afterloaders represented in the United States, and from five medical institutions, performing brachytherapy, using remote afterloaders. The three manufacturers include Nucletron, RTS Technology, and Omnitron. Of the five medical institutions participating in this study, three are medical centers associated with large teaching universities, one is a large private clinic, and one is a medium-size radiation oncology center at a private hospital.

The NMSS project manager is Dr. Patricia A. Rathbun. She can be reached at 301-504-1407.

RULES PUBLISHED, October 30, 1991–January 27, 1992

FINAL RULES

- "Material Control and Accounting Requirements for Uranium Enrichment Facilities Producing Special Nuclear Material of Low Strategic Significance"

  1. Published: 10/31/91

  2. Contact: Sher Bahadur, 301-492-3775

- "Revision of Fee Schedules, 100% Fee Recovery, Clarification of Size Standards"

  1. Published: 11/13/91

  2. Contact: James Holloway, Jr., 301-492-4301

PROPOSED RULES

- "Requirements for Possession of Industrial Devices"

  1. Published: December 27, 1991

  2. Contact: Joseph Mate, 301-492-3795

- "Clarification of Statutory Authority for Purposes of Criminal Enforcement"

  1. Published: January 3, 1992

  2. Contact: James Lieberman, 301-504-2741

INFORMATION NOTICES PUBLISHED
November 12, 1991–March 24, 1992

A. Training and Supervision of Individuals Supervised by an Authorized User—IN No. 91-71, dated November 12, 1991
Technical Contacts:
Janet R. Schlueter, 301-504-2633
Roy Caniano, 312-790-5721

This notice reminds licensees of the importance of providing adequate instruction and supervision to individuals working under the supervision of an authorized user. The regulatory requirements for the instruction of workers are described in 10 CFR 35.25, "Supervision." Additional requirements for the instruction of workers are described in 10 CFR 19.12, "Instruction to workers." The Statement of Considerations for Part 35, which is discussed in this notice, contains additional information on instruction and supervision. Supervised individuals who infrequently use radioactive materials, such as part-time cross-trained and contractor technologists, are of particular concern. NRC has received reports of recent events that led to misadministrations or violations, that indicate that some licensees are not providing adequate instruction or supervision to individuals working under the supervision of authorized users. Six recent cases are discussed.

B. Problems with Criticality Alarm Components/Systems—IN No. 91-84, dated December 26, 1991
Technical Contacts:
Scott Pennington, 301-504-2693
Gerald Troup, 404-331-5566

This notice reminds licensees of the importance of adequate reviews of plant modification, installation, maintenance, and response actions, to ensure that required criticality alarm systems meet their intended purpose. It discusses six recent cases of problems with criticality alarm systems. Because physical and electrical modifications have the clear potential to degrade or disable all or part of this system, licensees should ensure that they know the system's configuration and the routing of detector or power circuits, in detail, and that they have a comprehensive testing program and continuous monitoring of the system's integrity.

C. NRC Reporting Requirements for Contamination Events at Medical Facilities (10 CFR 30.50)—IN No. 91-86, dated December 27, 1991
Technical Contact: Robert L. Ayres, 301-504-3423

This notice explains more fully the kinds of contamination events involving byproduct material, as described in 10 CFR 30.50, that might be considered reportable to the U.S. Nuclear Regulatory Commission (NRC) by a medical facility performing procedures with byproduct material, particularly Iodine-131.

D. Revised Protective Action Guidance for Nuclear Incidents—IN No. 92-08, dated January 23, 1992
Technical Contacts:
Kevin M. Ramsey, 301-504-2534
W. Scott Pennington, 301-504-2693

This notice informs licensees of recent revisions to the "U.S. Environmental Protection Agency (EPA) Manual of Protective Action Guides and Protective Actions for Nuclear Incidents." The revisions include the use of committed effective dose equivalent units rather than whole-body dose units, a clarification of the most suitable offsite protective actions, and guidance for controlling doses to emergency workers onsite.

E. Brachytherapy Incidents Involving Iridium-192 Wire Used in Endobronchial Treatments—IN No. 92-10, dated January 31, 1992
Technical Contact:
Harriet Karagiannis, 301-492-4258

This notice describes two recent events where iridium-192 wire attached to an unirradiated flexible guide wire became detached from the guide wire, and what measures the licensees took to prevent such recurrences.

F. Uranium Oxide Fires at Fuel Cycle Facilities—IN No. 92-14, dated February 21, 1992
Technical Contacts:
Amar Datta, 301-504-2536
Charles H. Robinson, 301-504-2576

This notice describes two incidents of fire, at licensee facilities, involving uranium at various stages of oxidation, and alerts licensees to the potential for these fires. It discusses measures for preventing such fires and for upgrading fire detection, alarm, and suppression systems.

G. Spent Fuel Pool Reactivity Calculations—IN No. 92-91, dated March 24, 1992
Technical Contacts:
Jack Ramsey, 301-504-1167
Larry Kopp, 301-504-2879

This notice alerts addresses to potential errors in reactivity calculations for spent fuel pools.

A SAMPLING OF SIGNIFICANT EVENTS REPORTED TO THE U.S. NUCLEAR REGULATORY COMMISSION (NRC)

Event 1: Medical Diagnostic Misadministration

Date Notified: June 17, 1991

Licensee: I. Gonzalez Martinez Oncologic Hospital
Hato Rey, Puerto Rico

On June 17, 1991, a patient scheduled to receive a diagnostic dose of Iodine-131 (I-131) was mistakenly administered a dose of I-131 in the therapeutic range. The misadministration occurred when a nuclear medicine technologist misread the dose calibrator and administered 6.2 millicuries rather than 6.2 microcuries. The technologist realized the error 9 minutes after the dose was administered, when the printed dose label from the dose calibrator was checked. The physician-in-charge promptly administered potassium iodide solution to the patient, to reduce the uptake of the radioactive iodine. The licensee estimated, based on 24-hour uptake measurements, that the dose to the thyroid was 1612 rem.

The licensee continues to follow the patient's condition and has advised the Nuclear Regulatory Commission (NRC) that the patient has not experienced any adverse effects because of the misadministration.

The cause is attributed to human error by the nuclear medicine technologist. The technologist did not verify the dose by reviewing the printed dose label before administering the dose.

The licensee's corrective actions included taking disciplinary action against the technologist and requiring that the nuclear medicine supervisor check each dose before the dose is administered to a patient.

Event 2: Medical Therapy Misadministration

Date Notified: August 30, 1991

Licensee: William Beaumont Army Medical Center
El Paso, Texas

On August 30, 1991, a patient referred to the Medical Center for therapeutic radioiodine treatment of Graves' disease mistakenly received a 28.6- millicurie oral dosage of I-131, instead of the prescribed oral dosage of 15.0 millicuries I-131. As a result, the patient's thyroid received about 31,900 rads, instead of the 16,700 rads intended.

Before the administration, the radiopharmacist involved was informed that a radioiodine treatment for Graves' disease had been requested. He assumed that it was a 29-millicurie treatment rather than a 15-millicurie treatment. (At the Medical Center, a 15-millicurie dose is routinely used for Graves' disease, whereas a 29-millicurie

dosage is used for thyroid disorders such as multinodular toxic goiters.) When the radiopharmacist logged the dosage into the computer, after it had been measured by the dose calibrator, he failed to note the intended therapy dose in the referring physician's prescription. In addition, the consulting nuclear medicine physician did not verify the dosage to be administered with the intended dosage. The 28.6-millicurie incorrrect dosage was then administered to the patient.

The referring physician was notified on the day of the misadministration. The licensee stated that no adverse effects on the patient were noted.

The event was attributed to human error as a result of the radiopharmacist's and consulting nuclear-medicine physician's inattentiveness and brief experience at the facility.

The radiopharmacist and consulting nuclear-medicine physician were advised and reinstructed on proper drawing techniques and safeguards. For future therapies using radiopharmaceuticals, the consulting nuclear-medicine physician must visually check the amount of drawn radiopharmaceutical, as measured by the radiopharmacist or technologist, with the amount intended for the therapy. The licensee also intends that the consulting nuclear-medicine physician be familiar with the patient's case history before administering a therapeutic radiopharmaceutical dose.

Also, the licensee's Radiation Safety Officer (RSO) will conduct a training session in which all nuclear-medicine personnel will be required to review the videotape entitled, "Good Practices in Preparing and Administering Radiopharmaceuticals," prepared by NRC's Office for Analysis and Evaluation of Operational Data.

Event 3: Medical Therapy Misadministration

Date Notified: November 13, 1991

Licensee St. Joseph's Hospital and Medical Center
Paterson, New Jersey

On November 13, 1991, NRC Region I was notified by a letter dated October 30, 1991, from the licensee's acting RSO, that a therapeutic misadministration involving a strontium-90 (Sr-90) beta applicator, with a nominal activity of 95.5 millicuries, had occurred on October 25, 1991. The therapeutic treatment had been administered to the wrong patient.

The misadministration involved a 52-year-old male who was scheduled for a simulation for external beam therapy to the head and neck. This occurred when the radiation oncology department secretary directed the patient to wait in the wrong treatment room without his chart. The patient spoke minimal English, and the radiation oncologist did not speak the patient's language. The physician questioned the patient more than once as to which area of his body was being treated. The patient pointed toward his head as the area to be treated. Based on this poor exchange of information and without the benefit of a review of the patient's chart, the oncology physician then administered a Sr-90 dose to the patient's eye, without waiting to review the patient's chart. The licensee estimates that about 1000 rads were delivered in 11 seconds to the surface of the right eye. The licensee estimates that no harmful effects occurred to the patient as a result of this event.

An NRC medical consultant was retained to review the licensee's dosimetry, the possible biological effects of the dose, and the actions to prevent recurrence. The consultant agreed with the licensee's estimate of dose to the patient's eye and concluded that the possibility of cataracts was low.

The cause was attributed to failure to follow the hospital protocol, which requires reviewing the patient's chart before administering treatment.

The licensee's planned corrective actions include:

1. Patients will only be directed to the treatment area by an aide, who will hand the treatment charts directly to the physician.

2. Each patient's chart will include a polaroid photograph of the patient.

3. Access to the Sr-90 beta applicator storage area will be limited to the Physics Department and the Chief Technologist.

4. Physics staff will accompany the physicians during all Sr-90 beta applicator treatments and assist in determining the treatment times.

5. Staff training and reenforcement of appropriate patient-processing procedures and NRC requirements will be conducted.

NRC Region I conducted a special inspection on November 15, 1991, of the circumstances surrounding this misadministration. The incident was reviewed by an NRC medical consultant. On December 26, 1991, NRC transmitted to the licensee a Notice of Violation and Proposed Imposition of Civil Penalties. Two violations were identified: (1) the failure to review the patient's prescription, which resulted in the misadministration; and (2) the failure to report the misadministration to NRC within 24 hours of discovery.

Event 4: Medical Therapy Misadministration

Date: November 22, 1991

Licensee: University of Pittsburgh Presbyterian-
University Hospital
Pittsburgh, Pennsylvania

The licensee's RSO notified NRC that a therapeutic misadministration involving a cobalt-60 teletherapy unit had occurred at its Presbyterian University Hospital facility, on November 21, 1991. The therapeutic treatment had been administered to the wrong part of a patient's body.

The technologist had looked at the patient's chart, but set up the wrong treatment field. The patient received 287 rads to the thoracic vertebrae (upper back) instead of the prescribed 300 rads to the cervical vertebrae (lower neck). Because the patient had previously undergone thoracic vertebrae treatment, the technologist erroneously assumed that the thoracic treatment was continuing and administered the treatment without adequately reviewing the patient's chart, which indicated the correct treatment area.

The licensee has determined that the treatment will not have any adverse effects on the patient. The patient is suffering from metastatic cancer of the breast and was receiving palliative radiation treatments to the spine.

The cause was attributed to failure to follow the written prescription in the patient's chart. Corrective actions included stressing to the radiation technologists the need to carefully read patients' charts and to recognize notations of changes in the fields to be treated. When a field is completed on a patient, the administered dose is to be written down in the patient's chart, using a different color ink.

Event 5: Medical Therapy Misadministration

Date Notified: November 27, 1991

Licensee: Madison, Wisconsin

A patient was undergoing a series of five treatments for a cancer of the nasal septum, using a high-dose-rate iridium-192 afterloading unit. The initial four treatments were completed without incident. For the fifth treatment, on November 27, 1991, the operating physicist picked up the wrong patient's chart located next to the device's control panel and entered the program information into the computerized device. While the treatment was underway, a student technologist inquired about the length of time to complete the treatment. The prescribing physician and the operating physicist indicated different lengths of time. The physician, realizing there was an error, directed that the treatment be stopped immediately. Subsequently, it was discovered that the physicist had used the chart for the wrong patient and, therefore, entered incorrect treatment program information into the computer. The correct treatment information was then entered into the computer and the treatment series completed.

The erroneous treatment information positioned the iridium-192 source so that the patient's lips received an exposure for about 1 minute. The dose calculation by the licensee indicated that the patient received approximately 73 rads to the lips. According to the licensee, the radiation exposure received by the lips, for a correctly administered treatment to the nasal septum, would be about 23 rads. The licensee does not expect any consequences from the additional exposure to the patient's lips.

The physicist failed to verify the identify of the patient and assumed incorrectly that the chart at the control panel was for the patient undergoing treatment.

The licensee has directed that the operating physicist check the identity of each patient before treatment, using patient photos or other means of verification. Patient charts for treatment series will be placed in a specified location. No exceptions will be made to the training required of a user. In the future, training will include a general section on high-dose-rate afterloading devices.

Event 6: Exposure of a Non-radiation Worker

Date: September 1, 1989

Licensee: San Gabriel Valley Medical Center
San Gabriel, California
(California Licensee)

On August 1, 1989, an intracavitary procedure was performed at San Gabriel Valley Medical Center. Two cesium-137 sources, 42.2 millicuries each, were loaded into colpostat devices and inserted into the patient for treatment. After the procedure was completed, the physician removed the devices and placed them in a lead container. The container was then transported to the room where the cesium storage safe was located; however, the sources were not removed from the inserts and placed in the safe as they should have been. On September 1, an employee of the Medical Center removed the inserts still containing the sources from the lead transport container, and, thinking that they were empty, placed them in an envelope to be transported to Methodist Hospital, where they were intended to be used. The envelope was placed in the Radiology Department, where it was picked up by an employee of a private medical group, a few days later. This individual placed the envelope in his private car and drove to Methodist Hospital, which took approximately 25 minutes.

When the inserts were received by Methodist Hospital, the envelope was opened immediately, and the sources were discovered inside. They were placed in a lead transport container and removed to the storage safe by staff of the hospital.

San Gabriel Valley Medical Center hired a medical physicist to evaluate and determine the extent of exposures that individuals had received as the result of this incident. Extensive time and motion studies were conducted, as well as the processing of personnel-monitoring devices, to determine doses received. The individual who had transported the sources from one hospital to the

other was a non-radiation worker and therefore did not wear a personnel-monitoring device. It was estimated that he received about 106 rem to his right hand and 0.168 rem whole-body exposure. All others who came in contact with the sources wore personnel-monitoring devices. It was estimated that their exposures were within the occupational dose limits specified by the State's Radiation Control Regulations.

The Medical Center was cited for causing the delivery man to receive 106 rem to his right hand, as a result of this event. The hospital notified him in writing, of the nature and extent of his exposure, and provided him with a medical review. A medical examination of his hands, on the day after the exposure, and 3 weeks later, did not reveal any evidence of skin changes or other symptoms. Also, his blood count showed no significant abnormalities.

The apparent cause of this exposure was the failure of hospital employees to follow proper procedures for storage of brachytherapy sources after their use. The individual who transported the sources from the patient's room to the cesium storage location at the Medical Center did not remove them from the colpostat source holders and place them in the storage safe. By leaving the sources in the holders, other personnel were easily exposed, because the sources were invisible and could only be detected by careful examination or use of a survey meter.

The Medical Center purchased a bench-top Geiger-Meuller detector equipped with an audible alarm and installed it at its cesium storage location. The detector will alarm if sources are not secured inside the storage safe. Also, a refresher training was held for all staff, covering the proper handling of brachytherapy sources held under the license. This training included removal and replacement of sources from the storage safe, as well as quarterly inventories. Methods of surveying devices that contained cesium sources, before taking them out of service, were emphasized.

Event 7: Medical Therapy Misadministration

Date: May 3, 1991

Licensee: Northridge Hospital Medical Center
Northridge, California
(California Licensee)

On May 3, 1991, 15 millicuries of iodine-131 intended for patient "A" were administered in error to patient "B," who has the same first and last names as patient "A." The administration was made by the hospital's Certified Nuclear Medicine Technologist, without the responsible physician present, which is a violation of the California Radiation Control Regulations. Patient "B" had reported to the hospital's Outpatient Department for a preoperational chest x-ray, instead of reporting to her doctor's private office, as she was instructed. Patient "A" was scheduled to receive a hyperthyroidism treatment that same morning.

When her name was called, patient "B" answered and signed the consent form. She asked questions of her technologist about thyroid disorders and was given answers. The dose of 15 millicuries was administered.

Later that same day, patient "A" presented herself for the treatment. It was then that the hospital discovered that personnel had administered the dose to the wrong patient. Patient "B"'s doctor was contacted and consulted with the Chief Nuclear Medicine physician. They decided to give patient "B" 15 drops of a potassium iodide solution three times daily for 3 days, plus forced fluids to reduce the uptake of the radioactive iodine. She underwent the previously scheduled surgical procedure 3 days after the dose was administered, without any regard for possible patient exposure of surgical room staff.

This incident was reported to the wrong unit of California's Department of Health Services, by the hospital, 5 days after it occurred. Radiologic Health was not contacted until May 31, 1991, 28 days after the incident occurred, since personnel did not realize the significance of the event. An investigation was begun by the Radiologic Health Unit of the Los Angeles County Health Department, the inspection agency for this licensee. The inspector discovered that the hospital had originally estimated the patient's thyroid dose to be much lower than it actually was. The agency retained a consultant, who performed a complete workup of the patient. The patient's dose was established at 3000 rem to the thyroid, and she was informed of this in writing by the hospital. She was placed into a treatment followup program.

The consultant also evaluated exposures to the surgical room staff. Their exposures were determined to be minimal; they were also notified by the hospital.

An enforcement conference was held at the Los Angeles County Health Department, between members of the hospital administrative staff and representatives of the County and State Radiation Control Program staff. The hospital presented an extensive corrective action plan and explained new controls that would be put in place.

Representatives of the Radiologic Health Branch accepted the plan, and the case was referred to the city attorney's office, for determination of whether charges should be filed.

A SAMPLING OF SIGNIFICANT ENFORCEMENT ACTIONS AGAINST MATERIAL LICENSEES

One way to avoid regulatory problems is to be aware of enforcement problems others have faced. Thus, we have included here a sampling of some representative enforcement actions against materials licensees. These enforcement actions can include civil penalties, orders of various types, and notices of violations.

A. Civil Penalties and Orders

1. Consolidated NDE, Incorporated, Woodbridge, New Jersey
Supplement VII, EA 91-058

A Notice of Violation and Confirmatory Order Modifying License (Effective Immediately) was issued October 11, 1991. The order confirms that an individual would be allowed to act only as an assistant radiographer, and not as a radiographer, until such time as the licensee submits, and the Nuclear Regulatory Commission (NRC) accepts, the licensee's basis for being satisfied that the individual should act as a radiographer, as defined in 10 CFR 34.2. The action was taken because the individual, when he was acting as a radiographer, failed to provide complete and accurate information to NRC during and after an NRC inspection and created an inaccurate utilization record. A civil penalty was not proposed in this case, because a Confirmatory Action Letter, a civil penalty, and an Order Suspending Operation had previously been issued for the underlying problem.

2. Construction Engineering Consultants, Inc., Pittsburgh, Pennsylvania
Supplement VI, EA 91-077

A Notice of Violation and Proposed Imposition of Civil Penalty was issued July 30, 1991, to emphasize the importance of the use of the alarm ratemeters during the performance of radiographic operations. The action was based on a violation involving the failure of licensee radiographers to wear alarm rate dosimeters while performing radiography. The base civil penalty was escalated because NRC identified the violations and mitigated for the licensee's corrective action and good past performance. The licensee responded and requested termination of license; therefore, a letter withdrawing the civil penalty was issued November 6, 1991, concurrent with the termination of the license.

3. Fewell Geotechnical Engineering, Ltd., Pearl City, Hawaii
Supplements IV, V, VI, and V, EA 90-196

A Notice of Violation and Proposed Imposition of Civil Penalties was issued February 7, 1991, to emphasize the importance of complying with license and regulatory requirements, and of ensuring management oversight of the licensed program. The action was based on multiple willful radiation safety violations by a radiographer, including failure to survey after exposures, failure to adequately post the restricted area, failure to secure the source after exposures, and failure to prevent entry into the restricted area. In addition, the radiographer provided false information to NRC personnel as to his activities. A letter was issued October 18, 1991, that withdrew the civil penalty.

4. P.X. Engineering Company, Inc., Boston, Massachusetts
Supplements VI and VII, EA 90-065

A Notice of Violation and Proposed Imposition of Civil Penalty was issued February 21, 1991, to emphasize the importance of the licensee's responsibility for ensuring that: (1) licensed activities are conducted safely and in accordance with the conditions of the license; and (2) all information communicated to NRC is complete and accurate in all material respects. The action was based on the licensee's former RSO, who was also the licensee's radiographer, failing to provide adequate supervision of an individual acting as a radiographer's assistant, on a number of occasions between November 1987 and June 28, 1988. Also, the action was based on the RSO's failure to provide accurate information in response to an inspector's questions about his physical presence during the performance of radiography. The licensee responded in letters dated April 5, 1991, and May 29, 1991. After consideration of the licensee's responses, the staff concluded that the violations did occur as stated, and an Order Imposing Civil Penalty was issued October 1, 1991.

5. St. Joseph's Hospital and Medical Center, Paterson, New Jersey
Supplements IV, VI, and VII, EAs 91-128 and 91-168

A Notice of Violation and Proposed Imposition of Civil Penalties and Order Modifying License and Demand for Information were issued December 3, 1991, to emphasize the need for management to ensure that: (1) all employees provide complete and accurate information to NRC; and (2) activities at the facility are conducted safely and in accordance with regulatory requirements. This action was based on the failure of the individual serving as Chairman of the Radiation Safety Committee and acting RSO to provide complete and accurate information to NRC, unauthorized movement of a High Dose Rate afterloader, and failure to have interlocks on the door to the linear accelerator room. The Order Modifying License precludes use of the responsible individual as RSO or from serving on the Radiation Safety Committee for 3 years.

6. University of Missouri—Columbia, Columbia, Missouri
Supplements V and VI, EA 91-113

A Notice of Violation and Proposed Imposition of Civil Penalty was issued October 29, 1991, to emphasize the importance NRC places on attention to detail while preparing byproduct material for

distribution, and ensuring that byproduct material is properly shipped in accordance with NRC and DOT requirements. The action was based on two incidents in which a shipping technician inadvertently switched containers. As a result of these errors, packages were shipped with the wrong contents listed on the shipping papers and the radioactive labels, and recipients received the wrong byproduct material.

7. Veterans Administration Medical Center, Albany, New York
Supplements VI and VII, EA 91-050

A Notice of Violation and Proposed Imposition of Civil Penalty was issued November 4, 1991, to emphasize to licensee management that it has a fundamental responsibility in ensuring that NRC requirements are met, including the accuracy of required records; and that trained and qualified staff, as well as adequate resources, are essential to maintaining such assurance. The action was based on the failure to perform required physical inventories of sealed sources and creation of inaccurate records indicating that the inventories had, in fact, been performed.

8. Westinghouse Environmental & Geotechnical Services, Inc., Raleigh, North Carolina
Supplements IV, V, and VI, EA 91-140

A Notice of Violation and Proposed Imposition of Civil Penalty was issued November 14, 1991, to emphasize the importance of adequate program oversight and compliance with regulatory requirements and license conditions. The action was based on seven violations involving the licensee's radiation safety program. One of the more significant violations involved the licensee establishing a permanent commercial operation without obtaining a license amendment for that establishment.

9. Winona Memorial Hospital, Indianapolis, Indiana
Supplement VI, EA 91-124

A Notice of Violation and Proposed Imposition of Civil Penalty was issued October 16, 1991, to emphasize the need for effective management and oversight of NRC licensed activities. The action was based on violations involving the [illegible]iodic failure to: (a) perform the quarterly linearity and the annual accuracy tests of the dose calibrator; (b) conduct semiannual leak tests of a sealed source; (c) survey at the end of each day the areas where radiopharmaceuticals are used; (d) check the operation of the radioactive gas collection system and measure the ventilation rates in areas where radioactive gases are used; (e) hold quarterly meetings of the Medical Isotopes Committee and have the RSO in attendance in such meetings; (f) post certain required documents; and (g) retain certain required documents.

10. Wrangler Laboratories, Larsen Laboratories, and Orion Chemical Company, Provo, Utah
EA 87-223

An Order Suspending Licenses (Effective Immediately) was issued February 25, 1988, to the above firms. The action was based on an NRC investigation that indicated that the firms had: (1) failed to fulfill commitments made to NRC; (2) made contradictory statements to NRC and the State of Utah authorities; and (3) processed uranium in an unsafe manner, with inadequate contamination controls. The licensee responded to the Order on March 18, 1988. After consideration of the response, an Order Revoking License was issued August 15, 1988. A Hearing was requested and, after an initial decision, a Memorandum and Order (Terminating Proceeding) was issued September 26, 1991.

B. Severity Level III Violation, No Civil Penalty

1. Lippincott Engineering Associates, Riverside, New Jersey
Supplements IV, V, and VI, EA 91-150

A Notice of Violation was issued November 25, 1991, based on violations involving the failure to maintain proper security of licensed radioactive material located at the field site in Willow Grove. Specifically, an OSHA inspector observed a moisture/density gauge unattended within the perimeter of the fence of the field site. In addition, NRC inspectors determined that the gauge did not have a lock or an outer container that was locked, so as to prevent unauthorized or accidental removal of the sealed source from its shielded position. Other violations were also noted in the radiation safety area. A civil penalty was not proposed because of the licensee's prompt and comprehensive corrective actions, as well as its past good history.

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NUCLEAR REGULATORY COMMISSION
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