

# NMSS Licensee Newsletter



**U.S. Nuclear  
Regulatory  
Commission**

**Office of Nuclear  
Material Safety  
and Safeguards**

**NUREG/BR-0117  
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## **NRC REVIEW OF TOKAI-MURA NUCLEAR CRITICALITY ACCIDENT**

On September 30, 1999, a nuclear criticality accident occurred in a precipitation tank at the JCO Inc. facility located at Tokai-mura, Japan. The accident lasted about 20 hours and resulted in two worker fatalities and elevated radiation exposures to several hundred other workers and members of the public. [The exposure of members of the public is normally not expected for criticality accidents. However, the facility was located in a densely populated area, with the nearest residence only 100 meters (110 yards) from the area of the accident, and no actions were taken to evacuate people from the vicinity until about 5 hours after the accident was initiated, because of emergency management problems and the lack of a facility emergency plan.] About 160 local residents were evacuated from within 350 meters (385 yards) of the site boundary, and about 310,000 people were sheltered within a 10-kilometer (6.2 mile) radius of the site. Open news sources estimate the economic loss at over \$93 million. The Japanese government revoked the business license of JCO Inc. and initiated a criminal investigation. Subsequent reports from the Japanese regulatory authorities indicated that the accident was an irradiation event—caused by direct radiation, and not a contamination event. There were no measurable environmental consequences.

As a result of this accident, the President requested the U.S. Nuclear Regulatory Commission (NRC) to conduct a review of U.S. commercial facilities, to ensure that a similar accident would be unlikely to occur. NRC initiated steps to review the safety operations at U.S.-licensed and -certified fuel cycle facilities, determine the implications for NRC's oversight program, and issue a report addressing the lessons learned and implications. The proposed report

was made publicly available on April 24, 2000, as SECY-00-0085, "Review of the Tokai-mura Criticality Accident and Lessons Learned," and the staff briefed the Commission on the report during a public meeting on May 8, 2000.

The direct cause of the criticality accident was the conduct of operations at the JCO facility. Briefly, the event involved the dissolution of over 16 kilograms (36 lbs) of uranium oxide enriched to about 18.8% uranium-235 (U-235) in nitric acid, and their subsequent addition in 2.6-kilogram (5.7-lb) batches into an unfavorable geometry vessel (precipitation tank). This action resulted in a high concentration of U-235 that was sufficiently reflected and moderated for the geometry of the vessel to generate a supercritical power burst and sustain a quasi steady-state nuclear chain reaction for about 20 hours after the initial pulse. The actual processing operation violated the operating procedures that were required and approved by the regulatory authorities. Because there are indications that the company developed multiple sets of procedures to increase production efficiency without obtaining the approval of the regulatory authorities, the Government of Japan has initiated a criminal investigation.

NRC review of the reports from the Japanese government indicates that there were three overarching root causes: (1) inadequate regulatory oversight; (2) lack of an appropriate safety culture; and (3) inadequate worker training. The licensing review incorrectly concluded that there was no possibility of a criticality accident. Consequently, no criticality accident alarm system was required nor installed and the facility was not included in the National Plan for the Prevention of Nuclear Disasters (e.g., the facility did not have an emergency plan). Furthermore, the regulatory authorities had not inspected the facility since 1992.

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The safety culture that developed at the facility was also inappropriate. Deviations from approved operating procedures began to occur several years before the company developed a second set of procedures to use to increase productivity. The Production and Quality Assurance departments, reviewed and approved the second set of procedures but the Safety Department did not. Within a year before the accident, about one-third of the facility staff was laid off. Of the three workers involved in the accident, two had never operated the 18.8 percent enriched uranium process, and the third worker had only several months of experience the last time it was run, about 3 years ago. There was no management action taken before the restart of the 18.8 percent enriched production run, to assure that the safety limits were properly disseminated to the workers through proper procedures, postings, and training.

If the workers had been informed that certain actions could result in a criticality, this event, in

all likelihood, would not have occurred, because the workers would have understood the importance of adhering to the process safety limits.

After the accident, NRC increased NRC resident inspector focus on the implementation of criticality safety programs at the high-enriched uranium facilities and gaseous diffusion plants. NRC also issued Information Notice 99–31, to alert licensees to the circumstances surrounding the accident, and evaluated the lessons learned as they became available from various sources. A review of the individual deficiencies identified as contributing to the accident or emergency response problems determined that each was adequately addressed by the current NRC oversight program.

The staff concluded that the accident root causes were similar to causes of previous criticality accidents that have occurred in the world. The current safety program carried out at commercial U.S. fuel facilities makes a similar accident unlikely. Finally, emergency response plans provide defense-in-depth at U.S. facilities.

(Contact: William S. Troskoski, 301–415–8076; e-mail: wmt@nrc.gov)

### **RESPONSIBILITIES OF THE DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY**

This is the first in a series of articles explaining the responsibilities of each of the Divisions within the Office of Nuclear Material Safety and Safeguards (NMSS). Other Divisions and groups within NMSS will be discussed in future *NMSS Licensee Newsletters*.

NMSS is responsible for licensing, inspection, and environmental reviews for all activities regulated by the U.S. Nuclear Regulatory Commission (NRC), except operating power and all non-power

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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Office of Nuclear Material Safety  
and Safeguards

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U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555–0001

reactors. NMSS also performs safeguards technical review of non-reactor licensing activities, including export and import of special nuclear material. NMSS develops and implements NRC policy for the regulation of activities involving the use and handling of radioactive materials, such as: uranium recovery activities; fuel fabrication and development; medical, industrial, academic, and commercial uses of radioactive materials; safeguards activities; transportation of nuclear materials, including certification of transport containers; reactor spent fuel storage; safe management and disposal of low-level and high-level radioactive waste; and management of related decommissioning.

The Division of Industrial and Medical Nuclear Safety (IMNS) is one of four divisions in NMSS. IMNS directs NRC's principal rulemaking and guidance development, licensing, inspection, event response, and regulatory activities for materials—as opposed to reactors—licensed under the Atomic Energy Act of 1954, as amended, to ensure safety and quality associated with the possession, processing, and handling of nuclear material. NRC's four Regional Offices are responsible for licensing and inspection of about 5200 licenses in 18 States. Thirty-two other States, known as Agreement States, have assumed responsibility for nuclear materials and are responsible for about 16,000 licenses. IMNS provides central direction to NRC's regional programs and cooperates with the Agreement States on a national program for material safety. The direction of NRC's program includes oversight of health physics and radiation protection, nuclear safety review, and use of licensed materials in medicine, research, industry, and other purposes, with a focus on assuring safety and the effective and efficient delivery of regulatory services. IMNS is headed by Dr. Donald A. Cool, Director, and Dr. Josephine M. Piccone, Deputy Director.

IMNS also plans, develops, monitors, and directs technical rulemakings and regulatory guides, for all NMSS activities, including those related to fuel cycle and materials, safeguards, transportation, decommissioning, the management of nuclear waste, and closure of uranium recovery facilities. The division manages the agency program for "exempt" use of radioactive material and for evaluation of sealed sources and devices. As part of the national program for materials safety, IMNS provides technical support for training of regional and Agreement State licensing and inspection staffs and provides technical support and guidance to the Regions on licensing, inspection, and enforcement activities and, on

request, to the Agreement States. The division identifies and takes action to control safety issues; responds to allegations; and directs NRC contingency and response operations dealing with accidents, events, and incidents under its responsibility.

(Contact: Paul Goldberg, NMSS, 301-415-7842; e-mail: pfg@nrc.gov)

### **NRC ISSUES FINAL RULE AMENDING WELL-LOGGING REGULATIONS, 10 CFR PART 39**

On April 17, 2000, the U.S. Nuclear Regulatory Commission (NRC) published a final rule, in the *Federal Register* (65 FR 20337), amending 10 CFR Part 39, "Licenses and Radiation Safety Requirements for Well Logging," its regulations governing licenses and radiation safety requirements for well logging. The final rule modifies NRC regulations dealing with: low-activity energy compensation sources (ECS'); tritium neutron generator target sources; specific abandonment procedures in case of an immediate threat; changes to requirements for inadvertent intrusion on an abandoned source; and the codification of an existing generic exemption. It also authorizes the removal of obsolete date, and the updating of regulations regarding consistency with the Commission's metrication policy. The Environmental Assessment conducted for this rulemaking demonstrated that there would be no significant impact on public health and safety nor the environment, resulting from this amendment. The final rule became effective on May 17, 2000. Several of the more significant changes are:

1. The regulations were amended to recognize the use of a low-activity radioactive source, known as an ECS, contained within some well-logging tools used in well-logging, and to provide requirements governing its use. The ECS is used to calibrate the well-logging tool while the well is being drilled. This small radioactive source is used in addition to the larger radioactive source used to actually "log" a well. The ECS is typically less than 1.85 MBq (50 microcuries), as compared with the normal 110 GBq-to 740-GBq (3-to 20-curie) sources used in well-logging. 10 CFR Part 39, originally promulgated in 1987, did not provide any specific provisions for these low-activity sources, and many of the requirements in Part 39, when applied to an ECS, are not appropriate nor necessary to protect public health and safety and the environment.

Examples of requirements considered overly burdensome for licensees using ECS', include:

those addressing well abandonment (10 CFR 39.15 and 39.77); leak-testing (10 CFR 39.35); design and performance criteria for sealed sources (10 CFR 39.41); and monitoring of sources lodged in a well (10 CFR 39.69). The rule change provided that only those sections dealing with leak-testing (a revised Section 39.35 specifically addresses ECS); physical inventory (10 CFR 39.37); and records of material use (10 CFR 39.39), apply to the use of an ECS.

The most significant change excludes an ECS from the costly procedures for well abandonment if only an ECS is lost within oil and gas wells, where a surface casing is used to protect fresh-water aquifers. However, if a surface casing is not used, the well-abandonment requirements would continue to apply. The rule establishes 3.7 MBq (100 microcuries) as the limit for an ECS. The 3.7-MBq (100-microcurie) limit should allow licensees flexibility in designing new sources of this kind while maintaining their radioactivity within an environmentally safe level. Although ECS sources will not be required to meet the requirements in 10 CFR 39.41, their sources will be required to be registered pursuant to 10 CFR 32.210. Unless already otherwise exempted, ECS leak tests will need to be performed at a minimum of every 3 years.

2. Tritium neutron generator target sources would be subject to the requirements of Part 39, except for the sealed source design and performance criteria (10 CFR 39.41), and the well-abandonment procedures (10 CFR 39.15 and 39.77), when a surface casing is used to protect fresh-water aquifers. The rule established 1110 GBq (30 curies) of tritium as the limit for a tritium neutron generator target source. The tritium neutron generator target sources will continue to be required to be registered pursuant to 10 CFR 32.210 and to meet applicable industry standards.
3. Section 39.77 provides the requirements for notification and procedures for abandoning irretrievable well-logging sources. This section specifies that NRC must approve implementation of abandonment procedures before abandonment. In some circumstances, such as high well pressures that could lead to fires or explosions, the delay required to notify NRC could cause an immediate threat to public health and safety. This section was revised to allow a licensee to use its judgment to abandon a well immediately, without prior NRC approval, if the licensee believed a delay

could cause such a non-radiological threat. In case of an immediate abandonment, the licensee is required to notify NRC and justify the need for an immediate abandonment after the fact.

4. Section 39.15, which provides requirements for abandoning irretrievable sealed sources, has been revised to provide performance-based criteria for inadvertent intrusion on the source. This modification will allow licensees greater procedural latitude while continuing to ensure source integrity. For example, if a significant amount of drilling equipment must also be abandoned above the logging tool, the equipment itself may be deemed effective in preventing inadvertent intrusion on the source.
5. Two revisions were made to 10 CFR 39.41, "Design and performance criteria for sealed sources." The first incorporated an existing generic exemption for sealed sources that were manufactured before 1989 and met older standards. The second added an optional acceptable standard by referencing oil-well logging requirements in the American National Standards Institute/Health Physics Society document N43.6-1997.

(Contact: Bruce Carrico, NMSS, 301-415-7826, e-mail: jbc@nrc.gov)

## **NRC TO HOLD WORKSHOP ON DECOMMISSIONING ISSUES**

On July 21, 1997, the U.S. Nuclear Regulatory Commission (NRC) published the final rule on "Radiological Criteria for License Termination" (the License Termination Rule or LTR) as Subpart E to 10 CFR Part 20. NRC regulations require that a materials licensee submit a Decommissioning Plan (DP) to support the decommissioning of its facility if it is required by license condition, or if the procedures and activities necessary to carry out the decommissioning have not been approved by NRC and these procedures could increase the potential health and safety impacts on the workers or the public. NRC regulations also require that reactor licensees submit Post-shutdown Decommissioning Activities Reports and License Termination Plans (LTPs) to support the decommissioning of nuclear power facilities.

As part of our continuing efforts to involve the regulated community, and other stakeholders, in our Decommissioning program, we will hold a workshop November 8-9, 2000, at the Commission's Headquarters in Rockville, Maryland. The workshop will be to provide a

forum for us to describe, and obtain feedback from, nuclear industry and non-industry stakeholders, on our process, and guidance for developing and evaluating DPs and LTPs. We will also describe, and receive feedback on, current issues associated with the decommissioning of nuclear facilities, and identify areas and strategies for improving the decommissioning process.

Each day will feature presentations from NRC Headquarters and regional staffs and roundtable discussions on our process for reviewing DPs and LTPs, our expectations for the contents of DPs and LTPs, current policy and technical issues related to decommissioning, and key issues identified since promulgation of the LTR. When finalized, the agenda for the workshop will be posted on the NRC Website at: <http://www.nrc.gov/NMSSIDWM/DECOMIdecomm.html>

The workshop will be open to the public and invited licensees, industry and non-industry stakeholders, and State regulators. Registration will be held from 7:45 to 8:30 a.m. on the first day of the workshop, November 8, 2000, at the entrance of the Two White Flint North Auditorium at 11545 Rockville Pike, Rockville, MD. There will not be any pre-registration, nor registration fee, and the workshop will run from 8:30 a.m to 4:45 p.m. on both days. In addition, the workshop will be transcribed, and the transcripts, and any material presented at the workshop, will be posted on NRC's Website.

(Contact: Nick Orlando, 301-415-6749, e-mail: [dao@nrc.gov](mailto:dao@nrc.gov))

### **NRC STAFF FORMS INSTITUTIONAL CONTROLS WORKING GROUP**

On July 21, 1997, the U.S. Nuclear Regulatory Commission (NRC) published the final rule on "Radiological Criteria for License Termination" (the License Termination Rule) as Subpart E to 10 CFR Part 20 (62 FR 39058). Subpart E establishes criteria at 10 CFR 20.1402 for the release of sites for unrestricted use, if the residual radioactivity that is distinguishable from background results in a total effective dose equivalent to an average member of a critical group that does not exceed 0.25 milliSievert per year (mSv/yr) (25 mrem/yr) and the residual radioactivity has been reduced to levels that are as low as is reasonably achievable (ALARA). Subpart E also establishes criteria at 10 CFR 20.1403 for license termination with restrictions on future land use, as long as specific conditions are met, and criteria for license termination in

unusual situations where the site may exceed the 0.25-mSv/yr (25-mrem/yr) limit, but would not be permitted to exceed 0.10 mSv/yr (10 mrem/yr) or 0.50 mSv/yr (50 mrem/yr), under certain conditions. 10 CFR 20.1403(b) requires that licensees make provisions for legally enforceable institutional controls that provide reasonable assurance that the total effective dose equivalent from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.25 mSv/yr (25 mrem/yr). Institutional controls include measures to control access to the site and minimize disturbances to engineered measures established by the licensee to control the residual radioactivity. They include administrative mechanisms (e.g., land use restrictions) and may include, but not be limited to, physical controls (e.g., signs, markers, and fences).

NRC staff has formed an Institutional Controls Working Group to explore the issues associated with these institutional controls and develop suggested policies and procedures for addressing the issues. The Working Group will continue the efforts undertaken by the NRC staff in developing the guidance in draft Regulatory Guide DG-4006, "Demonstrating Compliance with the Radiological Criteria for License Termination" (DG-4006). Note that the guidance summarized in DG-4006 will be incorporated in the "Standard Review Plan (SRP) for Decommissioning" the NRC staff is currently developing.

The goals of the Working Group are to:

1. Identify policy issues associated with institutional controls for which resolutions are required and develop possible resolutions;
2. Develop model institutional control instruments, such as acceptable language for deed restrictions and financial assurance instruments;
3. Develop various decommissioning scenarios and the institutional controls that would be applicable to each scenario; and,
4. Develop/enhance current definitions in 10 CFR 1400-1405 and develop guidance on institutional controls.

The Working Group includes staff from the Office of Nuclear Material Safety and Safeguards and the Office of the General Counsel. Currently, the Working Group is reviewing the "Restricted Use/Alternate Criteria" section of the SRP.

(Contact: Dominick Orlando, 301-415-6749, e-mail: [dao@nrc.gov](mailto:dao@nrc.gov))

## CAVALIER CHALLENGE

The U.S. Nuclear Regulatory Commission (NRC) conducted a tabletop exercise, called Cavalier Challenge, in Lynchburg, Virginia, on May 24, 2000. This was a joint Federal, State, and local exercise to examine and validate the concepts of operations for responding to an event involving external threats or weapons of mass destruction at a nuclear facility, which would raise both radiological safety and law enforcement issues. Cavalier Challenge was designed to provide a structured discussion forum, based on a scenario or set of conditions, for decision-makers or responders in a low-stress, no-fault environment. The exercise was intended to be both educational and developmental in that disconnects, perceptions, and procedures could be identified, examined, and corrected.

The primary goals of Cavalier Challenge were to: (1) examine the relationships and understanding of participating organizations on how they would work together in response to an event with nuclear safety and law enforcement aspects; (2) foster a positive working relationship among responders to such an event; and (3) examine elements of the NRC/Federal Bureau of Investigation (FBI) concept of operations, incorporate lessons learned from this exercise, revise the concept, and distribute the concept for interim use to NRC, the FBI, and other responders. The exercise focused on three major activities: (1) examining the assessment and notification requirements and corresponding organizational interfaces of responders to an event with significant nuclear safety and law enforcement aspects; (2) examining the activation and deployment requirements of responders to the event; and (3) examining the response actions, command and control, and public interface requirements in response to the event.

This exercise was noticed as a closed meeting. Approximately 100 people were invited to participate as players or observers. Participants included personnel from NRC, the FBI, U.S. Department of Energy, Federal Emergency Management Agency, licensees, and State and local decision-makers and responders. Representing NRC at the exercise were Commissioner Jeffrey Merrifield; Region II Administrator Luis A. Reyes; Incident Response Organization (IRO) Director Frank Congel; Nuclear Material Safety and Safeguards (NMSS) Division of Fuel Cycle Safety and Safeguards Director Michael Weber; and supporting technical staff from NMSS, IRO, and Region II. This exercise used a fictitious facility located in

Lynchburg, VA. BWX Technology agreed to play the licensee at the exercise, which made the exercise more realistic. Most attendees thought the exercise was a success. It provided attendees with the opportunity to meet each other face-to-face. Many thought that future exercises should focus more on State/local responses and Federal assistance to State/local authorities, with a reduced emphasis on higher-level coordination, such as lead Federal agency determination. It was also noted that the NRC/FBI interface in public affairs should be further developed in future exercises.

(Contacts: Yen-Ju Chen, NMSS, 301-415-5615, e-mail: yjc@nrc.gov; Roberta Warren, NMSS, 301-415-8044, e-mail: rsw@nrc.gov)

## SIGNIFICANT ENFORCEMENT ACTIONS

Detailed information about these enforcement actions can be accessed via the U.S. Nuclear Regulatory Commission's (NRC's) homepage [<http://www.nrc.gov/OE/>]. Click on "Enforcement Actions." Cases are listed alphabetically. To access the complete enforcement action, click on the highlighted text after the name of the case.

### Medical

**Jersey City Medical Center**, Jersey City, New Jersey EA 2000-014. A Notice of Violation for a Severity Level III violation was issued February 22, 2000. The action was based on the failure (on at least eight occasions) to secure the Nuclear Medicine Department hot laboratory where radioactive material was located. A civil penalty was not proposed because the licensee had not been the subject of an escalated enforcement action within the last 2 years, and credit was warranted for corrective actions that were considered prompt and comprehensive after NRC had identified the violations.

**Pocatello Regional Medical Center**, Pocatello, Idaho EA 99-332. A Notice of Violation for a Severity Level III problem was issued on March 3, 2000. The action was based on the failures: (1) to secure a generator from unauthorized removal as it was stored in an unrestricted area; (2) to limit the external dose from a generator temporarily stored in an unrestricted area to .02 Sv (2 millirem) in any 1 hour; (3) to provide NRC with a written report within 30 days of an incident involving radiation levels in an unrestricted area that exceeded 10 times the limit contained in 10 CFR 20.1301; and (4) to conduct adequate surveys to evaluate any associated radiological hazards caused by the incident. A civil penalty was not proposed because the facility had not been the subject of escalated enforcement action within the

last two inspections and credit was warranted for corrective action that was prompt and comprehensive.

### **Radiography**

**Maxim Technologies of New York, Inc.**, Mechanicsville, New York EA 2000-002. A Notice of Violation was issued January 10, 2000, for a Severity Level III violation. The action involved the performance of radiography in Vermont and Connecticut (States under NRC jurisdiction), from August through October 1999, by individuals who were not certified through a radiographer certification program by a certifying entity. A civil penalty was not proposed because the facility has not been the subject of an escalated enforcement action and credit was also given for corrective actions that were considered prompt and comprehensive.

### **Well-Logging**

**Allegheny Wireline Services**, Weston, West Virginia EA 99-034 and 00-005. A Notice of Violation and Proposed Civil Penalty in the amount of \$5500 was issued on February 8, 2000. The action was based on a Severity Level III problem comprised of two violations concerning deliberate falsification of well site radiation surveys, and a Severity Level III violation regarding the deliberate failure of the Radiation Safety Officer to provide adequate oversight concerning the completion of the well site surveys. No credit was warranted for the identification of the problem or the violation since NRC identified it. Credit was given for corrective actions that included additional training, revising procedures for conducting radiation surveys, increasing field audit frequencies, and disciplinary action against the individuals involved.

### **Other**

**Mallinckrodt, Inc.**, Maryland Heights, Missouri EA 99-322. A Notice of Violation was issued on January 11, 2000, for a Severity Level III violation. The violation involved the failure to notify NRC and the State agency after declaring an Alert. A civil penalty was not issued because the licensee had not been the subject of escalated enforcement action. Credit was also warranted for corrective action because the corrective actions were prompt and comprehensive.

**West Virginia University**, Morgantown, West Virginia EA 99-300. A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$2750 was issued on February 4, 2000.

The action was based on a Severity Level III violation involving failures to secure from unauthorized removal, or limit access to, licensed material. The violations involve unsecured portable gauges and laboratories that were unlocked and unattended. The licensee had not been the subject of escalated action in the past 2 years, but credit was not warranted for corrective actions, because the security violation had not been corrected after the licensee had identified it on three separate occasions before the November 1999 inspection.

### **Individual Actions**

**Leonard Frye**—IA 99-050. A Notice of Violation was issued on February 8, 2000, based on an investigation involving the deliberate failure of the Radiation Safety Officer at Allegheny Wireline Services to provide oversight sufficient to ensure the completion of radiation surveys and radiation survey records, as required. An Order was not issued because of the individual's forthrightness in the case, and the corrective actions taken by the licensee.

(Contact: Sally Merchant, OE, 301-415-2747; e-mail: slm2@nrc.gov)

### **GENERIC COMMUNICATIONS ISSUED**

**(March 1, 2000—June 30, 2000)**

Note that these are only summaries of U.S. Nuclear Regulatory Commission generic communications. If one of these documents appears relevant to your needs and you have not received it, please call one of the technical contacts listed below. The Internet address for the U.S. Nuclear Regulatory Commission (NRC) library of generic communications is—[www.nrc.gov/NRC/GENACT/GC/index.html](http://www.nrc.gov/NRC/GENACT/GC/index.html). Please note that this address is case-sensitive and must be entered exactly as shown.

### **Information Notices (INs)**

IN 2000-02, "Failure of Criticality Safety Control to Prevent Uranium Dioxide Powder Accumulation," was issued on February 22, 2000. This notice was issued to all fuel cycle conversion, enrichment, and fabrication facilities, to alert them to a problem recently noted with safety-significant level probes that are not self-checking. A level probe in a uranium dioxide powder hopper failed without indicating a failed condition. This allowed powder to accumulate and approach the criticality safety mass limit before discovery.

Contact: Sheryl A. Burrows, NMSS, 301-415-6667, e-mail: sab2@nrc.gov.

IN 2000-03, "High-Efficiency Particulate Air Filter Exceeds Mass Limit Before Reaching Expected Differential Pressure," was issued on February 22, 2000. This notice was issued to all fuel cycle conversion, enrichment, and fabrication facilities to alert them to a potentially significant nuclear criticality risk for high-efficiency particulate air filters that could accumulate special nuclear material beyond a safe mass.  
Contact: Dennis C. Morey, NMSS, 301-415-6107, e-mail: dcm@nrc.gov.

IN 2000-04, "1999 Enforcement Sanctions for Deliberate Violations of NRC Employee Protection Requirements," was issued on February 25, 2000. This notice was issued to all licensees to remind them of the sanctions that could result from deliberately violating NRC Employee Protection requirements.  
Contact: Michael Stein, OE, 301-415-1688, e-mail: mhs@nrc.gov.

IN 2000-05, "Recent Medical Misadministrations Resulting from Inattention to Detail," was issued on March 6, 2000. This notice was issued to all medical licensees to remind addressees of the importance of following written directives and procedures, and the need to pay attention to detail, especially when verifying patient identity, programming treatment devices, and preparing treatment doses.  
Contacts: Susan L. Greene, NMSS, 301-415-7843, e-mail: slg@nrc.gov.  
John D. Jones, RIII/DNMS, 630-829-9832, e-mail: jdj@nrc.gov.

IN 2000-07, "National Institute for Occupational Safety and Health Respirator User Notice: Special Precautions for Using Certain Self-Contained Breathing Apparatus Air Cylinders" was issued on April 10, 2000. This notice was issued to all holders of operating licenses for nuclear power reactors, and non-power reactors, and all fuel cycle and material licensees required to have an NRC-approved emergency plan, to alert addressees to a recent Respirator User Notice, issued by the National Institute for Occupational Safety and Health, that recommends special attention and increased oversight and inspections for certain high-pressure aluminum seamless and aluminum composite hoop-wrapped cylinders made of aluminum alloy 6351-T6.  
Contacts: William M. Troskoski, NMSS, 301-415-8076, e-mail: wmt@nrc.gov.  
James E. Wiggington, NRR, 301-415-1059, e-mail: jew2@nrc.gov.

## Regulatory Issue Summaries (RIS)

RIS 2000-09, "Standard Review Plan for Licensee Requests to Extend the Time Periods Established for Initiation of Decommissioning Activities," was issued on June 26, 2000. This summary was issued to all material licensees to inform them that NRC will now implement the standard review plan entitled, "Licensee Requests to Extend the Time Period Established for Initiation of Decommissioning Activities."  
Contact: John T. Buckley, NMSS, 301-415-6607, e-mail: jtb@nrc.gov.

RIS 2000-10, "Technical Information to Facilitate Public Access to the U.S. Nuclear Regulatory Commission's Agency-Wide Documents Access and Management System (ADAMS)," was issued on June 30, 2000. This summary was issued to all NRC licensees to provide individuals and organizations outside of NRC with information that will assist them in accessing, via the Internet, the publicly available portion of NRC's ADAMS. This RIS provides detailed technical (computing) information for use by network or system administrators in resolving certain types of problems; directions for locating updated materials on the Internet, as they become available; and directions for contacting NRC staff who will provide support on this endeavor.  
Contact: NRC Public Document Room, 202-634-3273 or 800-397-4209, e-mail: pdr@nrc.gov.

(General Contact: Mark A. Sitek, NMSS, 301-415-5799, e-mail: mas3@nrc.gov)

## SELECTED FEDERAL REGISTER NOTICES

(April 1 - June 30, 2000)

NOTE: U.S. Nuclear Regulatory Commission (NRC) contacts may be reached by mail at the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

## FINAL RULES

"Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 65 FR 20337, April 17, 2000.  
Contact: Mark Haisfield, 301-415-6196, e-mail: mfh@nrc.gov.

"List of Approved Spent Fuel Storage Casks: PSNA VSC-24 Revision," 65 FR 24623, April 27, 2000.  
Contact: Richard Milstein, (301) 415-8149, e-mail: rim@nrc.gov.



"List of Approved Spent Fuel Storage Casks: TN-68 Addition," 65 FR 24855, April 28, 2000.  
Contact: Gordon Gundersen, 301-415-6195, e-mail, geg1@nrc.gov.

"List of Approved Spent Fuel Storage Casks: Holtec HI-STORM 100 Addition," 65 FR 25241, May 1, 2000.  
Contact: Merri Horn, 301-415-8126, e-mail mlh1@nrc.gov.

"Revision of Fee Schedules; 100% Fee Recovery, FY 2000," 65 FR 36946, June 12, 2000.  
Contact: Glenda Jackson, 301-415-6057; e-mail: gcj@nrc.gov.

List of Approved Spent Fuel Storage Casks: Standardized NUHOMS-24P and NUHOMS-52B Revision, 65 FR 38715, June 22, 2000.  
Contact: Stephanie P. Bush-Goddard, Ph.D., 301-415-6257, e-mail: spb@nrc.gov.

List of Approved Spent Fuel Storage Casks: VSC-24 Revision, 65 FR 38718, June 22, 2000.  
Contact: Gordon Gundersen, 301-415-6195, e-mail: geg1@nrc.gov.

## PROPOSED RULES

"Interim Storage for Greater Than Class C Waste," 65 FR 37712, June 16, 2000.  
Contacts: Mark Haisfield, 301-415-6196, e-mail mfh@nrc.gov; Philip Brochman, 301-415-8592, e-mail: pgb@nrc.gov.

List of Approved Spent Fuel Storage Casks: Standardized NUHOMS<Register>-24 and NUHOMS<Register>-52B Revision, June 22, 2000.  
Contact: Stephanie P. Bush-Goddard, Ph.D., 301-415-6257, e-mail: spb@nrc.gov.

List of Approved Spent Fuel Storage Casks: VSC-24 Revision, 65 FR 38795, June 22, 2000.  
Contact: Gordon Gundersen, 301-415-6195, e-mail: geg1@nrc.gov.

## OTHER NOTICES

"Notice of Issuance and Availability of NUREG-1617, Standard Review Plan for Transportation Packages for Spent Nuclear Fuel," 65 FR 20939, April 18, 2000.

"Notice of Issuance and Availability of NUREG-1567, Standard Review Plan for Spent Fuel Dry Storage Facilities," 65 FR 20839, April 18, 2000.

"Metabolic Solutions: Denial of Petition for Rulemaking," 65 FR 21673, April 24, 2000.  
Contact: James Smith, 301-415-6459, e-mail: jas4@nrc.gov.

"Notice of availability and request for comments: Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses for Special Nuclear Material of Less Than Critical Mass (NUREG-1556, Vol.17)," 65 FR 24514, April 26, 2000.  
Contact: Carrie Brown, 301-415-8092, e-mail: cxb@nrc.gov.

"Standard Review Plan for the Review of a License Application for the Tank Waste Remediation System Privatization Project: Notice of Availability," 65 FR 25004, April 28, 2000.  
Contact: Michael Tokar, 301-415-7251, e-mail: mxt@nrc.gov.

"Revision of the NRC Enforcement Policy," 65 FR 25368, May 1, 2000.  
Contacts: Bill Borchardt, OE, 301-415-2741, e-mail: rwb@nrc.gov.  
Renee Pedersen, OE, 301-415-2741, e-mail: rmp@nrc.gov.

"Notice of Termination of Section 274i Agreement with Louisiana," 65 FR 25508, May 2, 2000.  
Contact: Kevin Hsueh, 301-415-2598, e-mail: kph@nrc.gov.

"United Plant Guard Workers of America; Receipt of Petition for Rulemaking (PRM-76-1)," 65FR 30018, May 10, 2000.  
Contact: David L. Meyer, ADM, 301-415-7162 or toll-free: 1-800-368-5642; or e-mail: dlm1@nrc.gov.

"Memorandum of Understanding Between the Federal Bureau of Investigation and the Nuclear Regulatory Commission," 65 FR 31197, May 16, 2000.  
Contact: John Davidson, 301-415-8130, e-mail: jjd@nrc.gov.

"Notice of availability of NUREG/CR-6642, 'Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems,'" 65 FR 31620, May 18, 2000.  
Contact: Torre Taylor, 301-415-7900, e-mail: tmt@nrc.gov.

"Notice of Availability of NUREG-1700, 'Standard Review Plan for Evaluating Nuclear Power Reactor License Termination Plans,'" 65 FR 35675, June 5, 2000.

"State of Oklahoma: NRC Staff Assessment of a Proposed Agreement Between the Nuclear

Regulatory Commission and the State of Oklahoma (1st printing),” 65 FR 36169, June 7, 2000.

Contact: Patricia M. Larkins, 301-415-2309, e-mail: pml@nrc.gov.

“Notice of availability of NUREG-1712, ‘Nuclear Byproduct Material Risk Review: Results of Survey of NRC and Agreement State Materials Licensing and Inspection Personnel,’ ” June 8, 2000.

Contact: Ms. Torre Taylor, 301-415-7900, e-mail: tmt@nrc.gov.

“Nuclear Energy Institute; Receipt of Petition for Rulemaking (PRM-72-5),” 65 FR 36647, June 9, 2000.

Contact: David L. Meyer, 301-415-7162 or toll-free: 1-800-368-5642, e-mail: dlm1@nrc.gov.

“Notice of Availability and Request for Comments on draft NUREG-1556, Volume 18, ‘Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses,’ ” 65 FR 36846, June 12, 2000. Contact: Carrie Brown, 301-415-8092, e-mail: cxb@nrc.gov.

“Use of Screening Values to Demonstrate Compliance with the Final Rule on Radiological Criteria for License Termination,” 65 FR 37186, June 13, 2000.

Contact: Dr. Rateb (Boby) Abu-Eid, 301-415-5811; fax: 301-415-5398; or e-mail: bae@nrc.gov.

“Notice of Issuance and Availability of NUREG/CR-6672, ‘Reexamination of Spent Fuel Shipment Risk Estimates,’ ” 65 FR 37186, June 13, 2000.

“NRC Staff Assessment of a Proposed Agreement Between the Nuclear Regulatory Commission and the State of Oklahoma (2nd printing),” 65 FR 37437, June 14, 2000.

Contact: Patricia M. Larkins, 301-415-2309, e-mail: pml@nrc.gov.

“NRC Staff Assessment of a Proposed Agreement Between the Nuclear Regulatory Commission and the State of Oklahoma (3rd printing),” 65 FR 38607, June 21, 2000.

Contact: Patricia M. Larkins, 301-415-2309, e-mail: pml@nrc.gov.

“NRC Staff Assessment of a Proposed Agreement Between the Nuclear Regulatory Commission and the State of Oklahoma (4th printing),” 65 FR

39966, June 28, 2000.

Contact: Patricia M. Larkins, 301-415-2309, e-mail: pml@nrc.gov.

Natural Resources Defense Council; Receipt of Petition for Rulemaking, 65 FR 40548, June 30, 2000.

Contact: David L. Meyer, 301-415-7162 or toll-free: 1-800-368-5642 or e-mail: dlm1@nrc.gov.

“Governors’ Designees Receiving Advance Notification of Transportation of Nuclear Waste, 65 FR 40704, June 30, 2000.

Contact: Spiros Droggitis, 301-415-2367, e-mail: scd@nrc.gov.

(General Contact: Paul Goldberg, 301-415-7842, e-mail: pfg@nrc.gov)

## SIGNIFICANT EVENTS

*Event 1: Sodium Iodide Radiopharmaceutical Misadministration at Hermann Hospital in Houston, Texas*

*Date and Place*—August 4, 1999; Hermann Hospital; Houston, Texas.

*Nature and Probable Consequences*—On August 5, 1999, the licensee Radiation Safety Officer provided written notification to the Texas Department of Health, Bureau of Radiation Control (BRC) of a medical misadministration involving the administration of iodine-131 (I-131) to the wrong patient. The licensee reported that two female out-patients (who both spoke English as a second language) were involved in the error, which occurred on the morning of August 4, 1999. Patient A (for whom the therapeutic dose of I-131 was intended) was approximately 55 years old; Patient B (who inadvertently received the I-131 dose) was approximately 64 years old. Patient B had completed a scheduled bone density scan and was still in the nuclear medicine department. At that time, the technologist misidentified her as the patient who was to receive a therapeutic dose of I-131. Patient B was then administered 1.01 gigabecquerels (27.3 millicuries) of I-131 at approximately 10:40 a.m. (CDT) and was sent home. Patient A was later observed to still be in the waiting room needing to be administered the I-131. At this time, the licensee realized that the misadministration had occurred. Patient A was then administered the prescribed dose of I-131 and returned home.

At approximately 4:00 p.m. (CDT) on August 4, 1999, the Radiation Safety Officer, the Chief of the Nuclear Medicine Department and the

Nuclear Pharmacy Manager were dispatched to Patient B's home to discuss the misadministration with her and her husband. With the patient's consent, the Nuclear Medicine Physician initiated the administration of supersaturated potassium iodide (1 milliliter three times per day) and furosemide (lasix) at an initial dose of 40 milligrams per day, to reduce the patient's radiation exposure caused by the error. The administrations were completed at approximately 5:20 p.m. (CDT). The misadministered patient received a radiation dose to the thyroid of approximately 22,000 centiGray (rad). This radiation dose left the patient with an 85 percent chance of functional loss of her thyroid, and replacement thyroid hormone will be required indefinitely.

#### *Actions Take to Prevent Recurrence*

*Licensee*—The licensee changed its procedures for all outpatient therapeutic treatments that involve radioactive material. The patient information sheet form was changed to ask questions like: "What is your name?" "What is your date of birth?" ....instead of having questions requiring "yes" or "no" answers. The licensee will also ask outpatients to show a picture form of identification as a mean of properly identifying a person. For pediatric patients, the parent or guardian must confirm the identification of the patient.

*State Agency*—BRC staff conducted an investigation and agreed with the licensee's findings and believes that the licensee's corrective actions are adequate to prevent recurrence.

*Event 2: High Dose-Rate Remote Afterloader Misadministration at Queen's Medical Center in Honolulu, Hawaii.*

*Date and Place*—October 27, 1999; Queen's Medical Center; Honolulu, Hawaii.

*Nature and Probable Consequences*—On October 28, 1999, a medical physicist representing the licensee reported a medical misadministration, which occurred on the day before, involving a single fractional treatment. The treatment was performed using a Nucletron high-dose-rate (HDR) remote afterloading device loaded with an iridium-192 source of approximately 252 gigabecquerel (6.8 curies). The licensee categorized the treatment as a misadministration because the patient received an unintended dose of 380 centiGray (rad) to the right nasal cavity. This treatment was the first of four scheduled fractions intended to deliver a total

dose of 1520 centiGray (rad) to a specified location in the nasopharynx.

Initial simulation radiographs taken to determine the appropriate dwell positions indicated a standard distal dwell position of 995 millimeters (mm) was appropriate. After patient setup and insertion of the treatment catheter, a position simulator tool was used to verify the distal dwell position of the catheter. The position simulator, as used by a staff dosimetrist, indicated a distal dwell position of 950 mm and a repeat measurement gave the same value. During both measurements, the dosimetrist felt resistance when moving the slide pointer on the tool. Although the measured distal dwell position was different from that expected, the measured 950-mm value was believed to be correct because the dosimetrist was able to reproduce the measurement. In addition, because catheters were sometimes customized at the facility, by cutting them to shorter lengths when needed, the staff did not initially question the measured distance. None of the dwell position measurements was independently checked by other members of the radiation oncology staff. Treatment was subsequently initiated.

The following day, a different dosimetrist reviewed the case before delivering the second treatment fraction. Noting the recorded 950-mm distal dwell position as somewhat unusual, in that it was shorter than expected, he performed further checks. Using the position simulator tool, the dosimetrist noticed the measuring cable was difficult to move past the 950-mm position. However, the dosimetrist was able to extend the position simulator cable to the expected 955-mm position. As a further check, the dosimetrist set the position simulator to the 950-mm position and took new radiographic films of the patient's nasopharynx, which showed the distal dwell dummy source displaced 45 mm from the position intended. The dosimetrist performed a final verification of the actual distal dwell position using the Nucletron "Special Mode" and dummy source wire. (With this selection, a dummy source wire is run through the catheter, using the Nucletron unit, and the source travel is measured automatically.) When this mode of operation was used, the measured distal dwell position was again determined to be 995 mm.

#### *Actions Taken To Prevent Recurrence*

*Licensee*—To prevent similar problems the licensee initiated the following corrective actions: (1) the storage cabinet for HDR catheters was labeled to specify the distal dwell position associated with each transfer tube, to remind the operator to enter the correct value; (2) a new,

replacement position simulator, previously ordered by the licensee, was received and placed into operation; and (3) there was a requirement for a second member of the physics staff to double-check the measurement process and data involving any use of a position simulator. A worksheet used during the physics checks has been modified to document the presence of both individuals.

*NRC*—U.S. Nuclear Regulatory Commission (NRC) staff from the Region IV office conducted an inspection to review the circumstances associated with the misadministration. This case is still under review by an NRC medical consultant.

*Event 3: Gamma Stereotactic Radiosurgery (Gamma Knife) Misadministration at Healthsouth Doctor's Hospital, Inc., Coral Gables, Florida.*

*Nature and Probable Consequences*—The Florida Bureau of Radiation control (BRC) reported to the U.S. Nuclear Regulatory Commission (NRC) Headquarters Operations Center that a medical misadministration had occurred at the licensee's facility on January 25, 2000. A patient diagnosed with metastatic lung disease with up to 80 brain lesions identified was being treated with a stereotactic radiosurgery procedure using the Leksell Gamma System, Model 23016 (gamma knife). The patient was receiving her fourth of five treatments when the misadministration occurred. Each treatment consisted of 16 lesions for irradiation. A treatment plan was developed to deliver to each lesion a minimum peripheral dose of 12 Gray (1200 rad). The misadministration occurred when the patient received a 12-Gray (1200-rad) peripheral dose to lesion site 16 (MRI z coordinates 70.7 mm) instead of lesion site 47 (MRI z coordinates 85.0 mm). Site 16 was previously treated on December 28, 1999, with the same dose. Lesion site 16 was located 6-mm superior, from site 47 in the z plane. The MRI slices are 3-mm slices in the z direction. The MRI slice at z coordinate 67.9 did not resolve the lesion at site 47. The radiation safety officer (RSO) indicated that the incorrect MRI was displayed on the computer screen (z-70.7 mm instead of 65.0 mm) and the treatment plan was calculated at this incorrect coordinate. The RSO discovered this error on January 28, 2000, during the licensee's routine quality assurance review of the treatment, and reported it to the BRC that same date. The BRC conducted an on-site investigation on February 2, 2000, which included a review of the treatment plans, the written directive, physician-approval procedures, and a reenactment of a treatment plan for the remaining untreated sites. The event was determined to be caused by human

error when the wrong treatment site was selected in the computer. There was no malfunction of the gamma knife or computer equipment.

#### *Actions Taken to Prevent Recurrence*

*Licensee*—The licensee did not identify any corrective actions nor changes in quality management procedures, that would have prevented this type of human error. The licensee will pay closer attention to detail.

*State Agency*—State investigation found no violations of the license nor regulations. The licensee's quality assurance program found the error. The licensee had the wrong site set in the computer when the procedure was performed. The State did not identify any corrective actions or changes that would have prevented this event.

*NRC*—The Office of Nuclear Material Safety and Safeguards is in the process of developing an Information Notice to address gamma knife misadministrations caused by human error.

*Event 4: Significant extremity overexposure of radiation workers at Mallinckrodt Medical, Inc., in Maryland Heights, Missouri.*

*Date and Place*—March 31, 2000; Mallinckrodt Medical, Inc.; Maryland Heights, Missouri.

*Nature and Probable Consequences*—The licensee—a radiopharmaceutical manufacturing facility— notified the U.S. Nuclear Regulatory Commission (NRC) of an event involving an employee directly handling an unshielded molybdenum-99 (Mo-99) technetium-99 generator column. The column contained 700 gigabecquerels (19 curies) (Mo-99) and 300 gigabecquerels (8 curies) of technetium-99m (Tc-99m). Event reenactments determined that the individual may have held the column using his thumb and index finger of his left hand for as long as 50 seconds while attempting to correct alignment problems with the inlet and outlet needles. The individual wore a ring badge on the right hand to measure extremity dose, and this monitor read 0.057 sieverts (5.7 rems). Calculations indicated that the dose to the individual's thumb and index finger of the left hand may be as much as 25-gray (2500-rad) shallow dose equivalent.

The licensee's investigation into the event identified two additional exposure situations involving 13 other individuals in other areas of the facility.

One situation involved the hand-labeling of product vials that contained approximately 740

megabecquerels (20 millicuries) or iridium-111, an accelerator-produced radioactive material. Ten individuals, over the period between 1995 and 1999, inclusive, held the product vials in their left hands, with the index fingers on the tops of the vials and their thumbs on the bottoms, in close proximity to the radioactive material, and applied the labels with their right hands. The individuals all wore their extremity monitors on their right hands. Licensee calculations determined that the individuals involved in this practice received between 0.5- and 6-sievert (50- and 600-rem) shallow dose equivalents during calendar years 1995 through 1999. Several individuals received exposures in excess of 0.5 sievert (50 rems) in multiple years.

The other situation involved three additional individuals who worked in one of the licensee's product testing-laboratory. While performing their duties in this laboratory, the individuals removed aliquots of radioactive material for testing from product vials, using unshielded syringes, and in some instances, while holding the unshielded vials in their hands. These individuals received between 0.7- and 1.0-sievert (70- and 100-rem) shallow dose equivalents to their hands and fingers during calendar years 1997 and 1999. Again, some of the individuals received exposures in excess of 0.5 sievert (50 rems) in more than 1 year.

The licensee believed that the exposures recorded by the extremity monitors were the "doses of record," and did not recognize the significant difference between the recorded dose and the actual dose to the finger tips when handling unshielded vials and syringes of radioactive material. This contributed to the licensee not being fully aware of the extent of inadequate radiation-handling practices. The extremity monitor results for the individuals involved in these last two situations did not provide any indications that they were receiving doses in excess of NRC regulatory limits.

#### *Actions Taken to Prevent Recurrence*

*Licensee*—Corrective actions include procedure modification and conducting training sessions with employees to review all applicable procedures. The licensee hired a contractor to perform a Hazard/Barrier-Risk Assessment to ensure that the true root causes of this event are identified.

*NRC*—On July 18, 2000, NRC issued information Notice 00-10, "Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits." (This Information Notice alerted licensees to recent events that resulted in

personnel receiving occupational extremity doses in excess of the 0.5-sievert (50-rem) shallow dose equivalent limits specified in 10 CFR 20.1201(a)(2)(ii).

*Event 5: Gamma Stereotactic Radiosurgery (Gamma Knife) Misadministration at University of Maryland at Baltimore Hospital, Baltimore, Maryland.*

*Date and Place*—April 20, 2000; University of Maryland at Baltimore Hospital, Baltimore, Maryland.

*Nature and Probable Consequences*—The licensee reported a medical misadministration involving a 52-year-old female patient who was scheduled to receive gamma knife therapy to the 50 percent isodose line, for treatment of Pituitary Adenoma. The patient received 1260 centiGray (rad) to an unintended site, with a volume of approximately 0.18 cubic centimeter (cm) at the base of the frontal lobe. The unintended site was approximately 4.2 centimeters (cm) from the intended site. The Leksell Gamma System gamma knife (model 23016) uses 201 sealed Co-60 sources of 1.1 Tbq (30 Ci) each for the radiation treatment of human patients. The medical directive for this treatment was defined as 1800 cGy (rad) administered over six administrations. The misadministration occurred during the first administration. The unintended site would have received approximately 160 cGy (rad) during the first fraction, had the first fraction been completed as prescribed. The treatment planning for the patient was uneventful and was prepared and reviewed by a hospital gamma knife team of a radiation oncologist, a neurosurgeon, and a medical physicist. It appears from preliminary interviews that when two of the team members were adjusting the coordinates on the device's stereotactic frame, the Y and Z coordinates were reversed. The frame adjustment is supposed to be checked for accuracy by a nurse and the medical physicist. Normally, the coordinates are read out in a specific order. The licensee indicated that the order might have been reversed because of a specific frame orientation problem that occurs approximately once in every 20 treatments. When the licenses started to set up for the second administration, the error was noted. The treatment plan was reevaluated to include some partial dose to the tumor from the first administration, and the treatment was completed in seven administrations instead of six. The patient and the referring physician were notified of this misadministration on the same day the event occurred. The licensee is reviewing previous medical files to ensure that the switching of coordinates has not occurred before without a

misadministration being identified. The root cause of this event appears to be human errors during the setting and verification of patient-positioning parameters.

#### *Actions Taken to Prevent Recurrence*

*Licensee*—The licensee has developed and implemented an additional procedure that requires more attention and better confirmation of coordinate placement on the frame.

*State Agency*—The additional procedure developed by the licensee is under review by the Maryland Radiological Health Program (RHP). This event is still under investigation by RHP.

*NRC*—The Office of Nuclear Material Safety and Safeguards is in the process of developing an Information Notice to address gamma knife misadministrations caused by human error.

*Event 6: Gamma Stereotactic Radiosurgery (Gamma Knife) Misadministration at Healthsouth Medical Center, Birmingham, Alabama*

*Date and Place*—April 12, 2000; Healthsouth Medical Center; Birmingham, Alabama.

*Nature and Probable Consequences*—The licensee reported a misadministration where the gamma knife was set up incorrectly and delivered the dose to the wrong location of a patient's brain. A radiosurgery treatment was to be delivered to the Left Trigeminal Nerve of a 51-year-old woman, using the Leksell Gamma System (model 23016) gamma stereotactic radiosurgical unit (gamma knife) containing 243.9 T<sub>bq</sub> (6592.8 Ci) (activity of 8/1/95) of Co-60. On the same date, a 75-year-old man was admitted for the identical treatment. During the signature phase of plan approval, the dose-delivery sheet of the 75-year-old man's treatment protocol was inadvertently transposed with that of the 51-year-old woman's treatment protocol. As a result, the 51-year-old woman was treated with the radiosurgery parameters intended for the 75-year-old man. This resulted in an 8000-cGy (rad) dose to the wrong treatment site of the patient's Left Trigeminal Nerve. The

intended prescription dose to the treatment site was 8000 cGy (rad) at the 50 percent isodose line. The actual dose delivered to the intended treatment site was 20 cGy (rad) (maximum) as calculated by the licensee. A dose of 8000 cGy (rad) was delivered to a volume 88.6-cubic millimeter volume inside the skull of the woman, but outside of the intended treatment site. The misadministration was noted immediately after the delivery of the dose. The patient was notified verbally, within 24 hours. On April 20, 2000, the patient returned to the medical center and received treatment to the intended treatment site.

#### *Actions Taken to Prevent Recurrence*

*Licensee*—As a result of the misadministration, the licensee took immediate action to prevent the mixing of patient treatment protocol documentation. Each page of the treatment protocol was modified to contain a unique name and time stamp, which will be reviewed by the Radiation Oncologist or Medical physicist as evidenced by initialing each page of the protocol near this stamp), before the delivery of the radiosurgery treatment.

*State Agency*—the State staff conducted an investigation and agreed with the licensee's findings and believes that the licensee's proposal is adequate to prevent recurrence.

*NRC*—NMSS is in the process of developing an information Notice to address gamma knife misadministrations caused by human error.

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#### **CORRECTION**

In the March-April issue of the *NMSS Licensee Newsletter* (No. 00-01), the article entitled "New Source Calibration and Dosimetry for Palladium-103 and Interstitial Sources," contained errors in the conversion of gray units (Gy) to rad units. The correct figures are: 115 Gy (11,500 rad); 124 Gy (12,400 rad); and 135 Gy (13,500 rad).

**UNITED STATES  
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