

NMSS Licensee Newsletter



**U.S. Nuclear
Regulatory
Commission**

**Office of Nuclear
Material Safety
and Safeguards**

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NMSS Licensee Newsletter (December 2003)

<i>Contents</i>	<i>Page</i>
1. NRC Continues Efforts to Enhance Security of Radioactive Materials Through Issuance of Orders	1
2. Recent Evaluations of the Decommissioning Program	1
3. NMSS Responds to Davis-Besse Lessons Learned	3
4. Proposed Rule to Amend 10 CFR Part 35, "Medical Use of Byproduct Material"	4
5. Generic Communications Issued (September 10, 2003 - November 6, 2003)	4
6. Significant Enforcement Actions	6
7. Significant Events	8
8. Selected <i>Federal Register</i> Notices (October 1, 2003 - November 30, 2003)	9

NRC CONTINUES EFFORTS TO ENHANCE SECURITY OF RADIOACTIVE MATERIALS THROUGH ISSUANCE OF ORDERS

In late October 2003, the U.S. Nuclear Regulatory Commission (NRC) forwarded special correspondence to licensees, communicating Modified Safeguards Handling requirements necessary for receiving safeguards-sensitive Orders, which NRC is going to issue to licensees. In late November 2003, NRC proceeded to issue a draft Safeguards-Modified Handling Order to the high-

risk group of materials licensees known as manufacturing and distributing facilities, to improve security of radioactive materials. This Order included draft Additional Security Measures (ASMs) concerning the security of high-risk radioactive sources, and associated guidance for implementing the ASMs. The ASMs and guidance were drafted through a collaborative effort of NRC and State representatives tasked to develop additional materials security requirements in response to the events of September 11, 2001. During the week of December 8, 2003, NRC held a series of closed workshops with NRC licensees and Agreement State licensees, to discuss comments on the draft ASMs. NRC staff plans to issue the final implementing Orders by the end of December 2003.

(Contact: Rich Turtill, NMSS, 301-415-0260, e-mail: rht@nrc.gov)

RECENT EVALUATIONS OF THE DECOMMISSIONING PROGRAM

A. Results of License Termination Rule Analysis

The U.S. Nuclear Regulatory Commission's (NRC's) experience from using the License Termination Rule (LTR), since it was finalized in 1997, has revealed some important implementation issues impacting the decommissioning of NRC licensed sites. As a result, NRC conducted an analysis of LTR issues. The analysis of issues and recommendations was given to the Commission on May 2, 2003 (SECY-03-0069). On November 17, 2003, the Commission approved the implementation of the staff's recommendations. The LTR Analysis in SECY-03-0069 is publicly available on NRC's web site at <http://www.nrc.gov/reading-rm/doc-collection/commission/secys/2003>.

The LTR Analysis particularly emphasized resolving the institutional control issue so that the restricted release and alternate criteria provisions of

the LTR would be more available for licensee use. In addition to the institutional control issue, NRC also evaluated issues dealing with the relationship of the LTR release limits to other release limits, realistic exposure scenarios, measures to prevent future legacy sites, and intentional mixing. For each issue, NRC evaluated a range of options that could resolve the issue and then recommended a preferred option for Commission decision. For example, NRC is planning on using the following options to resolve the institutional control issue: 1) a risk-informed, graded approach for selecting institutional controls; 2) NRC monitoring institutional controls after license termination using a legal agreement and a deed restriction; and 3) NRC long-term control possession-only license. For the realistic exposure scenario issue, NRC is planning on using reasonably foreseeable future land uses, as opposed to defaulting to very conservative scenarios such as the resident farmer. Finally, many of the existing decommissioning sites that NRC regulates are complex and difficult to decommission for a variety of financial, technical, or programmatic reasons. NRC evaluated the lessons from these existing "legacy" sites and plans on changes to financial assurance and licensee operations, to minimize or prevent future legacy sites.

NRC is planning a variety of regulatory actions to address these issues, including: 1) a rulemaking for measures to prevent future legacy sites (changes to financial assurance and licensee operations); 2) revised guidance to support the rulemaking and to clarify institutional controls for restricted use, on-site burials, and realistic exposure scenarios; 3) revised inspection procedures and enforcement guidance to enhance monitoring and reporting; and 4) a Regulatory Issue Summary to inform a wide range of stakeholders about the LTR analysis of each issue, Commission direction, and actions planned to resolve each issue.

B. Decommissioning Program Evaluation

The U.S. Nuclear Regulatory Commission's (NRC's) Strategic Plan for fiscal year (FY) 2000-2005 identified a program evaluation entitled *Changes to the Decommissioning Process*, to be conducted in FY 2003. The NRC staff completed its evaluation in FY 2003 and the results are summarized below. The final report is available on NRC's Decommissioning web site, at <http://www.nrc.gov/materials/decommissioning.html>.

The objectives of the Decommissioning Program Evaluation were to: 1) evaluate the effectiveness of NRC's Division of Waste Management (DWM)

Decommissioning Program; 2) evaluate individual program changes/improvements; and 3) recommend future improvements. The scope of this program evaluation was limited to the regulation of decommissioning of nuclear materials facilities and fuel cycle facilities included on the Site Decommissioning Management Plan (SDMP) and complex site list during the FY 2001-FY 2003 time period. Also included within the scope of the program evaluation were those activities related to power reactor decommissioning that DWM was responsible for before the transfer of most power reactor decommissioning from the Office of Nuclear Reactor Regulation to the Office of Nuclear Material Safety and Safeguards during FY 2003.

The staff believes that the Decommissioning Program has been effective at meeting the Agency's strategic and performance measures and removing sites from the SDMP list after completion of decommissioning and license termination. The program also effectively used many types of self-assessments and program changes to improve the regulatory framework, decommissioning processes, internal program management processes, and public involvement. The staff believes these improvements have been useful and those that are ongoing should continue to be used.

The Program Evaluation also made recommendations to program managers that would improve internal program management. These recommendations include:

- 1) Establish a comprehensive Decommissioning Program perspective.
- 2) Implement the new Consolidated Decommissioning Guidance.
- 3) Improve staff availability and efficient utilization.
- 4) Expand management reviews of all decommissioning sites.
- 5) Compare and evaluate NRC's Decommissioning Program to similar programs.
- 6) Revise Annual Budget measures and targets.
- 7) Consider using incentives to facilitate licensee decommissioning.
- 8) Document and implement a continual improvement plan.

(Contact: Robert L. Johnson, 301-415-7282, e-mail: rlj2@nrc.gov)

NMSS RESPONDS TO DAVIS-BESSE LESSONS LEARNED

Over the past year and a half, the U.S. Nuclear Regulatory Commission (NRC) has been responding to the discovery of a corrosion-induced cavity in the reactor vessel head at the Davis-Besse Nuclear Power Station, located near Toledo, Ohio. The Davis-Besse reactor head damage represented a significant reduction in the safety margin of one of the plant's three barriers that separate radioactive reactor fuel from the public and the environment.

One of the actions NRC undertook in response to the discovery of the cavity was to charter a Lessons Learned Task Force (LLTF) to independently evaluate NRC's regulatory processes, to identify and recommend areas for improvement that may be applicable to either NRC or the nuclear industry. The LLTF identified several reasons that the vessel head degradation was not prevented, including:

- NRC, the licensee, and the nuclear industry failed to adequately review, assess, and follow up on relevant information pertaining to operating experience.
- The licensee failed to assure that plant safety issues would receive appropriate attention.
- NRC failed to integrate known or available information into its assessments of the licensee's safety performance.

The LLTF made several recommendations on how NRC could improve its oversight of licensed activities. In response to these recommendations, a Senior Management Review Team evaluated the LLTF report, and the results of its review were transmitted to the Commission in a January 3, 2003, memorandum from the Executive Director for Operations (accessible from the NRC website or through ADAMS at accession number ML023600434). The second attachment to that memorandum contains a table showing the Office of the Nuclear Material Safety and Safeguards Areas (NMSS) "Areas for Assessment," grouped in the following categories:

- Integrated assessment of nuclear material safety programs
- Analysis and use of operating experience information
- Use of risk in regulatory decisions
- Verification of the adequacy of licensee and regulatory actions

- Implementation of management expectations
- NRC staffing and training
- Licensee self-assessment and corrective action programs

NMSS divisions are addressing the "Areas for Assessment" on program-specific bases. Some of the activities that are being undertaken include:

- Examining ways to improve the evaluation of operating experience, including ways to best communicate lessons from events, generic issues, results from analyses of performance and trends, and safety insights.
- Examining ways to improve NMSS follow-up of generic communications through the inspection program.
- Refining the integrated assessment process, including NMSS efforts to support the Agency Action Review Meeting and annual reporting to the Commission on performance trends.
- Refining and reinforcing office-wide guidance on the proper use of risk information, including developing program-specific approaches for the use of risk methods.
- Integrating cross-organizational needs for explicit specialist skills and broader needs provided by generalists as part of the Strategic Workforce Planning initiative.

The Office's responses to the Davis-Besse Lessons Learned are being carried out within the context of "NMSS Values," with particular focus on our mission of maintaining adequate levels of safety, while striving for excellence through continuous improvement, growth, and learning. The activities that are being taken will enhance the effectiveness of internal and external communications, and will strengthen cooperation among NMSS organizations by fostering better organizational alignment on roles, responsibilities, and expectations.

Additional technical information on the Davis-Besse vessel head cavity can be found on NRC's website (www.nrc.gov) under the link, "Davis-Besse/Reactor Vessel Head Degradation." The monthly Davis-Besse NRC Update, which can be accessed through the News and Correspondence link on this webpage, describes the current status of NRC and licensee responses to this event, and it provides a brief description of its cause. (Contacts: Michael Markley, NMSS, 301-415-5723,

e-mail: mtm@nrc.gov; Pat Castleman, NMSS, 301-415-8118, e-mail: pic@nrc.gov)

PROPOSED RULE TO AMEND 10 CFR PART 35, "MEDICAL USE OF BYPRODUCT MATERIAL"

The U.S. Nuclear Regulatory Commission (NRC) seeks public comment on a proposed amendment to requirements for recognition of specialty board certifications.

NRC published a proposed rule to amend 10 CFR Part 35 in the *Federal Register* on December 9, 2003 (68 FR 68549) for a 75-day public comment period ending on February 23, 2004. The proposed amendments would revise NRC regulations to change requirements for recognition of specialty boards whose certifications may be used to demonstrate the adequacy of the training and experience of individuals to serve as radiation safety officers, authorized medical physicists, authorized nuclear pharmacists, or authorized users. The proposed rule would also revise the requirements for demonstrating the adequacy of training and experience for pathways other than the board certification pathway. Interested parties may submit comments on this proposed rule, as well as a companion draft Regulatory Analysis, via NRC's rulemaking web site at <http://ruleforum.llnl.gov>. Further information on the comment process, the availability of the proposed rule, and related documents, is available in the *Federal Register* notice, containing the proposed rule, referenced above (68 FR 68549).

(Contact: Roger W. Broseus, NMSS, Mail Stop T9-C24, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone 301-415-7608, e-mail: rwb@nrc.gov)

GENERIC COMMUNICATIONS ISSUED (September 10, 2003 - November 6, 2003)

The following are summaries of U.S. Nuclear Regulatory Commission (NRC) 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 NRC library of generic communications is: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html>. Please note that this address is case-sensitive and must be entered exactly as shown. If you have any questions or comments about generic

communications in general, please contact Ivelisse M. Cabrera, NMSS, at (301) 415-8152, or by e-mail: imc1@nrc.gov.

Bulletin (BL)

BL 2003-04, "Rebaselining of Data in the Nuclear Materials Management and Safeguards System," was issued on October 8, 2003. This bulletin was sent to all NRC licensees, Agreement State licensees, and Certificate Holders (hereafter referred to as licensees) who have in their possession, or are licensed to possess, one or more of the following: foreign obligated natural uranium, depleted uranium, or thorium; uranium enriched in the isotope uranium-235, uranium-233, plutonium, or plutonium-238; or who currently have unreconciled nuclear material balances with the Nuclear Materials Management and Safeguards System (NMMSS). NRC issued this bulletin to:

- (i) Notify licensees about performance concerns associated with their reporting data to, and the resulting material balances contained in, the NMMSS database;
- (ii) Request affected licensees to perform a one-time reporting of the quantities of special nuclear material (SNM) and/or foreign obligated source material in their possession, specified as:
 - (a) A quantity of SNM defined by 10 CFR 72.76, 72.78, 74.15, and 150.16, as 1 gram or more of contained uranium-235, uranium-233, plutonium, or 0.1 gram or more plutonium-238 that is greater than 10 percent of the total plutonium by weight; or
 - (b) A quantity of foreign obligated source material (i.e., natural uranium, depleted uranium, or thorium) defined by 10 CFR 40.64 and 150.17 as 1 kilogram or more.
- (iii) Request affected licensees to perform a one-time reporting of the quantities of other types of Government-owned materials, specified as any quantity of deuterium, tritium, curium, americium, neptunium, californium, berkelium, or enriched lithium in their possession;
- (iv) Request affected licensees to submit the results of this one-time reporting of the balances of the requested material types directly to NMMSS, as described in NUREG/BR - 0006 or 0007 and NMMSS Report D-24, as referenced in 10 CFR 40.64, 72.76, 72.78, 74.13, 74.15, 150.16, and 150.17, and to coordinate, with NMMSS staff, the resolution of any discrepancies that become evident, based on a comparison of the results of the one-time reporting and previously existing licensee nuclear material balances.

(Technical Contacts: Larry Harris, NSIR, e-mail: nmmss@nrc.gov; Brian Horn, NSIR, e-mail: nmmss@nrc.gov)

Information Notices (INs)

IN 2003-16, "Icing Conditions between Bottom of Dry Storage System and Storage Pad," was issued on October 6, 2003. This IN was sent to all 10 CFR Part 72 licensees and certificate holders to apprise them of an icing condition at an independent spent fuel storage installation that placed the dry spent fuel storage systems into an unanalyzed condition. (Technical contact: Stephen O'Connor, NMSS, 301-415-8561, e-mail: sco@nrc.gov)

IN 2003-20, "Derating Whiting Cranes Purchased before 1980," was issued on October 22, 2003. This IN was sent to all holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel, applicable decommissioning reactors, fuel facilities, and independent spent fuel storage installations. The purpose of this notice was to notify licensees of a recent report from Whiting Corporation concerning the derating of Whiting cranes sold before 1980.

(Technical contacts: Steven Jones, NRR, 301-415-2712, e-mail: srj@nrc.gov; Jack Foster, NRR, 301-415-3647, e-mail: jwf@nrc.gov; William C. Huffman, NMSS, 301-415-1141, e-mail: wch@nrc.gov)

Regulatory Issue Summaries (RIS')

RIS 2003-15, "Consolidation of the Region I and Region II Materials Program," was issued on September 05, 2003. This RIS was issued to all materials licensees to inform them of the consolidation of the Region I and Region II materials programs.

(Technical Contact: George C. Pangburn, RI, 610-337-5281, e-mail: gcp@nrc.gov)

RIS 2003-16, "NRC Threat Advisory and Protective Measures System," was issued on October 7, 2003. This RIS was sent to:

- (1) All NRC power reactor licensees;
- (2) All NRC research and test reactors;
- (3) All NRC decommissioning power reactors and independent spent fuel storage installations using wet storage;
- (4) All NRC independent spent fuel storage installations using dry storage;
- (5) All NRC Category I fuel facilities;

- (6) All NRC Category III fuel facilities;
- (7) The NRC-regulated uranium conversion facility;
- (8) All NRC-regulated gaseous diffusion plants; and
- (9) All NRC power reactor licensees, research and test reactor licensees, independent spent fuel storage installation licensees, and special nuclear material licensees, who possess spent nuclear fuel; and all general licensees, under 10 CFR 70.20a, who transport spent nuclear fuel greater than 100 grams.

NRC previously issued guidance regarding the Homeland Security Advisory System (HSAS) to certain groups of NRC licensees in RIS' 2002-12A, -12B, -12C, -12D, -12E, -12F, -12G, -12H, -12I, -12I Revision 1, and -12L. NRC is issuing this new RIS to identify a change in the implementation of the HSAS for the addressees above who received RIS' 2002-12A, -12B, -12C, -12D, -12E, -12F, -12G, -12H, -12I, and -12I Revision 1. The change is required by Homeland Security Presidential Directive -5, "Management of Domestic Incidents," dated February 28, 2003.

(Technical contact: Robert J. Stransky, Jr., NSIR, 301-415-6411, e-mail: rjs3@nrc.gov)

RIS 2003-17, "Complying with 10 CFR 35.59, 'Recentness of Training,' for Board-Certified Individuals Whose Training and Experience Were Completed More Than 7 Years Ago," was issued on October 3, 2003. This RIS was sent to all medical-use licensees and NRC master materials license medical-use permittees to provide guidance for licensees and permittees seeking to have individuals identified as authorized users (AUs), authorized medical physicists (AMPs), and authorized nuclear pharmacists (ANPs), under the following conditions: (1) The individual is certified by a specialty board recognized by NRC, but the board certification was received beyond the 7-year time frame allowed in 10 CFR 35.59; and (2) The individual is not currently identified on a medical-use license nor permit as an AU, AMP, or ANP, as appropriate in 10 CFR 35.13(b)(4).

This RIS: (1) clarifies that for limited-specific, Type B broad-scope, and Type C broad-scope medical-use licensees, only NRC, with input from the Advisory Committee on the Medical uses of Isotopes, as necessary, may determine what constitutes adequate "related continuing training and experience," for purposes of complying with 10

CFR 35.59, "Recentness of Training"; (2) describes the criteria NRC uses to evaluate "related continuing training and experience," under 10 CFR 35.59; (3) describes the information NRC reviews to make the determination; and (4) describes NRC's expectations for Type A broad-scope medical-use licensees.

(Technical contact: Donna-Beth Howe, Ph.D., NMSS, 301-415-7848, e-mail:dbh@nrc.gov)

(General Contact: Ivelisse M. Cabrera, NMSS, 301-415-8152, e-mail: imc1@nrc.gov)

SIGNIFICANT ENFORCEMENT ACTIONS

The U. S. Nuclear Regulatory Commission's (NRC's) enforcement program can be accessed via NRC's homepage at <http://www.nrc.gov/> under "What We Do." Documents related to cases can be accessed at <http://www.nrc.gov/>, "Electronic Reading Room," "Documents in ADAMS." ADAMS is the Agency-wide Document Access and Management System. Help in using ADAMS is available from the NRC Public Document Room, telephone: 301-415-4737 or 1-800-397-4209.

Gauges

IBS of America (EA-03-079)

On September 15, 2003, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$7500 was issued for a Severity Level III problem involving: (1) the failure to verify, before transfer, that an individual was authorized to receive licensed material; and (2) the failure to control and maintain constant surveillance of licensed material [approximately 370 megabecquerels (MBq) (10 millicuries (mCi)) and 925 MBq (25 mCi) of americium-241 contained in two sealed sources] from unauthorized removal or access. Although the civil penalty would have been fully mitigated, based on the normal civil penalty assessment process, a base civil penalty was assessed in accordance with Section VII.A.1.g of the Enforcement Policy, to reflect the significance of maintaining control of licensed material.

G.E. Inspection Services, Inc. (Formerly Liberty Technologies, Inc.) (EA-03-158)

On October 24, 2003, a Notice of Violation was issued for a Severity Level III violation involving the failure to secure from unauthorized removal, or limit access to, licensed material [approximately 20 gigabecquerels (550 millicuries) of gadolinium-153

contained in a radioactive device] located in an unrestricted area, and failure to control and maintain constant surveillance of this licensed material.

Menominee County Road Commission (EA-03-176)

On October 31, 2003, a Notice of Violation was issued for a Severity Level III violation involving the failure to secure from unauthorized removal, or limit access to, licensed material [nominally 296 megabecquerels (8.0 millicuries (mCi)) of cesium-137 and 1.5 gigabecquerels (40 mCi) of americium-241:beryllium in a moisture density gauge] in an unrestricted area at a temporary job site, and failure to control and maintain constant surveillance of this licensed material. Specifically, an operator left an unlocked moisture density gauge unsecured when he went to his vehicle and did not maintain constant surveillance of this device.

ABB, Inc. (EA-03-196)

On November 26, 2003, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$3000 was issued for a Severity Level III problem involving the failure to secure from unauthorized removal, or limit access to, licensed material [approximately 2.9 gigabecquerels (78 millicuries) of strontium-90 in a sealed source capsule] in an unrestricted area, and failure to control and maintain constant surveillance of this licensed material, resulting in the loss of the source into the public domain (most likely the county landfill). Although the civil penalty would have been fully mitigated, based on the normal civil penalty assessment process, a base civil penalty was assessed in accordance with Section VII.A.1.g of the Enforcement Policy, to reflect the significance of maintaining control of licensed material.

Medical

Caribe Medical Plaza (EA-03-134)

On October 9, 2003, a Notice of Violation was issued for a willful Severity Level III problem involving the failure [through its Radiation Safety Officer (RSO)] to ensure that radiation safety activities were being performed in accordance with the radiation safety program; the failure to provide radiation safety training; the failure to issue film or Thermoluminescent Dosimeter finger monitors to appropriate individuals; and the failure of a Caribe representative to provide information to the Commission that was complete and accurate in all material respects. Specifically, the licensee initiated

brachytherapy procedures without assuring, through the RSO, that individuals who would be involved in this activity received appropriate training or proper dosimetry.

Department of Veteran Affairs, AR (EA-03-162)

On October 31, 2003, a Notice of Violation was issued for a Severity Level III violation involving the failure to secure from unauthorized removal, or limit access to, licensed materials located in the nuclear medicine department's hot laboratory, which is a controlled area, nor did the licensee control and maintain constant surveillance of this licensed material. Specifically, the hot laboratory was left unattended, with a door open, and contained 74 gigabecquerels (GBq) (2 curies) of molybdenum-99 in a molybdenum-99/technetium-99m generator; 740 megabecquerels (20 millicuries (mCi)) of iodine-125 in 52 brachytherapy seeds; and 2.2 GBq (60 mCi) of cesium-137 in two sources.

Well Logging

Patterson Wireline (EA-03-084)

On September 9, 2003, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$3000 was issued for a Severity Level III problem involving the willful failures to: (1) wear personnel monitoring devices while handling licensed material; and (2) placard the transport vehicle used to transport licensed material.

Schlumberger Technology Corporation (EA-03-010)

On October 14, 2003, a Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$90,000 was issued for three Severity Level III problems involving: (1) the failure to keep 13 public radiation doses within the U.S. Nuclear Regulatory Commission (NRC) limits (\$78,000); (2) the willful failure to perform radiation surveys, and failure to maintain control of a radioactive well-logging source (\$6000); and (3) the failure to follow emergency procedures and secure the source after it was found (\$6000). Although the civil penalty would have been fully mitigated for the first issue, given the importance that NRC attaches to protecting members of the public from radiation exposures, NRC exercised discretion in accordance with Section VII.A.1 of the Enforcement Policy and assessed a separate \$6000 base civil penalty for each of the 13 radiation overexposures.

Individual Actions

Daniel Clark Woods (IA-03-038)

On October 24, 2003, a Notice of Violation was issued for a Severity Level III violation, based on the individual's deliberate activities while employed at G.E. Inspection Services, Inc. (GE-IS)(Formerly Liberty Technologies, Inc.). As senior radiographer for the licensee, the individual deliberately failed to secure from unauthorized removal, or limit access to, licensed material [approximately 20 gigabecquerels (550 millicuries) of gadolinium-153 contained in a radioactive device] located in an unrestricted area, and failed to control and maintain constant surveillance of this licensed material.

Shane Moran (IA-03-006)

On October 14, 2003, a Notice of Violation was issued for a Severity Level III violation, based on the individual's deliberate activities while employed at Schlumberger Technology Corporation. As a senior operator on a well logging crew, the individual knowingly failed to conduct a wellsite departure survey to ensure that the source was in its shielded container before the crew left the job site.

Shannon Kokkeler (IA-03-005)

On October 14, 2003, a Notice of Violation was issued for a Severity Level III violation, based on the individual's deliberate activities while employed at Schlumberger Technology Corporation. As a field engineer in training on a well logging crew, the individual knowingly failed to conduct a post-job survey, to ensure that the source was in its shielded container before loading the source shield onto the vehicle.

Patrick L. Patterson (IA-03-023)

On September 9, 2003, a Notice of Violation was issued for a Severity Level III violation, based on the individual's deliberate activities while employed at Patterson Wireline. As a logging supervisor doing work in the State of Alaska, he deliberately failed to wear a personnel dosimeter at all times during the handling of licensed material and deliberately failed to placard a transport vehicle used to transport licensed material.

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

SIGNIFICANT EVENTS

Event 1: Dose to Fetus at Community Hospital of Anderson, Anderson, Indiana

Date and Place: August 8, 2003; Community Hospital; Anderson, Indiana

Nature and Probable Causes: On August 8, 2003, Community Hospital of Anderson reported a misadministration wherein a 35-year old female patient/physician received an unintentional sodium iodine-131 (I-131) therapeutic dose of 1.1 gigabecquerels (29.8 millicuries). At the time of the therapy, the patient was unaware that she was pregnant and, as a result, an unintentional dose to her embryo/fetus was delivered. On August 25, 2003, the patient's gynecologist informed the hospital and the patient that she was approximately 15 weeks pregnant at the time of the therapy. Calculated total body dose to the fetus is 11.69 centigray cGy (rad) and the calculated dose to the fetal thyroid is 27,840 cGy (rad). NRC and the licensee's consulting physicist are in the process of assessing the doses to the fetus.

The event appeared to be an isolated occurrence. The root cause of the event was attributed to human error. Although the authorized physician user and the chief technologist asked the patient on several occasions, before the administration of the I-131 dosage, if she were pregnant or believed that she could possibly be pregnant, the patient denied the possibility of pregnancy. Because of other pre-existing medical conditions and consultations by other physicians informing the patient that she was unable to conceive, the patient believed that she could not become pregnant and declined taking a pregnancy test before the I-131 therapy. Further, the hospital staff, knowing that the patient was also a physician on staff at the hospital, did not pursue a pregnancy test because they believed that the patient would be aware of her pregnancy status.

Actions Taken to Prevent Recurrence

Licensee: The licensee reviewed its applicable procedures and determined that they were reasonable and appropriate.

Event 2: Misadministration Involving Patient at Rush Copley Medical Center, Aurora, Illinois

Date and Place: July 28, 2003; Rush Copley Medical Center; Aurora, Illinois.

Nature and Probable Causes: The licensee reported that a patient received 0.15 gigabecquerels (GBq)

(4 millicuries (mCi) of iodine-131 (I-131) instead of the intended 0.15 GBq (4 mCi) of thallium-201 (Tl-201) for a heart test. Both the exterior lead container and the syringe were labeled as containing Tl-201. It was not determined that the patient had been injected with the wrong radiopharmaceutical until after the gamma cameras used for patient imaging were checked a second time on the morning of July 29, 2003. Service engineers were called to the site to inspect the cameras after two failed attempts to image the patient. The cause became evident when the gamma camera flood source, made from what was thought to be the remaining Tl-201 diagnostic dose, showed peaks consistent with I-131. The assayed amount from records showed the dose to be within the expected range for a typical 0.15 GBq (4 mCi) Tl-201 diagnostic dose and was considered normal. The patient was contacted by the referring physician, onsite oncologists, the hospital administrator, and a lawyer. The licensee arranged to perform routine blood analysis throughout the year to monitor any changes in thyroid activity. The licensee contacted Medi-Physics, Incorporated (dba Amersham Health) in Wood Dale, Illinois, where the dose had been prepared. The pharmacy indicated that when prescriptions and labels were taken from the computer system, the 0.15-GBq (4-mCi) Tl-201 was mistakenly put in with four other prescriptions for 0.15-GBq (4-mCi) unit doses of I-131. The pharmacist did not note the difference in nuclides when the pre-generated Tl-201 label was applied to the syringe and lead container. The Illinois Department of Nuclear Safety sent an investigator to the licensee's facility on July 30, 2003 to observe the labeling on the container and syringe, receipt records, and gamma camera quality assurance tests, and, to verify by gamma spectrum analysis, the presence of I-131, as well as to conduct preliminary interviews. The investigation then moved to the pharmacy. Based on those visits, the information obtained largely confirmed the preliminary notification. The dose to the patient's thyroid was calculated to be approximately 5195 centigray (rad). The patient's whole body dose is approximately 1587 centisievert (rem). Blood tests suggest that the patient was hypothyroid as a pre-existing condition.

Actions Taken to Prevent Recurrence

Licensee: Corrective actions taken by the pharmacy included ceasing the dispensing of I-131 in syringes, retraining pharmacists, a dual verification system for all prescriptions received, a triple check system for dispensing of compounds, and the testing of a bar code system for all prescriptions.

(Contact: Angela R. Williamson, NMSS, 301-415-5030; e-mail arw@nrc.gov)

SELECTED FEDERAL REGISTER NOTICES (October 1, 2003 - November 30, 2003)

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

“Financial Assurance for Materials Licensees,” 68 FR 57327, October 3, 2003. (Contact: James Morris, NMSS, 301-415-0191, e-mail: jem2@nrc.gov)

“List of Approved Spent Fuel Storage Casks: Standardized NUHOMS-24P, -52B, and -61BT (Revision 6) (Direct final rule)” 68 FR 57785, October 7, 2003. (Contact: Margaret Stambaugh, NMSS, 301-415-5449, e-mail: mxs8@nrc.gov)

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(Contact: Dan Schultheisz, Radiation Protection Division, Office of Radiation and Indoor Air, Mailcode: 6608J, United States Environmental Protection Agency, Washington, DC, 20460-0001; telephone (202) 343-9300, e-mail: schultheisz.daniel@epa.gov)

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(Contact: Leslie W. Barnett, OCFO, 301-415-7540)

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