

# NMSS Licensee Newsletter



**U.S. Nuclear  
Regulatory  
Commission**

**Office of Nuclear  
Material Safety  
and Safeguards**

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## NMSS Licensee Newsletter (March - April 2002)

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### **NRC STAFF ISSUES DRAFT VOLUME 1 OF CONSOLIDATED NMSS DECOMMISSIONING GUIDANCE**

On January 31, 2002 (67 *Federal Register* 4764), the U.S. Nuclear Regulatory Commission's (NRC's) Office of Nuclear Material Safety and Safeguards (NMSS) announced the availability of a draft document entitled, "Consolidated NMSS Decommissioning Guidance: Decommissioning Process" (NUREG-1757, Vol. 1), for a 90-day public comment. This document provides guidance for the planning and implementation of the termination of licenses issued through NMSS licensing programs.

The guidance is intended for NRC staff, licensees, and the public, and is being developed in response to the NMSS performance goals, in NRC's Strategic Plan, of: (1) making NRC activities and decisions more effective, efficient, and realistic; and (2) reducing unnecessary regulatory burden on stakeholders. NRC is seeking public comment, to receive feedback from the widest range of interested parties and to ensure that all information relevant to developing the document is available to the NRC staff. This draft document is being issued for comment only and is not intended for interim use. NRC will review public comments received on the draft document. Suggested changes will be incorporated, where appropriate, in response to those comments, and a final document is planned to be issued for use in September 2002.

NUREG-1757 is available at the Commission's Public Document Room, U.S. NRC's Headquarters Building, 11555 Rockville Pike (First Floor), Rockville, Maryland, and electronically from the ADAMS Electronic Reading Room on the NRC web site at: <http://www.nrc.gov/reading-rm/adams.html>. NUREG-1757 is also available on the NRC web site at: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff>.

A free single copy of NUREG-1757 will be available to interested parties until the supply is depleted. Such copies may be requested by writing to the U.S. Nuclear Regulatory Commission, Distribution Services, Washington, DC 20555-0001 or submitting e-mail to [distribution@nrc.gov](mailto:distribution@nrc.gov).

(Contact: Jack Parrott, 301-415-6700; e-mail: [jdp1@nrc.gov](mailto:jdp1@nrc.gov))

## **STATUS OF REVISION TO 10 CFR PART 35, “MEDICAL USE OF BYPRODUCT MATERIAL”**

The revision to 10 CFR Part 35, “Medical Use of Byproduct Material,” is progressing. On February 11, 2002, the U.S. Nuclear Regulatory Commission (NRC) issued its report to Congress explaining why the regulatory burden could not be further reduced without adversely affecting public health and safety. The revised Part 35, when implemented, should generally achieve a significant reduction in burden. For the low-risk activities of diagnostic nuclear medicine, NRC believes that the regulatory burden is commensurate with the low risk of adverse impact on health and safety from these procedures.

NRC currently intends to publish the revised Part 35 as a final rule in the early spring of 2002. The rule will allow for a 6-month implementation period before the requirements go into effect. During that implementation period, NRC plans to publish NUREG-1556, Volume 9, for public comment, and conduct a public workshop on the draft document. NRC also plans a public workshop to obtain input from stakeholders to develop guidance for diagnostic-only, nuclear medicine licensing. Finally, NRC will post on its web site the draft inspection guidance and hold a public workshop to obtain stakeholder input. In addition, the NRC staff will be trained on the revised licensing and inspection guidance to familiarize it with requirements of Part 35. These efforts will effect a smooth transition and implementation of NRC’s risk-informed and performance-based approach to the regulation of medical uses of byproduct material.

(Contact: Roger Broseus, NMSS, 301-415-7608; e-mail: [rwb@nrc.gov](mailto:rwb@nrc.gov))

## **THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES SPRING 2002 COMMISSION BRIEFING AND PUBLIC MEETING**

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held its Spring meeting on February 19-20, 2002. During the February 19 session, ACMUI briefed the Commission on three areas: (1) ACMUI support of the implementation

of the revised 10 CFR Part 35, “Medical Use of Byproduct Material”; (2) efforts to coordinate the implementation of the revised Part 35 between State and Federal governments; and (3) staffing issues for certain medical professionals, as a result of the new training and experience requirements in revised Part 35.

During the first briefing topic, ACMUI gave strong support to the revised Part 35. It provided a point-by-point outline of the steps the U.S. Nuclear Regulatory Commission (NRC) and ACMUI took to ensure that the revision process was fair, balanced, and involved significant stakeholder input.

During the second briefing topic, ACMUI informed the Commission of specific actions that the Agency should consider to help bring State and Federal regulations into alignment, in light of the revised Part 35. ACMUI also gave recommendations to ensure uniformity in the implementation of the new rule.

While briefing the Commission on staffing issues, ACMUI expressed concern regarding licensees’ ability to retain and recruit medical physicists, radiation safety officers, and nuclear pharmacists. ACMUI ended this discussion with recommended specific short- and long-term initiatives that the Agency can undertake to mitigate what it perceived as unintended negative staffing consequences brought about by revised Part 35’s training and experience requirements.

During the February 20 session, ACMUI held a public meeting on a wide range of topics. Most were discussions of routine activities of interest in the regulated medical community (e.g., NRC position on dose assessment of “mixed” doses; status of the implementation of NUREG-1556, Vol. 9), although a few topics arose out of the September 11, 2001, events (e.g., security restrictions on the NRC website; and what NRC is doing to heighten security of radioactive material in the public domain). During the meeting, NRC staff informed the ACMUI that an effort to address ACMUI concerns on training and experience requirements had been initiated.

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

## SIGNIFICANT EVENTS

The U.S. Nuclear Regulatory Commission (NRC) is providing summaries of these events to inform licensees of conditions they may encounter and of actions that may be taken to deal with them.

### *Event 1: Radioactive Contamination of a Steel Mill*

*Date and Place:* July 13, 2001; Ameristeel Incorporated; Baldwin, Florida.

*Nature and Probable Consequences:* Ameristeel, Inc. (a non-licensee) reported that a radioactive device/source was melted at its facility in Florida. The Florida Bureau of Radiation Control (BRC) responded to the facility, along with the Mobile Emergency Response Laboratory. The team determined that the isotope was cesium-137 (Cs-137), but the source of the contamination was unknown. Investigators suspected that the contamination was from a sealed source belonging to a fixed gauge. Preliminary estimates placed the source activity at no more than 3.7 gigabecquerels (100 millicuries). The contamination was first identified when a radiation detector in the mill's baghouse alarmed. The source apparently eluded detection by multiple detectors designed to scan scrap metal loads before they are loaded into the furnace. The contamination was confined to two bag houses that collect dust from the furnace and the ductwork going from the furnace to the bag houses. There was no release of radioactive material outside of the facility and the steel product was not contaminated. The slag materials were surveyed and no Cs-137 was detected. Twenty-two individuals were working in the area at the time of the event and initial surveys indicated that nobody received any external exposure or contamination. These individuals were sent for whole-body surveys as a precautionary measure. The tests confirmed that there was no internal contamination of facility personnel. The facility was shut down for cleanup. Cleanup of the facility was determined to be a major operation, because of high heat conditions that posed a significant hazard even for workers in protective clothing and respirators. The BRC conducted a confirmatory survey, granted preliminary clearance, and determined that the facility met the radiological

criteria for unrestricted use. The facility stated that it was shut down for more than 24 days for decontamination. The total cost of cleanup is estimated at 10 to 12 million dollars.

### *Event 2: Distribution and Administration of Multiple Mislabeled Therapeutic Dosages Over a Period of Several Years*

*Date and Place:* December 14, 2001; Spectrum Pharmacy Inc.; Mishawaka, Indiana.

*Nature and Probable Consequences:* The U.S. Nuclear Regulatory Commission (NRC) licensee identified multiple instances, over the past 3 years, where it dispensed dosages of samarium-153 (Sm-153) that were 21 to 28 percent less than the quantity indicated on the dosage label. Sm-153 is a therapeutic radiopharmaceutical used to relieve bone pain associated with metastatic cancer. The licensee notified the nine affected client medical facilities. NRC Region III received written reports from each of the nine medical facilities, which reported a total of 61 individual medical events involving an underdose of Sm-153. The licensee's calibration procedures for Sm-153 did not properly account for the different shielding properties of plastic syringes and glass vials. Sm-153 is predominantly a beta-emitter; therefore, the material's container provides a shielding effect. The licensee received the bulk material in glass vials and drew the dosages into plastic barreled syringes for dispensing purposes. When the licensee began dispensing Sm-153 in April 1998, the staff determined a dose calibrator response factor (shielding factor) for the glass vial, but did not determine a similar factor for the plastic syringes (a lower shielding factor). As a result, the activity of the Sm-153 in syringes was measured as if it were still shielded by glass. Because the dose calibrator indicated activities 20 to 30 percent higher than expected, the pharmacy staff removed enough Sm-153 from the syringes to achieve the desired dose calibrator response, resulting in dispensed doses that were actually 20 to 30 percent too low.

### *Actions Taken to Prevent Recurrence*

*NRC:* NRC Region III conducted a special inspection of the licensee and selected customer facilities during January 2002. Region III is still evaluating this event.

(Contact: Roberto Torres, NMSS, 301-415-8112;  
e-mail: rjt@nrc.gov)

## **SIGNIFICANT ENFORCEMENT ACTIONS**

The U.S. Nuclear Regulatory Commission's (NRC's) enforcement program can be accessed via NRC's homepage [<http://www.nrc.gov/>] under "What We Do." Soon, cases will be listed under "document collections related to enforcement," which can be accessed from that page. Additionally, 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.

### ***Medical***

#### **V.A. Medical Center (EA 01-312)**

On December 28, 2001, a Notice of Violation was issued for a Severity Level III violation involving the failure to secure from unauthorized access, or maintain constant surveillance over, licensed material in an unrestricted area. A package containing iodine-131 was left unattended at the nuclear medicine reception desk, when the receptionist became involved with scheduling tasks.

#### **Advanced Medical Imaging and Nuclear Services (EA 01-313)**

On December 14, 2001, an immediately effective Order Suspending License was issued. The order was based on the licensee's possession and use of radioactive materials (including diagnostic administration to patients) without a required authorized user or Radiation Safety Officer.

### ***Radiopharmacy***

#### **Geodax Technology, Inc. (EA 01-257)**

On January 4, 2002, a Notice of Violation was issued for a Severity Level III violation involving the licensee allowing an individual to work as an authorized nuclear pharmacist (ANP) without

notifying the U.S. Nuclear Regulatory Commission (NRC) within 30 days after the date that the licensee allowed the individual to work as an ANP. Although a civil penalty would normally have been proposed, in this case NRC exercised discretion in accordance with Section VII.B.6 of the Enforcement Policy and refrained from issuing a penalty. Discretion was warranted because NRC concluded that: the potential safety consequences were low; the pharmacist was forthcoming during NRC's inspection; the Radiation Safety Officer promptly initiated supervision of the pharmacist, on being informed of the inspection finding; and all individuals involved accepted responsibility for the violation, and cooperated during the investigation.

#### **Central Pharmacy Services, Inc. (EA 01-283)**

On December 18, 2001, a Notice of Violation was issued for a Severity Level III problem involving the willful failure of an employee to: (1) wear a thermoluminescent finger badge when preparing, assaying, or dispensing millicurie quantities of radioactive material; and (2) use vial shields for preparing and dispensing radiopharmaceuticals.

#### **Spectrum Pharmacy, Inc. (EA-02-018)**

On February 23, 2002, a Notice of Violation was issued for a Severity Level III violation involving the failure to adequately measure the radioactivity of samarium-153 (Sm-153), before commercial distribution, which resulted in 61 misadministrations. The error occurred because the licensee failed to follow the pharmaceutical manufacturer's recommended procedures for determination of the dose calibrator calibration factor (potentiometer setting) for this radiopharmaceutical. Although the manufacturer's procedure was based on the use of a 10-cubic-centimeter (.338-oz) glass vial for the calibration, the licensee measured unit dosages of Sm-153 in plastic syringes. The error resulted in dosages that were 21 to 28 percent less than the amount listed by the dose calibrator.

### ***Radiography***

#### **Longview Inspection, Inc. (EA-01-267 and EA-01-281)**

On January 18, 2002, a Notice of Violation was

issued for a: (1) Severity Level III problem involving the failure to secure from unauthorized removal, or limit access to, licensed material [4.9 terabecquerels (133 curies) of iridium-192 in a radiography camera] in an unrestricted area; failure to control and maintain constant surveillance of licensed material; and failure to lock the camera or its container when at a temporary jobsite; and (2) a Severity Level III violation involving the failure to have an additional qualified individual observe radiography operations.

### ***Other***

#### **University of Wisconsin-Madison (EA 01-282)**

On December 21, 2001, a Notice of Violation and Imposition of Civil Penalty in the amount of \$3000 was issued for a Severity Level III violation involving the failure to secure from unauthorized removal, or limit access to, byproduct material (americium-241) contained in six sealed sources; and the failure to control and maintain constant surveillance of this licensed material. 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 importance of maintaining control of licensed material.

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

#### **GENERIC COMMUNICATIONS ISSUED (December 1, 2001 - January 31, 2002)**

Note that these are only 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 -- [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 2001-19, "Improper Maintenance and Reassembly of Automatic Oil Bubblers," was issued on December 17, 2001. This notice was issued 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, to alert them to recent problems resulting from improper maintenance and reassembly of automatic oil bubblers.

Contacts: Omid Tabatabai, NRR, 301-415-3738, e-mail: [oty@nrc.gov](mailto:oty@nrc.gov); Javier Brand, Region I, 301-474-3589, e-mail: [jmb3@nrc.gov](mailto:jmb3@nrc.gov).

IN 2002-03, "Highly Radioactive Particle Control Problems During Spent Fuel Pool Cleanout," was issued January 10, 2002. This notice was sent to all holders of operating licenses for nuclear power reactors, holders of licenses for permanently shutdown facilities with fuel onsite, and holders of licenses for non-power reactors, to alert them to recent issues involving evaluation and control of radioactive particles generated during removal of material from a spent fuel pool before shipping the material offsite for disposal. The issue emphasized in this notice is that highly radioactive (hot) particles represent a radiological hazard, not just in terms of shallow dose to the skin or an extremity, but also as a deep or whole-body dose.

Contacts: James E. Wigginton, NRR, 301-415-1059, e-mail: [jew2@nrc.gov](mailto:jew2@nrc.gov); James D. Noggle, Region I, 610-337-5063, e-mail: [jdn@nrc.gov](mailto:jdn@nrc.gov).

### ***Regulatory Issue Summaries (RIS')***

RIS 2001-24, "Status of Receipt of NRC Mail Following the Closing of the Brentwood Postal Facility," was issued on December 6, 2001. This summary was issued to all U.S. Nuclear Regulatory Commission (NRC) licensees, to provide them with information that will assist them in determining which method they should use to submit documents to NRC. The Agency is experiencing delays in the delivery of incoming mail because of the

inspection and investigation processes associated with the potential presence of anthrax in mail-handling facilities.

Contact: Michael L. Springer, ADM, 301-415-6222, e-mail: mls@nrc.gov.

RIS 2002-01, "Changes to NRC Participation in the International Nuclear Event Scale" (INES) was issued on January 14, 2002. This summary was issued to all U.S. Nuclear Regulatory Commission (NRC) licensees and certificate holders to inform them of NRC's increased level of participation in the INES. Licensees were informed that the requirements for reporting events and incidents to NRC will remain unchanged.

Contact: Robert J. Stransky, Jr., IRO, 301-415-6411, e-mail: rjs3@nrc.gov.

RIS 2002-02, "Lessons Learned Related to Recently Submitted Decommissioning Plans and License Termination Plans," was issued on January 16, 2002. This summary was issued to all U.S. Nuclear Regulatory Commission (NRC) licensees to inform them of lessons learned from reviews of recently submitted decommissioning plans (DPs) and license termination plans (LTPs). The RIS provides licensees with information that may help them develop more complete DPs and LTPs, which should result in more effective and efficient use of both licensees' and NRC's resources.

Contact: Stewart W. Brown, NMSS, 301-415-6605, e-mail: swb1@nrc.gov.

(General Contact: Kevin M. Ramsey, NMSS, 301-415-7887, e-mail: kmr@nrc.gov)

## **SELECTED FEDERAL REGISTER NOTICES**

**(November 30, 2001 - February 28, 2002)**

**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**

"List of Approved Spent Fuel Storage Casks: NAC-UMS Revision; Confirmation of Effective Date," 66 FR 67073, December 28, 2001.

Contact: Jayne M. McCausland, NMSS; 301-415-6219; e-mail: jmm2@nrc.gov.

"List of Approved Spent Fuel Storage Casks: FuelSolutions\TM\Cask System Revision; Confirmation of Effective Date," 67 FR 3431, January 24, 2002.

Contact: Merri Horn, NMSS; 301-415-8126; e-mail: mlh1@nrc.gov.

"Revised Filing Requirements," 67 FR 3584, January 25, 2002.

Contact: Carrie Brown, NMSS, 301-415-8092; e-mail: cxb@nrc.gov.

"List of Approved Spent Fuel Storage Casks: Standardized NUHOMS-24P, -52B, and -61BT Revision; Confirmation of Effective Date," 67 FR 5934, February 8, 2002.

Contact: Merri Horn, 301-415-8126; e-mail: mlh1@nrc.gov.

## **PROPOSED RULES**

"Specification of a Probability for Unlikely Features, Events, and Processes," 67 FR 3628, January 25, 2002.

Contacts: Timothy McCartin, 301-415-7285; e-mail: tjm3@nrc.gov; Clark Prichard, 301-415-6203; email: cwp@nrc.gov.

"List of Approved Spent Fuel Storage Casks: Standardized Advanced NUHOMS-24PT1 Addition," 67 FR 6203, February 11, 2002.

Contact: Jayne McCausland, 301-415-6219; e-mail: jmm2@nrc.gov.

## OTHER NOTICES

“Portsmouth Gaseous Diffusion Plant, United States Enrichment Corporation; Notice of Consideration of Request for Temporary Exemption,” 66 FR 63077, December 4, 2001.

Contact: Dan E. Martin, NMSS, 301-415-7254;  
e-mail: dem1@nrc.gov.

“Enforcement Program and Alternative Dispute Resolution; Request for Comments,” 66 FR 64890, December 14, 2001.

Contacts: Terrence Reis, OE, 301-415-3281;  
e-mail: txr@nrc.gov;  
Francis X. Cameron, OGC, 301-415-1642;  
e-mail: fxc@nrc.gov.

“Denial of Petition for Rulemaking by Jeffery C. Angel,” 67 FR 274, January 3, 2002.

Contact: Gary Comfort, NMSS, 301-415-8106;  
e-mail: gcc1@nrc.gov.

“Updated and Consolidated Decommissioning Policy and Guidance of the Nuclear Regulatory Commission’s Office of Nuclear Material Safety and Safeguards,” 67 FR 4764, January 31, 2002.

Contact: Jack D. Parrott, 301-415-6700;  
e-mail: jdp1@nrc.gov.

“Decommissioning Criteria for the West Valley Demonstration Project (M-32) at the West Valley Site; Final Policy Statement,” 67 FR 5003, February 1, 2002.

Contact: Chad Glenn, 301-415-6722;  
e-mail: cjl@nrc.gov.

“Solicitation of Comments on a Draft Standard Review Plan (NUREG-1569) for Staff Reviews for In-Situ Leach Uranium Extraction License Applications,” 67 FR 5347, February 5, 2002.

Contact: John Lusher, 301-415-7694;  
e-mail: jhl@nrc.gov.

“Solicitation of Comments on a Draft Standard Review Plan (NUREG-1620) for Staff Reviews of Reclamation Plans for Mill Tailings Sites Under Title II of the Uranium Mill Tailings Radiation Control Act,” 67 FR 5348, February 5, 2002.

Contact: John Lusher, 301-415-7694;  
e-mail: jhl@nrc.gov.

“Fitness-for-Duty Programs, Availability of Draft Outline and Rule Wording,” 67 FR 7093, February 15, 2002.

Contact: Garmon West, 301-415-1044; e-mail: fitnessforduty@nrc.gov.

“Department of Energy, Office of Civilian and Radioactive Waste Management; Nuclear Waste Repository Program: Yucca Mountain Site Recommendation to the President and Availability of Supporting Documents,” 67 FR 9048, February 27, 2002.

Contact: Yucca Mountain Site Characterization Office, Office of Civilian Radioactive Waste Management, U.S. Department of Energy, M/S 025, P.O. Box 364629, North Las Vegas, NV 89036-8629, telephone, 1-800-225-6972.

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

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

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