Office of Federal & State Materials & Environmental Management Programs

United States Nuclear Regulatory Commission Protecting People and the Environment

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J.S.NR(



# From the Desk of the FSME Director

In the last Newsletter, my first column highlighted the premium that we in the Office of Federal and State Materials and Environmental Management (FSME) place on engaging our stakeholders. FSME encourages substantive participation in the regulatory process for nuclear materials and waste program activities. Since that Newsletter was published, there have been several recent examples of that participation. The following highlights some of them.

In July, FSME staff made presentations at the 12th Annual Inter-Tribal Environmental Council meeting in Tulsa, Oklahoma. FSME's presentation highlighted the U.S. Nuclear Regulatory Commission (NRC) outreach and tribal liaison activities, and NRC staff from the Office of Nuclear Material Safety and Safeguards presented on NRC's transportation packaging regulatory authority and responsibilities.

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In August, the Organization of Agreement States (OAS) and the Conference of Radiation Control Program Directors (CRCPD) made presentations to the Commission and answered questions on a number of topics including: the relationship between NRC, States, and the Department of Homeland Security; Fingerprinting Orders; the use of rulemakings vis-a-vis Orders; the General License Program; Rulemaking Petitions; Training; and the State Perspective on the Closing of the Barnwell facility in 2008. The OAS presenters included: Cindy Cardwell of Texas, Barbara Hamrick of California, and Paul Schmidt of Wisconsin. Debbie Gilley from Florida, and John Winston of Pennsylvania represented CRCPD. Afterward, I heard from a number of sources, including the Commissioners, how effective and informative the session had been. It was certainly a great way for the States to inform the Commission of their positions and perspectives.

In September, Chairman Klein and Commissioner Lyons, and a significant number of NRC managers and staff, myself included, participated in the annual OAS meeting in Oklahoma City. I would like to thank Oklahoma for hosting this important event. In this meeting, we discussed a number of activities including: a medical regulatory issues panel; rulemaking petitions; the NRC Strategic Plan; knowledge management; NARM Transition and Implementation: Increased Controls; Fingerprinting; Low-Level Waste Strategic Assessment; and the National Source Tracking System. You will see separate discussions on several of these topics elsewhere in this Newsletter.

Also in September, FSME staff and managers held meetings in Grants, New Mexico, where they met with the public to discuss reclamation alternatives for the Grants mill tailings reclamation project. In Gallup, New Mexico, staff conducted scoping meetings on the Generic Environmental Impact Statement for Uranium Recovery Licensing. The meeting in Gallup included a number of Navajo participants. NRC presentations were translated into the Navajo language. Previously, the staff participated in scoping meetings in Casper, Wyoming and Albuquerque, New Mexico.

These meetings demonstrate FSME's commitment to seek local stakeholder views in convenient settings for interested parties. I encourage everyone to take advantage of our commitment to regulatory openness, and make your views heard. While I cannot ensure that our final regulatory decisions will always align with your suggestions, I can commit to you our pledge to provide ample access to our decision-making processes, and the methodologies and technical foundations upon which our decisions are based.

Charles L. Miller

Charles L. Miller

# COMMISSION APPROVES PLAN TO IMPROVE MATERIALS SECURITY

The Commission has approved an "Action Plan" to improve the security of byproduct materials. The Action Plan was developed in response to an investigation conducted by the U. S. Government Accountability Office (GAO) in early 2007, which identified vulnerabilities in the U.S. Nuclear Regulatory Commission (NRC) materials licensing process.

In the investigation, GAO staff used the name of a bogus company to apply for and obtain a valid NRC license, authorizing the possession of portable gauges containing radioactive sources. The GAO staff then modified the license using computer software to make it appear that a much greater number of gauges was authorized than allowed by the original license. When the NRC was notified of the investigation by GAO in late May 2007, NRC suspended issuance of new materials licenses for about two weeks, and implemented interim procedures which required on-site inspections or in-office meetings for new materials license applicants. (Exceptions may be made for applicants who already possess an NRC or Agreement State license.) NRC also notified the Agreement States of GAO's findings.

NRC has made numerous security improvements since 2001, but the improvements have focused on higher risk sources. The GAO investigation involved small, lower risk sources in portable gauges, which are subject to security requirements less stringent than higher risk sources.

When members of the U. S. Senate were notified of the GAO investigation, a Senate hearing was held on July 12, 2007, entitled "Dirty Bomb Vulnerabilities: Fake Companies, Fake Licenses, Real Consequences." NRC and GAO testified at the hearing. The hearing highlighted concerns that a terrorist organization might be able to obtain a license and radioactive material under false pretenses. In conjunction with the hearing, GAO and the Senate staff made recommendations to improve the security of the NRC materials licensing process.

Following the Senate hearing, the Commission directed the NRC staff to develop an Action Plan to address needed changes to improve the security of the NRC materials licensing process, to provide appropriate strategies for aligning Agreement State licensing with recommended changes, and to arrange an independent review of vulnerabilities in NRC's materials licensing process. The staff submitted the Action Plan to the Commission on August 25, 2007, and the Commission met to discuss it in an open meeting on September 4, 2007.

The Action Plan includes the following elements:

- An external review, by an independent panel of experts, of vulnerabilities in NRC's materials licensing process, and reevaluation of "goodfaith" presumptions in the licensing process.
- Development of revised pre-licensing procedures to assure that license applicants are legitimate organizations.
- Formation of a Materials Program Working Group, to include both NRC and Agreement State staff members, to address short-term and long-term security issues in the materials licensing process; including prevention of unauthorized transfers of radioactive material, prevention of counterfeiting of licenses, improving security of generally licensed devices, and coordination with Agreement States.
- Inclusion of Category 3 sources (as defined by the International Atomic Energy Agency), and possibly smaller sources, in the NRC National Source Tracking System (NSTS), already under development.
- Expansion of the NRC Web-Based Licensing System, already under development, to allow on-line verification of NRC and Agreement State licenses, and to contain an interface with the NSTS.
- Consideration in the current general license rulemaking of whether certain sources should be specifically licensed rather than generally licensed.

The Action Plan envisions both short-term and long-term actions, with some actions being taken within a few months, and others extending out two or more years. The Action Plan (SECY-07-0147, August 25, 2007) may be viewed on the NRC web site at: <u>http://www.nrc.gov/reading-rm/</u> <u>doc-collections/commission/secys/2007</u>.

The Commission approved the Action Plan on September 18, 2007. In approving the plan, the Commission identified the most pressing issues as trustworthiness of applicants for new licenses and authenticity of transactions involving licensees. The Commission emphasized the need for implementation of the Action Plan in a timely manner. Licensees will be kept informed of activities related to the plan. (Contact: John Hickey, Office of Federal and State Materials and Environmental Management Programs, 301-415-1281; email: jwh1@nrc.gov)

# SEALED SOURCE RECOVERY PROGRAM

Earlier this year, the National Nuclear Security Administration's (NNSA) Global Threat Reduction Initiative (GTRI) recovered its 15,000th excess radioactive sealed source. The sources are recovered and securely stored at Los Alamos National Laboratory (LANL) in New Mexico and at other contractor-operated facilities.

The program recovers excess, unwanted, or abandoned radioactive sealed sources and other radioactive material. Permanent disposal for some of the sources began in 2005 and was expanded during 2006. The 15,000th source came from a company near Los Angeles, which used the source to manufacture quality-control gauges for the plastic and paper industry. LANL staff from GTRI's Offsite Source Recovery Project (OSRP) inspected, packaged and shipped 306 obsolete and defective sources; small tungsten-shielded, teardrop-shaped items, each containing about 150 millicuries of americium-241.

The NNSA program focuses on isotopes that exceed regulatory criteria for class C low-level waste, and other unwanted sources that pose a risk of theft for use by terrorists. Most of the sources recovered and stored at LANL contain americium-241 or plutonium. Additionally, GTRI's recovery program addresses other alpha-emitters like californium, curium, and radium. It also conducts recovery projects for large devices containing cesium-137, cobalt-60, or strontium-90 sources. NNSA has removed more than 170,000 curies of unwanted radioactive material from owners who had no other disposition path. The sealed sources were once used in applications ranging from nuclear-powered cardiac pacemakers to gauges used in paper manufacturing and petroleum exploration.

"The source recovery project has achieved the goal of providing an end-of-life disposition pathway for the sealed source life cycle in the United States, including sources for which no disposal pathway previously existed," said LANL's Senior Project Leader Julia Whitworth. "The team's efforts guarantee continued medical and other beneficial uses of sealed sources, and solve the disposition problem of unwanted sources for future generations." Also this year, the NNSA entered a cooperative agreement with the Conference of Radiation Control Program Directors (CRCPD). The agreement provides \$2,000,000 over five years to support the CRCPD's Source Collection and Threat Reduction (SCATR) Project. The goal of this project is to address disposal needs for many smaller sources, which are not typically addressed by NNSA's other efforts. The strategy is to fund projects in individual states to consolidate large numbers of relatively small sources for more costeffective commercial disposal as are currently underway in Florida and Oregon.

In 2006, NNSA also began recovering U.S.-origin sealed sources distributed overseas. The LANL team has so far repatriated radioactive sources from South Africa, Iraq, Ecuador, and Australia. Several other projects with foreign countries, coordinated with the State Department and the International Atomic Energy Agency, are under way. For more information and to register unwanted sources, see the LANL OSRP website at http://osrp.lanl.gov.

(Contact: Joel Grimm, U.S. Department of Energy, 202-586-9681; email: joel.grimm@nnsa.doe.gov)

# RECENT EVENTS IN URANIUM ENRICHMENT

Progress continues for additional uranium enrichment capacity in the United States. As discussed below, two licenses have been issued for gas centrifuge uranium enrichment facilities, a third applicant has informed the NRC that it intends to submit an application for a gas centrifuge uranium enrichment facility, and a fourth applicant has informed the NRC that it plans to submit an application for a uranium enrichment facility which will use laser technology. These licensing actions continue a changeover from the current uranium enrichment technology used in the United States (gaseous-diffusion process) to the more efficient gas centrifuge and laser processes.

On June 23, 2006, the Nuclear Regulatory Commission (NRC) issued a license to Louisiana Energy Services (LES) to construct and operate a gas centrifuge uranium enrichment plant in Lea County, New Mexico. The license is the first issued by the NRC for a full-scale gas centrifuge uranium enrichment plant. The LES National Enrichment Facility will be the first commercial use in the United States of gas centrifuge technology for enriching uranium. LES began construction in August 2006. Operations will commence in mid-2009, reaching full capacity in 2013.

On April 13, 2007, the NRC issued a license to USEC Inc. to construct and operate a gas centrifuge enrichment plant in Piketon, Ohio, at the existing Portsmouth Gaseous Diffusion Plant (GDP) site. The new facility is called the American Centrifuge Plant (ACP). Facility construction began in May 2007, and will continue for 5 years through 2012. The ACP will begin initial production in 2009, reaching peak production in 2012.

AREVA NC Inc. (AREVA) met with the NRC in a closed meeting on May 21, 2007, and shortly thereafter went public with its plans to construct and operate a gas centrifuge uranium enrichment facility in the United States. The schedule proposed by AREVA is to select a site by the end of 2007, submit an application by mid 2008, have a license issued by mid 2010, start construction in late 2010, and begin operating in 2013.

In a letter dated June 29, 2007, General Electric Nuclear (GE) submitted an application to amend its Materials License SNM-1097 to authorize operation of a laboratory scale test loop and other experimental equipment for laser enrichment process research and development within the existing GE fuel manufacturing facility in Wilmington, North Carolina. GE intends to submit an application for a full-scale commercial uranium enrichment facility in early 2008.

For more information related to gas centrifuge uranium enrichment facility licensing, visit our website at http://www.nrc.gov/materials/fuelcycle-fac/gas-centrifuge.html.

(Contact: Brian W. Smith, Office of Nuclear Material Safety and Safeguards, 301-492-3137; e mail: bws1@nrc.gov)

## ATTESTATIONS FOR AUTHORIZED INDIVIDUALS SEEKING RSO STATUS

10 CFR 35.50 "Training for Radiation Safety Officer" provides several training and experience (T&E) pathways for individuals seeking authorization as the Radiation Safety Officer (RSO) for a medical use license. Paragraph (c)(2) establishes a pathway for authorized individuals (Authorized Medical Physicists, Authorized Nuclear Pharmacists, or Authorized Users) seeking RSO status, provided

that the authorized individual is identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking to assume RSO responsibilities. Paragraph (d) of 10 CFR 35.50 presently requires a written attestation<sup>1</sup>, signed by a preceptor RSO, applicable to all pathways, including the (c)(2) pathway for authorized individuals. However, feedback to NRC from stakeholders (licensees, authorized individuals seeking RSO status) has indicated that obtaining the currently-required preceptor RSO attestations for already-authorized individuals has been problematic, for a variety of reasons, and has impeded the appointment of authorized individuals as RSOs.

As a result of this feedback, the NRC examined the basis for this requirement and determined that needing a preceptor RSO attestation for authorized individuals seeking RSO status was an unintended consequence that occurred during the 2005 revision to the 10 CFR Part 35 T&E requirements. Specifically, the proposed rule (published for comment in the Federal Register on December 9, 2003) did not require RSO preceptor attestations for authorized individuals seeking RSO status. However, a change unrelated to this issue was made to the regulatory framework of 10 CFR 35.50 that inadvertently resulted in applying the requirement for the preceptor statement to these authorized individuals. The NRC does not believe that this requirement should be applicable to these authorized individuals, since their radiation safetyrelated training and experience has already been reviewed and accepted by NRC during the process through which they were granted authorized status. Additionally, these individuals' radiation safety performance has been subject to review during NRC inspections of licensee activities.

Accordingly, NRC intends to pursue rulemaking to eliminate the provision requiring RSO preceptor attestation for an authorized individual seeking RSO status for a medical use license. The standard procedures for rulemaking, including providing opportunity for public comment, will be followed.

Until the rulemaking is concluded, a licensee experiencing difficulty in obtaining the preceptor attestation required in 10 CFR 35.50(d) for an authorized individual seeking RSO status can request an exemption from this requirement under 10 CFR 35.19, "Specific exemptions."

<sup>&</sup>lt;sup>1</sup>The attestation is a written statement that the applicant has completed training and experience requirements listed in paragraph (c)(2) and paragraph (e) (i.e., has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval) of the regulation and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO

(Contact: Ronald Zelac, Office of Federal and State Materials and Environmental Programs, 301-415-7635; e-mail: rez@nrc.gov)

# DOSE LIMIT FOR PATIENT RELEASE UNDER 10 CFR 35.75

The December 2006 issue of the (NMSS/FSME) Licensee Newsletter contains an article which states that NRC's position for patients released under 10 CFR 35.75 is that the 5 millisievert (mSv) (0.5 rem) total effective dose equivalent (TEDE) limit on doses to other individuals from exposure to the released individual is an annual limit, and that the total dose resulting from multiple administrations to and multiple releases of an individual within a given year must be taken into consideration. While the regulatory history of the 1997 addition to 10 CFR Part 35 that established the patient release criteria in 10 CFR 35.75 supports the intent of an annual limit interpretation on doses, the wording of the regulation, which has not been changed since 1997, did not explicitly incorporate that intent.

The wording of 10 CFR 35.75, which does not indicate that the dose limit is an annual limit, was based on the presumption, appropriate at the time the regulation was being developed, that an individual who received a therapeutic radiopharmaceutical dosage or a therapeutic sealed source permanent implant and was released under the restrictions of 10 CFR 35.75 was highly unlikely to receive another treatment and again be released under 10 CFR 35.75 within a year, i.e., to receive multiple administrations and to undergo multiple releases within a given year. The presumption that patients receive single administrations of therapeutic doses in a given year, which is the basis used in developing the wording for the dose limit in 10 CFR 35.75, is no longer valid.

The position of the NRC, supported by the recommendations of both national and international organizations, remains that there should be an annual limit on the dose to other individuals from the release of an individual under the provisions of 10 CFR 35.75. NRC intends to pursue rulemaking to accomplish this intent. The normal procedures for rulemaking, including opportunity for public comment, will be followed.

(Contact: Ronald Zelac, office of Federal and State Materials and Environmental Programs, 301-415-7635; e-mail: rez@nrc.gov)

# NRC RELEASES MOST OF YANKEE NUCLEAR POWER STATION SITE FOR UNRESTRICTED PUBLIC USE

On August 10, 2007, FSME released a majority of the Yankee Nuclear Power Station site near Rowe, Massachusetts, for unrestricted public use. This action completes the decommissioning of the former nuclear power station portion of the site.

The land, approximately 30 acres, is below NRC safety requirements that allow a maximum radiation dose of 25 millirem per year from residual contamination. Release of this land for unrestricted use poses no threat to public health and safety.

Yankee's license still applies to the site's dry cask storage facility, where the spent nuclear fuel from the plant's 30 years of operation is safely stored, plus a small parcel of land surrounding this facility. The total land remaining under license is approximately five acres. The licensee, Yankee Atomic Electric Co., remains responsible for the security and protection of this land and the dry cask storage facility, and is required to maintain \$100 million in nuclear liability insurance coverage for the facility.

Yankee Nuclear Power Station began commercial operations in 1961, and ceased production October 1, 1991. Yankee Atomic Electric Co. initiated decommissioning shortly thereafter. Dismantlement and decommissioning were completed in July 2007. NRC surveys verified that cleanup met the 25 millirem per year requirement.

(Contact: John Hickman, Office of Federal and State Materials and Environmental Programs, 301-415-3017; e-mail: jbh@nrc.gov)

# STATUS UPDATE FOR IMPLEMENTATION OF NRC REGULATORY AUTHORITY FOR NARM

The U. S. Nuclear Regulatory Commission (NRC) has published its final rule expanding the definition of byproduct material subject to its regulatory authority, implementing certain provisions of the Energy Policy Act (EPAct) of 2005. The final regulation establishing requirements for licensing and regulating Section 11e.(3) and 11e.(4) byproduct material, as required by Section 651(e) of the EPAct, was published on October 1, 2007 (Volume 72, pages 55863-55937, of the *Federal Register* (72 FR 55863)). It adds certain naturally occurring and accelerator-produced radioactive material (NARM) to the definition of "byproduct material" in the NRC's regulations. These final regulations will become effective on November 30, 2007. The final regulations can be accessed on the NRC's Public Involvement Rulemaking Web site, which is located at <u>http://www.nrc.gov/about-nrc/</u> regulatory/rulemaking/public-involvement.html.

As authorized by Section 651(e) of the EPAct, the Commission issued a waiver on August 31, 2005, to allow continued use and possession of NARM while the Commission developed a regulatory framework for regulation of the new byproduct material. The Commission plans to terminate the waiver in phases, beginning November 30, 2007, and ending on August 7, 2009. On November 30, 2007 (the effective date of the final rule), the Commission will terminate the waiver for Federal Government agencies, Federally Recognized Indian Tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana.

At this time, the NRC has not established the timing and schedule for waiver terminations for the remainder of the non-Agreement States and U.S. Territories. Notices in the *Federal Register* will be published approximately 6 months before the effective dates of the waiver terminations to notify users of their waiver terminations and implementation dates of the rule.

Upon waiver termination, all persons who possess the new byproduct material in these States, U.S. Territories, or areas of exclusive Federal jurisdiction must be in compliance with the NRC regulations. However, the rule provides authorization for continued use of the new byproduct material prior to obtaining a license or license amendment, as long as applications are made within specified times. Such persons will either be required to: (1) apply for license amendments for the new byproduct material within 6 months from the date the waiver is terminated, if they hold an NRC specific license, or (2) submit a license application for the new byproduct material within 12 months from the date the waiver is terminated.

In conjunction with the effective date of the final rule, the NRC intends to terminate the waiver for all 34 Agreement States that provided a certification from their Governor to the NRC as described in the EPAct and the NRC's Transition Plan mandated by the EPAct. Users of the new byproduct material in Agreement States should contact their respective Agreement State regulatory agency with any questions related to the regulation of these materials. The EPAct requires the NRC to prepare and publish a transition plan that addresses both Agreement and non-Agreement States to facilitate an orderly transition of regulatory authority with respect to the newly added byproduct material. The draft transition plan is available for review via the NRC's Agency-wide Documents Access and Management System (ADAMS) at <u>http://www.nrc.gov/readingrm/adams.html</u>; click on the Web-based access link. The document is available in ADAMS under Accession No. ML062990137. The NRC anticipates that publication of the final transition plan in the *Federal Register*, which will not be substantively changed from the draft transition plan, will occur before the effective date of the final regulations.

Additional details about the implementation of the final rule on can be found in a recently issued Regulatory Issue Summary (RIS). RIS 2007-22 was issued on October 16, 2007, to inform recipients of the status of the NRC's efforts to implement the requirements of Section 651(e) of the Energy Policy Act of 2005 (EPAct) on "Treatment of Accelerator-Produced and Other Radioactive Material as Byproduct Material." This RIS updates the information contained in RIS 2007-05, "Status and Plans for Implementation of NRC Authority for Certain Naturally Occurring and Accelerator-Produced Radioactive Material," dated March 20, 2007. This RIS is available for review at http://www. nrc.gov/reading-rm/doc-collections/gen-comm/ reg-issues/2007/.

NRC staff is finalizing revisions to the NUREG-1556 guidance for Volume 9, "Program-Specific Guidance about Medical Use Licenses," Volume 13, "Program-Specific Guidance about Commercial Radiopharmacy Licenses," and the new Volume 21 "Program-Specific Guidance about Possession Licenses for Production of Radioactive Materials Using an Accelerator." The NRC provided stakeholders with an opportunity to comment on these NUREGs in the Spring/Summer of 2007. The NRC intends to finalize the licensing guidance in conjunction with the effective date of the final rule.

For more information on NARM-related activities, please go to the "NARM Toolbox" at the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) Web site at http://nrc-stp.ornl.gov/narmtoolbox.html.

(Contacts: Kim Lukes or Duane White, Office of Federal and State Materials and Environmental Management Programs, 301-415-6701 or 301-415-6272; e-mail: kxk2@nrc.gov or dew2@nrc.gov.)

# GENERIC COMMUNICATIONS ISSUED (July 1, 2007 - September 30, 2007)

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 <u>http://www. nrc.gov/reading-rm/doc-collections/gen-comm/</u> <u>index.html</u>. Please note that this address is casesensitive and must be entered exactly as shown.

#### **Bulletins (BLs)**

None.

#### **Generic Letters (Gls)**

None.

#### Information Notices (INs)

IN 2007-25, "Suggestions from the Advisory Committee on the Medical Use of Isotopes For Consideration to Improve Compliance With Sodium Iodide I-131 Written Directive Requirements in 10 CFR 35.40 and Supervision Requirements in 10 CFR 35.27" was issued July 19, 2007. This IN was issued to all medical-use licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

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

IN 2007-23, "Inadvertent Discharge of Halon 1301 Fire-suppression System from Incorrect and/or Out-of-Date Procedures," was issued August 8, 2007. This IN was issued to all holders of operating licenses for nuclear power reactors, except those who have permanently ended operations and have certified that fuel has been permanently removed from the reactor vessel. All holders of licenses for fuel cycle facilities.

(Technical contacts: Rex Wescott, NMSS, (301)492-3107; e-mail rgw@nrc.gov; and Naeem Iqbal, NRR, 301-415-3346; nxi@nrc.gov)

IN 2007-26, "Combustibility of Epoxy Floor Coatings at Commercial Nuclear Power Plants," was issued August 13, 2007. This IN was issued to all holders of operating licenses for nuclear power

all holders of operating licenses for nuclear power reactors and fuel cycle facilities except licensees for reactors that have permanently ceased operations and who have certified that fuel has been permanently removed from the reactor vessel.

(Technical contacts: Naeem Iqbal, NRR, (301) 415-3346; e-mail nxi@nrc.gov; and Darrell L. Schrum, Region III, (630) 829-9741; e-mail dls3@nrc.gov).

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

**RIS 2007-13, "Verification of the Authenticity of Materials Possession Licenses,"** was issued August 31, 2007. This RIS was issued to all U.S. Nuclear Regulatory Commission materials licensees, and all Agreement State Radiation Control Program Directors and State Liaison Officers.

(Technical contacts: Christian Einberg, FSME, (301) 415-5422; e-mail cee1@nrc.gov; Tomas Herrera, FSME, (301) 415- 7138; e-mail txh1@nrc. gov; and Jane Marshall, NMSS, (301) 492-3138; e-mail jem1@nrc.gov)

**RIS 2007-18, "Data for Updating the Interim Inventory of Radioactive Sources,"** was issued September 7, 2007. This RIS was issued to all U.S. Nuclear Regulatory Commission Part 40, Part 50, Part 70, Part 72, and Part 76 licensees and certificate holders who are authorized to possess sources of radioactive material at the Category "3.5" activity or higher.

(Technical contacts: William R. Ward, FSME, (301) 415-7038; e-mail wrw1@nrc.gov; and Nima Ashkeboussi, FSME, (301) 415-7637; e-mail naa@nrc.gov)

(General Contact: Angela R. McIntosh, FSME, 301-415-5030; email: arm@nrc.gov)

# SIGNIFICANT EVENTS

**Event #1:** Unauthorized Administration of Radiopharmaceutical

*Date and Place:* August 6, 2007, Piedmont, North Carolina

*Nature and Probable Causes:* The licensee reported that a nuclear medicine technologist performed a diagnostic cardiac imaging exam on himself. He administered himself with 1.46 gigabecquerel (39.4 millicuries) of Tc-99m myoview for a stress test and followed it up with 0.43 gigabecquerel (11.6 millicuries) of Tc-99m myoview for the rest test. Both administrations occurred on August 6, 2007, and were done without the licensee's or an authorized user's knowledge or consent. The

technologist used a dose intended for a patient that did not show up for a scheduled exam. The technologist later informed the authorized user of the incident. The North Carolina Radioactive Materials Branch will inspect the licensee. The nuclear medicine technologist's employment was terminated.

**Event #2** Overexposure During Radiographic Operations

*Date and Place:* September 14, 2007, Beaumont Texas

Nature and Probable Causes: The licensee reported potential personnel overexposures during industrial radiography on a 6.5 foot steel ladle at a steel mill east of Beaumont, Texas. The radiographers were using a OSA Global exposure device (Model 943) and a Co-60 source (Model A-424-14, serial #36391B) with an activity of 3.48 terabecquerel (94 curies). Two radiographers noticed that their pocket dosimeters read offscale (>200 milliRoentgen). The radiographers had just changed the film in the holder, which was located approximately seven inches from the source collimator. It appeared that the source had not been retracted into the exposure device. It was determined that the source was stuck approximately 1.5 feet from the exposure device, due to a crimped guide tube. A ladder was used to enter the ladle from one side and the source collimator was positioned on the opposite side with a magnetic hold. The magnetic hold fell off the ladle during radiography and damaged the guide tube, restricting full retraction of the source during the last two shots. A survey was taken on the last shot and the source was discovered to be unshielded. A specialist responded to the jobsite and successfully retracted the source. However, the source retrieval was difficult. During retrieval, the specialist's pocket dosimeter went off-scale (>5 Roentgen (R)). The specialist switched to another pocket dosimeter with a range of 0 to 20 R. At the completion of the retrieval, the specialist had an indicated exposure of 13 centisieverts (rem). The licensee sent all three individuals' badges off for emergency processing. The Radiation Emergency Assistance Center/Training Site recommended that the individuals be medically examined with follow up blood chemistry tests. The Texas Department of Health will investigate the incident.

(Contact: Angela R. McIntosh, FSME, 301-415-5030; e-mail: arm@nrc.gov)

#### SIGNIFICANT ENFORCEMENT ACTIONS

The NRC's enforcement program can be accessed via NRC's homepage [http://ww.nrc.gov/] under "What We Do." Documents related to cases can be accessed at [http://www.nrc.gov/], "Electronic Reading room," "ADAMS Documents." Help using ADAMS is available from the NRC Public Document Room, telephone: 301-415-4737 or 1-800-397-4209.

#### **Portable Gauges**

#### R&M Engineering, Inc. (EA-07-180; 07-181)

On October 23, 2007, a Notice of Violation (NOV) and Proposed Imposition of Civil Penalty in the amount of \$3,250 was issued for a Severity Level III violation of 10 CFR 30.34(i) involving the licensee's failure, on two instances, to maintain a minimum of two independent physical controls that formed tangible barriers to secure a portable gauge from unauthorized removal during a period when the portable gauge was not under the control and constant surveillance of the licensee. In the second instance, this resulted in the loss of the gauge into the public domain. Specifically, in the first instance, an authorized portable gauge user left the portable gauge unattended and unsecured in the bed of a company truck as he returned to the office to retrieve paperwork. In the second instance, the licensee failed to use two independent physical controls to secure a portable gauge after it fell out of a company vehicle onto a public highway and until it was retrieved and returned by a member of the public a few minutes later.

#### Alaska Industrial X-Ray, Inc. (EA-07-261)

On October 19, 2007, an Order Suspending Licensed Activities (Effective Immediately) was issued to Alaska Industrial X-Ray, Inc. (AIX) based on the NRC's determination that all AIX radiographers, including AIX's Radiation Safety Officer, and assistants, violated 10 CFR 34.41(a) by performing industrial radiographic operations at a temporary job site with only one qualified individual present during operations. The evidence the NRC relied on indicates that these activities have occurred on numerous occasions, for a period of up to three years. Because the NRC issued a Notice of Violation on April 25, 2001, for a willful violation of 10 CFR 34.41(a) at the same client facility location, serious concerns were raised regarding AIX's willingness to comply with the Commission's requirements and its ability to conduct licensed activities without undue risk to the public's health and safety, resulting in the issuance of this order suspending all radiographic operations authorized by AIX's license.

#### MC Squared, Inc. (EA-07-101; EA-07-104)

On September 13, 2007, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$3,250 was issued for a Severity Level III problem composed of two Severity Level III violations. The first violation involved the failure of MC Squared, Inc., an Agreement State licensee (licensee), to file NRC Form 241 at least three days prior to engaging in licensed activities within NRC jurisdiction. Specifically, the licensee stored or used a portable gauge containing byproduct material (americium-241 and cesium-137) at two Indian Reservations which are areas of exclusive NRC jurisdiction regarding the use of NRC-licensed materials. The licensee did not file NRC Form 241 prior to using the material at these sites. The second violation involved the licensee's failure to use a minimum of two independent physical controls to secure a portable gauge from unauthorized removal when the gauge was not under the control and constant surveillance of the licensee. This failure may have contributed to the theft of the gauge which was reported. Specifically, the licensee stored the gauge in an unlocked trailer, located in an unrestricted area when an authorized user was not present. Although the gauge was in a locked container, the gauge had no physical control to form tangible barriers to secure the gauge from unauthorized removal, because the gauge container was not secured to the trailer, nor was access to the trailer controlled.

#### Cal Testing Services, Inc. (EA-07-191)

On September 7, 2007, a Notice of Violation was issued for a Severity Level III violation involving a radiographer who, contrary to the requirements in 10 CFR 34.37(a), did not wear a personnel dosimeter on the trunk of the body, during radiographic operations. Specifically, the radiographer placed his personnel dosimeter into his coat pocket and subsequently removed his coat and left the coat (with dosimeter in the pocket) in the vicinity of the camera prior to radiographic operations.

#### Valley Quarries, Inc. (EA-07-156)

On August 16, 2007, a Notice of Violation (NOV) and Proposed Imposition of Civil Penalty in the amount of \$3,250 was issued for a Severity Level III violation of 10 CFR 30.34(i) involving the failure to maintain a minimum of two independent physical controls that formed tangible barriers to secure a portable gauge from unauthorized removal during a period when the portable gauge was not under the control and constant surveillance of the licensee, which may have contributed to the theft of the gauge. Specifically, a portable nuclear gauge was stolen from an unattended licensee vehicle that was parked at an employee residence. While the gauge was unattended, the licensee had only a single tangible barrier in place to prevent the theft.

#### PK Associates, Inc. (EA-07-166)

On August 2, 2007, a Notice of Violation was issued for a Severity Level III violation of 10 CFR 30.34(i). The violation involved the failure to maintain a minimum of two independent physical controls that formed a tangible barrier to secure a portable gauge from unauthorized removal during a period when the gauge was not under direct control or surveillance. Specifically, a Troxler portable gauge was found unattended on top of a two foot wall, adjacent to a new road construction project. The authorized user was out of the direct line of sight to the gauge, leaving the gauge unattended for approximately ten minutes.

#### C&W Enterprises, Inc. (EA-07-022)

On July 13, 2007, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$3,250 was issued for a Severity Level III violation. The violation of 10 CFR 30.34(i) involved the licensee's failure to use a minimum of two independent physical controls that formed tangible barriers to secure a portable gauge from unauthorized removal when the portable gauges was not under the control and constant surveillance of the licensee. Specifically, no tangible barrier was used to secure a portable gauge that was stored in a warehouse, prior to November 27, 2006, and on April 24, 2007, only one physical control that formed a tangible barrier was used to secure the portable gauge from unauthorized removal.

#### JCK & Associates (EA-07-127)

On June 8, 2007, a Notice of Violation and Exercise of Enforcement Discretion were issued for two Severity Level III violations. The first violation involved the licensee's failure to meet the terms and conditions of an order issued to the licensee for not paying its annual fees. The second violation involved the licensee's failure to use a minimum of two independent physical controls that form tangible barriers to secure three portable gauges from unauthorized removal, when the portable gauges were not under the control and constant surveillance of the licensee. Specifically, the licensee stored the gauges in unlocked transportation cases located inside an unoccupied, unlocked hallway that could be accessed by unauthorized individuals. Although a civil penalty would normally be issued in this case, enforcement discretion was exercised because the licensee has transferred all licensed material to an authorized recipient, its NRC license has been terminated, and the licensee has no intention of conducting NRClicensed activities in the future.

#### Radiography

#### Department of the Navy, Marine Corps Logistics Base (EA-07-091; EA-07-093)

On June 29, 2007, a Notice of Violation was issued for two Severity Level III violations in accordance with the Enforcement Policy. The first violation involved a radiography device containing a quantity of Iridium-92 that was mistakenly shipped and stored for a period of 12 days before it was discovered and recovered during a routine survey. Although the source was properly shielded, and it was unlikely that a member of the general public could gain access to it, significant radiation exposures could have occurred if the source had been improperly handled, transferred or removed from the facility, or if the source was removed from it's shielding. The second violation involved a radiographer who exposed a Cobalt-60 source before ensuring that the high radiation area was cleared. This failure resulted in radiation doses to the crew that exceeded expected exposures. The failure to clear the high radiation area before conducting operations created a potential for the exposures to have been in excess of regulatory limits.

#### Medical

#### University of Pittsburgh (EA-06-266; EA-06-278)

On July 23, 2007, a Notice of Violation and Confirmatory Order (Effective Immediately) were issued to the licensee, for a Severity Level Ill violation. As a result of an Alternative Dispute Resolution (ADR) mediation session conducted at the licensee's request, the NRC agreed to final disposition of this matter by citing a single violation of the requirements in 10 CFR 35.24(b). Specifically, the licensee through the Radiation Safety Officer (a) failed to ensure that the physical presence requirements of 10 CFR 35.615(f)(3) from May 13, 2004, to March 10, 2005; and (b) failed to ensure that written directives were consistently signed by all three members of a Gamma Knife team prior to administration of gamma stereo tactic radiosurgery treatments in accordance with 10 CFR 35.32 between 1998 and 2000. The NRC concluded that certain aspects of the 10

CFR 35.24(b) violation were willful. The licensee disputed this conclusion. The NRC and the licensee have agreed to disagree regarding any willful aspects of this violation. In light of the actions that the licensee has taken, or has committed to take, as described in the Confirmatory Order, as well as the fact that the violation did not result in any known safety consequences to patients, workers, or the public, the NRC agreed to issue a Notice of Violation without a civil penalty.

#### Hackley Hospital (EA-07-071)

On June 20, 2007, a Notice of Violation was issued for a Severity Level III violation involving a failure to develop written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's written procedures for prostate seed implant treatment did not include appropriate steps or guidance to ensure that radioactive sources were positioned in the patient in accordance with the written directive and treatment plan.

#### Cooper Health System (EA-07-102; EA-07-126)

On June 8, 2007, a Notice of Violation was issued for two Severity Level III violations. The first violation involved a failure to verify that a high dose rate remote afterloader brachytherapy treatment was administered in accordance with the treatment plan and written directive. The second violation involved a failure to report a medical event. Specifically, a high dose rate remote afterloader treatment fraction was delivered in which the source was positioned outside of the patient's body for a portion of the treatment. The dose delivered to the treatment site differed from the prescribed dose by more than 50 rem to an organ or tissue and the fractionated dose differed from the prescribed dose, for a single fraction, by 50 percent or more.

# SELECTED FEDERAL REGISTER NOTICES (August 1, 2007 – September 30, 2007)

"Regulatory Guide: Issuance, Availability" 72 FR 42137, August 1, 2007.

(Contact: John N. Ridgely, Office of Nuclear Regulatory Research, 301-415-6555; email: JNR@nrc.gov.)

"NUREG–1556, Volume 9, Revision 2, "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Medical Use Licenses; Draft Guidance Document for Comment" 72 FR 42442, August 2, 2007. Page 11

(Contact: Torre Taylor, Office of Federal and State Materials and Environmental Management Programs, 301-415-7900; e-mail: tmt@nrc.gov.)

"Privacy Act of 1974, as Amended; New Routine Use" 72 FR 43296, August 3, 2007.

(Contact: Sandra S. Northern, Office of Information Services, 301-415-6879; e-mail: ssn@nrc.gov.)

"10 CFR Parts 2 and 171 RIN 3150–AI15, NRC Size Standards; Revision" (P) 72 FR 44988, August 10, 2007.

(Contact: Michael Lesar, Office of Administration, 301-415-7163, e-mail: mtl@nrc.gov.)

"10 CFR Parts 32 and 35 RIN 3150–Al14 Medical Use of Byproduct Material - Minor Corrections and Clarifications: Proposed rule" 72 FR 45181, August 13, 2007.

(Edward M. Lohr, Office of Federal and State Materials and Environmental Management Programs, 301-415-0253, e-mail: eml1@nrc.gov.)

"10 CFR Part 72, RIN 3150–AI21, List of Approved Spent Fuel Storage Casks: TN–68 Revision 1" 72 FR 45948, August 16, 2007.

"Consolidated Decommissioning Guidance; Notice of Revision to, Withdrawal of Portions of, and Process for Updating (NUREG–1757)" 72 FR 46102, August 16, 2007.

(Duane W. Schmidt, Office of Federal and State Materials and Environmental Management Programs, 301-415–6919; e-mail: dws2@nrc.gov)

"10 CFR Parts 1, 2, 13 and 110, RIN 3150—AH74, Use of Electronic Submissions in Agency Hearings" 72 FR 49139, August 28, 2007.

(Darani Reddick, Office of the General Counsel, 301-415-3841, e-mail: dmr1@nrc.gov; or Steven Hamrick, Office of the General Counsel, 301-415-4106, e-mail: sch1@nrc.gov.) "Notice of Availability of NUREG-1854, NRC Staff Guidance for Activities Related to U. S. Department of Energy Waste Determinations, Draft final Report for Interim Use" 72 FR 50704, September 4, 2007.

(Contact: Michael Fuller, Office of Federal and State Materials and Environmental Management Programs, 301-415-0520, e-mail: mlf2@nrc.gov.)

(General Contact: Gwendolyn Davis, Office of Federal and State Materials and Environmental Management Programs, 301-415-8165; e-mail: gxd@nrc.gov)

# **NOTE TO READERS:**

In an attempt to keep the FSME Licensee Newsletter relevant, useful and informative, feedback on the content of the newsletter is welcome. Readers desiring to contribute articles, self-explanatory diagrams, suggestions for future articles, bulletins, web-site postings, and other items of interest to the FSME Licensee Newsletter readership, should contact Michael Williamson or Gwendolyn Davis, from the Office of Federal and State Materials and Environmental Management Programs, Rulemaking Branch A. Mr. Williamson may be contacted at 301-415-6234 or mkw1@nrc. gov. Ms. Davis may be contacted at 301-415-8165 or gxd@nrc.gov.

In addition, to ensure proper delivery of the FSME Licensee Newsletter, please report any address changes to Mr. Williamson to prevent any interruption of service.

Please send written correspondence and requests to:

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