

FSME
News

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OFFICE OF FEDERAL & STATE

MATERIALS & ENVIRONMENTAL

MANAGEMENT PROGRAMS

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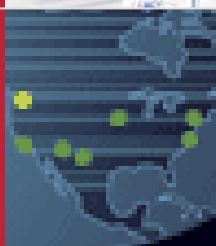
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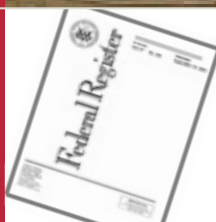
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Unwanted Irradiator Sources

Manufacturers have incorporated relatively high activity sources of cesium-137, cobalt-60, and iridium-192 in irradiators used in medicine and industry for purposes ranging from blood irradiation to food sterilization. Because the effectiveness of these irradiators is directly related to their radioactivity, service life diminishes with time. Management of sources that are no longer useful in a given application is becoming an increasing challenge for licensed users. While it is desirable to return sources to vendors or recycle and reuse residual radioactive material, the options are not always possible. In some cases, disposal is the best option. Unfortunately, disposal of sealed sources at commercial low-level waste (LLW) sites in the United States is complicated by two factors—access limitation and high disposal costs.

Both compact law and site waste acceptance criteria limit access to disposal sites. Under the Low-Level Radioactive Waste Policy Amendments Act of 1985, States that enter into interstate agreements, known as compacts, are granted the authority to exclude LLW from States outside their compact. Under this law, a licensee in Nebraska could be prevented from disposing of a source at the commercial site in Washington, because Nebraska is not part of the Northwest compact. Waste acceptance criteria, unlike compact restrictions, are primarily driven by U.S. Nuclear Regulatory Commission's (NRC) waste classification system in Title 10 of the Code of Federal Regulations (10 CFR) Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste." LLW is classified as Class A, B, C, or greater than Class C (GTCC) based on potential hazard and intended need for control and isolation. By law, States are responsible for disposal of Class A, B, and C LLW. The U.S. Department of Energy (DOE) is ultimately responsible for the disposal of GTCC LLW. DOE is in the process of completing an environmental impact statement for a GTCC disposal implementation strategy. In addition to LLW classification limitations, States that regulate LLW disposal may impose additional restrictions based on site specific conditions. Because of their relatively high radioactivity and small mass or volume, many irradiator sources are considered GTCC and do not meet the criteria for commercial disposal, even if they are within a sited compact. Further, DOE is not yet in the position to accept GTCC sources for disposal.





In cases in which irradiator sources do meet LLW disposal site waste acceptance criteria and are allowed by the host compact and State, disposal cost rates are likely to be high. Disposal cost rates are typically based on a complex formula that accounts for size, radioactivity, dose rate, and handling and processing challenges. Though physically small, the other factors used in setting disposal rates can result in disposal cost for an individual source to total tens of thousands of dollars. In addition, the cost of leasing certified packages, which are required for higher-activity shipments, can typically range in the tens to hundreds of thousands of dollars.

One potential relief for licensees may be the Global Threat Reduction Initiative OffSite Source Recovery Project (GTRI/OSRP), which is part of DOE's National Nuclear Security Administration (NNSA). This program is designed to identify and manage radioactive sealed sources that would represent a security threat if used in a radiological dispersal device (commonly referred to as a "dirty bomb"). These include Categories 1 and 2 quantities of radioactive sources listed in the International Atomic Energy Agency's "Code of Conduct on the Safety and Security of Radioactive Sources" (code of conduct), as well as aggregations of lower activity sources. The Categories 1 and 2 quantities of radioactive sources listed in the code of conduct are considered the most risk-significant and have been the focus of Federal and State efforts to place tighter controls for security. Disused and unwanted medical and industrial sources should be registered through the GTRI/OSRP secure Web site, <http://www.osrp.lanl.gov>. Information on disused sources that do not qualify for recovery by GTRI/OSRP is shared with the Conference of Radiation Control Program Directors (CRCPD) Source Collection and Threat Reduction (SCATR) Project. NNSA/GTRI funds the SCATR Project, but it is administered by CRCPD. SCATR helps licensees use commercially available disposal options and may, in certain cases, offer financial assistance as needed to generators that participate in the SCATR program. In addition, the NRC funds the CRCPD's Orphan Source Project which complements other efforts and focuses exclusively on orphan sources.

The GTRI and CRCPD projects have been effective in reducing the threat posed by disused and unwanted sources. Also, current Federal and State regulations and inspection programs provide assurance that these disused sources remain secure while in long-term storage. However, more efforts are needed to comprehensively and sustainably address this national security challenge since disposal is considered the most secure management approach. Several efforts are underway at both the U.S. Federal Government interagency level and at the State and compact level to expand options for addressing these industrial and medical sources in the interest of national security. The NRC is very engaged in these efforts. All parties acknowledge that there is not one solution, nor can one State, compact or agency solve this problem alone. Furthermore, sustainable and comprehensible solutions will need to address both front-end and end-of-life management of sealed sources.

In the United States, beneficial use of medical and industrial sources, while vital, lends itself to significant challenges regarding the end-of-life management of these sources. Such management ultimately requires the cooperation of a number of entities at both the State and Federal level. The NRC remains committed to working with NNSA, CRCPD, compacts and other interested parties in finding solutions to this important national security issue. Details regarding the disposal challenges, as identified above, are found in the Interagency's 2010 Radiation Source Protection and Security Task Force (task force) report to the President and Congress at <http://www.nrc.gov/security/byproduct/2010-task-force-report.pdf>. The task force activities have been the primary vehicle for advancing issues related to the domestic security of radioactive sources from potential terrorist threats. Since the task force provides a report to the President and Congress every 4 years, per legislative mandate, the task force will provide a status update on source recovery and disposition in 2014.

(Contact: James Shaffner, FSME, 301-415-5496 or James.Shaffner@nrc.gov or Kim Lukes, FSME, 301-415-670 or Kim.Lukes@nrc.gov)



FROM THE DESK OF THE DIRECTOR

It is hard to believe that a year has already passed since I assumed the role of FSME Director. In recognition of the success that the office had in fiscal year 2012, I would like to use this column to reflect upon some of our major achievements.

Starting with nuclear byproduct materials, staff in our Divisions of Materials Safety and State Agreements (DMSSA) and Program Planning/Budgeting and Program Analysis spent much of fiscal year 2012 working with States to complete efforts to deploy the Web-based licensing (WBL) system component of the Integrated Source Management Portfolio. The WBL provides an integrated system for management of radioactive materials licensing and inspection activities with Internet access to support flexible use by the NRC and Agreement States. Looking forward, we will integrate the final component of the portfolio, the license verification system, in the near future. DMSSA also developed recommendations on regulatory changes for permanent implant brachytherapy programs that will be incorporated into the ongoing 10 CFR Part 35, "Medical Use of Byproduct Material," expanded medical rulemaking effort.

Collaborative working groups on regulatory initiatives and outreach efforts have been the focus of our Division of Intergovernmental Liaison and Rulemaking (DILR). Numerous important rulemakings were proposed or finalized that will lead to regulatory changes affecting general licensees, distributors of source material, and spent fuel licensees and vendors, among others. A paper providing recommendations on the path forward for 10 CFR Part 20, "Standards for Protection Against Radiation," was sent to the Commission. Additionally, DILR has been tasked to develop a Tribal Policy Statement. Several Tribal outreach initiatives have taken place and additional opportunities are planned to receive feedback, which will allow us to formulate a more informed policy statement for the Commission's consideration.

Moving on to the decommissioning and waste arena, our Division of Waste Management and Environmental Protection (DWMEP) staff issued a final policy statement on volume reduction and low-level radioactive waste. DWMEP also issued the Nuclear Fuel Services Final Environmental Assessment and Final Technical Evaluation Reports for Savannah Site's River F Area Tank Farm and the West Valley Melter. In addition, DWMEP staff successfully terminated the University of Arizona's research and test reactor license; resolved policy and technical issues related to the Shallow Land Disposal Area; and engaged stakeholders on low-level waste topics related to the ongoing 10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste," rulemaking effort.

Recognizing the importance of maintaining a highly skilled workforce, FSME continued to provide training opportunities for our co-regulators in the Agreement States. In fact, a total of 453 Agreement State students attended the 40 training courses hosted by the NRC over the past fiscal year. FSME also continued extensive education and outreach efforts on safety culture. Finally, with regional and State assistance, we completed all of this year's Integrated Materials Performance Evaluation Program reviews to evaluate the technical adequacy and consistency of NRC and Agreement State materials programs.

As FSME transitions into fiscal year 2013, we remain committed to seek and maintain strong partnerships with our program stakeholders under a common goal of ensuring safety, security, and protection of the environment.

A handwritten signature in black ink that reads "Mark Satorius". The signature is fluid and cursive, with the first name being the most prominent.

Mark Satorius, Director



DECAY-IN-STORAGE

The Energy Policy Act of 2005 gave the NRC regulatory authority over certain naturally occurring and accelerator-produced radioactive material (NARM). Since August 7, 2009, all Federal agencies and Federally-recognized Indian Tribes and persons who possess NARM in non-Agreement States and U.S. Territories have been required to comply with NRC regulations.

For NRC medical use licensees, the regulation in 10 CFR 35.92, "Decay-in-Storage," states that a licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage without regard to its radioactivity if it meets certain conditions. For nonmedical use licensees, the same requirements for decay-in-storage are specified in a standard license condition.

The physical half-life for some NARM radionuclides commonly used by medical licensees is more than 120 days. For example, the physical half-life for cobalt-57 is 272 days, gadolinium-153 is 242 days, and germanium-68 is 271 days. The NRC regulations do not permit disposal of these radionuclides by decay-in-storage. Permissible methods of disposal of these sources are specified in 10 CFR Part 20, Subpart K, "Waste Disposal." Typically, these sources are transferred to an authorized recipient, such as the original source vendor or a waste processor.

A licensed radioactive source that has decayed to a quantity less than the amount listed in 10 CFR 30.71, "Schedule B," may not be considered an exempted quantity for purposes of disposal. The exemptions in 10 CFR 30.18(a), "Exempt Quantities," do not apply to a radioactive source that was subject to licensing at the time it was acquired.

(Contact: Sandra Gabriel, FSME, 301-801-3889, Sandra.Gabriel@nrc.gov or Michael Fuller, 301-415-0520, FSME, Michael.Fuller@nrc.gov)

ANNUAL INVENTORY RECONCILIATION

It's that time of the year again! The time to reconcile source inventories in the National Source Tracking System (NSTS) has arrived. You can reconcile your source inventory in the NSTS as early as January 1, 2013. The reconciliation must be completed by January 31, 2013. The annual inventory reconciliation (AIR) packages will be mailed out for each license in NSTS with an "active" source in the NSTS inventory. An "active" source is a source that is at or above Category 2 thresholds.

Inventories and instructions will be mailed out in large white envelopes at the end of December and the first week of January. If you do not receive an inventory package by January 10, 2013, please contact the NSTS Help Desk to request one at 1-877-671-6787 or e-mail at NSTSHelp@nrc.gov.

What can you do now to prepare? You can log into the NSTS and review your current inventory to ensure that all of the information is correct. If there are any issues, you may contact the NSTS help desk for assistance in resolving them. This will ensure timely completion of your AIR.

(Contact: Michelle Killian, FSME, 301-415-6711 or Michelle.Killian@nrc.gov)



SIGNIFICANT ENFORCEMENT ACTIONS

The NRC issued significant actions for failure to comply with regulations.



L.E. Gregg Associates (EA-12-108)

On July 27, 2012, the NRC issued a Notice of Violation to L.E. Gregg Associates for a Severity Level III violation. The violation involved a failure to file NRC Form 241, "Report of Proposed Activities in Non-Agreement States," at least 3 days before engaging in licensed activities within NRC jurisdiction, as required by 10 CFR 150.20(b). Specifically, on December 12–16, 2011, January 5–7, 2012, and February 21–24, 2012, L.E. Gregg Associates, which only holds a Kentucky Agreement State license, used and stored a portable nuclear gauge at temporary jobsites in West Virginia, a non-Agreement State, without obtaining a specific license issued by the NRC or filing NRC Form 241, "Report of Proposed Activities in Non-Agreement States," at least 3 days before engaging in such activity.

Gamma Irradiator Services (EA-12-088)

On July 11, 2012, the NRC issued a Notice of Violation to Gamma Irradiator Services (GIS) for a Severity Level III violation. The violation involved the failure to limit licensed activities to Category I self-shielded irradiators, as required by Condition 9 of GIS's NRC license (37-30850-01). Specifically, on May 2, 2003, February 25, 2005, June 15, 2007, and May 19, 2009, GIS performed maintenance activities on a JL Shepherd Model 81-22 irradiator, which is not a self-shielded (Category I) irradiator but, rather, a panoramic (Category II) irradiator.



American Radiolabeled Chemicals (EA-12-077)

On June 25, 2012, the NRC issued a Notice of Violation to American Radiolabeled Chemicals for a Severity Level III violation. The violation involved the failure to implement 10 CFR 20.1801, "Security of Stored Material." Specifically, on April 2, 2012, the licensee failed to secure from unauthorized removal or limit access to licensed material stored in a controlled area.

neo-pet, LLC (EA-12-068)

On June 13, 2012, the NRC issued a Notice of Violation to neo-pet, LLC, a licensee of the State of Ohio, for a Severity Level III violation. The violation involved the failed to adhere to 10 CFR 150.20, "Recognition of Agreement State Licenses." Specifically, on multiple occasions between April 6, 2010, and March 6, 2012, neo-pet, LLC, possessed and used doses of fluorine-18 in Indiana, a non-Agreement State, without filing an NRC Form 241 at least 3 days before engaging in licensed activities in areas of exclusive Federal jurisdiction.

Texas Gamma Ray, LLC (EA-10-102)

On May 15, 2012, the NRC issued a Confirmatory Order, which was effective immediately, to Texas Gamma Ray, LLC (TGR), to formalize commitments made as a result of an Alternative Dispute Resolution mediation session held on April 23, 2012. The commitments were made as part of a settlement agreement between TGR and the NRC regarding apparent violations of NRC requirements. The agreement resolves the apparent violations involving TGR's failure to: (1) meet two NRC security requirements, and (2) store radioactive material only at a location authorized by its license. Specifically, radioactive material was stored at a facility in Rock Springs, Wyoming, which was not an approved storage location. TGR agreed to a number of corrective actions, including paying a civil penalty of \$7,000, retrieving the licensed material from Wyoming and transferring it to an authorized storage site in Texas, revising internal procedures, requiring the radiation safety officer's approval for storing licensed material, and training all radiographers on the new procedures.



Flowserve Corporation (EA-12-060)

On April 30, 2012, the NRC issued a Notice of Violation to Flowserve Corporation for a Severity Level III violation. The violation involved a failure to obtain a specific license for export of reactor components, as required by 10 CFR 110.20, "General License Information." Specifically, in March 2010, Flowserve exported two reactor recirculation pump seal-repair kits, components subject to NRC licensing jurisdiction, to Mexico without obtaining an NRC specific license.

MEDICAL

The Christ Hospital (EA-12-142)

On August 28, 2012, the NRC issued a Notice of Violation to The Christ Hospital, for a Severity Level III violation. The violation involved the failure to file NRC Form 241 at least 3 days before engaging in licensed activities within NRC jurisdiction, as required by 10 CFR 150.20 (b). Specifically, on multiple occasions between January 2009 and March 8, 2012, The Christ Hospital—Mobile, a licensee of the State of Ohio, possessed and used syringes containing technetium-99m at a temporary job site in Indiana, a non-Agreement State, without first filing an NRC Form-241 with the NRC, at least 3 days before engaging in such activity.

MedStar Georgetown Medical Center (EA-12-085)

On August 3, 2012, the NRC issued a Notice of Violation to the MedStar Georgetown Medical Center (MGMC), for a Severity Level III violation. The violation involved the licensee's failure to control and maintain constant surveillance of the licensed material in a controlled area as required by 10 CFR 20.1802, "Control of Material Not in Storage." Specifically, between December 13 and 14, 2011, MGMC did not control and maintain constant surveillance of licensed material that was in an unsecured lead shielded container in the high dose-rate remote afterloader procedure room, a controlled area, for approximately 24 to 30 hours.

St. John Macomb-Oakland Hospital, Warren, MI (EA-12-172)

On October 16, 2012, the NRC issued a Notice of Violation to St. John Macomb-Oakland Hospital for a Severity Level III violation. The violation involved the failure to have written procedures in place that would provide high confidence that each high dose-rate remote afterloader (HDR) brachytherapy administration was in accordance with the written directive as required by 10 CFR Part 35.41 (a). Specifically, on July 9, 2012, the licensee's written procedures failed to ensure that the patient's endobronchial catheters were directly connected to the HDR unit such that the brachytherapy administration would occur in accordance with the written directive.

Information about the NRC's enforcement program can be accessed at <http://www.nrc.gov/about-nrc/regulatory/enforcement/current.html>. Documents related to cases can be accessed through ADAMS at <http://www.nrc.gov/reading-rm/adams.html>. Help in using ADAMS is available by contacting the NRC Public Document Room staff at 301-415-4737 or 1-800-397-4209 or by sending an e-mail to PDR.Resource@nrc.gov.

(Contact: Michele Burgess, FSME, 301-415-5868 or Michele.Burgess@nrc.gov)





SELECTED FEDERAL REGISTER NOTICES

July 11, 2012

Low-Level Radioactive Waste Regulatory Management Issues (Public meeting; request for comment)

Donald Lowman, FSME, 301-415-5452 or Donald.Lowman@nrc.gov or

Tarsha Moon, FSME, 301-415-6745 or Tarsha.Moon@nrc.gov

August 13, 2012

Workshop on Performance Assessments of Near-Surface Disposal Facilities: FEPs Analysis, Scenario and Conceptual Model Development, and Code Selection (Public meeting)

George Alexander, FSME 301-415-6755 or George.Alexander@nrc.gov or

Tarsha Moon, FSME, 301-415-6745 or Tarsha.Moon@nrc.gov

September 14, 2012

Annette User on Behalf of GE Osmonics, Inc.

(Petition for rulemaking; consideration in the rulemaking process)

Edward M. Lohr, FSME, 301-415-0253 or Edward.Lohr@nrc.gov

October 12, 2012

Draft Tribal Protocol Manual and Scoping for Proposed Policy Statement (Request for comments)

Cardelia H. Maupin, FSME, 301-415-2312 or Cardelia.Maupin@nrc.gov

October 16, 2012

Petition for Rulemaking Submitted by C-10 Research and Education Foundation, Inc. (Petition for rulemaking; partial consideration in the rulemaking process)

Jeffery Lynch, FSME, 301-415-5041, or Jeffery.Lynch@nrc.gov

December 7, 2012

Low-Level Waste Disposal (Regulatory basis and preliminary rule language; second request for comment)

Andrew Carrera, FSME, 301-415-1078 or Andrew.Carrera@nrc.gov

TO OUR READERS

In our attempt to keep the FSME Licensee Newsletter relevant, we welcome feedback on the contents of the newsletter. If you would like to suggest topics, please contact Vanessa Cox of FSME Rulemaking Project Management Branch. Please contact Ms. Cox by phone at 301-415-8342 or by e-mail at Vanessa.Cox@nrc.gov. In addition, report any e-mail address changes to ensure proper delivery of the FSME Licensee Newsletter and to prevent any interruption of service to Ms. Cox at FSME_Newsletter@nrc.gov.

Please send written correspondence to the following address:

Vanessa Cox, Editor FSME Licensee Newsletter

Office of Federal and State Materials and Environmental Management Programs

U.S. Nuclear Regulatory Commission

Two White Flint North, Mail Stop:T-8-F42

Washington, DC 20555-0001

