

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF FEDERAL AND STATE MATERIALS  
AND ENVIRONMENTAL MANAGEMENT PROGRAMS  
WASHINGTON, DC 20555-0001

May 07, 2009

**NRC REGULATORY ISSUE SUMMARY 2009-07  
STATUS UPDATE FOR THE IMPLEMENTATION OF NRC  
REGULATORY AUTHORITY FOR CERTAIN NATURALLY OCCURRING  
AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL**

**ADDRESSEES**

All U.S. Nuclear Regulatory Commission (NRC) material and fuel cycle licensees. All Radiation Control Program Directors and State Liaison Officers.

**INTENT**

The NRC is issuing this regulatory issue summary (RIS) to inform recipients of the status of the agency's efforts to implement the requirements of section 651(e) of the Energy Policy Act of 2005 (EPAAct) on "Treatment of Accelerator-Produced and Other Radioactive Material as Byproduct Material." No specific action or written response is required. The NRC encourages recipients of this RIS to share this information with known users of the newly defined byproduct materials resulting from the EPAAct, who may not currently possess an NRC byproduct materials license. The NRC is providing this Regulatory Issue Summary (RIS) to Agreement States for their information and distribution to their licensees as appropriate.

**BACKGROUND**

On August 8, 2005, the President signed the EPAAct into law. Section 651(e) of the EPAAct expands the definition of byproduct material as given in section 11e of the Atomic Energy Act of 1954 (AEA), as amended. This change places additional byproduct material under the NRC's jurisdiction, as defined in paragraphs 11e.(3) and 11e.(4) of the AEA. Thirty-Six States have previously certified that they have programs in place to properly regulate the newly defined byproduct materials.

**ML091030497**

## SUMMARY OF ISSUE

### Final Regulations

Section 651(e) of the EPA Act requires that the NRC issue final regulations that establish requirements for licensing and regulating AEA Sections 11e.(3) and 11e.(4) byproduct material, while cooperating with the States and using model State standards to the maximum extent practicable. The NRC published its final regulations on October 1, 2007 (Volume 72, page 55864, of the *Federal Register* (72 FR 55864)). These final regulations became effective on November 30, 2007, and can be accessed on the NRC's Public Involvement Rulemaking Web site at <http://www.nrc.gov/about-nrc/regulatory/rulemaking/public-involvement.html>.

### Waiver Issued on August 31, 2005 (70 FR 51581)

As authorized by section 651(e) of the EPA Act, the NRC issued a waiver on August 31, 2005, to allow the continued use and possession of naturally occurring and accelerator-produced radioactive materials (NARM) while it developed a regulatory framework for regulation of NARM as a new type of byproduct material. The waiver was issued for a period of four years from the date of EPA Act and will terminate on August 7, 2009.

The NRC has begun terminating the waiver in phases. The first phase of waiver terminations occurred on November 30, 2007 (the effective date of the final rule). On this date, the NRC terminated 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. The second phase of waiver terminations occurred on September 30, 2008. On this date, the NRC terminated the waiver for Idaho, Missouri, South Dakota, Vermont, West Virginia, Guam and all other territories and possessions of the United States that were not part of Phase 1. Upon waiver termination, all persons who possessed the new byproduct materials in these States, U.S. Territories, or areas of exclusive Federal jurisdiction were to be in compliance with NRC regulations. Being in compliance means that such persons are responsible for the proper handling, transfer, and disposal of these new byproduct materials as specified in NRC regulations.

The third and last phase of waiver terminations will occur on August 7, 2009, (74 FR 5797). This final phase will include Alaska, Connecticut, Hawaii, Michigan, New Jersey, and NRC licensees with headquarters in Canada. Additionally, the Commission terminated the waiver for non-Agreement States that entered into an Agreement with the NRC under Section 274b of the Atomic Energy Act of 1954, as amended, coincident with the effective date of such an agreement. The State of New Jersey has submitted an Agreement State application to the NRC. The New Jersey agreement may be completed prior to the waiver termination date at August 7, 2009. If their agreement goes into effect prior to the waiver termination date, then the waiver for New Jersey licenses will terminate to coincide the effective date of the agreement.

The NRC prepared and promulgated a transition plan (72 FR 59157), which was published in the *Federal Register* on October 19, 2007 to facilitate an orderly transition of regulatory authority with respect to the newly added byproduct material. As explained in the transition plan, under the final regulations, users of NARM in non-Agreement States and U.S. Territories are 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 byproduct materials license, or (2) submit a license application for the new byproduct material within 12 months from the date the

waiver is terminated. Upon receipt of either a license amendment or a new license application, the respective NRC regional office will notify the applicant of its receipt of the request. The notification will document that the applicant complied with this aspect of the regulations.

Existing NRC licensees should note that the NRC will not amend licenses to include authorization to produce radioactive material using an accelerator; the agency will require a separate license for these activities. Therefore, existing licensees should contact their NRC Regional Office and prepare to submit a new license application to obtain authorization for the production of radioactive materials using an accelerator.

In addition, new NRC license applicants that are seeking authorization to produce radioactive materials using an accelerator should submit a license application for that authorization and should submit a separate license application for any other radioactive material authorizations they may seek (e.g., manufacturing of radiopharmaceuticals and medical use of byproduct material).

#### Associated Supportive Activities

The NRC staff has finalized the guidance in NUREG-1556, "Consolidated Guidance about Materials Licenses," Volume 9, Revision 2, "Program-Specific Guidance About Medical Use Licenses," issued January 2008; Volume 13, Revision 1, "Program-Specific Guidance About Commercial Radiopharmacy Licenses," issued November 2007; and the new Volume 21, "Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator," issued October 2007. The NRC staff is also planning to make minor revisions, which reflect the regulation of the new byproduct material, to other NUREG-1556 licensing guidance and related inspection procedures (IPs) (e.g., IP 87125, "Materials Processor/Manufacturer Programs," and IP 87127, "Radiopharmacy Programs"). Information on NARM-related activities and recently issued Office of Federal and State Materials and Environmental Management Programs (FSME) generic communications are also available in the "NARM Toolbox" at the NRC's FSME Web site at <http://nrc-stp.ornl.gov/narmtoolbox.html>.

#### **BACKFIT DISCUSSION**

This RIS requires no action or written response. Any action on the part of addressees in accordance with the guidance contained in this RIS is strictly voluntary and, therefore, is not a backfit under any regulation in Title 10 of the *Code of Federal Regulations* (10 CFR).

#### **FEDERAL REGISTER NOTIFICATION**

The NRC did not publish a notice of opportunity for public comment on this RIS in the *Federal Register* because this RIS is informational and does not represent a departure from current regulatory requirements.

#### **RELATED GENERIC COMMUNICATIONS**

RIS 2008-13, "Status And Plans For Implementation of NRC Regulatory Authority for Certain Naturally-Occurring and Accelerator-Produced Radioactive Material."

## **PAPERWORK REDUCTION ACT STATEMENT**

This regulatory issue summary requires no specific action nor written response. If you have any questions about this summary, please contact the contact listed below or the appropriate regional office.

## **PUBLIC PROTECTION NOTIFICATION**

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting documents displays a currently valid OMB control number.

## **CONGRESSIONAL REVIEW ACT**

This RIS is not a rule as designated by the Congressional Review Act (5 U.S.C. §§ 801-808) and, therefore, is not subject to this Act.

**/RA/**

Robert J. Lewis, Director  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials and  
Environmental Management Programs

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Enclosure: Recently Issued FSME Generic Communications

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Enclosure: Recently Issued FSME Generic Communications

**ML091030497**

OFFICE	FSME/MSSA	FSME/MSSA	ADM/TechEd	OGC-NLO	OGC-CRA
NAME	SXu	ADWhite	K Azariah-Kribbs	BJones	TRothschild
DATE	4/13/09	4/15 /09	4/27 /09	4/ 23 /09	4/20/09
OFFICE	FSME/MSSA	OIS	FSME/MSSA	FSME/MSSA	
NAME	AMcIntosh	TDonnell	R Reis	RJLewis	
DATE	4/30/09	4/ 17/09	4/ 30/09	5/6 /09	

**OFFICIAL RECORD COPY**

List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications			
Date	GC No.	Subject	Addressees
12/01/08	RIS-2008-31	Licensing Requirements for Sentinel Lymph Node Biopsy	All U.S. Nuclear Regulatory Commission medical use licensees and NRC master material licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers
12/22/08	RIS-2008-10, Suppl. 1	Notice Regarding Forthcoming Federal Firearms Background Checks	All U.S. Nuclear Regulatory Commission licensees, certificate holders, and applicants for a license or certificate of compliance who use armed security personnel as part of their physical protection system and security organization. All Radiation Control Program Directors and State Liaison Officers
01/12/09	IN-2008-22	Molybdenum-99 Breakthrough in Molybdenum-99/Techneium-99m Generators	All U.S. Nuclear Regulatory Commission medical, radiopharmacy, molybdenum-99/technetium-99m generator manufacturers, and master material licensees authorized to manufacture or use generators. All Agreement State radiation control program directors and State liaison officers.
01/22/09	IN-2009-01	National Response Framework	All holders of operating licenses or certificates for nuclear power plants, research and test reactors, independent spent fuel storage installations, fuel cycle facilities, and radioactive materials. All holders of operating licenses for uranium recovery facilities and all holders of licenses or certificates for the following types of facilities undergoing decommissioning: nuclear power plants, research and test reactors, fuel cycle facilities, and uranium recovery facilities.
02/03/09	IN-2009-05	Contamination Events Resulting from Damage to Sealed Radioactive Sources During Gauge Dismantlement and Nonroutine Maintenance Operations	All U.S. Nuclear Regulatory Commission materials licensees; all Agreement State Radiation Control Program Directors and State Liaison Officers.
03/30/09	IN-2009-07	Withholding of Proprietary Information from Public Disclosure	All current holders of and potential applicants for licenses, certificates of compliance, permits, or standard design certifications, as well as any other persons submitting a request that information be withheld from public disclosure under the provisions of Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Section 2.390, "Public inspections, exemptions, requests for withholding.
<p>Note: This list contains the six most recently issued generic communications, issued by the Office of Federal and State Materials and Environmental Management Programs (FSME). A full listing of all generic communications may be viewed at the NRC public website at the following address: <a href="http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html">http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html</a></p>			