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

June 16, 2008

REGULATORY ISSUE SUMMARY 2008-13
STATUS AND PLANS FOR IMPLEMENTATION OF NRC REGULATORY AUTHORITY FOR CERTAIN NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) materials licensees, Radiation Control Program Directors, State Liaison Officers, and the NRC's Advisory Committee on the Medical Uses of Isotopes.

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 (EPAct) on "Treatment of Accelerator-Produced and Other Radioactive Material as Byproduct Material." This RIS updates the information contained in RIS 2007-22, "Status Update for Implementation of NRC Regulatory Authority for Certain Naturally-Occurring and Accelerator-Produced Radioactive Material." Recipients should review this information as it applies to all their operations and should consider appropriate actions. The information contained in this RIS does not constitute new NRC requirements; therefore, it requires no specific action or written response. The NRC encourages recipients of this RIS to share this information with known users of the newly defined byproduct materials resulting from the EPAct, who may not currently possess an NRC byproduct materials license. The NRC also encourages Agreement States to disseminate this RIS to manufacturers and distributors of the newly defined byproduct materials.

BACKGROUND

On August 8, 2005, the President signed the EPAct into law. Section 651(e) of the EPAct expanded the definition of byproduct material as given in Section 11e. of the Atomic Energy Act of 1954 (AEA), as amended. This change placed additional byproduct material under the NRC's jurisdiction, as defined in paragraphs 11e.(3) and 11e.(4) of the AEA.

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SUMMARY OF ISSUE

Final Regulations

Section 651(e) of the EPAct 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 EPAct, the NRC issued a waiver on August 31, 2005, to allow continued use and possession of naturally occurring and accelerator-produced radioactive materials (NARM) while it developed a regulatory framework for regulation of the new byproduct material.

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. 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 NRC is preparing for the second phase of waiver terminations. This phase of waiver terminations will occur on September 30, 2008. The agency has determined that Vermont, West Virginia, Missouri, Idaho, South Dakota, Guam, and all territories and possessions of the United States that were not identified as part of the first phase of waiver terminations will be included in the second phase on September 30, 2008. Waivers for the remaining non-Agreement States, which include Connecticut, Virginia, New Jersey, Michigan, Alaska, and Hawaii, will be terminated in the third phase of waiver terminations in the summer of 2009, but no later than August 7, 2009.

The NRC published a notice in the *Federal Register* on March 18, 2008, (73 FR 14376) that notified users of the second phase of waiver terminations. The NRC will publish another notice in the *Federal Register* approximately 6 months before the effective date of the third phase of waiver terminations. In addition, the NRC plans to terminate the waiver for any non-Agreement State that enters into agreement with the NRC under Section 274b. of the AEA coincident with the effective date of such an agreement. Pennsylvania is the first State to become an Agreement State during this transition period. The waiver terminated for Pennsylvania on the effective date of its agreement, March 31, 2008.

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.

Licensees or individuals of non-Agreement States and U.S. Territories covered by the first phase of the waiver terminations must submit license amendments to include NARM, if it is not already included on their licenses, by May 30, 2008, or must submit new license applications by December 1, 2008.

An existing NRC license may already authorize some of the radioactive material that falls under the newly expanded definition of byproduct material, since the term "byproduct material" includes NARM. For example, an existing NRC license with an authorization for any byproduct material with atomic numbers 1 though 83 or an authorization for a specific modality under Title 10 Part 35, "Medical Use of Byproduct Material," of the *Code of Federal Regulations* (e.g., 10 CFR 35.100, 10 CFR 35.200) could include accelerator-produced radionuclides such as thallium-201, iodine-123, gallium-67, indium-111, and fluorine-18. Therefore, those who hold current NRC materials licenses should review them carefully (e.g., source manufacturers and model numbers, possession limits, locations, authorized individuals) to ensure that they cover the possession, use, and/or storage of the new byproduct material. Licensees who have questions about amending an NRC license should contact the appropriate NRC regional office. Individuals who possess/use sufficient quantities of the new byproduct material within the NRC's regulatory jurisdiction to require a general license should refer to the NRC regulations in 10 CFR Part 31, "General Domestic Licenses for Byproduct Material," to determine whether the new byproduct material that they possess/use is regulated by the NRC as a generally licensed device. If so, then upon waiver termination, they must follow the registration and/or reporting requirements contained in the final regulations.

Enclosure 1 provides frequently asked questions associated with the implementation of the requirements of Section 651(e) of the EPAct. Enclosure 2 provides a list of generic communications recently issued by the Office of Federal and State Materials and Environmental Management Programs (FSME).

Associated Supportive Activities

The NRC staff has finalized the NUREG-1556 guidance for Volume 9, Revision 2, "Program-Specific Guidance About Medical Use Licenses"; Volume 13, Revision 1, "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 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"). Furthermore, the NRC staff is preparing a set of frequently asked questions on radium-226 that will be publicly available. The NRC has not yet finalized the schedule for completing these additional activities. Information on NARM-related activities is 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 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.

PAPERWORK REDUCTION ACT STATEMENT

This RIS contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The Office of Management and Budget (OMB) approved these information collections under approval numbers 3150-0044, -0014, -0017, -0016, -0001, -0010, and -0120.

PUBLIC PROTECTION NOTIFICATION

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information collection requirement unless the requesting document 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.

CONTACT

This RIS requires no specific action or written response. Questions about this summary should be addressed to one of the technical contacts listed below or to the appropriate NRC regional office.

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Enclosures:
1. Frequently Asked Questions (FAQs) Concerning Section 651(e) of the Energy Policy Act of 2005
2. Recently Issued FSME Generic Communications

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OFC	FSME/DMSSA	FSME/DMSSA	FSME/DMSSA	FSME/DMSSA	TechEd
NAME	DEWhite:tyh	KKLukes	ADWhite	AMcIntosh	CHsu for HChang
DATE	05/08/08	05/08/08	05/08/08	05/09/08	05/13/08
OFC	OGC-NLO	OGC-CRA	OIS	FSME/DMSSA	
NAME	BJones	TRothschild	TDonnell	TReis for RJLewis	
DATE	06/05/08	06/02/08	06/02/08	06/10/08	

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Frequently Asked Questions (FAQs) Concerning Section 651(e) of the Energy Policy Act of 2005

The U.S. Nuclear Regulatory Commission (NRC) has added the following frequently asked questions (FAQs) to those that are listed in the March 20, 2007, Regulatory Issue Summary 2007-05, "Status and Plans for Implementation of NRC Regulatory Authority for Certain Naturally-Occurring and Accelerator-Produced Radioactive Material."

1. When will the Phase 2 and Phase 3 waiver terminations occur and which non-Agreement States and U.S. Territories and possessions will be affected?

   The Phase 2 waiver terminations will occur on September 30, 2008, for the following entities:

PHASE 2 September 30, 2008	
Vermont	South Dakota
West Virginia	Guam
Missouri	All other territories and possessions of the United States that were not identified as part of Phase 1
Idaho	

   The Phase 3 waiver terminations should occur in the summer of 2009 but will occur no later than August 7, 2009, for the remaining non-Agreement States:

PHASE 3 Summer 2009	
Connecticut	Michigan
Virginia	Alaska
New Jersey	Hawaii

   In addition, the NRC plans to terminate the waiver for any non-Agreement State that enters 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. At this time, Pennsylvania is the only State to have become an Agreement State during this transition period. The waiver terminated on the effective date of Pennsylvania's agreement, March 31, 2008.

2. How does the NRC plan to handle licensing actions (i.e., amendment requests or applications for new licenses) before the applicable waiver termination dates?

   The NRC's statutory authority for regulating naturally occurring and accelerator-produced radioactive material (NARM) does not take effect until the waiver terminates for a particular State or jurisdiction. If the NRC does not have authority over a potential applicant because the waiver has not yet been

terminated, the applicable NRC regional office will not process an application for a NARM licensing action until the applicable waiver terminates. The NRC regional office can determine whether to keep the application until the waiver termination date. However, the NRC cannot legally process application fees from individuals applying for new NARM licensing actions before the regulations are applicable to that entity because the NRC does not have legal authority to charge applicants fees until the waiver termination date. According to the guidance on the timeliness of deposits in the U.S. Department of Treasury's Financial Manual, which the NRC follows, the NRC cannot hold any monies that the NRC receives for processing NARM licensing actions before the waiver termination date without depositing them. Therefore, the NRC regional offices will return any monies received for processing NARM licensing actions in advance of the applicable waiver termination dates.

This practice, which is followed by the regional offices, does not preclude individuals from continuing to use or possess NARM before their applicable waiver termination date, or during the time period that their licensing actions are being processed assuming that they were filed on time.

3. How can an applicant verify that his/her licensing action request (i.e., amendment request or application for new license) has been filed on time with the appropriate NRC regional office, based on the required timeframe outlined in the ''Plan for the Transition of Regulatory Authority Resulting from the Expanded Definition of Byproduct Material'' (transition plan) issued by the NRC on October 19, 2007, in the *Federal Register* (72 FR 59157)?

   The appropriate NRC regional office will confirm receipt of a request for either a license amendment within 6 months from the waiver termination date or a new license application within 12 months of the waiver termination date. The notification will document that the application has been filed on time.

4. Is there additional information available on radium-226?

   A set of FAQs will address radium-226, the new regulatory requirements, and how the rule will apply both to existing and potential new licensees and to members of the public who might have items containing radium-226 (e.g., antiquities, collectibles). The NRC will make these FAQs available in the near future on the "NARM Toolbox" at the Web site of the Office of Federal and State Materials and Environmental Management Programs at http://nrc-stp.ornl.gov/narmtoolbox.html.

5. Does the NRC have regulatory authority over devices containing NARM located and used at nuclear power plants in Agreement States?

   Historically, the NRC has combined a license for the possession and use of any byproduct materials or devices (Title 10, Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," of the *Code of Federal Regulations*

(10 CFR Part 30)) with the facility license (10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities"), with the exception of byproduct materials and devices for industrial radiography (10 CFR Part 34, "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations"). The NARM rule that became effective on November 30, 2007, included a change in the definition of byproduct material in 10 CFR Part 30 and 10 CFR Part 50 to include these devices and materials.

Because the Energy Policy Act of 2005 put this byproduct material under NRC jurisdiction, and, as stated above, the NRC has combined certain 10 CFR Part 30 byproduct materials and devices with the 10 CFR Part 50 facility license, the existing 10 CFR Part 50 license may cover NARM on the reactor site after November 30, 2007. Licensees should check their licenses to ensure that specific NARM in possession, storage, or use is covered within the byproduct section of their existing 10 CFR Part 50 licenses. Licensees should contact the appropriate NRC regional office if they have questions regarding the need to amend an existing NRC license to include any NARM that is not currently covered.

A 10 CFR Part 30 byproduct license combined with a 10 CFR Part 50 facility license applies only to byproduct materials that are located onsite at the facility. If reactor licensees in Agreement States use NARM offsite, for example, in a laboratory that is not covered in the 10 CFR Part 50 license, that NARM will be subject to the same regulations as other byproduct material within the Agreement State. Reactor licensees in Agreement States should contact their respective Agreement State regulatory agencies with any questions related to the regulation of offsite NARM. Radiography performed at the reactor site in an Agreement State continues to be under Agreement State jurisdiction.

6. Do NRC licensees located in Agreement States have 6 months or 12 months to either amend or apply for new licenses following the November 30, 2007, waiver termination date?

If an NRC licensee is located in an Agreement State and already possesses or is using NARM in the Agreement State where the waiver terminated, that licensee must comply with the 6 month/12 month time period for a license amendment/new license application from the November 30, 2007, waiver termination date. This especially applies to those NRC licensees with temporary jobsites included on their licenses. If the license lists several temporary jobsites (across jurisdictions within different phases of waiver terminations), licensees should apply for the license amendment or apply for a new license from the date of the very first waiver termination for the jurisdiction in which they will possess or be using NARM. For example, if an NRC license allows temporary jobsites anywhere in the United States where the NRC maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States, the licensee must apply for an amendment to the license within 6 months from the November 30, 2007, waiver termination

date if the licensee intends to use or possess NARM in a Phase 1 jurisdiction. However, if the license contains a permanent location for use or possession in a non-Agreement State or jurisdiction that did not have the waiver terminated on November 30, 2007, the licensee may wait until the waiver is terminated for that non-Agreement State or jurisdiction. For example, if an NRC licensee lists the corporate headquarters in a Phase 1 State as the address on the license but uses or possesses material at a permanent location in a Phase 2 State, the licensee may apply within 6 months from the September 30, 2008, waiver termination date.

7. What are some considerations that should be made when determining if an NRC license needs to be amended or a notification needs to be submitted in order to comply with the new NARM regulations?

   If a medical licensee (licensed under 10 CFR Part 35, “Medical Use of Byproduct Material”) currently uses or possesses NARM, the licensee should either request an amendment to the license or notify the appropriate regional office, if any of the following conditions apply:

   - Licensees intend to add a radionuclide(s) or change the possession limit currently authorized on the license. Licensees should note that NARM may already be authorized on the existing NRC license, since the term "byproducts materials" will include NARM. For example, an existing NRC license may already include NARM if it authorizes any byproduct material with atomic numbers 1 through 83 or authorizes a specific modality under 10 CFR Part 35 (e.g., 10 CFR 35.200).

   - Licensees intend to add an Authorized User, Authorized Nuclear Pharmacist, or Authorized Medical Physicist who will only use NARM.

   - Licensees intend to add or change the facility description and/or design currently approved by the NRC to include areas, facilities, or locations where NARM is used or possessed (e.g., add a positron emission tomography patient waiting room or a change in room shielding or material storage location).

   - Licensees intend to modify procedures or equipment related to NARM.

   The NRC strongly encourages licensees who use or possess NARM to contact the appropriate NRC regional office with any questions concerning a license amendment.

8. Should licensees report NARM-related events?

   Agreement State licensees and NRC licensees in non-Agreement States, U.S. Territories, or areas of exclusive Federal jurisdiction that have had their waiver

terminated must report NARM-related events to their appropriate regulatory agencies. Those regulatory agencies will track such events in the applicable event tracking databases (e.g., Nuclear Materials Events Database).

While non-Agreement State licensees that have not yet had their waivers terminated do not need to report NARM-related events to the NRC, they may be required to report applicable events to the appropriate State regulatory agencies.

List of Recently Issued FSME Generic Communications

Date	GC No.	Subject	Addressees
10/04/07	RIS-07-22	Status Update for Implementation of NRC Regulatory Authority for Certain Naturally-Occurring and Accelerator-Produced Radioactive Material	All NRC materials licensees. All Radiation Control Program Directors, State Liaison Officers, and the NRC's Advisory Committee on the Medical Uses of Isotopes
10/04/07	RIS-07-23	Date for Operation of National Source Tracking System	All licensees authorized to possess Category 1 or Category 2 quantities of radioactive materials. All Radiation Control Program Directors and State Liaison Officers
12/05/07	RIS-07-27	Improving Public Understanding of the Risks Associated with Medical Events	All NRC medical use licensees. All Radiation Control Program Directors, and State Liaison Officers
12/07/07	RIS-07-28	Security Requirements for Portable Gauges	All NRC portable gauge licensees. All Agreement State Radiation Control Program Directors and Liaison Officers
12/14/07	RIS-07-38	Ensuring Complete and Accurate Information in the Documentation of Training and Experience for Individuals Seeking Approval as Medical Authorized Users	All NRC medical use licensees and NRC master materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers
02/01/08	RIS-08-02	Actions to Increase the Security of High Activity Radioactive Sources	All NRC materials and master materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers

Note: This list contains the six most recently issued generic communications by the Office of Federal and State Materials and Environmental Management Programs. The NRC provides a list of all generic communications on its public Web site at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html.