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

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REGULATORY ISSUE SUMMARY 2007-05
STATUS AND PLANS FOR IMPLEMENTATION OF NRC REGULATORY AUTHORITY FOR CERTAIN NATURALLY-OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL

ADDRESSEES

All NRC materials licensees, Radiation Control Program Directors, State Liaison Officers, and NRC's Advisory Committee on the Medical Uses of Isotopes.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this Regulatory Issue Summary (RIS) 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." Enclosure 1 provides a list of recently issued generic communications and Enclosure 2 provides a list of Frequently Asked Questions associated with the implementation of the requirements of Section 651(e) of the EPAct. Recipients should review this information for general applicability to all their operations and consider actions, as appropriate. However, suggestions contained in this RIS are not new NRC requirements; therefore, no specific action or written response is required. Recipients of this RIS are encouraged 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. We also encourage our Agreement State partners 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 defined 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 section 11e.(3) and 11e.(4) of the AEA.

SUMMARY OF ISSUE

Progress Toward Completion of the Final Regulations

Section 651(e) of the EPAct requires that the Commission issue final regulations establishing requirements for licensing and regulating section 11e.(3) and 11e.(4) byproduct material, while cooperating with the States and using model State standards to the maximum extent practicable. As discussed below, NRC has made significant progress toward completion of the final regulations, which are currently expected to be published in the Spring of 2007.

The final regulations will become effective 60 days after the date of publication. The final rule will be posted on NRC's Public Involvement Rulemaking website, which is located at http://www.nrc.gov/about-nrc/regulatory/rulemaking/public-involvement.html. Throughout the

rulemaking process, the NRC has been actively working with both Agreement States and non-Agreement States, through the Organization of Agreement States and the Conference of Radiation Control Program Directors.

In addition, the NRC staff has consulted other stakeholders, including NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), other Federal agencies, professional organizations, and the medical community, regarding the rulemaking. On November 9, 2005, and August 22, 2006, the NRC held public meetings with stakeholders to discuss the rulemaking.

After receiving comments from the States and ACMUI on a draft of the proposed regulations, the NRC published the proposed regulations in the *Federal Register* (71 FR 42955) on July 28, 2006, for a 45-day public comment period. The NRC received a total of 39 comment letters on the proposed regulations.

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

As authorized by Section 651(e) of the EPAct, the Commission issued a waiver on August 31, 2005 to: (1) allow States to continue with their regulatory programs for NARM; (2) allow persons engaged in activities involving NARM to continue with their operations in a safe manner; and (3) allow continued use of radiopharmaceuticals for medical purposes. The waiver is in effect through August 7, 2009, unless terminated earlier by the Commission. The NRC believes that the public health and safety and common defense and security are adequately protected under the existing waiver, while NRC continues to prepare the final regulations.

The Commission plans to terminate the waiver in phases, after the final rule is issued, starting from the effective date of the rule (60 days after publication) and ending on August 7, 2009. During the initial phase for the waiver terminations, which will occur in conjunction with the effective date of the final rule, the Commission intends to terminate the waiver for Federal Government agencies, Federally Recognized Indian Tribes, Delaware, District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana. The approach used for the selection of these States and U.S. Territories considered: 1) the scope of the current State's regulatory program, 2) the estimated total number of licensees impacted, and 3) the State's level of interest in becoming an Agreement State. At this time, the timing and schedule for waiver terminations for the remainder of the non-Agreement States and U.S. Territories have not been established. However, the NRC intends to use the same selection approach for the remaining States and U.S. Territories.

Upon waiver termination, all persons that possess the new byproduct materials in these States, U.S. Territories, or areas of exclusive Federal jurisdiction must be in compliance with NRC regulations. Please note that being in compliance with the NRC regulations includes for example, meeting the reporting and recordkeeping requirements for the new byproduct material once the waiver is terminated. In addition, 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 byproduct materials license; or 2) submit a license application for the new byproduct material within 12 months from the date the waiver is terminated.

As noted above, the waiver for the remaining non-Agreement States and U.S. Territories will be terminated in phases. A notice in the *Federal Register* will be published approximately six months before the effective date of the waiver termination to notify users of their waiver terminations and implementation dates of the rule. NRC staff will notify impacted State regulators individually prior to the publication of the *Federal Register* notice. The NRC also plans to provide additional notification to known entities impacted by the initial phase of waiver terminations following publication of the final rule in the *Federal Register*.

In conjunction with the effective date of the final rule, the Commission also intends to terminate

the waiver for any of the 34 Agreement States that provide a certification from their Governor to the Commission. The certification shall document that their State has a program for licensing byproduct material, as defined in paragraph (3) or (4) of Section 11e. of the Atomic Energy Act of 1954, as amended, which is adequate to protect public health and safety, and that the State intends to continue to implement their authority with respect to the new byproduct material. The Governor's certification must be provided to the Commission on or before the date the final transition plan is published. Upon acceptance of the certification by the Commission and termination of the waiver, the State's Agreement will be considered to include AEA section 11e.(3) and 11e.(4) byproduct material. Users of the new byproduct materials in Agreement States should contact their respective Agreement State regulatory agency with any questions related to plans for continuing to regulate these materials.

Transition Plan

The EPAct requires the NRC to prepare and publish a transition plan to facilitate an orderly transition of regulatory authority with respect to the newly added byproduct material. The transition plan addresses both Agreement and non-Agreement States. On September 11, 2006, the staff forwarded an approach for developing and publishing the transition plan in "Transition Plan for the Regulation of Certain Byproduct Materials Mandated by the Energy Policy Act of 2005" to the Commission for its review and approval. On October 10, 2006, the Commission approved the NRC staff's approach for developing and publishing the transition plan in "Staff Requirements - Secy-06-0195 - Transition Plan for the Regulation of Certain Byproduct Materials Mandated by the Energy Policy Act of 2005." On October 25, 2006, the staff submitted the "Draft Transition Plan for Comment" to the Agreement States. These documents are available for review at the NRC's Agencywide Documents Access and Management System. Go to: http://www.nrc.gov/reading-rm/adams.html and click on the "Web-based access" link. Search for the documents using access numbers ML060180329 (Transition Plan); ML062830173 (Commission approval), and ML062990137 (Transition Plan for comment).

At this time, the NRC does not plan to make any substantive changes to the transition plan prior to publication. The NRC does plan to include in the transition plan dates that have not yet been determined, and to provide clarification of the overall time line for waiver terminations in non-Agreement States that are not planning to become Agreement States. This clarification will extend the date for waiver termination in some States, and is responsive to stakeholder comments received on the proposed rulemaking. The NRC anticipates that publication of the final Transition Plan will be published in conjunction with the final regulations in the *Federal Register* as required by Section 651(e) of the EPAct.

Associated Supportive Activities

The NRC staff is also working on several activities that will be needed to support NRC's new regulatory authority. Specifically, the NRC staff is working on finalizing revisions to the guidance in NUREG-1556, Volumes 9 and 13, and developing a new NUREG (NUREG-1556, Volume 21) which is focused on the production of radioactive material using an accelerator. The NRC will provide stakeholders with an opportunity to comment on these NUREGs in the Spring of 2007. NRC plans to finalize the licensing guidance after the final rule is published. These guidance documents will be noticed in the *Federal Register* and posted to the NRC's NUREG-1556 public web site at the following address: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. The NRC staff is also planning to make minor revisions, which reflect the regulation of the new byproduct materials, to NUREG 1556, Volumes 7, 8, 12, 16, 18, and 20, as well as to inspection procedures (IP) 87125, "Materials Processor/Manufacturer Programs," IP 87127, "Radiopharmacy Programs," and Manual Chapter 2800, "Materials Inspection Program." Furthermore, the NRC staff is preparing a set of "Frequently Asked Questions" on radium-226 that will be publicly available. The schedule for completing these additional activities has not yet been finalized. You may access the "NARM Toolbox" at the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) website at http://nrc-stp.ornl.gov/narmtoolbox.html for information on NARM related activities.

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 10 CFR.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published 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 does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq).

CONGRESSIONAL REVIEW ACT

This RIS is not a rule as designated by the Congressional Review Act (5 U.S.C. §§ 801-886) and, therefore, is not subject to the Act.

CONTACT

This RIS requires no specific action or written response. If you have any questions about this summary, please contact one of the technical contacts listed below, or the appropriate regional office.

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Enclosures:
1. List of Recently Issued FSME/NMSS Generic Communications
2. Frequently Asked Questions Concerning Section 651(e) of the EPAct

Recently Issued FSME/NMSS Generic Communications

Date	GC No.	Subject	Addressees
02/02/07	IN-07-03	Reportable Medical Events Involving Patients Receiving Dosages of Sodium Iodide Iodine-131 less than the Prescribed Dosage Because of Capsules Remaining in Vials after Administration	All U.S. Nuclear Regulatory Commission (NRC) medical use licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
02/28/07	IN-07-03	Potential Vulnerabilities of Time-reliant Computer-based Systems Due to Change in Daylight Saving Time Dates	All U. S. Nuclear Regulatory Commission (NRC) licensees and all Agreement State Radiation Control Program Directors and State Liaison Officers.
03/01/07	RIS-07-03	Ionizing Radiation Warning Symbol	All U.S. Nuclear Regulatory Commission (NRC) licensees and certificate holders. All Radiation Control Program Directors and State Liaison Officers

Note: NRC generic communications may be found on the NRC public website at http://www.nrc.gov, under Electronic Reading Room/Document Collections.

Frequently Asked Questions (FAQs)

1. What is the Energy Policy Act of 2005?

   The Energy Policy Act of 2005 (EPAct) is a major piece of Federal legislation that, among other things, gave the NRC authority to regulate certain naturally-occurring and accelerator-produced radioactive material (NARM) by expanding the definition of "byproduct material" in Sections 11e.(3) and 11e.(4) of the Atomic Energy Act of 1954 (AEA), as amended.

2. What is NARM?

   "NARM" is an acronym for naturally-occurring and accelerator-produced radioactive material.

3. What is "certain NARM"?

   The EPAct limited NRC authority to regulate only discrete sources of Radium-226, accelerator-produced radioactive material (ARM) that is produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity and discrete sources of naturally occurring radioactive material other than source material that the Commission in consultation with certain other Federal agencies determines would pose a threat similar to that posed by a discrete source of Radium-226 to the public health and safety or common defense and security that is produced, extracted, or converted after extraction for use for a commercial, medical, or research activity.

4. What is a particle accelerator?

   A particle accelerator (accelerator), is a machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum, and discharging the resultant particulate or other radiation into a medium at energies usually in excess of a megaelectron volt.

5. What are some examples of materials made radioactive by a particle accelerator?

   Examples of materials produced by an accelerator are Fluorine-18 used in positron emission tomography (PET) scanning, Cobalt-57 used in lead-in-paint analyzer devices and flood sources, and Gallium-67, Indium-111, Iodine-123, and Thallium-201 used for nuclear medicine diagnostic studies.

6. Who is affected by the EPAct?

   All persons that possess NARM under the expanded definition of byproduct material will be affected.

7. What does "expanded definition of byproduct material" or "new byproduct material" mean?

   Section 651(e) of the EPAct expanded the definition of byproduct material in Section 11(e) of the AEA by:

   (1) Adding any discrete source of Radium-226 that is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity; or any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction, before, on, or after the date of enactment of the EPAct for use for a commercial, medical, or research activity (Section 11e.(3) of the AEA); and

(2) adding any discrete source of naturally occurring radioactive material, other than source material, that the Commission, in consultation with certain Federal agencies, determines would pose a threat similar to the threat posed by a discrete source of Radium-226 to the public health and safety or the common defense and security; and is extracted or converted after extraction before, on, or after the date of enactment of the EPAct for use in a commercial, medical, or research activity (Section 11e.(4) of the AEA). Currently, there is not any radioactive material identified as 11e.(4) material.

8. Why was the NRC given the authority to regulate 11e.(3) and 11e.(4) material?

Congress gave the NRC the authority to regulate 11e.(3) and 11e.(4) material to promote a nationally consistent and uniform regulatory environment for health, safety, and security of these materials.

9. What is a “discrete source” with respect to “Radium”?

The EPAct required the NRC to include in its regulation a definition of the term “discrete source” for purposes of paragraphs (3) and (4) of section 11e. of the AEA. The definition of a discrete source has not been finalized at this time. The term “discrete source” will be defined in the final rule.

10. What is Radium-226?

Radium-226 is a decay product (daughter product, progeny) of the naturally-occurring Uranium-238 decay series. Its half-life is 1620 years.

11. When will the NRC final rule be published?

The NRC estimates that the final rule will be published in the *Federal Register* in the spring of 2007.

12 Where can stakeholders get more information concerning the rulemaking?

Further information and substantiating documents can be found at the NRC’s Public Involvement Rulemaking website at http://www.nrc.gov/about-nrc/regulatory/rulemaking/public-involvement.html.

13. What is the transition plan and where can I find a copy of the plan?

The staff has prepared a proposed transition plan to facilitate an orderly transition of regulatory authority for the new byproduct material between States and the NRC. A copy of the draft transition plan that is expected to be finalized and published in conjunction with the promulgation of the final rule can be accessed through NRC’s Agencywide Documents Access and Management System (ADAMS) under the accession number: ML062990212. The direct link to ADAMS is: http://www.nrc.gov/reading-rm/adams.html.

14. What is covered in the transition plan?

The transition plan facilitates the orderly transition of regulatory authority for the new byproduct material, and addresses the potential scenarios that may result in a transition of authority between the States and the NRC, and the conditions under which a State may exercise regulatory authority over the newly defined byproduct material.

15. What is the criteria under which an Agreement States may exercise authority over byproduct material?

There are two ways an existing Agreement State may include the new byproduct material in its AEA section 274b. Agreement: (1) the Governor of the State provides a "certification of adequacy" on the date of the publication of the transition plan; or (2) the Governor requests an amendment to the State's Agreement, as provided in section 274 of the AEA.

16. What is included in the Agreement State Governor's certification of adequacy?

The Governor of the State must certify to the Commission on or before the date of publication of the final transition plan that:

(1) the State has a program for licensing byproduct material, as defined in paragraph (3) or (4) of section 11e. of the AEA, that is adequate to protect the public health and safety, as determined by the Commission; and

(2) the State intends to continue to implement the regulatory responsibility of the State with respect to the byproduct material.

17. What is "Adequacy"?

Pursuant to NRC"s Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*, "adequacy" is the ability of a State program to protect health and safety if administration of the program provides reasonable assurance of protection of public health and safety in regulating the use of agreement material.

18. What if the Governor does not certify the State program's adequacy on the date of publication of the transition plan?

If the Governor does not certify the State program's adequacy on the date of publication of the transition plan, the Governor must formally request an amendment to the State's 274b. Agreement in accordance with NRC/FSME SA-700 procedures in order to continue to regulate these materials.

19. For Agreement States, is "compatibility" required before the Governor certifies adequacy?

No, a "compatibility" consideration is separate from a finding of adequacy. The compatibility will be assessed during subsequent IMPEP reviews of the state's program, and is not a component of the Governor's certification.

20. What if a non-Agreement State wants to continue to regulate 11e.(3) material?

If a non-Agreement State intends to continue regulatory responsibility for 11e.(3) material, the Governor of the non-Agreement State will need to request a 274b. Agreement with the Commission by following NRC/FSME procedure SA-700.

21. Have any non-Agreement States formally expressed intent in entering into a 274b. Agreement with the NRC?

The States of Pennsylvania, Virginia and New Jersey have formally expressed intent in signing a 274b. Agreement with the NRC.

22. What is the waiver?

The EPAct provides that the Commission may grant a waiver to any entity with respectto a matter related to the new byproduct material. The Commission issued such a waiver on August 31, 2005, effective through August 7, 2009 (except for the import and export of materials covered by the waiver) unless terminated earlier by the Commission.

The waiver allows all persons owning, using, and otherwise engaging in activities involving the material to continue with their activities and States to continue to regulate this material during the applicable waiver period, and during the period in which the NRC developed the final regulatory framework for regulating the new byproduct material.

23. How and when will the waiver be terminated for non-Agreement States?

Waiver terminations for the non-Agreement States will be executed in phases for groups of States and U.S. Territories between the effective date of the rule and August 7, 2009. The first phase of waiver terminations (Phase 1) will terminate waivers on the effective date of the final rule for the following entities:

PHASE 1 Summer 2007 (Estimated)	
Delaware	Montana
District of Columbia	Wyoming
Puerto Rico	Federal Government Agencies
U.S. Virgin Islands	Federally Recognized Indian Tribes
Indiana	

24. Can the waiver be terminated earlier than August 7, 2009?

The waiver can be terminated earlier by the Commission if the Commission determines that an earlier termination is warranted.

25. When will the waivers be terminated for non-Agreement States who do not enter into an agreement with the Commission under section 274 b. of the AEA and are not identified in Phase 1?

The details for additional phases for waiver termination have not yet been finalized. Once finalized, notifications of planned waiver terminations will be noticed in the *Federal Register* and letters will be sent to current materials licensees in those States.

26. Can the waiver be extended?

The waiver cannot be extended beyond four years after the date of the EPAct.

27. How does an Agreement State communicate to the NRC that it does not want to retain jurisdiction over the new byproduct material?

If an Agreement State does not intend to continue to regulate the new byproduct material, the Governor should formally indicate that decision to NRC.

28. Has the NRC received certifications from any Agreement State Governors?

    Yes, the NRC has currently received certifications from 23 Agreement State governors (AZ, AR, GA, IA, IL, KS, KY, MD, ME, MN, NE, NM, NV, NY, NC, OH, OK, OR, SC, TX, UT, WA, and WI). These certifications and any additional certifications received will be publicly available in ADAMS.

29. Will NRC retain regulatory authority for exempt distribution licenses for the new byproduct material?

    Yes. As discussed in the transition plan, the NRC understands that there are a limited number of State issued exempt distribution licenses for the new byproduct material which will transfer to NRC. The specific details of the transfer will be addressed on a case-by-case basis with the States and distributors.

30. Will Sealed Source or Device registration certificates for the new byproduct material transfer to NRC jurisdiction?

    Yes. As discussed in the transition plan, the NRC will assume regulatory authority for Sealed Source or Device registration certificates in Non-Agreement States and Agreement States with section 274b. Agreements that do not provide for the inclusion of this material. The NRC will also assume regulatory authority for Sealed Source or Device registration certificates for exempt distribution devices.

31. How does the NRC plan to regulate persons who possess radioluminescent devices or antiquities containing Radium-226?

    The NRC staff is evaluating stakeholder comments received in this area in response to the proposed rulemaking. In addition, the NRC staff is developing a set of “Frequently Asked Questions” concerning the regulation of discrete sources of Radium-226, which will be posted on the FSME website.

32. If I use or possess the new byproduct material within the NRC’s regulatory jurisdiction, (i.e., not solely within an Agreement State that is planning to continue to regulate the new byproduct materials as part of its 274b. Agreement with the NRC), how long will I have until I am expected to comply with the new regulations governing the expanded definition of byproduct material?

    All persons not solely within an Agreement State that is planning to continue to regulate the new byproduct materials as part of its 274b. Agreement with the NRC that possess NARM under the expanded definition of byproduct material must be in compliance with NRC regulations once the waiver is terminated for the particular State or U.S. Territory where the material is used or possessed. Please note that being in compliance with the NRC regulations includes meeting the reporting and recordkeeping requirements for the new byproduct material.

33. If I use or possess the new byproduct material within the NRCs regulatory jurisdiction, (i.e., not solely within an Agreement State that is planning to continue to regulate the new byproduct materials as part of its 274b. Agreement with the NRC) when will I need to apply for a license amendment or new license for the newly defined byproduct material?

    Upon termination of the waiver for the State or U.S. Territory, where the material is used or possessed, all persons not solely within an Agreement State that is planning to continue to regulate the new byproduct materials as part of its 274b. Agreement with the NRC will be required to 1) apply for a license amendment for the new byproduct

material within 6 months from the date the waiver is terminated, if you hold a 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. Please note that you should not submit an amendment or new license application for the newly defined byproduct material that will be used or possessed in a State or U.S. Territory prior to the termination of the waiver for that State or U.S. Territory.

34. If I use or possess the new byproduct material within the NRC's regulatory jurisdiction in a State or U.S. Territory where the waiver is terminated, will I need to have a license from the NRC before possessing the material?

Yes. If you did not use/possess the new byproduct material prior to termination of the waiver, you will need to receive a new license or an amendment to your current license for use/possession of the new byproduct material.

35. What should I do if I possess/use the new material within NRC's regulatory jurisdiction in a State or U.S. Territory where the waiver is terminated, and in quantities that do not require a specific byproduct materials license, but require a general domestic license from the NRC?

As noted in the answer to Question number 11, the NRC estimates that the final rule will be published in the *Federal Register* in the spring of 2007. Once the final rule is published, please refer to NRC regulations in 10 CFR Part 31 - General Domestic Licenses for Byproduct Material, in order to determine whether the new byproduct materials that you possess/use falls under NRC's regulations for general licenses. If the byproduct materials that you possess/use fall under the NRC's regulations for general licenses, you will need to follow registration and/or reporting requirements contained in the final regulations.