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

October 4, 2007

REGULATORY ISSUE SUMMARY 2007-22
STATUS UPDATE 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 2007-05, "Status and Plans for Implementation of NRC Authority for Certain Naturally-Occurring and Accelerator-Produced Radioactive Material," dated March 20, 2007. Recipients should review this information as it applies to all their operations and should consider appropriate actions. The guidance contained in this RIS does not constitute 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. The NRC 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 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 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 Commission issue final regulations that establish requirements for licensing and regulating AEA 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 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 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 Commission issued a waiver on August 31, 2005, to allow continued use and possession of naturally-occurring and accelerator-produced radioactive materials (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. Upon waiver termination, all persons who possess the new byproduct materials in these States, U.S. Territories, or areas of exclusive Federal jurisdiction must be in compliance with NRC regulations. Being in compliance with the NRC regulations means that such persons are responsible for the proper handling, transfer, and disposal of these new byproduct materials as specified in the NRC's regulations. 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. Upon receipt of either a license amendment or new license application, the respective NRC regional office will notify the applicant confirming receipt of the request. The notification will document that the applicant complied with this aspect of the regulations.

Please recognize that some of the radioactive material that fall under the newly expanded definition of byproduct materials may already be authorized on an existing NRC license, since the term "byproduct materials" will include the new NARM material. 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 10 CFR Part 35 (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, please review your current NRC materials license (e.g., source manufacturers and model numbers, possession limits, locations, authorized individuals) carefully to ensure it covers your possession, use and/or storage of the new byproduct material. Please contact your respective NRC regional office if you have questions about amending your NRC license.

Individuals who possess/use the new byproduct material within the NRC's regulatory jurisdiction, and in quantities that require a general license, should refer to the NRC regulations in 10 CFR Part 31 to determine whether the new byproduct materials that they possess/use are regulated by the NRC as a generally licensed device. If the byproduct material is regulated by

the NRC as a generally licensed device, then upon waiver termination the individual will need to follow registration and/or reporting requirements contained in the final regulations.

The approach used for the selection of the States and U.S. Territories for the initial phase of waiver terminations considered (1) the scope of the State's current 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 NRC has not established the timing and schedule for waiver terminations for the remainder of the non-Agreement States and U.S. Territories. However, the NRC intends to use the same selection approach for the remaining States and U.S. Territories. The NRC also plans to terminate the waiver for non-Agreement States that enter into an agreement with the NRC under Section 274b of the AEA, coincident with the effective date of such an agreement. A notice in the *Federal Register* will be published approximately 6 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.

In conjunction with the effective date of the final rule, the Commission intends to terminate the waiver for all 34 Agreement States that provided a certification from their Governor to the Commission. These certifications document that the respective States have 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 its authority with respect to the new byproduct material. Upon acceptance of the certification by the Commission and termination of the waiver, as described in Section 651(e) of the EPAct, the State's Agreement will be considered to include AEA 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 the regulation of these materials.

Transition Plan

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 http://www.nrc.gov/reading-rm/adams.html ; 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, which will not be substantively changed from the draft transition plan, will occur before the effective date of the final regulations.

Associated Supportive Activities

The 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.

Information on NARM-related activities is also available in 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. Also, enclosed with this RIS is a list of recently issued generic communications.

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

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 contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget, approval number 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. §§ 801-886) and, therefore, is not subject to the 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.

/RA/

Janet R. Schlueter, Director
Division of Materials Safety
and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Technical Contacts:

Duane E. White, FSME
(301) 415-6272
E-mail: dew2@nrc.gov

Kim K. Lukes, FSME
(301) 415-6701
E-mail: kxk2@nrc.gov

Rachel S. Browder, Region IV
(817) 276-6552
E-mail: rsb3@nrc.gov

Donna M. Janda, Region I
(610) 337-5371
E-mail: dmj@nrc.gov

Kevin G. Null, Region III
(630) 829-9854
E-mail: kgn@nrc.gov

Enclosure:
Recently Issued FSME/NMSS Generic Communications

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E-mail: dew2@nrc.gov

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(301) 415-6701
E-mail: kxk2@nrc.gov

Rachel S. Browder, Region IV
(817) 276-6552
E-mail: rsb3@nrc.gov

Donna M. Janda, Region I
(610) 337-5371
E-mail: dmj@nrc.gov

Kevin G. Null, Region III
(630) 829-9854
E-mail: kgn@nrc.gov

Enclosure:
Recently Issued FSME/NMSS Generic Communications

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OFC	FSME/DMSSA	FSME/ DMSSA	FSME/ DMSSA	Tech Ed	FSME/ DMSSA	OGC-NLO
NAME	DEWhite	ANMauer	ARMcIntosh	HChang	ADWhite	FXCameron
DATE	5/17/2007	5/17/2007	5/22/2007	5/22/2007	5/22/2007	6/04/2007

OFC	OGC-CRA	OIS	FSME/DILR	FSME/ DMSSA	FSME/ DMSSA
NAME	TRothschild	TDonnell	DKRathbun	SWMoore	JRSchlueter
DATE	6/04/2007	10/10 /07	5/22/2007	7/10/2007	9/07/2007

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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 medical use licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
02/28/07	IN-07-08	Potential Vulnerabilities of Time-reliant Computer-based Systems Due to Change in Daylight Saving Time Dates	All U. S. Nuclear Regulatory Commission licensees and all Agreement State Radiation Control Program Directors and State Liaison Officers
03/13/07	IN-07-10	Yttrium-90 Theraspheres® and Sirspheres® Impurities	All U.S. Nuclear Regulatory Commission (NRC) Medical Licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers
04/04/07	IN-07-13	Use of As-Found Conditions to Evaluate Criticality-related Process Upsets at Fuel Cycle Facilities	All licensees authorized to possess a critical mass of special nuclear material.
05/02/07	IN-07-16	Common Violations of the Increased Controls Requirements and Related Guidance Documents	All licensees who are implementing the U.S. Nuclear Regulatory Commission (NRC) Order Imposing Increased Controls (EA-05-090), issued November 14, 2005 and December 22, 2005
05/21/07	IN-07-19	Fire Protection Equipment Recalls and Counterfeit Notices	All holders of operating licenses for nuclear power reactors and fuel cycle facilities; except those licensees for reactors that have permanently ceased operations and who have certified that fuel has been permanently removed from the reactor vessel; and except those licensees for decommissioned fuel cycle facilities
06/11/07	IN-07-20	Use of Blank Ammunition	All power reactors, Category I fuel cycle facilities, independent spent fuel storage installations, conversion facility, and gaseous diffusion plants

Date	GC No	Subject	Addressees
07/19/07	IN-07-25	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	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.
08/08/07	IN-07-23	Inadvertent Discharge of Halon 1301Fire-suppression System from Incorrect and/or Out-of-date Procedures	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
08/13/07	IN-07-26	Combustibility of Epoxy Floor Coatings at Commercial Nuclear Power Plants	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.
09/13/07	IN-07-30	Radiological Controls Create Criticality Safety Accident Scenario for Fissile Solution Container Transport at Fuel Cycle Facility	All licensees authorized to possess a critical mass of special nuclear material.
03/01/07	RIS-07-03	Ionizing Radiation Warning Symbol	All U.S. Nuclear Regulatory Commission licensees and certificate holders. All Radiation Control Program Directors and State Liaison Officers
03/09/07	RIS-07-04	Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission	All holders of operating licenses for nuclear power reactors and holders of and applicants for certificates for reactor designs. All licensees, certificate holders, applicants, and other entities subject to regulation by the U.S. Nuclear Regulatory Commission (NRC) of the use of source, byproduct, and special nuclear material
03/20/07	RIS-07-05	Status and Plans for Implementation of NRC Regulatory Authority for Certain Naturally-occurring and Accelerator-produced Radioactive Material	All NRC materials licensees, Radiation Control Program Directors, State Liaison Officers, and NRC's Advisory Committee on the Medical Uses of Isotopes
04/05/07	RIS-07-07	Clarification of Increased Controls for Licensees That Possess Collocated Radioactive Material During Transportation Activities	All U.S. Nuclear Regulatory Commission (NRC) licensees issued NRC's Order Imposing Increased Controls and all Radiation Control Program Directors and State Liaison Officers

Date	GC No.	Subject	Addressees
05/04/07	RIS-07-09	Examples of Recurring Requests for Additional Information (RAIs) for 10 CFR Part 71 and 72 Applications	All holders of, and applicants for, a: (1) 10 CFR Part 71 certificate of compliance (CoC) for a radioactive material transportation package; (2) 10 CFR Part 72 CoC for a spent fuel storage cask; and (3) 10 CFR Part 72 specific license for an independent spent fuel storage installation (ISFSI)
06/27/07	RIS-06-27, Suppl. 1	Availability of NRC 313A Series of Forms and Guidance for Their Completion	All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC Master Materials licensees. All Radiation Control Program Directors and State Liaison Officers
05/15/07	RIS-07-10	Subscriptions To New List Server For Automatic Notifications Of Medical-Related Generic Communications, *Federal Register* Notices And Newsletters	All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC Master Materials licensees. All Radiation Control Program Directors and State Liaison Officers
08/31/07	RIS-07-13	Verification of the Authenticity of Materials Possession Licenses	All U.S. Nuclear Regulatory Commission materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers
09/07/07	RIS-07-18	Data for Updating the Interim Inventory of Radioactive Sources	All U.S. Nuclear Regulatory Commission (NRC) 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" (as defined below) activity or higher

Note: A full listing of generic communications may be viewed at the NRC public website at the following address: http://www.nrc.gov/Electronic Reading Room/Document Collections/Generic Communications.