October 20, 2005

TO: Stakeholders Impacted by NRC Regulation of Naturally Occurring and Accelerator Produced Radioactive Materials

SUBJECT: PUBLIC MEETING ON RULEMAKING TO ESTABLISH A REGULATORY FRAMEWORK FOR THE EXPANDED DEFINITION OF BYPRODUCT MATERIAL ESTABLISHED BY THE ENERGY POLICY ACT OF 2005

On August 8, 2005, the President signed the Energy Policy Act of 2005 (the Act). Section 651(e) of the Act expanded the definition of byproduct material in Section 11e. of the Atomic Energy Act of 1954 to include certain naturally occurring and accelerator produced radioactive materials (NARM) and required the U.S. Nuclear Regulatory Commission (NRC) to provide a regulatory framework for licensing and regulating the additional byproduct material. NRC is initiating a rulemaking to incorporate NARM into the Code of Federal Regulations.

On November 9, 2005, the NRC will host a public meeting with a "roundtable" format to allow stakeholders an opportunity to discuss concerns and interact with other interested parties on the subject of NRC regulation of NARM. The meeting will take place from 9:00 AM to 4:00 PM EST in Room T-2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, MD. The NRC is asking those planning to attend the meeting to preregister by contacting Jayne McCausland, (301) 415-6219, fax (301) 415-5369, or e-mail jmm2@nrc.gov. You may also register the day of the meeting beginning at 8:30 AM. Please allow time for NRC's security check-in procedures on the day of the meeting. If an attendee will require special services, such as services for the hearing impaired, please notify Ms. McCausland of these requirements when preregistering. Individuals unable to attend the meeting will be able to listen via teleconference. For teleconference information, please contact Ms. McCausland.

The format for this public meeting will be a "roundtable" format. Participants at the roundtable will be the invited representatives of the broad spectrum of interests who may be affected by this rulemaking. The roundtable format is being used for this meeting to promote a dialogue among the representatives at the table on the issues of concern. Although the focus of the discussion will be on the invited participants at the table, an opportunity will be provided for comment and questions from the audience. Questions on the meeting format, including participation in the roundtable, should be directed to the meeting facilitator, Francis "Chip" Cameron. Mr. Cameron can be reached at (301) 415-1642 or via e-mail fxc@nrc.gov.

The NRC staff is in the process of developing a notice of this public meeting which will be published soon in the Federal Register. The meeting notice and a meeting agenda will be posted on the NRC web site at: http://www.nrc.gov/public-involve/public-meetings/index.cfm.

Sincerely,

/RA/

Charles L. Miller, Director
Division of Industrial and
Medical Safety
Office of Nuclear Material Safety
and Safeguards

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NRC PUBLIC MEETING
AGENDA

RULEMAKING TO ESTABLISH A REGULATORY FRAMEWORK FOR THE EXPANDED DEFINITION OF BYPRODUCT MATERIAL ESTABLISHED BY THE ENERGY POLICY ACT

November 9, 2005
NRC Headquarters, Room T-2B3
Two White Flint North
11545 Rockville Pike
Rockville, MD

9:00 a.m.	Meeting format, ground rules, agenda, introductions Francis “Chip” Cameron, Facilitator
9:15 a.m.	Rulemaking background and schedule Leslie Kerr, NRC
	NMSS Energy Policy Act Task Force Douglas Broaddus, NRC
9:45 a.m.	Overarching issues:
	The role of State regulations as the starting point for NRC regulations
	Roundtable discussion
	Radiopharmaceutical implications -Availability to patients and physicians -Diagnostic and therapeutic applications -Other issues
	Roundtable discussion
10:45 a.m.	**BREAK**
11:00 a.m.	How to define “discrete source”; discrete sources of NORM in addition to radium-226
	Roundtable discussion
12:00 p.m.	**LUNCH**
1:15 p.m.	The point at which accelerator-produced material should come under NRC jurisdiction
	Roundtable discussion

2:00 p.m.	Waste disposal and transportation
	Roundtable discussion
2:45 p.m.	**BREAK**
3:00 p.m.	Other issues and wrap up
4:00 p.m.	Adjourn

Section 651 (e) of the Energy Policy Act of 2005

(e) TREATMENT OF ACCELERATOR-PRODUCED AND OTHER RADIOACTIVE MATERIAL AS BYPRODUCT MATERIAL.—

(1) DEFINITION OF BYPRODUCT MATERIAL.—Section 11 e. of the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)) is amended—

(A) by striking "means (1) any radioactive" and inserting the following: "means—

"(1) any radioactive".

(B) by striking "material, and (2) the tailings" and inserting the following: "material;

"(2) the tailings".

(C) by striking "content." and inserting the following: "content;

"(3)(A) any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after

the date of enactment of this paragraph for use for a commercial, medical, or research activity; or

"(B) any material that—

"(i) has been made radioactive by use of a particle accelerator; and

"(ii) is produced, extracted, or converted after extraction, before, on, or after the date of enactment of this paragraph for use for a commercial, medical, or research activity; and

"(4) any discrete source of naturally occurring radioactive material, other than source material, that—

"(A) the Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, 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

"(B) before, on, or after the date of enactment of this paragraph is extracted or converted after extraction for use in a commercial, medical, or research activity.".

(2) AGREEMENTS WITH GOVERNORS.—Section 274 b. of the Atomic Energy Act of 1954 (42 U.S.C. 2021(b)) is amended by striking "State—" and all that follows through paragraph (4) and inserting the following: "State:

"(1) Byproduct materials (as defined in section 11 e.).

"(2) Source materials.

"(3) Special nuclear materials in quantities not sufficient to form a critical mass.".

(3) WASTE DISPOSAL.—

(A) DOMESTIC DISTRIBUTION.—Section 81 of the Atomic Energy Act of 1954 (42 U.S.C. 2111) is amended—

(i) by striking "No person may" and inserting the following:

"a. IN GENERAL.—No person may".

(ii) by adding at the end the following:

"b. REQUIREMENTS.—

"(1) IN GENERAL.—Except as provided in paragraph (2), byproduct material, as defined in paragraphs (3) and (4) of section 11 e., may only be transferred to and disposed of in a disposal facility that—

"(A) is adequate to protect public health and safety; and

"(B)(i) is licensed by the Commission; or

"(ii) is licensed by a State that has entered into an agreement with the Commission under section 274 b., if the licensing requirements of the State are compatible with the licensing requirements of the Commission.

"(2) EFFECT OF SUBSECTION.—Nothing in this subsection affects the authority of any entity to dispose of byproduct material, as defined in paragraphs (3) and (4) of section 11 e., at a disposal facility in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.).

"c. TREATMENT AS LOW-LEVEL RADIOACTIVE WASTE.—Byproduct material, as defined in paragraphs (3) and (4) of section 11 e.,

disposed of under this section shall not be considered to be low-level radioactive waste for the purposes of—

"(1) section 2 of the Low-Level Radioactive Waste Policy Act (42 U.S.C. 2021b); or

"(2) carrying out a compact that is—

"(A) entered into in accordance with that Act (42 U.S.C. 2021b et seq.); and

"(B) approved by Congress.".

(B) DEFINITION OF LOW-LEVEL RADIOACTIVE WASTE.—Section 2(9) of the Low-Level Radioactive Waste Policy Act (42 U.S.C. 2021b(9)) is amended—

(i) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and indenting the clauses appropriately;

(ii) in the matter preceding clause (i) (as redesignated by subparagraph (A)) by striking "The term" and inserting the following:

"(A) IN GENERAL.—The term"; and

(iii) by adding at the end the following:

"(B) EXCLUSION.—The term 'low-level radioactive waste' does not include byproduct material (as defined in paragraphs (3) and (4) of section 11 e. of the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)).".

(4) FINAL REGULATIONS.—

(A) REGULATIONS.—

(i) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Commission, after consultation with States and other stakeholders, shall issue final regulations establishing such requirements as the Commission determines to be necessary to carry out this section and the amendments made by this section.

(ii) INCLUSIONS.—The regulations shall include a definition of the term "discrete source" for purposes of paragraphs (3) and (4) of section 11 e. of the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)) (as amended by paragraph (1)).

(B) COOPERATION.—In promulgating regulations under paragraph (1), the Commission shall, to the maximum extent practicable—

(i) cooperate with States; and

(ii) use model State standards in existence on the date of enactment of this Act.

(C) TRANSITION PLAN.—

(i) DEFINITION OF BYPRODUCT MATERIAL.—In this paragraph, the term "byproduct material" has the meaning given the term in paragraphs (3) and (4) of section 11 e. of the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)) (as amended by paragraph (1)).

(ii) PREPARATION AND PUBLICATION.—To facilitate an orderly transition of regulatory authority with respect to byproduct material, the Commission, in issuing regulations under subparagraph (A), shall prepare and publish a transition plan for—

(I) States that have not, before the date on which the plan is published, entered into an agreement with the Commission under section 274 b.

of the Atomic Energy Act of 1954 (42 U.S.C. 2021(b)); and

(II) States that have entered into an agreement with the Commission under that section before the date on which the plan is published.

(iii) INCLUSIONS.—The transition plan under clause (ii) shall include—

(I) a description of the conditions under which a State may exercise authority over byproduct material; and

(II) a statement of the Commission that any agreement covering byproduct material, as defined in paragraph (1) or (2) of section 11e. of the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)), entered into between the Commission and a State under section 274 b. of that Act (42 U.S.C. 2021(b)) before the date of publication of the transition plan shall be considered to include byproduct material, as defined in paragraph (3) or (4) of section 11e. of that Act (42 U.S.C. 2014(e)) (as amended by paragraph (1)), if the Governor of the State certifies to the Commission on the date of publication of the transition plan that—

(aa) the 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, that is adequate to protect the public health and safety, as determined by the Commission; and

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

(D) AVAILABILITY OF RADIOPHARMACEUTICALS.—In promulgating regulations under subparagraph (A), the Commission shall consider the impact on the availability of radiopharmaceuticals to—

(i) physicians; and

(ii) patients the medical treatment of which relies on radiopharmaceuticals.

(5) WAIVERS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Commission may grant a waiver to any entity of any requirement under this section or an amendment made by this section with respect to a matter relating to byproduct material (as defined in paragraphs (3) and (4) of section 11 e. of the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)) (as amended by paragraph (1))) if the Commission determines that the waiver is in accordance with the protection of the public health and safety and the promotion of the common defense and security.

(B) EXCEPTIONS.—

(i) IN GENERAL.—The Commission may not grant a waiver under subparagraph (A) with respect to—

(I) any requirement under the amendments made by subsection (c)(1);

(II) a matter relating to an importation into, or exportation from, the United States for a period

ending after the date that is 1 year after the date of enactment of this Act; or

(III) any other matter for a period ending after the date that is 4 years after the date of enactment of this Act.

(ii) WAIVERS TO STATES.—The Commission shall terminate any waiver granted to a State under subparagraph (A) if the Commission determines that—

(I) the State has entered into an agreement with the Commission under section 274 b. of the Atomic Energy Act of 1954 (42 U.S.C. 2021(b));

(II) the agreement described in subclause (I) covers byproduct material (as described in paragraph (3) or (4) of section 11 e. of the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)) (as amended by paragraph (1))); and

(III) the program of the State for licensing such byproduct material is adequate to protect the public health and safety.

(C) PUBLICATION.—The Commission shall publish in the Federal Register a notice of any waiver granted under this subsection.