

POLICY ISSUE NOTATION VOTE

September 11, 2006

SECY-06-0195

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: TRANSITION PLAN FOR THE REGULATION OF CERTAIN
BYPRODUCT MATERIALS MANDATED BY THE ENERGY POLICY ACT
OF 2005

PURPOSE:

To request Commission approval of the approach outlined in the transition plan for the regulation of certain byproduct materials required by the Energy Policy Act of 2005 (EPAAct), including the criteria to be used to determine if Agreement State programs authorized to license byproduct material, as defined in paragraph (3) or (4) of section 11e. of the Atomic Energy Act of 1954, as amended (AEAct), are adequate to protect public health and safety. The staff also requests Commission approval to request State comment on the draft transition plan. This paper does not address any new commitments.

SUMMARY:

The staff has prepared a proposed plan to facilitate an orderly transition of regulatory authority (transition plan) with respect to certain naturally occurring and accelerator produced radioactive materials (NARM), now included in the definition of byproduct material in section 11e. of the AEAct. Preparation and publication by the Commission of a transition plan is required by section 651(e) of the EPAAct. The proposed transition plan addresses the potential scenarios

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that may result in a transition of authority between the U.S. Nuclear Regulatory Commission (NRC) and the States, the conditions under which a State may exercise regulatory authority over the newly defined byproduct material, and the proposed basis for the Commission to use in determining the adequacy of a State's program for licensing the newly defined byproduct material.

The staff proposes an approach for finalizing the proposed transition plan that includes early review and comment by the States. The staff's proposed approach also addresses several issues associated with the date of publication of the transition plan, and the timing of Governors' certifications provided by section 651(e) of the EAct.

The resources necessary to implement the staff's proposed approach for finalizing and publishing the transition plan are currently included in the Fiscal Year (FY) 2006 and 2007 budgets. The staff recommends that the Commission approve the staff's approach for finalizing and publishing the transition plan, and the proposed basis for the Commission to determine adequacy for the States' programs for licensing the newly defined byproduct material.

BACKGROUND:

As discussed in SECY-06-0069, "Proposed Rule: Requirements for Expanded Definition of Byproduct Material," section 651(e) of the EAct expanded the definition of byproduct material, as defined in section 11e. of the AAct, to include certain discrete sources of radium, certain accelerator-produced radioactive material, and certain discrete sources of naturally occurring radioactive material (the new byproduct material), thereby, placing these materials under NRC jurisdiction. Section 651(e)(4)(C) of the EAct (Enclosure 1) requires that, in issuing regulations for the expanded definition of byproduct material, the Commission prepare and publish a plan to facilitate an orderly transition of regulatory authority with respect to the new byproduct material.

The EAct requires that the transition plan address both Agreement and non-Agreement States (including U.S. Territories and the District of Columbia) and include a description of the conditions under which a State may exercise regulatory authority over the new byproduct material. The transition plan must also include a statement of the Commission that any agreement between the Commission and a State under section 274b. of the AAct, covering byproduct material and entered into before the date of publication of the transition plan, shall be considered to include the new byproduct material, provided the Governor of the State certifies to the Commission on the date of the publication of the transition plan that: (1) the State has a program for licensing the newly defined byproduct material, 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. (Hereafter, this will be referred to as "the Governor's certification.") Currently, 34 States have an Agreement with the Commission, under section 274b. of the AAct, covering byproduct material.

Section 651(e)(5) of the EAct authorizes the Commission to issue waivers of the requirements of section 651(e), and requires the Commission to subsequently terminate any such waiver issued to a State, on determining that: 1) the State has entered into an Agreement with the Commission under section 274b. of the AAct; 2) the Agreement covers the new byproduct material; and 3) the State's program for licensing such byproduct material is adequate to protect the public health and safety. The Commission issued such a waiver to States and persons

using the new byproduct material on August 31, 2005 (70 FR 51581).

DISCUSSION:

In coordination with Agreement and non-Agreement State representatives, the staff has prepared a draft transition plan (Enclosure 2) in response to the requirements discussed above. The transition plan describes the proposed process for an orderly transition of authority for Agreement States and non-Agreement States, under likely and potential scenarios the staff has identified.

Development of the Transition Plan

In developing the draft transition plan, the staff evaluated the circumstances under which a transition of regulatory authority could occur, and identified several key issues that needed to be addressed in these scenarios. Five unique scenarios were identified as covering the range of likely or potential transition situations. These scenarios are addressed in the draft transition plan and are as follows:

1. Agreement States that plan to continue to regulate the new byproduct material and provide a Governor's Certification as described in section 651(e)(4)(C)(iii)(II) of the EPAct;
2. Agreement States that plan to regulate the new byproduct material, but do not provide a Governor's Certification;
3. Agreement States that do not plan to continue to regulate the new byproduct material;
4. non-Agreement States that plan to continue to regulate the new byproduct material and request a 274b. Agreement; and
5. non-Agreement States that do not plan to continue to regulate the new byproduct material.

In evaluating the applicable requirements of the EPAct and potential transition scenarios, the staff identified the following key issues: 1) the extent to which stakeholder comments should be solicited on the transition plan; 2) obstacles that may preclude obtaining the Governor's certification of adequacy from all 34 Agreement State Governors *on the date of publication of the transition plan*; 3) the timing for publication of the transition plan; and 4) the basis for the Commission to determine adequacy in reviewing Governors' certifications. The staff's resolution and/or proposed approach for addressing each of these issues is described below.

Stakeholder Review and Comment

The EPAct requires that the Commission publish the transition plan in issuing the final regulations, but does not require that the plan be published for comment. Recognizing the potential significant implications of the transition plan for the States, the staff proposes to request early State review and comment on the draft transition plan. This will also provide the States with advance notice of the proposed transition process, and certain time-sensitive issues in the transition plan described later in this paper, before the effective date of the final rule implementing the expanded definition of byproduct material (the NARM final rule). After consideration of comments from the States, the staff will finalize the transition plan, and determine the timing for publication of the plan in the *Federal Register*. If the comments result

in the need for substantial revision to the transition plan, or indicate the need to address policy issues, the staff will provide the Commission with its proposed resolution of the comments, and issues, and a proposed final version of the transition plan for approval. The date the final transition plan is published in the *Federal Register* is important because the Governor's certification and other transition actions depend on the date of publication (see "Transition of Authority in States that have entered into Agreements with the Commission," under Section 274b of the AEAct). Therefore, the staff proposes that the final version of the transition plan be provided to the States before it is published in the *Federal Register*. This will ensure that the States are aware of any changes incorporated in the final version of the transition plan before it is published, and allow States to make any needed planning adjustments for the time-sensitive actions in the plan.

The staff proposes not to publish the transition plan for public comment for the following reasons: 1) the key concepts of the transition plan are already described in the *Federal Register* notice (FRN) for the proposed rulemaking on the "Expanded Definition of Byproduct Material"; 2) the information applicable to other stakeholders in the draft transition plan is consistent with the information in the FRN for the proposed rule; 3) interested persons can provide comments on the transition plan in response to the proposed rule FRN; and 4) any comments received on the transition plan in response to the proposed rule FRN will be considered along with any State comments received when preparing the proposed final transition plan. However, the staff proposes that this paper, and its enclosures, be made publicly available in accordance with current NRC policy and practice.

Communication Plan

The staff is developing a communication plan to assure consistent dispatch of accurate information and key messages concerning the transitions of authority. In addition to the Agreement and non-Agreement States, the staff plans to communicate and coordinate with other government entities, such as U.S. Territories and possessions, the District of Columbia, and Indian tribes, that may be affected by or interested in the activities described in the Transition Plan. The staff will also work with these entities to identify users of the new byproduct material within their jurisdictions.

Transition of Authority in States That Have Entered into Agreements with the Commission under Section 274b. of the AEAct

Agreement States That Plan to Continue to Regulate the New Byproduct Material

The EPAAct provides two ways that an Agreement State may include the new byproduct material in its AEAct section 274b. Agreement: 1) the Governor of the State provides the certification described in section 651(e)(4)(C)(iii)(II) of the EPAAct; or 2) the Governor requests an amendment to the State's Agreement, as provided for in section 274 of the AEAct.

The Governor's certification described in section 651(e)(4)(C)(iii)(II) of the EPAAct avoids the need to amend the State's Agreement in accordance with the requirements of section 274 of the AEAct. However, if a Governor chooses not to either provide the certification or request an amendment to the State's Agreement, NRC must assert its authority to regulate the new byproduct material in the State.

Timing of the Governor's Certification and Publication of the Transition Plan

Section 651(e)(4)(C)(iii)(II) of the EAct provides that “the Governor of the State certify to the Commission on the date of publication of the transition plan...” This phrase “on the date of publication ” has presented several challenges to the staff in developing the draft transition plan. First, the Agreement State representatives advise, and the NRC staff agrees, that arranging for all 34 Agreement State Governors to make their certifications on the day the transition plan is published would be extremely difficult, if not impossible, and impose an undue burden on the Agreement States and NRC. Second, it is unlikely that the specific date the transition plan will be published could be provided to the Agreement States in advance, because the staff of the *Federal Register* may not be able to provide a guaranteed date of publication. Third, the staff is aware that gubernatorial elections will be held in 27 of the 34 Agreement States this November, which will make preplanning for the Governor's certification very difficult for any State that will have an administration change.

To provide adequate opportunity for Agreement States to prepare and provide the Governor's certification, the staff recommends that the Commission provide flexibility in the process and timing for Governors to submit their certifications, as follows: 1) allow the Governor's certification to be provided in advance of, and effective on, the date of publication of the transition plan; and 2) allow flexibility as to the date of publication of the transition plan. To be consistent with the applicable language in the EAct, a Governor's certification provided before the publication of the transition plan must include a statement that the certification is effective on the date of publication of the transition plan. To provide the maximum opportunity for States to alleviate potential scheduling problems, the staff recommends that the Commission allow Agreement States to begin submitting Governors' certifications anytime after the draft transition plan is provided to the States for comment. Staff plans to work with the Agreement States to facilitate the process by developing a sample certification letter which the Governors could use to provide the necessary information to the Commission. Flexibility for the date of publication of the transition plan would also provide additional time for Agreement State programs to coordinate the certification with the Governor's office in a State where an administration change occurs, and would allow NRC to adjust the date of publication to allow a State, with an unforeseen delay in obtaining the Governor's certification, additional time to obtain the certification before the plan is published.

The EAct does not specify a date the transition plan must be published, but requires that it be published, “in issuing the final regulations,” for the new byproduct material. The staff is not proposing a specific date for publication of the transition plan at this time, but expects that the transition plan will be published between the date the NARM final rule is published and the date the rule becomes effective. Publishing the transition plan outside this date range has several drawbacks. A publication date before the NARM final rule is published would not allow States an opportunity to consider changes made in the final rule before the Governor makes the certification of adequacy. A publication date after the effective date of the NARM final rule would result in the transition plan being published after the initial transition of authority for Government agencies and federally recognized Indian tribes (the proposed NARM rule provides that Government agencies and federally recognized Indian tribes would be subject to the new requirements on the date the rule becomes effective). In addition, the effectiveness of the “phased approach” for waiver terminations, described in the draft transition plan, would be reduced if the plan is published after the effective date of the NARM final rule. Specifically, either the time available for prior notification of waiver terminations would need to be reduced or

the number of waiver termination phases would need to be reduced, with greater reductions occurring the longer publication of the transition plan is deferred. Providing additional flexibility to allow Governors' certifications earlier should reduce, and may eliminate the potential need to publish the final transition plan after the effective date of the rule.

Basis for Determining Adequacy in Reviewing Governor Certifications

The EAct provides that the Governor certify that, "The State has a program for licensing the newly covered byproduct material that is adequate to protect the public health and safety, as *determined by the Commission...*" (emphasis added). However, the EAct does not specify criteria for the Commission to use in determining whether an Agreement State's program for licensing the new byproduct material is adequate, nor does it specify the process by which the criteria should be applied.

The staff proposes to use the criteria in NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program" (IMPEP), as the basis for determining adequacy of the Agreement States' programs to license the new byproduct material. This approach will allow the staff to use existing adequacy criteria, which are currently used to evaluate the performance of both Agreement State and Regional licensing programs. This approach has the added advantage that the criteria are already familiar to the staff and Agreement States. The staff further proposes basing the determination of adequacy on the results of prior IMPEP reviews of the Agreement States' programs.

The staff notes that before the EAct, IMPEP did not specifically evaluate Agreement States' programs for licensing NARM. However, based on its interactions with the States, the staff understands and has been informed that all the Agreement States license NARM and AAct materials, without distinction, as "radioactive material." That is, each Agreement State has one program for licensing radioactive materials that does not distinguish between NARM and section 11e.(1) byproduct material. On this basis, the staff believes that previous IMPEP reviews of Agreement States' programs for licensing 11e.(1) byproduct material have, in effect, also evaluated the States' programs with regard to their adequacy for licensing the new byproduct material.

Under this approach, the determination of adequacy based on prior IMPEP findings would require that the Governor's certification be supported by a confirmation that: 1) the State's program for licensing the new byproduct material is the same as its program for licensing 11e.(1) byproduct material; 2) the State intends to continue to license the new byproduct material under its existing licensing program; and 3) no changes have been made to the State's licensing program that would impact the previous IMPEP finding of adequacy. The supporting confirmation could be provided either with the Governor's certification, or separately by the State radiation control program. Either way, this confirmation forms the basis for a determination of adequacy, based on prior IMPEP findings.

Upon receiving a Governor's certification, the staff will review the findings of the Management Review Board (MRB) from the last IMPEP review, to confirm that the State's program for licensing section 11e.(1) byproduct material was found adequate. If such a finding was made, the staff will recommend that the Governor's certification be accepted if it includes the information required by the EAct, and is supported by the confirmations described above.

In cases where a new Agreement State has not yet had an IMPEP review, a State is unable to provide the supporting confirmations, or a State has an MRB finding of "Adequate but Needs Improvement," the staff would evaluate the State's program on a case-by-case basis, using the IMPEP criteria for adequacy. For State's with an MRB finding of "Adequate but Needs Improvement," the staff will consider the impact of the areas needing improvement on the State's Program for regulating NARM.

The staff believes that this approach will provide a sufficient basis for determining the adequacy of an Agreement State's program for licensing the new byproduct material. Additionally, the State's performance in licensing all byproduct material will be formally evaluated during subsequent IMPEP reviews. The Office of State and Tribal Programs (STP) is revising the IMPEP procedures to incorporate review of the State's program for licensing the new byproduct material during future IMPEP reviews.

Agreement States That Elect Not to Include the New Byproduct Material in Their 274 b. Agreements

The staff has interacted with the States and has received an indication that all Agreement States plan to continue to regulate the new byproduct material. However, for completeness, the transition plan includes a provision to cover the situation in which an Agreement State elects not to regulate the new byproduct material. If such a situation occurs, the plan provides that the staff will work with the State to determine the date on which the regulatory authority of the State will end, which can be no later than August 8, 2009. The staff proposes to follow the same approach for the transition of authority in this situation as is described below for non-Agreement States that do not request an Agreement.

Transition of Authority for Non-Agreement States

A non-Agreement State has the option to request an Agreement with the Commission, under section 274b. of the AEAct, for authority to regulate only the new byproduct material. Any State that, on August 8, 2009, does not have such an Agreement, must discontinue its regulatory authority over the new byproduct material.

Non-Agreement States That Request Agreements

Any request from a State to enter into a 274b. Agreement covering the new byproduct material, before August 8, 2009, (i.e., the date that the time-limited waiver must expire), will be reviewed in accordance with the STP procedure SA-700, "Processing an Agreement." Every effort will be made to complete an Agreement as soon as practical, without compromising quality and completeness. The staff understands that situations may arise which may delay the completion and effective date of an Agreement. If an Agreement cannot be completed for a State before the waiver expires on August 8, 2009, the staff will determine, on a case-by-case basis, options to limit the impact of the transition of authority on affected users of the new byproduct material in the State.

Non-Agreement States That do Not Request Agreements

To facilitate an orderly transition of regulatory authority for non-Agreement States that do not intend to establish section 274b. Agreements with the Commission before August 8, 2009, the

draft transition plan provides for terminating the waiver for such States, and all individuals in such States, before August 8, 2009. As indicated in SECY-06-0069, the staff proposes a phased approach for earlier waiver terminations, to prevent abrupt transitions of authority on the date the waiver expires. This would allow for an orderly transition to NRC of users of the new byproduct material in such States; allow the staff to consider the extent to which regulatory oversight for the new byproduct material is provided by the various States when determining the timing for waiver terminations; and would spread out the resource impact on the NRC staff for licensing and inspection of the new licensees or existing NRC licensees that possess/use the new byproduct material.

Consistent with the approach proposed for Government agencies and federally recognized Indian tribes in the proposed NARM rule, the draft transition plan provides that other users could also continue to use the new byproduct material without NRC-issued licenses covering the material after the rule becomes effective on termination of the waiver, if they: 1) comply with the new NRC rules applicable to the material; and 2) apply for new licenses or license amendments for the new byproduct material within the specified time frames. The staff proposes to use a variety of means to ensure that users of the material are aware of the transitions of authority, including publication of a "Notification of Waiver Termination and Implementation Dates of Rule."

The staff, in coordination with the State, and considering the extent to which regulatory oversight for the new byproduct material is provided by the State, will determine the timing for the discontinuance of the State's regulatory authority for the material. Waiver terminations will be executed for groups of States at periodic intervals occurring between the effective date of the rule and August 8, 2008, (i.e., 12 months before the end of the waiver period). This approach provides flexibility for the timing of transitions, and will allow the staff to work with the States to ensure that affected users are notified of the transitions, and ensures that all users are provided sufficient time to apply for new licenses or license amendments, as applicable.

Transition of Exempt Distribution Licenses

The staff understands that there are a limited number of Agreement State licenses that authorize the distribution of NARM whose subsequent possession, use, transfer, and disposal by all other persons are exempted from licensing and regulatory requirements. These licenses, insofar as they authorize the exempt distribution of 11e.(3) materials, will transfer to NRC, as required by 10 CFR 150.15(a)(6). The specifics of such transfers will be addressed directly with the involved States, on a case-by-case basis. In the future, only NRC will issue licenses for the distribution of 11e.(3) and 11e.(4) products that contain the new byproduct material to persons who are exempt from licensing and regulatory requirements.

Transition of Sealed Source or Device Registrations

All States currently have the authority to evaluate and issue registration certificates on the radiation safety of sealed sources or devices (SSDs) containing NARM. Most Agreement States' section 274b. Agreements provide for the Commission to discontinue its authority for the evaluation of SSDs containing byproduct materials. An Agreement State, whose section 274b. Agreement includes the new byproduct material and involves SSD authority, will retain its authority and responsibility for SSDs containing the new byproduct material. For non-Agreement States, and Agreement States whose 274b. Agreements do not include SSD authority, the staff proposes to transfer existing SSD registration certificates to NRC, on termination of the waiver for the States. Initially, the staff will review the SSD registration certificates only to determine if they provide sufficient information for licensing the use of the SSDs. The staff will perform complete reviews of the SSDs and supporting documentation during subsequent amendment requests, or any time potential safety concerns are identified for the SSDs.

Government Agencies and Federally Recognized Indian Tribes

Under the AEAct, byproduct material licenses for Government agencies and federally recognized Indian tribes are issued by the Commission. For completeness, the proposed draft transition plan also addresses the transition of authority for Government agencies and federally recognized Indian tribes that wish to continue to use the new byproduct materials after the effective date of the NARM final rule. As discussed in the proposed NARM rule, since there is currently limited regulatory oversight for the newly added byproduct material at government agencies and federally recognized Indian tribe facilities, the staff will terminate the waiver for these facilities on the effective date of the rule. However, a transitional period for them to submit a license amendment or application will be provided.

RECOMMENDATIONS:

That the Commission:

1. Approve the staff's proposed approach for developing and publishing the transition plan, as described herein. To provide Agreement States, in which gubernatorial elections will occur, an opportunity to coordinate certifications with the current Governors before the elections, the staff requests the Commission expedite its review of this paper and draft transition plan, and provide a final Staff Requirements Memorandum by September 22, 2006.
2. Approve the staff's use of the criteria in Management Directive 5.6, "Integrated Materials Performance Evaluation Program," as a basis for the Commission to determine if Agreement State programs to license the new byproduct material are adequate to protect public health and safety.
3. Approve the staff's proposal to request early State review and comment on the draft transition plan.

RESOURCES:

Completing the development and publication of the transition plan under the staff's proposed approach will require 0.6 full-time equivalents (FTE) in FY 2007, and less than 0.1 FTE in FY 2006. This includes 0.1 FTE to address State comments and revise and publish the final transition plan, and 0.5 FTE to receive and review Governors' certifications and to prepare and issue acceptance notifications after a determination of adequacy is made. Currently budgeted resources are sufficient under the staff's proposed approach.

However, if insufficient Governors' certifications are provided by several States, up to an additional 0.25 FTE in FY 2007 may be required to request additional information from the State and complete the staff's review. Also, if a Governor chooses to not provide, or is unable to provide, a certification of adequacy, and the State subsequently submits a formal amendment to its 274b. Agreement to include the new byproduct material, 1.0 FTE in FY 2007 would be required to conduct a full review of the State's request, and to issue and publish the amended Agreement. However, the flexibility provided for Governors to submit their certifications under the staff's proposed approach is intended to minimize the potential for such a situation, and no additional resources are expected to be required to conduct such a review.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

/RA by William F. Kane Acting For/

Luis A. Reyes
Executive Director
for Operations

Enclosures:

1. Section 651(e)(4)(C) of the Energy Policy Act of 2005
2. Draft transition plan

RESOURCES:

Energy Policy Act Text Applicable to the Transition Plan

SEC. 651. NUCLEAR FACILITY AND MATERIALS SECURITY.

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

(4) FINAL REGULATIONS

(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.

Enclosure 1

1 **A Plan for the Transition of Regulatory Authority Resulting from**
2 **the Expanded Definition of Byproduct Material**
3
4

5 **I. INTRODUCTION**
6

7 The Energy Policy Act of 2005 (EPAcT) expanded U.S. Nuclear Regulatory Commission
8 (NRC or Commission) regulatory authority over radioactive materials to include new
9 byproduct material, as defined in paragraphs (3) and (4) of section 11e. of the Atomic
10 Energy Act of 1954, as amended (AEA), hereinafter referred to as the new byproduct
11 material. The expanded NRC authority pre-empted existing State regulatory authority
12 over the subject materials. NRC is authorized, however, to discontinue its regulatory
13 authority over the new byproduct material under certain conditions, allowing States to
14 exercise regulatory authority over these materials.
15

16 The EPAcT requires the Commission to prepare and publish a transition plan to facilitate
17 an orderly transition of regulatory authority with respect to the new byproduct material.
18 The plan must address States that have, before the date on which the plan is published,
19 entered into agreements with the Commission, under section 274b. of the AEA¹
20 (Agreement States), and States that have not entered into such agreements (non-
21 Agreement States). The plan must also include a description of the conditions under
22 which a State may exercise regulatory authority over the new byproduct material.
23

24 To meet the requirements of the EPAcT, the transition plan must include a statement of
25 the Commission that any Agreement between the Commission and a State² under

¹ Section 274b. of the AEA authorizes the Commission to enter into an agreement with the Governor of a State that provides for discontinuance of the Commission's regulatory authority in the State over byproduct material as defined in section 11e., source materials, and special nuclear materials in quantities not sufficient to form a critical mass.

² Section 274n. of the AEA defines the term "State" to mean any State, Territory, or possession of the United States, the Canal Zone, Puerto Rico, and the District of Columbia.

1 section 274b. of the AEA, covering byproduct material and entered into before the date
2 of publication of the transition plan, must be considered to include the new byproduct
3 material, if the Governor of the State certifies to the Commission, on the date of the
4 publication of the transition plan that: (1) the State has a program for licensing the new
5 byproduct material that is adequate to protect the public health and safety, as
6 determined by the Commission; and (2) the State intends to continue to implement the
7 regulatory responsibility of the State with respect to the new byproduct material. This
8 Transition Plan is being promulgated in response to those requirements.
9

10 II. BACKGROUND

11
12 On August 8, 2005, the President signed into law the Energy Policy Act of 2005. Pub. L.
13 No. 109-58, 119 Stat 594 (2005). Before then, byproduct material had been defined in
14 section 11e. of the AEA as: (1) any radioactive material (except special nuclear material)
15 yielded in or made radioactive by exposure to the radiation incident to the process of
16 producing or using special nuclear material; and (2) the tailings or wastes produced by
17 the extraction or concentration of uranium or thorium from any ore processed primarily
18 for its source material content.
19

20 Section 651(e) of the EPAct, among other things, expanded the definition of byproduct
21 material in section 11e. of the AEA, thereby placing additional byproduct material under
22 NRC's jurisdiction. Section 651(e) further required the Commission to provide a
23 regulatory framework for licensing and regulating this additional byproduct material.
24

25 In particular, section 651(e) of the EPAct expanded the definition of byproduct material
26 by adding paragraphs (3) and (4) to the definition of byproduct material in section 11e.
27 Section 11e.(3) defines, as byproduct material:

28
29 “(A) any discrete source of radium-226 that is produced, extracted, or
30 converted after extraction, before, on, or after the date of enactment of
31 this paragraph for use for a commercial, medical, or research activity; or

1 (B) any material that--

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

3 and

4 (ii) is produced, extracted, or converted after extraction, before,
5 on, or after the date of enactment of this paragraph for use for a
6 commercial, medical, or research activity.

7
8 Section 11e.(4) defines, as byproduct material, any discrete source of naturally
9 occurring radioactive material (NORM)³, other than source material, that--

10
11 (A) the Commission, in consultation with the Administrator of the
12 Environmental Protection Agency, the Secretary of Energy, the Secretary
13 of Homeland Security, and the head of any other appropriate Federal
14 agency, determines would pose a threat similar to the threat posed by a
15 discrete source of radium-226 to the public health and safety or the
16 common defense and security; and

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

19
20 **III. THE AGREEMENT STATE PROGRAM**

21
22 In 1959, the AEA was amended to adopt section 274, *Cooperation with States*. As
23 provided in section 274b., the Governor of a State may request an Agreement with the
24 Commission in which NRC discontinues, and the State assumes, regulatory authority
25 over categories of materials, that may include source, byproduct, and special nuclear
26 materials (in quantities insufficient to form a critical mass). Collectively, the materials
27 that are authorized for regulation by States under such Agreements are known as “AEA
28 materials” or “Agreement materials.”
29

³Note: At this time, NRC has not identified any NORM currently in use that would meet the definition of section 11e.(4).

1 The Commission may enter into an Agreement if it finds that the State program is
2 compatible with the Commission's program for regulation of such materials, and that it is
3 adequate to protect the public health and safety with respect to the materials covered by
4 the proposed Agreement. Under section 274j.(1) of the AEA, the Commission must
5 periodically review Agreement State programs and the actions the States take under the
6 Agreements, to ensure compliance with the provisions of that section.

7
8 **A. Concept of Compatibility**

9
10 In 1997, the Commission adopted a Policy Statement declaring that an Agreement State
11 radiation control program is compatible with the Commission's regulatory program when
12 the State program does not create conflicts, duplications, gaps, or other conditions that
13 jeopardize an orderly pattern in the regulation of agreement material Nationwide [see
14 *Statement of Principle and Policy for the Agreement State Program; Policy Statement*
15 *on Adequacy and Compatibility of Agreement State Programs*, (62 FR 46517;
16 September 3, 1997)]. Thus, compatibility focuses primarily on the potential effects of a
17 State action or inaction either on a Nationwide basis or on interstate commerce crossing
18 into other jurisdictions.

19
20 Generally, a State program is compatible if the elements of the program are similar to
21 the corresponding elements of the NRC program. Some elements, such as basic
22 radiation protection standards and program elements with transboundary implications,
23 should be essentially identical, whereas other elements may need only to meet the
24 same essential objectives. The detailed criteria for Agreement State compatibility are
25 set out in NRC Management Directive 5.9, *Adequacy and Compatibility of Agreement*
26 *State Programs*.

27
28 **B. Concept of Adequacy**

29
30 The 1997 Commission Policy Statement declares that an Agreement State radiation
31 control program is adequate to protect public health and safety if administration of the

1 program provides reasonable assurance that the level of protection afforded by the
2 State program is at least as protective as NRC's materials regulatory program.

3
4 The continuing adequacy and compatibility of an Agreement State radiation control
5 program is determined through the Integrated Materials Performance Evaluation
6 Program (IMPEP). NRC periodically reviews the adequacy and compatibility of each
7 Agreement State's radiation protection program using the same set of performance
8 criteria used to evaluate the equivalent NRC licensing and inspection programs. For
9 further information on this program, please see NRC Management Directive 5.6,
10 *Integrated Materials Performance Evaluation Program (IMPEP)*, on the NRC website
11 (www.nrc.gov).

13 IV. REGULATION OF RADIOACTIVE MATERIALS BEFORE THE EPAct

14
15 For the purposes of this discussion, before the EPAct, radioactive materials could be
16 divided into three groups: those regulated only by NRC (e.g., formula quantities of
17 special nuclear material); those regulated only by State or local agencies [e.g., Naturally
18 Occurring and Accelerator-Produced Radioactive Material (NARM)]; and those
19 radioactive materials that may be regulated by NRC, or by a State under an Agreement
20 pursuant to section 274b. of the AEA.

21
22 Since 1954, NRC (and its predecessor agency, the U.S. Atomic Energy Commission)
23 has regulated the non-military use of a limited set of radioactive materials. Collectively,
24 the set of regulated materials is known as AEA material. The basis for assertion of
25 Federal authority over the AEA materials was the belief that they posed (at that time) a
26 new hazard beyond the ability of the States to control. NORM (mostly radium-226) and
27 accelerator-produced radioactive materials (ARM) were relatively rare and did not pose
28 an overwhelming problem for the States to control.

29
30 AEA material originally consisted of source and special nuclear materials, and byproduct
31 materials as now defined in section 11e.(1). In 1978, the AEA definition of "byproduct

1 material” was amended to add section 11e.(2), that included the tailings from uranium or
2 thorium ore processed primarily for their source material content. Other NORM and
3 ARM were not included in the definition of byproduct material before enactment of the
4 EPAct, and thus were not AEA materials and were not subject to NRC regulation.

5 These radioactive materials were under individual State regulatory authority.

7 **V. REGULATORY CHANGES REQUIRED BY SECTION 651(e) OF THE EPAct**

8
9 By amending the definition of ‘byproduct material’ to include certain ARM and NORM,
10 including radium-226, the EPAct has made these radioactive materials AEA materials
11 subject to NRC regulation. Note that only certain ARM and NORM that meet the criteria
12 set out in the EPAct are byproduct material. The criteria for ARM that is defined as
13 byproduct material are that the material: (1) is made radioactive by use of a particle
14 accelerator; (2) is produced, extracted, or converted after extraction, before, on, or after
15 the enactment date of the EPAct; and (3) is produced, extracted, or converted after
16 extraction, for use for a commercial, medical, or research activity. For radium-226 and
17 other NORM to be byproduct material, it must meet the last two criteria, plus be a
18 “discrete source.” ARM and NORM that do not meet these criteria are not AEA
19 byproduct material.

20
21 Independent State regulation of the new byproduct material is pre-empted by the EPAct.
22 States now may only regulate the materials through an agreement with the Commission,
23 under section 274b. of the AEA. Other ARM and NORM that do not meet the definition
24 of byproduct material could continue to be regulated under individual State authority.

25
26 This transition plan addresses only transitions of authority related to the newly defined
27 byproduct material described in Section 651(e) and not to issues raised in other sections
28 of the EPAct.

30 **VI. TRANSITION OF AUTHORITY**

1 **A. Preliminary Activities**

2

3 At the time the EAct was signed into law, NRC did not have regulations in place that
4 would specifically apply to the new byproduct material. Time was needed for the
5 development of a revised regulatory program, to allow for the orderly transition of
6 regulatory authority over this material.

7

8 Section 651(e)(5) of the EAct authorizes the Commission to issue waivers of the
9 requirements of section 651(e) for up to 4 years, if the Commission determines that the
10 waiver is in accordance with the protection of the public health and safety and promotion
11 of the common defense and security. The Commission determined that such a waiver
12 should be granted to entities engaging in activities involving the new byproduct material,
13 and it would be in the best interests of the public to allow the continued use of the new
14 byproduct material, and to allow the States to continue to regulate the new byproduct
15 material until the Commission could codify new regulations for these materials. The
16 Commission issued such a waiver on August 31, 2005 (70 FR 51581). As required by
17 section 651(e) of the EAct, the Commission must terminate any waiver issued under
18 section 651(e), regarding a State, on determining that: 1) the State has entered into an
19 agreement with the Commission under section 274b. of the AEA; 2) the Agreement
20 covers section 11e.(3) or 11e.(4) byproduct material; and 3) the State's program for
21 licensing such byproduct material is adequate to protect the public health and safety. In
22 addition, any waiver issued under section 651(e) may be effective only until August 8,
23 2009, unless the Commission terminates it earlier.

24

25 NRC conducted a rulemaking to cover the new byproduct materials. Final rules were
26 published on [insert date and FR citation], in accordance with the EAct requirements.
27 The rules are to become effective 60 days after publication for some licensees, and later
28 for others, as described in this transition plan and the Federal Register Notice for the
29 final rule. Revisions to NRC Policy and Guidance documents were undertaken in
30 parallel with the rulemaking.

31

1 **B. Conditions Under Which a State May Exercise Authority Over 11e.(3) and 11e.(4)**
2 **Byproduct Material**

3
4 A State may exercise regulatory authority over the new byproduct material in one of two
5 ways: (1) under the Commission-issued waiver (until August 8, 2009); or (2) under an
6 AEA section 274b. Agreement. Starting on August 8, 2009, or earlier if the waiver is
7 terminated for the State under EPA Act section 651(e)(5)(B)(ii), the State may exercise its
8 own authority over the new byproduct material only under an AEA section 274b.
9 Agreement.

10
11 If the State does not already have such an Agreement, the Governor of the State may
12 request an Agreement with the Commission. The Commission may enter into an
13 Agreement if the documentation supporting the Governor's request demonstrates that:
14 (1) the State has a program to regulate the materials covered by the proposed
15 Agreement; and (2) the State program is adequate to protect the public health and
16 safety and is compatible with the Commission's program for byproduct material.

17
18 NRC staff will evaluate the Governor's request using NRC/Office of State and Tribal
19 Programs (STP) Procedure SA-700, *Processing an Agreement*. This procedure is
20 posted on the NRC website (www.nrc.gov). Printed hard copies may also be obtained
21 from the NRC Public Document Room.

22
23 The Commission may enter into an Agreement covering one or more of the following
24 categories of materials: source material; special nuclear material in quantities not
25 sufficient to form a critical mass; byproduct material as defined in section 11e.(1),
26 11e.(2), 11e.(3), or 11e.(4); the regulation of the land disposal of byproduct, source, or
27 special nuclear waste materials received from other persons; and the safety evaluation
28 of sealed sources or devices containing sealed sources.

29
30 **1. Transition of Authority in States That have Entered into Agreements with the**
31 **Commission Under AEA Section 274b., Before Publication of This Plan.**

1 There are two ways an existing Agreement State may include the new byproduct
2 material in its AEA section 274b. Agreement: 1) the Governor of the State provides the
3 certification described in section 651(e)(4)(C)(iii)(II) of the EPAct on the date of
4 publication of the transition plan; or 2) using the standard process, whereby the
5 Governor requests an amendment to the State's Agreement, as provided in section 274
6 of the AEA.

7
8 The Governor's certification avoids the need to amend the State's Agreement in
9 accordance with the formal requirements of section 274 of the AEA. If a Governor
10 chooses not to provide the certification described in the EPAct, NRC will assert its
11 authority to regulate the new byproduct material.
12

13 **2. Basis for Finding Adequacy in Reviewing Governor Certifications**

14
15 For Agreement States whose Governors provide a certification, the Commission will find
16 the States' programs adequate to protect health and safety if the criteria of NRC
17 Management Directive 5.6, *Integrated Materials Performance Evaluation Program*
18 (*IMPEP*), are satisfied. For an Agreement State whose program for licensing 11e.(1)
19 byproduct material has been previously evaluated under IMPEP, the Commission will
20 base its determination of adequacy on the State's prior IMPEP findings if: 1) the State's
21 program for licensing 11e.(3) and 11e.(4) byproduct material is not separate and
22 distinct⁴ from its program for licensing 11e.(1) byproduct material; 2) the State intends to
23 continue to license the new byproduct material under its existing program; and 3) no
24 changes have been made to the State's licensing program that would impact the
25 previous IMPEP finding of adequacy. If the State provides confirmation that these
26 criteria are met, the Commission will consider a finding of adequate performance from
27 the State's last IMPEP review as an indicator that the State's program for licensing
28 section 11e.(3) and 11e.(4) byproduct material is adequate to protect health and safety.
29

⁴The Commission understands that the Agreement States license NARM and section 11e.(1) byproduct material without distinguishing between the materials.

1 If a State's last IMPEP review did not result in a finding of adequate performance, or the
2 State is unable to provide confirmation that the criteria described above are met, the
3 Commission will consider the State's program, and any improvements it has proposed to
4 the IMPEP Management Review Board, on a case-by-case basis to determine if the
5 State's program for licensing section 11e.(3) and 11e.(4) byproduct material is adequate
6 to protect health and safety.

7
8 For a new Agreement State that has not yet had a program review under IMPEP, the
9 Commission will review the statements of program structure, policies, and procedures
10 that accompanied the State Governor's Request for an Agreement, and accept the
11 statements of program structure, policies and procedures as adequate if they satisfy the
12 criteria for adequacy set out in IMPEP, and the State confirms that the State's program
13 for licensing 11e.(3) and 11e.(4) byproduct material is not separate and distinct from its
14 program for licensing 11e.(1) byproduct material, and that the State intends to continue
15 to license the new byproduct material under its existing program.

16
17 The Governor's certification should be addressed to the Chairman of the Commission.
18 On receipt, the Chairman or his designee will review the certification. If the Governor's
19 certification contains the statements required by the EPAct, and the Commission
20 determines that the State's program to license the new byproduct material is adequate
21 to protect health and safety, the Chairman will accept the Governor's certification on
22 behalf of the Commission, and the Governor will be notified of the acceptance. As of
23 the date that the certification is accepted by the Commission, the State's Agreement will
24 be considered to include AEA section 11e.(3) and 11e.(4) byproduct material, and the
25 waiver will be terminated for the State. The certification will become a part of the
26 Agreement, but the Agreement document will not be otherwise amended.

27
28 **3. Agreement States That Elect Not to Include AEA Section 11e.(3) and 11e.(4)**
29 **Byproduct Material in Their Agreements.**

30
31 If an Agreement State elects not to continue to regulate the new byproduct material

1 under an existing section 274b. Agreement, the State should, on or before **[date to be**
2 **determined]**, notify the Commission that it intends to discontinue its regulatory authority
3 for the new byproduct material. NRC is requesting that such an Agreement State also
4 provide NRC with a list of affected users/licensees, in its notification.

5
6 To facilitate an orderly transition of regulatory authority for an Agreement State that
7 does not intend to continue to regulate the new byproduct material, NRC intends to
8 terminate the waiver for the State, and all individuals in the State, before
9 August 8, 2009. The timing of the waiver termination for the State will be determined in
10 consultation with representatives of the State's regulatory program.

11
12 NRC plans to use the phased approach for earlier waiver terminations described in
13 Section **VI. C. 1.**, "**Non-Agreement States That Do Not Request an Agreement,**" for
14 Agreement States that do not intend to continue to regulate the new byproduct material.
15 This approach will prevent an abrupt transition of authority on the date the waiver
16 expires. Likewise, NRC plans to notice waiver terminations in the *Federal Register*, for
17 Agreement States that do not intend to continue to regulate the new byproduct material,
18 in the same manner as described in Section **VI. C. 1.**, for non-Agreement States that do
19 not request Agreements. Also, the actions with which users of the new byproduct
20 material in such Agreement States will be required to comply will be the same as those
21 described in Section **VI. C. 1.**, for users in non-Agreement States that do not request
22 Agreements.

23
24 **4. Agreement States That Do Not, On the Date of Publication of the Transition Plan,**
25 **Certify Adequacy for 11e.(3) and 11e.(4) Byproduct Material**

26
27 Section 651(e) of the EPA Act provides that any Agreement covering byproduct material,
28 as defined in paragraph (1) or (2) of section 11e. of the AEA, entered into between the
29 Commission and a State under section 274b. of that Act before the date of publication of
30 this transition plan shall be considered to include byproduct material, as defined in
31 paragraph (3) or (4) of section 11e. of the AEA, if the Governor of the State certifies to

1 the Commission on the date of publication of this transition plan that: (a) the State has a
2 program for licensing byproduct material, as defined in paragraph (3) or (4) of section
3 11e. of the AEA, that is adequate to protect the public health and safety, as determined
4 by the Commission; and (b) the State intends to continue to implement the regulatory
5 responsibility of the State with respect to the byproduct material.

6
7 If the Governor of a State has not made such a certification to the Commission, and the
8 State intends to continue to implement its regulatory authority over these materials, the
9 State may be required to amend its AEA section 274b. Agreement to include the new
10 byproduct material.

11
12 **C. Transition of Authority in States That have Not Entered into an Agreement with**
13 **the Commission Under AEA Section 274b. (Non-Agreement States) Before**
14 **Publication of This Plan**

15
16 **1. Non-Agreement States that do not request an Agreement.**

17
18 Any State that, on August 8, 2009, does not have an Agreement with the Commission
19 under section 274b. of the AEA, which covers 11e.(3) or 11e.(4) new byproduct
20 material, must discontinue its regulatory authority over the byproduct material.

21
22 To facilitate an orderly transition of regulatory authority for States that do not intend to
23 establish AEA section 274b. Agreements with the Commission before August 8, 2009,
24 NRC intends to terminate the waiver for such States, and all individuals in such States,
25 before August 8, 2009. NRC plans to use a phased approach for the earlier waiver
26 terminations, to prevent an abrupt transition of authority on the date the waiver expires.
27 The timing of waiver terminations for the States will be determined in consultation with
28 representatives of the States' regulatory programs. Waiver terminations will be
29 executed for groups of States, at periodic intervals occurring between the effective date
30 of the rule and August 8, 2009. Starting at Midnight, local time, on the effective date of
31 the waiver termination, NRC will assume regulatory authority over section 11e.(3) and

1 11e.(4) byproduct material within the States.

2
3 Each waiver termination for a group of States will be noticed in the *Federal Register* as
4 a "Notification of Waiver Termination and Implementation Dates of Rule," approximately
5 6 months before the effective date of the waiver termination. The notifications will
6 provide the effective date of the waiver terminations, and will identify the States to which
7 the waiver terminations will apply. The notifications also will provide specific actions with
8 which users of the newly added byproduct material in the affected States will need to
9 comply to continue to use the material. The actions with which the users will be required
10 to comply are expected to be similar to those provided for Government agencies and
11 federally recognized Indian Tribes in NRC's amended rules applicable to the new
12 byproduct material [insert date and FR citation], which became effective on [April 7,
13 2007]. In a manner similar to the process outlined in Section VI. F., if non-Federal
14 entities in these States wish to continue using the new byproduct material, they will
15 either: 1) be required to apply for license amendments for the new byproduct material,
16 within 6 months from the date the waiver is terminated for their State, if they hold an
17 NRC specific byproduct materials license; or 2) submit a license application for the new
18 byproduct material, within 12 months from the date the waiver is terminated for their
19 State.

20
21 NRC plans to terminate the waiver no later than August 8, 2008, for all individuals in
22 States that do not plan to establish AEA section 274b. Agreements with NRC. This
23 should allow all users in States sufficient time to submit license applications within the
24 periods described above.

25
26 NRC will cooperate with States for which the waiver will be terminated to identify users
27 of the byproduct material within the States, and provide notifications to the users of the
28 impending transition of authority. In addition to the notifications described above, NRC
29 will issue press releases, and initiate interactions with industry groups and other
30 stakeholders in an effort to ensure that all users in the affected States are aware of the
31 transition of authority and requirements for continued use of the new byproduct material.

1 **2. Non-Agreement States That Request AEA Section 274b. Agreements Covering**
2 **Section 11e.(3) or 11e.(4) Byproduct Materials.**

3
4 The Governor of any State that does not have an Agreement with the Commission
5 under section 274b. may request an Agreement that covers section 11e.(3) or 11e.(4)
6 byproduct material, and also may request an Agreement that covers any or all of the
7 other materials and activities as described in the discussion in Section VI. B.,
8 **“Conditions Under Which a State May Exercise Authority over 11e.(3) and 11e.(4)**
9 **Byproduct Material.”** The request should follow the NRC/STP Procedure SA-700,
10 *Processing an Agreement*, starting with a request for an Agreement as soon as
11 practical. A copy of the procedure is available on the NRC website (www.nrc.gov).
12

13 The NRC staff will recommend that the Commission approve an Agreement if the
14 State’s Program for regulating the requested byproduct materials meets the criteria in
15 NRC/STP Procedure SA-700, *Processing an Agreement*. If the Commission approves,
16 the Agreement will become effective on a date selected by the State, and specified in
17 the Agreement. If the effective date is before August 8, 2009, the Commission will
18 terminate the waiver for all persons in that State on the effective date of the Agreement.
19

20 Requests from States to enter into 274b. Agreements before the time-limited waiver
21 expires on August 8, 2009, will be reviewed in accordance with the STP procedure SA-
22 700, *Processing an Agreement*. Every effort will be made to complete an Agreement as
23 soon as practical, without compromising quality and completeness. The Commission
24 understands that situations may arise that may delay the completion and effective date
25 of Agreements. If any Agreements cannot be completed before the waiver expires on
26 August 8, 2009, the Commission may consider, on a case-by-case basis, options to limit
27 the impact on affected users of 11e.(3) and 11e.(4) byproduct material in the States.
28

29 **D. Transition of Exempt Distribution Licenses for NARM From State Jurisdiction to**
30 **NRC Jurisdiction**

1 The Commission, pursuant to 10 CFR 150.15, retains the authority to license the
2 distribution of byproduct material to persons who are exempt from regulatory
3 requirements. Since the Commission did not have jurisdiction over section 11e.(3) and
4 11e.(4) byproduct material previously, the States had the authority to issue licenses for
5 the distribution of NARM to persons who were exempt from licensing and regulatory
6 requirements. With the expansion of the definition of byproduct material, NRC authority
7 pre-empts the States' authority to issue such licenses.

8
9 NRC understands that there are a limited number of State issued exempt distribution
10 licenses for the new byproduct material, which will transfer to NRC on termination of the
11 waiver for the State. The specifics of the transfer will be addressed directly with the
12 involved States and distributors, on a case-by-case basis. On expiration or earlier
13 termination of the waiver, NRC will issue licenses for the distribution of products
14 containing AEA section 11e.(3) and 11e.(4) byproduct material to persons who are
15 exempt from licensing and regulatory requirements.

16
17 **E. Transition of Sealed Source or Device Registration Certificates for NARM From**
18 **State Jurisdiction to NRC Jurisdiction**

19
20 Since, previously, the States had jurisdiction over NARM (including the new byproduct
21 material), the States also had authority for the evaluation of radiation safety information
22 on sealed sources or devices (SSDs) containing NARM, and the registration of such
23 SSDs for distribution. Most Agreement States' section 274b. Agreements provide for
24 the Commission to discontinue its authority for the evaluation of radiation safety
25 information on SSDs containing byproduct materials, and for the registration of the
26 SSDs for distribution. An Agreement State whose section 274b. Agreement provides for
27 the Commission to discontinue its SSD authority shall retain this authority and
28 responsibility for SSDs containing the new byproduct material, after the waiver expires
29 on August 8, 2009, or on earlier waiver termination by the Commission, if the State's
30 274b. Agreement includes the new byproduct material.

1 After the waiver expires on August 8, 2009, or on earlier waiver termination by the
2 Commission, NRC will assume regulatory authority over radiation safety evaluations and
3 registration of SSDs containing the new byproduct material in non-Agreement States,
4 and in Agreement States whose section 274b. Agreements do not provide for the
5 Commission to discontinue its authority for radiation safety evaluations and registration
6 of SSDs containing byproduct material. In addition, NRC will also assume regulatory
7 authority over all radiation safety evaluations and registrations of exempt distribution
8 devices containing the new byproduct material that previously may have been licensed
9 by the States.

10
11 NRC will cooperate with States for which the regulatory authority over radiation safety
12 evaluations and registrations of SSDs containing the new byproduct material will transfer
13 from the State to the NRC, to provide a notification to affected holders of active SSD
14 registrations in the States, of the impending transition of authority. NRC is also
15 requesting that such States provide NRC with copies of affected SSD registrations.

16
17 **F. Federal Entity Licensees of the Commission and Unlicensed Federal Users**

18
19 Under the AEA byproduct, source, and special nuclear material, licenses for
20 Government agencies and federally recognized Indian Tribes are issued by the
21 Commission, and are not subject to State regulation. Since NRC was not previously
22 authorized to license NARM, these entities may not have an NRC license authorizing the
23 new byproduct material. NRC plans to terminate the waiver for Government agencies
24 and federally recognized Indian Tribes on the effective date of the final rule [**insert**
25 **effective date; i.e., April 8, 2007, or 60 days after the date of publication of the final**
26 **rule**] and these users will be subject to the new requirements on that date. Such
27 entities who wish to continue to use the new byproduct material must either: 1) apply for
28 license amendments for the new byproduct material, within 6 months from the effective
29 date of the rule, if they hold NRC specific byproduct materials licenses; or 2) submit
30 license applications for the new byproduct material, within 12 months from the effective
31 date of the rule, if new NRC specific byproduct materials licenses are needed.

1 **G. Notification of Transition Actions**

2

3 Section 651(e)(5)(c) of the EAct requires NRC to publish a notice of any waiver
4 granted under section 651(e)(5) in the *Federal Register*. As described above, NRC
5 published such a waiver on August 31, 2005. NRC is required by section 274e.(1) of
6 the AEA to notice in the *Federal Register* any new or amended AEA section 274b.
7 Agreements. Any new or amended Agreements will be published as required by section
8 274e.(1) of the AEA.

9

10 Although the EAct does not specifically require NRC to notice a waiver termination,
11 NRC will publish in the *Federal Register* any "Notification of Waiver Termination and
12 Implementation Dates of Rule." NRC will also make publicly available the acceptance of
13 a Governor's certification.

14

15 NRC normally provides notifications of any new AEA section 274b. Agreements to
16 Congress, Federal Agencies, and States. NRC plans to also notify these entities of any
17 waiver termination.

18

19 **References**

20

21 1. Atomic Energy Act of 1954, as amended.

22

23 2. Conference of Radiation Control Program Directors, Inc. (CRCPD), "Suggested State
24 Regulations for Control of Radiation," available at the CRCPD website
25 www.crcpd.org/free_docs.asp.

26

27 3. Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat 594 (2005).

28

29 4. U.S. Nuclear Regulatory Commission, Management Directive 5.6, "Integrated Materials
30 Performance Evaluation Program (IMPEP)," available in the Electronic Reading Room
31 on the NRC website www.nrc.gov.

- 1 5. U.S. Nuclear Regulatory Commission, Management Directive 5.9, “Adequacy and
2 Compatibility of Agreement State Programs,” available in the Electronic Reading Room
3 on the NRC website www.nrc.gov.
4
- 5 6. U.S. Nuclear Regulatory Commission, Office of State and Tribal Programs, Procedure
6 SA-700, “Processing an Agreement,” available at the NRC Office of State and Tribal
7 Programs website www.hsr.d.o.gov/nrc/home.html.
8
- 9 7. U.S. Nuclear Regulatory Commission, “Statement of Principle and Policy for the
10 Agreement State Program; Policy Statement on Adequacy and Compatibility of
11 Agreement State Programs,” 62 FR 46517, September 3, 1997
12
- 13 8. U.S. Nuclear Regulatory Commission, Guidance on New Agreements, NRC Handbook
14 5.8 , “Proposed Section 274b. Agreements With States,” available in the Electronic
15 Reading Room on the NRC website www.nrc.gov.