

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 EAct;
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 EAct 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 EAct 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 EAct 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 EAct; 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 EAct 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 AEAct 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 EAct, 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
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Enclosures:

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

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