

# A Plan for the Transition of Regulatory Authority Resulting from the Expanded Definition of Byproduct Material

## I. INTRODUCTION

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

The EPAAct requires the Commission to prepare and publish a transition plan to facilitate an orderly transition of regulatory authority with respect to the new byproduct material. The plan must address States that have, before the date on which the plan is published, entered into agreements with the Commission, under section 274b. of the AEA<sup>1</sup> (Agreement States), and States that have not entered into such agreements (non-Agreement States). The plan must also include a description of the conditions under which a State may exercise regulatory authority over the new byproduct material.

To meet the requirements of the EPAAct, the transition plan must include a statement of the Commission that any Agreement between the Commission and a State<sup>2</sup> under

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<sup>1</sup> 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.

<sup>2</sup> 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)<sup>3</sup>, 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.”  
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<sup>3</sup>Note: 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](http://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](http://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 distinct<sup>4</sup> 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.

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29  
<sup>4</sup>The 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](http://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](http://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](http://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](http://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](http://www.hsr.d.o.gov/nrc/home.html).  
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- 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](http://www.nrc.gov).