

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 (EPAAct) 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 EPAAct 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 EPAAct, 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 EPAAct 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 EPAAct 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 EPAAct, 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 EPAAct 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 EPAAct 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.

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

1 For a new Agreement State that has not yet had a program review under IMPEP, the
2 Commission will base its determination of adequacy on the following: 1) the State's
3 program for licensing 11e.(3) and 11e.(4) byproduct material is not separate and distinct
4 from its program for licensing 11e.(1) byproduct material; 2) the State intends to
5 continue to license the new byproduct material under its existing program; and 3) no
6 changes have been made to the State's licensing program that would impact the
7 Commission's decision to enter into the AEA section 274b. Agreement.

8
9 The Governor's certification should be addressed to the Chairman of the Commission.
10 On receipt, the Chairman or his designee will review the certification. If the Governor's
11 certification contains the statements required by the EPA Act, and the Commission
12 determines that the State's program to license the new byproduct material is adequate
13 to protect health and safety, the Chairman will accept the Governor's certification on
14 behalf of the Commission, and the Governor will be notified of the acceptance. As of
15 the date that the certification is accepted by the Commission, the State's Agreement will
16 be considered to include AEA section 11e.(3) and 11e.(4) byproduct material, and the
17 waiver will be terminated for the State. The certification will become a part of the
18 Agreement, but the Agreement document will not be otherwise amended.

19
20 The NRC will verify the adequacy of the State's program to license the new byproduct
21 material during subsequent IMPEP reviews.

22
23 **3. Agreement States That Elect Not to Include AEA Section 11e.(3) and 11e.(4)**
24 **Byproduct Material in Their Agreements.**

25
26 If an Agreement State elects not to continue to regulate the new byproduct material
27 under an existing section 274b. Agreement, the State should, on or before **[date to be**
28 **determined]**, notify the Commission that it intends to discontinue its regulatory authority
29 for the new byproduct material. NRC is requesting that such an Agreement State also
30 provide NRC with a list of affected users/licensees, in its notification.

31

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

6
7 NRC plans to use the phased approach for earlier waiver terminations described in
8 Section VI. C. 1., "**Non-Agreement States That Do Not Request an Agreement,**" for
9 Agreement States that do not intend to continue to regulate the new byproduct material.
10 This approach will prevent an abrupt transition of authority on the date the waiver
11 expires. Likewise, NRC plans to notice waiver terminations in the *Federal Register*, for
12 Agreement States that do not intend to continue to regulate the new byproduct material,
13 in the same manner as described in Section VI. C. 1., for non-Agreement States that do
14 not request Agreements. Also, the actions with which users of the new byproduct
15 material in such Agreement States will be required to comply will be the same as those
16 described in Section VI. C. 1., for users in non-Agreement States that do not request
17 Agreements.

18
19 **4. Agreement States That Do Not, On the Date of Publication of the Transition Plan,
20 Certify Adequacy for 11e.(3) and 11e.(4) Byproduct Material**

21
22 Section 651(e) of the EPA Act provides that any Agreement covering byproduct material,
23 as defined in paragraph (1) or (2) of section 11e. of the AEA, entered into between the
24 Commission and a State under section 274b. of that Act before the date of publication of
25 this transition plan shall be considered to include byproduct material, as defined in
26 paragraph (3) or (4) of section 11e. of the AEA, if the Governor of the State certifies to
27 the Commission on the date of publication of this transition plan that: (a) the State has a
28 program for licensing byproduct material, as defined in paragraph (3) or (4) of section
29 11e. of the AEA, that is adequate to protect the public health and safety, as determined
30 by the Commission; and (b) the State intends to continue to implement the regulatory
31 responsibility of the State with respect to the byproduct material.

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

5
6 **C. Transition of Authority in States That have Not Entered into an Agreement with**
7 **the Commission Under AEA Section 274b. (Non-Agreement States) Before**
8 **Publication of This Plan**

9
10 **1. Non-Agreement States that do not request an Agreement.**

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

15
16 To facilitate an orderly transition of regulatory authority for States that do not intend to
17 establish AEA section 274b. Agreements with the Commission before August 8, 2009,
18 NRC intends to terminate the waiver for such States, and all individuals in such States,
19 before August 8, 2009. NRC plans to use a phased approach for the earlier waiver
20 terminations, to prevent an abrupt transition of authority on the date the waiver expires.
21 The timing of waiver terminations for the States will be determined in consultation with
22 representatives of the States' regulatory programs. Waiver terminations will be
23 executed for groups of States, at periodic intervals occurring between the effective date
24 of the rule and August 8, 2009. Starting at Midnight, local time, on the effective date of
25 the waiver termination, NRC will assume regulatory authority over section 11e.(3) and
26 11e.(4) byproduct material within the States.

27
28 Each waiver termination for a group of States will be noticed in the *Federal Register* as
29 a "Notification of Waiver Termination and Implementation Dates of Rule," approximately
30 6 months before the effective date of the waiver termination. The notifications will
31 provide the effective date of the waiver terminations, and will identify the States to which

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

14
15 NRC plans to terminate the waiver no later than August 8, 2008, for all individuals in
16 States that do not plan to establish AEA section 274b. Agreements with NRC. This
17 should allow all users in States sufficient time to submit license applications within the
18 periods described above.

19
20 NRC will cooperate with States for which the waiver will be terminated to identify users
21 of the byproduct material within the States, and provide notifications to the users of the
22 impending transition of authority. In addition to the notifications described above, NRC
23 will issue press releases, and initiate interactions with industry groups and other
24 stakeholders in an effort to ensure that all users in the affected States are aware of the
25 transition of authority and requirements for continued use of the new byproduct material.

26
27 **2. Non-Agreement States That Request AEA Section 274b. Agreements Covering**
28 **Section 11e.(3) or 11e.(4) Byproduct Materials.**

29
30 The Governor of any State that does not have an Agreement with the Commission
31 under section 274b. may request an Agreement that covers section 11e.(3) or 11e.(4)

1 byproduct material, and also may request an Agreement that covers any or all of the
2 other materials and activities as described in the discussion in Section VI. B.,
3 **“Conditions Under Which a State May Exercise Authority over 11e.(3) and 11e.(4)**
4 **Byproduct Material.”** The request should follow the NRC/STP Procedure SA-700,
5 *Processing an Agreement*, starting with a request for an Agreement as soon as
6 practical. A copy of the procedure is available on the NRC website (www.nrc.gov).
7

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

15 Requests from States to enter into 274b. Agreements before the time-limited waiver
16 expires on August 8, 2009, will be reviewed in accordance with the STP procedure SA-
17 700, *Processing an Agreement*. Every effort will be made to complete an Agreement as
18 soon as practical, without compromising quality and completeness. The Commission
19 understands that situations may arise that may delay the completion and effective date
20 of Agreements. If any Agreements cannot be completed before the waiver expires on
21 August 8, 2009, the Commission may consider, on a case-by-case basis, options to limit
22 the impact on affected users of 11e.(3) and 11e.(4) byproduct material in the States.
23

24 **D. Transition of Exempt Distribution Licenses for NARM From State Jurisdiction to**
25 **NRC Jurisdiction**
26

27 The Commission, pursuant to 10 CFR 150.15, retains the authority to license the
28 distribution of byproduct material to persons who are exempt from regulatory
29 requirements. Since the Commission did not have jurisdiction over section 11e.(3) and
30 11e.(4) byproduct material previously, the States had the authority to issue licenses for
31 the distribution of NARM to persons who were exempt from licensing and regulatory

1 requirements. With the expansion of the definition of byproduct material, NRC authority
2 pre-empts the States' authority to issue such licenses.

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

11
12 **E. Transition of Sealed Source or Device Registration Certificates for NARM From**
13 **State Jurisdiction to NRC Jurisdiction**

14
15 Since, previously, the States had jurisdiction over NARM (including the new byproduct
16 material), the States also had authority for the evaluation of radiation safety information
17 on sealed sources or devices (SSDs) containing NARM, and the registration of such
18 SSDs for distribution. Most Agreement States' section 274b. Agreements provide for
19 the Commission to discontinue its authority for the evaluation of radiation safety
20 information on SSDs containing byproduct materials, and for the registration of the
21 SSDs for distribution. An Agreement State whose section 274b. Agreement provides for
22 the Commission to discontinue its SSD authority shall retain this authority and
23 responsibility for SSDs containing the new byproduct material, after the waiver expires
24 on August 8, 2009, or on earlier waiver termination by the Commission, if the State's
25 274b. Agreement includes the new byproduct material.

26
27 After the waiver expires on August 8, 2009, or on earlier waiver termination by the
28 Commission, NRC will assume regulatory authority over radiation safety evaluations and
29 registration of SSDs containing the new byproduct material in non-Agreement States,
30 and in Agreement States whose section 274b. Agreements do not provide for the
31 Commission to discontinue its authority for radiation safety evaluations and registration

1 of SSDs containing byproduct material. In addition, NRC will also assume regulatory
2 authority over all radiation safety evaluations and registrations of exempt distribution
3 devices containing the new byproduct material that previously may have been licensed
4 by the States.

5
6 **D** NRC will cooperate with States for which the regulatory authority over radiation safety
7 evaluations and registrations of SSDs containing the new byproduct material will transfer
8 from the State to the NRC, to provide a notification to affected holders of active SSD
9 registrations in the States, of the impending transition of authority. NRC is also
10 requesting that such States provide NRC with copies of affected SSD registrations.
11

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

13
14 Under the AEA byproduct, source, and special nuclear material, licenses for
15 Government agencies and federally recognized Indian Tribes are issued by the
16 Commission, and are not subject to State regulation. Since NRC was not previously
17 authorized to license NARM, these entities may not have an NRC license authorizing the
18 new byproduct material. NRC plans to terminate the waiver for Government agencies
19 and federally recognized Indian Tribes on the effective date of the final rule [**insert**
20 **effective date; i.e., April 8, 2007, or 60 days after the date of publication of the final**
21 **rule]** and these users will be subject to the new requirements on that date. Such
22 entities who wish to continue to use the new byproduct material must either: 1) apply for
23 license amendments for the new byproduct material, within 6 months from the effective
24 date of the rule, if they hold NRC specific byproduct materials licenses; or 2) submit
25 license applications for the new byproduct material, within 12 months from the effective
26 date of the rule, if new NRC specific byproduct materials licenses are needed.
27

28 **G. Notification of Transition Actions**

29
30 Section 651(e)(5)(c) of the EPA Act requires NRC to publish a notice of any waiver
31 granted under section 651(e)(5) in the *Federal Register*. As described above, NRC

1 published such a waiver on August 31, 2005. NRC is required by section 274e.(1) of
2 the AEA to notice in the *Federal Register* any new or amended AEA section 274b.
3 Agreements. Any new or amended Agreements will be published as required by section
4 274e.(1) of the AEA.

5
6 Although the EPAct does not specifically require NRC to notice a waiver termination,
7 NRC will publish in the *Federal Register* any "Notification of Waiver Termination and
8 Implementation Dates of Rule." NRC will also make publicly available the acceptance of
9 a Governor's certification.

10
11 NRC normally provides notifications of any new AEA section 274b. Agreements to
12 Congress, Federal Agencies, and States. NRC plans to also notify these entities of any
13 waiver termination.

14 15 **References**

- 16
17 1. Atomic Energy Act of 1954, as amended.
18
19 2. Conference of Radiation Control Program Directors, Inc. (CRCPD), "Suggested State
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21 www.crcpd.org/free_docs.asp.
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23 3. Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat 594 (2005).
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25 4. U.S. Nuclear Regulatory Commission, Management Directive 5.6, "Integrated Materials
26 Performance Evaluation Program (IMPEP)," available in the Electronic Reading Room
27 on the NRC website www.nrc.gov.
28
29 5. U.S. Nuclear Regulatory Commission, Management Directive 5.9, "Adequacy and
30 Compatibility of Agreement State Programs," available in the Electronic Reading Room
31 on the NRC website www.nrc.gov.

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