

NUCLEAR REGULATORY COMMISSION

[NRC-2016-0094]

Policy Statement for the Agreement State Program

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed policy statement; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has revised and consolidated two policy statements on NRC's Agreement State Programs: the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" and the "Statement of Principles and Policy for the Agreement State Program." The resulting proposed single policy statement has been revised to add that public health and safety includes physical protection of agreement material.¹

DATES: Submit comments by **[INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for

Docket ID NRC-2016-0094. Address questions about NRC dockets to Carol Gallagher;

¹ The term 'agreement material' means the materials listed in Subsection 274b. of the Atomic Energy Act of 1954, as amended (AEA), over which the States may receive regulatory authority.

telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Mail comments to:** Cindy Bladey, Office of Administration, Mail Stop:
OWFN 12-H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Lisa Dimmick, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-0694, e-mail: Lisa.Dimmick@nrc.gov.

SUPPLEMENTARY INFORMATION:

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2016-0094 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2016-0094.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is publicly available in ADAMS) is provided the first time that it is mentioned in the SUPPLEMENTARY INFORMATION section.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC-2016-0094 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

The “Adequacy and Compatibility of Agreement State Programs” (62 FR 46517; September 3, 1997) presents the NRC’s policy for determining the adequacy and compatibility of Agreement State programs. The “Statement of Principles and Policy for the Agreement State Program” (62 FR 46517; September 3, 1997) describes the respective roles and responsibilities of the NRC and the States in the administration of programs carried out under the 274b. State Agreement.² The application of these two policy statements has significant influence on the safety and security of agreement material and on regulation of the more than 22,000 Agreement State and NRC materials licensees.

In the 1990s, the “Policy Statement on Adequacy and Compatibility of Agreement State Programs” and the “Statement of Principles and Policy for the Agreement State Program” were developed by working groups consisting of Agreement States representatives and the NRC staff. A number of workshops and meetings were also held to gather stakeholder input. The Commission approved both policy statements in the Staff Requirements Memorandum (SRM) to SECY-95-112, “Final Policy Statement on Adequacy and Compatibility of Agreement State

² Section 274 of the AEA provides a statutory basis under which the NRC discontinues portions of its regulatory authority to license and regulate byproduct materials; source materials; and quantities of special nuclear materials under critical mass. The mechanism for the transfer of NRC’s authority to a State is an agreement signed by the Governor of the State and the Chairman of the Commission, in accordance with Subsection 274b. of the AEA.

Programs,” and SECY-95-115, “Final ‘Statement of Principles and Policy for Agreement State Program’ and ‘Procedures for Suspension and Termination of an Agreement State Program’,” dated June 29, 1995 (ADAMS Accession No. ML003759325), but deferred implementation until all implementing procedures were completed and approved by the Commission. In the June 30, 1997, SRM to SECY-97-054, “Final Recommendations on Policy Statements and Implementing Procedures for: ‘Statement of Principles and Policy for the Agreement State Program’ and ‘Policy Statement on Adequacy and Compatibility of Agreement State Programs’,” the Commission approved the accompanying implementing procedures for the policy statements (ADAMS Accession No. ML051610710). The policy statements became effective on September 3, 1997 (62 FR 46517).

The NRC staff’s efforts to update the Agreement State policy statements began with the Commission’s direction provided in the SRM to SECY-10-0105, “Final Rule: Limiting the Quantity of Byproduct Material in a Generally Licensed Device (RIN 3150-AI33),” issued on December 2, 2010 (ADAMS Accession No. ML103360262). The Commission directed the NRC staff to update the Commission’s “Policy Statement on Adequacy and Compatibility of Agreement State Programs” and associated guidance documents to include both safety and source security considerations in the determination process. Because Agreement State adequacy and compatibility are key components of the Integrated Materials Performance Evaluation Program (IMPEP),³ the Commission’s “Statement of Principles and Policy for the Agreement State Program” was revised concurrently. As directed, the NRC staff’s revisions to the policy statements added that public health and safety includes physical protection of agreement material.

³ The NRC developed the IMPEP to evaluate the adequacy and compatibility of Agreement State programs and the adequacy of the NRC’s nuclear materials program activities.

The Commission approved publication of the proposed updates to the two policy statements in the revised SRM to SECY-12-0112, "Policy Statements on Agreement State Programs," dated May 28, 2013 (ADAMS Accession No. ML13148A352). The NRC staff published the two proposed policy statements on June 3, 2013 (78 FR 33122), for a 75-day comment period. After receiving requests from the Organization of Agreement States (OAS) and the State of Florida to extend the public comment period, the NRC extended the comment period to September 16, 2013 (78 FR 50118; August 16, 2013). The NRC held two public meetings (July 18 and August 6, 2013), and a topical session during the OAS annual meeting in Reno, Nevada on August 28, 2013. The NRC staff specifically solicited comment on Compatibility Category B, and whether or not the policy statements should maintain the language from the 1997 "Policy Statement on Adequacy and Compatibility of Agreement State Programs" describing the adoption and number of compatible regulations.

The NRC staff received 51 comments on the policy statements, in general, and 45 comments on Compatibility Category B from 13 commenters, including Agreement States, industry organizations, and individuals. Consistency and flexibility were underlying themes expressed in the comments. The need for consistent application of the NRC's policies and flexible implementation of these policies was mentioned in written comments, and was also expressed orally during the public meetings and OAS topical session. The NRC changed the policy statements as a result of the written comments and input from attendees to the two public meetings and the OAS topical session.

In COMSECY-14-0028, "Agreement State Program Policy Statements: Update on Recent Activities and Recommendations for Path Forward," dated July 14, 2014 (ADAMS Accession No. ML14156A277), the NRC staff proposed a plan to provide a consolidated policy statement. The Commission approved this plan in the SRM to COMSECY-14-0028, dated August 12, 2014 (ADAMS Accession No. ML14224A618). Accordingly, the NRC staff

developed a single consolidated proposed policy statement for comment. In finalizing the policy statement, NRC staff identified and eliminated redundant language between the two policy statements, and removed detailed information on IMPEP and the “Principles of Good Regulation” (ADAMS Accession No. ML15083A026), as this material is not typically included in a high-level policy statement. The proposed single policy statement is included in its entirety in Section IV, “Proposed Policy Statement for the Agreement State Program,” of this document.

III. Discussion of Proposed Changes

The NRC’s proposed consolidated policy statement addresses the Commission direction in the SRMs to SECY-10-0105, SECY-12-0112, and COMSECY-14-0028 and reflects written public comments and input received from public meetings and the OAS topical session. The NRC staff’s disposition of comments is presented in a comment resolution table (ADAMS Accession No. ML14073A549).

The Commission’s proposed consolidated policy removes details on IMPEP and the “Principles of Good Regulation.” The NRC added context and makes the proposed policy statement clearer and more consistent with other recent NRC policy statements. Lastly, the Commission added a description of the National Materials Program (NMP).

In response to the *Federal Register* notice (FRN) on June 3, 2013 (78 FR 33122), 45 comments were received on the description of Compatibility Category B in the proposed policy statement. In the FRN, the NRC specifically solicited comment on the following topics concerning Compatibility Category B:

1. *To clarify the meaning of a “significant transboundary implication,”⁴ the NRC is proposing to define a significant transboundary implication as “one which crosses regulatory*

⁴ The NRC staff solicited public comment on the phrase “significant transboundary implication” in the *Federal Register* on June 3, 2013 (78 FR 33122).

jurisdictions, has a particular impact on public health and safety, and needs to be addressed to ensure uniformity of regulation on a nationwide basis.” However, the NRC recognizes that the use of the word “particular” can be vague and cause confusion. The NRC is requesting specific comments on the proposed draft definition of “significant transboundary implication” and whether the word “particular” should be replaced with the phrase “significant and direct.”

Based on comments received, the NRC staff noted that there is a wide variation on the interpretation of the description of Compatibility Category B and of the definition of significant transboundary implication. In light of this, the Commission is proposing a new description of Compatibility Category B to eliminate the phrase “significant transboundary implication.” The new language, (i.e., “cross jurisdictional boundaries”) embodies the original description of Compatibility Category B and eliminates the confusion surrounding the language incorporated into the 1997 version of the policy statement.

2. Program elements with significant transboundary implications are illustrated by examples in the 1997 version of the policy statement. The NRC staff concluded the examples listed are not all-inclusive and could lead to misinterpretation by stakeholders, Agreement States, and the NRC staff. The NRC staff is seeking additional comment on whether or not the examples should be retained in this section of the policy statement.

The majority of commenters requested that examples of program elements considered Compatibility Category B continue to be included in the description. No changes were made to the policy statement. The Commission retained examples in Section E.2.ii.

3. The NRC is requesting comments on the description of Compatibility Category B as written in Section IV. of this notice and whether or not the movement of goods and services, which historically has been a main factor in determining whether an issue has transboundary implications, should be considered in the definition of significant transboundary implication.

Specific comments were received regarding the consideration of the movement of goods and services. The majority of the commenters felt that it was not necessary to include the consideration of the movement of goods and services in the description of Compatibility Category B. The Commission has concluded that the movement of goods and services should not be considered in assessing compatibility and made no change to the proposed policy statement.

4. The NRC is requesting comments on whether or not economic factors should be a consideration when making a Compatibility Category B determination. The NRC believes that health and safety should be the primary consideration in making a Compatibility B determination and that economic factors should not be a consideration.

The comments included several comments that differed on whether or not economic factors should be considered. Based on the comments received and in reviewing previous rationale on this topic as discussed in SECY-95-112 “Final Policy Statement on Adequacy and Compatibility of Agreement State Programs,” the Commission determined that economic factors (i.e., those costs incurred by the regulated community to comply with regulatory requirement(s)) should not be considered. No change to the proposed policy statement has been made.

The NRC also solicited specific comment on the use of alternative wording regarding the expectation on the number of regulatory requirements that Agreement States will be requested to adopt in an identical manner to maintain compatibility. The 1997 version of the policy statement had specific text in three places regarding the expectation for adopting requirements in an identical manner to maintain compatibility. Six commenters supported returning the wording back to the text that was originally published in 1997. Based on comments received, the Commission retained the original language from the 1997 version in the proposed policy statement.

Two commenters questioned the description of Compatibility Category D and indicated the description in the policy statement as published in the *Federal Register* on June 3, 2013 (78 FR 33122), appears to discuss compatibility in general and does not describe Compatibility Category D as it is defined in Management Directive 5.9, “Adequacy and Compatibility of Agreement State Programs” (ADAMS Accession No. ML041770094). The Commission agreed and moved the language listed under Compatibility Category D, in the proposed policy statement, to the introductory paragraph of Section E.2., “Compatibility,” and revised the description of Compatibility Category D in Section E.2.iv.

The criteria for adequacy and compatibility as proposed in this policy statement will provide Agreement States with flexibility in the administration of their individual programs. Recognizing that Agreement States have responsibilities for radiation sources other than agreement material, this proposed policy statement would allow Agreement States to fashion their programs so as to reflect specific State needs and preferences while accomplishing a compatible national program consistent with Section 274 of the AEA.

The requirements in Compatibility Categories A, B, and C will allow the NRC to ensure that an orderly pattern for the regulation of agreement material exists nationwide. The NRC believes that this approach achieves a proper balance between the Agreement States’ need for flexibility and the need for coherent and compatible regulation of agreement material across the country.

IV. Proposed Policy Statement for the Agreement State Program

A. PURPOSE.

The purpose of this policy statement for the Agreement State Program is to describe the respective roles and responsibilities of the U.S. Nuclear Regulatory Commission (NRC) and Agreement States in the administration of programs carried out under Section 274 of the Atomic

Energy Act of 1954, as amended (AEA).⁵ Section 274 provides broad authority for the NRC to establish a unique Federal and State relationship in the administration of regulatory programs for the protection of public health and safety in the industrial, medical, commercial, and research uses of agreement material. This policy statement supersedes the “Policy Statement on Adequacy and Compatibility of Agreement State Programs” and the “Statement of Principles and Policy for the Agreement State Program.”

This policy statement addresses the Federal-State interaction under the AEA to (1) establish and maintain agreements with States under Subsection 274b. that provide for discontinuance by the NRC, and the assumption by the State, of responsibility for administration of a regulatory program for the safe and secure use of agreement material; (2) ensure that post-agreement interactions between the NRC and Agreement State radiation control programs are coordinated; and (3) ensure Agreement States provide adequate protection of public health and safety and maintain programs that are compatible with the NRC’s regulatory program.

Although not defined in the AEA, the National Materials Program (NMP) is a term to describe the broad collective effort within which both NRC and the Agreement States function in carrying out their respective regulatory programs for agreement material. The mission of the NMP is to provide a coherent national system for the regulation of agreement material with the goal of protecting public health and safety through compatible regulatory programs. Under the NMP, the NRC and Agreement States function as regulatory partners. The roles and responsibilities of the NRC and the Agreement States are based on their legislative authority, program needs, and expertise. Two national organizations—the Organization of Agreement States (OAS) and Conference of Radiation Control Program Directors, Inc. (CRCPD)—which are composed of State radiation protection programs, also play important roles within the NMP.

⁵ Subsection 274b. of the AEA authorizes the NRC to enter into an agreement by which the NRC discontinues and the State assumes regulatory authority over some or all of these materials. The material over which the State receives regulatory authority under such agreement is termed “agreement material.”

B. BACKGROUND.

This policy statement is intended solely as guidance for the NRC and the Agreement States in the implementation of the Agreement State Program. This policy statement does not itself impose legally binding requirements on the Agreement States. In addition, nothing in this policy statement expands the legal authority of Agreement States beyond that already granted to them by Section 274 of the AEA and other relevant legal authority; nor does this policy statement diminish or constrain the NRC's authority under the AEA. Implementation procedures adopted pursuant to this policy statement shall be consistent with the legal authorities of the NRC and the Agreement States.

This policy statement presents the NRC's policy for determining the adequacy and compatibility of Agreement State programs. This policy statement clarifies the meaning and use of the terms "adequate to protect public health and safety" and "compatible with the NRC's regulatory program" as applied to Agreement State programs. The terms "adequate" and "compatible" represent fundamental concepts in the Agreement State programs authorized in 1959 by Section 274 of the AEA. Subsection 274d. states that the NRC shall enter into an Agreement under Subsection 274b., which discontinues the NRC's regulatory authority over specified AEA radioactive materials and activities within a State, provided that the State's program is adequate to protect public health and safety and is compatible with the Commission's regulatory program. Subsection 274g. authorizes and directs the NRC to cooperate with States in the formulation of standards to assure that State and NRC programs for protection against hazards of radiation will be coordinated and compatible. Subsection 274j.(1) requires the NRC to periodically review the Agreements and actions taken by States under the Agreements to ensure compliance with the provisions of Section 274.

The NRC and Agreement State radiation control programs maintain regulatory authority for the safe and secure handling, use, and storage of agreement material. These programs have always included the security of agreement material as an integral part of their health and safety mission as it relates to controlling and minimizing the risk of exposure to workers and the public. Following the events of September 11, 2001, the NRC's regulatory oversight has included developing and implementing enhanced security measures. For the purposes of this policy statement, public health and safety includes physical protection of agreement material.

C. STATEMENT OF LEGISLATIVE INTENT.

In 1954, the AEA did not initially specify a role for the States in regulating the use of nuclear material. Many States were concerned as to what their responsibilities in this area might be and expressed interest in clearly defining the boundaries of Federal and State authority over nuclear material. This need for clarification was particularly important in view of the fact that although the Federal Government retained sole responsibility for protecting public health and safety from the radiation hazards of AEA radioactive materials, defined as byproduct, source, and special nuclear material, the States maintained the responsibility for protecting the public from the radiation hazards of other sources such as x-ray machines and naturally occurring radioactive material.

Consequently, in 1959, Congress enacted Section 274 of the AEA to establish a statutory framework under which States could assume and the NRC could discontinue regulatory authority over byproduct, source, and small quantities of special nuclear material insufficient to form a critical mass. The NRC continued to retain regulatory authority over the licensing of certain facilities and activities including, nuclear reactors, quantities of special nuclear material sufficient to form a critical mass, the export and import of nuclear materials, and matters related to common defense and security.

The legislation did not authorize a wholesale relinquishment or abdication by the Commission of its regulatory responsibilities but only a gradual, carefully considered turnover. Congress recognized that the Federal Government would need to assist the States to ensure that they developed the capability to exercise their regulatory authority in a competent and effective manner. Accordingly, the legislation authorized the NRC to provide training, with or without charge, and other services to State officials and employees as the Commission deems appropriate. However, in rendering this assistance, Congress did not intend that the NRC would provide any grants to a State for the administration of a State regulatory program. This was fully consistent with the objectives of Section 274 to qualify States to assume independent regulatory authority over certain defined areas under their Agreement and to permit the NRC to discontinue its regulatory responsibilities in those areas.

In order to discontinue its authority, the NRC must find that the State program is compatible with the NRC program for the regulation of agreement material and that the State program is adequate to protect public health and safety. In addition, the NRC has an obligation, pursuant to Subsection 274j. of the AEA, to periodically review existing Agreement State programs to ensure continued adequacy and compatibility. Subsection 274j. of the AEA provides that the NRC may terminate or suspend all or part of its agreement with a State if the NRC finds that such termination is necessary to protect public health and safety or that the State has not complied with the provisions of Subsection 274j. In these cases, the NRC must offer the State reasonable notice and opportunity for a hearing. In cases where the State has requested termination of the agreement, notice and opportunity for a hearing are not necessary. In addition, the NRC may temporarily suspend all or part of an agreement in the case of an emergency situation.

D. PROGRAM IMPLEMENTATION.

1. Implementation of the Agreement State Program is described below and includes (a) Principles of Good Regulation; (b) performance assessment on a consistent and systematic basis; (c) the responsibility to ensure adequate protection of public health and safety, including physical protection of agreement material; (d) compatibility in areas of national interest; and (e) sufficient flexibility in program implementation and administration to accommodate individual State needs.

i. Principles of Good Regulation.

In 1991, the Commission adopted the “Principles of Good Regulation” to serve as a guide to both agency decision making and to individual behavior of NRC employees. There are five Principles of Good Regulation: independence, openness, efficiency, clarity, and reliability. Adherence to these principles has helped to ensure that the NRC’s regulatory activities have been of the highest quality, and are appropriate and consistent. The “Principles of Good Regulation” recognize that strong, vigilant management and a desire to improve performance are prerequisites for success, for both regulators and the regulated industry. The NRC’s implementation of these principles has served the public, the Agreement States, and the regulated community well. Such principles are useful as a part of a common culture of the NMP that the NRC and the Agreement States share as co-regulators. Accordingly, the NRC encourages each Agreement State to adopt a similar set of principles for use in its own regulatory program. These principles should be incorporated into the day-to-day operational fabric of the NMP.

ii. Performance Assessment.

To ensure that Agreement State programs continue to provide adequate protection of public health and safety and are compatible with the NRC’s regulatory program, periodic program assessment is needed. The NRC, in cooperation with the Agreement States, established and implemented the IMPEP. The IMPEP is a performance evaluation process that

provides the NRC and Agreement State management with systematic, integrated, and reliable evaluations of the strengths and weaknesses of their respective radiation control programs and identification of areas needing improvement.

iii. Adequate to Protect Public Health and Safety.

The NRC and the Agreement States have the responsibility to ensure adequate protection of public health and safety in the administration of their respective regulatory programs, including physical protection of agreement material. Accordingly, the NRC and Agreement State programs shall possess the requisite supporting legislative authority, implementing organization structure and procedures, and financial and human resources to effectively administer a radiation control program that ensures adequate protection of public health and safety.

iv. Compatible in Areas of National Interest.

The NRC and the Agreement States have the responsibility to ensure that the radiation control programs are compatible. Such radiation control programs should be based on a common regulatory philosophy including the common use of definitions and standards. The programs should be effective and cooperatively implemented by the NRC and the Agreement States and also should provide uniformity and achieve common strategic outcomes in program areas having national significance.

Such areas of national significance include aspects of licensing, inspection and enforcement, response to incidents and allegations, and safety reviews for the manufacture and distribution of sealed sources and devices. Furthermore, communication using a nationally accepted set of terms with common understanding, ensuring an adequate level of protection of public health and safety that is consistent and stable across the nation, and evaluation of the effectiveness of the NRC and Agreement State programs for the regulation of agreement

material with respect to protection of public health and safety are essential to maintaining a strong NMP.

v. Flexibility.

With the exception of those compatibility areas where programs should be essentially identical, Agreement State radiation control programs have flexibility in program implementation and administration to accommodate individual State preferences, State legislative direction, and local needs and conditions. A State has the flexibility to design its own program, including incorporating more stringent, or similar, requirements provided that the requirements for adequate protection of public health and safety are met and compatibility is maintained. However, the exercise of such flexibility should not preclude a practice authorized by the AEA, and in the national interest.

2. New Agreements.

Section 274 of the AEA requires that once a decision to request Agreement State status is made by the State, the Governor of that State must certify to the NRC that the State desires to assume regulatory responsibility and has a program for the control of radiation hazards adequate to protect public health and safety with respect to the materials within the State that would be covered by the proposed agreement. This certification will be provided in a letter to the NRC that includes a number of documents in support of the certification. These documents include the State's enabling legislation, the radiation control regulations, staffing plan, a narrative description of the State program's policies, practices, and procedures, and a proposed agreement.

The NRC's policy statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement" (46 FR 7540, January 23, 1981; as amended by policy statements published at 46 FR 36969, July 16, 1981; and 48 FR 33376, July 21, 1983), describes the content these

documents are required to cover. The NRC reviews the request and publishes notice of the proposed agreement in the *Federal Register* to provide an opportunity for public comment. After consideration of public comments, if the NRC determines that the proposed State program is adequate for protection of public health and safety and compatible with the NRC's regulatory program, the Governor and Chairman of the NRC sign a formal document memorializing the agreement.

3. Program Assistance.

The NRC will offer training and other assistance to States, such as assistance in developing regulations and program descriptions to help individual States prepare their request for entering into an Agreement and to help them prior to the assumption of regulatory authority. Following approval of the agreement and assumption of regulatory authority by a new Agreement State, to the extent permitted by resources, the NRC may provide training opportunities and offer other assistance such as review of proposed regulatory changes to help Agreement States administer their regulatory responsibilities. However, it is the responsibility of the Agreement State to ensure that they have a sufficient number of qualified staff to implement their program. If the NRC is unable to provide the training, the Agreement State will need to do so.

The NRC may also use its best efforts to provide specialized technical assistance to Agreement States to address unique or complex licensing, inspection, incident response, and limited enforcement issues. In areas where Agreement States have particular expertise or are in the best position to provide immediate assistance to the NRC or other Agreement States, they are encouraged to do so. In addition, the NRC and Agreement States will keep each other informed about relevant aspects of their programs.

If an Agreement State experiences difficulty in implementing its program, the NRC will, to the extent possible, assist the State in maintaining the effectiveness of its radiation control

program. Under certain conditions, an Agreement State can also voluntarily return all or part of its Agreement State program.

4. Performance Evaluation.

Under Section 274 of the AEA, the NRC retains oversight authority for ensuring that Agreement State programs provide adequate protection of public health and safety and are compatible with the NRC's regulatory program. In fulfilling this statutory responsibility, the NRC will determine whether the Agreement State programs are adequate and compatible prior to entrance into a Subsection 274b. agreement and will periodically review the program to ensure they continue to be adequate and compatible after an agreement becomes effective.

The NRC, in cooperation with the Agreement States, established and implemented the IMPEP. As described in Management Directive 5.6 "Integrated Materials Performance Evaluation Program (IMPEP)," IMPEP is a performance evaluation process that provides the NRC and Agreement State management with systematic, integrated, and reliable evaluations of the strengths and weaknesses of their respective radiation control programs and identification of areas needing improvement. The same criteria are used to evaluate and ensure that regulatory programs are adequate to protect public health and safety and that Agreement State programs are compatible with the NRC's program. The IMPEP process employs a Management Review Board, composed of senior NRC managers and an Agreement State liaison provided by the OAS to make a determination of program adequacy and compatibility.

As a part of the performance evaluation process, the NRC will take necessary actions to help ensure that Agreement State radiation control programs remain adequate and compatible. These actions may include more frequent IMPEP reviews of Agreement State programs and providing assistance to help address weaknesses or areas needing improvement within an Agreement State program. Monitoring, heightened oversight, probation, suspension, or termination of an agreement may be applied for certain program deficiencies or emergencies

(e.g. loss of funding, natural or man-made events, pandemic). The NRC's actions in addressing program deficiencies or emergencies will be a well-defined predictable process that is consistently and fairly applied.

5. Program Funding.

Section 274 of the AEA permits the NRC to offer training and other assistance to a State in anticipation of entering into an Agreement with the NRC. Section 274 of the AEA does not allow Federal funding for the administration of Agreement State radiation control programs. Given the importance to public health and safety of having well trained radiation control program personnel, the NRC may offer certain relevant training courses and notify Agreement State personnel of their availability. These training programs also help to ensure compatible approaches to licensing and inspection and thereby strengthen the NMP.

6. Regulatory Development.

The NRC and Agreement States will cooperate in the development of both new and revised regulations and policies. Agreement States will have early and substantive involvement in the development of regulations affecting protection of public health and safety and of policies and guidance documents affecting administration of the Agreement State program. The NRC and Agreement States will keep each other informed about their individual regulatory requirements (e.g., regulations, orders, or license conditions) and the effectiveness of those regulatory requirements so that each has the opportunity to make use of proven regulatory approaches to further the effective and efficient use of resources. In order to avoid conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis, Agreement States should provide a similar opportunity to the NRC to make it aware of, and to provide the opportunity to review and comment on, proposed changes in regulations and significant changes to Agreement State programs, policies, and regulatory guidance.

Two national organizations composed of State radiation protection programs facilitate participation and involvement with the development of regulations, guidance, and policy. The OAS provides a forum for Agreement States to work with each other and with the NRC on regulatory issues, including centralized communication on radiation protection matters between the Agreement States and the NRC. The CRCPD assists its members in their efforts to protect the public, radiation workers, and patients from unnecessary radiation exposure. One product of the CRCPD is the Suggested State Regulations for use by its members. The NRC reviews Suggested State Regulations for compatibility.

E. ADEQUACY AND COMPATIBILITY.

In accordance with Section 274 of the AEA, any State that chooses to establish an Agreement State program must provide for an acceptable level of protection of public health and safety. This is the “adequacy” component. The Agreement State must also ensure that its program serves an overall nationwide interest in radiation protection. This is the “compatibility” component.

By adopting the criteria for adequacy and compatibility as discussed in this policy statement, the NRC provides a broad range of flexibility in the administration of individual Agreement State programs. Recognizing the fact that Agreement States have responsibilities for radiation sources other than agreement material, the NRC allows Agreement States to fashion their programs to reflect specific State needs and preferences.

The NRC will minimize the number of NRC regulatory requirements that the Agreement States will be requested to adopt in an identical manner to maintain compatibility. At the same time, requirements in these compatibility categories allow the NRC to ensure that an orderly pattern for the regulation of agreement material exists nationwide. The NRC believes that this approach achieves a proper balance between the need for Agreement State flexibility and the

need for an NMP that is coherent and compatible in the regulation of agreement material across the country.

Program elements⁶ for adequacy focus on the protection of public health and safety within a particular Agreement State while program elements for compatibility focus on the impacts of an Agreement State's regulation of agreement material on a nationwide basis or its potential effects on other jurisdictions. Some program elements for compatibility may also impact public health and safety; therefore, they may also be considered program elements for adequacy.

In identifying those program elements for adequate and compatible programs, or any changes thereto, the NRC staff will coordinate with the Agreement States.

1. Adequacy.

An "adequate" program includes those program elements of a radiation control regulatory program necessary to maintain an acceptable level of protection of public health and safety within an Agreement State. An Agreement State's radiation control program is adequate to protect public health and safety if administration of the program provides reasonable assurance of protection of public health and safety in regulating the use of agreement material. The level of protection afforded by the program elements of the NRC's materials regulatory program is presumed to be adequate to provide a reasonable assurance of protection of public health and safety. Therefore, the overall level of protection of public health and safety provided by a State program should be equivalent to, or greater than, the level provided by the NRC program. To provide reasonable assurance of protection of public health and safety, an Agreement State program should contain the five essential program elements, identified in

⁶ For the purposes of this policy statement, "program element" means any component or function of a radiation control regulatory program, including regulations and other legally binding requirements imposed on regulated persons, which contributes to implementation of that program.

items i. through v. of this section, that the NRC and Agreement States will use to define the scope of the review of the program. The NRC and Agreement States will also consider, when appropriate, other program elements of an Agreement State that appear to affect the program's ability to provide reasonable assurance of the protection of public health and safety.

i. Legislation and Legal Authority:

Agreement State statutes shall: (a) authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under an Agreement with the NRC; (b) authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health and safety; (c) authorize the State to license, inspect, and enforce legally binding requirements such as regulations and licenses; and (d) be otherwise consistent with applicable Federal statutes. In addition, the State should have existing legally enforceable measures such as generally applicable rules, orders, license provisions, or other appropriate measures, necessary to allow the State to ensure adequate protection of public health and safety in the regulation of agreement material in the State. Specifically, Agreement States should adopt legally binding requirements based on those identified by the NRC because of their particular health and safety significance. In adopting such requirements, Agreement States shall implement the essential objectives articulated in the NRC requirements.

ii. Licensing.

The Agreement State shall conduct appropriate evaluations of proposed uses of agreement material, before issuing a license to authorize such use, to ensure that the proposed licensee's need and proposed uses of agreement material are in accordance with the AEA and that operations can be conducted safely. Licenses shall provide for reasonable assurance of public health and safety protection in the conduct of licensed activities.

iii. Inspection and Enforcement.

The Agreement State shall periodically conduct inspections of licensed activities involving agreement material to provide reasonable assurance of safe licensee operations and to determine compliance with its regulatory requirements. When determined to be necessary by the State, the State should take timely enforcement action against licensees through legal sanctions authorized by State statutes and regulations.

iv. Personnel.

The Agreement State shall be staffed with a sufficient number of qualified personnel to implement its regulatory program for the control of agreement material.

v. Incidents and Allegations.

The Agreement State shall respond to and conduct timely inspections or investigations of incidents, reported events, and allegations involving agreement material within the State's jurisdiction to provide reasonable assurance of protection of public health and safety.

2. Compatibility.

A "compatible" program consists of those program elements necessary to sustain an orderly pattern of regulation of radiation protection. An Agreement State has the flexibility to adopt and implement program elements within the State's jurisdiction that are not addressed by the NRC, or program elements not required for compatibility (i.e., those NRC program elements not assigned to Compatibility Category A, B, or C). However, such program elements of an Agreement State relating to agreement material shall (1) be compatible with those of the NRC (i.e., should not create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis); (2) not preclude a practice authorized by the AEA and in the national interest; and (3) not preclude the ability of the Commission to evaluate the effectiveness of the NRC and Agreement State programs for agreement material with respect to protection of public health and safety. For purposes of

compatibility, the State shall adopt program elements assigned Compatibility Categories A, B, and C.

i. Category A - Basic Radiation Protection Standards.

This category includes basic radiation protection standards that encompass dose limits, concentration and release limits related to radiation protection in part 20 of title 10 of the *Code of Federal Regulations* (10 CFR), that are generally applicable, and the dose limits for land disposal of radioactive waste in 10 CFR 61.41.⁷ Also included in this category are a limited number of definitions, signs, labels, and scientific terms that are necessary for a common understanding of radiation protection principles among licensees, regulatory agencies, and members of the public. Such State standards should be essentially identical to those of the NRC, unless Federal statutes provide the State authority to adopt different standards. Basic radiation protection standards do not include constraints or other limits below the level associated with “adequate protection” that take into account considerations such as economic cost and other factors.

ii. Category B – Cross Jurisdictional Program Elements.

This category pertains to a small number of program elements that cross jurisdictional boundaries and that should be addressed to ensure uniformity of regulation on a nationwide basis. Examples include, but are not limited to, sealed source and device registration certificates, transportation regulations, and radiography certification. Agreement State program elements shall be essentially identical to those of the NRC. Because program elements used in

⁷ The NRC will implement this category consistent with its earlier decision in the low-level waste area to allow Agreement States the flexibility to establish pre-closure operational release limit objectives, as low as is reasonably achievable goals or design objectives at such levels as the State may deem necessary or appropriate, as long as the level of protection of public health and safety is essentially identical to that afforded by NRC requirements.

the Agreement State Program are necessary to maintain an acceptable level of protection of public health and safety, economic factors⁸ should not be considered.

iii. Category C - Other NRC Program Elements.

These are other NRC program elements that are important for an Agreement State to implement in order to avoid conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. Such Agreement State program elements should embody the essential objective of the corresponding NRC program elements. Agreement State program elements may be more restrictive than NRC program elements; however, they should not be so restrictive as to prohibit a practice authorized by the AEA and in the national interest without an adequate public health and safety or environmental basis related to radiation protection.

iv. Category D - Program Elements Not Required for Compatibility.

These are program elements that do not meet any of the criteria listed in Compatibility Category A, B, or C above and are not required to be adopted for purposes of compatibility.

v. Category NRC - Areas of Exclusive NRC Regulatory Authority.

These are program elements over which the NRC cannot discontinue its regulatory authority pursuant to the AEA or provisions of title 10 of the *Code of Federal Regulations*. However, an Agreement State may inform its licensees of these NRC requirements through an appropriate mechanism under the State's administrative procedure laws as long as the State adopts these provisions solely for the purposes of notification, and does not exercise any regulatory authority as a result.

F. CONCLUSION.

⁸ For the purposes of this policy statement, economic factors are those costs incurred by the regulated community to comply with regulations that impact more than one regulatory jurisdiction in the NMP.

The NRC and Agreement States will continue to jointly assess the NRC and Agreement State programs for the regulation of agreement material to identify specific changes that should be considered based on experience or to further improve overall safety, performance, compatibility, and effectiveness.

The NRC encourages Agreement States to adopt and implement program elements that are patterned after those adopted and implemented by the NRC to foster and enhance an NMP that establishes a coherent and compatible nationwide program for the regulation of agreement material.

Dated at Rockville, Maryland, this 25th day of May, 2016.

For the Nuclear Regulatory Commission.

/RA/

Annette L. Vietti-Cook,
Secretary for the Commission.