

NUCLEAR REGULATORY COMMISSION

[NRC-2012-xxxx]

**Policy Statement on Adequacy and Compatibility of Agreement State Programs;
Statement of Principles and Policy for the Agreement State Program**

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft policy statement revision; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing revisions to its policy statements on Agreement State Programs. Both the “Policy Statement on Adequacy and Compatibility of Agreement State Programs” and the “Statement of Principles and Policy for the Agreement State Program” have been revised to add information on security of radioactive materials, safety culture, and incorporate changes in the NRC’s policies and procedures since they became effective in 1997. The revised “Policy Statement on Adequacy and Compatibility of Agreement State Programs” will define “significant transboundary implication.” The NRC is specifically requesting comments on the draft definition of “significant transboundary implication” under Compatibility Category B.

DATES: Submit comments by **[insert date 75 days from 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 access information and comment submissions related to the proposed revisions to the policy statements, which the NRC possesses and are publicly available, by searching on <http://www.regulations.gov> under Docket ID **NRC-2012-XXXX**. You may submit comments by any of the following methods:

- **Federal rulemaking Web site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2012-XXXX**. Address questions about NRC dockets to Carol Gallagher; telephone: 301-492-3668; e-mail: Carol.Gallagher@nrc.gov.

- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail reply confirming receipt, then contact us at 301-415-1677.

- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

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

FOR FURTHER INFORMATION CONTACT: Lisa Dimmick, Office of Federal and State Materials and Environmental Management Programs, 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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- V. Proposed Revision to Statements of Principles and Policy for the Agreement State Program.
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I. Accessing Information and Submitting Comments.

A. Accessing Information

Please refer to Docket ID **NRC-2012-XXXX** when contacting the NRC about the availability of information for the proposed revisions of the policy statements. You may access information related to the proposed revisions of the policy statements, which the NRC possesses and are publicly available, by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2012-XXXX**.

- **NRC's Agencywide Documents Access and Management System (ADAMS):**

You may access public documents online in the NRC Library 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 in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced.

- **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-2012-XXXX** in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

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 submissions into ADAMS.

II. Background.

On August 25, 1993, the Commission requested the NRC staff to recommend improvements to the NRC's Agreement State Program to assure adequate protection of public health and safety. Among these improvements, the NRC staff with participation from Agreement State representatives developed two policy statements. The policy statements are entitled "Policy Statement on Adequacy and Compatibility of Agreement State Programs" and "Statement of Principles and Policy for the Agreement State Program." The Commission approved both policy statements on June 29, 1995, but deferred their implementation until all implementing procedures were completed and approved by the Commission. These policy statements became effective on September 3, 1997 (62 FR 46517).

In Staff Requirements Memorandum (SRM), "SECY-10-0105, Final Rule: Limiting the Quantity of Byproduct Material in a Generally Licensed Device" (ADAMS Accession No. ML103360262) dated December 2, 2010, 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) process¹, the

¹ The NRC developed the IMPEP process to evaluate the adequacy and compatibility of Agreement State Programs and the adequacy of the NRC's nuclear materials program activities.

Commission's policy statement on the "Statement of Principles and Policy for the Agreement State Program" is being revised concurrently. Two working groups operating in accordance with NRC Management Directive 5.3, "Agreement State Participation in Working Groups," dated August 22, 2007 (ADAM Accession No. ML070940610), are drafting the revisions of these policy statement. The two working groups met concurrently and periodically interfaced in developing the proposed revisions. The revisions include adding information on security of radioactive materials, safety culture, and changes in NRC policies and procedures.

III. Discussion.

The Commission tasked staff with updating the Commission's policy statement, "Policy Statement on Adequacy and Compatibility of Agreement State Programs" and associated guidance, to include both safety and source security in the determination process. The policy statement as issued in 1997 continues to remain relevant and effectively serves the mission of the agency. However, staff concluded that the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" and the "Statement of Principles and Policy for the Agreement State Program" both required revision to meet the intent of the SRM by clarifying that security is part of the agency's health and safety mission and update the policy statements to include current policies, procedures, and practices.

Following the events of September 11, 2001, the NRC's regulatory oversight was enhanced by developing and implementing additional security measures. While safety and source security have always been inherent to the protection of public health and safety, the working groups recognized that the two policy statements needed to specifically acknowledge that the NRC and Agreement State oversight of these enhanced security measures should not

be confused with the NRC's mission to promote the common defense and security. The working groups revised the purpose sections of the policy statements to indicate that public health and safety includes physical protection of agreement material.

The two working groups also reconciled a difference in terminology in the policy statements as they were originally published. The "Policy Statement on Adequacy and Compatibility of Agreement State Programs" used the term "agreement material" as byproduct, source, and small quantities of special nuclear material as defined in Section 274b. of the Atomic Energy Act (AEA) of 1954, as amended. The "Statement of Principles and Policy for the Agreement State Program" used the term "AEA material" to describe the same material. While the terms "agreement material" and "AEA material" are generally viewed as synonymous, using different terms in the policies may be construed that the NRC intended the terms to have different meanings. The working groups decided to use the term "agreement material" throughout both policy statements.

Policy Statement on Adequacy and Compatibility of Agreement State Programs

The working group revised the Compatibility Category B discussion to clarify the meaning of "significant transboundary implication." Program elements with significant transboundary implications were illustrated by examples in the 1997 policy statement. The working group concluded the examples were not all-inclusive and could lead to misinterpretation by stakeholders, Agreement States, and the NRC staff. In an attempt to clarify the meaning of a significant transboundary implication, the working group is proposing to define significant transboundary implication as one which crosses regulatory 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, in comments received from Agreement States, the working group realized that the use of the word “particular” can be vague and cause confusion. To help resolve this ambiguity, the NRC staff is specifically asking for public comment on the draft definition of “significant transboundary implication.”

Additional changes to the policy statement were made under the section entitled “Compatibility.” For Compatibility Category B, the working group added that economic factors should not be considered for program elements with significant transboundary implications. The decision for a compatibility category determination should be based on public health and safety and not financial implications. For Compatibility Category C, the working group felt it was important to clarify that program elements and regulations assigned this category of compatibility could be more restrictive than the equivalent NRC program element or regulation.

Statement of Principles and Policy for the Agreement State Program

Several changes were made throughout the document to demonstrate a clear connection between public health and safety and security. The NRC and Agreement State radiation control programs maintain regulatory oversight for the safe and secure handling of nuclear materials. These programs have always included the security of nuclear materials as an integral part of their health and safety mission as it relates to minimizing the risk of exposure to workers and the public. Throughout the 1997 policy statement, the phrase “safe use” of material was used. To foster security for purposes of public health and safety, the phrase “safe use” of material was replaced with “safe and secure use” of material.

The working group also added that organizations performing regulated activities are encouraged to establish and promote a positive safety culture as described in the Final Safety

Culture Policy Statement (76 FR 34773; June 14, 2011). While not incorporated in regulation, many of the traits of a positive safety culture are inherent in existing radiation safety programs. The working group believes organizations overseeing regulated activities involving nuclear material should take steps to promote and maintain a positive safety culture.

Several updates were made to align the policy statement with current practices under IMPEP. The working group expanded the text addressing the actions taken by the NRC as a result of program review findings. Options to address performance issues include monitoring, heightened oversight, probation, suspension, and termination.

IV. Proposed Revision to Policy Statement on Adequacy and Compatibility of Agreement State Programs.

PURPOSE:

Section 274 of the AEA of 1954, as amended, provides for a special Federal-State regulatory framework for the control of byproduct, source, and small quantities of special nuclear material (hereinafter termed “agreement material”) as identified by Section 274b. of the AEA. The NRC, by agreement with a State under Section 274 of the AEA, discontinues² its authority in certain areas to the State Government as long as the State program is adequate to protect public health and safety and compatible with the Commission's³ program. For the

² Other NRC documents have used the term “relinquish” rather than “discontinue” of regulatory authority. Since both terms are essentially the same, either term can be used to describe NRC discontinuance of regulatory authority under a Section 247b. Agreement.

³ For the purposes of this Policy Statement the definition of Commission is equivalent to Title 10 of the *Code of Federal Regulations* Part 1.1: Commission means the five members of the NRC or a quorum thereof sitting as a body, as provided by Section 201 of the Energy Reorganization Act of 1974, as amended.

purpose of this Policy Statement, “public health and safety” includes physical protection of agreement material.

Section 274 further directs the Commission to periodically review State programs to ensure compliance with the provisions of Section 274. This Policy Statement presents the NRC’s policy for determining the adequacy and compatibility of Agreement State programs established in accordance with Section 274. This Policy Statement clarifies the meaning and use of the terms “adequate to protect public health and safety” and “compatible with the Commission's regulatory program” as applied to the Agreement State program. The Policy Statement also describes the general framework that will be used to identify those program elements that Agreement State programs should implement to adequately protect public health and safety and to be compatible with the Commission's regulatory program. For the purposes of this Policy Statement, “program element” means any component or function of a radiation control regulatory program, including regulations and/or other legally binding requirements imposed on regulated persons, that contributes to implementation of that program. Finally, the Policy Statement reflects principles discussed in the Commission's “Statement of Principles and Policy for the Agreement State Program,” which should be considered in conjunction with this Policy Statement.

This Policy Statement is solely guidance for the Commission 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. Implementation procedures adopted under this Policy Statement shall be consistent with the legal authorities of the Commission and the Agreement States.

BACKGROUND:

The terms “adequate” and “compatible” represent fundamental concepts in the Agreement State program authorized in 1959 by Section 274 of the AEA. Subsection 274d. states that the Commission shall enter into an Agreement under subsection 274b., discontinuing the NRC's regulatory authority over certain materials in a State, provided that the State's program is adequate to protect public health and safety and is compatible, in all other respects, with the Commission's regulatory program. Subsection 274g. authorizes and directs the Commission to cooperate with States in the formulation of standards to assure that State and Commission standards will be coordinated and compatible. Subsection 274j(1) requires the Commission to periodically review the Agreements and actions taken by States under the Agreements to ensure compliance with the provisions of Section 274. Therefore, the Commission must review the actions taken by States under the Agreements to ensure that the programs continue to be adequate to protect public health and safety and compatible with the Commission's program.

In identifying those program elements for adequate and compatible programs, or any changes thereto, the NRC staff will seek the advice of the Agreement States. The Commission will consider such advice in its final decision.

DISCUSSION:

In accordance with Section 274 of the AEA, an Agreement State program should provide for an acceptable level of protection of public health and safety in an Agreement State (the “adequacy” component). The Agreement State should also ensure that its program serves an overall nationwide interest in radiation protection (the “compatibility” component).

Program elements for adequacy focus on the protection of public health and safety within a particular 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. Many program elements for compatibility also impact public health and safety; therefore, they may also be considered program elements for adequacy.

1. Adequacy

An "adequate" program should consist of those program elements not required for compatibility but necessary to maintain an acceptable level of protection of public health and safety within an Agreement State. These program elements make up the category Health and Safety. 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 that which is adequate to provide a reasonable assurance of protection of public health and safety. 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 five essential program elements, identified in Sections A. through E., that the Commission will use to define the scope of its review of the program. The Commission will also consider, when appropriate, other program elements of an Agreement State which appear to affect the program's ability to provide reasonable assurance of public health and safety protection. Such consideration will occur only if concerns arise.

A. Legislation and Legal Authority

State statutes should:

- 1) 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 Commission;
- 2) Authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health and safety;
- 3) Authorize the State to license, inspect, and enforce legally binding requirements such as regulations and licenses; and
- 4) Be otherwise consistent with applicable Federal statutes.

In addition, the State should have existing legally enforceable measures such as generally applicable rules, 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. For those items that have significant health and safety implications, the NRC shall identify legally binding requirements that should be adopted by Agreement States. The NRC expects that there will be a limited number of such requirements. In adopting such requirements, Agreement States should adopt the essential objectives of those of the Commission.

B. Licensing

The State should conduct appropriate evaluations of proposed uses of agreement material, before issuing a license, to assure that the proposed licensee's operations can be conducted safely. Licenses should provide for reasonable assurance of public health and safety protection in relation to the licensed activities.

C. Inspection and Enforcement

The State should 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.

D. Personnel

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

E. Incidents and Allegations

The State should 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 should consist of those program elements necessary to meet a larger nationwide interest in radiation protection. Those program elements are generally limited to areas of regulation involving radiation protection standards and activities with significant transboundary implications. An Agreement State radiation control program is compatible with the Commission's regulatory program when its program does not create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the

regulation of agreement material on a nationwide basis. For purposes of compatibility, the State should address the following Categories A, B, and C:

A. Category A - Basic Radiation Protection Standards

For purposes of this Policy Statement, this category includes “basic radiation protection standards” meaning dose limits, concentration and release limits related to radiation protection in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20 that are generally applicable, and the dose limits in 10 CFR 61.41.⁴ 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 Commission, 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 permissible balancing considerations such as economic cost and other factors.

B. Category B - Program Elements with Significant Transboundary Implications

The Commission will limit this category to program elements that have significant transboundary implications. The Commission expects that these will be limited in number. A significant transboundary implication is one which crosses regulatory jurisdictions, has a particular impact on public health and safety, and needs to be addressed to ensure uniformity of

⁴ The Commission will implement this category consistent with its earlier decision in the low-level waste area to allow Agreement States 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 at least equivalent to that afforded by Commission requirements.

regulation on a nationwide basis. Economic factors should not be considered. Agreement State program elements should be essentially identical to those of the Commission.

C. Category C - Other Commission Program Elements

These are other Commission program elements that are important for an Agreement State to have 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 Commission program elements. Agreement State program elements may be more restrictive than Commission program elements.

D. Category D - Program Elements not Required for Compatibility

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 assigned a Compatibility D). However, such program elements of an Agreement State relating to agreement material should:

- 1) Be compatible with those of the Commission (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, or effectively preclude, a practice⁵ in the national interest without an

⁵ For the purposes of this Policy Statement, "practice" means a use, procedure, or activity associated with the application, possession, use, storage, or disposal of agreement material. The term "practice" is used in a broad and encompassing manner in this Policy Statement but does not include economic considerations. The term encompasses both general and specific activities involving the use of agreement materials.

adequate public health and safety or environmental basis related to radiation protection; and

3) Not preclude, or effectively 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.

E. Category NRC - Areas of Exclusive NRC Regulatory Authority

These are program elements that, in accordance with the AEA and provisions of 10 CFR, address areas of regulation where the NRC cannot discontinue its authority. However, an Agreement State may inform its licensees of these NRC provisions through a mechanism that is appropriate 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 of them.

SUMMARY AND CONCLUSIONS:

To foster and enhance a coherent and consistent nationwide program for the regulation of agreement material, the Commission encourages Agreement States to adopt and implement program elements that are patterned after those adopted and implemented by the Commission. However, the fact that an Agreement State's program is compatible with that of the Commission does not affect that State's obligation to maintain an adequate program as described in this Policy Statement.

By adopting the criteria for adequacy and compatibility as discussed in this Policy Statement, the Commission will provide Agreement States a broad range of flexibility in the administration of individual programs. Recognizing the fact that Agreement States have

responsibilities for radiation sources other than agreement material, the Commission allows Agreement States to fashion their programs so as to reflect specific State needs and preferences.

The Commission will identify regulatory requirements that the Agreement States will be requested to adopt in an identical manner to maintain compatibility. The expectation is that these requirements will be limited. Requirements in these compatibility categories allow the Commission to ensure that an orderly pattern for the regulation of agreement material exists nationwide. The Commission believes that this approach achieves a proper balance between the need for Agreement State flexibility and the need for coordinated and compatible regulation of agreement material across the country.

V. Proposed Revisions to Statement of Principles and Policy for the Agreement State Program.

A. Statement of Principles and Policy for the Agreement State Program

PURPOSE:

The purpose of this Statement of Principles and Policy for the Agreement State Program is to clearly describe the respective roles and responsibilities of the NRC and States in the administration of programs carried out under Section 274 of the AEA of 1954, as amended. Section 274 provides broad authority for the NRC to establish Federal and State cooperation in the administration of regulatory programs for the protection of public health and safety in the industrial, medical, commercial, and research uses of nuclear materials.

This Policy Statement addresses the Federal-State interaction under the AEA:

1) to establish and maintain agreements with States under Section 274b. that provide for discontinuance⁶ by the NRC, and the assumption by the State, of responsibility for administration of a regulatory program for the safe and secure use of byproduct, source, and small quantities of special nuclear material; and 2) ensure that post-agreement interactions among the NRC and Agreement State radiation control programs are coordinated, compatible, and continue to provide adequate protection of public health and safety.

Section 274 of the AEA provides for a special Federal-State regulatory framework for the control of byproduct, source, and small quantities of special nuclear material as identified by Section 274b. of the AEA. The NRC, by agreement with a State, discontinues its authority under Section 274 of the AEA over practices involving some or all of these materials. The material over which the State receives regulatory authority under such agreements is hereinafter termed “agreement material.”

The NRC and Agreement State radiation control programs maintain regulatory oversight for the safe and secure handling, use, and storage of agreement material. These programs have always included the security of nuclear materials as an integral part of their health and safety mission as it relates to 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 these enhanced security measures.

This Policy Statement establishes principles, objectives, and goals that the Commission expects will be reflected in the implementing guidance and programs of the NRC

⁶ Other NRC documents have used the term “relinquish” rather than “discontinue” of regulatory authority. Since both terms are essentially the same, either term can be used to describe NRC discontinuance of regulatory authority under a Section 247b. Agreement.

and Agreement States to meet their respective program responsibilities and that should be achieved in the administration of these programs.

This Policy Statement is intended solely as guidance for the Commission 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. Implementation procedures adopted pursuant to this Policy Statement shall be consistent with the legal authorities of the Commission and the Agreement States.

STATEMENT OF LEGISLATIVE INTENT:

The AEA did not initially specify a role for the States in regulating the use of nuclear materials. Many States were concerned as to what their responsibilities in this area might be and expressed interest in seeing that the boundaries of Federal and State authority were clearly defined. 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 byproduct, source, and special nuclear material, the responsibility for protecting the public from the radiation hazards of other sources such as x-ray machines and radium had been borne for many years by the States.

Consequently, in 1959 Congress enacted Section 274 of the AEA to establish a statutory framework under which States could assume certain regulatory jurisdiction over byproduct, source, and special nuclear material in quantities less than a critical mass. The primary purpose of the legislation was to authorize the Commission to discontinue its regulatory authority over the use of these materials and for assumption of this authority by the States. The

Commission retained regulatory authority over the licensing of certain facilities and activities such as nuclear reactors, larger quantities of special nuclear material, the export and import of nuclear materials, and matters related to common defense and security.

In considering the legislation, 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 Commission to provide training and other services to State officials and employees. However, in rendering this assistance, Congress did not intend that the Commission 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 of regulatory jurisdiction and to permit the Commission to discontinue its regulatory responsibilities in those areas.

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

B. Principles of Program Implementation and Program Assessment

The NRC is responsible to ensure that the regulatory programs of the NRC and the Agreement States collectively establish a coherent nationwide effort for the control of agreement material. The basic elements of such regulatory programs include principles of good regulation in program administration and the ability to assess program performance on a consistent and systematic basis; the ability to ensure adequate protection of public health and safety including security of these nuclear materials; compatibility in areas of national interest; and sufficient flexibility to accommodate local needs and conditions. Each of these elements is reflected and addressed in specific sections of this Policy Statement.

1. Good Regulation Principles

In 1991, the Commission adopted "Principles of Good Regulation" to serve as a guide to both agency decision making and to individual behavior as NRC employees. Adherence to these principles has helped to ensure that the NRC's regulatory activities have been of the highest quality, 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 Commission believes that the NRC's implementation of these principles has served the public, the Agreement States, and the regulated community well. The Commission further believes that such principles may be useful as a part of a common culture that the NRC and the Agreement States share as co-regulators. Accordingly, the Commission encourages each Agreement State to adopt a similar set of principles for use in its own regulatory program.

Regulatory decisions and actions should be developed and implemented in an open and publicly credible manner and should be able to withstand scrutiny. Such scrutiny should be welcomed by the regulator. The regulator should be independent and impartial in its actions, and this should be clearly evident. Regulations and regulatory decisions should be based on assessments of the best available information from affected and interested individuals and organizations, as well as on the best available knowledge from research and operational experience. Significant decisions, for example, a change in enforcement policy, should be documented explaining the rationale for such decisions. The public should have an opportunity for early involvement in significant regulatory program decisions. Where several effective alternatives are available, the alternative that best assures safety while considering differing views should be adopted, considering the resources needed to implement that alternative. Regulations should be necessary, and appropriate, to assure safety, and should be clear, coherent, logical, and practical. Regulatory actions should be fully consistent with regulations or other legally binding requirements and good public policy and should lead to stability and predictability in the planning and implementation of radiation control programs.

Failure to adhere to these principles of good regulation in the conduct of operations should be a sufficient reason for a regulatory program to self-initiate program changes that will result in needed improvements. All involved should welcome expressions of concern that indicate a program may not be operating in accordance with these principles and revise their program to more completely reflect these principles.

It is not intended that these principles of good regulation be established as formal criteria against which the NRC and Agreement State programs would be assessed. Rather, the expectation is that these principles will be incorporated into the day-to-day operational fabric of the NRC and Agreement State materials programs. These principles should be used in the

formulation of policies and programs, implementation of those policies and programs, and assessments of program effectiveness. Application of these principles will ensure that complacency will be minimized, that adequate levels of protection of public health and safety are being provided, and that Government employees tasked with the responsibility for these Federal and State regulatory programs serve the public in an effective, efficient, and responsive manner. These principles are primarily for the use of NRC and Agreement State materials program managers and staff in the self assessment of their respective programs and to use in the establishment of goals and objectives for the continual improvement of their respective programs. Deficiencies identified during the conduct of NRC Region and Agreement State formal program performance reviews may indicate that the program is not adhering to these principles of good regulation. The organization being assessed should factor the need for these principles into its actions to address identified deficiencies.

2. 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 controlling the safe and secure use of agreement materials. 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. In addition, the NRC and Agreement States expect individuals and organizations performing regulated activities involving nuclear materials to promote, establish, and maintain a positive safety culture.

3. Compatible in Areas of National Interest

The NRC and the Agreement States have the responsibility to ensure that consistent and compatible radiation control programs are administered. Such radiation control programs should be based on a common regulatory philosophy including the common use of definitions and standards. They should not only be effective and cooperatively implemented by the NRC and the Agreement States, but also should provide uniformity and consistency in program areas having national significance.

Such areas include those affecting interstate commerce, movement of goods and provision of services, enhanced security of nuclear materials, and safety reviews for the manufacture and distribution of sealed sources and devices. Also necessary is the ability to communicate using a nationally accepted set of terms with common understanding, the ability to ensure an adequate level of protection of public health and safety that is consistent and stable across the nation, and the ability of the NRC and each Agreement State to evaluate the effectiveness of the NRC and Agreement State programs for the regulation of agreement material with respect to protection of public health and safety.

4. Flexibility

With the exception of those compatibility areas where all programs should be essentially identical, to the extent possible, Agreement State radiation control programs for agreement materials should be provided with flexibility in program implementation to accommodate individual State preferences, State legislative direction, and local needs and conditions. However, the exercise of such flexibility should not preclude, or effectively preclude, a practice authorized by the AEA, and in the national interest. That is, a State would have the flexibility to design its own program, including incorporating more stringent, or similar, requirements provided that the requirements for adequacy are still met and compatibility is maintained, and the more stringent requirements do not preclude or effectively preclude a practice in the national interest without an adequate public health and safety or environmental basis related to radiation protection.

C. 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 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, a narrative description of the State program's policies, practices, and procedures, and a proposed agreement.

The NRC has published criteria describing the necessary 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 Commission determines that the State program is adequate and compatible, and approves the agreement, a formal agreement document is signed by the Governor and the Chairman of the NRC.

D. 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 for entrance into agreements and to help them prior to the assumption of regulatory authority. Following assumption of regulatory authority by a new Agreement State, to the extent permitted by resources, the NRC may provide training opportunities and other assistance such as review of proposed regulatory changes to help States administer their regulatory responsibilities. The NRC may also use its best efforts to provide specialized technical assistance to Agreement States to address unique or complex licensing, inspection, 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. The NRC will provide an opportunity for Agreement States to have early and substantive involvement in rulemaking, policy, and guidance development activities. 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.

If an Agreement State experiences difficulty in program administration, the Commission would use its best efforts to assist the State in maintaining the effectiveness of its radiation control program. Such assistance could address an immediate difficulty or a chronic difficulty affecting the State's ability to discharge its responsibility to continue to ensure adequate protection of public health and safety.

E. Performance Evaluation

Under Section 274 of the AEA, as amended, the Commission retains authority for ensuring that Agreement State programs continue to provide adequate protection of public health and safety. In fulfilling this statutory responsibility, the NRC will evaluate Agreement State radiation control programs to determine that they are adequate and compatible prior to entrance into a Section 274b. agreement and ensure they continue to be adequate and compatible after an agreement is effective.

The Commission, 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. Performance indicators 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 (MRB), composed of senior NRC managers and an Agreement State Liaison to make a determination of program adequacy and compatibility.

As a part of the performance evaluation process, the Commission will take any 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 provision of assistance to help address weaknesses or areas needing improvement within an Agreement State program. Enhanced oversight, suspension, or termination of an agreement may be considered for serious program deficiencies or emergencies. The NRC's actions will be based on a well defined and predictable process and a performance evaluation program that will be consistently and fairly applied.

F. Levels of Agreement State Program Review Findings

The following discussion outlines the nature of the NRC findings regarding the NRC's Agreement State review process.

1. Adequacy

Finding 1--Adequate To Protect Public Health and Safety

If the NRC finds that an Agreement State program has met all of the review criteria or that only minor deficiencies exist, the NRC would find that the Agreement State's program is adequate to protect public health and safety.

Finding 2--Adequate To Protect Public Health and Safety with Improvement Needed

If the NRC finds that an Agreement State program protects public health and safety, but is deficient in meeting some of the review criteria, the NRC may find that the Agreement

State's program is adequate with improvement needed. The NRC would consider in its determination plans that the State has to address any of the deficiencies noted during the review. In cases where less significant Agreement State deficiencies previously identified have been uncorrected for a significant period of time, the NRC may also find that the program is adequate with improvement needed.

Finding 3--Not Adequate to Protect Public Health and Safety

If the NRC finds that an Agreement State program is significantly deficient in some or all of the review criteria, the NRC would find that the Agreement State's program is not adequate to protect public health and safety.

2. Compatibility

Finding 1--Compatible

If the NRC determines that an Agreement State program contains all required NRC program elements for compatibility, or only minor discrepancies exist, the program would be found compatible.

Finding 2--Not Compatible

If the NRC determines that an Agreement State has a program that disrupts the orderly pattern of regulation among the collective regulatory efforts of the NRC and other Agreement States (i.e., creates conflicts, gaps, or duplication in regulation), the program would be found not compatible.

G. NRC Actions as a Result of These Findings

The following discussion outlines the options available to the NRC as a result of making any of the above findings. The appropriate action will be determined on a case-by-case basis by the MRB. Subsequent to an Agreement State program review, the findings would be recounted in a letter to senior level State management.

If the NRC finds that a State program is adequate and compatible, no further action would be required, except a response by the State to any recommendations.

If serious performance issues are noted during the program review, NRC may increase the frequency of contacts with the State to keep abreast of developments and conduct onsite follow-up reviews to assure that progress is being made on correcting those issues. Circumstances that can lead to more frequent contact between the NRC and the Agreement State program include the following: identification of serious program deficiencies, previously identified deficiencies that have gone uncorrected for a significant period of time, and/or deficiencies in adopting required compatibility program elements.

If findings of subsequent reviews show that the State has taken appropriate corrective actions and that these actions have shown a sustained improvement in performance, the MRB will determine whether the status of an Agreement State program may be moved to another level of oversight. If the MRB finds that all deficiencies have been corrected, it may determine that the Agreement State program is adequate and/or compatible.

Options to address serious performance issues include one or more of the following actions: monitoring, heightened oversight, probation, suspension, and termination.

1. Monitoring

Monitoring is an informal process that allows the NRC to maintain an increased level of communication with an Agreement State Program through periodic (usually bimonthly) calls between the NRC and State managers/staff. Monitoring is implemented in cases where weaknesses in a program have resulted in, or are likely to result in, less than satisfactory performance for one or more performance indicators. Monitoring may be considered based on results of a routine IMPEP review, a followup IMPEP review, a periodic meeting or other interaction with the Agreement State program. In cases where one or more performance indicators remain less than satisfactory or further degraded, the MRB will consider placing a State on Heightened Oversight.

2. Heightened Oversight

Heightened Oversight is a formalized process that allows the NRC to maintain an increased level of communication with an Agreement State usually through monthly calls between the NRC and State managers/staff. Heightened Oversight is implemented in cases where significant program weaknesses are identified, but are not determined to be serious enough to find the program inadequate to protect public health and safety. In addition to the monthly calls, a State placed on Heightened Oversight is required to submit a Program Improvement Plan describing actions to be taken by the State to address the program deficiencies, including specific goals and milestones. The Program Improvement Plan allows the NRC to monitor the actions being taken and the implementation schedule for those actions that address the weaknesses identified based on the results of an IMPEP review, a periodic meeting, or other interaction with the Agreement State program. If programmatic weaknesses are serious enough to find the program inadequate to protect public health and safety, or if

weaknesses continue throughout the period of heightened oversight, the MRB may elect to make a recommendation to the Commission to place the Agreement State on probation.

3. Probation

Probation is a formalized process, requiring Commission approval and notification to the Agreement State's governor, which allows the NRC to maintain an increased level of communication with an Agreement State program. Probation is considered in cases where the State's program is found to be not adequate to protect public health and safety, or not compatible with the NRC's program. An Agreement State may also be placed on probation when it has not addressed previously identified program weaknesses. The process allows the NRC to monitor the actions being taken by the State to correct the identified weaknesses and the implementation schedule for those actions.

Probation would include all the requirements for Heightened Oversight previously described. In addition, the NRC would communicate its findings to a higher level of State management. Written notification of probationary status would be sent to the Governor of the State, a notice published in the *Federal Register*, and a press release issued. Notice would also be given to the State's Congressional delegation, the appropriate Congressional committee(s), and all Agreement and non-Agreement States.

If requested, the NRC may provide technical support for the maintenance of the regulatory program. The probationary period would normally be one year or less. At the end of that time, if the State has not addressed the deficiencies, the NRC may extend the probationary period or institute suspension or termination proceedings.

4. Suspension

Section 274j. of the AEA gives the Commission authority to suspend all or part of its agreement with a State if the suspension is required to protect public health and safety, or if the State has not complied with one or more of the requirements of Section 274 of the AEA. In cases where program deficiencies are such that the Commission must take action to protect public health and safety, or if the program has not complied with one or more of the requirements of Section 274 of the AEA, the Commission may suspend all or part of its agreement with the State. In cases where a State has failed to respond in an acceptable manner during the probationary period, suspension may be considered.

Before reaching a final decision on suspension, the Commission will notify the State and provide the State an opportunity for a hearing on the proposed suspension. Notice of the proposed suspension will also be published in the *Federal Register*. Suspension, rather than termination, would be the preferred option in those cases where the State provides evidence that the program deficiencies are temporary and that the State is committed to correcting the deficiencies that led to the suspension.

In addition to the normal suspension authority, Section 274j(2) of the AEA also addresses emergency situations and gives the Commission authority to temporarily suspend all or part of its agreement with a State without notice or hearing if an emergency situation exists requiring immediate action to protect public health and safety, and the State has failed or is unable to take necessary action within a reasonable time.

In cases where the Commission decides to suspend the agreement, the NRC would communicate its findings to a higher level of State management. The NRC would issue an order temporarily suspending all or part of the 274b. agreement and an order to State licensees

notifying them of the temporary suspension of all or part of the 274b. agreement. Written notification of suspension would be sent to the Governor of the State, a notice published in the *Federal Register*, and a press release issued. Notice would also be given to the State's Congressional delegation, the appropriate Congressional committee(s), and all Agreement and non-Agreement States.

5. Termination

Section 274j. of the AEA gives the Commission authority to terminate all or part of its agreement with a State if such termination is required to protect public health and safety, if the State program has not complied with one or more of the requirements of Section 274 of the AEA (e.g., is found to be not compatible with the Commission's program for regulation of agreement materials), or by State request. When the Commission finds such significant program deficiencies, the Commission would institute formal proceedings to terminate its agreement with the State.

In cases where a State has failed to respond in an acceptable manner during the probationary period and there is no prospect for improvement, termination will be considered. Before reaching a final decision on termination, the Commission will notify the State and provide the State an opportunity for a hearing on the proposed termination. In cases where the State has requested termination of the agreement, notice and opportunity for a hearing are not necessary.

Also, notice of the proposed termination will be published in the *Federal Register*. There may be cases where termination will be considered even though the State program has not been placed on probation.

H. Program Funding

Currently, Section 274 of the AEA does not allow Federal funding for the administration of Agreement State radiation control programs. 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. However, it is the NRC policy not to fund the establishment of new Agreement State programs. Regarding training, given the importance in terms of public health and safety of having well trained radiation control program personnel, the NRC offers certain relevant training courses and notifies Agreement State personnel of their availability.

I. 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 affecting administration of the Agreement State program. The NRC also reviews Suggested State Regulations proposed by the Conference of Radiation Control Program Directors for compatibility. The NRC and Agreement States will keep each other informed about their individual regulatory requirements (e.g., regulations 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.

J. Program Evolution

The NRC-Agreement State program is dynamic and the NRC and Agreement States will continue to jointly assess the NRC and Agreement State programs for the regulation of agreement materials to identify specific changes that should be considered based on experience or to further improve overall performance and effectiveness. The changes considered may include possible legislative changes. The program should also include the formal sharing of information and views such as briefings of the Commission by the Agreement States.

VI. Paperwork Reduction Act.

This Policy Statement does not contain information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting documents displays a currently valid Office of Management and Budget control number.

Dated at Rockville, Maryland, this _____ day of _____, 2012.

For the Nuclear Regulatory Commission.

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