



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 9, 2013

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-12-0112

TITLE: POLICY STATEMENTS ON AGREEMENT STATE
PROGRAMS

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of January 9, 2013.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

A handwritten signature in black ink, appearing to read "Annette Vietti-Cook", written over a horizontal line.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Macfarlane
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
EDO
PDR

VOTING SUMMARY - SECY-12-0112

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MACFARLANE	X				X	10/31/12
COMR. SVINICKI		X			X	12/10/12
COMR. APOSTOLAKIS	X				X	11/26/12
COMR. MAGWOOD		X			X	12/11/12
COMR. OSTENDORFF	X				X	9/26/12

NOTATION VOTE

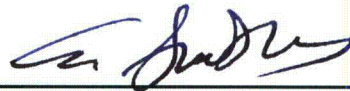
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: Commissioner Apostolakis
SUBJECT: SECY-12-0112 – POLICY STATEMENTS ON
AGREEMENT STATE PROGRAMS

Approved X Disapproved Abstain

Not Participating

COMMENTS: Below Attached X None



SIGNATURE

11/26/12

DATE

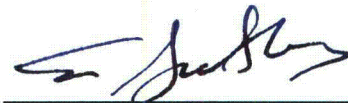
Entered on "STARS" Yes No

Commissioner Apostolakis'
Comments on SECY-12-0112 – Policy Statements on Agreement State Programs

I approve staff's recommendation to seek public comment on proposed revisions to the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" and to the "Statement of Principles and Policy for the Agreement State Program" subject to the attached edits and the following comments.

I agree with Commissioner Ostendorff that comments should be solicited on the definition of transboundary implications. Staff should include a specific section in the Federal Register that would frame the issues and propose possible alternate definitions for comment. Staff should also explore whether the Policy Statement should change transboundary implications to align with Item 3 in the Statement of Principles document.

As a separate matter, staff should engage the Agreement States to develop a recommendation and implementation plan for a performance-based approach for determining compatibility of a State's radiation control program. States could be afforded the flexibility to use approaches, other than rulemaking, to implement new NRC generated requirements. A performance-based approach would not rely on a requirement to adopt within three years from the effective date of the NRC generated regulations to determine compatibility of a State's program. Staff should provide the recommendation and implementation plan to the Commission for approval.



George Apostolakis 11/26/12

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

Deleted: special

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.

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. NRC's implementation of these principles has served the public, the Agreement States, and the regulated community well. The Commission further suggests 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,

Deleted: The Commission believes that the

Deleted: believes

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, these principles ~~should~~ 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

Deleted: the expectation is that

Deleted: will

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. **Under certain conditions Agreement States can also voluntarily return parts or all of its Agreement State program, e.g., Sealed Source and Device evaluations and uranium recovery regulatory oversight (SECY-95-0136).**

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 **Integrated Materials Performance Evaluation Program (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 **NRC** 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

Deleted: IMPEP

Deleted: Commission

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 **IMPEP** 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 **IMPEP** 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

(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

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.

Deleted: Currently,

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 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.

Deleted: The NRC also reviews Suggested State Regulations proposed by the Conference of Radiation Control Program Directors for compatibility.

The Conference of Radiation Control Program Directors, Inc. (CRCPD) assists its members in their efforts to protect the public, radiation worker and patient from unnecessary radiation exposure. CRCPD's mission, in part, is "to promote consistency in addressing and resolving radiation protection issues." The CRCPD provides a forum for centralized communication on radiation protection matters between the states and the federal government, and between the individual states. One product of this forum is the development of the CRCP Suggested State Regulations for use by its members. The NRC also reviews Suggested State Regulations for compatibility.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MAGWOOD
SUBJECT: SECY-12-0112 – POLICY STATEMENTS ON AGREEMENT STATE PROGRAMS

Approved Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below _____ Attached None _____



SIGNATURE

11 December 2012

DATE

Entered on "STARS" Yes No _____

**Commissioner Magwood's Comments on SECY-12-0112,
"Policy Statements on Agreement State Programs"**

I appreciate the hard work of the staff and our Agreement State partners in the review and update of the subject policy statements. While the public focuses its attention on the activities of the NRC, the reality is that Agreement State personnel are more often on the front lines of radiation protection. These dedicated professionals quietly assure that nearly 19,000 industrial, medical, and other licensees in a manner that protects the health, safety, and security of the public and the workers involved. State organizations with these responsibilities are very often buried in bureaucracies that do not appreciate the unique and important work they do, making staffing, funding, and the update of regulations more difficult than is either necessary or wise.

The NRC's relationship with Agreement States has been a work in progress since the inception of the program. This effort to update the policy statements represents the latest concept of the relationship. While these policy statements include necessary updates and changes, they do represent neither a careful, policy-level consideration of the relationship between the states and the NRC nor the many difficult challenges that today face state programs across the country. In that respect, these draft policy statements are a disappointment, though not a surprising one. It is clear to me that such a consideration would require the Commission to engage these issues as a matter of high priority. Given the exigencies that have dominated the last two years, this simply has not been possible. However, I am hopeful that we will be in a position to discuss this matter more fully in the coming year.

For the present, however, I see nothing gained by delaying public consideration of the draft policy statements. They are the result of very good, very cooperative work between NRC and Agreement State staffs and provide an important opportunity to engage the public in a discussion of these very important issues. I therefore approve staff's recommendation to seek public comment on the proposed revisions to the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" and to the "Statement of Principles and Policy for the Agreement State Program" subject to the edits provided by Commissioners Apostolakis and Svinicki. I also support Commissioner Svinicki's comments regarding the use of the term "relinquish" and the new inclusion of "safety culture expectations" among the mandatory elements of Agreement State programs. Further, I agree with Commissioners Ostendorff and Apostolakis that comments should be solicited on the definition of transboundary implications.

Most important, I also agree with Commissioner Apostolakis that the staff should engage the Agreement States to develop a recommendation for a performance-based approach for determining compatibility of State's radiation control program. However, in addition to compatibility, the staff should also engage the Agreement States on a revised set of performance metrics which could replace, supplement, or expand upon the IMPEP program to

determine the adequacy of states' radiation safety programs such that both the adequacy and compatibility of the program is measured holistically.

I suggest that staff also develop a question that could be included in the *Federal Register* notice to seek input on how we might develop a performance-based approach for measuring compatibility and adequacy. Given the current environment of limited resources, it is imperative that the agency, working with our Agreement State partners, be able to develop a clear set of performance based metrics that consider the limitations the of Agreement States Programs and provide increased flexibility without compromising public health and safety.

While not the wholesale, strategic policy review of the program I believe is warranted, I believe seeking public input on these policy statements can provide us a very beneficial platform from which additional discussion may proceed.

 12/11/12

William D. Magwood, IV

Date

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: Commissioner Ostendorff
SUBJECT: SECY-12-0112 – POLICY STATEMENTS ON
AGREEMENT STATE PROGRAMS

Approved X Disapproved Abstain

Not Participating

COMMENTS: Below Attached X None

W Ostendorff
SIGNATURE

9/10/12
DATE

Entered on "STARS" Yes X No

Commissioner Ostendorff's Comments on SECY-12-0112, "Policy Statements on Agreement State Programs"

I approve publishing for comment in the *Federal Register* draft revisions to the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" and the "Statement of Principles and Policy for the Agreement State Program," subject to the attached edits. In addition to the edits to the policy statements, the staff should make conforming changes to the *Federal Register* Notice. Given that a great majority of nuclear materials are regulated by the Agreement States, the NRC's partnership with the States is a critical aspect of the agency's operations. These policy statements provide a critical framework for the NRC's relationship with the States in advancing the nationwide regulation of nuclear materials.

Historically, whether an issue has transboundary implications, and therefore requires close alignment of State and Federal regulations, has been an area of concern due to the need for a flexible yet consistent national regulatory program. I therefore appreciate the staff's efforts to further define "transboundary implications" and, given the diverse opinions on this issue, solicit comments on the proposed revised definition. I share the Agreement States' concern, however, that the use of the word "particular" in the definition may cause confusion. The staff should solicit comments on whether replacing "particular" with "significant and direct," the language used in Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs," would be more appropriate and provide additional clarity. Additionally, the staff should solicit comments on whether the definition should include consideration of the movement of goods and services, which has historically been the main factor in determining whether an issue has transboundary implications.

I also appreciate the open and transparent manner in which the staff documented the dissenting opinions on two of the proposed changes to the policy statement describing the adoption of compatible regulations. I appreciate that the staff's revisions were intended to clarify that the Commission's authority to determine the compatibility requirements of its regulations is not limited; however, the current language in these sections has not and should not be interpreted as limiting the Commission's authority. Because revisions to language that has been in place since 1997 may suggest that the Commission is revisiting its policies and half of the working group disagreed that a revision in these areas was needed, the staff should maintain the current language. The staff should, however, solicit comments on these sections of the policy statements and provide its analysis of these comments to the Commission in the notation vote paper that will be submitted to request finalization of the policy statements.

**Policy POLICY STATEMENT statement on ON Adequacy ADEQUACY and AND
Compatibility COMPATIBILITY
Of of Agreement AGREEMENT STATE state PROGRAMS programs**

Purpose PURPOSE:

Section 274 of the Atomic Energy Act (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. radioactive materials under which Tthe U.S. Nuclear Regulatory Commission (NRC), by agreement with a State under Section 274 of the AEA, discontinues¹ relinquishes its authority in certain areas to the State Ggovernment as long as the State program is adequate to protect public health and safety and compatible with the Commission's² program. For the 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 provisions of Section 274. This Policy Statement presents the NRC's Nuclear Regulatory Commission's policy for determining the adequacy and compatibility of Agreement State programs established in accordance with pursuant to 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 elements³ that Agreement State programs should implement to be adequately to 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

¹ 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 274b. Agreement.

² 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.

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement .

States beyond that already granted to them by Section 274 of the ~~A~~Atomic Energy Act 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.

Background~~BACKGROUND:~~

_____ The terms "adequate" and "compatible" represent fundamental concepts in the Agreement State program authorized in 1959 by Section 274 of the Atomic Energy Act of 1954, as amended (AEA). Subsection 274d. states that the Commission shall enter into an Agreement under subsection 274b., discontinuing 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 ~~review~~ periodically review the Agreements and actions taken by States under the Agreements to ensure compliance with provisions of Section 274. ~~Therefore~~In other words, 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.

~~Section 274 of the AEA requires that Agreement State programs be both "adequate to protect the public health and safety" and "compatible with the Commission's program." These separate findings are based on consideration of two different objectives. First, an Agreement State program should provide for an acceptable level of protection of public health and safety in an Agreement State (the "adequacy" component). Second, the Agreement State should ensure that its program serves an overall nationwide interest in radiation protection (the "compatibility" component). As discussed in more detail below, an "adequate" program should consist of those program elements necessary to maintain an acceptable level of protection of public health and safety within an Agreement State. A "compatible" program should consist of those program elements necessary to meet a larger nationwide interest in radiation protection generally limited to areas of regulation involving radiation protection standards and activities with significant transboundary implications. Program elements for adequacy focus on the protection of public health and safety within a particular State, whereas 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.~~

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

DISCUSSION:

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement .

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 include 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^[a]. 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 source, byproduct, and small quantities of special nuclear material (hereinafter termed "agreement material.") as identified by Section 274b. of the AEA. The level of protection afforded by the program elements of 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. below, that the Commission will use to define the scope of its review of the program. The Commission also will 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:

— 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;

1)

— Authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health and safety;

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement .

2)

— Authorize the State to license, inspect, and enforce legally binding requirements such as regulations and licenses; and

3)

4) Be otherwise consistent with applicable Federal statutes, ~~as appropriate, such as Pub. L. 95-604, The Uranium Mill Tailings Radiation Control Act (UMTRCA).~~

_____ 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 Specifically, Agreement States should adopt a limited number of legally binding requirements that should be adopted by Agreement States based on those of NRC because of their particular health and safety significance. 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 periodically 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. Response to Events/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

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

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 promoting an orderly pattern^[a2] of regulation of 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 categories A, B, and C ~~identified below~~:

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) CFR Part 20 that are generally applicable, and the dose limits in 10 CFR 61.41.¹ 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 a small number^[a3] of program elements (e.g., transportation regulations and sealed source and device registration certificates) that have significant transboundary implications. A significant transboundary implication is one which crosses regulatory jurisdictions, has a particular impact on public health and safety, and^[a4] needs to be addressed to ensure uniformity of regulation

¹ The Commission will implement this category consistent with its earlier decision in the low-level waste-LLW area to allow Agreement States flexibility to establish pre-closure operational release limit objectives, as low as reasonably achievable ALARA-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.

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement .

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 ~~C~~ Other Commission Program Elements

These are other Commission program elements ~~(e.g., reciprocity procedures)~~ 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.

Category

D. D ~~D~~ Program Elements not Required for Compatibility

An Agreement State has the flexibility to adopt and implement program elements based on those of the Commission (other than those identified in A, B, and C above) or other program elements within the State's jurisdiction that are not addressed by NRC, or program elements not required for compatibility (i.e., those NRC program elements assigned a compatibility D). However, such

~~All~~ 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 practice² in the national interest without an adequate public health and safety or environmental basis related to radiation protection; ~~and/or~~
- 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 - E ~~E~~ Areas of Exclusive NRC Regulatory Authority

² 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.

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement .

These are program elements that in accordance with the AEA and provisions of 10 CFR, address areas of regulation ~~that cannot be relinquished to Agreement States pursuant to the AEA or provisions of Title 10 of the Code of Federal Regulations where the NRC cannot discontinue its authority~~. However, an Agreement State may inform its licensees ~~of certain~~ 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 ~~pursuant as a result of~~ to them.

Summary and Conclusions **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. ~~In doing so, 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, ~~recognizing the fact that Agreement States have responsibilities for radiation sources in addition to agreement material.~~

The Commission will minimize the number of ~~NRC~~^[a5] regulatory requirements that the Agreement States will be requested to adopt in an identical manner to maintain compatibility. ~~At the same time, R~~requirements in these compatibility categories ~~will~~ 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.

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

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 discontinuance¹ 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 that Agreement State programs, 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 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.

¹ 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.

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

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, ~~and~~ 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 relinquish/discontinue its authority ~~to a particular State~~, the Commission must find that a particular State program is compatible with the Commission's program for the regulation of radioactive/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 Act/AEA, to periodically review existing Agreement State programs to ensure continued adequacy and compatibility. Section 274j of the Act/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.

A. ~~C~~—Principles of Program Implementation and Program Assessment

The NRC is responsible to for -ensuring 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;

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

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 minimizes the use of resources 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

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

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. Coherent Nationwide Effort~~

~~The mission of the NRC is to assure that civilian use of nuclear materials in the United States is carried out with adequate protection of public health and safety. NRC acknowledges its responsibility, shared with the Agreement States, to ensure that the regulatory programs of the NRC and the Agreement States collectively establish a coherent nationwide effort for the control of AEA materials. The basic elements of such regulatory programs include ability to ensure adequate protection of public health and safety, compatibility in areas of national interest, sufficient flexibility to accommodate local needs and conditions, ability to assess program performance on a consistent and systematic basis, and principles of good regulation in program administration.~~

~~Each of these elements is reflected and addressed in specific sections of this Policy Statement.~~

~~3.~~ **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 ~~uses~~safe and secure use of ~~AEA~~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.

~~4.~~ **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 ~~be~~ 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 Category 1 and 2 nuclear materials~~^[a2], and safety reviews for the manufacture and distribution of sealed sources~~sources and devices sold nationwide~~. 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.

~~5.~~

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

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 ~~AEA~~ **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.

B. ~~D.~~ New Agreements

Section 274 of the ~~Atomic Energy Act~~ **AEA** requires that once a decision to ~~seek 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.

C. ~~E.~~ 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 ~~can~~ **may** provide training **opportunities** and other assistance such as review of proposed regulatory changes to help States administer their regulatory responsibilities. ~~The~~ NRC ~~would~~ **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, ~~the 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

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

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.

D. ~~F.~~ 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 provide oversight ~~evaluate~~ Agreement State radiation control programs to ~~ensure~~ determine whether ~~that~~ they are adequate and compatible prior to entrance into a Section 274b agreement and ~~that~~ ensure they continue to be adequate and compatible after an agreement is effective.

_____ The Commission, in cooperation with the Agreement States, ~~will establish~~ established and ~~implement~~ implemented the IMPEP. The IMPEP is a performance evaluation program to provide 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 ~~this~~ 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: ~~(1) Periodic assessments more frequent IMPEP reviews~~ of Agreement State ~~radiation control~~ programs ~~against established review criteria;~~ ~~(2) and~~ provision of assistance to help address weaknesses or areas needing improvement within an Agreement State ~~radiation control~~ program ~~requiring improvement, to the extent permitted by NRC resources;~~ ~~(3) placing a State on a probationary status for serious program deficiencies that require heightened, Enhanced~~ oversight; ~~(4) temporary, suspension of an agreement and reassertion of NRC regulatory authority in an emergency if an Agreement State program experiences any immediate program difficulties preventing the State from continuing to ensure adequate protection of public health and safety; and (5) suspension, or termination of an agreement and reassertion of NRC regulatory authority if the Agreement State program experiences difficulties that jeopardize the State's ability to continue to ensure adequate protection of public health and safety may be considered for serious program deficiencies~~ or ~~to continue to maintain a compatible program emergencies.~~ The basis for 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.

E. ~~G.~~ 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.

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

1. Adequacy

Finding 1--Adequate To Protect Public Health and Safety and (or not) Compatible

_____ If the NRC finds that ~~a State program has met all of the an~~ Agreement State program ~~has met all of the~~ review criteria or that only minor deficiencies exist, the ~~Commission~~NRC would find that the Agreement State's program is adequate to protect public health and safety. ~~If the NRC determines that a State program contains all required NRC program elements for compatibility, or only minor discrepancies exist, the program would be found compatible. If the NRC determines that a 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.~~
Finding 2--Adequate, but Needs To Protect Public Health and Safety with Improvement and (or not) Compatible 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, but needs 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 but in need of 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. ~~If the NRC determines that a 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.~~

Finding 3--Inadequate to Protect Public Health and Safety and (or not) 2--Not Compatible

~~If the NRC finds that a State program is significantly deficient in some or all of the review criteria, the NRC would find that the State's program is not adequate to protect public health and safety. If the NRC determines that a State program contains all required NRC program elements for compatibility, or only minor discrepancies exist, the program would be found 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.~~

H.

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

F. 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 ~~NRC management.~~

Letters

~~In all cases, subsequent~~the MRB. Subsequent to an Agreement State program review, the findings would be recounted in a letter to senior level State management. ~~In the event that~~ _____ 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 ~~suggestions or recommendations.~~ ~~In the case where minor deficiencies are noted or areas for improvement are identified, the State would be requested to describe their proposed corrective action. If the corrective action appears appropriate, no further NRC action is required. If additional clarification of the corrective actions is needed, additional correspondence may be necessary.~~ recommendations.

Follow-up Reviews

~~In the event that deficiencies~~ _____ 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 ~~program deficiencies.~~ ~~If, during follow-up reviews, it is shown that the State has taken corrective actions, a letter finding the State adequate and compatible would be provided.~~ 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.

Probationary Status

~~There are three circumstances that can lead to an adequate but needs improvement or incompatible State program being placed in a probationary status: (1) There are cases in which program deficiencies may be serious enough to require immediate heightened oversight; (2) in other cases, Agreement State program deficiencies previously identified may have been uncorrected for a significant period of time; and (3) if the NRC determines that a State program has been late in adopting required compatibility program elements and significant disruption in the collective nationwide efforts to regulate AEA materials has occurred. If the NRC was not confident that the State would address the program deficiencies in an expeditious and effective manner, the Commission would place the State program on probation.~~

~~As a result of placing a State program on probation~~ 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

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

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. ~~Notice~~Written notification of such probationary status would normally be addressed sent to the Governor of the State. ~~Notice would also be~~, a notice published in the Federal Register. ~~A copy of the letter to the Governor would be placed in the Public Document Room,~~ and a press release would be issued. Notice would also be given to the State's

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

Congressional delegation, the appropriate Congressional committee(s), and all Agreement and non-Agreement States.

~~Once a State program is placed on probation, the NRC would heighten its oversight of the program. This would include obtaining commitments from the State in the form of a management plan to describe actions to be taken by the State to address the program deficiencies, including specific goals and milestones. The NRC would increase observation of State program activities under the agreement to assure adequate protection of public health and safety. If _____ If requested and in accordance with terms agreed to by the parties, the NRC would consider providing, the NRC may provide~~ technical support for the maintenance of the regulatory program. The probationary period would ~~last for a specified period of time. This period would not~~ normally be ~~more than~~ one year, ~~but could be extended based on extenuating circumstances or less~~. At the end of that time, if the State has not addressed the deficiencies, the NRC ~~would~~ may extend the probationary period or institute suspension or termination proceedings.

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

1.4. **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 ~~the Commission finds that~~ program deficiencies ~~related to either adequacy or compatibility~~ 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 ActAEA, the Commission ~~would~~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 ~~would~~may be considered. ~~If the situation is not resolved, termination will 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 ActAEA 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.

2.5. **Termination**

Section 274j of the ~~Atomic Energy Act~~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, ~~or~~ if the State program has not complied with one or more of the requirements of Section 274 of the ActAEA (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.

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

____ 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.

G. ~~I.~~ Program Funding

____ Currently, Section 274 ~~of the AEA~~ does not allow ~~federal~~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~~. 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.

H. ~~J.~~ Regulatory Development

____ The NRC and Agreement States will cooperate in the development of both new and revised regulations and poli~~ci~~es. Agreement States will have early and substantive involvement in the development of ~~new~~ regulations affecting protection of public health and safety and of ~~new poli~~ci~~es~~ affecting administration of the Agreement State program. ~~Likewise, the~~ The NRC ~~expects to have the States provide it with early and substantive involvement in the development of new~~ 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.

~~K.~~

I. 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 AEA~~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.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: Chairman Allison M. Macfarlane
SUBJECT: SECY-12-0112 – POLICY STATEMENTS ON AGREEMENT STATE PROGRAMS

Approved X Disapproved Abstain

Not Participating

COMMENTS: Below Attached X None



SIGNATURE

10/31/12

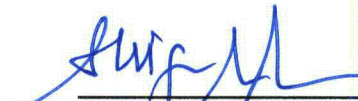
DATE

Entered on "STARS" Yes X No

**Chairman Macfarlane's Comments on SECY-12-0112,
"Policy Statements on Agreement State Programs"**

I approve the staff's recommendation to publish draft revisions to the Policy Statement on Agreement State Programs and the Statement of Principles and Policy for the Agreement State Program for public comment. I commend the staff for taking the initiative to go beyond the initial Commission direction, and to integrate safety culture principles into these documents. The better we can ensure that both NRC and the Agreement States have a common understanding of what "safety culture" means and how it is implemented, the stronger our programs will be. To be clear, I do not see this as a current problem, but I believe that incorporating this concept in our policy statement will ensure alignment in the future.

I thank the staff for presenting the Commission with a paper including a dissenting opinion. The working group was split on the issue of Compatibility Category B in the Policy Statement on Adequacy and Compatibility. The dissent was held by half of the working group members, including the State representatives. Currently, I support the draft documents as presented in SECY-12-0112, however, because these are draft documents, the staff should take advantage of the opportunity and specifically solicit public comments on the alternative versions of the sentences in question (the 1997 version compared to the proposed revisions). I look forward to reading the thoughts of States, licensees, and members of the public on this issue.


Allison M. Macfarlane

10/31/12
Date

NOTATION VOTE


RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER SVINICKI
SUBJECT: SECY-12-0112 – POLICY STATEMENTS ON
AGREEMENT STATE PROGRAMS

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below _____ Attached XX None _____



SIGNATURE

12/10/12

DATE

Entered on "STARS" Yes No _____

Commissioner Svinicki's Comments on SECY-12-0112
Policy Statements on Agreement State Programs

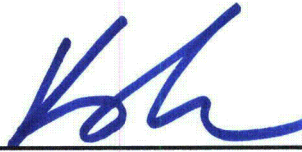
I approve the staff's request to publish for public comment in the *Federal Register* the draft revisions to the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" and the "Statement of Principles and Policy for the Agreement State Program," subject to the attached edits and following comments. Where edits have been provided solely to the policy statements, conforming changes should also be made to the policy statement language, when it is incorporated into the *Federal Register* notice.

I do not approve expunging the term "relinquish" from the policy statements and inserting the word "discontinue." It has been my observation that the NRC communicates two distinct concepts with these terms, when read in context. The NRC "relinquishes" its regulatory authority over certain areas to the State government but maintains its ultimate, supervisory control of Agreement State programs through the conduct of its Integrated Management Performance Evaluation Program and its ability to impose sanctions for underperforming programs, including probation, suspension, or termination. The NRC "discontinues" its responsibility for the ongoing administration of a regulatory program exercising control over agreement material. An important, albeit subtle, distinction is lost by discontinuing the use of the word "relinquish," which communicates more precisely the condition of NRC's authority over Agreement State programs. The attached edits are intended to re-establish this distinction.

The insertion of safety culture expectations in the section of the "Statement of Principles and Policy for the Agreement State Program" that defines the mandatory elements that Agreement State programs "shall possess" for a positive determination of adequacy is confusing and inconsistent with the purpose of the section. The Commission has promulgated a free-standing policy statement outlining its expectations regarding safety culture and has worked with the Agreement States in its development and dissemination. My edits would remove this ill-placed and superficial reference to the Commission's safety culture policy.

I approve Commissioner Ostendorff's proposal that comments should be solicited on the definition of transboundary implications. Staff should include a section in the *Federal Register* notice, framing the issues and proposing possible alternative definitions to be commented on, including the option of replacing "particular" with "significant and direct." The policy statement should retain its current language, until comment has been received and evaluated. Additionally, the inserted prohibition on considering any economic factors related to transboundary implications under compatibility Category B is not explained. This revision

should be removed and comments solicited on the underlying issue. I also agree with Commissioner Ostendorff that while staff may have intended its proposed revisions to the policy statement describing the adoption of compatible regulations to clarify the Commission's authority, it is not clear that this change is necessary in practice. The policy statement should retain its existing language while comments are solicited on these sections of the policy statement.



Kristine L. Svinicki

12/10 /12

KLS edits
as noted.

Policy-POLICY STATEMENT ~~statement on~~ **ON Adequacy-ADEQUACY and AND**
Compatibility-COMPATIBILITY
Of Agreement-AGREEMENT STATE ~~ate~~ **PROGRAMS** ~~ograms~~

PurposePURPOSE:

Section 274 of the Atomic Energy Act (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 ~~radioactive materials under which~~ ~~the U.S. Nuclear Regulatory Commission (NRC), by agreement with a State under Section 274 of the AEA,~~ ~~discontinues~~ ~~relinquishes~~ its authority in certain areas to the State ~~G~~overnment as long as the State program is adequate to protect public health and safety and compatible with the Commission's² program. ~~For the purpose of this Policy Statement, "public health and safety" includes physical protection of agreement material.~~

stet
X

Section 274 further directs the Commission to periodically review State programs to ensure compliance with provisions of Section 274. This Policy Statement presents the ~~NRC's~~ ~~Nuclear Regulatory Commission's~~ policy for determining the adequacy and compatibility of Agreement State programs established in accordance with ~~pursuant to~~ Section 274. This Policy Statement clarifies the meaning and use of the terms "adequate to protect public health and safety"¹ and "compatible with the Commission's regulatory program"² as applied to the Agreement State program. The Policy Statement also describes the general framework that will be used to identify those program elements³ that Agreement State programs should implement to ~~be~~ adequately to 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

¹ 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 274b. Agreement.

X

Formatted: Font: (Default) Arial, 11 pt

² 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.

Formatted: Font: (Default) Arial

Formatted: Font: (Default) Arial, 11 pt

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement .

States beyond that already granted to them by Section 274 of the ~~AE~~**Atomic Energy Act** 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.

Formatted: Header distance from edge: 1"

Background~~BACKGROUND:~~

The terms "adequate" and "compatible" represent fundamental concepts in the Agreement State program authorized in 1959 by Section 274 of the ~~Atomic Energy Act of 1954, as amended~~ (AEA). Subsection 274d. states that the Commission shall enter into an Agreement under subsection 274b., discontinuing 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 review periodically~~ **review** the Agreements and actions taken by States under the Agreements to ensure compliance with provisions of Section 274. ~~Therefore~~**In other words**, 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.

stet
x (The change creates a split infinitive.)

~~Section 274 of the AEA requires that Agreement State programs be both "adequate to protect the public health and safety" and "compatible with the Commission's program." These separate findings are based on consideration of two different objectives. First, an Agreement State program should provide for an acceptable level of protection of public health and safety in an Agreement State (the "adequacy" component). Second, the Agreement State should ensure that its program serves an overall nationwide interest in radiation protection (the "compatibility" component). As discussed in more detail below, an "adequate" program should consist of those program elements necessary to maintain an acceptable level of protection of public health and safety within an Agreement State. A "compatible" program should consist of those program elements necessary to meet a larger nationwide interest in radiation protection generally limited to areas of regulation involving radiation protection standards and activities with significant transboundary implications. Program elements for adequacy focus on the protection of public health and safety within a particular State, whereas 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.~~

stet this sentence and make it the first sentence on page 3, first paragraph. X

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

DISCUSSION:

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement .

[~~Start sentence from Page 2~~]

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 ~~source, byproduct, and small quantities of special nuclear material (hereinafter termed "agreement material.") as identified by Section 274b of the AEA.~~ The level of protection afforded by the program elements of 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. below**, that the Commission will use to define the scope of its review of the program. The Commission also will 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.

Formatted: Underline

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0.64" + Indent at: 0.89"

A. Legislation and Legal Authority

Formatted: Font: Not Bold

State statutes should:

— 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;

1)

— Authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health and safety;

Formatted: Indent: Left: 0", Hanging: 0.19", Numbered + Level: 1 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0.25" + Indent at: 0.5"

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement .

2)

—Authorize the State to license, inspect, and enforce legally binding requirements such as regulations and licenses; and

3)

4) Be otherwise consistent with applicable Federal statutes, ~~as appropriate, such as Pub. L. 95-604, The Uranium Mill Tailings Radiation Control Act (UMTRCA).~~

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 Specifically, Agreement States should adopt a limited number of~~ legally binding requirements ~~that should be adopted by Agreement States based on those of NRC because of their particular health and safety significance.~~ 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 ~~periodically~~ 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.

[Changes the meaning of periodic "evaluation occurs after licensing.]
X

Formatted: Font: Not Bold
Formatted: Indent: First line: 0.63"

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.

Formatted: Font: Not Bold
Formatted: Indent: First line: 0.63"

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.

Formatted: Font: Not Bold
Formatted: Indent: First line: 0.63"

E. ~~Response to Events~~ 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

Formatted: Font: Not Bold
Formatted: Indent: First line: 0.63"

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement .

State's jurisdiction to provide reasonable assurance of protection of public health and safety.

2. Compatibility

Formatted: Underline

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 categories A, B, and C ~~identified below~~:

A. Category A – Basic Radiation Protection Standards

Formatted: Font: Not Bold

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) ~~CFR Part~~ 20 that are generally applicable, and the dose limits in 10 CFR 61.41.¹ 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.

Formatted: Numbered + Level: 1 +
Numbering Style: A, B, C, ... + Start at: 1 +
Alignment: Left + Aligned at: 0.64" + Indent
at: 0.89"

Formatted: Indent: First line: 0.63"

B. Category B – Program Elements with Significant Transboundary Implications

Formatted: Font: Not Bold

The Commission will limit this category to a small number of program elements (e.g., ~~transportation regulations and sealed source and device registration certificates~~) 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 regulation on a nationwide basis. ~~Economic~~

Formatted: Numbered + Level: 1 +
Numbering Style: A, B, C, ... + Start at: 1 +
Alignment: Left + Aligned at: 0.64" + Indent
at: 0.89"

Formatted: Indent: First line: 0.5"

¹ The Commission will implement this category consistent with its earlier decision in the low-level waste ~~LLW~~ area to allow Agreement States flexibility to establish pre-closure operational release limit objectives, as low as reasonably achievable ALARA 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.

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement .

~~factors should not be considered.~~ Agreement State program elements should be essentially identical to those of the Commission.

[This sentence appears to represent a shift in policy. Leave it out but solicit for comment on including it.] X

C. Category C – Other Commission Program Elements

These are other Commission program elements ~~(e.g., reciprocity procedures)~~ 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.

(This sentence needs a qualifier. There are a lot of limits on how restrictive, before running afoul of other trans boundary or compatibility issues.) X

Category D. D – Program Elements not Required for Compatibility

An Agreement State has the flexibility to adopt and implement program elements ~~based on those of the Commission (other than those identified in A, B, and C above) or other program elements~~ within the State's jurisdiction that are not addressed by NRC, or program elements not required for compatibility (i.e., those NRC program elements assigned a compatibility D). However, such -

All 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 practice² in the national interest without an adequate public health and safety or environmental basis related to radiation protection; ~~and/or~~
- 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 - E. Areas of Exclusive NRC Regulatory Authority

² 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.

Formatted: Font: Not Bold

Formatted: Numbered + Level: 1 + Numbering Style: A, B, C, ... + Start at: 1 + Alignment: Left + Aligned at: 0.64" + Indent at: 0.89"

Formatted: Indent: First line: 0.5"

Formatted: Numbered + Level: 1 + Numbering Style: A, B, C, ... + Start at: 1 + Alignment: Left + Aligned at: 0.64" + Indent at: 0.89"

Formatted: Font: Not Bold

Formatted: Indent: Left: 0.5", Hanging: 0.13"

Formatted: Indent: Left: 0", Hanging: 0.63"

Formatted: Font: Not Bold

Formatted: Numbered + Level: 1 + Numbering Style: A, B, C, ... + Start at: 1 + Alignment: Left + Aligned at: 0.64" + Indent at: 0.89"

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement .

These are program elements that, **in accordance with the AEA and provisions of 10 CFR**, address areas of regulation ~~that cannot be relinquished to Agreement States pursuant to the AEA or provisions of Title 10 of the Code of Federal Regulations where the NRC cannot discontinue its authority.~~ However, an Agreement State may inform its licensees ~~of certain~~ 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 ~~pursuant as a result to them~~ *de ?*

Formatted: Indent: First line: 0.5"

stet to prior form.

Summary and Conclusions 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. ~~In doing so,~~ **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. ~~, recognizing the fact that Agreement States have responsibilities for radiation sources in addition to agreement material.~~

The Commission will ~~minimize the number of NRC~~ **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. At the same time,** Requirements in these compatibility categories ~~will~~ 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.

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

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 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 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 that Agreement State programs, 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 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.

¹ 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 274b. Agreement.

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

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~~ ^{relinquish} 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, and 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 ~~relinquish~~ ^{relinquish} ~~discontinue~~ its authority ~~to a particular State~~ ^{to a particular State}, the Commission must find that a particular State program is compatible with the Commission's program for the regulation of radioactive 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 ActAEA, to periodically review existing Agreement State programs to ensure continued adequacy and compatibility. Section 274j. of the ActAEA 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.

A. C. Principles of Program Implementation and Program Assessment

The NRC is responsible ^{for im} 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

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

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

name the five principles.

Do not paraphrase the principles. Use the actual language of the principles, as published by the NRC.

X
X

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

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. Coherent Nationwide Effort

~~The mission of the NRC is to assure that civilian use of nuclear materials in the United States is carried out with adequate protection of public health and safety. NRC acknowledges its responsibility, shared with the Agreement States, to ensure that the regulatory programs of the NRC and the Agreement States collectively establish a coherent nationwide effort for the control of AEA materials. The basic elements of such regulatory programs include ability to ensure adequate protection of public health and safety, compatibility in areas of national interest, sufficient flexibility to accommodate local needs and conditions, ability to assess program performance on a consistent and systematic basis, and principles of good regulation in program administration.~~

~~Each of these elements is reflected and addressed in specific sections of this Policy Statement.~~

3. 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 ~~use~~ safe and secure use of AEA 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.

4. 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 be 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~~ ^{Category 1 and 2 radioactive sources} and devices sold nationwide. 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.

5.

Set
No basis has been provided for deleting. If there is an issue here, keep this text and solicit for comment on the underlying issue.

Safety culture policy is not of context in this section discussing NRC's determination of adequacy of an

Formatted: Font: Bold
agreement State program. The context of this section is the elements an Agreement State program "shall possess."

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

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.

D. ~~F.~~ 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 ~~provide oversight~~ ~~evaluate~~ Agreement State radiation control programs to ~~ensure~~ ~~determine~~ ~~that they are~~ adequate and compatible prior to entrance into a Section 274b. agreement and ~~that~~ ~~ensure~~ they continue to be adequate and compatible after an agreement is effective.

The Commission, in cooperation with the Agreement States, ~~will establish~~ ~~established~~ and ~~implement~~ ~~implemented~~ the IMPEP. The IMPEP is a performance evaluation ~~program to~~ ~~provide~~ ~~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 ~~this~~ ~~the~~ performance evaluation process, the ~~Commission~~ ^{NRC} will take any necessary actions to help ensure that Agreement State radiation control programs remain adequate and compatible. These actions may include: ~~(1) Periodic assessments more frequent~~ ~~IMPEP reviews~~ of Agreement State ~~radiation control~~ programs ~~against established review criteria;~~ ~~(2) and~~ provision of assistance to help address weaknesses or areas ~~needing improvement~~ within an Agreement State ~~radiation control~~ program ~~requiring improvement, to the extent permitted by NRC resources;~~ ~~(3) placing a State on a probationary status for serious program deficiencies that require heightened~~ Enhanced oversight; ~~(4) temporary, suspension of an agreement and reassertion of NRC regulatory authority in an emergency if an Agreement State program experiences any immediate program difficulties preventing the State from continuing to ensure adequate protection of public health and safety; and (5) suspension, or termination of an agreement and reassertion of NRC regulatory authority if the Agreement State program experiences difficulties that jeopardize the State's ability to continue to ensure adequate protection of public health and safety may be considered for serious program deficiencies or to continue to maintain a compatible program.~~ emergencies. The ~~basis for~~ 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.

E. ~~G.~~ 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.

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

1. Adequacy

Finding 1--Adequate To Protect Public Health and Safety and (or not)

Compatible

If the NRC finds that ~~a State program has met all of the an~~ Agreement State program has met all of the review criteria or that only minor deficiencies exist, the ~~Commission~~NRC would find that the Agreement State's program is adequate to protect public health and safety. ~~If the NRC determines that a State program contains all required NRC program elements for compatibility, or only minor discrepancies exist, the program would be found compatible. If the NRC determines that a 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.~~

Finding 2--Adequate but Needs To Protect Public Health and Safety with Improvement and (or not) Compatible 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 ~~but needs 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 ~~but in need of 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 ~~aan~~ Agreement State program contains all required NRC program elements for compatibility, or only minor discrepancies exist, the program would be found compatible. ~~If the NRC determines that a 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.~~

Finding 3--Inadequate to Protect Public Health and Safety and (or not)

2--Not Compatible

~~If the NRC finds that a State program is significantly deficient in some or all of the review criteria, the NRC would find that the State's program is not adequate to protect public health and safety.~~ If the NRC determines that ~~a State program contains all required NRC program elements for compatibility, or only minor discrepancies exist, the program would be found compatible.~~ If the NRC determines that ~~aan~~ 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.

H.

Formatted: Underline

X

X

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

1.4. 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 ~~the Commission finds that~~ program deficiencies ~~related to either adequacy or compatibility~~ 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 ~~ActAEA~~, the Commission ~~would~~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 ~~would~~may be considered. ~~If the situation is not resolved, termination will 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 ~~ActAEA~~ 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.~~

2.5. Termination

Section 274j. of the ~~Atomic Energy Act~~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, ~~or~~ if the State program has not complied with one or more of the requirements of Section 274 of the ~~ActAEA~~ (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. ~~or when requested by a 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.~~

For Reference Only—Document is a redline strikeout version of the proposed draft update showing the working group changes made to the original 1997 policy statement.

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.

G. ~~Program~~ Funding

Currently, Section 274 of the AEA does not allow ~~federal~~ 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~~. 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~~ ~~may offer~~ ~~x~~ certain relevant training courses and ~~notifies~~ ^{notify} Agreement State personnel of their availability.

(consistent with other changes.)

H. ~~Regulatory~~ Development

The NRC and Agreement States will cooperate in the development of both new and revised regulations and ~~policy~~ policies. Agreement States will have early and substantive involvement in the development of new regulations affecting protection of public health and safety and of new ~~policy~~ policies affecting administration of the Agreement State program. ~~Likewise, the~~ The NRC ~~expects to have the States provide it with early and substantive involvement in the development of new~~ 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.

Formatted: Normal

~~K~~

I. 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 ~~AEA~~ 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.

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.

X

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~~ 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). X

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 ^{to} of these policy statement. ^s 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. X X

III. Discussion.

The Commission tasked ^{the} 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, ^{the} 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. X X

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" ^{to refer to} 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 ^{as an indication} 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 ^a 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."

Change back and solicit for comment on proposed change. X

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.

X

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 ^{impart the concept that} foster security ^{is a necessary component} 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

X

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.

X

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.

to include such as

X

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, allowing the State Government to assume that authority as long as the State program is adequate to protect public health and safety and compatible with the Commission's³ program. For the

relinquishes

allowing

to assume that authority

X
X

~~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.~~

X
X

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, ^{which} ~~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. X

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., ^{relinquishing} ~~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 ^{include} ~~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.

^{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 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 ^{that} ~~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.

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 a small number of} 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. *[needs a qualifier]* X

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 ^{not} assigned a Compatibility ^{A, B, C, or E} D). X

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~~ ^{relinquish} 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