

I. **Proposed Revision to Policy Statement on Adequacy and Compatibility of Agreement State 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 ~~radioactive materials under which~~ 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~~, relinquishes its ~~regulatory~~ authority in certain areas ~~and~~ allows the State ~~government~~ Government to assume that regulatory authority, as long as the State program is adequate to protect public health and safety and compatible with the Commission's ~~program.~~¹ 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 the provisions of Section 274. This Policy Statement presents the ~~Nuclear Regulatory Commission's~~ NRC's policy for determining the adequacy and compatibility of Agreement State programs established ~~pursuant to~~ 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 elements² that Agreement State programs should implement to ~~be adequate to~~ adequately protect public health and safety and to be compatible with the ~~Commission's~~ 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 contributes to implementation of that program. Finally, the Policy Statement reflects principles discussed in the ~~Commission's~~ Commission's "Statement of Principles and Policy for the Agreement State Program," which should be considered in conjunction with this Policy Statement.

This Policy Statement is solely guidance for the Commission and the Agreement States in the implementation of the Agreement State program. This Policy Statement does not itself impose legally binding requirements on the Agreement States. In addition, nothing in this Policy Statement expands the legal authority of Agreement States beyond that already granted to them by Section 274 of the ~~Atomic Energy Act~~ AEA and other relevant legal authority. ~~Nor does this Policy Statement diminish or constrain the NRC's authority under the AEA.~~ Implementation procedures adopted ~~pursuant to~~ under this Policy Statement shall be consistent with the legal authorities of the Commission and the Agreement States.

¹ For the purposes of this Policy Statement the definition of Commission is equivalent to Title 10 of the *Code of Federal Regulations*: 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.

² ~~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.~~

~~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 ~~b., discontinuing 274b., relinquishing 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 review periodically the Agreements and actions taken by States under the Agreements to ensure compliance with the provisions of Section 274. ~~In other words~~ 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:

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~~ Commission’s program.” 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). ~~Second, the~~ The Agreement State should also 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~~ 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.

In identifying **1. Adequacy**

An “adequate” program should include those program elements ~~not required for adequate~~ compatibility but necessary to maintain an acceptable level of protection of public health and compatible programs, or any changes thereto, the Commission will seek the advice of the safety within an Agreement States. These program elements make up the category Health and ~~will consider such advice in its final decision.~~

Safety Adequacy: 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 material.~~ The level of protection afforded by the program elements of the NRC's materials regulatory program is presumed to be that which is adequate to provide a reasonable assurance of protection of public health and safety. ~~The~~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 ~~below, in Sections A. through E.,~~ that the Commission will use to define the scope of its review of the program. The Commission will also ~~will~~ consider, when appropriate, other program elements of an Agreement State ~~which~~that 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. ~~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, ~~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. ~~Specifically, For those items that have significant health and safety implications, the NRC shall identify legally binding requirements that should be adopted by Agreement States should adopt. The NRC expects that there will be a limited number of legally binding requirements based on those of NRC because of their particular health and safety significancesuch requirements.~~ In adopting such requirements, Agreement States should adopt the essential objectives of those of the Commission.

B. ~~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- and securely. Licenses should provide for reasonable assurance of public health and safety protection in relation to the licensed activities.

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

1. Compatibility

A "compatible" program should consist of those program elements necessary to meet a larger nationwide interest in promoting an orderly pattern 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~~the following 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"~~"standards" meaning dose limits, concentration and release limits related to radiation protection in Part 20 of Title 10 of the Code of Federal Regulations (10 CFR ~~part 20~~), that are generally applicable, and the dose limits in 10 CFR 61.41.³ 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

³ The Commission will implement this category consistent with its earlier decision in the ~~LL~~low-level waste area to allow Agreement States flexibility to establish pre-closure operational release limit objectives, ALARAas 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.

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”~~“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 (e.g., transportation regulations and sealed source and device registration certificates) that have significant transboundary implications. 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 (~~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; however, they should not be so restrictive as to prohibit a licensed activity.~~

D. ~~Category 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~~State's jurisdiction that are not addressed by the NRC.

All, or program elements not required for compatibility (i.e., those NRC program elements not assigned a Compatibility A, B, or C). 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 practice⁴ in the national interest without an adequate public health and safety or environmental basis related to radiation protection; ~~and~~

⁴ ~~“Practice”~~ 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”~~“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 radioactive agreement materials ~~such as industrial and medical uses and specific activities within a practice such as industrial radiography and brachytherapy.~~

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. ~~E~~-Category NRC - Areas of Exclusive NRC Regulatory Authority

These are program elements that 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*. 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 to them as a result~~.

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~~State's program is compatible with that of the Commission does not affect that ~~State's~~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 regulatory requirements that the Agreement States will be requested to adopt in an identical manner to maintain compatibility. ~~At the same time, The expectation is that these~~ requirements will be limited. 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.

Topics for Additional Comment.

The NRC is requesting additional comments on key topics in response to direction received from the Commission on the development of both Policy Statements (SRM-SECY-12-0112, "Policy Statements in Agreement State Programs"). Specifically, the NRC is seeking comments on the following topics:

1. Policy Statement on Adequacy and Compatibility of Agreement State Programs, Item 1.B. Compatibility Category B

a) To clarify the meaning of a “significant transboundary implication,” the NRC 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, the NRC recognizes that the use of the word “particular” can be vague and cause confusion. The NRC is requesting specific comments on the proposed draft definition of “significant transboundary implication” and whether the word “particular” should be replaced with the phrase “significant and direct.”

b) Program elements with significant transboundary implications are illustrated by examples in the 1997 version of the Policy Statement.

c) The NRC staff concluded the examples listed are not all-inclusive and could lead to misinterpretation by stakeholders, Agreement States, and the NRC staff. The NRC staff is seeking additional comment on whether or not the examples should be retained in this section of the policy statement.

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

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

f) The NRC is requesting comments on alternative versions of wording regarding what types of program elements will be assigned a Compatibility Category B designation as well as how limited in number these will be. The original Policy Statement published in 1997 stated, in part: “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 Working Group proposed keeping the language in the 1997 version of the Policy Statement; however, some believed that this statement could be interpreted to imply that the Commission is limited in its ability to assign rules in this compatibility category. Therefore, alternative language was proposed as follows: “The Commission will limit this category to program elements that have significant transboundary implications. The Commission expects that these will be limited in number.” Some members of the working group disagreed with this alternative language and believed that the original language should be retained. The details of this discussion are in Enclosure 3 of SECY-12-0112, “Policy Statements on Agreement State Programs.” In summary, some members of the Working Group believed that the original language in the 1997 version of the Policy Statement was not intended to dictate the Commission’s authority but rather was to remind those staff proposing designations of compatibility B to the Commission for consideration that program elements of this designation should be few as opposed to many and should involve only significant transboundary implications. Additionally, by removing the distinction that there should be a small number of program elements, it deemphasizes the idea that Agreement States should be given flexibility when addressing the majority of program elements necessary for a compatible program.

2. Policy Statement on Adequacy and Compatibility of Agreement State Programs, Item. Summary and Conclusions

The NRC is requesting comments on alternative versions of wording regarding the expectation on the number of regulatory requirements that Agreement States will be requested to adopt in an identical manner to maintain compatibility. This language would cover all

regulatory requirements as compatibility category A, B, and C. (Agreement States are required to adopt regulatory requirements listed as Health and Safety to ensure their program is adequate to protect public health and safety, but not for compatibility purposes). In the third paragraph under "Summary and Conclusions" of the original Policy Statement published in 1997, it stated, in part: "The Commission will minimize the number of NRC regulatory requirements that the Agreement States will be requested to adopt in an identical manner to maintain compatibility." The Working Group proposed keeping this sentence as written; however, some members of the Working Group believed that that this sentence could be interpreted to imply that there is a requirement that the Commission minimize such requests to Agreement States, rather than a statement that reflects the expectation that situations justifying such requests will not arise frequently. The sentence was revised as follows: "The Commission will identify regulatory requirements that the Agreement States will be requested to adopt in an identical manner to maintain compatibility. The expectation is that these requirements will be limited." Some members of the Working Group disagreed with this revision and believed that the original language should be retained. The details of this discussion are in Enclosure 3 of SECY-12-0112, "Policy Statements on Agreement State Programs." In summary, some members of the Working Group believed that the original text places emphasis on the effort to minimize unnecessary burden on the Agreement States' means to accomplish the same goals as the NRC. Additionally, the suggested changes do not encourage careful consideration as to whether there are other possible options to meet the same intended goal.

3. Performance Based Approach for Determining Compatibility

Currently, Agreement States are afforded some flexibility to use approaches other than rulemaking, such as license conditions or orders, to implement requirements. The NRC staff is seeking additional input on whether a performance-based approach for determining compatibility of an Agreement State's radiation control program should be developed. Agreement States could be afforded additional flexibility to use other approaches to implement requirements. A performance-based approach would not rely on a requirement to adopt within 3 years from the effective date of the NRC regulation in order to determine compatibility of an Agreement State program. In a separate Commission vote paper, the NRC staff will use input from comments received on this topic to create a recommendation and an implementation plan to provide to the Commission for approval.

4. Adequacy Determinations of Agreement State Programs

The NRC staff is seeking additional input on whether: (1) a revised set of performance metrics could be used to replace, supplement, or expand upon IMPEP in determining adequacy of an Agreement State's radiation control program; and (2) a single holistic determination can be made that would accurately reflect the overall adequacy and compatibility of a program. Given the current environment of limited resources, it is imperative that the NRC be able to develop a clear set of performance based metrics that consider the limitations of an Agreement State program and provide increased flexibility without compromising public health and safety. In a separate Commission vote paper, the NRC staff will use input from comments received on this topic to create a recommendation or series of recommendations for Commission approval.