Policy-POLICY STATEMENTtatement on ON Adequacy-ADEQUACY and AND Compatibility-COMPATIBILITY OFof Agreement-AGREEMENT STATEtate PROGRAMSrograms

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 Tthe 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 Government as long as the State program is adequate to protect public health and safety and compatible with the Commission's 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 withpursuant 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

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¹<u>Other NRC documents have used the term "relinquish" rather than "discontinue" of regulatory authority.</u> 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,

States beyond that already granted to them by Section 274 of the AEAtomic 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.

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BackgroundBACKGROUND:

The terms "adequate" and "acompatible" 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. ThereforeIn 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 NRCCommission will seek the advice of the Agreement States. -andThe Commission will consider such advice in its final decision.

DISCUSSION:

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

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

1) Adequacy:

An "adequate" program should consist of those program elements not required for compatibility but necessary to maintain an acceptable level of protection of public health and safety within an Agreement State. These program elements make up the category Health and Safety. An Agreement State's radiation control program is adequate to protect public health and safety if administration of the program provides reasonable assurance of protection of public health and safety in regulating the use of ce, 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;

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- 2)
- Authorize the State to license, inspect, and enforce legally binding requirements such as regulations and licenses; and
- 3)
- 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 Statesbased 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 EventsIncidents and Allegations

The State should respond to and conduct timely inspections or investigations of incidents, reported events, and allegations involving agreement material within the

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

2. Compatibility

A "compatible" program should consist of those program elements necessary to meet a larger nationwide interest in radiation protection. Those program elements are generally limited to areas of regulation involving radiation protection standards and activities with significant transboundary implications. An Agreement State radiation control program is compatible with the Commission's regulatory program when its program does not create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. For purposes of compatibility, the State should address 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 Ppart 20 that are generally applicable, and the dose limits in 10 CFR 61.41. 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. <u>Category B - Program Elements with Significant Transboundary</u> 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. The Commision expects that these will be limited in number. A significant transboundry 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

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.

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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 (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 -- 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 (-fi.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; ander
- 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

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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.

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 Regulationswhere
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.

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 NRCidentify 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.

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