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

AGENCY: Nuclear Regulatory Commission.

ACTION: Final policy statements.

SUMMARY: The Nuclear Regulatory Commission (NRC) is publishing two final policy statements: the "Statement of Principles and Policy for the Agreement State Program," and "Policy Statement on Adequacy and Compatibility of Agreement State Programs."

EFFECTIVE DATE: September 3, 1997.

ADDRESSES: Documents referenced in this notice are available for inspection in the Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC, between 7:45 am and 4:15 pm.

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SUPPLEMENTARY INFORMATION:

I. Background

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

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. The draft Policy Statement was published in the *Federal Register* on August 5, 1994 (59 FR 40058). At the Commission's request, the public comment period scheduled to end on October 4, 1994, was extended to December 19, 1994 (59 FR 52316).

A final Policy Statement was prepared based on the public comments, other activities and issues before the Commission, e.g., the "Policy Statement on Adequacy and Compatibility of Agreement State Programs," issues discussed at public briefings of the Commission by the Organization of Agreement States (OAS), and the Commission's deliberations on the Integrated Materials Performance Evaluation Program. On May 5, 1995, the NRC staff submitted to the Commission the "Final Statement of Principles and Policy for the Agreement State Program" and "Procedures for Suspension and Termination of an Agreement State Program" (SECY 95-115) that contained the full analysis of

comments. By Staff Requirements Memorandum dated June 29, 1995, the Commission provided comments on the Statement of Principles and Policy for the Agreement State Program and directed staff to develop procedures for placing an Agreement State in probationary status and for implementing the phase-in of a new Agreement State program.

On October 3, 1996, the NRC staff submitted to the Commission the Statement of Principles and Policy for the Agreement State Program that had been modified as directed by the Commission (SECY 96-213). Further revisions were made to ensure consistency with the revised Policy Statement on Adequacy and Compatibility of Agreement State Programs. The procedures for suspension, emergency suspension and termination of agreements were finalized on April 25, 1996, and the procedure for placing an Agreement State in probationary status was finalized on July 3, 1996.

B. Statement on Adequacy and Compatibility of Agreement State Programs.

On July 21, 1994 (59 FR 37269), the Commission published in the *Federal Register*, for public comment, a draft Policy Statement regarding the adequacy of Agreement State programs to protect public health and safety and compatibility with NRC regulatory programs. The comment period for the draft Policy Statement was scheduled to expire on October 19, 1994, but was extended to December 19, 1994 (59 FR 52317). In addition, a public workshop was held on November 15, 1994 (59 FR 52321) to provide an opportunity for Agreement States and interested members of the public to provide comments on the draft Policy Statement.

A final "Policy Statement on Adequacy and Compatibility of Agreement State Program" was prepared based on the public comments and other activities and issues before the Commission. On May 3, 1995, the NRC staff submitted to the Commission the "Final Policy Statement on Adequacy and Compatibility of Agreement State Programs" (SECY 95-112) that contained the full analysis of comments.

C. Status of the Policy Statements

The Commission approved both policy statements in principle with a Staff Requirements Memorandum dated June 29, 1995, but deferred their implementation until all implementing procedures were completed and approved by the Commission. On August 2, 1995 (60 FR 39463), the

Commission published in the *Federal Register* the status of these two policy statements and a notice of their availability.

NRC staff also prepared draft implementing procedures for phased implementation of a new Agreement State program that contained language for a standard agreement (Management Directive 5.8 and its associated handbook). Comments on the draft implementing procedures for phased implementation of new agreements and the standard agreement were requested from the Agreement States on November 15, 1996. The complete analysis of these comments is included in "Final Recommendations on Policy Statements and Implementing Procedures for: Statement of Principles and Policy for the Agreement State Program and Policy Statement on Adequacy and Compatibility of Agreement State Programs" (SECY 97-054, dated March 3, 1997) that is available for inspection at the NRC Public Document Room. A summary of the comments appears with the text of the final policy statement in this notice.

In October 1995, a Working Group consisting of representatives of Agreement States and the NRC was formed to develop implementing procedures for the "Policy Statement on Adequacy and Compatibility of Agreement State Programs." The formation of this Working Group was announced in the *Federal Register* on December 1, 1995 (60 FR 61716). A notice announcing availability of the initial Working Group report (August 21, 1996) and implementing procedures was published in the *Federal Register* on September 19, 1996 (61 FR 49357). Comments also were requested specifically from Agreement States and panelists who participated in the November 15, 1994, public workshop. The analysis of State and public comments is part of the supplemental report of the Working Group dated January 27, 1997, that is available for inspection at the NRC Public Document Room. A summary of the comments appears with the text of the final policy statement in this notice.

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

A. Comment Summary

Comment letters were received from twelve Agreement States on the implementing procedures for phased agreements (Management Directive 5.8). There was strong opposition from the Agreement States on the inclusion of mandatory phased agreements for states seeking Agreement State status. Staff

analyzed the comments and agreed with the concerns associated with the use of phased agreements. Changes were made to the Policy Statement to remove the phased agreement concept and to include revisions offered by the Agreement States, as appropriate. The Policy Statement was also edited to conform it to the position that Agreement States have flexibility to impose legally binding requirements on its licensees through mechanisms other than rules.

The text of the final policy statement follows.

B. The Commission Policy

Statement of Principles and Policy for the Agreement State Program

1. *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 U.S. Nuclear Regulatory Commission (NRC) and States in the administration of programs carried out under Section 274 of the Atomic Energy Act 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, and research uses of nuclear materials.

This Policy Statement addresses the Federal-State interaction under the Atomic Energy Act to: (1) Establish and maintain agreements with States under Section 274(b) that provide for discontinuance by the NRC, and the assumption by the State, of responsibility for administration of a regulatory program for the 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 and compatible and that Agreement State programs continue to provide adequate protection of public health and safety.

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.

2. Statement of Legislative Intent: The Atomic Energy Act of 1954 did not 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 Atomic Energy Act 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.

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 its authority to a particular State, the Commission must find that the program is compatible with the Commission's program for the regulation of radioactive materials and that the State program is adequate to protect public health and safety. In addition, the Commission has an obligation, pursuant to Section 274(j) of the Act, to review existing Agreement State programs to ensure continued adequacy and compatibility. Section 274(j) of the Act 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 274(j). 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.

C. Principles of Program Implementation

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 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 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 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 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 NRC and Agreement State materials programs. These principles should be used in the formulation of policies and programs, implementation of those policies and programs, and assessments of program effectiveness. Application of these principles will ensure that complacency will be minimized, that adequate levels of protection of public health and safety are being provided, and that government employees tasked with the responsibility for these Federal and State regulatory programs serve the public in an effective, efficient, and responsive manner. These principles are primarily for the use of NRC and Agreement State materials program managers and staff in the self assessment of their respective programs and to use in the establishment of goals and objectives for the continual improvement of their respective

programs. Deficiencies identified during the conduct of NRC Region and Agreement State formal program performance reviews may indicate that the program is not adhering to these principles of good regulation. The organization being assessed should factor the need for these principles into its actions to address identified deficiencies.

2. 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. Adequate to Protect Public Health and Safety

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 of AEA materials. Accordingly, 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.

4. Compatible in Areas of National Interest

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 effective and cooperatively implemented by 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, and safety reviews for sealed source 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 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. 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 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 Atomic Energy Act, 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.

D. New Agreements

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

E. Program Assistance

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, NRC can provide training and other assistance such as review of proposed regulatory changes to help States administer their regulatory responsibilities. NRC would also use its best efforts to provide specialized technical assistance to Agreement States to address unique or complex licensing, inspection, and enforcement issues. In areas where Agreement States have particular expertise or are in the best position to provide immediate assistance to the NRC, the Agreement States are encouraged to do so. In addition, NRC and Agreement States will keep each other informed about relevant aspects of their programs. 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.

F. Performance Evaluation

Under Section 274 of the Atomic Energy Act of 1954, 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, NRC will provide oversight of Agreement State radiation control programs to ensure that they are adequate and compatible prior to entrance into a Section 274(b) agreement and that they continue to be adequate and compatible after an agreement is effective. The Commission, in cooperation with the Agreement States, will establish and implement a performance evaluation program to provide 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.

As a part of this 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 include: (1) Periodic assessments of Agreement State radiation control programs against established review criteria; (2) provision of assistance to help address weaknesses or areas 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 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 or to continue to maintain a compatible program. 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.

G. Levels of Agreement State Program Review Findings

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

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 Agreement State program review criteria or that only minor deficiencies exist, the Commission would find that the 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 Improvement and (or not) Compatible

If the NRC finds that a State program protects public health and safety, but is deficient in meeting some of the review criteria, the NRC may find that the State's program is adequate, but needs improvement. 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, NRC may also find that the program is adequate but in need of improvement. 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 3—Inadequate to Protect Public Health and Safety and (or 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 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.

H. 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 to an Agreement State program review, the findings would be recounted in a letter to senior level State management. In the event that 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.

Follow-up Reviews

In the event that deficiencies 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.

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, the NRC would communicate its findings to a higher level of State management. Notice of such probationary status would normally be addressed to the Governor of the State. Notice would also be 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.

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 requested and in accordance with terms agreed to by the parties, the NRC would consider providing 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. At the end of that time, if the State has not addressed the deficiencies, the NRC would institute suspension or termination proceedings.

Suspension

Section 274j of the Atomic Energy Act 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 Act. 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 Act, the Commission would 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 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 Act 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 to take necessary action within a reasonable time.

Termination

Section 274j of the Atomic Energy Act gives the Commission authority to terminate 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 Act (e.g., is found to be not compatible with the Commission's program). When the Commission finds such significant program deficiencies, the Commission would institute 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.

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.

I. Program Funding

Currently, Section 274 does not allow federal funding for the administration of Agreement State radiation control programs. Section 274 permits the NRC to offer training and other assistance to a State in anticipation of entering into an Agreement with NRC, however, it is 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.

J. Regulatory Development

NRC and Agreement States will cooperate in the development of new regulations and policy. 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 affecting administration of the Agreement State program. Likewise, the NRC expects to have the States provide it with early and substantive involvement in the development of new Suggested State Regulations. 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. 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 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.

III. Policy Statement on Adequacy and Compatibility of Agreement State Programs

A. Comment Summary

Ten comment letters were received, one from the Organization of Agreement States, six Agreement State program directors, two industry organizations and one environmental group. The Joint NRC-Agreement State Working Group for Development of Implementing Procedures for the Final Policy Statement on Adequacy and Compatibility of Agreement State Programs analyzed the comments and changes were made to the Policy Statement (1) to add additional clarifying language for the terms "adequacy" and "compatibility" and the cooperative nature of the NRC—Agreement State relationship; (2) to

conform it to the position that Agreement States have flexibility with respect to the legally binding mechanism by which regulatory requirements needed for adequacy or compatibility are adopted; and (3) to simplify the language describing compatibility categories. Changes also were made in response to the June 30, 1997 Staff Requirements Memorandum. These changes (1) reflect that program elements for compatibility also impact public health and safety and may also be considered program elements for adequacy; (2) clarify the definition of basic radiation protection standard; and (3) clarify that States may not adopt program elements reserved exclusively to NRC. The implementing procedures were changed to reflect the final Policy Statement.

One Agreement State specifically commented that it did not believe that Section 274 of the AEA required compatibility of programs or program elements after an agreement is effective except for requirements pertaining to the Uranium Mill Tailings Radiation Control Act in section 274(o). This position also was reflected in the recommended changes to the Policy Statement submitted by the Organization of Agreement States.

The Commission does not agree with this interpretation of the AEA. Both Sections 274d.(2) and 274g. indicate that the Commission must find a State program to be compatible with that of NRC in order to enter into a Section 274b. agreement with the State. It is the Commission's view that, pursuant to Section 274, an Agreement State's program should be compatible with NRC's program for the duration of the Agreement for the following reasons:

Subsection 274g. authorizes and directs the Commission to cooperate with the States in the formulation of radiation protection standards "to assure that the State and Commission programs for the protection against hazards of radiation will be coordinated and compatible." This provision demonstrates Congress' intention that the compatibility between the NRC and Agreement State programs should be maintained on a continuing basis.

Section 274j.(1) calls on the Commission to suspend or terminate an Agreement State's program if "the State has not complied with one or more of the requirements" of the Section 274. The Commission believes that this phrase "one or more of the requirements," encompasses all requirements of Section 274, including the requirement for compatibility.

Under subsection 274d.(2), the Commission is authorized to enter into an agreement with a State if the Commission makes both requisite findings that the State program is compatible with the NRC's program and adequate to protect public

health and safety. Absent a continuing compatibility requirement, an Agreement State could divert from having a compatible program the day after any agreement is signed with NRC. This would render the Commission's initial compatibility finding required by Section 274d.(2) meaningless.

Therefore, the Commission does not believe that Congress intended such meaning for the compatibility requirement and no changes were made to the Policy Statement in response to this comment.

The text of the final policy statement follows.

B. The Commission Policy

Policy Statement on Adequacy and Compatibility of Agreement State Programs

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 the NRC, by agreement with a State, 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. Section 274 further directs the Commission to periodically review State programs to ensure compliance with provisions of Section 274. This Policy Statement presents the Nuclear Regulatory Commission's policy for determining the adequacy and compatibility of Agreement State programs established 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 elements¹ that Agreement State programs should implement to be adequate to protect public health and safety and to be compatible with the Commission's regulatory 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

¹ 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.

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 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: 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 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 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 provisions of Section 274. 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 Commission will seek the advice of the Agreement States and will consider such advice in its final decision.

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. 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 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;

Authorize the State to promulgate regulatory requirements necessary to provide

reasonable assurance of protection of public health and safety;

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

Be otherwise consistent with 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, Agreement States should adopt a limited number of legally binding requirements based on those of NRC because of their particular health and safety significance. In adopting such requirements, Agreement States should adopt the essential objectives of those of the Commission.

B. Licensing

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

C. Inspection and Enforcement

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

D. Personnel

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

E. Response to Events 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.

Compatibility

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. 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 10 CFR part 20 that are generally applicable, and the dose limits in 10 CFR 61.41.² 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. 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. 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.

² The Commission will implement this category consistent with its earlier decision in the LLW area to allow Agreement States flexibility to establish pre-closure operational release limit objectives, 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

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.

All program elements of an Agreement State relating to agreement material should:

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);

Not preclude, or effectively preclude, a practice³ in the national interest without an adequate public health and safety or environmental basis related to radiation protection; or

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. 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.

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.

³ "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. The term encompasses both general activities involving use of radioactive materials such as industrial and medical uses and specific activities within a practice such as industrial radiography and brachytherapy.

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, 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, 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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Paperwork Reduction Act Statement

These final policy statements do not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval number 3150-0183.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Small Business Regulatory Enforcement Fairness Act.

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

Dated at Rockville, Md., this 27th day of August, 1997.

For the Nuclear Regulatory Commission—
John C. Hoyle,
Secretary of the Commission.