

UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20556-0001

January 13, 1994

TIME SENSITIVE INFORMATION

ALL AGREEMENT STATES, PENNSYLVANIA, OHIO, OKLAHOMA, AND MASSACHUSETTS

WORKSHOP TO DISCUSS THE DRAFT POLICY STATEMENT FOR AGREEMENT STATE ADEQUACY AND COMPATIBILITY (SP-94-012)

The purpose of this correspondence is to invite you or a representative from your State to attend the "Workshop On the Draft Policy Statement for Agreement State Adequacy and Compatibility." The Nuclear Regulatory Commission (NRC) staff plans to convene a public workshop with representatives of Agreement States, Non-Agreement States, the regulated community, public groups and the general public to discuss the draft policy statement for Agreement State adequacy to protect public health and safety and compatibility of Agreement State regulatory programs with that of the NRC. The purpose of the workshop is to seek comments and recommendations from the full spectrum of interested parties on the various issues pertaining to the draft policy statement. Enclosed for your information is a copy of the draft policy statement which will be the focus of discussion at the workshop (SECY 93-349 dated December 21, 1993).

The workshop will be held on February 22-23, 1994 at the Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland, 301-652-2000. The times are:

Tuesday, February 22, 1994 1:00 p.m. - 5:00 p.m. 6:00 p.m. - 8:00 p.m.

Wednesday, February 23, 1994 8:30 a.m. - 12:30 p.m.

A block of rooms have been reserved for workshop participants at the Bethesda Holiday Inn beginning February 22, 1994. The rate for a single room is \$92.00 plus 12% tax, which includes a full American breakfast buffet. The NRC will provide invitational travel for one representative from each State for the cost of lodging plus \$30.00 per day for subsistence expenses. A voucher form will be provided at the workshop.

Make your reservation by calling the Bethesda Holiday Inn reservation number at 1-800-638-5954. When making your reservations, please identify yourself as a participant in the NRC workshop, Group #3991. You must make your reservations by February 13, 1994.

Your travel arrangements should be made by calling Carlson Travel Network, NRC's travel contractor, at 202-554-1850. <u>DO NOT PURCHASE YOUR OWN PLANE</u> <u>TICKET</u>. NRC will reimburse participants for travel by auto at 25 cents per mile, not to exceed the lowest airfare.

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The name and social security number along with travel information is needed for the person representing your State. Please call Calson Travel first to obtain the cost of your ticket, then complete the enclosed travel form and fax it to Brenda Hill at (301) 504-3502 by February 4, 1994.

If you have any questions, please contact Ms. Cardelia H. Maupin at 301-504-2312. In addition, specific travel related questions should be directed to Ms. Brenda Hill at 301-504-2348.

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PL Richard L. Bangart, Director \ Office of State Programs

Enclosures: As stated SP-94-012

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Original signed by: S. A. Schwartz

Richard L. Bangart, Director Office of State Programs

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PLEASE FAX THE FOLLOWING INFORMATION TO BRENDA HILL (301-504-3502) BY FEBRUARY 4, 1994

DATES:	February 22-23, 1994
TRAVEL DATES:	
LOCATION:	Holiday Inn, Bethesda, Maryland
NAME OF REPRESENTATIVE:	
SOCIAL SECURITY #:	
DEPARTURE CITY (AIRPORT)	
DATE OF DEPARTURE:	
DATE OF RETURN:	
COST OF AIRFARE (FROM CARLSON TRAVEL):	



December 21, 1993

SECY-93-349

For: The Commissioners

From: James M. Trylor Executive Director for Operations

Subject: DRAFT POLICY STATEMENT FOR AGREEMENT STATE ADEQUACY AND COMPATIBILITY WITH NRC REGULATORY PROGRAMS NECESSARY TO PROTECT PUBLIC HEALTH AND SAFETY

Purpose:

To provide the Commission with a draft policy statement for Agreement State programs' compatibility with NRC regulatory programs and adequacy to protect public health and safety. The staff seeks Commissio. approval of the draft policy statement and approval of publication of the document for public comment. After Commission approval, the staff plans to conduct a public meeting to discuss the draft policy statement with the Agreement States, the industry and the public.

Summary:

The Commission in Staff Requirements Memorandum (SRM) dated October 22, 1993, SECY-93-290, "Draft Policy Options on Compatibility," directed the staff to develop examples of the various aspects of the Agreement State program compatibility determinations using the two compatibility options presented in the SECY paper. After the October 24-27, 1993, discussions of the options and the examples at the All Agreement States Meeting, the staff developed a final draft policy which takes into consideration the Commission direction and the input from the States. The draft policy statement was developed using the approach discussed in SECY-93-290, "Draft Policy Options on Compatibility."

Contact: Cardelia H. Maupin, OSP 504-2312

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NOTE: TO BE MADE PUBLICLY AVAILABLE AT COMMISSION MEETING SCHEDULED FOR MONDAY, JANUARY 10, 1994

Background:

The enactment of Section 274 of the Atomic Energy Act (AEA) of 1954, as amended, in 1959 authorized the Commission to enter into Agreements with the Governor of a State providing for discontinuance of the regulatory authority of the Commission with respect to byproduct, source and special nuclear materials. The terms "compatible" and "adequate" constitute core concepts in the Commission's Agreement State program under Section 274 of the AEA. Subsection 274d. states that the Commission shall enter into an Agreement under subsection b., relinquishing regulatory authority over certain materials to a State, if the State's program is both adequate to protect public health and safety and compatible with the Commission's regulatory program. Subsection 274g. authorizes and directs the Commission to cooperate with the States in the formulation of standards to assure that State and Commission standards will be coordinated and "compatible." Subsection 274(j)(1) requires the Commission to periodically review the Agreements and actions taken by the States under the Agreements to insure compliance with the provisions of section 274.

Although the terms "compatible" and "adequate" are fundamental requirements in the Agreement State program under Section 274 of the AEA, these terms are not defined in the Act. Neither has the Commission provided a formal definition or formal comprehensive guidance for these terms in implementing Section 274. The guiding concept over the years since the beginning of the Agreement State program in the area of compatibility has been to encourage uniformity to the maximum extent practicable while allowing flexibility, where possible, to accommodate local regulatory concerns. For example, in 1960, the U.S. Atomic Energy Commission (AEC) proposed the following statement with respect to uniformity of radiation standards in the criteria for entering into Agreements with the Commission: "By uniformity is meant no more and no less than those standards fixed by Part 20 of the AEC regulations." On January 3, 1961, the statement was modified to require uniformity on maximum permissible doses, levels, and concentrations based on officially approved radiation protection guides. Finally, on March 24, 1961, the Commission's policy for entering into Agreements with States stated, in part:

3. Uniformity in radiation standards. It is important to strive for uniformity in technical definitions and terminology, particularly as related to such things as units of measurements and radiation dose. There shall be uniformity of maximum permissible doses and levels of radiation and concentrations of radioactivity, as fixed by Part 20 of the AEC regulations based on approved radiation protection guides. 6. Labels, signs and symbols. It is desirable to achieve uniformity in labels, signs and symbols, and the posting thereof. However, it is essential that there be uniformity in labels, signs, and symbols affixed to radioactive products which are transferred from person to person.

In 1966, approximately eight years after the enactment of Section 274, the Commission issued a policy statement which defined compatibility. "Compatibility means substantial uniformity, as between AEC and the States, of regulatory standards and policies without their necessarily being identical" and "....adequacy to protect public health and safety." In 1967, the AEC staff defined a "compatible State" program as one which is practical, workable, and substantially uniform (but not identical) with the AEC's program."

The Commission's approach to making compatibility determinations has evolved slowly over the life of the Agreement State program. Compatibility has often been implemented in case-by-case decisions by the Commission. Internal procedures were developed by the staff to designate degrees of "compatibility" (i.e. uniformity), from "essentially verbatim" to "no degree of uniformity required" with sections of the Commission's regulations. At the same time, since 1962, the Agreement State program has expanded and developed significantly both in the number of Agreement States, as well as depth of experience and expertise of State regulators. More recently, the Commission has involved the States earlier in the process of developing new regulations and determining what level of "compatibility" (i.e. uniformity) will be required of the Agreement States. However, the compatibility question continues to be a cause of concern to the Agreement States.

On April 2, 1993, the Commission directed the staff to develop a compatibility policy. While developing the policy, the staff participated in discussions with the Agreement States, the non-Agreement States, the regulated community, and the general public. A working group was formed and a draft issues paper was developed. The draft issues paper was discussed with the Agreement States in a public meeting in May 1993 and draft options, SECY-93-290, were discussed in October 1993 at the All Agreement States Meeting. The Agreement and non-Agreement States, the regulated community and the general public participated in a public workshop on the final issues paper in July 1993.

Results of Discussions with Various Groups

A. States

The States would like to see a minimum number of requirements for compatibility determinations. From the comments that surfaced at the July 1993 public workshop and during the October 1993 All Agreement States Meeting in Tempe, Arizona, the following positions, though not a formal consensus, emerged:

The States are in favor of:

- 1. uniformity of requirements that are necessary to assure interstate commerce, i.e., labels, signs and symbols.
- 2. uniformity of radiation standards necessary to protect public health and safety. However, States want the flexibility to set stricter dose limits when local conditions warrant them.
- early and substantive involvement in the deliberations on the development of regulations.
- B. Regulated Community

The regulated community wants strict adherence to uniform national radiation standards so that licensees meet the same standards in all States and will not be subject to different regulations in different States.

C. Environmental Group

An environmental advocacy group indicated that Federal and State regulations should be the minimum requirements with the proviso that communities may have the flexibility to go beyond those regulations.

In the formulation of this draft policy statement, the staff has carefully considered the views of the Agreement States, the regulated community, the environmental group and other members of the public.

Discussion:

The question posed by the current task to develop a compatibility policy centers on making a determination of what components or elements of a State radiation control program are needed beyond those which establish and maintain an adequate radiation control program. Presently, adequacy of Agreement State programs is only applied to program elements in terms of their direct or indirect bearing on public health and safety and compatibility is only

applied to the degree of conformity between State regulations and NRC's regulations. However, staff believes that some regulations should be a matter of adequacy to protect public health and safety and some program elements should be a matter of compatibility. In order to fully understand this concept, the relationship between adequacy and compatibility must be examined.

Section 274 of the Atomic Energy Act requires that Agreement State programs be both "adequate to protect the public health and safety" and "compatible with the Commission's program." Thus, under the proposed compatibility policy, these separate findings must be based on consideration of two different objectives; first, providing for an acceptable level of protection for public health and safety in an Agreement State (the "adeguacy" component), and second, providing for the overall national interest in radiation protection, (the "compatibility" component). An "adequate" program, including regulations, and other program elements, such as organization and resources, would need to consist of those attributes considered necessary by the Commission to maintain an acceptable level of protection of the public health and safety within the Agreement State. A "compatible" program, including radiation protection standards and other program elements, would need to consist of those attributes considered necessary by the Commission to meet a larger national interest in radiation protection. The requirements for adequacy would focus on the protection of public health and safety within a particular State, whereas the requirements for compatibility would focus on the extraterritorial effect of State action or inaction either on other States or on the national program for radiation protection.

As a basis for determining what ultimately will be required for compatibility, the Commission must first identify what is necessary for a State program to be "adequate." Adequacy requirements would be based on the identification of those NRC regulations and other program elements whose objectives are to protect the public health and safety in the conduct of a particular type of activity, for example, the medical use of radioisotopes. For activities conducted in an Agreement State, the State would need to demonstrate that it has a regulatory framework in place, through some legally binding measure, to provide for adequate protection of the public health and safety in the conduct of that activity. Examples of the attributes that would be necessary for adequacy would be regulations such as those in 10 CFR Part 20 and an effective enforcement program. The adequacy requirements would also address the means to effectively implement the program, for example inspection and enforcement policy and procedures, as well as adequate resources. Adequacy would require that the level of protection of public health and safety provided by the Agreement State is equivalent to, or greater than, that provided by the NRC. Adequacy would

not require that NRC regulations be implemented essentially verbatim or through a particular mechanism such as a regulation, unless one of the compatibility criteria for identical adoption needed to be met, (see discussion below). The State would have the flexibility to determine how best to implement the requirements of the NRC regulations. However, this flexibility shall be exercised in a responsible manner and shall not be used to bar or preclude a practice without an adequate safety or environmental basis, or to bar a practice needed for national interest. The staff plans to conduct a comprehensive analysis of the Commission's regulations to determine which regulations are necessary for State adoption, by legally binding means, to maintain an adequate level of protection.

The development of the common performance indicators for the evaluation of Agreement States and the NRC regional offices will be directly related to adequacy requirements for Agreement State programs, and consequently, will need to be closely coordinated with the staff efforts to define the elements of an adequate State program. In December 1993, the staff currently plans to provide the Commission with a paper further describing the use of common performance indicators in NRC region and Agreement State reviews. The staff plans to use the performance indicators, supplemented appropriately, to evaluate the adequacy of an Agreement State program. The current proposed performance indicators program contemplates using a Management Review Board (MRB) to make the decision on the adequacy of existing Agreement State programs. The initial adequacy determination of a proposed new Agreement State program will be made by the Office of State Programs, rather than the MRB, because the adequacy of a proposed new program is not dependent on effectiveness of actual program implementation. The staff plans to follow this same split of responsibilities for the compatibility determination of an Agreement State program, with the MRB making the compatibility determinations for existing Agreement State programs, and the Office of State Programs making the initial compatibility determinations for proposed new programs. The initial adequacy and compatibility determinations for proposed new Agreement State programs are reviewed and approved by the Commission. Due to the relationship between adequacy and compatibility, the staff believes that for existing programs it would be beneficial for the MRB to evaluate compatibility as well as adequacy. Indicators of compatibility will be developed by the staff. In order to ensure that the specific elements necessary for an adequacy determination are identified in time to be used at the beginning of the common performance indicators program, now scheduled for early 1994, the staff intends to review those regulations currently in the Divisions 1 and 2 of Internal Procedures B.7, "Criteria for Compatibility Determinations." During the regulations review, staff will make a preliminary

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identification of regulations appropriate for elements of an adequate Agreement State Program.

As noted earlier, compatibility requirements are necessary to achieve some larger national interest beyond that required for adequate protection of the public health and safety. For cases where the Commission, in cooperation with the Agreement States, finds it necessary to protect this larger national interest, the Agreement States would be required to establish provisions in their programs that are essentially identical to the NRC regulatory program. The determination of the national interest would focus on State action or inaction that would have extraterritorial impacts either on other States or on the effectiveness of the national program. The compatibility indicators that would be used to guide the compatibility determinations would consist of answering the question of whether identical requirements in a State program are necessary to--

- avoid a significant burden on interstate commerce; for example, requiring uniform standards for consumer products;
- ensure clear communication on fundamental radiation protection terminology; for example, "byproduct material" or "total effective dose equivalent";
- ensure clear communication and common understanding as to certain central radiation protection concepts applicable to all licensees; for example, the establishment of uniform standards as to radiation dose limits for workers and members of the public; or
- assist the NRC in evaluating the effectiveness of the overall national program for radiation protection; for example, requirements derived from national program initiatives incorporated into memoranda of understanding with other federal agencies; or for example requirements for reports or records needed for an NRC study of medical misadministrations.

If none of the above criteria is met, the State would have the flexibility to design its programs to meet local needs and conditions, assuming that the requirements for adequacy are still met. For example, to meet local needs and conditions, States could for particular classes of licensees adopt more stringent radiation protection requirements so long as the basic dose standards applicable to all licensees are essentially identical to those of the NRC. However, an Agreement State shall not adopt more stringent regulations which will bar or preclude a practice without an adequate safety or environmental basis, or bar a practice needed in the national interest. To ensure that more stringent radiation protection requirements are limited to

particular classes of licenses and do not bar or preclude practices, Agreement States will be requested to submit proposed more stringent requirements to the NRC for review.

Revocation of Agreements

Revocation of an Agreement can occur when an Agreement State program is either inadequate or incompatible. The proposed MRB, reviewing discrete common performance indicators, would judge the overall adequacy of an Agreement State program. Similarly, the MRB would review discrete "compatibility indicators" and determine the overall compatibility of an Agreement State program. For either of the adequacy or compatibility determination, failure to satisfy an individual indicator may not necessarily result in an overall finding of inadequacy or incompatibility. In some situations, individual indicator weakness(es) could result in a "marginal" finding by the MRB calling for Agreement State improvements. In extreme cases, indicator(s) failure could lead to inadequate or incompatible findings resulting in the initiation of program revocation with perhaps an interim step of program probation or suspension. In terms of the compatibility evaluation, the significance of performance indicator "incompatibility" in an individual State will be judged on the basis of the impact on the national program.

The staff has developed definitions pertaining to an adequate and compatible Agreement State Program. These definitions are:

Adequate means:

An acceptable level of protection of the public health and safety from the radiation hazards associated with the use of byproduct, source, and special nuclear materials.

An Adequate Agreement State Program means:

An effectively implemented regulatory program containing elements, regulations, policies, and procedures considered necessary by the Commission to provide an acceptable level of protection for the public health and safety from the radiation hazards associated with the use of byproduct, source, and special nuclear materials.

Compatible means:

The consistency between NRC and Agreement State regulatory programs which is needed in order to establish a national radiation protection program for the regulation of byproduct, source and special nuclear material which assures an orderly and effective regulatory pattern in the administration of this

national program. Compatibility shall be aimed at ensuring that the flow of interstate commerce is not impeded, that effective communication in the radiation protection field is maintained, that central radiation protection concepts applicable to all licensees are maintained, and that information needed for the study of trends in radiation protection and other national program needs are ascertained.

A Compatible Agreement State Program means:

A regulatory program containing elements, regulations, policies, and procedures considered necessary by the Commission to effectively implement the term "compatible" as defined above.

Based upon the preceding discussions on criteria and definitions, the staff has developed a draft policy statement. The draft policy in the form of a <u>Federal Register</u> notice is enclosed (Enclosure 1). The draft policy statement is based upon a review of various regulations and programmatic elements. In order to solicit public comments on the draft policy statement, staff proposes to publish the document in the Federal Register and solicit public comments for 90 days. In addition, the staff plans to hold a public meeting to solicit comments. After the receipt and analysis of the public comments, staff will submit a proposed final policy statement for Commission approval.

Staff Actions Following Commission Approval of Draft Policy:

- 1. Publish draft policy statement in <u>Federal Register</u> for public comment. This effort, including the analysis of comments, will require an expenditure of 0.25 FTE.
- Conduct a public meeting to discuss the draft policy statement. This effort, including the analysis of comments, will require the expenditure of 0.25 FTE and \$10,000 for invitational travel.
- 3. Prepare a Commission Paper transmitting the final proposed Policy Statement to the Commission for approval. This effort will require the expenditure of 0.1 FTE.
- Review Internal Procedure B.7 to identify regulations necessary for an adequacy determination during an implementation transition period. This effort will require 0.1 FTE.
- 5. Conduct a review of NRC regulations and programs to determine those required for Agreement States to be adequate and compatible. This effort will take six months with an expenditure of 1 FTE.

6. Develop procedures to be followed during the Agreement State program reviews using the compatibility and adequacy policy statement and the common performance indicators, as supplemented for Agreement State reviews. The procedure will require Commission approval of proposed Agreement State program review findings of inadequacy or incompatibility. The procedures will also establish the process for suspending an Agreement State program, placing it on probation, and reasserting NRC jurisdiction. This effort will require 0.2 FTE.

Resources needed for those actions are either already budgeted in the FY 1994-98 five year plan, will be reprogrammed from lower priority Office of State Programs' activities, or will be obtained by using personnel or rotational assignments to OSP.

Coordination:

The Office of General Counsel has reviewed the draft policy statement and has no legal objection.

Recommendation:

That the Commission:

1. Approve the draft policy statement and publish the document in the <u>Federal Register</u> notice.

2. Note:

- A 90-day public comment period will be provided.
- Copies of the <u>Federal Register</u> notice will be provided to the Agreement States, potential Agreement States and to other interested parties upon request.
- Appropriate Congressional committees will be informed (Enclosure 2).
- A public announcement (Enclosure 3) will be issued when the draft policy statement is filed with the Office of the Federal Register.

Staff believes that the draft policy should also be applicable to the area of low level waste disposal (LLW) and also believes that the draft policy is consistent with the Commission's previous actions regarding compatibility in the area of LLW.

Japles M. Taylor Executive Director for Operations

Enclosures: As stated

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Tuesday, January 18, 1994.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Monday, January 10, 1994, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

This paper is tentatively scheduled for discussion at an Open Meeting during the Week of <u>January 10, 1994</u>. Please refer to the appropriate Weekly Commission Schedule, when published, for a specific date and time.

DISTRIBUTION: Commissioners OGC OCAA OIG OPA OCA OPP EDO ACNW SECY ADEQUACY AND COMPATIBILITY OF NRC AND AGREEMENT STATE RADIATION CONTROL PROGRAMS NECESSARY TO PROTECT PUBLIC HEALTH AND SAFETY: DRAFT STATEMENT OF POLICY

AGENCY: Nuclear Regulatory Commission

ACTION: Draft Statement of Policy

SUMMARY: The Nuclear Regulatory Commission is revising its general statement of policy regarding the review of Agreement State radiation control programs. This action is necessary to clarify the meaning and use of adequacy and compatibility as applied to a radiation control program. This draft policy statement would not be intended to have the force and effect of law or binding effect; it is intended as guidance to the Agreement States, NRC staff, and the public to make clear how the Commission intends to evaluate the adequacy and compatibility of NRC and Agreement State programs.

DATES: Comments are due on or before _____, 1994.

ADDRESSES: Send written comments to Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Services Branch. Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. on Federal workdays.

FOR FURTHER INFORMATION CONTACT: Cardelia Maupin, State Agreements Program, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 504-2312.

SUPPLEMENTARY INFORMATION:

I. Background

The terms "compatible" and "adequate" constitute core concepts in the Commission's Agreement State program under Section 274 of the Atomic Energy Act (AEA) of 1954, as amended, in 1959. Subsection 274d. states that the Commission shall enter into an Agreement under subsection b., relinquishing regulatory authority over certain materials to a State, if the State's program is both adequate to protect public health and safety and compatible with the Commission's regulatory program. Subsection 274g. authorizes and directs the Commission to cooperate with the States in the formulation of standards to assure that State and Commission standards will be coordinated and "compatible." Subsection 274(j)(1) requires the Commission to periodically review the Agreements and actions taken by the States under the Agreements to insure compliance with the provisions of section 274. Although the terms "compatible" and "adequate" are fundamental

requirements in the Agreement State program under Section 274 of the AEA, these terms are not defined in the Act. Neither has the Commission provided a formal definition or formal comprehensive guidance for how the term should be interpreted in implementing Section 274. The guiding concept over the years since the beginning of the Agreement State program in the area of compatibility has been to encourage uniformity to the maximum extent practicable while allowing flexibility, where possible, to accommodate local regulatory concerns. This concept has been implemented in case-by-case decisions by the Commission and in internal procedures developed by the staff to assign designations of degrees of "compatibility" (i.e. uniformity), from "essentially verbatim" to "no degree of uniformity required," to sections of the Commission's regulations. More recently, the Commission has attempted to involve the States earlier in the process of developing new regulations and determining what level of "compatibility" (i.e. uniformity) will be required of the Agreement States.

The Commission's approach to making compatibility determinations has evolved slowly over the life of the Agreement State program. At the same time, since 1962, the Agreement State program has expanded and developed significantly both in the number of Agreement States, as well as depth of experience and expertise of State regulators. To clarify the matter of compatibility, the Commission has directed the staff to develop a comprehensive interpretation and application of compatibility.

On April 2, 1993, the Commission directed the staff to develop a compatibility policy. While developing the policy, the staff participated in discussions with the Agreement States, the non-Agreement States, the regulated community, and the general public. A working group was formed and a draft issues paper was developed. The draft issues paper was discussed with the Agreement States in a public meeting in May 1993 and draft options, SECY-93-290, were discussed in October 1993 at the All Agreement States Meeting. The Agreement and non-Agreement States, the regulated community and the general public participated in a public workshop on the final issues paper in July 1993.

Results of Discussions with Various Groups

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The regulated community wants strict adherence to uniform national radiation standards so that licensees meet the same standards in all States and will not be subject to different regulations in different States.

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An environmental advocacy group indicated that Federal and State regulations should be the minimum requirements with the proviso that communities may have the flexibility to go beyond those regulations.

In the formulation of this draft policy statement, the staff has carefully considered the views of the Agreement States, the regulated community, the environmental group and other members of the public.

II. Discussion:

The question posed by the current task to develop a compatibility policy centers on making a determination of what components or elements of a State radiation control program are needed beyond those which establish and maintain an adequate radiation control program. Presently, adequacy of Agreement State programs is only applied to program elements in terms of their direct or indirect bearing on public health and safety and compatibility is only applied to the degree of conformity between State regulations and NRC's regulations. However, staff believes that some regulations should be a matter of adequacy to protect public health and safety and some program elements should be a matter of compatibility. In order to fully understand this concept, the relationship between adequacy and compatibility must be examined.

Section 274 of the Atomic Energy Act requires that Agreement State programs be both "adequate to protect the public health and safety" and "compatible with the Commission's program." Thus, under the proposed compatibility policy, these separate findings must be based on consideration of two different objectives; first, providing for an acceptable level of protection for public health and safety in an Agreement State (the "adequacy" component), and second, providing for the overall national interest in radiation protection, (the "compatibility" COmponent). An "adequate" program, including regulations, and other program elements, such as organization and resources, would need to consist of those attributes considered necessary by the Commission to maintain an acceptable level of protection of the public health and safety within the Agreement State. A "compatible" program, including radiation protection standards and other program elements, would need to consist of those attributes considered necessary by the Commission to meet a larger national interest in radiation protection. The requirements for adequacy would focus on the protection of public health and safety within a particular State, whereas the requirements for compatibility would focus on the extraterritorial effect of State action or inaction either on other States or on the national program for radiation protection.

As a basis for determining what ultimately will be required for compatibility, the Commission must first identify what is necessary for a State program to be "adequate." Adequacy requirements would be based on the identification of those NRC regulations and other program elements whose objectives are to protect the public health and safety in the conduct of a particular type of activity, for example, the medical use of radioisotopes. For activities conducted in an Agreement State, the State would need to demonstrate that it has a regulatory framework in place, through some legally binding measure, to provide for adequate protection of the public health and safety in the conduct of that activity. Examples of the attributes that would be necessary for adequacy would be regulations such as those in 10 CFR Part 20 and an effective enforcement program. The adequacy requirements would also address the means to effectively implement the program, for example inspection and enforcement policy and procedures, as well as adequate resources. Adequacy would require that the level of protection of public health and safety provided by the Agreement State is equivalent to, or greater than, that provided by the NRC. Adequacy would not require that NRC regulations be implemented essentially verbatim or through a particular mechanism such as a regulation, unless one of the compatibility criteria for identical adoption needed to be met, (see discussion below). The State would have the flexibility to determine how best to implement the requirements of the NRC regulations. However, this flexibility

Enclosure 1

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shall be exercised in a responsible manner and shall not be used to bar or preclude a practice without an adequate safety or environmental basis, or to bar a practice needed for national interest. The staff plans to conduct a comprehensive analysis of the Commission's regulations to determine which regulations are necessary for State adoption, by legally binding means, to maintain an adequate level of protection.

The development of the common performance indicators for the evaluation of Agreement States and the NRC regional offices will be directly related to adequacy requirements for Agreement State programs, and consequently, will need to be closely coordinated with the staff efforts to define the elements of an adequate State program. In December 1993, the staff currently plans to provide the Commission with a paper further describing the use of common performance indicators in NRC region and Agreement State reviews. The staff plans to use the common performance indicators, supplemented appropriately, to evaluate the adequacy of an Agreement State program. The current proposed common performance indicators program contemplates using a Management Review Board (MRB) to make the decision on the adequacy of existing Agreement State programs. The initial adequacy determination of a proposed new Agreement State program will be made by the Office of State Programs, rather than the MRB, because the adequacy of a proposed new program is not dependent on effectiveness of actual program implementation. The staff plans to follow this same split of responsibilities for the compatibility determination of an Agreement State program, with the MRB making the compatibility determinations for existing Agreement State programs, and the Office of State Programs making the initial compatibility determinations for proposed new programs. The initial adequacy and compatibility determinations for proposed new Agreement State programs are reviewed and approved by the Commission. Due to the relationship between adequacy and compatibility, the staff believes that for existing programs it would be beneficial for the MRB to evaluate compatibility as well as adequacy. Indicators of compatibility will be developed by the staff. In order to ensure that the specific elements necessary for an adequacy determination are identified in time to be used at the beginning of the common performance indicators program, now scheduled for early 1994, the staff intends to review those regulations currently in the Divisions 1 and 2 of Internal Procedures B.7, "Criteria for Compatibility Determinations." During the regulations review, staff will make a preliminary identification of regulations appropriate for elements of an adequate Agreement State Program.

As noted earlier, compatibility requirements are necessary to achieve some larger national interest beyond that required for adequate protection of the public health and safety. For cases

where the Commission, in cooperation with the Agreement States, finds it necessary to protect this larger national interest, the Agreement States would be required to establish provisions in their programs that are essentially identical to the NRC regulatory program. The determination of the national interest would focus on State action or inaction that would have extraterritorial impacts either on other States or on the national program. The compatibility indicators that would be used to guide the compatibility determinations would consist of answering the question of whether identical requirements in a State program are necessary to---

- avoid a significant burden on interstate commerce; for example, requiring uniform standards for consumer products;
- ensure clear communication on fundamental radiation protection terminology; for example, "byproduct material" or "total effective dose equivalent;"
- ensure clear communication and common understanding as to certain central radiation protection concepts applicable to all licensees; for example, the establishment of uniform standards as to radiation dose limits for workers and members of the public; or
- assist the NRC in evaluating the effectiveness of the overall national program for radiation protection; for example, requirements derived from national program initiatives incorporated into memoranda of understanding with other federal agencies; or for example requirements for reports or records needed for an NRC study of medical misadministrations.

If none of the above criteria is met, the State would have the flexibility to design its programs to meet local needs and conditions, assuming that the requirements for adequacy are still met. For example, to meet local needs and conditions, States could for particular classes of licensees adopt more stringent radiation protection requirements so long as the basic dose standards applicable to all licensees are essentially identical to those of the NRC. However, an Agreement State shall not adopt more stringent regulations which will bar or preclude a practice without an adequate safety or environmental basis, or bar a practice needed in the national interest. To ensure that more stringent radiation protection requirements are limited to particular classes of licenses and do not bar or preclude practices, Agreement States will be requested to submit proposed more stringent requirements to the NRC for review.

Revocation of Agreements

Revocation of an Agreement can occur when an Agreement State program is either inadequate or incompatible. The proposed MRB, reviewing discrete common performance indicators, would judge the overall adequacy of an Agreement State program. Similarly, the MRB would review discrete "compatibility indicators" and determine the overall compatibility of an Agreement State program. For either of the adequacy or compatibility determination, failure to satisfy an individual indicator may not necessarily result in an overall finding of inadequacy or incompatibility. In some situations, individual indicator weakness(es) could result in a "marginal" finding by the MRB calling for Agreement State improvements. In extreme cases, indicator(s) failure could lead to inadequate or incompatible findings resulting in the initiation of program revocation with perhaps an interim step of program probation or suspension. In terms of the compatibility evaluation, the significance of performance indicator "incompatibility" in an individual State will be judged on the basis of the impact on the national program.

III. Policy Statement

For the purpose of evaluating the adequacy of Agreement State regulatory programs to protect public health and safety, adequate and an adequate Agreement State Program mean:

Adequate means:

An acceptable level of protection of the public health and safety from the radiation hazards associated with the use of byproduct, source, and special nuclear materials.

An Adequate Agreement State Program means:

An effectively implemented regulatory program containing elements, regulations, policies, and procedures considered necessary by the Commission to provide an acceptable level of protection for the public health and safety from the radiation hazards associated with the use of byproduct, source, and special nuclear materials. THE ELEMENTS OF AN ADEQUATE PROGRAM INCLUDE:

1. PROTECTION.

The Agreement State program shall be designed and administered to protect the public health and safety of its citizens against radiation hazards.

2. REGULATIONS.

An Agreement State program shall adopt regulations or other legally binding measures, except those designed as radiation protection standards or other regulations necessary for compatibility purposes, equivalent to, or more stringent than, those designated by the NRC.

3. INSPECTION PROGRAM.

The State regulatory program shall provide for the inspection of the possession and use of radioactive materials by the regulatory authority. The State inspection of license facilities, equipment, procedures and use of materials shall provide reasonable assurance that the public health and safety is being protected. Inspection and testing shall be conducted to assist in determining compliance with regulatory requirements. Frequency of inspection shall be related directly to the hazards associated with amount and kind of material and type of operation licensed. The minimum inspection frequency, including initial inspections, shall be no less than the NRC inspection frequency. An adequate inspection program includes: preparation and use of procedures and policy memoranda to assure technical quality in the inspection program and review of inspection actions by senior staff or supervisors. The inspection staff technical expertise should be similar to NRC staff qualifications.

4. ENFORCEMENT PROGRAM.

Licensee noncompliance with requirements necessary for the safe possession and use of radioactive materials shall be subject to enforcement through legal sanctions, and the regulatory authority shall be authorized by law with the necessary powers for prompt enforcement.

5. STAFFING AND PERSONNEL QUALIFICATIONS.

The regulatory agency shall be sufficiently staffed with an adequate number of qualified personnel to effectively implement the radiation control program. Agreement State

staff shall be qualified using criteria no less strirgent than criteria used for NRC staff.

6. ADMINISTRATIVE PROCEDURES.

State practices for assuring the effective administration of the radiation control program, including provisions for public participation where appropriate, shall be incorporated in procedures for:

- (a) Formulation of rules of general applicability;
- (b) Approving or denying applications for licenses authorizing the possession and use of radioactive materials; and
- (c) Taking enforcement actions against licensees.

7. STATUTES.

State statutes and/or duly promulgated regulations shall be established to authorize the State to carry out the requirements under Section 274b of the Atomic Energy Act, as amended and any other statutes as appropriate, such as Public Law 95-604, Uranium Mill Tailings Radiation Control Act (UMTRCA).

8. LABORATORY SUPPORT.

The State shall have available calibrated field and laboratory instrumentation sufficient to independently determine the licensee's control of materials, to validate the licensee's measurements, and to respond to events involving radioactive material.

9. LICENSING PROGRAM.

The State regulatory program review of license applications for the purpose of evaluating the applicant's qualifications, facilities, equipment, procedures and use of materials shall provide reasonable assurance that the public health and safety are being protected. An adequate licensing program includes: preparation and use of licensing guides and policy memoranda to assure technical quality in the licensing program and review of licensing actions by senior staff or supervisors. In addition, procedures involving the licensing of products containing radioactive material intended for interstate commerce should require a high degree of uniformity with those of the NRC. The review staff technical expertise should be similar to NRC staff qualifications.

10. INVESTIGATION (RESPONSE TO EVENTS).

The State regulatory program shall provide for timely and effective investigation of incidents, reportable events, allegations and any potential wrongdoing.

11. BUDGET.

The State radiation control program (RCP) shall have adequate budgetary support to implement an effective program. The total RCP budget must provide adequate funds for salaries, training, travel costs associated with the compliance program, laboratory and survey instrumentation and other equipment, contract services, and other administrative costs.

In addition, compatible and compatible Agreement State Program shall mean:

Compatible means:

The consistency between NRC and Agreement State regulatory programs which is needed in order to establish a national radiation protection program for the regulation of byproduct, source and special nuclear material which assures an orderly and effective regulatory pattern in the administration of this national program. Compatibility shall be aimed at ensuring that the flow of interstate commerce is not impeded, that effective communication in the radiation protection field is maintained, that central radiation protection concepts applicable to all licensees are maintained, and that information needed for the study of trends in radiation protection and other national program needs are ascertained.

A Compatible Agreement State Program means:

A regulatory program containing elements, regulations, policies, and procedures considered necessary by the Commission to effectively implement the term "compatible" as defined above.

The following criteria shall be applied to program elements and regulations to determine whether they need to be adopted by Agreement States in a manner essentially identical to that of the NRC for the purposes of compatibility:

 avoid a significant burden on interstate commerce; for example, requiring uniform standards for consumer products;

- ensure clear communication on fundamental radiation protection terminology; for example, "byproduct material" or "total effective dose equivalent";
- ensure clear communication and common understanding as to certain central radiation protection concepts applicable to all licensees; for example, the establishment of uniform standards as to radiation dose limits for workers and members of the public; or
- * assist the NRC in evaluating the effectiveness of the overall national program for radiation protection; for example, requirements derived from national program initiatives incorporated into memoranda of understanding with other federal agencies; or for example requirements for reports or records needed for an NRC study of medical misadministrations.

If none of the above criteria is met, the State would have the flexibility to design its programs to meet local needs and conditions, assuming that the requirements for adequacy are still met. For example, to meet local needs and conditions, States could for particular classes of licensees adopt more stringent radiation protection requirements so long as the basic dose standards applicable to all licensees are essentially identical to those of the NRC. However, an Agreement State shall not adopt more stringent regulations which will bar or preclude a practice without an adequate safety or environmental basis, or bar a practice needed in the national interest. To ensure that more stringent radiation protection requirements are limited to particular classes of licenses and do not bar or preclude practices, Agreement States will be requested to submit proposed more stringent requirements to the NRC for review.

Based upon the discussions above, the following examples of elements of a compatible program are proposed:

1. RADIATION LABELS, SIGNS, AND SYMBOLS.

States must have radiation labels, signs and symbols identical to that of the national standard.

2. Uniform Manifest.

State regulatory programs shall establish a manifest system in accordance with 10 CFR Part 20.

3. TRANSPORTATION REGULATIONS.

State regulations regarding transportation of radioactive materials must be identical or essentially verbatim as those in 10 CFR Part 71.

4. EVENT REPORTING.

The State regulatory program shall require licensee reporting in a manner so that information on identical type events is consistent with the reporting established by the NRC. This information shall be provided to the NRC.

5. RECIPROCITY.

The State regulatory program shall have reciprocal recognition of out-of-State licensees and Federal licensees through a process which authorizes safe conduct of operation within the Agreement State.

6. RECORDS AND REPORTS.

The State regulatory program shall require that holders and users of radioactive materials (a) maintain records covering personnel radiation exposures, radiation surveys and disposal of materials, (b) keep records of the receipt and transfer of the material, (c) maintain reports of significant incidents involving radioactive materials.

7. RADIATION PROTECTION TERMINOLOGY.

The State regulatory program shall adopt fundamental radiation protection terminology in a manner essential identical to NRC definition of these terms to ensure clear communication in the radiation protection area. Some examples of these terms are "byproduct material;" "total effective dose equivalent;" "rem;" "rad;" and "curie."

8. RADIATION PROTECTION STANDARDS.

The State regulatory program shall adopt uniform radiation protection standards applicable to all its licensees as to allowable dose exposures to workers and members of the public. However, a State may adopt more stringent doses and release limits for particular licensees or classes of licensees based upon local needs and conditions.

Not withstanding the provisions above, the Agreement States shall exercise their regulatory authority in a responsible manner and shall not adopt more stringent regulations or requirements as a means to bar or preclude a practice without an adequate safety or environmental basis, or bar a practice needed in the national interest. In order to permit the NRC to provide early coordination and oversight of any proposed more stringent regulations or requirements, NRC will request Agreement States to submit any such regulations or requirements for NRC review before publication as a draft rule for comment or before the institution of the requirement as a legally binding measure.

PAPERWORK REDUCTION ACT STATEMENT

This request for comments does not constitute information collection under the exception from the definition of information contained in 5 CFR 1320.7(j)(4) and therefore is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

Dated at Rockville, Maryland, this day of

, 1994.

For the Nuclear Regulatory Commission

Samuel J. Chilk Secretary of the Commission

DRAFT LETTER TO CONGRESS FORWARDING FEDERAL REGISTER NOTICE

The Honorable Richard H. Lehman, Chairman Subcommittee on Energy and Mineral Resources Committee on Natural Resources United States House of Representatives Washington, DC 20515

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee are copies of a public announcement and a draft policy statement on the adequacy and compatibility of Agreement State regulatory programs with that of the NRC which is to be published in the <u>Federal Register</u>.

The Commission is issuing the draft policy statement for a 90-day public comment period.

Sincerely,

Dennis K. Rathbun, Director Office of Congressional Affairs

Enclosures:

- Public Announcement (to be attached when the announcement is issued)
- 2. <u>Federal Register Notice</u> (to be attached by OCA when the FRN is signed)

cc: Representative Barbara Vucanovich

Identical Letters to:

The Honorable Joseph I. Lieberman, Chairman Subcommittee on Clean Air and Nuclear Regulation Committee on Environment and Public Works United States Senate Washington, DC 20510

cc: Senator Alan K. Simpson

The Honorable Philip R. Sharp, Chairman Subcommittee on Energy and Power Committee on Energy and Commerce United States House of Representatives Washington, D. C. 20515

cc: Representative Michael Bilirakis

DRAFT PUBLIC ANNOUNCEMENT

REQUEST FOR COMMENTS ON THE DRAFT CRITERIA AND DRAFT POLICY STATEMENT ON ADEQUACY AND COMPATIBILITY OF AGREEMENT STATES PROGRAMS WITH NRC REGULATORY PROGRAMS

The Nuclear Regulatory Commission is publishing for public comment draft criteria and a draft policy statement, proposing elements that are necessary for an adequate and compatible Agreement State radiation control program.

An earlier request for comments in the <u>Federal Register</u> notice was made on December 23, 1991 (56 FR 66457) in which the Nuclear Regulatory Commission requested comments on the compatibility of Agreement States programs with NRC regulatory programs. Since that time, the staff has held discussions with the Agreement States, the non-Agreement States, the regulated community of licensees, and the general public on this issue. The Commission has carefully considered the views of the Agreement States, the industry and the public in the formulation of draft criteria and a draft policy statement on adequacy and compatibility.

The draft criteria and draft policy statement were published in the <u>Federal Register</u> on <u>, 199</u>. Interested persons are invited to submit written comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, ATTN: Document and Services Branch by <u>Comments can be delivered to: 11555 Rockville</u> Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. on Federal workdays.