



OFFICE OF THE SECRETARY

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

April 21, 1994

RELEASED TO THE PDR 5/10/94 [initials]

REVISED

MEMORANDUM TO: James M. Taylor Executive Director for Operations
FROM: John C. Hoyle, Assistant Secretary
SUBJECT: SECY-93-349 - DRAFT POLICY STATEMENT FOR AGREEMENT STATE ADEQUACY AND COMPATIBILITY WITH NRC REGULATORY PROGRAMS NECESSARY TO PROTECT PUBLIC HEALTH AND SAFETY

The Commission (with all Commissioners agreeing) has approved publication of the draft Policy Statement in the Federal Register subject to the comments and changes indicated in items 1) through 4) below. Prior to publication, the staff should provide the revised Policy Statement and proposed Federal Register notice to the Commission for review in a negative consent format. (EDO) (SECY Suspense: 4/29/94)

- 1) Compatibility Criterion No. 3 should be expanded to read "... common dose limits applicable to all licensees in 10 CFR Part 20 and 10 CFR Part 61." The staff should explicitly seek public comments on whether any other dose or radiation protection related release limits in 10 CFR should be included in this criterion. Additionally, the staff should not list 10 CFR Part 61.41 as an "example of a more stringent requirement" as shown on page 5 of SECY-94-025. Also, to reflect the addition of Part 61 to Criterion No. 3, the last sentence of paragraph numbered 8, entitled "Radiation Protection Standards" on page 12 of the draft Federal Register notice should be deleted and appropriate modifications as a result of this deletion be made throughout the Policy Statement.

The interpretation of Criterion No. 3 should not be limited to only Subpart C and Subpart D of 10 CFR Part 20. A broader view is needed to account for subsequent amendments to 10 CFR Part 20 that may set forth dose limits.

SECY NOTE: THIS SRM, SECY-93-349, AND THE VOTE SHEETS OF ALL COMMISSIONERS WILL BE MADE PUBLICLY AVAILABLE 10 WORKING DAYS FROM THE DATE OF THIS SRM

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- 2) The Federal Register notice should explicitly invite public comment on the applicability of this Policy Statement to low-level waste regulation.
- 3) The draft Policy Statement should be revised to achieve consistency in terminology and include definitions of key terms such as "element" and "practice." Both terms should be defined using the definitions provided in SECY-94-025.
- 4) The staff should update the proposed Policy Statement, incorporate the editorial changes indicated in the attachment and make other changes necessary to conform the proposed Policy Statement to SECY-94-025 and this SRM.

The staff should perform a preliminary analysis in which the four proposed compatibility criteria are applied to the existing Division I rules that are set forth in Internal Procedure B.7 in Parts 20 and 61. The purpose of the preliminary analysis is to determine which of those provisions will continue to be required to be essentially identical with the NRC regulatory framework in order to achieve a larger national interest beyond that required for adequate protection of the public health and safety within the State. The staff should compare the list of NRC provisions that result from an application of the four proposed compatibility criteria with the Division I items that were set forth in Internal Procedure B.7. The staff should provide an explanation of why an item might be deleted from the existing Division I rules as a result of applying the compatibility criteria and also which of the four compatibility criteria would cause an existing Division I rule to essentially stay on the list. The list should be updated as necessary to reflect the regulations currently in effect.

(EDO) (SECY Suspense: 5/20/94)

At the conclusion of the pilot program on the use of common performance indicators (as identified in SECY-94-011) and following consideration of the public comments on the draft Policy Statement and, assuming that the idea of using common performance indicators is valid, the staff must reconcile the proposed elements of an adequate program with the common performance indicators.

(EDO) (SECY Suspense: 11/18/94)

The staff should hold the proposed workshop during the public comment period.

Attachment:
As stated

cc: The Chairman
Commissioner Rogers
Commissioner Remick
Commissioner de Planque
OGC
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)

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

the terms "adequate" and "compatible."

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.

an Agreement State

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

discontinuing NRC's

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

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:

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~~ ^{should} ~~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 ^{should} "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

also applied

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

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

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 ^{must} ~~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;

3. TRANSPORTATION REGULATIONS.

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

with ———→

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 ^{operations} within the Agreement State.

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similar ———→

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^{ly} 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."

about ———→

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.

Notwithstanding 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

John C. Hoyle

↳
Acting ~~Samuel J. Chirk~~
Secretary of the Commission

the State action. For the specific case of more stringent dose limits for a particular class of licensees or where practices are precluded or effectively precluded, Commission review of the circumstances of these State actions will provide additional assurance that the national interest in radiation protection is not being undermined. The staff believes that only a very few of the State actions in this area of flexibility will involve more stringent dose limits, as opposed to more stringent requirements for such items as training or reporting.

Compatibility. The "compatibility" requirement would focus on those elements of a State program which would be required to be essentially identical with the NRC regulatory framework in order to achieve a larger national interest beyond that required for adequate protection of the public health and safety within the State. The draft policy establishes four criteria that the NRC would use to determine which elements of the NRC regulatory program, including specific NRC regulations, that the State would be required to incorporate in an essentially identical manner into its regulatory program. The staff proposes to revise criterion 3 as used in SECY-93-349 to read, "Ensure the establishment of common dose limits applicable to all licensees in 10 CFR Part 20." This change will clarify the previously used wording "ensure clear communication and common understanding as to certain central radiation protection concepts applicable to all licensees." The staff has defined these "central radiation protection concepts" as the dose limits applicable to all licensees in 10 CFR Part 20 of the Commission's regulations. The four criteria are--

1. to avoid a significant burden on interstate commerce;
2. to ensure clear communication on fundamental radiation protection terminology;
3. to ensure the establishment of common dose limits applicable to all licensees in 10 CFR Part 20; or
4. to assist the Commission in evaluating the effectiveness of the overall national program for radiation protection.

Using the above criteria, the staff will evaluate the NRC regulatory program to determine those program elements, including regulations, which are required to be essentially identical (examples are provided below). The dose limits applicable to all licensees in 10 CFR Part 20 will automatically be required to be identical through the application of criterion 3, above. States will not have the flexibility to deviate from the program elements that the Commission requires for compatibility.

6. Definition of Element

The term "element" as used in the draft policy statement can more appropriately be described as "program element." "Element" or "program element" is used to describe any of the essential components and functions of a radiation protection regulatory program. Therefore, the term is used

generically to include any aspect of a radiation protection regulatory program that is necessary to implement a program adequate to protect public health and safety and/or compatible with the NRC regulatory program. The term "element" may include organizational structure, staffing level, inspection frequency, regulations, policies and procedures or any other component or function that the Commission considers necessary.

C. Definition of Practice

The term "practice" in SECY-93-349 describes a use, procedure or activity associated with the application, possession, storage or disposal of byproduct, source and special nuclear materials. The term "practice" is very broad and encompassing in nature. For example, the term "practice," as applied in the draft policy statement, not only applies to very general activities involving radioactive materials such as industrial radiography, low-level waste disposal, nuclear medicine procedures, and well logging, but also includes specific activities conducted within these very broad activities, such as shallow land burial, sanitary sewerage disposal, and incineration of materials.

D. Examples For the Compatibility Criteria

1. Avoid a significant burden on interstate commerce.

- The adoption of transportation requirements for all Agreement States should be essentially identical to assure that the flow of radioactive materials in or through another jurisdiction is not impeded. For example, if States were allowed to change 10 CFR 71.47, "External Radiation Standards for all Packages" then it would be very difficult to transport radioactive material packages.

2. Ensure clear communication on fundamental radiation protection terminology.

- The adoption of the definition of the terms "rem," "rad," and "Roentgen" would be essentially identical by all Agreement States.

3. Ensure the establishment of common dose limits applicable to all licensees in 10 CFR Part 20.

- The adoption of the basic dose limits for all classes of licensees set forth in Subpart C, "Occupational Dose Limits," and Subpart D, "Radiation Dose Limits for Individual Members of the Public," of 10 CFR Part 20 would need to be adopted, essentially identical by all Agreement States.

4. To assist the Commission in evaluating the effectiveness of the overall national program for radiation protection.