

1

2 **Proposed Policy Statement for the Agreement State Program**

3 A. PURPOSE.

4 The purpose of this policy statement for the Agreement State Program is to describe the
5 respective roles and responsibilities of the U.S. Nuclear Regulatory Commission (NRC) and
6 Agreement States in the administration of programs carried out under Section 274 of the Atomic
7 Energy Act of 1954, as amended (AEA).¹ Section 274 provides broad authority for the NRC to
8 establish a unique Federal and State relationship in the administration of regulatory programs
9 for the protection of public health and safety in the industrial, medical, commercial, and research
10 uses of agreement material. This policy statement supersedes the “Policy Statement on
11 Adequacy and Compatibility of Agreement State Programs” and the “Statement of Principles
12 and Policy for the Agreement State Program.”

13 This policy statement addresses the Federal-State interaction under the AEA to
14 (1) establish and maintain agreements with States under Subsection 274b. that provide for
15 discontinuance by the NRC, and the assumption by the State, of responsibility for administration
16 of a regulatory program for the safe and secure use of agreement material; (2) ensure that
17 post-agreement interactions between the NRC and Agreement State radiation control programs
18 are coordinated; and (3) ensure Agreement States provide adequate protection of public health
19 and safety and maintain programs that are compatible with the NRC’s regulatory program.

20 Although not defined in the AEA, the National Materials Program (NMP) is a term to
21 describe the broad collective effort within which both NRC and the Agreement States function in
22 carrying out their respective regulatory programs for agreement material. The mission of the
23 NMP is to provide a coherent national system for the regulation of agreement material with the

¹ Subsection 274b. of the AEA authorizes the NRC to enter into an agreement by which the NRC discontinues and the State assumes regulatory authority over some or all of these materials. The material over which the State receives regulatory authority under such agreement is termed “agreement material.”

goal of protecting public health and safety through compatible regulatory programs. Under the NMP, the NRC and Agreement States function as regulatory partners. The roles and responsibilities of the NRC and the Agreement States are based on their legislative authority, program needs, and expertise. Two national organizations—the Organization of Agreement States (OAS) and Conference of Radiation Control Program Directors, Inc. (CRCPD)—which are composed of State radiation protection programs, also play important roles within the NMP.

B. BACKGROUND.

This policy statement is intended solely as guidance for the NRC 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; nor does this policy statement diminish or constrain the NRC’s authority under the AEA. Implementation procedures adopted pursuant to this policy statement shall be consistent with the legal authorities of the NRC and the Agreement States.

This policy statement presents the NRC’s policy for determining the adequacy and compatibility of Agreement State programs. This policy statement clarifies the meaning and use of the terms “adequate to protect public health and safety” and “compatible with the NRC’s regulatory program” as applied to Agreement State programs. The terms “adequate” and “compatible” represent fundamental concepts in the Agreement State programs authorized in 1959 by Section 274 of the AEA. Subsection 274d. states that the NRC shall enter into an Agreement under Subsection 274b., which discontinues the NRC’s regulatory authority over specified AEA radioactive materials and activities within a State, provided that the State’s program is adequate to protect public health and safety and is compatible with the

Commission's regulatory program. Subsection 274g. authorizes and directs the NRC to cooperate with States in the formulation of standards to assure that State and NRC programs for protection against hazards of radiation will be coordinated and compatible. Subsection 274j.(1) requires the NRC to periodically review the Agreements and actions taken by States under the Agreements to ensure compliance with the provisions of Section 274.

The NRC and Agreement State radiation control programs maintain regulatory authority for the safe and secure handling, use, and storage of agreement material. These programs have always included the security of agreement material as an integral part of their health and safety mission as it relates to controlling and minimizing the risk of exposure to workers and the public. Following the events of September 11, 2001, the NRC's regulatory oversight has included developing and implementing enhanced security measures. For the purposes of this policy statement, public health and safety includes physical protection of agreement material.

C. STATEMENT OF LEGISLATIVE INTENT.

In 1954, the AEA did not initially specify a role for the States in regulating the use of nuclear material. Many States were concerned as to what their responsibilities in this area might be and expressed interest in clearly defining the boundaries of Federal and State authority over nuclear material. 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 AEA radioactive materials, defined as byproduct, source, and special nuclear material, the States maintained the responsibility for protecting the public from the radiation hazards of other sources such as x-ray machines and naturally occurring radioactive material.

Consequently, in 1959, Congress enacted Section 274 of the AEA to establish a statutory framework under which States could assume and the NRC could discontinue

74 regulatory authority over byproduct, source, and small quantities of special nuclear material
75 insufficient to form a critical mass. The NRC continued to retain regulatory authority over the
76 licensing of certain facilities and activities including, nuclear reactors, quantities of special
77 nuclear material sufficient to form a critical mass, the export and import of nuclear materials,
78 and matters related to common defense and security.

79 The legislation did not authorize a wholesale relinquishment or abdication by the
80 Commission of its regulatory responsibilities but only a gradual, carefully considered turnover.
81 Congress recognized that the Federal Government would need to assist the States to ensure
82 that they developed the capability to exercise their regulatory authority in a competent and
83 effective manner. Accordingly, the legislation authorized the NRC to provide training, with or
84 without charge, and other services to State officials and employees as the Commission deems
85 appropriate. However, in rendering this assistance, Congress did not intend that the NRC
86 would provide any grants to a State for the administration of a State regulatory program. This
87 was fully consistent with the objectives of Section 274 to qualify States to assume independent
88 regulatory authority over certain defined areas under their Agreement and to permit the NRC to
89 discontinue its regulatory responsibilities in those areas.

90 In order to discontinue its authority, the NRC must find that the State program is
91 compatible with the NRC program for the regulation of agreement material and that the State
92 program is adequate to protect public health and safety. In addition, the NRC has an obligation,
93 pursuant to Subsection 274j. of the AEA, to periodically review existing Agreement State
94 programs to ensure continued adequacy and compatibility. Subsection 274j. of the AEA
95 provides that the NRC may terminate or suspend all or part of its agreement with a State if the
96 NRC finds that such termination is necessary to protect public health and safety or that the
97 State has not complied with the provisions of Subsection 274j. In these cases, the NRC must
98 offer the State reasonable notice and opportunity for a hearing. In cases where the State has

requested termination of the agreement, notice and opportunity for a hearing are not necessary. In addition, the NRC may temporarily suspend all or part of an agreement in the case of an emergency situation.

D. PROGRAM IMPLEMENTATION.

1. Implementation of the Agreement State Program is described below and includes (a) Principles of Good Regulation; (b) performance assessment on a consistent and systematic basis; (c) the responsibility to ensure adequate protection of public health and safety, including physical protection of agreement material; (d) compatibility in areas of national interest; and (e) sufficient flexibility in program implementation and administration to accommodate individual State needs.

i. Principles of Good Regulation.

In 1991, the Commission adopted the "Principles of Good Regulation" to serve as a guide to both agency decision making and to individual behavior of NRC employees. There are five Principles of Good Regulation: independence, openness, efficiency, clarity, and reliability. Adherence to these principles has helped to ensure that the NRC's regulatory activities have been of the highest quality, and are 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 NRC's implementation of these principles has served the public, the Agreement States, and the regulated community well. Such principles are useful as a part of a common culture of the NMP that the NRC and the Agreement States share as co-regulators. Accordingly, the NRC encourages each Agreement State to adopt a similar set of principles for use in its own regulatory program. These principles should be incorporated into the day-to-day operational fabric of the NMP.

124 ii. Performance Assessment.

125 To ensure that Agreement State programs continue to provide adequate protection of
126 public health and safety and are compatible with the NRC's regulatory program, periodic
127 program assessment is needed. The NRC, in cooperation with the Agreement States,
128 established and implemented the IMPEP. The IMPEP is a performance evaluation process that
129 provides the NRC and Agreement State management with systematic, integrated, and reliable
130 evaluations of the strengths and weaknesses of their respective radiation control programs and
131 identification of areas needing improvement.

132 iii. Adequate to Protect Public Health and Safety.

133 The NRC and the Agreement States have the responsibility to ensure adequate
134 protection of public health and safety in the administration of their respective regulatory
135 programs, including physical protection of agreement material. Accordingly, the NRC and
136 Agreement State programs shall possess the requisite supporting legislative authority,
137 implementing organization structure and procedures, and financial and human resources to
138 effectively administer a radiation control program that ensures adequate protection of public
139 health and safety.

140 iv. Compatible in Areas of National Interest.

141 The NRC and the Agreement States have the responsibility to ensure that the radiation
142 control programs are compatible. Such radiation control programs should be based on a
143 common regulatory philosophy including the common use of definitions and standards. The
144 programs should be effective and cooperatively implemented by the NRC and the Agreement
145 States and also should provide uniformity and achieve common strategic outcomes in program
146 areas having national significance.

147 Such areas of national significance include aspects of licensing, inspection and
148 enforcement, response to incidents and allegations, and safety reviews for the manufacture and

distribution of sealed sources and devices. Furthermore, communication using a nationally accepted set of terms with common understanding, ensuring an adequate level of protection of public health and safety that is consistent and stable across the nation, and evaluation of the effectiveness of the NRC and Agreement State programs for the regulation of agreement material with respect to protection of public health and safety are essential to maintaining a strong NMP.

v. Flexibility.

With the exception of those compatibility areas where programs should be essentially identical, Agreement State radiation control programs have flexibility in program implementation and administration to accommodate individual State preferences, State legislative direction, and local needs and conditions. A State has the flexibility to design its own program, including incorporating more stringent, or similar, requirements provided that the requirements for adequate protection of public health and safety are met and compatibility is maintained. However, the exercise of such flexibility should not preclude a practice authorized by the AEA, and in the national interest.

2. New Agreements.

Section 274 of the AEA requires that once a decision to request 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 that would be 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, staffing plan, a narrative description of the State program's policies, practices, and procedures, and a proposed agreement.

The NRC's policy statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement" (46 FR 7540, January 23, 1981; as amended by policy statements published at 46 FR 36969, July 16, 1981; and 48 FR 33376, July 21, 1983), describes the 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 NRC determines that the proposed State program is adequate for protection of public health and safety and compatible with the NRC's regulatory program, the Governor and Chairman of the NRC sign a formal document memorializing the agreement.

3. Program Assistance.

The NRC will offer training and other assistance to States, such as assistance in developing regulations and program descriptions to help individual States prepare their request for entering into an Agreement and to help them prior to the assumption of regulatory authority. Following approval of the agreement and assumption of regulatory authority by a new Agreement State, to the extent permitted by resources, the NRC may provide training opportunities and offer other assistance such as review of proposed regulatory changes to help Agreement States administer their regulatory responsibilities. However, it is the responsibility of the Agreement State to ensure that they have a sufficient number of qualified staff to implement their program. If the NRC is unable to provide the training, the Agreement State will need to do so.

The NRC may also use its best efforts to provide specialized technical assistance to Agreement States to address unique or complex licensing, inspection, incident response, and limited enforcement issues. In areas where Agreement States have particular expertise or are in the best position to provide immediate assistance to the NRC or other Agreement States,

they are encouraged to do so. In addition, the NRC and Agreement States will keep each other informed about relevant aspects of their programs.

If an Agreement State experiences difficulty in implementing its program, the NRC will, to the extent possible, assist the State in maintaining the effectiveness of its radiation control program. Under certain conditions, an Agreement State can also voluntarily return all or part of its Agreement State program.

4. Performance Evaluation.

Under Section 274 of the AEA, the NRC retains oversight authority for ensuring that Agreement State programs provide adequate protection of public health and safety and are compatible with the NRC's regulatory program. In fulfilling this statutory responsibility, the NRC will determine whether the Agreement State programs are adequate and compatible prior to entrance into a Subsection 274b. agreement and will periodically review the program to ensure they continue to be adequate and compatible after an agreement becomes effective.

The NRC, in cooperation with the Agreement States, established and implemented the IMPEP. As described in Management Directive 5.6 "Integrated Materials Performance Evaluation Program (IMPEP)," IMPEP is a performance evaluation process that provides the 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. The same criteria are used to evaluate and ensure that regulatory programs are adequate to protect public health and safety and that Agreement State programs are compatible with the NRC's program. The IMPEP process employs a Management Review Board, composed of senior NRC managers and an Agreement State liaison provided by the OAS to make a determination of program adequacy and compatibility.

As a part of the performance evaluation process, the NRC will take necessary actions to help ensure that Agreement State radiation control programs remain adequate and compatible.

These actions may include more frequent IMPEP reviews of Agreement State programs and providing assistance to help address weaknesses or areas needing improvement within an Agreement State program. Monitoring, heightened oversight, probation, suspension, or termination of an agreement may be applied for certain program deficiencies or emergencies (e.g. loss of funding, natural or man-made events, pandemic). The NRC's actions in addressing program deficiencies or emergencies will be a well-defined predictable process that is consistently and fairly applied.

5. Program Funding.

Section 274 of the AEA permits the NRC to offer training and other assistance to a State in anticipation of entering into an Agreement with the NRC. Section 274 of the AEA does not allow Federal funding for the administration of Agreement State radiation control programs. Given the importance to public health and safety of having well trained radiation control program personnel, the NRC may offer certain relevant training courses and notify Agreement State personnel of their availability. These training programs also help to ensure compatible approaches to licensing and inspection and thereby strengthen the NMP.

6. Regulatory Development.

The NRC and Agreement States will cooperate in the development of both new and revised regulations and policies. Agreement States will have early and substantive involvement in the development of regulations affecting protection of public health and safety and of policies and guidance documents affecting administration of the Agreement State program. The NRC and Agreement States will keep each other informed about their individual regulatory requirements (e.g., regulations, orders, 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. 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, 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.

Two national organizations composed of State radiation protection programs facilitate participation and involvement with the development of regulations, guidance, and policy. The OAS provides a forum for Agreement States to work with each other and with the NRC on regulatory issues, including centralized communication on radiation protection matters between the Agreement States and the NRC. The CRCPD assists its members in their efforts to protect the public, radiation workers, and patients from unnecessary radiation exposure. One product of the CRCPD is the Suggested State Regulations for use by its members. The NRC reviews Suggested State Regulations for compatibility.

E. ADEQUACY AND COMPATIBILITY.

In accordance with Section 274 of the AEA, any State that chooses to establish an Agreement State program must provide for an acceptable level of protection of public health and safety. This is the “adequacy” component. The Agreement State must also ensure that its program serves an overall nationwide interest in radiation protection. This is the “compatibility” component.

By adopting the criteria for adequacy and compatibility as discussed in this policy statement, the NRC provides a broad range of flexibility in the administration of individual Agreement State programs. Recognizing the fact that Agreement States have responsibilities for radiation sources other than agreement material, the NRC allows Agreement States to fashion their programs to reflect specific State needs and preferences.

273 The NRC will minimize the number of NRC regulatory requirements that the Agreement
274 States will be requested to adopt in an identical manner to maintain compatibility. At the same
275 time, requirements in these compatibility categories allow the NRC to ensure that an orderly
276 pattern for the regulation of agreement material exists nationwide. The NRC believes that this
277 approach achieves a proper balance between the need for Agreement State flexibility and the
278 need for an NMP that is coherent and compatible in the regulation of agreement material across
279 the country.

280 Program elements² for adequacy focus on the protection of public health and safety
281 within a particular Agreement State while program elements for compatibility focus on the
282 impacts of an Agreement State's regulation of agreement material on a nationwide basis or its
283 potential effects on other jurisdictions. Some program elements for compatibility may also
284 impact public health and safety; therefore, they may also be considered program elements for
285 adequacy.

286 In identifying those program elements for adequate and compatible programs, or any
287 changes thereto, the NRC staff will coordinate with the Agreement States.

288
289 1. Adequacy.

290 An "adequate" program includes those program elements of a radiation control
291 regulatory program necessary to maintain an acceptable level of protection of public health and
292 safety within an Agreement State. An Agreement State's radiation control program is adequate
293 to protect public health and safety if administration of the program provides reasonable
294 assurance of protection of public health and safety in regulating the use of agreement material.
295 The level of protection afforded by the program elements of the NRC's materials regulatory

² For the purposes of this policy statement, "program element" means any component or function of a radiation control regulatory program, including regulations and other legally binding requirements imposed on regulated persons, which contributes to implementation of that program.

program is presumed to be adequate to provide a reasonable assurance of protection of public health and safety. Therefore, the overall level of protection of public health and safety provided by a State program should be equivalent to, or greater than, the level provided by the NRC program. To provide reasonable assurance of protection of public health and safety, an Agreement State program should contain the five essential program elements, identified in items i. through v. of this section, that the NRC and Agreement States will use to define the scope of the review of the program. The NRC and Agreement States will also consider, when appropriate, other program elements of an Agreement State that appear to affect the program's ability to provide reasonable assurance of the protection of public health and safety.

i. Legislation and Legal Authority:

Agreement State statutes shall: (a) 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 NRC; (b) authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health and safety; (c) authorize the State to license, inspect, and enforce legally binding requirements such as regulations and licenses; and (d) be otherwise consistent with applicable Federal statutes. In addition, the State should have existing legally enforceable measures such as generally applicable rules, orders, 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 legally binding requirements based on those identified by the NRC because of their particular health and safety significance. In adopting such requirements, Agreement States shall implement the essential objectives articulated in the NRC requirements.

321 ii. Licensing.

322 The Agreement State shall conduct appropriate evaluations of proposed uses of
323 agreement material, before issuing a license to authorize such use, to ensure that the proposed
324 licensee's need and proposed uses of agreement material are in accordance with the AEA and
325 that operations can be conducted safely. Licenses shall provide for reasonable assurance of
326 public health and safety protection in the conduct of licensed activities.

327
328 iii. Inspection and Enforcement.

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

334 iv. Personnel.

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

337 v. Incidents and Allegations.

338 The Agreement State shall respond to and conduct timely inspections or investigations
339 of incidents, reported events, and allegations involving agreement material within the State's
340 jurisdiction to provide reasonable assurance of protection of public health and safety.

341 2. Compatibility.

342 A "compatible" program consists of those program elements necessary to sustain an
343 orderly pattern of regulation of radiation protection. An Agreement State has the flexibility to
344 adopt and implement program elements within the State's jurisdiction that are not addressed by
345 the NRC, or program elements not required for compatibility (i.e., those NRC program elements

not assigned to Compatibility Category A, B, or C). However, such program elements of an Agreement State relating to agreement material shall (1) be compatible with those of the NRC (i.e., should not create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis); (2) not preclude a practice authorized by the AEA and in the national interest; and (3) not 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. For purposes of compatibility, the State shall adopt program elements assigned Compatibility Categories A, B, and C.

i. Category A - Basic Radiation Protection Standards.

This category includes basic radiation protection standards that encompass dose limits, concentration and release limits related to radiation protection in part 20 of title 10 of the *Code of Federal Regulations* (10 CFR), that are generally applicable, and the dose limits for land disposal of radioactive waste in 10 CFR 61.41.³ Also included in this category are a limited number of definitions, signs, labels, and scientific terms that are necessary for a common understanding of radiation protection principles among licensees, regulatory agencies, and members of the public. Such State standards should be essentially identical to those of the NRC, 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 considerations such as economic cost and other factors.

³ The NRC will implement this category consistent with its earlier decision in the low-level waste area to allow Agreement States the flexibility to establish pre-closure operational release limit objectives, as low as is reasonably achievable goals or design objectives at such levels as the State may deem necessary or appropriate, as long as the level of protection of public health and safety is essentially identical to that afforded by NRC requirements.

ii. Category B – Cross Jurisdictional Program Elements.

This category pertains to a small number of program elements that cross jurisdictional boundaries and that should be addressed to ensure uniformity of regulation on a nationwide basis. Examples include, but are not limited to, sealed source and device registration certificates, transportation regulations, and radiography certification. Agreement State program elements shall be essentially identical to those of the NRC. Because program elements used in the Agreement State Program are necessary to maintain an acceptable level of protection of public health and safety, economic factors⁴ should not be considered.

iii. Category C - Other NRC Program Elements.

These are other NRC program elements that are important for an Agreement State to implement 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 NRC program elements. Agreement State program elements may be more restrictive than NRC program elements; however, they should not be so restrictive as to prohibit a practice authorized by the AEA and in the national interest without an adequate public health and safety or environmental basis related to radiation protection.

iv. Category D - Program Elements Not Required for Compatibility.

These are program elements that do not meet any of the criteria listed in Compatibility Category A, B, or C above and are not required to be adopted for purposes of compatibility.

v. Category NRC - Areas of Exclusive NRC Regulatory Authority.

These are program elements over which the NRC cannot discontinue its regulatory authority pursuant to the AEA or provisions of title 10 of the *Code of Federal Regulations*.

⁴ For the purposes of this policy statement, economic factors are those costs incurred by the regulated community to comply with regulations that impact more than one regulatory jurisdiction in the NMP.

391 However, an Agreement State may inform its licensees of these NRC requirements through an
392 appropriate mechanism under the State's administrative procedure laws as long as the State
393 adopts these provisions solely for the purposes of notification, and does not exercise any
394 regulatory authority as a result.

395
396 F. CONCLUSION.

397 The NRC and Agreement States will continue to jointly assess the NRC and Agreement
398 State programs for the regulation of agreement material to identify specific changes that should
399 be considered based on experience or to further improve overall safety, performance,
400 compatibility, and effectiveness.

401 The NRC encourages Agreement States to adopt and implement program elements that
402 are patterned after those adopted and implemented by the NRC to foster and enhance an NMP
403 that establishes a coherent and compatible nationwide program for the regulation of agreement
404 material.