

**ENSURING NATIONAL COMPATIBILITY ACROSS
MULTIPLE REGULATORY AUTHORITIES**

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The primary regulatory authority for the safety and security of radioactive materials in the United States is the Nuclear Regulatory Commission (NRC). However, due to increased state interest in nuclear energy and technologies in the 1950s, the Atomic Energy Act was amended in 1959 to allow the states to enter into agreements with the Atomic Energy Commission (now the NRC) where the federal government discontinues and individual states assume regulatory authority over certain radioactive and nuclear materials and their uses within the state's border. As of 2020, there are 39 Agreement States who, along with the NRC, co-regulate the civilian sector and oversee the National Materials Program (NMP). Although the NRC has discontinued its authority within these individual states, the NRC maintains oversight authority to ensure that each state maintains program elements¹ that are adequate to protect public health and safety and that are compatible with NRC requirements. The NRC retains the authority over activities designated vital to protect the common defense and security of the United States and may only allow Agreement States to conduct some of these activities by special agreement. The framework for the NMP is described in the Commission's "Agreement State Program Policy Statement."

An Agreement State radiation control program is compatible with the NRC's regulatory program when the State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation² of radioactive material included in the agreement (e.g., agreement material), on a nationwide basis. Compatibility focuses primarily on the potential effects of a State's action or inaction either on the regulation of agreement material on a nationwide basis or on other jurisdictions. The concept of compatibility does not directly address matters of health and safety within a particular Agreement State; such matters are addressed directly under adequacy. However, many program elements for compatibility may affect public health and safety; therefore, they also may be considered program elements for adequacy. Further, basic radiation protection standards and other program elements that address or cross jurisdictional boundaries (between two Agreement States or NRC and an Agreement State), although important for health and safety within the State, should ensure uniformity of regulation nationwide for compatibility purposes.

The characterization process for individual program elements is categorized into one of six criteria. The process used to assign a health and safety or compatibility category to an individual program element is described in NRC's Management Directive 5.9, "Adequacy and Compatibility of Program Elements for Agreement State Programs," and is based upon a series of questions to identify a particular compatibility or health and safety significance.

¹ Program elements are any component or function of a radiation control regulatory program, including regulations, staffing, licensing and inspection procedures, incident response, and/or other legally binding requirements, imposed on regulated persons that contributes to implementation of that program.

² The physical protection of radioactive materials is included in the regulatory structure for all agreement materials. That is, safety and physical protection are fully integrated.

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Each program element is tested by asking the series of questions below in the order given. The answers to these questions determine the compatibility category for each NRC program element or identify it as having particular health and safety significance.

- Question (1): Do the essential objectives of the program element address a regulatory area reserved solely to the authority of the NRC? If the response to the question is “yes,” the category designation is “NRC.” If the response to the question is “no,” then proceed to Question (2).
- Question (2): Do the essential objectives of the program element address or define a basic radiation protection standard as defined by the policy statement or is it a definition, term, sign, or symbol needed for a common understanding of radiation protection principles? If the response to this question is “yes,” the compatibility category designation is “A.” If the response to the question is “no,” then proceed to Question (3).
- Question (3): Do the essential objectives of the program element address or define an issue that crosses jurisdictional boundaries? If the response to this question is “yes,” the compatibility category designation is “B.” If the response to the question is “no,” then proceed to Question (4).
- Question (4): Would the absence of the essential objectives of the program element from an Agreement State program create a conflict, gap, or other condition which impacts the orderly regulatory pattern? If the response to this question is “yes,” the compatibility category designation is “C.” If the response to the question is “no,” then proceed to Question (5) to determine whether the program element should be identified as having particular health and safety significance.
- Question (5): Would the absence of the essential objectives of the program element from an Agreement State program create a situation that could directly result in exposure to an individual in excess of the radiation protection standards found in compatibility category A? If the response to this question is “yes,” the program element is not required for purposes of compatibility, but is identified as having particular health and safety significance, then category H&S applies. If the response to the question is “no,” then the program element must be identified as compatibility category “D.”

Under this process Agreement States will need to adopt some program elements that are nearly identical to those established by the NRC but may have flexibility to be more restrictive for other program elements. With regard to Compatibility Category A and B, the Agreement State program elements have to be essentially identical to those of the NRC. The term essentially identical means the interpretation of the text must be the same regardless of the version (NRC or Agreement State) and often means the wording is the same. For Compatibility Category C and Category H&S, Agreement State program elements have to meet the essential objective of the program element. The essential objective is the action that is to be achieved, modified, or prevented by implementing and following the regulation or other program element. In some instances, the essential objective may be a numerical value (e.g., restriction of radiation exposures to a maximum value) or it may be a more general goal (e.g., the conduct of a radiation survey). For example, the dose limits for radiation workers are identical across all NMP jurisdictions and designated as Compatibility Category A; however, the dose limit allowed for license termination are designated as Compatibility Category C which allows Agreement States to be more restrictive than NRC’s limit of 250 microSieverts per year. Consequently, there is no variation in the dose limits for radiation workers, but the license termination dose limits vary across the NMP.

The determination of the adequacy or compatibility criteria for program elements, particularly regulations, begins during their development. Agreement States are given

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multiple opportunities during the rulemaking process to comment on the regulations and the compatibility designations; they work with NRC in the development of the proposed regulations. Licensees and the public can also comment on the proposed compatibility designations. Whereas the Agreement States often want flexibility in the designations (Compatibility Category C or Category H&S) to allow the state to take into account local requirements imposed on them (but not the NRC), licensees often desire more uniformity nationally (Compatibility Category B) to minimize the differences in requirements as licenses move from one jurisdiction to another. Licensees that operate at field locations or have offices across the country in several states face the challenge of meeting similar but not identical regulatory requirements because of compatibility. In recent years, the tension between flexibility and uniformity in compatibility designations were seen during the development of the current training and educational requirements for medical providers and for certain reporting requirements. Agreement States, licensees and professional organizations were active in pursuing their positions on compatibility. It is not until the NRC Commission approves the final regulations are the compatibility designations finalized.

For the NMP to work effectively, the 40 regulatory agencies that comprise the NMP need to have their regulations compatible. Once the NRC adopts amendments to its regulations, the Agreement States have 3 years to adopt compatible requirements. This is a challenge for many Agreement States given the wide range of processes and levels of government that approve state regulations. The time periods for Agreement States to adopt compatible regulations range from 6 months to 3 years with a one-year period being typical. Agreement States will often wait 1 to 2 years and bundle the NRC amendments into one rulemaking package. Over the last 15 years, more Agreement States have made the decision to adopt part or all of their radioactive materials regulations by reference to the NRC regulations to overcome their lengthy internal processes for adopting the required NRC regulations. The other approach frequently taken by Agreement States is the adoption of legally binding requirements through the amendment of the impacted licenses. This is a particularly effective method when the NRC amendment only impacts a class of licensees. The NRC is required by the Atomic Energy Act to periodically review each Agreement State program to ensure that they maintain an adequate and compatible program. This is accomplished through the Integrated Materials Performance Evaluation Program (IMPEP). IMPEP reviews are conducted every 4 to 5 years and has found that nearly all Agreement States maintain compatibility with NRC requirements. In cases where an Agreement State has not updated their regulatory requirements in a timely manner, the impact on the NMP is minimal.