

U.S. NUCLEAR REGULATORY COMMISSION MANAGEMENT DIRECTIVE (MD)

MD 5.9

**ADEQUACY AND COMPATIBILITY OF
PROGRAM ELEMENTS FOR
AGREEMENT STATE PROGRAMS**

DT-18-08

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Approved By: Marc L. Dapas, Director
Office of Nuclear Material Safety and Safeguards

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Division of Materials Safety, Security, State, and Tribal Programs

Contact Name: Duncan White

EXECUTIVE SUMMARY

Management Directive (MD) 5.9, “Adequacy and Compatibility of Program Elements for Agreement State Programs,” is being revised to—

- Reflect organizational changes resulting from the merger of the Office of Nuclear Material Safety and Safeguards and the Office of Federal and State Materials and Environmental Management Programs in October 2014.
- Reflect changes and revisions made when the Policy Statement on Adequacy and Compatibility of Agreement State Programs and the Policy Statement of Principles and Policy for the Agreement State Program were combined to form the Agreement State Program Policy Statement.
- Incorporate changes to Compatibility Category B.
- Update the compatibility review process to include that the Standing Committee on Compatibility reviews program elements (including regulations).

In addition, the MD has been retitled from “Adequacy and Compatibility of Agreement State Programs” to “Adequacy and Compatibility of Program Elements for Agreement State Programs.”

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I. POLICY

The U.S. Nuclear Regulatory Commission will evaluate Agreement State programs established pursuant to Section 274 of the Atomic Energy Act of 1954, as amended, to ensure they are adequate to protect public health and safety and compatible with NRC's regulatory program.

II. OBJECTIVES

- Establish the process the NRC staff will follow to determine when certain proposed or final NRC program elements must be adopted by an Agreement State as legally binding requirements for its licensees, and whether adoption is required for the purpose of compatibility or health and safety as set out in the NRC's Agreement State Program Policy Statement (82 *Federal Register* (FR) 48535).

- Identify the NRC program elements that must be implemented by an Agreement State as legally binding requirements for its licensees to maintain a program that is adequate to protect public health and safety and compatible with NRC's regulatory program.
- Describe how the NRC staff should apply provisions of the policy statement to current and future Agreement State program elements.

III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY

A. Executive Director for Operations (EDO)

Delegates to the Deputy Executive Director for Materials, Waste, Research, State, Tribal, Compliance, Administration and Human Capital Programs oversight of the program to evaluate adequacy and compatibility of Agreement State programs.

B. Deputy Executive Director for Materials, Waste, Research, State, Tribal, Compliance, Administration and Human Capital Programs (DEDM)

Oversees the program to evaluate adequacy and compatibility of Agreement State programs.

C. Director, Office of Nuclear Material Safety and Safeguards (NMSS)

Implements the program to evaluate adequacy and compatibility of Agreement State programs.

D. Director, Division of Materials Safety, Security, State, and Tribal Programs, NMSS

1. Reviews the adequacy and compatibility of Agreement State programs through the Integrated Materials Performance Evaluation Program (IMPEP).
2. Reviews, evaluates, and determines, in coordination with other NRC offices, those NRC program elements that an Agreement State must adopt for adequacy or compatibility.
3. Assists in the review, evaluation, and determination of those NRC regulations that an Agreement State must adopt as legally binding requirements for its licensees for the purpose of compatibility or health and safety.
4. Coordinates the review of Agreement State program elements with other NRC offices.

E. General Counsel

1. Assists in the review, evaluation, and determination of those NRC regulations that an Agreement State must adopt as legally binding requirements for its licensees for the purpose of compatibility or health and safety.

2. Assists in the review, evaluation, and determination of those NRC program elements that an Agreement State must adopt for adequacy or compatibility.
3. Advises staff on findings regarding the adequacy and compatibility of Agreement State program elements.

F. Regional Administrators

Assist in the review, evaluation, and determination of those NRC program elements that an Agreement State must adopt as legally binding requirements for its licensees for the purpose of compatibility or health and safety.

G. Standing Committee on Compatibility

1. Establishes a working group to enhance the existing compatibility determination process through the independent review of program elements required for Agreement State compatibility with NRC requirements.
2. Ensures consistency during the rulemaking process by documenting the basis for decisions made in regards to compatibility determinations while taking into consideration program element implementation issues and the NRC staff's review of State regulations and other program elements under the IMPEP.
3. Evaluates and documents compatibility designations as described in this MD. (See Section II of this handbook, for further details.)

IV. APPLICABILITY

The policy and guidance in this directive and associated handbook apply to all NRC employees who are responsible for, and participate in, the review and evaluation of Agreement State regulatory programs, or who are involved in development and promulgation of NRC regulations or other program elements for byproduct, source, and special nuclear materials.

V. DIRECTIVE HANDBOOK

Handbook 5.9 describes the criteria and the process that will be used to determine the compatibility and health and safety components of NRC program elements that an Agreement State must adopt for an adequate and compatible program.

VI. REFERENCING STATE PROCEDURES

Not all NRC procedures have been updated to reflect the new office name of NMSS. In the interim, current procedures are still in effect, but may indicate Office of Federal and State Materials and Environmental Management Programs (FSME) in the document title and

content. All procedures may be found on the NMSS Web site (<https://scp.nrc.gov>), by selecting “NMSS Procedures” under the “Resources & Tools” tab.

VII. REFERENCES

Code of Federal Regulations

Code of Federal Regulations, Title 10.

Nuclear Regulatory Commission Documents

Commission Paper, COMKC-91-007, “Improving Cooperation with Agreement States,” memorandum from Samuel J. Chilk, Secretary, to James M. Taylor, Executive Director for Operations, and Harold R. Denton, Director, Office of Governmental and Public Affairs, April 11, 1991 ([ML010100091](#)).

Management Directives—

5.3, “Agreement State Participation in Working Groups.”

5.6, “Integrated Materials Performance Evaluation Program (IMPEP).”

6.3, “The Rulemaking Process.”

9.17, “Organization and Functions, Office of the Executive Director for Operations.”

“Agreement State Program Policy Statement,” October 18, 2017, 82 FR 48535.

Office of Federal and State Materials and Environmental Management Programs (FSME) (currently Nuclear Material Safety and Safeguards (NMSS))
Procedures—

SA-200, “Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements,” June 5, 2009 ([ML091190055](#)).

SA-201, “Review of State Regulatory Requirements,” July 27, 2007 ([ML072270636](#)).

Office of State Programs (currently Nuclear Material Safety and Safeguards (NMSS))
Procedures—

NMSS Web site:
<https://scp.nrc.gov>.

United States Code

Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.).

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- Update the compatibility review process to include that the Standing Committee on Compatibility reviews program elements (including regulations).

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I. INTRODUCTION

A. Overview

The U.S. Nuclear Regulatory Commission (NRC) Agreement State Program Policy Statement (policy statement) sets forth the approach that the NRC will use to determine those program elements that must be adopted by an Agreement State to maintain an adequate and compatible program. This handbook describes the specific criteria and process that will be used to identify those program elements that must be adopted by an Agreement State for purposes of compatibility, as well as for identifying those program elements that need to be adopted due to considerations of particular health and safety significance. It further describes how the NRC staff is to apply the provisions of the policy statement to current and future program elements for the purposes of adequacy and compatibility. However, it should be noted that, the overall determination of adequacy for an NRC Region or an Agreement State and compatibility for an Agreement State is made pursuant to Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)."

B. Agreement State Program Policy Statement

1. An Agreement State radiation control program is adequate to protect public health and safety if administration of the program provides reasonable assurance of the protection of public health and safety in regulating the handling, use, and storage of agreement material. The NRC presumes that the implementation of the NRC's materials regulatory program elements affords a level of protection that provides a reasonable assurance of adequate protection of public health and safety. Legally binding requirements are used by States to implement certain program elements such as regulations, license conditions, and orders.
2. 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 regulation of agreement material (source, byproduct, and small quantities of special nuclear material as identified by Section 274b. of the Atomic Energy Act (AEA), as amended) on a nationwide basis. Compatibility focuses primarily on the potential effects of State 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 cross jurisdictional boundaries, although important for health and safety within the State, should ensure uniformity of regulation nationwide for compatibility purposes.

3. On the basis of the policy statement, program elements (including regulations) can be placed into six categories (A, B, C, D, NRC, health and safety (H&S)) to form the basis for evaluating and classifying the program elements. These are summarized below.

- (a) Compatibility Category A

Program elements in Compatibility Category A are those that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. The program elements adopted by an Agreement State should be essentially identical to those of the NRC to provide uniformity in the regulation of agreement material on a nationwide basis.

- (b) Compatibility Category B

Program elements in Compatibility Category B are those that apply to activities that cross jurisdictional boundaries. These program elements have a particular impact on public health and safety and need to be adopted in an essentially identical manner in order to ensure uniformity of regulation on a nationwide basis.

- (c) Compatibility Category C

Program elements in Compatibility Category C include those program elements that are important for an Agreement State to have in order to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State shall embody the essential objectives of these NRC program elements. The Agreement State program elements may be more restrictive than the NRC program elements provided that the essential objective is met, and the State requirements do not jeopardize an orderly pattern of regulation of agreement material on a nationwide basis.

- (d) Compatibility Category D

Program elements in Compatibility Category D are those that do not meet any of the criteria of Compatibility Categories A, B, or C, or have a particular health and safety role and, thus, do not need to be adopted by Agreement States for purposes of compatibility. An Agreement State has the flexibility to choose whether or not to adopt and implement these program elements that fall within its jurisdiction. However, if an Agreement State chooses to adopt such program elements, they should be adopted in a manner such that 1) they are comparable with those of the NRC, 2) they do not preclude, or effectively preclude a practice in the national interest without adequate protection of public health and safety, security, or environmental basis related to radiation protection, and 3) they do not

preclude, or effectively preclude the ability of the NRC to evaluate the effectiveness of the Agreement State program with respect to the protection of public health and safety.

(e) Category NRC

Program elements designated as Category NRC are those elements that address areas of regulation that cannot be discontinued when a State enters into an Agreement with the NRC pursuant to the AEA or provisions of Title 10 of the *Code of Federal Regulations* (CFR). The NRC maintains regulatory authority over these program elements and the Agreement States must not adopt these NRC program elements.

(f) Health and Safety

Although not required for compatibility, the State must adopt program elements in this category, that embody the basic health and safety aspects of the NRC's program elements because of particular health and safety considerations.

II. CATEGORIZATION CRITERIA

Many program elements for compatibility (Categories A, B, or C) may affect public health and safety; therefore, they also may be considered program elements for adequacy.

A. Compatibility Category A

1. To be included in Compatibility Category A, an NRC program element must be applicable to a basic radiation protection standard or sign/label/scientific term or definition that is necessary to understand basic radiation protection principles. Basic radiation protection standards do not include constraints or other limits below the level associated with "adequate protection" that take into account permissible considerations, such as economic cost, and other factors.
2. Examples of program elements in this category include, but are not necessarily limited to, the following:
 - (a) Public dose limits (e.g., 10 CFR 20.1301) plus any regulation that relates directly to these dose limits,
 - (b) Concentration and release limits,
 - (c) Occupational dose limits (e.g., 10 CFR 20.1201) plus any regulation that directly relates to these dose limits,
 - (d) Dose limits in 10 CFR 61.41,
 - (e) Radiation symbol,

- (f) Caution signs and labels,
- (g) Scientific terms (e.g., conventional and Systeme Internationale (SI) units, definitions of types of radioactive material), and
- (h) Definitions needed for common understanding (e.g., restricted area, year, stochastic).

B. Compatibility Category B

1. To be included in Compatibility Category B, an NRC program element must apply to activities that cross jurisdictional boundaries.
2. Examples of program elements in this category include, but are not necessarily limited to, the following:
 - (a) Transportation requirements (e.g., low level radioactive waste manifests, packaging requirements),
 - (b) Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material,
 - (c) Security plan requirements,
 - (d) Requirements for approval of products that are distributed nationwide (e.g., sealed sources and devices),
 - (e) Definitions of products (e.g., sources and devices) that licensees routinely transport in multiple jurisdictions,
 - (f) Radiographer certification, and
 - (g) Content and format of sealed source and device registration certificates.

C. Compatibility Category C

1. To be included in Compatibility Category C, an NRC program element must relate to regulatory areas that could create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis if not implemented by an Agreement State. Such Agreement State Program elements shall embody the essential objective of the corresponding NRC program element and, if not implemented, would result in an undesirable consequence. The essential objective(s) for a particular regulation may be found in the Statements of Consideration published with the final rule in the Federal Register. For other program elements required for compatibility, the essential objectives may be found in the letter transmitting the requirement to the Agreement States.

2. Examples of undesirable consequences include, but are not necessarily limited to, the following:
 - (a) An exposure to an individual in a different jurisdiction in excess of the basic radiation protection standards established for compatibility in Category A;
 - (b) Undue burden on interstate commerce (e.g., additional recordkeeping or training requirements);
 - (c) Preclusion of an effective review or evaluation by the NRC and Agreement State programs for agreement material with respect to protection of public health, safety, and security;
 - (d) Preclusion of a practice authorized by the AEA in the national interest;
 - (e) Incidents of such significance that they are required to be reported to the NRC;
 - (f) Lack of minimum level of safety for agreement material-containing products distributed nationwide; and
 - (g) Disruption of the regulation of agreement material on a nationwide basis.
3. Examples of program elements in this category include, but are not necessarily limited to, the following:
 - (a) Reports of lost or stolen agreement material or medical events,
 - (b) Radiation surveys for industrial radiographers and well loggers,
 - (c) Documents and records required at temporary job sites,
 - (d) Licensing and inspection manuals, and
 - (e) License termination requirements.

D. Compatibility Category D

Program elements that do not meet any of the criteria of Compatibility Categories A, B, or C, or have a particular health and safety role, are Compatibility Category D and are not required to be adopted for the purposes of compatibility.

Examples of program elements in this category include, but are not necessarily limited to, the following:

- (a) Exemptions to regulations,
- (b) Enforcement policies, and
- (c) Collection of information for Office of Management and Budget (OMB) clearances.

E. Category NRC

1. The program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of Title 10 of the *Code of Federal Regulations*.
2. Examples include, but are not necessarily limited to, the following:
 - (a) Issuance of licenses for production and utilization facilities,
 - (b) Regulation of activities in Federal offshore waters or exclusive Federal jurisdiction,
 - (c) Export and import of nuclear materials, and
 - (d) Matters related to common defense and security.
3. Issuance of licenses for distribution to exempt persons. Although an Agreement State may not adopt program elements reserved to the NRC, it may wish to inform its licensees of certain requirements via an appropriate mechanism that is consistent with the particular State's administrative procedure laws, but does not confer regulatory authority on the State.
4. Examples of program elements in this category include, but are not necessarily limited to, the following:
 - (a) Agreement State licensee submission to the NRC of nuclear material transfer reports pursuant to 10 CFR 150.16,
 - (b) Agreement State licensee compliance with safeguards agreement between the United States and the International Atomic Energy Agency pursuant to 10 CFR 150.17a and 10 CFR Part 75, and
 - (c) Agreement State licensee submission to the NRC of tritium reports pursuant to 10 CFR 150.19.

F. Health and Safety

1. The program elements in this category are not required for compatibility. These program elements are considered to have particular health and safety significance based on the "two or fewer failures criteria." If this program element and its essential objectives are not adopted by an Agreement State, an individual could receive an exposure in excess of the basic radiation protection standards in Compatibility Category A resulting from the higher probability of a failure occurring with, at most, one other failure event (i.e., two or fewer failures to protect public health and safety).

2. Examples of such program elements include, but are not necessarily limited to, the following:
 - (a) Requirement for irradiator interlocks,
 - (b) Safety checks for medical gamma stereotactic radiosurgery facilities, and
 - (c) Package opening procedures.

III. CATEGORIZATION PROCESS FOR NRC PROGRAM ELEMENTS

The protocol to be used to assign a compatibility category to program elements or to identify a program element as having particular health and safety significance is illustrated in the exhibit of this handbook. The basis of the flow chart is a series of questions that are listed below. 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.

- A.** 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).
- B.** 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).
- C.** 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).
- D.** 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.

- E. 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, i.e., category H&S applies. If the response to the question is “no,” then the program element must be identified as compatibility category “D.”

IV. APPLICABILITY TO NRC PROGRAM ELEMENTS

A. Current NRC Program Elements

The compatibility category or identification of particular health and safety significance for current NRC program elements that are applicable to the regulation of agreement materials are found in the Office of Nuclear Materials Safety and Safeguards (NMSS) State Agreement (SA) Procedure, SA-200, “Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements.”

B. Future NRC Program Elements

1. The staff should determine the compatibility category or identification of particular health and safety significance for a proposed rule at the time the rulemaking plan is formulated and coordinate this determination with the Agreement States according to MD 6.3, “The Rulemaking Process,” and current NMSS Policy and Procedures. The NRC staff shall use this handbook to determine the compatibility category or to identify particular health and safety significance for each draft rulemaking plan.
2. The Standing Committee on Compatibility (Committee) was established commensurate with MD 5.3, “Agreement State Participation in Working Groups,” to enhance the existing compatibility determination process through the independent review of program elements required for compatibility. The Committee will review program elements, including regulation changes in their proposed format, which are a matter of compatibility and provide feedback to the project manager preparing the program element. Commission Papers requesting publication of a proposed rule for comment should address the Committee’s findings and any unresolved designations. The final rule should be provided to the Committee if there are any changes to compatibility designations, any new sections to the rule, and when there were unresolved compatibility designations with the proposed rule. Revisions to NRC program elements that are applicable to the regulation of agreement materials and a matter of compatibility with the Agreement States should be reviewed by the Committee.

V. APPLICABILITY TO AGREEMENT STATE PROGRAM ELEMENTS

A. Agreement State Program Elements

1. General

Any changes to Agreement State program elements should conform to the policy and implementing procedures set out in this handbook.

2. Future Regulations

Proposed and final Agreement State regulations for agreement materials that are submitted to the NRC will be reviewed in accordance with guidance provided in SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," and SA-201, "Review of State Regulatory Requirements." Results of the evaluation will be transmitted to the State in accordance with NMSS internal procedures.

3. New or Changed Program Elements

The NRC staff will review the adoption and implementation of any new or revised (non-regulation) program element by an Agreement State in accordance with the review procedures set out in MD 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," at the time of the next regularly scheduled program review.

B. Evaluation of Applications for Agreement State Status

The NRC staff will apply the compatibility and health and safety categorization criteria and process in this handbook when reviewing the program elements contained in applications for Agreement State status.

VI. ADDITIONAL IMPLEMENTING ISSUES

A. Use of Management Directive 5.9

For IMPEP reviews, the review teams will use this handbook to assess the status of the State's program elements with regard to those that must be adopted for compatibility or for health and safety reasons. Specific Agreement State regulations will be assessed as they are submitted by the State and the results of the NRC's review are available to the IMPEP review team at the time of the State's program review. However, the overall determination of adequacy and compatibility of individual Agreement State programs will be made in accordance with MD 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)."

B. Essential Objectives

1. For those program elements in Compatibility Category C, adoption of the essential objective(s) by an Agreement State means that the State is compatible with regard to that program element. A State has the flexibility to adopt essential objectives that are more stringent.
2. For those program elements identified as having particular health and safety significance, adoption of the essential objective(s) by an Agreement State means that the State is providing a level of protection equivalent to the NRC with respect to that program element. A State has the latitude to adopt essential objectives that are more stringent.

C. Essentially Identical

Program elements in Compatibility Categories A and B adopted by Agreement States should be essentially identical to those of the NRC. If a requirement adopted by an Agreement State differs in any significant respect from that of the NRC, the State should explain how its requirement is essentially identical to the NRC requirement. An example of a difference in the State requirement that would not be considered significant would be use of the term “deterministic” in place of the term “nonstochastic.” In this case, the former term is one commonly accepted in the international radiation protection community. Similarly, the use of SI units rather than conventional units would be deemed essentially identical. Further, the adoption by States of more recent technical information (e.g., with regard to reference man) would be viewed as being essentially identical. Finally, changes to reflect an increased scope of State authority (e.g., use of the term “radioactive material” in place of the term “byproduct material”) or wording needed to conform to State administrative procedures (e.g., use of State agency name in place of “Commission”) would not be considered significantly different.

D. Legally Binding Requirements

1. Where appropriate, Agreement States must adopt program elements in Compatibility Categories A, B, and C, or those identified as having particular health and safety significance, and applicable to all licensees, in the form of a rule or other generic legally binding requirement, in a manner consistent with the State's administrative laws. The use of generic requirements will help to avoid inconsistency and confusion that may result from the imposition of individual requirements on a case-by-case basis.

2. Requirements applicable to more than a few licensees should also be adopted in the form of a generic requirement. However, since the appropriate approach in this circumstance will depend on the types and numbers of licensees involved, the State's approach will be reviewed on a case-by-case basis.
3. The mechanism used by the State must be legally binding on the licensee(s) and enforceable as law. Examples of legally binding requirements are license conditions (including licensee commitments referenced in "tie-down" conditions), and orders. The State has the responsibility of demonstrating that its requirements adopted other than by regulation are legally binding.

E. Timeframes for Adoption

1. The NRC regulations or equivalent legally binding requirements should be adopted and implemented in a timeframe such that the effective date of the State requirement for its licensees is not later than 3 years after the effective date of the NRC's final rule. Certain circumstances (e.g., adoption of a basic radiation protection standard or other rule that will have significant impact on the regulation of agreement material on a nationwide basis) may warrant that the effective dates for both NRC and Agreement State licensees be the same. In some cases, and with sufficient justification, health and safety considerations may warrant adoption by the States in less than the recommended 3-year timeframe.
2. Program elements, other than regulations or equivalent legally binding requirements, that have been designated as necessary for maintenance of an adequate and compatible program, should be adopted and implemented by the Agreement States within 6 months of such designation by the NRC. In some cases, with sufficient justification for health and safety considerations or by Commission direction, the period for adoption by the States may need to be less than the recommended 6-month timeframe. If, due to other factors, an Agreement State cannot adopt and implement such a program element within the 6-month timeframe, then the State and the NRC will agree upon a mutually acceptable timetable for adoption and implementation.
3. The Standing Committee on Compatibility will review the time frames for adoption for proposed program elements and provide feedback to the NRC staff. The Committee's view with respect to time frames for adoption should be addressed as detailed in Section IV.B of this handbook.

F. Resolution of Compatibility Designation and Interpretive Issues

The Standing Committee on Compatibility should be consulted regarding any compatibility designation or interpretive issues involving regulations or other program elements. Resolution of compatibility and interpretive matters brought to the attention of the Committee should be documented in accordance with NRC policies and procedures.

VII. GLOSSARY

Conflict

The essential objectives of regulations or other program elements are different, and an undesirable consequence is likely to result in another jurisdiction or in the regulation of agreement material on a nationwide basis.

Cross Jurisdictional

With regard to Compatibility Category B, a practice or licensed activity that necessitates identical requirements to ensure an orderly regulatory pattern for the use and regulation of agreement material between all Agreement States and NRC jurisdictions. This does not include activities conducted between the United States and other nations.

Duplication

Identical regulations or other program elements in different jurisdictions that are already in place that apply to the same material. Note: this definition applies primarily to review of Agreement State regulations.

Effective Date

The date the regulation or legally binding requirement can be enforced by the regulatory agency.

Essential objective (of a regulation or program element)

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 exposures to a maximum value) or it may be a more general goal (e.g., access control to a restricted area).

Essentially identical

The interpretation of the text must be the same regardless of the version (NRC or Agreement State).

Failure criteria (two or fewer)

If the essential objective of the program element was not adopted or implemented, then there is a higher probability an event could occur, alone, or in conjunction with, at most, one other event, that could result in exposure of an individual in excess of radiation protection standards (i.e., failure to protect public health and safety). This criteria is used to determine if the program element should be categorized as health and safety.

Gap

The essential objectives of NRC regulations or program elements are absent from the Agreement State program and an undesirable consequence is likely to result in another jurisdiction or in the regulation of agreement materials on a nationwide basis.

Legally Binding Requirement

Any regulations, orders, license conditions, or other regulatory instruments that are enforceable by the regulator.

Orderly Regulatory Pattern

The methodical and coherent national regulatory system for agreement material that protects public health and safety through compatible regulatory programs.

Practice

A use, procedure, or activity associated with the application, possession, use, storage, or disposal of agreement material. The term encompasses both general activities involving use of radioactive materials such as industrial and medical uses, and specific activities within a practice such as industrial radiography and brachytherapy.

Program element

Any component or function of a radiation control regulatory program, including regulations, procedures, and/or other legally binding requirements, imposed on regulated persons that contributes to implementation of that program.

EXHIBIT

EXHIBIT CHARACTERIZATION PROCESS FOR PROPOSED NRC PROGRAM ELEMENTS

