



Office of Nuclear Material Safety and Safeguards Procedure Approval

Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements, Interim Procedure State Agreement (SA) SA-200

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NOTE

***Any changes to the procedure will be the responsibility of the NMSS Procedure Contact.
Copies of the NMSS procedures are available through the NRC website.***

I. INTRODUCTION

This procedure establishes the compatibility and health and safety components assigned to the U.S. Nuclear Regulatory Commission (NRC) regulations and program elements as determined in accordance with Management Directive (MD) and Handbook 5.9, *Adequacy and Compatibility of Program Elements for Agreement State Programs*.

II. OBJECTIVE

To provide guidance to the NRC staff, Agreement States, and States pursuing Agreement State status on the compatibility and health and safety components assigned to NRC regulations and other program elements.

III. BACKGROUND

- A. On October 18, 2017, the NRC published a merged revision to the 1997 Policy Statements (Policy Statement on the Adequacy and Compatibility of Agreement State Program and the Statement of Principles and Policy for the Agreement State Program). The resulting "Agreement State Program Policy Statement" set forth the approach that the Commission will use when determining which of its regulations and program elements should be adopted by an Agreement State to maintain an adequate and compatible program. The Agreement State Program Policy Statement also specifies that an Agreement State should have legally binding requirements to maintain adequate protection of public health and safety. The Policy Statement defines "program element" as any component or function of a radiation control regulatory program, including regulations or other legally binding requirements imposed on regulated persons, which contributes to implementation of that program. It identifies those NRC program elements required for adequacy and having a particular health and safety component as those that are designated as Categories A, B, C, D, NRC, and H&S: and those required for compatibility include those regulations and other legally binding requirements designated as Compatibility Categories A, B, C, and D (see Section V.B.1.d of this procedure for definitions of these compatibility categories).
- B. MD 5.9 describes the criteria and process the NRC staff should follow to determine which NRC regulations and other program elements should be adopted by an Agreement State for purposes of adequacy and compatibility. In accordance with MD 5.9, each regulation and program element is analyzed and classified with a specific compatibility category designation or health and safety component.
- C. Office of Nuclear Material Safety and Safeguards (NMSS) State Agreements (SA) Procedure SA-200 was developed for use by Agreement State and NRC staff. It identifies the assigned compatibility category or health and safety component for each rule and program element, as determined in accordance with MD 5.9. The component classifications are set out in individual tables as described further below.

IV. ROLES AND RESPONSIBILITIES

- A. The Director, Division of Material Safety, Security, State, and Tribal Programs (MSST), is responsible for carrying out the responsibilities outlined in MD 5.9.
- B. The Branch Chief, State Agreement and Liaison Programs Branch, Division of Materials Safety, Security, State, and Tribal Programs (MSST), is responsible for assigning a staff member to serve as the State Regulation Review Coordinator (SRRC), assisting in procedure updates, and determination of rule and program element compatibility designations in accordance with MD 5.9.
- C. The SRRC is responsible for the review, evaluation and resolution of adequacy and compatibility concerns that are identified during the review of Agreement State regulations and other program elements, in collaboration and coordination with Agreement State and NRC personnel.
- D. The Standing Committee on Compatibility is responsible for:
 - 1. The independent review of regulations and other program elements required for Agreement State compatibility with NRC requirements.
 - 2. Ensuring consistency during the rulemaking process by documenting the basis for decisions made regarding compatibility determinations while taking into consideration program element implementation issues, the NRC staff's review of State regulations, and other program elements under the Integrated Materials Performance Evaluation Program (IMPEP).
 - 3. Evaluating and documenting compatibility designations as described in MD 5.9.

V. GUIDANCE

The NRC staff should follow the guidance presented in MD Handbook 5.9, which describes the criteria and the process that will be used to determine the compatibility category designations and health and safety components of NRC regulations and program elements that an Agreement State should adopt for an adequate and compatible program.

A. Title 10 *Code of Federal Regulations* (CFR)

A current section-by-section summary of the compatibility and health and safety categories of regulations in Title 10 of the CFR can be found on the NMSS website's Regulation Toolbox.¹

¹ The Statements of Consideration for NRC regulations developed prior to September 3, 1997, do not contain the compatibility designations and associated rationale for compatibility designation. For NRC rules developed after September 3, 1997, the Statements of Consideration contain a section entitled,

The NRC staff should follow the guidance that an Agreement State need not adopt a specific regulation if the Agreement State has no licensees that would be subject to that regulation. In such cases, the Agreement State would need to commit to adopting the regulation, or to impose the regulation through license conditions or other legally binding means, if an application were to be received by the Agreement State for a license authorizing materials subject to that regulation.

MD Handbook 5.9, Appendix A contains program elements that are applicable to the regulation of agreement materials. The analysis was based on the categorization criteria and processes set out in MD 5.9. Per MD 5.9, Part VI.E. program elements should be adopted within 6 months unless otherwise specified. The Parts of 10 CFR on the NMSS website for which tables are provided below have been analyzed section-by-section; those Parts that do not have a corresponding table have been determined to address areas in which Agreement States either do not have regulatory authority or that are applicable specifically to NRC's regulatory program and need not be addressed by an Agreement State. For completeness, those Parts that address areas of exclusive NRC authority are listed in Table 1. Those Parts that generally are applicable specifically to NRC's regulatory program, but are not areas of exclusive NRC authority, are listed in Table 2. Any future changes to these determinations will be reflected in revisions to Tables 1 and 2 and to the individual section-by-section analysis tables on the website or in Appendix A, as appropriate.

Table 1
Specific Parts of Title 10 of the Code of Federal Regulations That Address Areas of Exclusive NRC Authority
Parts 10, 11, 25, 26, 50, 51, 52, 53, 54, 55, 60, 62, 72, 73 ² , 74, 75 ³ , 76, 81, 95, 100, 110, 140, and 160.

"Agreement State Compatibility," which includes information on NRC rule compatibility designation and rationale.

² Section 73.67 (Physical Protection of Special Nuclear Material of Moderate and Low Strategic Significance) of 10 CFR Part 73 is applicable to certain Agreement State licensees pursuant to 10 CFR 150.14. Agreement States, therefore, may wish to inform their licensees of the provisions of this part through a mechanism that is appropriate under the State's administrative procedure laws, but does not confer regulatory authority on the State in this area of exclusive NRC jurisdiction.

³ Part 75 (Safeguards on Nuclear Material - Implementation of US/IAEA Agreement) may be applicable to certain Agreement State licensees as delineated in Section 75.2 - Scope. Agreement States, therefore, may wish to inform their licensees of the provisions of this part through a mechanism that is appropriate under the State's administrative procedure laws, but does not confer regulatory authority on the State in this area of exclusive NRC jurisdiction.

Table 2
Specific Parts of Title 10 of the Code of Federal Regulations That Address Areas That Generally Are Applicable Only to NRC's Regulatory Program
Parts 1, 2, 4, 7, 8, 9, 12, 13, 14, 15, 16, 21 ⁴ , 170, and 171

B. Regulations and Program Element Review Summary Sheets (RSS)

1. The RSS, also known as the Regulation Amendment Tracking System (RATS) sheet, is based on the "Summary of Change" document which is created when the NRC revises its regulations. The Summary of Change document contains all regulation changes that were included in the rulemaking. This document is included as an enclosure to the State and Tribal Communication (STC) letter announcing the rulemaking.

The RSS or RATS sheet is also used to document the NRC staffs' review of the Agreement State's equivalent rule provisions; these sheets can be found on the Regulation Toolbox of the NMSS website at:

https://scp.nrc.gov/rss_regamendents.html). The sheet is divided into eight columns: NRC Regulation Section; Section Title; State Section; Compatibility Category; Summary of Change to the CFR; Difference Yes/No; Significant Yes/No; and If Difference Why or Why Not was a Comment Generated.

- a. The "NRC Regulation Section" column contains the numbering of the regulation section as it appears in the 10 CFR.
- b. The "Section Title" column contains the section title as it appears in 10 CFR.
- c. The "State Section" will be used by NRC staff during a review of Agreement State regulations to list that State's corresponding regulation section.
- d. The "Compatibility Category" column contains the compatibility or health and safety category for the regulation section that has been determined in accordance with the categorization criteria in MD 5.9.

Compatibility Categories & Health and Safety Identification:

⁴ The provisions in Part 21 derive from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this Part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the certain provisions of Part 21, States may not have the statutory authority to do so.

- A = Basic radiation protection standard or related definitions, signs, labels or scientific terms necessary for a common understanding of radiation protection principles. The Agreement State program element should be essentially identical to that of NRC;
- B = This category pertains to a limited number of program elements that cross jurisdictional boundaries, and should be addressed to ensure uniformity of regulation on a nationwide basis. The Agreement State program element should be essentially identical to that of NRC;
- C = Program element, the essential objectives of which should be adopted by the Agreement State to avoid conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. The manner in which the essential objectives are addressed need not be the same as NRC, provided the essential objectives are met;
- D = Not required for purposes of compatibility;
- NRC = These are NRC program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the Atomic Energy Act or provisions of 10 CFR regulations. The State should not adopt these program elements;
- H&S⁵ = Program elements identified by H&S in the Comment column are not required for purposes of compatibility; however, they do have particular health and safety significance. The Agreement State should adopt the essential objectives of such program elements to maintain an adequate program.
- [] = A bracket around a category means that the Section may have been adopted elsewhere and it is not necessary to adopt it again.

- e. The “Summary of Change to the CFR” Section contains the revised rule text for those sections of the 10 CFR included in the rulemaking.

⁵ 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 the essential objectives of the program element were not adopted by the 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 failure occurring with, at most, one other failure event. (Management Directive 5.9., Handbook, Part II, Section F)

- f. The “Difference Yes/No” column will be used by NRC staff during a review of Agreement State regulations to indicate whether the corresponding Agreement State regulation differs from NRC’s regulation.
 - g. The “Significant Yes/No” column will be used by NRC staff during a review of Agreement State regulations to indicate whether an identified difference found in the Agreement regulation, is in accordance with the Compatibility Category or Health and Safety designation assigned to the regulation.
 - h. The “If Difference Why or Why Not was a Comment Generated” column will state what the difference is, and whether or not that difference is in accordance with the regulation’s Compatibility Category designation. If the difference makes the regulation non-compatible, NRC staff will also list what changes are needed to make the Agreement State regulation compatible and address health and safety issues.
2. Staff should be aware of the following:
- a. The following sections are found in multiple Parts of 10 CFR: *Purpose, Scope, Interpretations, Communications, OMB Approval, Violations, Criminal Penalties and Inspections*. These sections are all essentially identical from Part to Part. These requirements are not required for either compatibility or health and safety reasons. The Agreement State may elect to adopt similar sections based on its requirements;
 - b. When using the Review Summary Sheets for Regulation Adoption for New Agreement State Programs (i.e., 10 CFR sheets: https://scp.nrc.gov/regsumsheets_newregs.html), unless otherwise indicated in the tables, the compatibility category or identification of health and safety significance applies to the entire section of the Part. See, for example, the table for 10 CFR Part 20, Section 20.2003, where individual paragraphs are assigned different components.
3. A Program Element Table indicating the Compatibility Categories for those program elements other than regulations can be found on the NMSS website/Regulation Toolbox at <https://scp.nrc.gov/regtoolbox.html>. The table is divided into four columns as indicated below: Program Element; Required For; Compatibility Category; and Comments. Staff should use MD 5.6, *Integrated Materials Performance Evaluation Program* along with other IMPEP guidance documents in the review of these program elements.
- a. The “Program Element” column describes the program element.
 - b. The “Required For” column provides whether the program element is required for purposes of adequacy, including those that have a particular health and safety significance, compatibility, or both.

- c. The "Compatibility Category" column contains the compatibility category designation assigned to each program element.
- d. The "Comment" column contains the rationale and supporting information as to why a program element was designated as being required for compatibility, adequacy including those with a particular health and safety significance, or both.

C. Approvals

- 1. Approvals of compatibility category designations of final regulations and program elements will be done in accordance with MD 5.9 and MD 6.3, *The Rulemaking Process*.
- 2. Approvals of revisions to compatibility category designations of rules will be submitted to the Commission for approval. The rules developed after September 1997, are in accordance with MD 5.9, and MD 6.3, which included Commission review and approval and public notice in the *Federal Register*; thus, it is essential to obtain Commission approval of any revisions.

D. Compatibility Resolution

MD 5.9, Section III., Organizational Responsibilities and Delegations of Authority, provides that NMSS will implement the program to evaluate adequacy and compatibility of Agreement State programs and in coordination with other NRC offices will review, evaluate, and determine those NRC regulations that an Agreement State should adopt as legally binding requirements for the purpose of compatibility or health and safety. In accordance with this provision, the "Compatibility Resolution (CR)" process was initiated. This process is used to clarify or resolve minor differences that are considered acceptable between the language used in the NRC's regulation as compared to the regulation of an Agreement State. Significant compatibility issues will require Commission approval and will be handled outside of the CR process. (Also see Section V.C.2. of this procedure).

The NRC staff will document these clarifications in a "CR document." The CR document will identify the issue, provide a discussion of the issue, and provide observations and/or conclusions of the staff's resolution of the issue. The CR document will be reviewed by the Standing Committee on Compatibility for consistency with MD 5.9 and will require concurrence by all relevant offices. The CR document will be distributed to the Agreement States and States pursuing Agreement State status, the Organization of Agreement States (OAS), the Conference of Radiation Control Program Directors, Inc. (CRCPD), and all relevant NRC staff. A list of all CR documents will be maintained on the NMSS website at: <https://scp.nrc.gov/regtoolbox.html>.

VI. APPENDIX

None

VII. REFERENCES

Management Directives (MD) available at <https://scp.nrc.gov>.

NMSS SA Procedures available at <https://scp.nrc.gov>.

Title 10, Code of Federal Regulations available at: <https://www.nrc.gov/reading-rm/doc-collections/cfr/>

VIII. ADAMS Reference Documents

For knowledge management purposes, listed below are all previous revisions of this procedure, as well as associated correspondence with stakeholders, that have been entered into the NRC's Agencywide Document Access Management System (ADAMS).

No.	Date	Document Title/Description	Accession Number
1	02/06/01	Final STP Procedure SA-200	ML010580517
2	10/25/02	STP-02-075, Opportunity to Comment on Draft Revisions to STP Procedure SA-200	ML022980631
3	10/08/04	Final STP Procedure SA-200	ML042820600
4	10/08/04	Resolution of Comments	ML042820609
5	03/22/05	Final STP Procedure SA-200	ML050770486 (pkg. ML51030417)
6	06/05/09	Final FSME Procedure SA-200	ML091190055