



Office of Nuclear Material Safety and Safeguards Procedure Approval

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

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NOTE

***Any changes to the procedure will be the responsibility of the NMSS Procedure Contact.
Copies of NMSS procedures are available through the NRC Web site at <https://scp.nrc.gov>.***

I. INTRODUCTION

This procedure establishes the compatibility, and health and safety (H&S) 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 Agreement States, States pursuing Agreement State status, and the NRC staff on the adequacy, compatibility and H&S components assigned to NRC regulations and other program elements.

III. BACKGROUND

- A. On October 18, 2017, the NRC published a merged revision to the two 1997 Policy Statements (i.e., 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, including security of radioactive materials. 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 H&S component as those that are designated as compatibility 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, and C (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 are analyzed and classified with a specific compatibility category designation or H&S component.
- C. This procedure was developed for use by Agreement State and NRC staff. It identifies the assigned compatibility category or H&S component for each rule and program element, as determined in accordance with MD 5.9. The terms "rules" and "regulations" are used interchangeably in this procedure. The component classifications are set out in individual tables as described in Section V.A. of this procedure.

IV. ROLES AND RESPONSIBILITIES

- A. The Director, Division of Material Safety, Security, State, and Tribal Programs (MSST), is responsible for the implementation of MD 5.9.
- B. The Branch Chief for the State Agreement and Liaison Programs Branch, MSST is responsible for assigning a staff member to serve as the State Regulation Review Coordinator (SRRC), assisting in procedure updates, and determining 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 legislation, regulations, and other program elements, in collaboration and coordination with the Agreement State and NRC staff.
- D. The Standing Committee on Compatibility is responsible for:
 - 1. The independent review of regulations and other program elements (e.g., inspection procedures, licensing guidance, pre-licensing guidance checklist, etc.) required for Agreement State adequacy and 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 (a) program element implementation issues, (b) the NRC staff's review of State regulations, and (c) 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 the Handbook of MD 5.9, which describes the criteria and the process that will be used to determine the adequacy and compatibility category designations and H&S 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 H&S categories of regulations in Title 10 of the CFR can be found on the Regulation Toolbox of the

state communications portal Web site at:
https://scp.nrc.gov/regsumsheets_newregs.html.¹

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.

The Handbook of MD 5.9 contains information regarding program elements that are applicable to the regulation of agreement materials. Management Directive 5.9 provides the process and the categorization criteria. In accordance with MD 5.9, program elements should be adopted within 6 months unless otherwise specified. The Parts of 10 CFR on the state communications portal Web site 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 program element and 10 CFR tables on the Web site, as appropriate.

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

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, 73², 74, 75³, 76, 81, 95, 100, 110⁴, 140, and 160.

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, 21⁵, 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

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. The 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 grant 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. The 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 grant regulatory authority on the State in this area of exclusive NRC jurisdiction.

⁴Section 110.54(a) (Reporting Requirements) may be applicable to certain Agreement State licensees as delineated in Section 110.1, Purpose and Scope. The Agreement States, therefore, may wish to inform their licensees of the provisions of this section through a mechanism that is appropriate under the State's administrative procedure laws, but does not grant regulatory authority on the State in this area of exclusive NRC jurisdiction.

⁵ 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.

on the Regulation Toolbox of the state communications portal Web site 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 H&S category for the regulation section that has been determined in accordance with the categorization criteria in MD 5.9.

Compatibility Categories and H&S Identification:

- A = 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 = These limited number of program elements 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 = These program elements 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. 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 = Not required for purposes of compatibility;

NRC = These are NRC program elements that address areas of regulation that cannot be discontinued when a State enters into an Agreement with the NRC pursuant to the Atomic Energy Act or provisions of 10 CFR regulations. The State should not adopt these program elements;

H&S⁶ = Program elements identified by H&S in the Comment column are not required for purposes of compatibility; however, they do have particular H&S significance. Although not required for compatibility, the State must adopt program elements in this category, that embody the basic H&S aspects of the NRC's program elements because of particular H&S considerations; and

[] = 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.
- 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 the 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 State regulation, is in accordance with the compatibility category or H&S 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 H&S issues.

⁶ 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).

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 adequacy, compatibility or H&S reasons. The Agreement State may elect to adopt similar sections based on their 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 H&S significance applies to the entire section of the Part. See, for example, the 10 CFR table for 10 CFR Part 20, Section 20.2003, where individual paragraphs are assigned different components.
3. A *Program Element Table and Associated Compatibility Categories as Noted in SA-200* can be found on the Regulation Toolbox of the state communications portal Web site at: <https://scp.nrc.gov/regtoolbox.html> for both regulation and non-regulation program elements. The table is in alignment with the program elements outlined in the Agreement State Program Policy Statement and includes: The Program Element, State Requirement, Adequacy/Compatibility Category, and References. Staff should use SA-107, *Reviewing the Non-Common Performance Indicator, Legislation, Regulations, and Other Program Elements*; SA-201, *Review of State Regulatory Requirements*; and MD 5.6, *Integrated Materials Performance Evaluation Program* along with other IMPEP guidance documents in the review of these program elements.

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

Section III in MD 5.9, Organizational Responsibilities and Delegations of Authority, provides that the Office of Nuclear Material Safety and Safeguards (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 adequacy, compatibility or H&S. In accordance with this provision, the “Compatibility Resolution (CR)” process was initiated. This CR 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 (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, the Conference of Radiation Control Program Directors, Inc., and all relevant NRC staff. A list of all CR documents will be maintained on the state communications portal Web site at: <https://scp.nrc.gov/regtoolbox.html>.

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/>

Program Element Table and Associated Compatibility Categories as noted in SA-200; <https://scp.nrc.gov/regtoolbox.html>

Program Elements: Regulation and Non-Regulation: <https://scp.nrc.gov/regtoolbox.html>

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
7	11/19/19	Interim NMSS Procedure SA-200	ML19311C784
8	07/02/20	Comment Resolution	ML20184A179
9	08/27/20	Final NMSS Procedure SA-200	ML20183A325