



## Office of Nuclear Material Safety and Safeguards Procedure Approval

### *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*

**SA-200**

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Issue Date:

Review Date:

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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 program elements.

**III. BACKGROUND**

- A. On October 18, 2017, this Policy Statement was revised and merged with The Statement of Principles and Policy for the Agreement State Program. The resulting Agreement State Program Policy Statement sets 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 a compatible program. The Policy Statement also specifies that an Agreement State should have legally binding requirements to maintain adequate protection of public health and safety.
- B. Management Directive (MD) 5.9 describes the criteria and process the NRC staff should follow to determine which NRC regulations and program elements should be adopted by an Agreement State for purposes of compatibility as well as health and safety. 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. NMSS Procedure SA-200 was developed for use by NRC and Agreement State 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, Section 5.9-032.

- B. The Branch Chief, 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 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 in collaboration and coordination with NRC staff members and Agreement State personnel. The SRRC also is responsible for updating this procedure at a frequency established by MSST management.

## **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. In addition, the NRC staff should follow the guidance that a State need not adopt a specific regulation if the State has no licensees that would be subject to that regulation. In such cases, however, the 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 State for a license authorizing materials subject to that regulation.

MD 5.9, Section 5.9-03, Organizational Responsibilities and Delegations of Authority, provides that NMSS 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 wording used in the NRC regulations as compared to the Agreement State language. Staff will use the CR process to clarify or resolve minor concerns regarding the compatibility determinations of State Regulations, and will document the results in the "CR document". Significant compatibility issues will require Commission approval and will be handled outside of the CR process. (Also see Section D.3)

The CR document will identify the issue, provide a discussion of the issue, and provide observations and/or conclusion 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 (see charter: ML12296A075) and will require concurrence by all relevant offices. The CR 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/regresources.html>

A. Title 10 Code of Federal Regulations (CFR) Regulations Addressing Agreement Materials

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 at: <https://scp.nrc.gov/regtoolbox.html>

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 V program elements should be adopted within 6 months.

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<sup>1</sup> On September 3, 1997, the Commission implemented the Policy Statement. The Statements of Consideration for NRC regulations developed prior to September 3, 1997, do not contain the current compatibility designations and associated rationale for compatibility designation under the Policy Statement. 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.

The Parts of 10 CFR on the NMSS website for which tables are provided 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 the purpose of completeness, those Parts that totally 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<sup>1</sup>, 74, 75<sup>2</sup>, 76, 81, 95, 100, 110, 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, 21,<sup>3</sup> 170, and 171

B. Regulation and Other Program Element Tables

1. The Regulation Review Summary Sheet Table (as described above in section V.A, the second paragraph) is divided into seven columns. These columns are: NRC Regulation Section; Section Title; State Section; Compatibility Category; 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.

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1 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.

2 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.

3 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 provisions of Part 21, States may not have the statutory authority to do so.

- 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 compatibility or health and safety category for the regulation section that has been determined in accordance with the categorization criteria in MD 5.9.
  - i. Compatibility Categories & Health and Safety Identification

The key to the categories represented by either the symbols “A,” “B,” “C,” “D,” “NRC” or “H&S” are as follows:

A = Basic radiation protection standard or related definitions, signs, labels or terms necessary for a common understanding of radiation protection principles. The State program element should be essentially identical to that of NRC;

B = Program element with significant direct transboundary implications. The State program element should be essentially identical to that of NRC;

C = Program element, the essential objectives of which should be adopted by the State to avoid conflicts, duplications or gaps. 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&S<sup>4</sup> = 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 State should adopt the essential objectives of such program elements in order 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 “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 is or is not different from NRC’s regulation.
- f. 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.
- g. 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.
- h. In using the regulation tables, staff should be aware of the following points:
  - i. The following sections are found in multiple Parts of 10 CFR: *Purpose, Scope, Interpretations, Communications, OMB Approval, Violations, Criminal Penalties and Inspections*. They are all essentially identical from Part to Part. These requirements are not required for either compatibility or health and safety reasons. The State may elect to adopt similar sections based on its requirements;
  - ii. 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.

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<sup>4</sup>An NRC program element that is not required for compatibility should be adopted by Agreement States because of a particular health and safety role in the regulation of Agreement material. If the essential objectives of the program element were not adopted, it could result directly (i.e., two or fewer failures) in an exposure to an individual in excess of the basic radiation protection standards. The concept embodied by “two or fewer failures” is that if the essential objectives of the program element were not adopted and implemented, then an event could occur that would not have taken place were the essential objectives adopted. This alone or in conjunction with, at most, one other event could result in exposure of an individual in excess of limits set by basic radiation protection standards. (Management Directive 5.9., Handbook, Part II, Section E)

2. The Program Element Table is divided into three columns. These columns are: Program Element; Required For; and Comments. As directed by the Commission in Staff Requirements Memorandum, SECY-93-349-Draft Policy Statement for Agreement State Adequacy and Compatibility, dated April 21, 1994, the program elements identified in the table are consistent with the common and non-common performance indicators identified in Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Staff should use Management Directive 5.6 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 or compatibility.
  - c. The "Comment" column contains the rationale and supporting information as to why a program element was designated as being required for either compatibility or adequacy.

C. Reviews

1. The SRRC will review and revise these procedures, as needed, in accordance with MD 5.9.
2. The SRRC will recommend to the Director of MSST the cycle for review and update of this procedure taking into consideration periodic updates to incorporate new final rules or program elements adopted by the Commission. The revision of this procedure will also take into consideration any changes to the compatibility category designation of current NRC regulations and program elements.
3. Significant revisions to this procedure will be distributed for review and comment to NMSS staff, OGC, the Agreement States, States pursuing Agreement State status, OAS and CRCPD. A review and comment period of at least 30 days will be provided.
4. The SRRC will review and address any comments provided on the revisions. Any significant comments will be coordinated with management and staff as appropriate.

D. Approvals

1. Approvals of compatibility category designations of final regulations 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, were developed in accordance with MD 5.9, and MD 6.3, *The Rulemaking Process*, which included Commission review and approval and public notice in the *Federal Register*; thus, it is essential to obtain Commission approval of these revisions.

## **VI. APPENDIX**

Appendix A - Program elements

## **VII. REFERENCES**

1. NMSS Procedure SA-201, *Review of State Regulatory Requirements*
2. Title 10, Code of Federal Regulations
3. Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*
4. *Agreement State Program Policy Statement*, dated October 18, 2017 [82 FR 48535](#).
5. Management Directive 6.3, *Rulemaking Process*
6. Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*

## **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).

<b>No.</b>	<b>Date</b>	<b>Document Title/Description</b>	<b>Accession Number</b>
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

## Appendix A PROGRAM ELEMENTS

PROGRAM ELEMENT	REQUIRED FOR	Compatibility Category	COMMENTS
Legislation and Legal Authority	Adequacy or Compatibility		See discussion in Agreement State Program Policy Statement <a href="#">82 FR</a>
<ul style="list-style-type: none"> <li>• Statutes</li> <li>• Regulations</li> <li>• Legally Binding Requirements</li> </ul>	Adequacy, Compatibility or Health and Safety		See Regulation Tables for 10 CFR Parts on the NMSS website at: <a href="#">ht</a>
<ul style="list-style-type: none"> <li>• Guidance documents and interpretations</li> </ul>		D	
Licensing	Adequacy & Compatibility		See Agreement State Program Policy Statement <a href="#">82 FR 48535</a>
<ul style="list-style-type: none"> <li>• Reciprocal recognition of licenses</li> </ul>		C	This program element has significant effects on the regulation of agree type of license and time period recognized under reciprocity. Although as would be required by a classification of "B."
<ul style="list-style-type: none"> <li>• Written procedures</li> </ul>		C	
<ul style="list-style-type: none"> <li>• Maintenance of records, especially for decommissioning</li> </ul>		C	
<ul style="list-style-type: none"> <li>• Licensing files</li> </ul>		C	
<ul style="list-style-type: none"> <li>• Security (PLG)</li> </ul>		C	
<ul style="list-style-type: none"> <li>• Financial Assurance</li> </ul>	Health and Safety	H&S	

<b>PROGRAM ELEMENT</b>	<b>REQUIRED FOR</b>	<b>Compatibility Category</b>	<b>COMMENTS</b>
Inspection and Enforcement	Adequacy & Compatibility		See Agreement State Program Policy Statement
<ul style="list-style-type: none"> <li>• Written procedures</li> </ul>		C	
<ul style="list-style-type: none"> <li>• Radiological laboratory support</li> </ul>		D	
<ul style="list-style-type: none"> <li>• Instrumentation</li> </ul>		D	
Staffing and Training	Adequacy & Compatibility		See Agreement State Program Policy Statement <a href="#">82 FR 48535</a>
<ul style="list-style-type: none"> <li>• Qualification procedures</li> </ul>		C	There should be minimal education and experience requirements for administrative requirements.
Response to Events and Allegations	Adequacy & Compatibility		See Agreement State Program Policy Statement <a href="#">82 FR 48535</a>
<ul style="list-style-type: none"> <li>• Written procedures</li> </ul>		C	
<ul style="list-style-type: none"> <li>• Major incident investigation procedures</li> </ul>		C	Need to prevent gaps in reporting effectiveness of national program
<ul style="list-style-type: none"> <li>• Procedures for investigation of “wrongdoing”</li> </ul>		C	
Sealed source and device program	Adequacy & Compatibility		Non-common performance indicator
<ul style="list-style-type: none"> <li>• Standard review plan</li> </ul>		C	

PROGRAM ELEMENT	REQUIRED FOR	Compatibility Category	COMMENTS
<ul style="list-style-type: none"> <li>• Format and content of registration certificates</li> </ul>		B	Need to have national consistency so that all RCPs can rely on the sp
<ul style="list-style-type: none"> <li>• Inclusion of Information in the National SS&amp;D registry</li> </ul>		B	Need to have national consistency so that all RCPs can rely on the sp
<ul style="list-style-type: none"> <li>• Written procedures</li> </ul>		C	
<ul style="list-style-type: none"> <li>• Financial Assurance</li> </ul>		H&S	
Exchange of information		C	Necessary for effective regulation of agreement materials on a national agreement material with respect to protection of public health and safe
<ul style="list-style-type: none"> <li>• Event reporting</li> </ul>		C	See previous comment. In addition, Agreement State event reporting dated June 30, 1997. Failure to comply with this provision can serve
<ul style="list-style-type: none"> <li>• Notifications <ul style="list-style-type: none"> <li>o Security</li> <li>o Department of Transportation (DOT)</li> </ul> </li> </ul>		C	
Legal assistance		D	
Technical advisory committees		D	
Technical assistance and support		D	
Program funding, including program support services		D	
Organization, management & location of radiation control program		D	

