

Office of Nuclear Material Safety and Safeguards Procedure Approval

Review of Regulations and Other Program Elements by the Standing Committee on Compatibility, State Agreements (SA) Procedure, SA-202

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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

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I. INTRODUCTION

This procedure establishes the process for the Standing Committee on Compatibility (Committee) review of proposed regulations and other program elements.

II. OBJECTIVE

To provide guidance to the Agreement State and NRC staff on the process that the Committee will follow for considering changes that may impact Agreement State implementation of proposed regulations and other program elements.

III. BACKGROUND

On October 18, 2017, the Commission issued the Agreement State Program Policy Statement (Policy Statement), which provides the agency's approach for determining which program elements (including regulations) should be adopted by an Agreement State to maintain an adequate and compatible program. The Policy Statement defines "program element" as any component or function of a radiation control regulatory program, including regulations or other legally binding requirements (orders, license conditions) imposed on regulated persons, which contributes to implementation of that program. It identifies the NRC program elements that the Agreement States should implement in order to have an adequate program and those program elements that have a particular health and safety (H&S) component, as those that are designated as Compatibility Categories A, B, C, D, NRC, and H&S. The Policy Statement also identifies the program elements that the Agreement States should implement in order to be compatible with NRC's program as those that are designated as Compatibility Categories A, B and C.

On July 12, 2008, the final charter was established for the Standing Committee on Compatibility (Committee) and revised on October 3, 2012 (Agencywide Documents Access Management System (ADAMS) Accession No. ML12269A247). The Standing Committee on Compatibility, which is directed by Management Directive (MD) 5.3, Agreement State Participation in Working Groups, serves to help ensure consistency during promulgation of regulations and other program elements. The Committee accomplishes this by reviewing and documenting its decisions on the basis for compatibility determinations, and by identifying implementation issues that may be encountered during the NRC staff's review of State regulations under the Integrated Materials Performance Evaluation Program (IMPEP). The Committee offers an independent review and assessment of the staff's determinations of the compatibility category designation for each new or revised program element, including regulations and other legally binding requirements to ensure consistency with MD 5.9, Adequacy and Compatibility of Program Elements for Agreement State Programs. The Committee's activities are also discussed in MD 5.9, Office of Nuclear Material Safety and Safeguards (NMSS) Policy and Procedure (P&P) 6-10, NMSS Procedures for Preparation and Review of Rulemaking Packages, and NMSS State Agreement (SA) Procedure SA-801A, Agreement State Participation in Rulemaking Working Groups.

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IV. ROLES AND RESPONSIBILITIES

A. Committee responsibilities:

- 1. Independently reviews regulations and other program elements required for Agreement State adequacy and compatibility with NRC requirements.
- 2. Ensures 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 IMPEP.
- 3. Evaluates and documents compatibility designations as described in MD 5.9.
- 4. Provides the Committee's determinations/recommendations to the responsible Project Manager or representative.

B. Committee membership:

- 1. The Committee consists of voting and non-voting members with the following membership:
 - a. Division of Materials Safety, Security, State and Tribal Programs (MSST) State Agreement and Liaison Programs Branch (SALB) Chief or Senior technical staff, Co-chair.
 - b. Organization of Agreement States' (OAS) Director of Rulemaking, Cochair.
 - c. Division of Rulemaking, Rulemaking and Project Management Branch, Chief.
 - d. Agreement State program representative appointed by OAS.
 - e. Office of General Counsel representative.
 - f. State Regulation Review Coordinator (MSST/SALB), Recording Secretary and non-voting member.
- 2. The Co-chairs should have extensive experience with compatibility determinations and the Agreement State program by performing Agreement State regulation reviews, participating on IMPEP review teams, preparing State regulations, or working for a program that has been reviewed under the IMPEP. Members should have experience in making compatibility determinations based on the principles of MD 5.9.
- 3. In order to maintain objectivity, Committee members are not to be directly involved in the development of the particular regulation or program element being evaluated.

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- C. Project Managers, or a representative responsible for the development of regulations, guidance, or other program elements affecting radioactive materials licenses under Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30, 40 or 70, are responsible for submitting any new or revised program elements to the Committee for review.
- D. Any NRC or Agreement State member in the National Materials Program (NMP) may request the Committee conduct a review of a compatibility designation or other interpretive issue involving regulations or other program elements, e.g., essential objectives, applicability of program elements/regulations to certain Agreement States.

V. GUIDANCE

A. General Committee Practices

- 1. The Committee should review any new or revised regulations and other program elements that may impact any component or function affecting the compatibility of a radiation control regulatory program.
- The Committee 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.
- The Committee's NRC Co-chair or Recording Secretary should be informed
 of any new or revised regulation or other program element at the initial
 planning stages in order to schedule an agenda item for a Committee
 meeting.
- 4. All Committee meetings are pre-decisional in nature and are closed to the public. Depending on the nature of the request for a Committee review, a formal meeting may not be required for the Committee to make its determination. The Recording Secretary and the individual requesting a Committee review, in consultation with the Co-Chairs, will determine if a formal meeting is required.
- 5. The responsible Project Manager, or representative, should provide the documentation of the draft program element for the Committee's review prior to the meeting and present the item at the scheduled Committee meeting.
- 6. After the Committee deliberates, the NRC Co-chair will provide a summary of their comments in writing to the Project Manager/representative. The Recording Secretary will document the review in the meeting minutes.
- 7. In the event where Committee members cannot reach a unanimous recommendation on an issue, the meeting minutes should reflect the outcome and why there was a lack of consensus. The Commission Paper and State and Tribal Communications (STC) or Radiation Control Program Directors

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¹ See NMSS Administrative (AD) Procedure AD-200, Format for STC and RCPD Letters.

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(RCPD)¹ letter should also reflect the outcome and the reasons for the lack of consensus.

B. Review of Regulations

- 1. The Committee will review proposed regulations, draft final regulations in accordance with the schedule in NMSS Policy and Procedure 6-10.
- 2. The responsible Project Manager, or representative, should work with the Recording Secretary to schedule a Committee meeting.
- 3. The responsible Project Manager, or representative, should provide the documentation of the proposed or draft final regulation for the Committee's review as early as practical prior to the meeting. This documentation typically includes the draft Commission Paper and draft Federal Register notice that includes a section on Agreement State Compatibility, a table listing the compatibility category designations, rule language, and response to comments.
- 4. The Committee will typically conduct its review of the compatibility determinations prior to Office concurrence for each proposed and draft final rulemaking package, so as not to be disruptive to the rulemaking schedule. Committee recommendations for each rule will then be included in the Commission paper when a rule is sent forward for Commission consideration in accordance with NMSS P&P 6-10.

C. Review of Other Program Elements

- 1. The Committee will review any new or revised program element from regulatory programs within the NMP in accordance with the review procedures set out in MD 5.6, Integrated Materials Performance Evaluation Program (IMPEP), SA-200, Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements, and the Policy Statement.
- 2. Once a determination is made that a new or revised program element will be developed, the responsible Project Manager or their representative should inform the Committee's Recording Secretary or NRC Co-Chair.
- 3. Some examples of other program elements that should be reviewed by the Committee include:
 - a. Revision to Inspection Manual Chapters;
 - b. Request for implementation of a policy on maximum possession limits for radioactive material licenses;
 - c. Revisions to guidance documents, e.g., NUREG-1556 series, NUREG-1757;

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- d. Pre-Licensing Guidance;
- e. Medical Licensing Guidance issued in accordance with 10 CFR 35.1000;
- f. Materials Inspector and License Reviewer Qualification Procedures.
- 4. The responsible Project Manager, or representative, should provide the documentation implementing the program element for the Committee's review as early as practical prior to the meeting. This documentation typically includes the proposed or draft final guidance document, and the draft STC letter transmitting the guidance to the Agreement States for their implementation.
- 5. The Committee will normally conduct its review of the compatibility determinations prior to Office concurrence so as not to disrupt the agency review schedule.
- D. Resolution of Compatibility Designation and Interpretive Issues
 - 1. The Committee should be consulted regarding any compatibility designation or interpretive issues involving regulations or other program elements.
 - 2. A request for the Committee's review of any compatibility designation or interpretive issues involving regulations or other program elements should be made to the Committee's Recording Secretary or Co-Chairs.
 - 3. The Committee's review will be in accordance with the review procedures set out in MD 5.6, SA-200 and the Policy Statement.

VI. REFERENCES

"Agreement State Program Policy Statement", dated October 6, 2017, 82 FR 46840 and October 18, 2017, 82 FR 48535

Management Directives, https://scp.nrc.gov/procedures.html

Final Charter - Joint NRC/Agreement State Working Group, Standing Committee on Compatibility, dated July 12, 2008 (ADAMS Accession Nos. ML082610634 and ML12269A247)

NMSS SA Procedures: https://scp.nrc.gov/procedures.html

NUREG series publications: https://www.nrc.gov/reading-rm/doc-collections/#nuregs

NMSS Policy and Procedure 6-10, NMSS Procedures for Preparation and Review of Rulemaking Packages (non-public)

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VII. 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 ADAMS.

No.	Date	Document Title/Description	Accession Number
1	09/16/20	Notification of Issuance and Opportunity	ML20178A481
		to Comment on Interim State	
		Agreement (SA) Procedure SA-202	
2	04/07/21	Final NMSS Procedure SA-202	ML21081A103