



Office of Nuclear Material Safety and Safeguards Procedure Approval

Review of State Regulatory Requirements, State Agreements (SA) Procedure SA-201

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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 process for the U.S. Nuclear Regulatory Commission's (NRC's) review and comment on proposed and final Agreement State regulations, other Agreement State legally binding requirements (LBR), and Suggested State Regulations (SSRs) promulgated by the Conference of Radiation Control Program Directors, Inc. (CRCPD).

NOTE: In this document the word State refers to both the Agreement States and CRCPD; and the terms "rules" and "regulations" are used interchangeably.

II. OBJECTIVES

- A. To provide guidance for use by the Agreement States and those States applying for Agreement State status on the preparation and submittal of proposed and final State regulations and other LBRs (e.g., license conditions and orders); and for use by the CRCPD on the preparation and submittal of SSRs, for the NRC staff's review.
- B. To establish the procedures to be followed by the NRC staff for review of Agreement State regulations or other LBRs, and SSRs including the scope of review, staff responsibilities, timeliness, and products to be prepared and communicated to the Agreement State documenting the results of the review.
- C. To provide guidance to NRC staff on the significance of differences between Agreement State regulations, other LBRs, or SSRs and the NRC's regulations.
- D. To meet the following performance objectives:
 - 1. An acceptance review of incoming packages should be completed within 3 days of receipt by the State Agreement and Liaison Programs Branch (SALB), Division of Materials Safety, Security, State and Tribal Programs (MSST). In doing this review, the State Regulation Review Coordinator (SRRC) reviews the package to ensure that all of the components needed for review are submitted. If the submission is complete, the NRC (through the AgreementStateRegs.Resource@nrc.gov mailbox) sends a verification e-mail to the State program acknowledging the receipt, and the staff member assigned to review the package;
 - 2. Incoming regulation submission packages that have been determined to be complete should be assigned to the reviewer within 3 business days of the acceptance review, and the Agreement State or CRCPD should be notified accordingly;
 - 3. The technical review should be completed within 14 business days of assignment;

4. Concurrence from other offices should be completed within 14 business days of the request for concurrence. In a case involving the concurrence of more than one other office, the process will be carried out concurrently. Legal review should be completed within 14 business days. Potential legal issues should be addressed in a timely manner.
5. The Agreement State will be contacted before the final regulation review letter is sent, to relay any comments resulting from the review.
6. A final comment letter will be sent electronically, and a paper copy will be mailed within 60 to 120 days from the receipt of a complete package.
7. The overall annual goal for completion of review submission packages is to complete 85 percent of review packages within 60 days of receipt of a complete package, and 100 percent within 120 days of receipt of a complete package.

III. BACKGROUND

- A. Each Agreement State has the responsibility to promulgate regulations or other LBRs that satisfy the compatibility requirement of Section 274 of the Atomic Energy Act of 1954, as amended. Agreement States generally fulfill that responsibility through promulgation of regulations. Each Agreement State possesses detailed knowledge of its own requirements; therefore, Agreement States should determine whether their regulations or other LBR are compatible with the NRC's regulations and identify where there are significant differences which could affect compatibility.
- B. Agreement States, and all States seeking an Agreement with the NRC, are requested to submit for review, proposed amendments to their regulations or other proposed LBRs. Such requests may be submitted prior to or at the same time they are published for public comment. While it is not mandatory that proposed regulations, LBRs, and SSRs be submitted to the NRC for review, it is highly recommended to avoid the need to revise final regulations, LBRs, and SSRs, once published.
- C. Agreement States are required to submit final regulations or other final LBRs to the NRC for a compatibility review. The requested submittal must include requirements satisfying the compatibility and health and safety (H&S) designations associated with equivalent regulations of the NRC.
- D. To assist Agreement States in promulgating compatible regulations or other LBRs within 3 years of the effective date of changes to the NRC's regulations, the NRC staff prepares and publishes a *Summary of Change Document*. Included in the document is identification of each regulation, the specific sections modified or established by the regulation change, the effective date of the change, and the compatibility or H&S designation. This information is also found

in the Regulation Toolbox on the state communications portal Web site:
<https://scp.nrc.gov/regresources.html>.

IV. ROLES AND RESPONSIBILITIES

- A. The MSST Director has overall responsibility for the review and determination of the compatibility of State regulations.
- B. The MSST Deputy Director is designated to receive State regulations and has the responsibility for managing, reviewing, and signing the NRC regulations review letter. This includes reviewer assignments, assignment of due dates, and changes to due dates. The Deputy Director also keeps the State Regulation Review Coordinator (SRRC) informed when a State regulation review package is received so the SRRC can track the status of the review through closure. The Deputy Director may designate the Branch Chief, SALB or the SRRC to carry out these responsibilities, including signing the regulation review letter for the Deputy Director, as necessary.
- C. The SALB Branch Chief is the first line supervisor for the SRRC. The Branch Chief may be designated by the Deputy Director to carry out the Deputy Director's responsibilities, including reviewer assignments, or signature authority for the regulation review letter, as necessary.
- D. The SRRC is responsible for the overall coordination, tracking, auditing, and quality control of the regulation review process. As part of this responsibility, the SRRC: (1) audits the technical reviewer's draft comment letter, and reviewer summary sheets to ensure technical and procedural consistency of reviews among reviewers; (2) addresses potential delays or other issues associated with specific regulation reviews; (3) maintains the *Chronology of NRC Amendments* list; (4) acts as the point of contact for questions during the review process, (5) serves as liaison between the submitter, the reviewer, and the Office of the General Council (OGC) throughout the review process; (6) facilitates preparation of a final letter and compatibility comment sheet, if applicable; and (7) as designated by the Deputy Director and Branch Chief, the SRRC may also assign technical reviewers, due dates, and approve changes to due dates.
- E. The Regional State Agreements Officers (RSAOs) and the Office of Nuclear Material Safety and Safeguards (NMSS) staff are responsible for conducting the technical reviews of Agreement State regulations, as assigned.
- F. Administrative support to the regulation review process includes the processing of all incoming and outgoing correspondence and review documents in the Agencywide Document Access and Management System (ADAMS).

V. GUIDANCE

This guidance applies to Agreement States, those States seeking an Agreement, and the CRCPD, and pertains to the submittal of proposed and final regulations or LBRs to the NRC staff for review. The NRC goal is to conduct a single review for proposed regulations and LBRs, and a single review for final promulgated regulations and LBRs to confirm they are compatible with equivalent NRC regulations. The NRC will not routinely conduct more than one review of the proposed regulations or LBRs. Although many Agreement States base their regulations on the CRCPD SSRs, until the SSRs are updated and reviewed regarding compatibility and given federal concurrence by the NRC, the Agreement State should not assume that regulations based on SSRs are necessarily compatible.

A. Overview

1. Proposed and final regulations and LBRs should be submitted for review to the MSST Deputy Division Director. When possible, regulations should be submitted electronically to AgreementStateRegs.Resource@nrc.gov with a carbon copy (cc) to the MSST Deputy Director. Contact information for the MSST Deputy Director can be found on the Regulation Toolbox at: <https://scp.nrc.gov/regcontacts.html>. In accordance with NRC procedures, all incoming regulations will be entered into ADAMS.
2. The [Regulation Toolbox](#) on the state communications portal Web site contains guidance on the submission of proposed and final regulations, and other LBRs. Sample letters on the form, content, and process to be followed for preparation and submittal of proposed and final regulations, and other LBRs to the NRC staff for review can be downloaded for use by both the Agreement States and NRC technical reviewers.
3. Regulations should be submitted to the NRC at least 120 days prior to the date by which comments are needed.
4. LBRs that an Agreement State proposes to adopt to meet an NRC rule should be submitted using the same submittal process as a regulation review. In the submittal letter, the Agreement State should explain how the LBR meets the requirements of the NRC rule. Agreement States should only submit LBRs for review that are intended to substitute for NRC rules. Agreement States should submit these prior to implementation. The use of LBRs instead of promulgating a regulation amendment will be documented on the State Regulation Status (SRS) sheet. An Agreement State should not add or implement any license conditions meant to meet the requirements of an NRC rule that have not been reviewed by the NRC
5. LBRs that an Agreement State proposes to add, other than for those submitted to meet the requirements of an NRC rule as stated above, should also be submitted to NRC for a compatibility review before implementation, unless it is one of the standard license conditions that are listed in NUREG-

1556, Volume 20. As noted in the Agreement State Program Policy Statement, an Agreement State has the flexibility to adopt and implement program elements within the State's jurisdiction (i.e., those items that are not areas of exclusive NRC regulatory authority such as 10 CFR Parts 10, 11, and 150) that are not addressed by the NRC, or program elements not required for compatibility (i.e., those NRC program elements not assigned to Category A, B, or C). However, such program elements of an Agreement State relating to agreement material shall (1) should not create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis; (2) not preclude a practice authorized by the AEA and in the national interest; and (3) not preclude the ability of the NRC to evaluate the effectiveness of Agreement State programs for agreement material with respect to protection of public health and safety. For purposes of compatibility, the State shall adopt program elements assigned compatibility categories A, B, and C¹. Any constraints that prevent the Agreement State from promulgating a rule that satisfies the compatibility or H&S designation in a timely fashion should be documented in the submittal letter to the NRC

6. Agreement States can incorporate NRC regulations by reference if authorized by State administrative law. This approach can be an efficient and effective method for adopting and maintaining compatible regulations with the NRC within the usual 3-year time frame. However, the Agreement State will still need to submit the regulations that were incorporated by reference for NRC review to avoid any delays due to NRC comments after the final rules are promulgated.
7. Additional relevant information, as necessary, may be requested, such as a copy of the State regulations package, public proceedings, advisory committee comments, and public comments that influenced the text of the final regulations.
8. The Agreement State has the responsibility of demonstrating that the requirements adopted other than by regulation, are legally binding on the licensee.
9. A regulatory review process flowchart can be found in the Regulation Toolbox on the state communications portal Web site:
<https://scp.nrc.gov/regulationtoolbox/regreviewprocess.pdf>
10. An Agreement State is not required to adopt amendments that are not included in the Agreement State's regulatory authority under their 274b Agreement with the NRC. For example, an Agreement State without uranium mill authority does not have to adopt uranium mill tailings regulations or revisions to the uranium mill tailings requirements. These rulemakings will be noted as "non-applicable" on the State's SRS sheet.

¹ The Policy Statement and MD 5.9 contain definitions of the compatibility categories.

B. Requirements for submission

The Agreement State, State applying for Agreement State status or CRCPD, in its transmittal letter to the NRC, should:

1. identify the specific regulation sections that are being changed using a tracked changes or similar format;
2. identify the amendment(s) for which the regulations are being submitted using the name and Regulation Amendment Tracking System (RATS) ID number. (Sample transmittal letters can be found in the Regulation Toolbox on the state communications portal Web site);
3. include a cross reference table indicating:
 - a) the equivalent State to NRC regulations;
 - b) whether there are significant differences between the State rule and the equivalent NRC rule, and whether the Agreement State believes its regulation satisfies the compatibility and H&S component criteria in Management Directive (MD) 5.9, *Adequacy and Compatibility of Program Elements for Agreement State Programs*; and
 - c) for those sections that are not compatible, describe the State's rationale for promulgating a regulation that is not compatible with the NRC's regulation.

C. Review Period

The 60-day review period will begin following confirmation by the SRRC that all required information has been provided. The Agreement State and CRCPD will be notified electronically that the submission has been accepted for review. A regulation submission package that is missing the required information may lead to delays in the review. The Agreement States, States applying for Agreement State status, and CRCPD are encouraged to contact the SRRC prior to submitting a package for review to ensure that all required items have been addressed.

D. Technical Reviewer Assignment

The Deputy Director (or designee) will normally assign review of a regulation to the RSAO responsible for the State. If the RSAO is not available or unable to meet the projected due date because of competing priority work assignments, the Deputy Director (or designee) will assign the review to other NMSS staff or evaluate the use of contractor assistance. Reviews will normally be assigned within 2 business days of receipt of a complete State package. The technical reviews should be completed within 14 business days; however, the SRRC may

extend this period for large or complex regulation packages, or due to scheduling conflicts.

E. Technical Reviewer

1. Conducts a comparison of the submitted regulation(s) with the equivalent NRC regulation(s) to determine if the regulation is compatible. Differences that are identified, which either significantly change or affect the intent of the regulation, should be analyzed further and a determination made whether the regulation meets (or does not meet) the compatibility or H&S objective of the equivalent NRC regulation. A table listing the *Criteria for Comparing Regulations and Identifying Differences* to assist the reviewer in determining when a difference is significant, can be found on the state communications portal at: <https://scp.nrc.gov/regtoolbox.html>. Additional guidance can be found in Management Directive 5.9, and NMSS Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*.
2. Completes a review summary sheet (RSS) to document the review. The reviewer will indicate whether there is a difference, whether or not the difference is significant, and the reviewer's reasoning for generating or not generating a comment on the difference. Review summary sheets can be found on the state communications portal at: https://scp.nrc.gov/rss_regamendments.html.
3. Limits review to those portions of an Agreement State's regulation that are being added or amended by the State's rulemaking action and identified in the transmittal letter. The reviewer should also limit review to those parts or sections of the regulation that are either required for compatibility or H&S, as described in SA-200 (i.e., compatibility categories A, B, and C or H&S).
4. Consults, as necessary, with other NRC offices to support completion of the regulation review based on issues raised during the review and their significance. When reviewing the regulations for States seeking an Agreement with the NRC, the reviewer will follow NMSS Procedure SA-700, *Processing an Agreement* for coordination with other offices.
5. Prepares a draft letter documenting the results of the review. The letter should be addressed to the Radiation Control Program Director or the Executive Director of the CRCPD, unless specified otherwise, and should be prepared for signature by the MSST Deputy Director. The standard format and content for the letter are contained in the sample letters found in the Regulation Toolbox on the state communications portal Web site. All letters should use the Regulatory Information Distribution System (RIDS) codes SP (05-08), corresponding to NRC Regions I, III, or IV, on the concurrence sheet. Comments resulting from the review should be set out in an enclosure to the letter. A *Sample Compatibility Comment Table Enclosure to Letter* for

reviewer use can be found on the state communications portal at:
<https://scp.nrc.gov/regtoolbox.html>.

6. Responds to questions or issues raised by OGC or other offices.

F. Legal Review

1. OGC will perform a review of the technical reviewers' determinations, including the draft letter, review summary sheets and any comments identified from the technical review subject to the following:
 - a. For the first five proposed Agreement state regulation packages submitted for a new RATS ID, OGC will perform a full review;
 - b. After the first five proposed reviews as stated above, OGC will perform a review of only those provisions for which the technical reviewer has identified a significant difference between the State and NRC regulations, unless the SRRC requests that a full review be performed;
 - c. For final/revised final regulations for which OGC has reviewed the proposed, OGC will perform a limited review if additional significant differences are identified;
 - d. For final regulations where the State had not submitted the proposed regulations for review, OGC will perform a full review;
 - e. For those rulemakings that involve minor revisions, e.g., corrections, organizational name changes, OGC will not perform a review unless requested by the SRRC;
 - f. Upon SRRC request, OGC will perform an expanded review of any proposed or final regulations and LBRs.
2. OGC will provide "no legal objection" (NLO) to the review letter after all issues and comments that they have identified are resolved.

G. The SRRC

1. Acts as the point of contact for questions during the review process.
2. Conducts a review for technical completeness of incoming State transmittal letters and regulation packages within 3 business days of the receipt of a review request, and assigns an internal tracking number to the submission;
3. Electronically notifies the Agreement State, State applying for Agreement State status, or CRCPD acknowledging acceptance of the submission, once all required documents are received.
4. Serves as liaison between the submitter, the reviewer, and OGC throughout the review process. Facilitates preparation of a final letter and compatibility comment sheet, if applicable.

5. Schedules meetings with management and other offices to resolve any issues.
6. Updates the SRS Data Sheet after each compatibility review to reflect the current review. The SRS Data Sheet is to be included as an enclosure to the comment letter. The SRS sheet also contains all rulemaking amendments that the State needs to address. An example SRS sheet can be found on the state communications portal at: <https://scp.nrc.gov/regtoolbox.html>.
7. Prepares and requests review by OGC, if applicable. This request is sent electronically to the RIDS OGC mailbox, and contains the following information: date of request, criteria for OGC review as stated in item 1 above, package tracking number, requested date of response (typically 14 business days), name of the Agreement State program and program director, the package title, ADAMS package link, and the SRRC name and contact number.
8. If necessary, coordinates the request for consultant or contractor assistance in review of proposed or final State regulations in accordance with procedures established by NMSS. When requesting such assistance, the SRRC should:
 - a) Prepare a cover letter and attach the regulations package for forwarding to the consultant or contractor following the NMSS procedure.
 - b) Evaluate the comments as the basis for development of a comment letter to the State upon return of the consultant's or contractor's review report.

VI. REFERENCES

1. Management Directives available at <https://scp.nrc.gov>
2. NMSS SA Procedures available at <https://scp.nrc.gov>
3. NUREG-1556, Volume 20 available at: <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>
4. Regulation Toolbox available at <https://scp.nrc.gov/regresources.html>

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 NRC's Agencywide Document Access Management System (ADAMS).

No.	Date	Document Title/Description	Accession Number
1	7/23/01	STP-01-059, Opportunity to Comment on Draft Revisions to STP Procedure SA-201	ML012050534
2	1/29/03	STP-03-010, Opportunity to Comment on Draft Revisions to STP Procedure SA-201	ML030290744
3	6/19/03	Final STP Procedure SA-201	ML031750279
4	8/07/03	Summary of Comments on SA-201	ML032190296
5	8/31/06	STP-06-080, Opportunity to Comment on Draft Revisions to STP Procedure SA-201	ML062440197
6	11/19/19	Interim NMSS Procedure SA-201	ML19311C539
7	7/2/20	Resolution of Comments	ML20184A178
8	8/27/20	Final NMSS Procedure SA-201	ML20183A323