



Office of Nuclear Material Safety and Safeguards Procedure Approval

Reviewing the Non-Common Performance Indicator, Legislation, Regulations, and Other Program Elements

SA-107

Issue Date:

Review Date:

Andrea Kock, Director
*Division of Materials Safety, Security, State,
and Tribal Programs*

Date:

Paul Michalak, Chief
*State Agreement and Liaison Programs Branch
Division of Material Safety, Security, State,
and Tribal Programs*

Date:

Michelle Beardsley, Procedure Contact
*State Agreement and Liaison Programs Branch
Division of Material Safety, Security, State,
and Tribal Programs*

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 document describes the procedure for conducting reviews of Agreement State radiation control programs for the Non-Common Performance Indicator, Legislation, Regulations, and Other Program Elements, specified in NRC Management Directive (MD) 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*.

II. OBJECTIVE

To ensure that an Agreement State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of radioactive materials under the Atomic Energy Act, as amended.

III. BACKGROUND

For Agreement State program reviews, an assessment of both adequacy and compatibility is necessary to ensure that State programs are adequate to protect public health and safety; and are compatible with the U.S. Nuclear Regulatory Commission's (NRC) regulatory program. This indicator is considered a "non-common" performance indicator because it is not applicable to the NRC's radiation control program.

IV. ROLES AND RESPONSIBILITIES

A. Team Leader:

Determines which team member is assigned lead review responsibility for this performance indicator.

B. Principal Reviewer:

1. Reviews State program elements, legislation, regulations, and other generic legally binding requirements (including orders and license conditions); conducts staff discussions; and documents information pertinent in determining the compatibility of the State's program, and the adequacy of the authority to conduct Agreement State regulatory functions.
2. Meets the appropriate requirements specified in SA-111, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members and Team Leaders*

V. GUIDANCE

A. Scope



1. Program elements are considered any component or function of a radiation control program, including licensing, inspection, staffing, event response, regulations and/or other legally binding requirements imposed on regulated persons that contribute to the implementation of that program. Statutes and regulations comprise one of the basic components of an Agreement State radiation control program, since they provide the program's regulatory framework.
2. Statutes
 - a. Under Section 274 of the Atomic Energy Act of 1954, as amended, Agreement States administer regulatory programs under their own State statutes. State laws should provide specific elements of authority to the Agreement materials program.
 - b. State laws should not create duplications, gaps or conflicts in regulations between the State and the NRC, other State agencies, or other Federal agencies.
 - c. State laws should not seek to regulate materials or activities reserved to the NRC.
 - d. Any State statute used to provide specific elements of authority to the Agreement State program will be reviewed by the NRC in accordance with NMSS Procedure SA 201, Review of State Regulatory Requirements.
3. Regulations
 - a. Each Agreement State has the responsibility to promulgate generic legally binding requirements that satisfy the compatibility requirement of Section 274 of the Atomic Energy Act of 1954, as amended. States generally fulfill that responsibility through promulgation of regulations. Regulations will be reviewed by the NRC in accordance with Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-201, *Review of State Regulatory Requirements*.
 - b. Regulations designated as necessary for health, safety, and security will be reviewed by the NRC in accordance with NMSS Procedure SA-201, *Review of State Regulatory Requirements*.
 - c. To assist States in promulgating compatible regulations or other generic legally binding requirements within 3 years of the effective date of changes in NRC regulations, the NRC staff prepares and publishes a Chronology of NRC Amendments. Included in the chronology is the



identification of each regulation change, the specific sections revised or established by the regulation change, the effective date of the change, and the compatibility or health and safety designation.

- d. The State Regulation Status Data Sheet (SRS) for each Agreement State is available on the NMSS website: <https://scp.nrc.gov/rulemaking.html> to assist States in identifying the necessary regulations or other generic legally binding requirement necessary for adequacy and compatibility.

4. Program Elements other than Statutes and Regulations

- a. Appendix A to NMSS Procedure SA-200, *Compatibility Categories and Health & Safety Identification for NRC Regulations and Other Program Elements*, was developed for use by the NRC and Agreement State staff. It identifies the assigned compatibility or health and safety designation for each program element, as determined in accordance with Management Directive 5.9 (MD 5.9), *Adequacy and Compatibility of Program Elements for Agreement State Programs*.
- b. Each Agreement State has the responsibility to address program elements other than regulations that satisfy the compatibility requirement of Section 274 of the Atomic Energy Act of 1954, as amended,
- c. Program elements, other than regulations should normally be adopted and implemented by the State within 6 months of the effective date unless a different timetable for adoption and implementation was identified and communicated to the Agreement States. A list of program elements can be found at [add link].

B. Evaluation Procedures

The principal reviewer should refer to Section III, Evaluation Criteria, of MD 5.6, *Integrated Materials Performance Evaluation Program*, for specific evaluation criteria. The principle reviewer should complete the work to determine the status of the Agreement State's rules prior to the on-site portion of the review. This work should be coordinated with the State Regulation Review Coordinator (SRRC), State Agreement and Liaison Programs Branch (SALB), Division of Materials Safety, Security, State, and Tribal Programs (MSTR), and the State's Regional State Agreements Officer (RSAO). As noted in Management Directive 5.6, the criteria for a satisfactory program is as follows:

1. State statutes authorize the State to establish a program for the regulation of agreement material, provide authority for the assumption of regulatory responsibility under the agreement with the NRC, and do not create gaps or



conflicts in the National Materials Program due to compatibility or health, safety, and security discrepancies.

2. The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
3. State statutes are consistent with Federal statutes, as appropriate.
4. The State has legally enforceable measures, such as generally applicable rules, license provisions, or other appropriate measures, necessary to allow the State to ensure adequate protection of public health, safety, and security in the regulation of agreement material.
5. The State has compatible legally binding requirements, regulations, and other program elements in accordance with 1MD 5.9, and NMSS procedures SA-200 and SA-201.
6. NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety are adopted and implemented within 3 years after the effective date of the NRC's final rule or as approved by the Commission.
7. Other program elements that have been designated as necessary for maintenance of an adequate and compatible program are adopted and implemented by an Agreement State within 6 months of such designation and issuance by the NRC.

Appendix A contains examples to assist the reviewer in identifying less than satisfactory programs.

C. Review Details.

The principal reviewer should evaluate and document the review of the following:

1. Legislation that affects the radiation control program, including any legislation that has been passed since the last review, that affects the State's authority to:
 - a. Promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security of radioactive materials.
 - b. License, inspect, and enforce legally binding requirements such as regulations and licenses.
2. Agreement State statutes to ensure consistency with Federal statutes, as appropriate.
3. The adoption and implementation of legally binding requirements, regulations, and other program elements in accordance with MD 5.9, and NMSS Procedures SA-200, *Compatibility Categories and Health & Safety Identification for NRC Regulations and Other Program Elements*, and SA-



201, *Review of State Regulatory Requirements.*

4. The State has existing legally enforceable measures in place such as generally applicable rules, license conditions, orders, or other appropriate provisions, necessary to allow the State to ensure adequate protection of public health and safety, and security in the regulation of agreement material.
5. The State's administrative rulemaking process allows for the adoption of regulations in an appropriate amount of time and includes sufficient periods for public comment.
5. All regulations required for purposes of compatibility or health and safety are adopted in a time frame so that the effective date of the State requirement is not later than three years after the effective date of the NRC's final rule. The NMSS' Chronology of Amendments is a list of NRC regulation amendments including the NRC effective date and State adoption due date, (see NMSS website: <https://scp.nrc.gov/asletters/>).

When deciding on the finding for this indicator, the principal reviewer should take into account the following items:

- a. Compatibility significance of the rules.

The compatibility significance of any regulations that have not been adopted, or not adopted timely. Significant or essential regulations are those that are designated as Compatibility Category A or B as defined in NMSS Procedure SA-200, Compatibility Categories and Health & Safety Identification for NRC Regulations and Other Program Elements. One or a combination of the following circumstances may pertain to regulations or program elements that have not been adopted and should be considered in reaching a proposed finding recommendation: e.g., the adoption of the "Transportation Requirements," Part 71, is more significant than "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 32, 35, 36, and 39 amendments. The State may have postponed adoption of the less significant rule to expedite the adoption of the more significant regulation.

- b. Rules not needed at the time of the review, e.g., the State may have postponed adoption of "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendment since they do not have licensees authorized for this activity.
- c. The root cause of the delay in promulgation of regulations, and the State managements' actions to address and correct the problem, e.g., a State could experience significant staff loss, which the State managed and recovered from through hiring, training and prioritizing workload such that



at the time of the on-site review, all regulations had been promulgated and the root cause for the delay has been addressed to ensure that the State would not experience the same difficulty in the future.

- d. Status of regulations in the legislative process, e.g., the State has completed draft regulations, and the draft regulation package is either out for public comment, or within the State's administrative procedures for final promulgation.
- e. The significance of outstanding comments on final regulations, e.g., a comment stating that the State omitted requirements for significant provisions included in the rulemaking.

D. Discussion of Findings with State.

The reviewer should follow the guidance given in NMSS Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*, for discussion of technical findings with reviewers, supervisors, and managers.

VI. APPENDICES

- A. Frequently Asked Questions
- B. Examples of Less than Satisfactory Findings

VII. REFERENCES

1. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*.
2. Management Directive 5.9, *Adequacy and Compatibility of Program Elements for Agreement State Programs*.
3. NMSS Procedure SA-111, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members and Team Leaders*.
4. NMSS Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*.
5. NMSS Procedure SA-200, *Compatibility Categories and Health & Safety Identification for NRC Regulations and Other Program Elements*.
6. NMSS Procedure SA-201, *Review of State Regulatory Requirements*.

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	6/17/99	SP-99-040, Opportunity to Comment on Draft Revisions to OSP Procedure SA-107	ML07010237
2	1/7/00	Final OSP Procedure SA-107	ML272010239
3	8/3/07	FSME-07-079, Opportunity to Comment on Draft Revisions to FSME Procedure SA-107	ML072070211
4	3/24/08	Summary of Comments on SA-107	ML080860450
5	3/27/08	Final FSME Procedure SA-107	ML080860464
6	XX/XX/19	Final NMSS Procedure SA-107	ML19XXXXXXX

Appendix A

FREQUENTLY ASKED QUESTIONS (FAQs)

1. Q. Can the review team make a preliminary finding of compatibility for the overall program, if the finding for this performance indicator is satisfactory, but needs improvement?

A. The review team should make a recommendation for an overall finding of compatibility if the State is found satisfactory or satisfactory, but needs improvement for this performance indicator and no other compatibility issues have been identified in other performance indicators. If the team finds a State unsatisfactory for this performance indicator, the recommended finding to the Management Review Board should be “not compatible”.
2. Q. If a State has adopted legally binding requirements instead of a regulation, do we still require the State to adopt the regulation in order to be considered satisfactory for this indicator?

A. Implementation of a NRC regulation through a legally binding requirement is an acceptable approach, and if the legally binding requirement is issued within 3 years, the State should be considered as meeting the requirement for this regulation.
3. Q. If a State adopts legally binding requirements, is it necessary for the NRC to review the requirement before NRC considers the requirement acceptable?

A. Agreement States should submit legally binding requirements in accordance with NMSS Procedure SA-201, *Review of State Regulatory Requirements* for review. If a State has issued legally binding requirements, but has not sought NRC review, the review team should make a recommendation to the State to provide all legally binding requirements for NRC review, but the State should be given credit for addressing the requirement.
4. Q. If the Agreement State staff has just begun work on drafting the necessary regulations, however State management has not received the completed package. Can the review team give the State credit for being in the process of promulgating the regulations?

A. For the review team to consider the State in the process of promulgating the necessary regulations, the State should have completed draft regulations and the draft regulation package should be either out for public comment or within the State’s administrative procedures for final promulgation.
5. Q. The review team has found that the State had not promulgated “Minor Corrections, Clarifying Changes, and a Minor Policy Change,” 10 CFR Parts 20, 32, 35, 36, and 39 amendments (63 FR 393477 and 63 FR 45393) and

“Transfer for Disposal and Manifest; Minor Technical Conforming Amendments,” 10 CFR Part 20 amendment (63 FR 50127). Although both of these amendments revise regulations that have been identified as Category A and B, would these be considered significant regulations for determining the finding for this performance indicator?

A. Minor revisions and clarifications to Category A or B regulations are normally not considered as significant as the initial revision to the regulations.

6. Q. The review team has found that the State promulgated an amendment in accordance with the NRC’s policies and procedures; however the State is not implementing the compatible requirement or is interpreting the requirements differently than the NRC in the licensing program.

A. The review team should identify the issue associated with the implementation to both the State and the Management Review Board as a compatibility issue.

7. Q. What does it mean for both the Agreement State and the review team when a regulation is being held in abeyance?

A. If a regulation is being held in abeyance, specific guidance will be provided to both the Agreement States and review teams as to the manner in which the Agreement States’ regulations are to be factored into the IMPEP review findings.

As of 2019, only three regulations have been held in abeyance, i.e., temporarily set aside. In these three specific cases, the NRC staff continued to review Agreement State proposed and final rules but held any compatibility determination in abeyance on those rules if the Agreement State’s rules met the essential elements of the NRC’s rule, even if the Agreement State’s rules were more restrictive than the NRC’s rule. For Agreement States without a rule or with a rule less restrictive than the NRC’s rules, the staff factored this determination into the results of the NRC’s review of the State’s proposed and final rules and the compatibility findings during IMPEP reviews.

8. Q. Could the lack of program element implementation affect the overall finding for compatibility of a state’s program?

A. The lack of program elements can affect the overall finding for compatibility, especially if the team identifies performance issues that are directly related to the lack of these procedures. For example, if a State has not implemented the Pre-licensing Checklist within 6 months of issuance, and the IMPEP review team finds that the State has issued a license to an unknown entity which has resulted in the malicious use of radioactive material, a finding of “not compatible” may be appropriate.

Appendix B

EXAMPLES OF LESS THAN SATISFACTORY PROGRAMS

The following are examples of review findings that resulted in a program being found **“satisfactory, but needs improvement”** for this indicator:

- a) The State had not adopted and implemented several significant rulemaking packages within the 3-year adoption due date, however, the final regulations were in the legislative process for promulgation.
- b) The State had adopted and implemented final regulations for all RATS IDs that became due during the review period; however, the compatibility comments identified during the NRC review were that the State’s final regulations omitted many required regulations.
- c) The State passed legislation that affected the radiation control program which they did not submit for NRC’s review, and some aspects of the legislation were found to be in conflict with their 274b Agreement.
- d) The State issued license conditions that were not submitted for NRC review, and were found to be not compatible with NRC’s regulations.
- e) The State had not implemented the essential objectives of IMC 2800 within 6 months, which resulted in their inspection procedures being not compatible.

The following are examples of review findings that resulted in a program being found **“unsatisfactory”** for this indicator:

- a) The State had not implemented the Pre-licensing checklist and had issued a license to an unknown entity.
- b) The State had not adopted and implemented most of the significant regulations within the 3-year period.
- c) The State passed enabling legislation which contained provisions to allow for the disposal of high level radioactive waste which is not authorized under their 274b Agreement.