



## Office of Nuclear Material Safety and Safeguards Procedure Approval

### ***Reviewing the Non-Common Performance Indicator, Legislation, Regulations, and Other Program Elements, Interim Procedure State Agreement (SA)-107***

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Paul Michalak, Branch Chief, NMSS/MSST/SALPB	Original signed by Paul Michalak	Date: 11/14/2019
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Terry Derstine Chair, Organization of Agreement States		Date: 11/14/2019
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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 Integrated Materials Performance Evaluation Program (IMPEP) reviews of Agreement State radiation control programs for the Non-Common Performance Indicator, Legislation, Regulations, and Other Program Elements, specified in the U.S. Nuclear Regulatory Commission (NRC) Management Directive (MD) 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*.

## **II. OBJECTIVE**

To ensure that an Agreement State 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 IMPEP reviews, an assessment of both adequacy and compatibility is necessary to ensure that programs are adequate to protect public health and safety; and are compatible with the NRC's 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:**

Assigns lead review responsibility for this performance indicator, to a team member who meets the appropriate qualification requirements in the Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-111, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members and Team Leaders*.

### **B. Principal Reviewer:**

1. Reviews Agreement State legislation, regulations (including legally binding requirements such as orders and license conditions), and applicable program elements (as defined in Section V.A.1. of this procedure);
2. Conducts discussions with program management and staff to understand the impacts of any changes made to the State's legislation, if applicable, and determines the complexity of the rule adoption process;
3. Documents information pertinent in determining the indicator finding of satisfactory, satisfactory, but needs improvement or unsatisfactory; and also for the overall finding of compatibility of the Agreement State's program;

4. Determines whether performance deficiencies identified in other indicators, e.g., untimely/no implementation of program elements (written procedures, directives) have an impact on this indicator finding, or the overall findings of adequacy and compatibility.

## **V. GUIDANCE**

### **A. Scope**

#### **1. 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. State laws should not create duplications, gaps or conflicts in regulations between the State and the NRC, other State agencies, or other Federal agencies. State laws should not seek to regulate materials or activities reserved to the NRC.
- b. Any State statute used to provide specific elements of authority to the Agreement State program will be reviewed by the NRC in accordance with SA-201, *Review of State Regulatory Requirements*.

#### **2. Regulations**

- a. Each Agreement State has the responsibility to promulgate legally binding requirements that satisfy Section 274 of the Atomic Energy Act of 1954, as amended. States generally fulfill that responsibility through promulgation of regulations or license conditions. Regulations and other legally binding requirements used in place of regulations are reviewed by the NRC throughout the review period in accordance with the SA-201, *Review of State Regulatory Requirements*.
- b. Regulation changes promulgated by the NRC are due for Agreement State adoption within three years of the effective date of the regulation unless otherwise specified and communicated to the Agreement States. 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/regresources.html>).

#### **3. Program Elements other than Statutes and Regulations**

- a. 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. Appendix A to SA-200, *Compatibility Categories and Health & Safety Identification for NRC Regulations and Other Program Elements*, was developed for use by the Agreement State and NRC staff. It identifies the assigned compatibility or health and safety designation for each program element, as determined in accordance with 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 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: <https://scp.nrc.gov/regtoolbox.html>.

**B. Evaluation Process**

The principal reviewer should refer to Section III, Evaluation Criteria, of MD 5.6 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 (MSST), and the State's Regional State Agreements Officer (RSAO). As noted in MD 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<sup>1</sup>, 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

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<sup>1</sup> The term 'agreement material' means the materials listed in Section 274b. of the Atomic Energy Act of 1954, as amended, over which the States may receive regulatory authority (i.e., byproduct material, source material, and certain quantities of special nuclear material) .

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 MD 5.9, and 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 of this procedure contains examples to assist the reviewer in identifying less than satisfactory programs.

C. Review Details.

1. The principal reviewer should evaluate and document the review of the following:
  - a. Enacted legislation that affects the radiation control program. The reviewer should determine whether any changes have been made to the State's statutes that affect the Agreement Program since the last IMPEP review; and confirm that the revised legislation has been submitted to the NRC for review to ensure that any changes to the State statutes are consistent with Federal statutes, as appropriate. Discussions should be held with Agreement State program management to determine the impact(s) of the changes on the radioactive materials program.
  - b. The Agreement State's administrative rulemaking process. The reviewer should ensure that the State's process allows for the timely adoption and implementation of legally binding requirements, regulations, and other program elements in accordance with MD 5.9 and SA-200; and further, that it allows sufficient time for public comments.
  - c. The Agreement State's regulation status at the time of the review. The reviewer should ensure that 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. 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 the Agreement State and the Principal Reviewer in identifying the necessary regulations or other legally binding requirements required for adoption.

- d. The membership and statutory responsibilities for State radiation oversight boards and the board's actions during the review period, if any.
2. When deciding on the finding for this indicator, the principal reviewer should consider the following items:
    - a. The compatibility significance of the rules. The compatibility significance of any regulations that have not been adopted, not adopted timely, or have outstanding comments on final regulations will be considered. Significant or essential regulations are those that are designated as Compatibility Category A or B (not including minor corrections) as defined in SA-200. 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: 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 Agreement State may have postponed adoption of the less significant rule to expedite the adoption of the more significant regulation or adopt multiple regulation changes together.
    - b. Rules not needed at the time of the review, e.g., the Agreement 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. In this scenario, these regulations should not be considered overdue for adoption.
    - c. The root cause of the delay in promulgation of regulations, and the Agreement State managements' actions to address and correct the problem, e.g., an Agreement State could experience significant staff loss, which was 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 Agreement State would not experience the same difficulty in the future.
    - d. Status of regulations in the legislative process, e.g., the Agreement State has completed draft regulations, and the draft regulation package is either out for public comment, or within the Agreement State's administrative procedures for final promulgation.

- e. The significance of outstanding comments on final regulations. Even though a State may have adopted final regulations for a given rulemaking, comment(s) identified during the NRC review stating that many of the significant provisions were omitted, may render the State's regulations not compatible.
  3. When deciding on the overall finding of Agreement State program compatibility, the team should make a recommendation for an overall finding of "compatible" 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".
- D. Discussion of Findings with State.
  1. The reviewer should follow the guidance provided in SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*, regarding discussions related to this indicator with cognizant staff and management. If performance issues are identified by the reviewer(s) that lead to programmatic weaknesses, the reviewers should seek to identify the root cause(s) of the issues which can be used as the basis for developing recommendations for corrective actions. Section II.A.3 of SA-100 contains criteria regarding the development of recommendations by the IMPEP team.
  2. In terms of general guidance for the IMPEP review team, a finding of "satisfactory" should be considered when none or only a few or small number of the cases or areas reviewed involve performance issues/deficiencies (e.g., inspection, licensing, staffing, etc.) ; an "unsatisfactory" finding should be considered when a majority or a large number of cases or areas reviewed involve performance issues/deficiencies, especially if they are chronic, programmatic, and/or of high-risk significance; and a finding of "satisfactory, but needs improvement" should be considered when more than a few or a small number of the cases or areas reviewed involve performance issues/deficiencies in high-risk-significant regulatory areas, but not to such an extent that the finding would be considered unsatisfactory.

## **VI. APPENDICES**

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

## **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/>

## **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	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

### EXAMPLES OF LESS THAN SATISFACTORY FINDINGS OF PROGRAM PERFORMANCE

#### NOTE:

The effectiveness of a program is assessed through the evaluation of criteria listed in Section III, Evaluation Criteria, of Management Directive 5.6 for this performance indicator. These criteria are NOT intended to be exhaustive but provide a starting point for the IMPEP review team to evaluate this indicator. The review team should also take into consideration other relevant mitigating factors that may have an impact on the program's performance under this performance indicator. The review team should consider a less than satisfactory finding when the identified performance issue(s) is/are programmatic in nature, and not isolated to one aspect, case, individual, etc. as applicable.

This list is not all inclusive and will be maintained and updated in the IMPEP Toolbox on the state communications portal website.

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

- a) The Agreement State had not adopted and implemented several (i.e., more than two, but not many) significant rulemaking packages within the 3-year adoption due date, however, the final regulations were in the legislative process for promulgation.
- b) The Agreement 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 Agreement State's final regulations omitted more than a few of the required regulations.
- c) The Agreement State passed legislation that affected the radiation control program which they did not submit for NRC's review, and a few of the aspects of the legislation were found to conflict with their 274b Agreement.
- d) The Agreement State implemented a license condition that was not submitted for NRC review, and was found to be not compatible with equivalent NRC regulations.

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

#### NOTE:

This list is not all inclusive and will be maintained and updated in the IMPEP Toolbox on the state communications portal website.

- a) The Agreement State had not implemented the Pre-licensing checklist and had issued a license to an unknown entity and after a State investigation, it was determined that the unknown entity had used the authorized materials for malicious purposes.
- b) The Agreement State had not adopted and implemented a majority of the significant safety and/or security-related regulations within the 3-year period.
- c) The Agreement State passed enabling legislation which contained provisions for the State to regulate the siting of a facility to dispose of high-level radioactive wastes which is not authorized under their 274b Agreement.
- d) The Agreement State issued a license condition for visiting medical authorized users and did not submit it for NRC review. This provision is not compatible with 10 CFR Part 35. The State's investigation of the use of this condition by licensees found cases in which authorized medical users were allowed to practice without the proper training and experience credentials.

## Appendix B

### FREQUENTLY ASKED QUESTIONS (FAQs)

1. 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 an 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. Agreement States should submit all legally binding requirements to the NRC for a compatibility review (see Q. & A. 3 below).
2. 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 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.
3. Q. If the Agreement State staff has just begun work on drafting the necessary regulations; however, the Agreement State program 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 legislative procedures for final promulgation.
4. 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.

5. Q. The review team has found that the Agreement State promulgated an amendment in accordance with the NRC's policies and procedures; however, the Agreement 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.
- 6.Q. Could the lack of program element implementation affect the overall finding for compatibility of an Agreement State?
- A. The lack of implementation 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 an Agreement 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.