



## Office of Nuclear Material Safety and Safeguards Procedure Approval

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

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*Director, NMSS/MSST*

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David Crowley

*Chair, Organization of Agreement States*

A handwritten signature in blue ink that reads "David Crowley".

*Date: 9/15/2020*

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**ML20183A328**

#### **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 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 regulatory program.

The terms "rules" and "regulations" are used interchangeably in this procedure.

## **IV. ROLES AND RESPONSIBILITIES**

### **A. Team Leader**

1. In coordination with the IMPEP Program Manager, the Team Leader determines which team member is assigned lead review responsibility.
2. Communicates the team's findings to Program management and ensures that the team's findings are in alignment with MD 5.6.

### **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 for the overall finding of compatibility of the Agreement State's program.
4. Determines whether performance deficiencies identified in other indicators, (e.g., untimely or no implementation of program elements such as written procedures or checklists) have an impact on this indicator finding, or the overall findings of adequacy and compatibility.
5. Informs the Team Leader of the team's findings throughout the onsite review.
6. Presents the team's findings to the Program at the staff exit meeting.
7. Completes their portion of the IMPEP report for the Legislation, Regulations, and Other Program Elements performance indicator.
8. Attends the Management Review Board meeting for the IMPEP review; presents and discusses the team's findings for the Legislation, Regulations, and Other Program Elements performance indicator (this can be done either in person or remotely).

## **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 State's radiation control 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 State Agreements (SA) Procedure 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 in accordance with SA-201.

- b. Each Agreement State can implement an NRC regulation through a legally binding requirement (license conditions, orders) provided the Agreement State submits the legally binding requirement to the NRC for a compatibility review. Agreement States should submit legally binding requirements in accordance with SA-201 for review.
- c. Regulation changes promulgated by the NRC are due for Agreement State adoption within 3 years of the effective date of the regulation unless otherwise specified and communicated to the Agreement States. The Chronology of NRC Amendments is a list of NRC regulation amendments including the NRC effective date and State adoption due date, (see <https://scp.nrc.gov/regresources.html>).

3. Program Elements Other than Statutes and Regulations

- a. The Agreement State Program Policy Statement defines “program element” as any component or function of a radiation control regulatory program, including regulations or other legally binding requirements, imposed on regulated persons, which contributes to implementation of that program. The Policy Statement further notes that 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) that are not addressed by the NRC, or program elements not required for compatibility (*i.e.*, those NRC program elements not assigned to compatibility category A, B, or C). The program elements for both regulations and non-regulations can be found at: <https://scp.nrc.gov/regtoolbox.html>. This list identifies the assigned compatibility, and adequacy 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 for regulations and non-regulations requiring Agreement State implementation can be found at: <https://scp.nrc.gov/regtoolbox.html>.

B. 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 State 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 radiation control 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 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 for each Agreement State is available at: <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. Whether the State has any radiation oversight boards.

If so, the reviewer should determine whether these boards have appropriate membership, and the statutory authority to carry out these responsibilities. The reviewer should examine the board's actions during the review period, if any, to determine whether they present any conflicts with NRC's regulatory program.

- e. Whether the State has "sunsetting" requirements for their regulations.

Sunsetting means the law shall cease to have effect after a specific date unless further action is taken to extend the law. If the State's regulations are to be sunset, the reviewer should evaluate where the State is in the process of promulgating all regulations before the sunset date.

2. When determining the finding for this indicator, the principal reviewer should consider the following items when deciding between the findings of satisfactory; satisfactory, but needs improvement; or unsatisfactory:

- a. The compatibility significance of the rules will need to be taken into consideration. The compatibility significance of any regulations that have not been adopted, not adopted timely, or have outstanding significant 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. For example, the adoption of the "Transportation Requirements," Title 10 of the *Code of Federal Regulations* (10 CFR) 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. There may be regulations/rules (with a compatibility category of A or B) that have not been adopted but are considered minor. Minor revisions and clarifications to Category A or B regulations are normally not considered as significant as the initial revision to the regulations.
- c. There may be regulations that are not needed at the time of the review. For example, 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 and have not approved any well logging licensees to perform work under reciprocity during the review period). In this scenario, these regulations might not be considered overdue for adoption.
- d. The root cause of the delay in promulgation of regulations, and the Agreement State managements' actions to address and correct the problem will need to be taken into consideration. For example, 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.
- e. The status of regulations in the State's rulemaking process will need to be taken into consideration. For example, if 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. In this scenario the State may be given credit for being in the process of promulgating the regulations.

- f. The significance of outstanding comments on final regulations will need to be taken into consideration. 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 and therefore, might still be considered overdue.
3. When determining the overall finding for this indicator, the review team should consider the following items:
    - a. The lack of implementation or the misinterpretation of regulations should be identified.
    - b. The lack of implementation of program elements such as inspection or licensing procedures, Pre-licensing guidance, especially if the team identifies performance issues that are directly related to the lack of these program elements.
  4. 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" with the NRC's regulatory program.

**C. Evaluation Process**

The principal reviewer should refer to Section III, Evaluation Criteria, of MD 5.6 for specific evaluation criteria. The principal reviewer should complete the work to determine the status of the Agreement State's regulations prior to the on-site portion of the review. This work should be coordinated with the State Regulation Review Coordinator, State Agreement and Liaison Programs Branch, Division of Materials Safety, Security, State, and Tribal Programs, and the State's Regional State Agreements Officer. 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.

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<sup>1</sup> The term 'agreement material' means the byproduct material, source material, and certain quantities of special nuclear material listed in Section 274b. of the Atomic Energy Act of 1954, as amended, over which the State receives regulatory authority.

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 MD 5.9, SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*, and SA-201.
6. NRC regulations that should be adopted by an Agreement State for purposes of compatibility or adequacy, and 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.

Note: *Examples of Less than Satisfactory Findings of Program Performance* can be found in the IMPEP Toolbox on the state communications portal. These examples may assist the reviewer in identifying less than fully satisfactory findings of a Program's performance.

D. Discussion of Findings with the State

1. The reviewer should follow the guidance given in NMSS Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*, for discussing technical findings with staff, supervisors, and management.
2. If the IMPEP review team identifies programmatic performance issues, the IMPEP review team should seek to identify the root cause(s) of the issues, which can be used as the basis for developing recommendations for corrective actions. The NMSS procedure SA-100 contains criteria regarding the development of recommendations by the IMPEP team.

## VI. 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/>.

Agreement State Program Policy Statement published October 18, 2017, 82 FR 48535.

## 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).

<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	7/2/20	Resolution of Comments	ML20184A180
7	9/15/20	Final NMSS Procedure SA-107	ML20183A328