

**Office of Nuclear Material Safety and Safeguards**

**Procedure Approval**

***Reviewing the Non-Common Performance Indicator,***

 ***Compatibility Requirements***

**SA-107**

Issue Date:

Review Date:

Daniel S. Collins

*Director, NMSS/MSTR Date:*

Paul Michalak

*Branch Chief, NMSS/MSTR/ASPB Date:*

Michelle Beardsley

*Procedure Contact, NMSS/MSTR/ASPB Date:*

**ML1**

***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 radioactive materials programs using Non-Common Performance Indicator, Compatibility Requirements, 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 compatible with the Nuclear Regulatory Commission (NRC) regulatory program. This indicator is considered a “non-common” performance indicator because it is not applicable to NRC Regional radioactive materials programs.

**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 including legislation and regulations, and other generic legally binding requirements (including orders and license conditions); conducts staff discussions; and documents information pertinent to the compatibility of the State and the adequacy of the authority to conduct Agreement State functions.
2. Meets the appropriate requirements specified in MD 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*.

**V. GUIDANCE**

A. Scope

1. Program elements are considered any component or function of a radiation control regulatory program, including regulations and/or other legally binding requirements imposed on regulated persons, that contributes to the implementation of that program. Statutes and regulations comprise one of the basic components of an Agreement State radioactive materials program, since they provide the program's regulatory framework.
2. Statutes
3. 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.
4. State laws should not create duplications, gaps or conflicts in regulation, between the State and the NRC, State agencies, other Federal agencies, or State and local agencies.
5. The State laws should not seek to regulate materials or activities reserved to NRC.
6. Regulations
7. 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.*
8. Regulations designated as necessary for health and safety will be reviewed by the NRC in accordance with NMSS Procedure SA‑201, *Review of State Regulatory Requirements.*
9. 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 identification of each regulation change, the specific sections modified or established by the regulation change, the effective date of the change, and the compatibility or health and safety designation.
10. The State Regulation Status Data Sheet (SRS) for each Agreement State is also available on the NMSS home page to assist States in identifying the necessary regulations or other generic legally binding requirement necessary for adequacy and compatibility.

1. Program Elements other than Statutes and Regulations
2. 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 State staff. It identifies the assigned compatibility or health and safety component for each rule and program element, as determined in accordance with MD 5.9.
3. 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 as listed in Appendix A of SA-200.
4. 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 through normal written communication with the States.

B. Evaluation Procedures

1. The principal reviewer should refer to Part III, Evaluation Criteria, of MD 5.6, *Integrated Materials Performance Evaluation Program*, for specific evaluation criteria.
2. Any changes to State legislation since the last IMPEP review affecting the radiation control program should be reviewed.
3. The status of all regulations adopted in the radiation control program or other generic legally binding requirements since the last IMPEP review, as well as the status of any regulations currently in the rulemaking process, should be determined.
4. The principle reviewer should complete as much of 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), Agreement State Programs Branch (ASPB), Division of Materials Safety, State, Tribal and Rulemaking Programs (MSTR).
5. The status of the State’s regulations and other generic legally binding requirements should be discussed with the appropriate Regional State Agreements Officer (RSAO) and the SRRC.
6. The principle reviewer should coordinate with the principle reviewers responsible for other common and non-common performance indicators for the status of the program elements listed in Appendix A of SA-200 that impact the assessment of compatibility and health and safety for the program.

C. Review Guidelines

1. A copy of the SRS data sheet for the State from the NMSS home page will be included in the IMPEP questionnaire for the State to review, verify as correct, and update the information since the last IMPEP review.
2. Information from the IMPEP questionnaire on legislation, regulations, legally binding requirements and other program elements required for compatibility should be used by the principal reviewer as a starting point for discussions with the State.
3. Findings

 a. A “satisfactory” finding may be appropriate in the following circumstances:

1. If the State program has no significant changes to the statutes affecting the program’s regulatory authority, no overdue regulations, legally binding requirements or other program elements, and meets all the other evaluation criteria for this performance indicator in MD 5.6, the review team should recommend to the Management Review Board (MRB) that the State’s performance with respect to this indicator, be found satisfactory.
2. If the State program has adopted all but a few essential regulations or other program elements, and meets all the other evaluation criteria for this performance indicator in MD 5.6, the review team should consider recommending to the MRB that the State’s performance with respect to this indicator, be found “satisfactory.” Essential regulations are usually considered Compatibility Category A or B as defined in NMSS Procedure 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 recommendation:

*1.* Compatibility significance of the rules.

For example, 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 postponed adoption of the less significant rule in order to expedite the adoption of the more significant regulation.

*2.* Rules not needed at the time of the review.

For example, a State may not have issued any licenses for well logging licensees so that “Energy Compensation Sources for Well Logging and Other Regulatory Clarifications,” 10 CFR Part 39 amendment is not necessary at this time. The State has postponed adoption.

iii. If the State program has no overdue regulations or other program elements at the time of the onsite review, but experienced difficulties during the review period adopting regulations within the three-year period, the review team should consider whether the State’s performance with respect to this indicator, be found “satisfactory” or “satisfactory but needs improvement.” The review team will need to consider in their evaluation of this performance indicator the root cause of the delay in promulgation of regulations, the State managements’ actions which addressed and corrected the problem and the compatibility significance of the regulations or elements. For example, 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.

b. A “satisfactory but needs improvement” finding may be appropriate in the following circumstances:

i. If the State program has not adopted several essential regulations or other program elements, the review team should consider whether to recommend to the MRB that the State’s performance with respect to this indicator, be found “satisfactory but needs improvement” or “unsatisfactory.” For a finding of “satisfactory but needs improvement,” one or a combination of the following circumstances may pertain to regulations or program elements that have not been adopted:

*1.* Compatibility significance of the rules.

For example, the adoption of the “Medical Use of Byproduct Material,” 10 CFR 20, 32 and 35 amendments and implementation of “Increased Controls for Risk‑Significant Radioactive Sources” (NRC Order EA‑05‑090) are more significant than “Minor Corrections, Clarifying Changes, and a Minor Policy Change,” 10 CFR Parts 20, 32, 35, 36, and 39 amendments. The State has postponed adoption of the less significant rule in order to expedite the adoption of the more significant regulation and legally binding requirements.

*2.* Rules not needed at the time of the review.

For example, a State may not have issued any licenses for well logging licensees so that “Energy Compensation Sources for Well Logging and Other Regulatory Clarifications,” 10 CFR Part 39 amendment is not necessary at this time. The State has postponed adoption.

*3.* Status of draft regulations within the State’s administrative procedures

A State has experienced difficulties adopting regulations within the three-year period, but the State has drafted regulations and begun the process of promulgating the necessary regulations.

*4.* Status of program elements other than statutes and regulations.

 A State has experienced difficulties in implementing standard format and content of sealed source and device registration certificates and is not consistently reporting events in the appriopriate time frame.

ii. For the review team to consider that the State is 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 to be given consideration for a “satisfactory but needs improvement” finding.

c. An “unsatisfactory” finding may be appropriate in the following circumstances:

I. If the State program has not adopted over ten regulations or other program elements required for compatibility, has experienced difficulties or has often been unable to adopt regulations during the review period, the review team should consider whether the State’s performance with respect to this indicator, be found unsatisfactory or satisfactory but needs improvement.

ii. If a State has not begun drafting regulations or has only an internal draft package that has not been transmitted for external review by stakeholders in the promulgation process, the review team should give consideration for an unsatisfactory finding.

iii. If a State is not retaining records for decommissioning, is not reporting events to the NRC and is not using the criteria for Pre-licensing screening, the review team should give consideration for an unsatisfactory finding.

D. Review Details.

For compatibility requirements, 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 and safety.

b. License, inspect, and enforce legally binding requirements such as regulations and licenses.

2. State statutes are consistent with Federal statutes, as appropriate.

3. The State has adopted legally binding requirements, regulations, and other program elements in accordance with MD 5.9, *Adequacy and Compatibility of Agreement State Programs*, and the current revisions of 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 provisions, or other appropriate measures, necessary to allow the State to ensure adequate protection of public health and safety 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 period(s) for public comment.

6. 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 3 years after the effective date of NRC’s final rule. The NMSS’ Chronology of Amendments is a list of NRC regulation amendments including the NRC effective date. The most recent chronology can be found on the NMSS home page (www.nrc.gov > About NRC > Organization and Functions > Office of Nuclear Material Safety and Safeguards. In the "Related Information" box, select Agreement State Program and then go to "Resources and Tools" and select "State and Tribal Communication Letters”).

7. The status of any regulations currently in the rulemaking process.

8. There is sufficient full‑time equivalent staff (FTE) in the program dedicated to regulation adoption and oversight.

9. The State submits proposed regulations or other generic legally binding requirements following the guidance in NMSS Procedure SA-201, *Review of State Regulatory Requirements*. Specifically, draft rules and generic legally binding requirements are sent to MSTR for review and comment.

10. Other program elements that have been designated as necessary for maintenance of an adequate and compatible program are adopted and implemented within 6 months following NRC designation.

11. The State has implemented legally binding requirements, regulations, and other program elements in accordance with MD 5.9, *Adequacy and Compatibility of Agreement State Programs* and the current revisions of NMSS Procedure SA-200, *Compatibility Categories and Health & Safety Identification for NRC Regulations and Other Program Elements*.

E. 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. APPENDIXES**

A. Frequently Asked Questions

**VII. REFERENCES**

1. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*.

2. Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*.

3. Management Directive 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*.

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 |

**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 with recommendations for 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 essential 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 critical 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 2014, only three regulations have been held in abeyance, that is 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.