

Office of Nuclear Material Safety and Safeguards Procedure Approval

Reviewing the Common Performance Indicator, Status of Materials Inspection Program State Agreements (SA) Procedure SA-101

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Kevin Williams <i>Director, NMSS/MSST</i>	Kevin Williams Digitally signed by Kevin William Date: 2020.09.04 13:17:36 -04'00	^s Date:		
Lizette Roldan-Otero, Ph.E Acting Branch Chief, NMS	Lizette Roldan-Otero Digitally signed by Lizette Roldan-Otero Date: 2020.09.08 07:29:12 -05'00 S/MSST/SALB	Date:		
Joe O'Hara Procedure Contact, NMSS	S/MSST/SALB Digitally signed by Joseph M. O'Hara O'Hara Date: 2020.09.04 14:19:41 -04'00'	Date:		
David Crowley Chair, Organization of Agr	Date:9/15/2020			
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NOTE Any changes to the procedure will be the responsibility of the NMSS Procedure Contact				
Conies of NMSS procedu	res are available through the NRC Web site	at https://scn.prc.gov		

I. INTRODUCTION

This document describes the procedure for conducting reviews of the Agreement States and U.S. Nuclear Regulatory Commission (NRC) radiation control programs (Programs) for the common performance indicator, Status of Materials Inspection Program specified in the U.S. Nuclear Regulatory (NRC) Management Directive (MD) 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*.

II. OBJECTIVES

- A. To verify that initial inspections and inspections of Priority 1, 2, and 3, licensees are performed at the frequency prescribed in NRC Inspection Manual Chapter (IMC) 2800, *Materials Inspection Program*.
- B. To verify that licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 2800 or compatible policy developed by radiation control programs using a similar risk-informed performance-based approach.
- C. To verify that deviations from inspection schedules are approved by Program Management and that the reasons for the deviations are documented.
- D. To verify there is a plan to perform any overdue inspections and reschedule any missed or deferred inspections. To determine a basis has been established for not performing any overdue inspections or rescheduling any missed or deferred inspections.
- E. To verify that inspection findings are communicated to licensees within 30 calendar days, or 45 calendar days for a team inspection, after inspection completion as specified in IMC 0610, *Nuclear Material Safety and Safeguards Inspection Reports* and IMC 2800.

III. BACKGROUND

Periodic inspections of licensed activities are essential to ensure that activities are conducted in compliance with regulatory requirements and consistent with good safety and security practices. Inspection frequency, designated by a priority code, is based on the relative risk of the radiation hazard of the licensed activity. For example, a Priority 1 licensee presents the greatest risk to health and safety of workers, members of the public, and the environment; therefore, Priority 1 licensees require the most frequent inspections. Information regarding the number of overdue inspections is a significant measure of the status of a radiation control inspection program.

IV. ROLES AND RESPONSIBILITIES

A. IMPEP Review Team Leader (Team Leader)

- 1. In coordination with the IMPEP Program Manager, the Team Leader determines which team member is assigned lead review responsibility and assigns other team members to provide support, as necessary.
- 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 relevant documentation, conducts management and staff discussions, and maintains a summary of all statistical inspection information received.
 - 2. Calculates the percentage of Priority 1, 2, 3, and initial inspections completed overdue in accordance with Appendix A: *Overdue Inspection Calculation Worksheet* of this procedure.
 - 3. Verifies that reciprocity inspections are completed in accordance with the NRC's IMC 2800.
 - 4. Reviews inspection communications sent to licensees to verify that findings are communicated to the licensee in accordance with the NRC's IMC 2800.
 - 5. Informs the Team Leader of the team's findings throughout the on-site 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 performance indicator reviewed.
 - 8. Attends the IMPEP Management Review Board meeting presents and discusses the team's findings for the Status of Materials Inspection Program performance indicator (this can be done either in-person or remotely).

V. GUIDANCE

A. Scope

This procedure evaluates the quantitative performance of routine Priority 1, 2, 3 and initial inspections of the Agreement State or NRC program and inspections of reciprocity licensees in accordance with IMC 2800 since the last IMPEP review.

- B. Review Guidelines
 - 1. Evaluate the response generated by the Program to relevant questions in the IMPEP questionnaire. Depending on the level of detail of the information

provided, the response to the questionnaire relative to this indicator may be useful to focus the review.

- 2. Evaluate the status of materials and security inspections by gathering the following information:
 - a. The number of Priority 1, 2, and 3, and initial inspections completed overdue during the review period and overdue at the time of the review;
 - b. The amount of time past the applicable inspection due dates for any Priority 1, 2, and 3, and initial overdue inspections;
 - c. The reason Priority 1, 2, and 3, and initial inspections were completed overdue or are overdue at the time of the review;
 - d. The safety or security significance of not performing or deferring any overdue inspections;
 - e. The timeliness of issuance of inspection findings to licensees;
 - f. The inspection frequencies used by an Agreement State. The reviewer should verify the Program's inspection frequencies are at least as frequent as those listed in IMC 2800. The reviewer should document any Agreement State inspection frequencies that are conducted at frequencies that are longer than those specified in IMC 2800, the Program's rationale for conducting them at a greater frequency, and any impacts to health, safety, security, or the environment. An Agreement State program should not be penalized for failing to meet internally developed inspection schedules that are more aggressive (i.e., licensees or license types that are more frequently inspected) than those specified in IMC 2800;
 - g. Overdue inspections are not determined based on the inspection frequencies established by any Agreement State. The inspection frequencies in IMC 2800 are used as the baseline metric for determining if an inspection is overdue. A number of Agreement States have more aggressive inspection schedules than those prescribed in IMC 2800. However, in cases where an Agreement States inspection frequency is less stringent than IMC 2800, the reviewer should note the difference(s) and determine if there are performance issues as a result. Several Agreement States have set less stringent frequencies for certain categories of licensees. The State needs to have a documented rationale for the difference(s) and the Management Review Board will make the final determination if public health and safety are jeopardized based on the difference(s); and

- h. The performance of reciprocity inspections in accordance with the guidance in IMC2800, or the details of and justification for the Agreement State's or NRC's reciprocity inspection policy.
- C. The Principal Reviewer should evaluate the following during the on-site review:
 - 1. Examine information on the status of routine Priority 1, 2, 3 and initial inspections and reciprocity inspections completed by the Program during the review period.
 - a. If available, the reviewer should examine the inspection information contained in the Program's database. If the Program uses the Web Based Licensing system, information can be obtained by running a query against the new licensing actions (i.e., to determine initial inspection due dates) and inspection activities; or,
 - b. If the Program does not have a database or such data cannot be easily retrieved or provided, to cross-reference and verify information, the reviewer should examine a representative number of Priority 1, 2, and 3 and reciprocity inspection records, as well as other relevant documents involving inspection findings, using the following guidance:
 - i. All inspections performed since the last IMPEP review are subject for review.
 - ii. The reviewer should sample as many inspections as possible to determine the rating for this indicator and note in the report that only a sampling was performed. This means that the team members will need to pull files and review information from inspection reports. The reviewer will need to document in the report the values and assumptions used for the overdue calculation based on the sampling. If possible, the reviewer should include in the report the total number of Priority 1, 2, and 3 and initial inspections conducted by the Program during the review period, as well as the number that were overdue for inspection at the time of the review.
 - iii. A risk-informed sample of the Program's inspections based on safety and security significance should be selected. The selected inspection casework should focus on the Program's highest-risk licensed activities. The use of risk-informed sampling, rather than random sampling, maximizes the effectiveness of the review of casework. The sampling should also ensure inclusion of the full range of Priority 1, 2, and 3 modalities licensed by the Agreement States and NRC (e.g., industrial, medical, academic) as well as a representative sample of security inspections of Category 1 and 2 risk significant radioactive material and service provider licensees.

- 2. Determine the percentage of overdue Priority 1, 2, and 3, and initial inspections for the review period. Appendix A of this procedure contains guidance for the overdue inspection calculation with a sample worksheet for use by the reviewer.
 - a. Routine inspections of Priority 1 and 2 licensees are considered overdue if the inspections exceed the IMC 2800 frequencies plus the following applicable maximum window:
 - i. Priority 1 inspections completed greater than 6 months past the inspection due date;
 - ii. Priority 2 inspections completed greater than 12 months (1 year) past the inspection due date; and,
 - b. Routine inspections of Priority 3 and 5 licensees and telephonic contact of Priority T licensees are considered overdue if the inspections or contact exceed the IMC 2800 frequencies plus 1 year.
 - c. Initial inspections are normally considered overdue if the inspections are performed greater than 12 months after the date of issuance of the license, however, if the licensee does not yet possess licensed material or has not yet performed any principal activities, the initial inspection may be rescheduled to within 18 months of license issuance. When determining the number of initial inspections performed or overdue, all initial inspections must be included. This includes initial inspections of all priority codes, including Priority 5.
 - d. Reciprocity inspections are evaluated separately and should not be included in the calculation.
 - e. The information and definitions in IMC 2800 should be used when making a calculation and determining the status of inspections in Appendix A. If the Agreement State program defines overdue inspections using different definitions than the NRC, the reviewer should note the differences in terminology or definitions in the IMPEP report.
- 3. Attempt to ascertain the reason(s) for any overdue inspections. This can be accomplished through discussions with individual inspectors as well as Program management.
- 4. Include an assessment of the issuance of inspection findings. Inspection findings in most cases should be provided to licensees within 30 days of the exit meeting with the licensee or 45 days of the exit meeting with the licensee for a team inspection, or a time period specified in the compatible Agreement State procedure.

- 5. Evaluate the performance of reciprocity inspections in comparison to the criteria in IMC 2800 and the NRC or Agreement State reciprocity policy.
- 6. Review the Agreement State Program's inspection frequencies. While this indicator primarily focuses on quantitative performance, the reviewer should also include a qualitative evaluation of an Agreement State Program's inspection frequencies. If the Agreement State Program's inspection frequencies deviates from the frequencies established in IMC 2800, the reviewer should evaluate what if any health, safety, and/or security impacts have occurred as a result of the deviation. Additionally, the reviewer should ensure documentation exists that justifies why the deviation in inspection frequency exists.
- 7. Flexibility may be used to make the determination of the rating for this indicator. The reviewer should consider the status of the Program and any mitigating factors that may have prohibited the Program from conducting inspections during the review period. The reviewer's assessment should include the examination of plans to perform any overdue inspections or reschedule any missed or deferred inspections. The reviewer should determine that a basis has been established by the Program for not performing any overdue inspections or rescheduling any missed or deferred inspections.
 - a. For example, if a State has no overdue inspections at the time of the review and has addressed the root cause of the overdue inspections, then there may not be any performance issue and as such, a finding of satisfactory may be appropriate (also taking into consideration the other factors for this indicator). However, if the State has not addressed the root cause of the overdue inspections or has not developed a management plan or other effort to address the issue, then a rating of satisfactory, but needs improvement, or unsatisfactory may be appropriate (also taking into consideration the other factors for this indicator). Additionally, review teams may make specific recommendations to address these types of performance issues.
- D. Review Information Summary

At a minimum, the summary maintained by the reviewer should include the following information:

- 1. Number of Priority 1, 2, and 3 inspections that were completed on time during the review period;
- 2. Number of Priority 1, 2, and 3 inspections that were completed overdue during the review period, and the range of time past due the inspections were completed;

- 3. Number of Priority 1, 2, and 3 inspections that are overdue at the time of the review, and the range of time past due the inspections are at the time of the review;
- 4. Number of initial inspections that were completed on time during the review period;
- 5. Number of initial inspections that were completed overdue during the review period, and the range of time past due the inspections were completed;
- 6. Number of initial inspections that are overdue at the time of the review, and the range of time past due the inspections are at the time of the review;
- 7. Number of reciprocity licensees for each year of the review period and the number of reciprocity inspections that were completed during each year of the review period; and
- 8. Number of inspection findings from Priority 1, 2, and 3, and initial inspections that were issued to the licensees more than 30 days, or 45 days for a team inspection, after the inspection exit meeting was held and the amount of time past the due date that the late inspection findings were sent or are overdue. The reviewer should also document the reason any inspection findings were dispatched overdue.
- E. Evaluation Process
 - 1. The reviewer should refer to Part III, *Evaluation Criteria*, of MD 5.6 for specific evaluation criteria. As noted in MD 5.6, the criteria for a satisfactory Program is as follows:
 - a. Less than 10 percent of initial and high priority licensees (Priority 1, 2, and 3) are inspected at frequencies greater than those prescribed in IMC 2800 or compatible Agreement State procedure.
 - b. Inspection findings are communicated to the licensee according to the criteria prescribed in IMC 2800 or compatible Agreement State procedure.
 - c. Reciprocity inspections are performed in a manner that meets the requirements identified in IMC 2800 and applicable guidance, or compatible Agreement State procedures; or the Agreement State program has developed and successfully implemented an alternative policy for reciprocity inspections in lieu of IMC 2800 and applicable guidance, using a similar risk-informed, performance-based approach for determining reciprocity licensees.

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

- 2. The IMPEP Team should follow the guidance provided in SA-100, Implementation of the Integrated Materials Performance Evaluation Program (IMPEP), regarding discussions related to this indicator with inspectors, supervisors, and managers.
- 3. If performance issues are identified, the reviewer should consider whether the root causes of these issues affect more than the Status of Materials Inspection Program Indicator. Issues impacting this performance indicator could have a negative impact on other performance indicators. As a general matter, a performance issue, and associated root causes, should be assigned to only the most appropriate performance indicator and not counted against multiple indicators.
- F. Discussion of Findings with the Radiation Control Program
 - 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. APPENDIX

Overdue Inspection Calculation Worksheet

VII. REFERENCES

Management Directives (MD) available at https://scp.nrc.gov.

NMSS SA Procedures available at <u>https://scp.nrc.gov</u>.

NRC Inspection Manual Chapters available at <u>https://www.nrc.gov/reading-rm/doc-</u>collections/insp-manual/manual-chapter/.

NRC Inspection Procedures available at <u>https://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/</u>.

NRC Generic Communications available at <u>https://www.nrc.gov/reading-rm/doc-collections/gen-comm/</u>.

NRC/Agreement State Working Groups available at <u>https://scp.nrc.gov</u>.

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 ADAMS.

No.	Date	Document Title/Description	Accession Number
1	10/24/02	STP-02-074, Opportunity to Comment on Draft Revisions to STP Procedure SA-101	ML022970629
2	01/24/03	Summary of Comments on SA-101	ML031130704
3	04/04/03	STP Procedure SA-101	ML031080519
4	04/19/07	FSME-07-037, Opportunity to Comment on Draft Revision to FSME Procedure SA-101	ML071090427
5	06/14/07	Summary of Comments on SA-101	ML072160015
6	07/23/07	FSME Procedure SA-101	ML072160012
7	03/28/16	STC-16-028, Closeout of Temporary Instructions TI-001 and 002	ML16084A626
8	04/27/16	Closeout Memo of Independent Review Panel/Materials Program Working Group Recommendation for TI 001 and 002	ML16041A299
9	12/18/19	STC-19-079, Opportunity to Comment of Interim SA-101	ML20183A152 ML20183A153
10	12/18/19	Interim NMSS Procedure SA-101	.ML19353A763
11	07/22/20	Resolution of Comments	.ML20184A180
12	09/25/20	Final NMSS Procedure SA-101	ML20220A475

Guidance for calculating the number of overdue inspections:

- 1. Priority 1, 2, and 3 inspections and all initial inspections are considered in the calculation. An inspection will be considered overdue if it falls under one of the following cases:
 - a. A Priority 1 inspection completed greater than 6 months past the inspection due date (18 months since the start of the last inspection);
 - b. A Priority 2 inspection completed greater than 12 months past the inspection due date (36 months since the start of the last inspection);
 - c. A Priority 3 inspection completed greater than 12 months past the inspection due date (48 months since the start of the last inspection); and
 - d. An initial inspection completed greater than 12 months from the date of license issuance, or greater than 18 months if the licensee did not possess licensed material in the first 12 months.
- 2. Inspection frequencies are compared to the NRC inspection priorities listed in IMC 2800 rather than the Program's internal inspection frequencies.
- 3. Multiple overdue inspections for the same licensee are counted as a single event. Depending on the inspection priority, there may be more than one inspection for a specific licensee conducted during the review period. However, if more than one inspection is significantly overdue and/or not yet completed, the reviewer should count them as one missed or overdue inspection but should note examples of the overdue ranges for the IMPEP report. The IMPEP policy is to credit the Program for the inspections they perform yet keep track of how late overdue inspections were eventually conducted. Thus, inspections that "should have been performed" are not double or triple counted in the calculation, but the reviewer should document how late the overdue inspection was performed or if it is still overdue at the time of the review.

For example, if a Program inspects a Priority 1 licensee only once in a 4-year period, this is counted as one overdue inspection and the reviewer should note the number of months exceeding the 18-month grace period. Even though the inspection could be overdue 30 months, it would be counted as one overdue inspection.

4. The percentage of overdue inspections during the review period should be calculated as follows:

Multiply the ratio below by 100 to obtain the percentage.

<u>Number of Priority 1, 2, and 3 and initial inspections overdue</u> Number of Priority 1, 2, and 3 and initial inspections completed

For example:

$$\frac{\% \text{ overdue} = 100 \text{ x}}{(\text{PCO} + \text{PU} + \text{ICO} + \text{IU})}$$

$$(\text{PCO} + \text{PU} + \text{ICO} + \text{IU} + \text{PC} + \text{IC})$$

Where:

PCO = number of Priority 1, 2, and 3 inspections completed overdue during the review period

PU = number of Priority 1, 2, and 3 inspections overdue at the time of the review

PC = number of Priority 1, 2, and 3 inspections completed on time during the review period

ICO = number of initial inspections completed overdue during the review period

IU = number of initial inspections overdue at the time of the review

IC = number of initial inspections completed on time during the review period

5. The following is a sample calculation:

The Program performed 80 Priority 1, 2, and 3 inspections on time during the review period and ten (10) Priority 1, 2, and 3 inspections were performed overdue during the review period. Additionally, at the time of the review there was two (2) Priority 1, 2, or 3 inspections that are still overdue. The Program performed ten (10) initial inspections on time during the review period and performed five (5) initial inspections overdue during the review period. At the time of the review, there was one (1) initial inspection that was still overdue.

PCO = 10 PU = 2 PC = 80 So: $\% = 100 \times (\frac{PCO + PU + ICO + IU}{(PCO + PU + ICO + IU)})$ (PCO + PU + ICO + IU + PC + IC) $= 100 \times (\frac{10 + 2 + 5 + 1}{(10 + 2 + 5 + 1 + 80 + 10)})$ $= 100 \times 18/108 = 16.7\%$

6. The overdue inspection calculation is just one piece of information that the reviewer uses to determine the appropriate rating for this indicator. Regardless of how close a calculation is to 25 percent (or 10 percent), the reviewer should take the Program's overall performance involving the other aspects of this indicator, (e.g., the root cause of the overdue inspections and the Program Management's actions to address the issues) into account when determining an appropriate rating for this indicator.

State/NRC_____ Time period covered by IMPEP Review _____

One entry per inspection

INSPECTION STATUS REVIEWER WORKSHEET						
Entry #	Licensee Name	License Number	Priority 1, 2 3, or initial	Last inspection date or license issued date, if initial inspection	Date due	50% window for Priority 1 and 2 1-year window for Priority 3 No window for initial
1	Sample Company A	12-2345	1	1/1/13	1/1/14	7/1/14
2	Sample Company B	23-4567	Initial	5/1/13	5/1/14	N/A

INSPECTION STATUS REVIEWER WORKSHEET (cont.)						
Entry	Date Performed	Amount of time overdue	Date inspection completed	Date inspection findings issued	Report issued within 30 days, 45 days for team inspection if not, days over	
0	9/1/14	2 months	9/1/14	9/15/14	Yes	
0	7/1/14	2 months	7/1/14	8/20/14	No – 18 days	