



## Office of Nuclear Material Safety and Safeguards State Procedure Approval

### ***Reviewing the Common Performance Indicator, Status of Materials Inspection Program SA-101***

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#### **NOTE**

***Any changes to the procedure will be the responsibility of the Procedure Contact. Copies of the procedures are available through the NRC Website.***


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## I. INTRODUCTION

This document describes the procedure for conducting reviews of the U.S. Nuclear Regulatory Commission (NRC) and Agreement State radioactive materials programs using the common performance indicator, Status of Materials Inspection Program [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 candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 1220, *Processing of NRC Form 241, "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters," and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20*. (Note: Agreement State programs can develop an alternative policy for reciprocity inspections in lieu of IMC 1220, using a similar risk-informed performance-based approach for determining reciprocity licensees that are candidates for inspection.)
- C. To verify that deviations from inspection schedules are coordinated between technical staff and management.
- D. To verify that there is a plan to perform any overdue inspections and reschedule any missed or deferred inspections. To determine that 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 in a timely manner (30 calendar days after inspection completion as specified in IMC 0610, *Nuclear Material Safety and Safeguards Inspection Reports*).

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### 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 (every year). Information regarding the number of overdue inspections is a significant measure of the status of a radioactive materials inspection program. In order to determine this information, the capability for maintaining and retrieving statistical data on the status of an inspection program must exist.


### IV. ROLES AND RESPONSIBILITIES

#### A. Team Leader

Determines which team member(s) is assigned as the principal reviewer for this performance indicator.

#### B. Principal Reviewer

1. Meets the appropriate requirements specified in MD 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*.
2. Reviews relevant documentation, conducts management and staff discussions, and maintains a summary of all statistical information received.
3. Informs the Team Leader of their findings throughout the review.
4. Completes their portion of the IMPEP report for the performance indicator(s) reviewed.

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5. Attends the IMPEP Management Review Board meeting for the review and is prepared to discuss their findings (this can be done either in-person or via teleconference).


## V. GUIDANCE

### A. Scope

1. This procedure specifically excludes inspections of licensees that are not authorized for the possession, use, or storage of byproduct material, as defined in 10 CFR 20.1003.
2. This procedure applies to the review of the status of radioactive materials inspection activities in NRC and the Agreement States.
3. This procedure evaluates the quantitative performance of the NRC Region or Agreement State over the review period, which is the period of time since the last IMPEP review.
4. This procedure does not apply to the status of inspections related to the non-common indicators, i.e. uranium recovery program and low-level radioactive waste program. Refer to the specific SA procedure applicable to non-common indicator review.

### B. Evaluation Procedures

1. The principal reviewer should refer to Part III, *Evaluation Criteria*, of MD 5.6 for specific evaluation criteria. The criteria should be applied to the data on inspections during the entire review period, and should not focus on the status of the NRC or Agreement State inspection program during only a particular portion of the review period (i.e. beginning of the review period or at the time of the review only).
2. The principal reviewer should examine any information on the status of inspections completed by the NRC Region or Agreement State during the review period.

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- a. If available, the principal reviewer should examine the inspection information contained in the program's database; 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 candidate 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 candidates for review.
    - ii. The principal reviewer should perform a risk-informed sample of the program's inspections based on safety and security significance. The selected inspection casework should focus on the program's highest-risk licensees. 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 NRC and Agreement States (e.g. industrial, medical, academic) as well as a representative sample of security inspections of high risk IAEA Category 1 and 2 sources and service provider licensees.
3. As part of the evaluation criteria for this indicator, the principal reviewer will determine the percentage of overdue Priority 1, 2, and 3, and initial inspections for the review period. Appendix A contains guidance for the overdue inspection calculation with a sample worksheet for use by the principal reviewer.
  - a. Inspections of Priority 1, 2, and 3 licensees are considered overdue if the inspections exceed the IMC 2800 frequencies plus the following applicable maximum window (25 percent of the assigned inspection interval):




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- i. Priority 1 inspections completed greater than 3 months past the inspection due date;
    - ii. Priority 2 inspections completed greater than 6 months past the inspection due date; and,
    - iii. Priority 3 inspections completed greater than 9 months past the inspection due date.
  - b. Initial inspections are considered overdue if the inspections were performed greater than 12 months after the date of issuance of the license.
  - c. Reciprocity inspections are evaluated separately and should not be included in the calculation.
  - d. The principal reviewer should use the information and definitions in IMC 2800, for consistency, when determining the status of inspections. If the NRC Region or Agreement State defines overdue inspections using different definitions, a reasonable attempt should be made to make the calculation using the information and definitions from IMC 2800. This may be achieved by reviewing inspection casework files and applying the information to the worksheet in Appendix A. If the reviewer is unable to calculate the status of inspections using the information and definitions in IMC 2800, the reviewer may use the NRC Region's or Agreement State's data or information, but must note the differences in terminology or definitions in the IMPEP report.
4. The principal reviewer should attempt to ascertain the reason(s) for any overdue inspections. This can be accomplished through discussions with individual inspectors as well as Program management.

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5. The review should include an assessment of the issuance of inspection findings. Inspection findings should be provided to licensees within 30 days of completion of the inspection. If the inspection findings are not related to items important to health and safety or security, some flexibility in the dispatch of inspection findings may be given due to mitigating circumstances.
6. The performance of reciprocity inspections should be evaluated in comparison to the criteria in IMC 1220 or alternative Agreement State policy.
7. While this indicator primarily focuses on quantitative performance, review of this indicator should also include a qualitative evaluation of the justifications for an Agreement State to revise its internal inspection frequencies or deviate from those specified in IMC 2800.
8. In applying the criteria, some flexibility may be used to make the determination of the rating for this indicator. The review team should take into account the current status of the program and any mitigating factors that may have prohibited the program from conducting timely inspections during the review period. The review team's assessment should include the examination of plans to perform any overdue inspections or reschedule any missed or deferred inspections. The principle 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. For example, if greater than 25 percent of the Priority 1, 2, and 3, and initial inspections completed during the review period were completed overdue, yet the inspections were completed within a reasonable period of time past the due date or management took appropriate steps to work off a significant inspection backlog, an unsatisfactory rating may not be appropriate. In such cases, the principal reviewer should discuss the matter with the IMPEP Team Leader and be prepared to give justification for the rating.

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9. If any significant problems or issues are identified (e.g., a preliminary finding that one or more categories of licenses are being inspected at a frequency that is less stringent than that specified in IMC 2800 – a longer inspection interval), the principal reviewer should immediately discuss this preliminary finding with the Team Leader, who will provide guidance to the reviewer on how best to obtain additional information from the NRC or Agreement State that might explain the situation. The Agreement State must have documented a rationale for setting longer inspection intervals than specified in IMC 2800. In addition to reviewing the rationale, to understand the deviation in inspection frequency, a discussion with first-level NRC or State management would be in order.

#### C. Review Guidelines

1. The response generated by the NRC or Agreement State to relevant questions in the IMPEP questionnaire should be used to focus the review.
2. The principal reviewer should be familiar with IMC 2800, which prescribes inspection frequencies. The principal reviewer should also be familiar with IMC 1220, which provides criteria for performing reciprocity inspections. The principal reviewer should also be cognizant of any additional inspection guidance, such as Temporary Instructions, that may describe deviations in inspection frequencies.
3. When reviewing the NRC Program, the principal reviewer should consult with the appropriate contact in the Office of Nuclear Material Safety and Safeguards (NMSS) to obtain the most current statistical information regarding the inspection performance. WBL can also be extremely useful in obtaining information such as the inspection type, dates, and summary of findings. NMSS compiles such data on a routine basis and is capable of sorting overdue inspections by inspection priority and by State. In addition, NMSS normally maintains correspondence between Headquarters and the Regions that may relate to revised inspection performance goals or other programmatic adjustments.




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4. When reviewing an Agreement State, the principal reviewer should use inspection data provided by the State from the questionnaire and information provided during the on-site review. The State 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. In addition, the reviewer should be sure that overdue inspections are tallied in a consistent fashion, (i.e., counting Priority 1, 2, and 3 licensees as overdue only when the inspection date exceeds the 25 percent window specified in IMC 2800.)
5. For inspection of reciprocity licensees, the criteria for determining candidate licensees are specified in IMC 1220, Appendix III.

**D. Review Details**

To evaluate the status of materials and security inspections, the principal reviewer should evaluate the following:

1. The number of overdue Priority 1, 2, and 3, and initial inspections;
2. The amount of time past the applicable inspection due dates for any Priority 1, 2, and 3, and initial overdue inspections;
3. The reason Priority 1, 2, and 3, and initial inspections were completed overdue or are overdue at the time of the review;
4. The safety or security significance of not performing or deferring any overdue inspections;
5. The timeliness of issuance of inspection findings to licensees;

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6. The inspection frequencies used by an Agreement State and verify they are at least as frequent as those listed in IMC 2800. The principal reviewer should document any Agreement State inspection frequencies that are conducted at frequencies that are longer than those specified in IMC 2800;
7. The performance of reciprocity inspections in accordance with the guidance in IMC 1220, or the details of and justification for the NRC or Agreement State's alternative reciprocity inspection policy;
8. The NRC or Agreement State's method for determining inspection timeliness and the method's consistency with IMC 2800. Certain notifications by licensees and non-inspection visits to licensee facilities should not be counted as inspections. For example, telephone and written notifications should be documented, but not counted as inspections.
9. The protocol employed by the NRC or Agreement State to reduce inspection intervals based on poor licensee performance;
10. Any deviations from inspection schedules and verify that they are normally coordinated between inspectors and program management.

**E. Review Information Summary**

At a minimum, the summary maintained by the principal 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;

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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 that were candidates for inspection for each year of the review period, as described in IMC 1220 or alternative Agreement State policy, and the number of reciprocity inspections of candidate licensees that were completed during each year of the review period;
8. Number of inspection findings from Priority 1, 2, and 3, and initial inspections that were issued to the license more than 30 days after the inspection during the review period, or are overdue at the time of the review, and the amount of time past the proper dispatch date that the late inspection findings were sent or are overdue. The principal reviewer should also document the reason any inspection findings were dispatched overdue.

F. Discussion of Findings with NRC or State.

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 reviewers, supervisors, and management.


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## VI. APPENDIXES

- A. Overdue Inspection Calculation Worksheet
- B. Frequently Asked Questions

## VII. REFERENCES

1. NMSS Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*, ML070330665.
2. Inspection Manual Chapter 0610, *Nuclear Material Safety and Safeguards Inspection Reports*.
3. Inspection Manual Chapter 1220, *Processing of NRC Form 241, "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters," and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20*.
4. Inspection Manual Chapter 2800, *Materials Inspection Program*.
5. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program*, ML041410578.
6. NRC Management Directive 5.10, *Formal Qualifications for IMPEP Team Members*, ML041410573.

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## 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	10/24/02	STP-02-074, Opportunity to Comment on Draft Revisions to STP Procedure SA-101	ML022970629
2	1/24/03	Summary of Comments on SA-101	ML031130704
3	4/4/03	STP Procedure SA-101	ML031080519
4	4/19/07	FSME-07-037, Opportunity to Comment on Draft Revisions to FSME Procedure SA-101	ML071090427
5	6/14/07	Summary of Comments on SA-101	ML072160015
6	7/23/07	FSME Procedure SA-101	ML072160012

# **Appendix A**

## **Overdue Inspection Calculation Worksheet**

Guidance for calculating the number of overdue inspections:

1. Inspections considered in the calculation are Priority 1, 2, and 3 inspections and all initial inspections. An inspection will be considered overdue if it falls under one of the following cases:
  - a. A Priority 1 inspection completed greater than 3 months past the inspection due date (15 months total);
  - b. A Priority 2 inspection completed greater than 6 months past the inspection due date (30 months total);
  - c. A Priority 3 inspection completed greater than 9 months past the inspection due date (45 months total);
  - d. An initial inspection completed greater than 1 year from the date of license issuance
2. Inspections are always compared to NRC Priorities in IMC 2800.
3. Multiple overdue inspections for the same licensee are counted as a single event. Depending on the 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 principal reviewer should count them as one missed or overdue inspection, but should note examples of the overdue ranges for the IMPEP report.

For example, if only one inspection was conducted for a Priority 1 licensee during a four year period, for the purpose of the overdue inspection calculation, this would be considered one (1) overdue inspection and the reviewer should note the number of months exceeding the 15 month period. Even though the inspection could be overdue 30 months, it would still be counted as one (1) overdue inspection.

## Appendix A (continued)

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

$$\% \text{ overdue} = 100 \times$$

$$\frac{\text{Number of Priority 1, 2, and 3 and initial inspections not completed on time per NRC IMC 2800}}{\text{Number of Priority 1, 2, and 3 and initial inspections that should have been completed}}$$

To determine the numerator and denominator:

$$\% \text{ overdue} = 100 \times$$

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

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:

Say 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.

$$\begin{aligned} \text{PCO} &= 10 \\ \text{PU} &= 2 \end{aligned}$$

$$\begin{aligned} \text{PC} &= 80 \\ \text{ICO} &= 5 \end{aligned}$$

$$\begin{aligned} \text{IU} &= 1 \\ \text{IC} &= 10 \end{aligned}$$

So:

$$\% = 100 \times \frac{(\text{PCO} + \text{PU} + \text{ICO} + \text{IU})}{(\text{PCO} + \text{PU} + \text{ICO} + \text{IU} + \text{PC} + \text{IC})}$$

$$= 100 \times \frac{(10 + 2 + 5 + 1)}{(10 + 2 + 5 + 1 + 80 + 10)}$$

$$= 100 \times \frac{18}{108} = 16.7\%$$



Time Period covered by IMPEP Review

### One entry per inspection

[illegible]

## **Appendix B**

### **Frequently Asked Questions**

- Q1: Is there any leniency to counting overdue inspections of Priority 1, 2, and 3 licensees as the NRC IMC 2800 frequency plus 25 percent?
- A1: No. For Priority 1, 2, and 3 inspections completed over the 25 percent, the inspection should be considered overdue and documented as such in the calculation. Review teams may take other mitigating factors into consideration and describe them in the narrative portion of the report as appropriate.
- Q2: If a program inspects a Priority 1 licensee only once in a 3-year period, why do we only count that as one overdue inspection?
- A2: 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.
- Q3: How important is the overdue inspection calculation to the rating for this indicator? For example, what if the number of overdue inspections turns out to be just under or over 25 percent?
- A3: The overdue inspection calculation is just one piece of information that the review team uses to determine the appropriate rating for this indicator. Regardless of how close a calculation is to 25 percent (or 10 percent), the review team should take the program’s overall performance involving the other aspects of this indicator, 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.
- Q4: What if the data necessary to perform the overdue calculation is not easy to get or determine?
- A4: In this case, the review team should sample as many inspections as possible to help 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 review team will need to document in the report the values and assumptions used for the overdue calculation based on the sampling. If possible, the review team 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.

Q5: What if a State deviates from the inspection frequencies prescribed in IMC 2800?

A5: 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 review team 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).

Q6: What if a State conducted many Priority 1, 2, and 3, and initial inspections overdue during the review period as a result of staff turnover, but have caught up on all the overdue inspections at the time of the review?

A6: 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.

Q7: For the initial inspections, are only Priority 1, 2, and 3 licensees counted in the calculation?

A7: No. 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.

Q8: If the State has an alternative policy for reciprocity inspections, what criteria should the IMPEP team use to determine if the alternative policy is acceptable?

A8: The alternative policy allows the states the maximum flexibility in crafting a policy unique to their own circumstances to ensure a risk informed, performance based, approach to inspecting reciprocity licensees. Given the unique circumstances that each State faces, the NRC concluded that setting fixed numerical minimum

## **Appendix B (continued)**

requirements was not a practical approach.

If an Agreement State does have an alternative policy, the review team should review the State's policy and consider the following items:

- a) Does the policy have clear criteria to select the candidate licensees that operate under reciprocity?
- b) Does the policy have performance measures to demonstrate that the State is conducting a sufficient number and type of reciprocity inspections to ensure safety and security are protected and the program does not create any gaps, duplicates or gaps in the National Materials Program?
- c) If the State does not meet its performance measure under the alternative policy, was an evaluation conducted and corrective action taken?
- d) Does the policy require a representative sample of high risk (priority 1 through 3), IAEA Category 1 and 2 sources and service providers to be inspected?
- e) Does the policy take into account the compliance history of the reciprocity licensee?
- f) Does the policy achieve a consistency in the selection process by ensuring the right number of licensees are inspected and not a specified percentage of licensees types.

The IMPEP team should review an Agreement State's alternative policy in the same manner as those States who use the criteria in IMC 1220. The questions above can serve as guide, but the team should be open to innovative approaches used by the Agreement States to select candidate licensees.