



FSME Procedure Approval

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

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NOTE

These procedures were formerly issued by the Office of State and Tribal Programs (STP). Any changes to the procedure will be the responsibility of the FSME Procedure Contact as of October 1, 2006. Copies of FSME procedures will be available through the NRC website.



Procedure Title:
***Reviewing the Common Performance Indicator,
Status of Materials Inspection Program***
Procedure Number: SA-101

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I. INTRODUCTION

This document describes the procedure for conducting reviews of the U.S. Nuclear Regulatory Commission (NRC) Regional 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 core inspections are performed at the proper interval, as prescribed in NRC Inspection Manual Chapters (IMC) 2800, *Materials Inspection Program*. Note: As used in this procedure, the phrase “core inspections” refers to all initial inspections of new licensees and all routine inspections of Priority 1, 2, and 3 licensees.
- B. To verify that candidate reciprocity licensees are inspected in accordance with the frequencies 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*.
- C. To confirm that deviations from inspection schedules are normally coordinated between technical staff and management.
- D. To determine that there is a plan to reschedule any missed or deferred inspections or a basis has been established for not rescheduling any missed inspections.
- E. To confirm that inspection findings are communicated to licensees in a timely manner (30 calendar days as specified in IMC 0610, *Inspection Reports*).

III. BACKGROUND

Periodic inspections of licensed operations are essential to ensure that activities are conducted in compliance with regulatory requirements and consistent with good safety practices. Inspection frequency, designated by a priority, is based on the potential radiation hazard of the licensee's program. For example, a Priority 1 licensee presents the greatest risk to public health and safety and the environment and thus requires 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, and thus 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. Reviews relevant documentation, conducts staff discussions, and maintains a summary of all statistical information received.
2. Meets the appropriate requirements specified in MD 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program Team Members*.

V. GUIDANCE

A. Scope

1. This procedure specifically excludes inspections of non-Atomic Energy Act materials or licensees.
2. This procedure applies to the review of the status of radioactive materials inspection activities common to the NRC and the Agreement States.
3. This procedure evaluates the quantitative performance of the NRC Region or Agreement State over the period of time since the last IMPEP review. This time frame is defined as the review period.

B. Evaluation Procedures

1. The principal reviewer should refer to Part III (Evaluation Criteria) of MD 5.6 for specific evaluation criteria. These criteria should be applied to the data on inspections during the entire review period, not to the status of the NRC Regional or Agreement State inspection program at the time of the

review only. The Glossary in MD 5.6 defines the terms "Materials Inspections" and "Overdue Core Inspections."

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.
 - a. If available, the principal reviewer should examine any computer printouts of inspection information generated from the program's database; and,
 - b. If such lists cannot be provided and/or to evaluate the timeliness of issuance of inspections results to licensees, the reviewer should examine a representative number of core and reciprocity inspection records, as well as documents involving inspection findings, using the following guidance:
 - i. All inspections performed since the last IMPEP review are candidate for review.
 - ii. The principal reviewer should perform a risk-informed sample of the program's inspections based on safety 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. By focusing on safety significant actions, the reviewer has a greater probability of identifying programmatic weaknesses that would have the greatest impact on public health and safety.
3. As part of the evaluation criteria for this indicator, the principal reviewer will determine the percentage of overdue core inspections for the review period. Appendix A contains in-depth 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 that exceed the IMC 2800 frequencies plus the following applicable maximum window (25 percent of the assigned inspection interval):

- 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 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 MD 5.6 Glossary definitions, 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 definitions from MD 5.6. This may have to 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 MD 5.6 definitions, the reviewer may use the NRC Region's or Agreement State's figures, but must note the differences in terminology or definitions in the IMPEP report.
4. The principal reviewer should examine the geographic distribution of overdue inspections and note whether the numbers are disproportionate to the State-wide or Region-wide distribution of licenses.
 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 health and safety are not compromised, some flexibility may be given due to certain circumstances.
 6. The performance of reciprocity inspections should be evaluated in comparison to the requirements of IMC 1220.
 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.

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 reschedule any missed or deferred inspections or the basis established by the program for not rescheduling the inspections. For example, if greater than 25 percent of the core 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 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.
9. If any significant problems or issues are identified (e.g., a preliminary finding that one or more large categories of licenses are not being inspected at the appropriate interval), the principal reviewer should immediately discuss this preliminary finding with the team leader, who will instruct the reviewer how best to obtain additional information from the NRC Region or Agreement State that might explain the situation. In most cases, a discussion with first-level Regional or State management would be the preferred option.

C. Review Guidelines

1. The response generated by the NRC Region 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 for core inspections. The principal reviewer should also be familiar with IMC 1220, which prescribes inspection frequencies for reciprocity inspections. The principal reviewer should also be cognizant of any additional guidance, such as Temporary Instructions, concerning inspection frequencies.

3. When reviewing an NRC Region, the principal reviewer should consult with the appropriate contact in the Office of Federal and State Materials and Environmental Management Programs (FSME) to obtain the most current statistical information regarding the Region's inspection performance. FSME compiles such data on a monthly basis and is capable of sorting overdue inspections by inspection priority and by State. In addition, FSME normally maintains correspondence between Headquarters and the Regions that may relate to revised inspection performance goals or other programmatic adjustments.
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 than those specified in IMC 2800. In addition, the reviewer should be sure that overdue inspections are tallied in a consistent fashion, (i.e., those more than 25 percent past the frequency specified in IMC 2800.) 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 inspections, the principal reviewer should evaluate the following:

1. The number of overdue core inspections;
2. The amount of time past the applicable inspection due dates for any core overdue inspections;
3. The reason core inspections were completed overdue;
4. The safety significance of canceling or deferring any overdue inspections;
5. The timeliness of issuance of inspection findings to licensees;
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 do not match those detailed in IMC 2800 for inclusion in the IMPEP report;

7. The performance of reciprocity inspections in accordance with the guidance in IMC 1220 or the details of and justification for the Agreement State's alternative reciprocity inspection policy;
8. The NRC Region's or Agreement State's method for determining inspection timeliness and the method's consistency with IMC 2800. Certain notifications and visits 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 Region or Agreement State to reduce or extend inspection frequencies based on 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 overdue during the review period and the range of time past due the inspections were completed;
2. 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;
3. Number of Priority 1, 2, and 3 inspections that were completed during the review period;
4. Number of initial inspections that were completed overdue during the review period and the range of time past due the inspections were completed;
5. 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;
6. Number of initial inspections that were completed during the review period;

7. Number of reciprocity licensees that are candidates for inspection per year as described in IMC 1220 and the number of reciprocity inspections of candidate licensees that were completed each year during the review period;
 8. Number of inspection findings from core inspections that were sent to the licensee 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 late.
- F. Discussion of Findings with Region or State.

The reviewer should follow the guidance given in FSME Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*, for discussing technical findings with reviewers, supervisors, and management.

VI. APPENDIXES

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

VII. REFERENCES

1. FSME Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*.
2. Inspection Manual Chapter 0610, *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*.
6. NRC Management Directive 5.10, *Formal Qualifications for IMPEP Team Members*.

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

Appendix A

Overdue Inspection Calculation Worksheet

Guidance for calculating the number of overdue core inspections:

1. Core inspections include Priority 1, 2, and 3 inspections and all initial inspections. A core 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
2. Inspections are always compared to NRC priorities in IMC 2800.
3. Multiple due inspections for the same licensee are counted as a single event. Depending on the Priority, the reviewer could expect to have more than one inspection for a specific licensee conducted during a four year 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, 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 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 1 overdue inspection.

Appendix A (continued)

4. The percentage of overdue inspections should be calculated as follows:

$$\% = 100 \times \frac{\text{Number of core inspections not completed on time by NRC IMC 2800}}{\text{Number of core inspections that should have been completed}}$$

Or, to break it down, if:

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

Then:

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

5. The following is a sample calculation:

$$\text{PCO} = 10$$

$$\text{PC} = 80$$

$$\text{IU} = 1$$

$$\text{PU} = 2$$

$$\text{ICO} = 5$$

$$\text{IC} = 10$$

So:

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

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

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

Appendix B

Frequently Asked Questions

- Q: Is there any leniency to counting overdue inspections as the NRC IMC 2800 frequency plus 25 percent?
- A: In the past, we have allowed two days to compensate for a weekend. For anything more than two days over the 25 percent, the inspection should be considered overdue and documented as such.
- Q: 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?
- A: Our 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 counted in the calculation, but the reviewer should document how late the overdue inspection was performed.
- Q: 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?
- A: 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 into account.
- Q: What if the data necessary to perform the overdue calculation is not easy to get or determine?
- A: In this case, the review team 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 get 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 the total number of core inspections conducted by the State in the report.
- Q: What if a State deviates from the inspection frequencies prescribed in IMC 2800?
- A: 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

Appendix B (continued)

States have more aggressive inspection schedules than those prescribed in IMC 2800. In cases where an Agreement State's inspection frequency is less stringent than IMC 2800, the review team should note the difference(s) and determine if there are performance issues. Several 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).

- Q: What if a State conducted many core inspections overdue as a result of staff turnover, but have caught up on all the overdue inspections at the time of the review?
- A: If a State presently has no backlogged inspections, previously addressed the root cause of the overdue inspections and took management action to address and solve the issue, then there may not be any performance issue and as such, a finding of satisfactory may be appropriate. However, if the State has not addressed the root cause, 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.
- Q: What if an established licensee has a name change only, should the reviewer consider the first inspection to be conducted under the new name as an initial inspection?
- A: If a licensee has only had a name change and is issued a new license, even under a change of ownership or transfer of control, an initial inspection is not required unless the organization controlling the licensed activities changes substantially; the licensee significantly increases the types, quantities, or forms of materials on the license; the licensee significantly increases the different uses authorized on the license; the licensee significantly increases the number of authorized users; or, the new license authorizes one or more new facilities.