



FSME Procedure Approval

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

Issue Date:

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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.



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*Reviewing the Common Performance Indicator,
Status of Materials Inspection Program*
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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 ~~inspection activities using~~ **the Common Performance Indicator #1, Status of Materials Inspection Program** [Management Directive (MD) 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*].

II. OBJECTIVES

- A. To verify that core ~~licensees~~ **inspections** are ~~inspected~~ **performed** at the **proper** interval, ~~in accordance with frequencies as~~ prescribed in NRC Inspection Manual Chapters (IMC) 2800, *Materials Inspection Program*. Note: ~~Per NRC-IMC 2800~~ **As used in this procedure, the phrase “core inspections”** ~~are~~ **refers to** all initial inspections (~~Priorities 1, 2, 3, 5, and 7~~) **of new licensees** and all routine inspections of Priority 1, 2, ~~or~~ **and** 3 licensees.
- B. To verify that **candidate** reciprocity licensees are inspected in accordance with the frequencies prescribed in ~~NRC-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 ~~working~~ **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 ~~NRC-IMC 0610~~, *Inspection Reports*).
- ~~F. To determine that inspections are not scheduled with any geographic bias.~~

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

~~The team leader for the Regional or State review d~~**Determines** which team member(s) is assigned ~~lead review responsibility~~**as the principal reviewer** for this performance indicator. ~~The principal reviewer should meet the appropriate requirements specified in MD 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program Team Members*.~~

B. Principal Reviewer

- ~~The principal reviewer is responsible for r~~**Reviewing**s relevant documentation, conducting**s** staff discussions, and maintaining**s** a summary of all statistical information received.
- Meets the appropriate requirements specified in MD 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program Team Members*.**

V. GUIDANCE

A. Scope

- This procedure specifically excludes inspections of non-Atomic Energy Act materials or licensees.**
- ~~±~~**2.** This procedure applies ~~only to~~ **the** review of the status of ~~nuclear~~**radioactive** materials ~~safety program~~ inspection activities common to ~~the~~ **NRC** and ~~the~~ **Agreement States**. ~~This primarily refers to byproduct, source, and special nuclear materials (non-reactor) inspections.~~

23. 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.

~~3. This procedure specifically excludes inspections of non-Atomic Energy Act materials or licensees.~~

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.

23. As part of the evaluation criteria for this indicator, the principal reviewer will determine the percentage of overdue core inspections for the review period. ~~This calculation involves the inspections of Priority 1, 2, and 3 licensees, as well as initial inspections of all new licensees. Overdue core inspections for Priority 1, 2, and 3 licensees include inspections conducted at intervals that exceed the NRC IMC 2800 frequencies, with the following maximum windows: (1) Priority 1 inspections completed greater than 3 months past the inspection due date; (2) Priority 2 inspections completed greater than 6 months past the inspection due date; and (3) Priority 3 inspections completed greater than 9 months past the inspection due date (Note: A different set of criteria may be applied to those licensees who have received an extension on their inspections, e.g., Priority 1 licensees whose inspection frequency has been extended to once every 2 years would be overdue if the inspection is completed greater than 6 months -- instead of the normal 3 month window -- past the inspection due date). Initial inspections completed greater than 6 months after receipt of licensed material or 12 months after license issuance (whichever comes first) are also included in the calculation. Reciprocity inspections should not be included in this calculation. 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.
38. 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 ~~on-time~~ during the review period. ~~This~~ **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

as-overdue inspections, yet the inspections were completed within a reasonable period of time past the due date; or if management took appropriate steps to work off the 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.

- ~~4. While this indicator focuses primarily on quantitative performance, review of this indicator should also include a qualitative evaluation that examines the justifications for a Region or State to revise its internal inspection frequencies.~~
- ~~5. The issuance of inspection findings is another important aspect of this indicator. Inspection findings should be sent to licensees within 30 days of the inspection. Providing health and safety have not been compromised, some flexibility may be given due to certain circumstances.~~
- ~~6. It is important for the principal reviewer to use MD 5.6 Glossary definitions, for consistency, in tabulating status of inspections and overdue inspections. If the Region or State calculates inspections or overdue inspections using different definitions, a reasonable attempt should be made to calculate these figures using the definitions from MD 5.6. This information may be obtained by reviewing specific license casework files for core licensees using the Appendix A worksheet. If the reviewer is unable to obtain these counts using MD 5.6 definitions, the reviewer should use the Region's or State's figures, but should note the differences in terminology or definitions.~~
- ~~7. The principal reviewer should examine any printouts listing information on inspections completed by the Region or State during the review period. If such lists cannot be provided, the reviewer should examine a representative number of core, reciprocity, and initial inspections, as well as documents involving inspection findings.~~
- ~~8. The principal reviewer should examine the overdue inspections and note whether the locations are disproportionate with the State-wide or Region-wide distribution of licenses.~~
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 ~~NRC-IMC 2800, (available on the NRC external homepage)~~ which ~~describes~~**prescribes inspection frequencies** for core inspections. The principal reviewer should also be familiar with ~~NRC-IMC 1220, which describes~~**prescribes** inspection frequencies for reciprocity inspections. The principal reviewer should also be ~~familiar with~~**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 ~~Division of Industrial and Medical Nuclear Safety, Materials Safety Branch,~~**appropriate contact in the Office of Nuclear Material Safety and Safeguards (NMSS), Federal and State Materials and Environmental Management Programs (FSME)** to obtain the most current statistical information regarding the Region's inspection performance. ~~NMSS~~**FSME** compiles such data on a monthly basis; and is capable of sorting overdue inspections by inspection priority and by State. In addition, ~~NMSS~~**FSME** normally maintains correspondence between ~~NMSS~~**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 ~~NRC-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 ~~NRC-IMC 2800~~.) For inspection of reciprocity licensees, the

~~priorities~~ **criteria for determining candidate licensees** are specified in NRC IMC 1220, Appendix III.

D. Review Details.

~~For~~ **To evaluate** the status of materials inspections, the principal reviewer should evaluate the following:

1. ~~The N~~ **Number** of overdue core inspections;
2. The amount of time past the applicable inspection due dates for any core overdue inspections;
3. ~~The R~~ **Reason** core inspections were completed overdue;
4. ~~The S~~ **Safety** significance of canceling or deferring any overdue inspections;
5. ~~Whether inspection findings were issued in a timely fashion (30 days)~~ **The timeliness of issuance of inspection findings to licensees;**
6. ~~Whether~~ **The** inspection frequencies used by an Agreement State **and verify they** are at least as frequent as those listed in NRC-IMC 2800. The principal reviewer should ~~obtain~~ **document any** Agreement State inspection frequencies that do not match those detailed in NRC-IMC 2800 ~~to assist in the overall evaluation of the performance for this indicator~~ **for inclusion in the IMPEP report;**
7. ~~Whether~~ **The performance of** reciprocity inspections ~~are completed in accordance with the guidance given in NRC-IMC 1220 or the details of~~ and justification for the Agreement State's alternative reciprocity inspection policy;
8. ~~Whether or not~~ **The NRC Region's or Agreement State's method for determining** ~~is counting~~ inspection timeliness **and the method's consistency** ~~in a manner consistent with NRC-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. ~~Whether the Region or State considers the delivery of new licenses as an initial inspection. The principal reviewer may need to evaluate the scope of activities conducted by the Region or State during the delivery of new licenses to determine if this visit is an acceptable alternative to an initial inspection.~~
109. ~~Whether an appropriate~~ **The** protocol is employed by the **NRC** Region or **Agreement** State to reduce or extend inspection frequencies **based on licensee performance**;
110. ~~Whether~~ **Any** deviations from inspection schedules **and verify that they** are normally coordinated between ~~working staff~~ **inspectors** and ~~Region or State~~ **program** management.

E. Review Information Summary

At a minimum, the summary maintained by the principal reviewer ~~will~~ **should** include a tally of (See Appendix A for sample worksheet for the overdue core inspection calculation) **the following information**:

1. **Number of** Priority 1, 2, and 3 inspections that were completed overdue during the review period and the **amount** **range** of time past ~~the inspection due date~~ the inspections were completed;
2. **Number of** Priority 1, 2, and 3 inspections that are overdue at the time of the review and the **amount** **range** of time past ~~the inspection due date~~ the inspections are at the time of the review;
3. Number of Priority 1, 2, and 3 inspections that were completed ~~over~~ **during** the review period;
4. **Number of** initial inspections that were completed overdue during the review period and the **amount** **range** of time past ~~the inspection due date~~ the inspections were completed;
5. **Number of** initial inspections that are overdue at the time of the review and the **amount** **range** of time past ~~the inspection due date~~ the inspections are at the time of the review;
6. Number of initial inspections that were completed ~~over~~ **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 ~~candidate~~ 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 ~~late 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 late.**
- F. Discussion of Findings with Region or State.

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

VI. APPENDICES

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

VII. REFERENCES

1. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program*.
2. NRC Management Directive 5.10, *Formal Qualifications for IMPEP Team Members*.
3. NRC Inspection Manual Chapter 0610, *Inspection Reports*.
4. NRC 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*.
5. NRC Inspection Manual Chapter 2800, *Materials Inspection Program*.
6. **STPFSME** Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*.

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

Appendix A

Overdue Inspection Calculation Worksheet

Guidance for calculating the number of overdue core inspections:

1. ~~Overdue~~ Core inspections include Priority 1, 2, and 3 inspections (conducted at intervals that exceed the NRC IMC 2800 frequencies by more than 25 percent) and all initial inspections of all licensees, that is. A core inspection will be considered overdue if it falls under one of the following cases:
 - a. A Priority 1 inspections completed greater than 3 months past the inspection due date (15 months total);
 - b. A Priority 2 inspections completed greater than 6 months past the inspection due date (30 months total);
 - c. A Priority 3 inspections completed greater than 9 months past the inspection due date (45 months total);
 - d. An initial inspections
 - ~~i. completed greater than 6 months after receipt of licensed material; or~~
 - ~~ii. completed greater than 12 months after license issuance, whichever comes first.~~
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, ~~however~~, the inspection should be considered overdue and documented as such.
- Q: If a program inspects a Priority 1 licensee only once in a ~~three~~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 ~~should use~~ **uses into** determining 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 ~~the~~ 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, ~~even if you cannot use all of the inspections in the calculation.~~
- Q: What if a State ~~conducted all initial inspections at 7 months instead of 6 months~~ **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**

Appendix B (continued)

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. In cases where an Agreement States inspection frequency is less stringent than IMC 2800, ~~the review team should note the difference(s) in any inspection frequencies and determine if there are performance issues. Several States have set different~~ less stringent frequencies for ~~different~~ certain categories of licensees. For example, one State does conduct initial inspections at 7 months and another has set the frequency for HDRs at every 2 years instead of the annual frequency as noted in NRC IMC 2800. However, both ~~The States had developed~~ needs to have a documented rationale for these difference(s) and the review teams determined and the Management Review Board agreed that there were no performance issues identified with this approach ~~will make the final determination if public health and safety are jeopardized based on the difference(s).~~

- ~~Q: How long should an individual team member keep their detailed notes of the review findings.~~
- ~~A: In cases where a State is on heightened oversight or for any common or non-common performance indicator for which the team makes an unsatisfactory finding, the detailed notes should be retained until the follow-up review is completed.~~
- 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, ~~with recommendations for~~ but needs improvement, or unsatisfactory may be appropriate.
- Q: What if an established licensee has a name change only, should the reviewer considered the first inspection to be conducted under the new name ~~and license number~~ as an initial inspection?
- A: If a licensee has only had a name change ~~and license number~~ and is issued a new license, even under a change of ownership or transfer of control, ~~the inspection should not be considered as 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.