

March 28, 2005

SUMMARY OF COMMENTS ON SA-102, "Reviewing the Common Performance Indicator, Technical Quality of Inspections"

I. Sent to the Agreement States for Comment: June 28, 2004 (STP-04-045)

Comments Dated: Alabama - 6/29/04 (e-mail - no comments)
North Dakota - 6/30/04 (e-mail - no comments)
Minnesota - 6/30/04 (e-mail)
Florida - 7/6/04 (e-mail)
New Mexico - 7/13/04 (e-mail)
Washington - 7/21/04 (e-mail)

Minnesota

Comment:

There appears to be some discrepancy among the sections of the procedure regarding inspector accompaniments. The procedure indicates that a supervisor should accompany each inspector annually. However, in the Frequently Asked Questions, it states that in a small program inspectors may be accompanied by senior staff on an annual basis. Minnesota suggests that "small State" be defined and references to "supervisors" should be eliminated or complimented by "or qualified inspector."

Response:

The Frequently Asked Question (FAQ) regarding annual accompaniments by senior staff has been revised to apply to all States and not just small States. The text in the body of the procedure was not revised because it is the expectation of the NRC that the annual accompaniments be performed by the supervisor, if available. However, in certain circumstances, it is preferred that the accompaniments be conducted by senior staff if the supervisor is not available for the accompaniments. The revised texts for the FAQ reads as follows:

Q: In Agreement States, can senior staff conduct accompaniments?

A: Yes, it is acceptable to have senior staff perform inspector accompaniments under certain circumstances. In Agreement States where the program manager is the immediate supervisor, accompaniments may be performed by experienced senior staff instead of the program manager if the program manager is fulfilling other obligations. In an Agreement State that is experiencing staffing issues where there is a vacancy in a supervisory position, the accompaniments may be performed by experienced senior staff during the time the vacancy is unfilled. It is the expectation that supervisors generally conduct the accompaniments; however, it is preferable to have the accompaniments conducted by an experienced, qualified inspector in the circumstance that the supervisor is not available to accompany the inspectors.

Florida

Comment 1:

In regard to Item II, Objectives, Paragraph A., NRC should not have as an IMPEP audit objective to ensure Agreement States perform what NRC considers a performance-based and risk-informed inspection. Note that this objective is in direct conflict with the FAQ response whether inspections can be prescriptive. Agreement States must have the freedom to determine what type of inspection they want to perform based on their organizational structure. I suggest this objective be changed to say, "To ensure that inspections of licensed activities focus on health and safety issues and that the licensees are in compliance with applicable regulations and conditions of their license."

Response:

The procedure has been revised to eliminate the conflict between the procedure and the FAQs. The objective has been modified to focus on health and safety issues regardless of the nature of the inspection. The revised text reads as follows:

- A. To ensure that inspections of licensed activities ~~are performance and risk-based~~ and focus on health and safety issues **in accordance with NRC Manual Chapter 2800, *Materials Inspection Program***.

Comment 2:

In regard to Item V., Guidance, Paragraph F., this comment may already be addressed since it is under the heading of "Guidance" and the text uses the word "should" instead of "shall." NRC needs to be aware that this guidance may be difficult to follow in Agreement States with large number of inspectors. For example in Florida we have eight inspection offices scattered throughout the state. In past IMPEP's it has taken NRC two weeks to perform the accompaniments and then the full audit team may not meet until 2-3 weeks later. I recommend that the language be modified to allow the IMPEP team leader some flexibility. You may also have an issue that when the full IMPEP team meets the accompaniments results may be modified based on the other team member's indicator findings. This issue should be communicated during the accompaniment close out. I suggest the following language: "Unless determined differently by the team leader, results of inspection accompaniments should be communicated to the inspector and program management the week of the accompaniment, especially if the evaluation uncovers performance deficiencies. If possible, the team member completing the accompaniments should schedule a close-out meeting with the team leader and program management to ensure that all findings are fully communicated and understood. It should also be communicated that the results are preliminary and may be modified by the IMPEP audit team and must be approved by the MRB"

Response:

We appreciate the comment and agree that it is important to communicate the results of the inspector accompaniments in a timely manner. We believe that the procedure as initially written provided some flexibility; however, the text will be revised to reflect this comment and to enhance the flexibility of communicating the results of the accompaniments. Since this is a guidance document, the word "should" will continue to be used instead of "shall." The revised text will read as follows:

5. **Unless determined otherwise by the team leader, results of the inspector accompaniments should be communicated to the inspector and program**

management the week of the accompaniment, especially if the evaluation uncovers performance deficiencies. If possible, the team member completing the accompaniments should schedule a close-out meeting with program management to ensure that all findings are fully communicated and understood. The team member performing the accompaniments should communicate to the State/Regional program management that the results of the accompaniments are preliminary and will be used in the overall assignment of a finding for this indicator. ~~If evaluation uncovers significant difference, these should be discussed with the inspector's supervisor within one week of the accompaniment. Otherwise, feedback should be conveyed at the time of the IMPEP review.~~

Comment 3:

Appendix C should be deleted. Appendix C is not referenced anywhere in procedure SA-102. (Appendices A and B can be filled out and are referenced in SA-102) While Appendix C is a good training document for IMPEP team members, it does not add anything to procedure SA-102. Also making it part of SA-102 does not allow NRC to change or add to it as new questions or issues appear. I suggest that an FAQ section be added to the IMPEP training manual that is updated each year.

Response:

We appreciate the comment and have taken it into consideration. However, the FAQ sections for other procedures have been well received by IMPEP team members, and we believe that they add value to the procedure. We understand that the revision process will limit the frequency of updates to the FAQs for each indicator. Additional guidance will be transmitted to IMPEP team members electronically via the "IMPEP Flyer" when necessary (if a revision to the procedure has not been scheduled). For consistency with other procedures, we believe that the appropriate place for the FAQs is in the appendix of the IMPEP indicator procedures. No change will be made to the procedure based on this comment.

New Mexico

Comment:

In Section V ("Guidance"), Subsection F, Paragraph 5. The text deals with communicating the findings of the inspection accompaniments. I recommend revising as follows:

"Results of inspection accompaniments shall be communicated to the inspector and program management the week of the accompaniment, noting performance deficiencies and strengths. The team member completing the accompaniments shall schedule a close-out meeting with program management to ensure that all findings are fully communicated and understood."

I inserted "shall" into the places of "should" because it is fair to communicate the results soon after the accompaniments in a close-out meeting.

Response:

We appreciate the comment and have taken it into consideration. Please see the response to Florida's Comment 2.

Washington

Comment:

On Page 5 of Part V.B.3., the 3rd sentence should be amended to read:

A representative mix of license categories (e.g. hospitals and medical centers having brachytherapy, high dose rate after-loaders, intravascular brachytherapy, gamma knife or other heliotherapy); research and academic use (e.g. research/development laboratories, colleges and universities); industrial use (e.g. industrial radiography, industrial gauges, irradiators and well-logging); and broad-scope licensees should be selected for review.

Response:

This sentence has been revised to be consistent with IMPEP policy of focusing on Priority 1, 2, and 3 licenses as well as initial licenses. Parts of this comment have been incorporated. The revised text reads as follows:

A **representative** mix of medical ~~and academic use (e.g., universities, community hospitals; medical centers; brachytherapy licenses, including high-dose rate remote afterloaders teletherapy; gamma stereotactic radiosurgery, and emerging technologies licenses, physicians, broad scope facilities, etc);~~ **research and academic use (e.g., research/development laboratories and colleges/universities); manufacturing and distribution, including nuclear pharmacies;** and industrial use (e.g., ~~research and development, industrial radiography, irradiators, and well logging, etc.)~~ licenses should be ~~sought~~ **selected for review.**

II. Sent to the NRC Offices for Comment: June 28, 2004

Comments Dated: OGC - 7/1/04 (mark-up)
Region IV - 7/13/04 (email - no comments)
Region III - 7/13/04 (e-mail)
NMSS - 7/23/04 (memo)
Region I - 7/28/04 (email)

OGC

Comment:

Comment on spelling of a word in the Frequently Asked Questions.

Response:

We agree with the comment and the procedure will be revised accordingly.

Region III

Comment 1:

Section II. A.: Performance-based inspections are not required as indicated. See Q&A question regarding prescriptive inspections.

Response:

We agree with this comment. See response to Florida's Comment 1.

Comment 2:

Section V. D. 1.: The term “compliance action” should be removed. Note: Current NRC inspection reports do not require documentation of each of the listed areas. Our inspection reports are now “bare bones” and inspections performance-based. We suggest that the procedure list areas for review, but not necessarily require each area to be covered.

Response:

The procedure will be revised to replace the term “compliance action” with “case.” In regard to the note on the above comment, we believe that the procedure has been written to provide flexibility to the reviewer in the course of evaluating the casework. The language used in this section of the procedure and in all sections of the procedure is “should” as opposed to “shall.” The section also contains a clause that the reviewer should only look for the items in the list if they are applicable. No change to the procedure will be made based on the note in the comment.

Comment 3:

Section V. D. 2.: The procedure states that the reviewer should evaluate any information missing from the file. The obvious intent is to determine if the inspection file is complete.

Response:

We appreciate the comment and the procedure will be revised as follows:

~~Any information missing from the file, e.g.,~~ **The completeness of the inspection files.**
The reviewer should ensure that all relevant documents, letters, file notes, and telephone conversations **are complete and in the file;**

Comment 4:

Section V. D. 13.: The correct title for Appendix A should be “IMPEP Inspection File Reviewer Guidance.”

Response:

We agree with this comment and the procedure will be revised accordingly.

Comment 5:

Section V. E. 6.: Change “closeout” to “follow-up”

Response:

We agree with this comment and the procedure will be revised accordingly.

Comment 6:

Section VI. A.: The correct title for Appendix A should be “IMPEP Inspection File Reviewer Guidance.”

Response:

We agree with this comment and the procedure will be revised accordingly.

Comment 7:

Appendix A: On page 3 (in two places), change the term “compliance file” to “inspection file.”

Response:

We agree with this comment and the procedure will be revised accordingly.

Comment 8:

Q&As: Question 4 references “small” states. The term “small” is not defined. We suggest that the policy address all states, regardless of size.

Response:

See response to Minnesota’s comment.

Comment 9:

Q&As: Answer 5: Replace “cause” with “causes”

Response:

We agree with this comment and the procedure will be revised accordingly.

Comment 10:

Q&As: Question and Answer 8: We suggest that the term “reviewer has reviewed” be changed to “reviewer has evaluated” for better flow.

Response:

We agree with this comment and the procedure will be revised accordingly.

Comment 11:

Q&As: Answer 8: Replace “the review” with “the reviewer.” Also, delete the term “a majority of” from the last sentence.

Response:

We agree with this comment and the procedure will be revised accordingly.

Comment 12:

Q&As: Answer 9: Change “During an IMPEP review during NRC Fiscal Year 2003” to “During an IMPEP review in Fiscal Year 2003.”

Response:

Although it is implied that “Fiscal Year” refers to the “NRC Fiscal Year,” we believe that the language as it currently stands provides clarification. However, to avoid any possible confusion, when referring to specific IMPEP reviews, we will use the calendar year that the review occurred in as the year of reference. In this particular case, the calendar year and the fiscal year for this particular review. The text will be revised to read: “During an IMPEP review in 2003.”

NMSS

Comment 1:

All main body pages: need total # of pages and issue date.

Response:

The page numbers and issue date will be incorporated into the procedure during the last step of finalization.

Comment 2:

II.B.: poorly worded, should take advantage of opportunity to clarify.

Response:

The language will be revised as follows:

- B. To ensure that inspection findings are well-founded and well-documented in reports ~~describing the scope of each inspection, all violations and health and safety matters, the scope of each licensee's program, discussions with licensee management and each licensee's response.~~

Comment 3:

V.B.1.: "Overdue Core Inspections", Inspections is plural.

Response:

We agree with this comment and the procedure will be revised accordingly.

Comment 4:

V.C.1.: poorly worded; doesn't flow to sub-paragraphs a., b., & c.

Response:

The text was revised as follows:

- C. Review Guidelines.
 - 1. **Prior to the on-site review, the principal reviewer should review:**
 - 1a. The response generated by the Region or **Agreement** State to relevant questions in the IMPEP questionnaire. **The response to the questionnaire relative to this indicator** should be used to focus the review.
 - 2b. For the Regions, tallies of completed inspections can be obtained from the ~~Licensing Management~~ **License Tracking** System (LMTS). This information can be obtained prior to the Regional visit from the Office of Nuclear Material Safety and Safeguards, Division of Industrial and Medical Nuclear Safety, Materials Safety **and Inspection** Branch. **The** LMTS has limited ability to sort these records, depending on the needs of the principal reviewer. Once the appropriate files are selected, a call to the Regional office can be made to have the inspection files pulled, and ready for review at the time of the visit.
 - 3c. For Agreement States, inspection reports are not normally submitted to the Office of State **and Tribal** Programs. The principal reviewer should work with the IMPEP team leader in selecting the appropriate inspection files for review.

Comment 5:

V.C.1.b.: "The LTS (or its replacement)"; add the words in parentheses.

Response:

We appreciate the comment. However, at this time there will be no change to the procedure based on this comment. We will update the language during the next revision if the License Tracking System has been replaced at that time.

Comment 6:

V.D.1.: “compliance action”? Change to “case”

Response:

We agree with this comment and the procedure will be revised accordingly.

Comment 7:

V.D.11.: Should a verification of instrumentation calibration be listed here?

Response:

We agree with this comment. Section V.D.11 has been revised. The revised text reads as follows:

11. Instrumentation is adequate, **calibrated**, and functioning properly for surveying license operations (e.g., survey meters, air samples, lab counting equipment for smears, **and** identification of isotopes, etc.);

Comment 8:

V.D.12.: This seems to fit better under V.F. rather than V.D.

Response:

We appreciate the comment. However, we believe that Section V.D. is the appropriate location of this paragraph. This paragraph addresses the State/Regional supervisor accompaniments of inspectors. Section V.F. provides guidance on inspector accompaniments performed by the IMPEP team member in conjunction with the on-site review. There will be no change to the procedure based on this comment.

Comment 9:

V.D.13.: “IMPEP **Inspection** File Reviewer Guidance”; Inspection, not Compliance, also add the ‘er’ on Reviewer

Response:

See response to Region III’s Comment 4.

Comment 10:

VI.A.: “IMPEP **Inspection** File Reviewer Guidance”; Inspection, not Compliance.

Response:

See response to Region III’s Comment 6.

Comment 11:

VII.2.: *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*; spell out IMPEP as it is in the MD title.

Response:

We agree with this comment and the procedure was revised accordingly.

Comment 12:

Appendices A, B, & C: Page numbering? Title header?

Response:

Headers and page numbers will be inserted consistent with other STP procedures during finalization of the procedure.

Comment 13:

Appendices A & B: "INFORMATION NEEDED FOR APPENDIX" change to "GENERAL INFORMATION"

Response:

We agree with this comment and the procedure will be revised accordingly.

Comment 14:

Appendices A & B: "COMMENTS FOR APPENDIX", change to "ADDITIONAL COMMENTS"

Response:

We agree with this comment. However, we replaced "COMMENTS FOR APPENDIX" with "COMMENTS" to avoid confusion as to what appendix the comments pertain to.

Comment 15:

Appendix B, Inspection section: Line item "Review of incidents, overexposures, etc." appears to have inadvertently been dropped from the prior version.

Response:

The line item "Review of incidents, overexposures, etc." was not dropped from the procedure. That particular line on the table had carried over to a separate page. The appendix will be modified so all line items for the inspection section are all on the same page. We appreciate your careful observation.

Comment 16:

Appendix C, Answer 2: change "mandates" to "allows"

Response:

We agree with this comment. The term "mandates" may be too strong of a term in this application. The procedure will be revised accordingly.

Comment 17:

Appendix C, Answers 2 and 3: "Agreement State" not "State"

Response:

We agree with this comment and the procedure will be revised accordingly.

Comment 18:

Appendix C, Question 7: Prescriptive Inspections? What are they? Where are they defined?

Response:

Prescriptive inspections are the opposite of performance-based inspection. The more common term for prescriptive inspections is “compliance-based inspections.” These are inspections where the inspector looks at the details of the program and furnishes a detailed inspection report to the licensee. Prescriptive inspections may not be directly defined in any NRC document; however, it is a common term in IMPEP guidance and reports.

Region I

Comment 1:

Section V.C.1.b. ,Add: or can be viewed in ADAMS

Response:

This comment was initially intended to be incorporated into the procedure; however, due to the NRC’s current information security initiatives and the removal of some information from ADAMS, we believe that the primary reviewer should proceed through the steps as outlined in the procedure. In the event that the primary reviewer for this indicator is an Agreement State representative, that individual will be unable to access all the necessary files in ADAMS.

Comment 2:

Section V. E. ,Add: 9. Comments related to performance issues

Response:

We agree with this comment and the procedure will be revised accordingly.

Comment 3:

Appendix C answer to 5th question, Change: The reviewer should not bring the concern to the attention of the licensee and the inspector. Instead it should read that the reviewer should call the State or Regional Supervisor. The reviewer should let the State or Region explain the concern to their licensee.

Response:

We agree with this comment and the procedure will be revised accordingly.

Comment 4:

Appendix C question 9, Change: Should supervisors who routinely perform inspections be accompanied?

Response:

The questions was revised to read as:

Q: If a supervisor routinely performs inspections in an Agreement State, should the supervisor be accompanied annually also?

Comment 5:

Appendix C last answer, Change: If the concerns are of health and safety significance, it is the responsibility of the reviewer to bring the concerns to the attention of the **{delete:licensee and the}** inspector **{add: and his/her supervisor}**.

Response:

We agree with this comment and the procedure will be revised accordingly.