

June 14, 2007

SUMMARY OF COMMENTS ON SA-101, REVIEWING THE COMMON PERFORMANCE INDICATOR, STATUS OF MATERIALS INSPECTION PROGRAM

I. Sent to the Agreement States for Comment: April 19, 2007 (FSME-07-037)

Comments/Dated: OAS Board - 4/25/07 (e-mail)
California - 5/14/07 (e-mail)
OAS Board - 5/18/07 (e-mail)
Illinois - 5/22/07 (e-mail)

OAS Board

Comment 1:

On page 4/17, Section V.B.2.b., second line; add "inspection records" after "reciprocity."

Response:

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

Comment 2:

On page 5/17, Section V.B.3.b., second line; there needs to be subject verb agreement for "inspection was."

Response:

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

Comment 3:

On page 6/17, Section V.B.5., "inspection" be "inspections."

Response:

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

Comment 4:

On page 9/17, Section V.D.8., delete "is counting."

Response:

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

Comment 5:

On page 10/17, Section V.D.10., the word "between" should not be deleted.

Response:

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

Comment 6:

On page 13/17, Appendix A, Item 3; the word "them" should be before "as" not after "as."

Response:

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

CaliforniaComment:

Section V.B., language should be added to acknowledge the flexibility provided in the November 4, 2005 "Prioritization Methodology for Increased Controls" (STP 05-079). That document states that in order to ensure the Increased Controls inspections are performed in a timely manner, "inspection intervals of routine inspections for licensees not in Groups 1-4 [i.e., not issued the Increased Controls] may need to be temporarily extended in order to ensure that the higher risk IC licensees can be inspected in the first year after implementation of the Increased Controls."

California suggests adding, in Section V.B., after Item 7, an item such as: Additionally, flexibility should be afforded in accordance with the November 4, 2005, "Prioritization Methodology for Increased Controls" (STP 05-079). This guidance allows for the temporary extension of inspection intervals for non-Increased Controls licensees to accommodate the need to ensure the higher risk Increased Controls licensees are inspected in a timely manner.

Response:

We appreciate the comment; however, at this time, the integration of the Increased Controls into the Integrated Materials Performance Evaluation Program (IMPEP) is documented in STP Temporary Instruction (TI) 002. We do not foresee the additional language as a permanent change to SA-101, which is intended to be a long-term use procedure. The proposed language is more appropriate to incorporate into TI-002, which specifically addresses guidance for IMPEP team members in regard to the Increased Controls and is to be used in conjunction with SA-101. We do believe that this comment is a necessary modification to the IMPEP procedures, and it will be incorporated into TI-002 at its next revision, which will be in the very near future.

OAS BoardComment 7:

In section V.B., language should be added to acknowledge the flexibility provided in the November 4, 2005 "Prioritization Methodology for Increased Controls" (STP 05-079). That document states that in order to ensure the Increased Controls inspections are performed in a timely manner, "inspection intervals of routine inspections for licensees not in Groups 1-4 [i.e., not issued the Increased Controls] may need to be temporarily extended in order to ensure that the higher risk IC licensees can be inspected in the first year after implementation of the Increased Controls."

Response:

See response to California's comment.

Comment 8:

The OAS Executive Board suggests adding, in Section V.B., after Item 7, an item such as: Additionally, flexibility should be afforded in accordance with the November 4, 2005, "Prioritization Methodology for Increased Controls" (STP 05-079). This guidance allows for the temporary extension of inspection intervals for non-Increased Controls licensees to

accommodate the need to ensure the higher risk Increased Controls licensees are inspected in a timely manner.

Response:

See response to California's comment.

Illinois

Comment 1:

Our main concern focuses around a letter (STP-05-070) from the NRC that concerns SA-101. This letter provided a prioritization methodology for inspections of licensees who had to implement the increased controls. Throughout that letter, reference is made to allowing flexibility in order to ensure that the high priority IC licensees would be inspected as soon as possible. The last section in that letter deals with 'deviations from IM 2800 routine inspections' where it was acknowledged that during the 3 year IC inspection implementation period, adjustments may need to be made to the 'routine' inspections. Such deviations indeed have had to occur since several of the high risk licensees needed to be inspected earlier than IM 2800 priorities. In addition, inspections of other licensees, in particular reciprocity licensees coming to Illinois, were extended/suspended to accommodate the high priority IC inspections for the past year. However, there does not appear to be any recognizable acknowledgment of those allowances in the drafted SA-101. Towards that end, the agency suggests the inclusion of the phrase 'or prioritization methodologies' into the last sentence of V.C.2. of the draft or more appropriately, an overt reference to STP-05-070 somewhere in the text of the IMPEP Review Procedure.

Response:

See response to California's comment. Additionally, we will take the comment on the extension/suspension of reciprocity inspections into account when revising TI-002.

Comment 2:

Secondly, we have a very minor comment concerning Appendix B, the Frequently Asked Questions. The last question in that Appendix indirectly deals with initial inspections. The FAQ contends that the first inspection following a change in ownership should entail categorization as an initial inspection. Normally, we would agree. However, there are several cases where there is a change in ownership that does not result in any substantial change in the staff at the site or involve any changes in the license commitments (please consider GE Healthcare's routine change in ownership as an example). As such, we don't believe the next inspection should be considered an 'initial inspection' and subject to the initial inspection requirements. The NRC should take into consideration the intention behind labeling a first visit as an 'initial inspection'. The purpose of that visit is to let the 'new' licensee become acquainted with the inspection process and the expectations required by the regulation and license as well as allow the regulatory agency to understand the nature of the authorization and activities that occur at the site. When the staff and commitments don't change, that purpose becomes moot even though there has been a change in ownership.

Response:

We agree with this comment. Please see response to Region III's Comment 3.

II. Sent to the NRC Offices for Comment: May 16, 2007

Comments/Dated: DWMEP - 5/17/07 (e-mail)
Region III - 6/5/07 (e-mail)
Region I - 6/11/07 (telephone)
DILR - 6/12/07 (e-mail)

DWMEP

Comment 1:

Suggest that you replace the word “judgmental” in the first and third sentences with “risk-informed,” because it better describes the intent of the sampling as well as the concept of focusing on safety significant issues.

Response:

We agreed with this comment, and the procedure was revised accordingly.

Comment 2:

Also suggest you replace the word “efficiency” in the third sentence with “effectiveness” as a risk-informed approach is not always more efficient (i.e., “more” outcome using “less” effort/resources). Rather, a risk-informed approach ensures that the review focuses on safety significant issues and this is a more effective review from a health protection standpoint.

Response:

We agreed with this comment, and the procedure was revised accordingly.

Region III

Comment 1:

Section II. One of the goals for this indicator should be to ensure that NRC Regions and Agreement States perform Increased Controls security inspections at the proper intervals. This issue should also be addressed in Section V., “Guidance.”

Response:

We appreciate the comment; however, at this time, the integration of the Increased Controls into the Integrated Materials Performance Evaluation Program (IMPEP) is documented in STP Temporary Instruction (TI) 002, which covers Increased Controls aspects of IMPEP reviews for all indicators. This is a more efficient manner for making quick changes to how IMPEP reviews are conducted with respect to Increased Controls from lessons learned. After the initial implementation period is concluded and additional guidance is given on Increased Controls inspections beyond that point, any additional guidance for IMPEP review teams with respect to Increased Controls will be incorporated in the respective permanent procedure for the applicable indicators. No changes were made to the procedure in response to this comment.

Comment 2:

Section V.D.8. This paragraph is confusing. We suggest that the term “is counting” be removed from the first sentence.

Response:

See response to OAS Board’s Comment 4.

Comment 3:

Appendix B. The last Q and A addresses initial inspections. We suggest that language from MC 2800 Section 05.03(b) "Initial Inspections" be used to fully answer the question of whether an initial inspection is warranted in the given circumstances.

Response:

We agreed with this comment, and the text was revised to read as follows:

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 increases the types, quantities, or forms of materials on the license; the licensee significantly increases the different uses authorized on the license; the licensee one or more new facilities.

Region I

All comments were editorial and were incorporated into the procedure.

DILRComment 1:

Section V.B.2.b. The sentence starts with "[i]f such lists cannot be provided..." This sections reads as if samples of inspection documents should only be examined if computer printouts are not generated. Both data from 2a. and 2b. should be examined if available. I suggest adding "and" at the end of 2a., deleting "If such lists cannot be provided (in 2b.)," and starting the sentence with "The reviewer should examine..."

Response:

We agreed with this comment in part. To determine the timeliness of inspections when computer-generated reports are not available, the principal reviewer must evaluate a sample of inspection reports completed during the review period. To determine the timeliness of the issuance of inspections results to licensees, the principal reviewer must evaluate a sample of inspection reports completed during the review period regardless. Therefore, we have modified Section V.B.2.a. and b. to read as follows:

- 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 inspection 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:

Comment 2:

In Section V.B.2.b.ii., we refer to a "judgemental" sample. I believe the term is too subjective and is open to interpretation for individual reviewers. I would delete "judgemental" from both procedures and not attempt to define its use versus "randomness".

Response:

See response to DWMEP's Comment 1.