

April 14, 2005

SUMMARY OF COMMENTS ON SA-108, "Reviewing the Non-Common Performance Indicator, Sealed Source and Device Evaluation Program"

Comment 1: I. Introduction - The procedure discusses the review of Agreement State SS&D programs. Since the SS&D program in NMSS is also periodically reviewed, the procedure should be expanded to also capture this program. (RI)

Response:

Reference to performing reviews of NRC's SS&D program are in the Introduction section of the current draft and is retained in the final version.

Comment 2: III. Background - The last sentence, regarding States with inactive SS&D programs, is covered in the Guidance Section and need not be added here. (RIII)

Response:

The reference in the Guidance section explains how the review should be performed in States with inactive SS&D programs. The reference to the same in the Background section states the requirement. Both references are retained in the final procedure as they serve fundamentally different purposes.

Comment 3: III. Background - The procedure frequently references the use of NUREG-1556, Volume 3. Since the procedure was recently revised, and may be revised again in the future, the procedure (SA-108) should add "latest version" when referring to NUREG-1556, Volume 3. (RI)

Response:

Revised final procedure will have a footnoted referenced: "When performing a review, use the latest version of this and all guidance material."

Comment 4: III. Background - Line three should read "... provides information on conducting SS&D reviews that provides useful guidance . ." (NMSS)

Response:

The wording "may provide" has been changed to "provides" in the referenced sentence.

Comment 5: IV. Roles and Responsibilities - The title of MD 5.10 is incorrect in the first paragraph. (RIII)

Response:

The title of MD 5.10 has been corrected.

Comments

6 & 7: V. Guidance, A. Scope, Sections A.1 and A.3 - The evaluation of SS&D staffing and training should be conducted in the same manner as the Common Performance Indicator but not necessarily as part of that evaluation. (RIII)

V. Guidance, A. Scope, Sections A.1 and A.3 - The first line, should read "... should be conducted in the same manner as, and as part of, the Common Performance Indicator." (NMSS)

Response:

The wording has been modified as follows: The evaluation of SS&D staffing and training should be conducted in a manner similar to, but not necessarily a part of, Common Performance Indicator, Technical Staffing and Training, to more accurately reflect current practice.

Comment 8: V Guidance, B. Evaluation Procedures, Sections B and B.1 - The term "Sealed Source and Device, Handbook 5.6" needs to reference to MD 5.6. (RIII)

Response:

The wording has been modified to reflect the correct reference.

Comment 9: V. Guidance, B.Evaluation Procedures, Section B.1 - Reference to IM-1246, Formal Qualification Programs in the Nuclear Materials Safety and Safeguards Program Area, or to Agreement State equivalent qualification program for SS&D reviewers should be included in SA-108 for consistency with other IMPEP procedures. (STP)

Response:

The procedure has been modified by adding reference to MC-1246 and MD-103 for clarity.

Comment 10: V Guidance, B. Evaluation Procedures, Section B.6 - The title of SA-105 is incorrect. (RIII)

Response:

The title of STP Procedure SA-105 has been corrected.

Comment 11: V. Guidance, B. Evaluation Procedures, Section B.6. - Guidance is needed to inform reviewers of the need to search all NMED incidents for generic issues related to sources and devices. (STP)

Response:

The search of the NMED database for the purposes of an IMPEP review may provide background information about a program's adequacy when responding to incidents and events. Such a review may, or may not, disclose the presence or absence of generic issues related to the day-to-day use of radioactive materials and the accidents, incidents and events that are a consequence of routine use. The writing group believes that more reliance should be placed on

the information developed by another existing process when determining the adequacy of a program's response to possible safety issues.

NMSS performs a monthly trend analysis on events involving sources and devices as required in Policy and Procedure Letter 1.57, NMSS Generic Assessment Process. Observed trends are reported to the program responsible for issuing the safety evaluation. The expectation is that the issuing organization would review the event's circumstances; take appropriate action to review the adequacy of the safety evaluation; and, if necessary, take action to appropriately amend the manufacturing license and the registry certificate. It is expected that the SS&D reviewer would determine if such notifications had been received under this process; the effectiveness of the State's response to these notifications; and the adequacy of the response when compared to the actions that would be reasonably expected to be taken by other evaluation programs within the national program.

This section has been revised to more accurately reflect the envisioned review process.

Comment 12: V Guidance, C. Review Guidelines, Section C.3 and Section F - SA-100 is incorrectly referenced. It should reference Part V “Guidance” not Part IV. (RIII)

Response:

The reference has been corrected.

Comment 13: V Guidance, D. Review Details, Section D.5 - Remove NRC for consistency. (RIII)

Response:

The term NRC has been removed from this section.

Comment 14: V. Guidance, E. Review Information Summary - The final report summary of SS&D actions reviewed during an IMPEP review may not always be Appendix F. (RIII)

Response:

The comment is correct and the wording has been modified to indicate that the list of cases reviewed usually appears in Appendix F.

Comment 15: V. Guidance, E. Review Information Summary -The review summary should include a cross reference to SA-100 for proper report format and an emphasis on reporting only significant findings. (STP)

Response:

Wording is added to this section to clarify the need to refer to STP Procedure SA-100 and the identification of only significant findings.

Comment 16: References -The titles of SA-100, SA-104 and SA-105 are incorrect. (RIII)

Response:

The titles have been corrected in this section.

Comment 17:

Additional Comments - The States of Washington, Iowa, North Carolina, Texas, and NRC's Region IV also provided comments on the draft procedure. These comments were general in nature and supportive of the new procedure. None identified areas of change. (WA, NC, IA, TX, RIII)

Response:

We appreciate the support of the new document. No changes to the draft document were made as a result of these comments.

Comments on grammar, spelling, format and style.

Most of these comments have been addressed.