

(STP-05-049, June, Program, SA-108)

June 30, 2005

ALL AGREEMENT STATES, MINNESOTA, PENNSYLVANIA

FINAL PROCEDURE SA-108, "REVIEWING THE NON-COMMON PERFORMANCE INDICATOR, SEALED SOURCE AND DEVICE EVALUATION PROGRAM" (STP-05-049)

The NRC/Agreement State Working Group has completed Procedure SA-108, *Reviewing the Non-Common Performance Indicator, Sealed Source and Device Evaluation Program*. This procedure provides guidance for reviewing sealed source and device evaluation programs during Integrated Materials Performance Evaluation Program (IMPEP) reviews. The final procedure and the Resolution of Comments can be found at: <http://www.hsr.doe.gov/nrc/procfm.htm>. This procedure incorporates and documents current practices and reflects Agreement State comments received in response to our February 27, 2004, All Agreement States Letter [STP-04-011](#) and comments received from NRC Offices.

If you have any questions regarding this communication, please contact me at 301-415-3340 or the individual named below.

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STP Procedure Approval

Reviewing the Non-Common Performance Indicator, Sealed Source and Device Evaluation Program - SA-108

Issue Date: 6/20/2005

Review Date: 6/20/2008

Paul H. Lohaus
Director, STP

Original signed by:
Paul H. Lohaus

Date: 6/20/2005

Dennis K. Rathbun
Deputy Director, STP

Original signed by:
D. K. Rathbun

Date: 6/20/2005

John G. Zabko
Procedure Contact, STP

Original signed by:
John G. Zabko

Date: 5/25/2005

NOTE

The STP Director's Secretary is responsible for the maintenance of this master copy document as part of the STP Procedure Manual. Any changes to the procedure will be the responsibility of the STP Procedure Contact.



Procedure Title:
*Reviewing the Non-Common Performance Indicator -
Sealed Source & Device Evaluation Program*
Procedure Number: SA-108

Page: 1 of 6
Issue Date:
6/20/05

I. INTRODUCTION

This document describes the procedure for conducting reviews of the U.S. Nuclear Regulatory Commission (NRC) and Agreement State sealed source and device (SS&D) evaluation activities using the Non-Common Performance Indicator: *Sealed Source and Device Evaluation Program* [NRC Management Directive (MD) 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*].

II. OBJECTIVES

To verify the adequate implementation of the three subelements under this indicator - (a) Technical Staffing and Training, (b) Technical Quality of the Product Evaluation Program, and (c) Evaluation of Defects and Incidents Regarding SS&Ds.

III. BACKGROUND

Adequate technical evaluations of SS&D designs are essential to ensure that SS&Ds will maintain their integrity and that the design is adequate to protect public health and safety. *NUREG-1556, Volume 3, *Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration*, provides information on conducting SS&D reviews and establishes useful guidance for review teams. Three subelements, noted above, will be evaluated to determine if the SS&D program is satisfactory. Agreement States with authority for SS&D evaluation programs who are not performing SS&D reviews are required to commit in writing to having an SS&D evaluation program in place before performing evaluations.

IV. ROLES AND RESPONSIBILITIES

A. Team Leader

Determines which team member(s) is assigned review responsibility for this performance indicator. The reviewer(s) should meet the applicable requirements specified in MD 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*.

* When performing a review, use the latest version of this and all guidance material.

B. SS&D Reviewer

Selects documents for review for each of the three subelements (e.g., training records, SS&D evaluations, event reports); reviews relevant documentation; conducts staff discussions, and maintains a summary of the review for this indicator.

V. GUIDANCE

A. Scope

This guidance applies to the three subelements to be reviewed under this indicator.

1. Evaluation of SS&D staffing and training should be conducted in a manner similar to, but not necessarily a part of, the Common Performance Indicator: Technical Staffing and Training, focusing on the training and experience necessary to conduct SS&D activities. The minimum qualifying criteria for SS&D staff authorized to sign registration certificates should be specified by the program and should be used in the review.
2. Review for adequacy, accuracy, completeness, clarity, specificity, and consistency of the technical quality of completed SS&D evaluations issued by the NRC or the Agreement State.
3. Reviews of SS&D incidents should be conducted in a manner similar to, but not necessarily a part of, the Common Performance Indicator: *Technical Quality of Incident and Allegation Activities*, to detect possible manufacturing defects and the root causes of these incidents. The incidents should be evaluated to determine if other products may be affected by similar problems. Actions and notifications to NRC, Agreement States, and others should be conducted as specified in the Office of State and Tribal Programs (STP) Procedure [SA-300](#), *Reporting Material Events*.
4. This guidance specifically excludes SS&D evaluations of non-Atomic Energy Act materials.

B. Evaluation Procedures

The reviewer should refer to MD 5.6, Part III, Evaluation Criteria, Non-Common Performance Indicator: Sealed Source and Device Evaluation Program, for the SS&D evaluation program criteria, in accordance with the subelements for this indicator.

1. The minimum training and qualification requirements for reviewers should be documented and be in compliance with MD 5.6, Part II, Non-Common Performance Indicator: Technical Staffing and Training. The reviewer should determine whether the training and experience of all SS&D personnel meet these or equivalent requirements.
 - a. For NRC, SS&D training and qualification requirements are documented in NRC Manual Chapter (MC) 1246, *Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area*.
 - b. Agreement States should have established, documented training and qualification requirements that are either equivalent to NRC MC 1246 or have implemented Appendix A of STP Procedure [SA-103](#), *Reviewing the Common Performance Indicator, Technical Staffing and Training*.
2. All SS&D evaluations completed since the last IMPEP review are candidates for review.
3. The reviewer should select a representative sample based on the number and the type of evaluations performed during the review period. The selected sample should represent a cross-section of the Agreement States or NRC's evaluations completed and include as many different reviewers and categories (e.g., new registrations, amendments, inactivations, or reactivations) as practical.
4. If the initial review indicates an apparent weakness on the part of a reviewer(s), or problems with respect to one or more type(s) of SS&D or event evaluations, additional samples should be reviewed to determine the extent of the problem or to identify a systematic weakness. The findings, if any, should be documented in the report. If previous reviews indicated a programmatic weakness in a particular area, additional casework in that area should be evaluated to assure that the weakness has been addressed.
5. The reviewer should determine whether or not a backlog exists, based on the criteria established by the program, and if the backlog has any impact on health and safety.
6. The review of incidents involving SS&Ds should be conducted in accordance with the guidance provided in Section V of STP Procedure [SA-105](#), *Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities*.

7. For Agreement States, the reviewer should also determine if the program has received notification from the NRC about potential generic SS&D issues discovered during trend analysis of the Nuclear Materials Events Database (NMED) events and identified in accordance with NRC in Policy and Procedure Letter 1.57, NMSS Generic Assessment Process. The reviewer would determine if such notifications had been received under this process; the effectiveness of the State's response to these notifications; 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; Policy and Procedure Letter 1.57; and, the program's effort to notify NRC and Agreement States of the corrective actions by the issuance of a revised certificate.
8. In cases where an Agreement State may have SS&D evaluation authority but is not performing SS&D reviews, the reviewer should verify that the program has committed in writing to having an evaluation program, as described in Section (C)(2) of Part II, MD 5.6, in place before performing evaluations.

C. Review Guidelines.

1. The response to questions relevant to this indicator in the IMPEP Questionnaire should be used to focus the review.
2. The reviewer should be familiar with NUREG 1556, Vol. 3, which provides guidance for SS&D evaluations.
3. Any issues identified in the last IMPEP review should be resolved in accordance with Section V.H.4, STP Procedure [SA-100](#), *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*.

D. Review Details.

For SS&D evaluations, the reviewer should evaluate the following:

1. Technical correctness with regard to all aspects of evaluations. The checklist in NUREG 1556, Vol. 3, or equivalent document, may be used to verify the full range of considerations;
2. Completeness of applications and proper signature by an authorized official;

3. Records to document significant errors, omissions, deficiencies or missing information (e.g., documents, letters, file notes, and telephone conversation records). The decision making process, including any significant deficiencies related to health and safety is noted during the evaluation, and adequately documented in the records;
4. The adequacy of the limitations and/or other considerations of use;
5. The conduct of the concurrence review, as defined in the Glossary, MD 5.6;
6. Acceptance of variances or exceptions to industry standards in accordance with NUREG 1556 Vol. 3, or equivalent guidance;
7. Guidance, checklists, regulations, and policy memoranda to ensure consistency with current accepted practice, standards and guidance.
8. Appropriate use of signature authority for the registration certificates.

E. Review Information Summary

The summary maintained by the reviewer for preparation of the final report will include, at a minimum:

1. The applicant's name;
2. The registration certificate number;
3. The type of action, e.g., new registration, amendment, inactivation, or reactivation;
4. The date of issuance;
5. The "use code" of the registration certificate, re: NUREG 1556, Vol. 3;
7. Narrative of the comments if any.

This summary of the review information usually, but not always, appears in Appendix F. The summary should follow the guidance in STP Procedure SA-100 and should be limited only to significant findings. Also, the information should be redacted, if necessary, to protect individual confidentiality. In addition, any comments on a particular file should not be detailed enough to link source, type, and quantity of radioactive material to a specific licensee.

- F. Discussion of Findings with the NRC or the Agreement State.

The reviewer should follow the guidance given in STP Procedure SA-100 for discussing technical findings with reviewers, supervisors, and management.

VI. APPENDICES

Not Applicable.

VII. REFERENCES

1. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program*.
2. NRC Management Directive 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*.
3. NRC Manual Chapter 1246, *Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area*
4. NUREG 1556 Volume 3, Rev. 1, *Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration*
5. Policy and Procedure Letter 1.57, *NMSS Generic Assessment Process*
6. STP Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*.
7. STP Procedure SA-103, *Reviewing the Common Performance Indicator, Technical Staffing and Training*.
8. STP Procedure SA-104, *Reviewing the Common Performance Indicator, Technical Quality of Licensing Actions*.
9. STP Procedure SA-105, *Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities*.
10. STP Procedure SA-300, *Reporting Material Events*.



STP Procedure Approval

Reviewing the Non-Common Performance Indicator, Sealed Source and Device (SS&D) Evaluation Program - SA- 108

Issue Date:

Review Date:

Paul H. Lohaus
Director, STP

Date:

Dennis K. Rathbun
Deputy Director, STP

Date:

John G. Zabko
Procedure Contact, STP

Date:

NOTE

The STP Director's Secretary is responsible for the maintenance of this master copy document as part of the STP Procedure Manual. Any changes to the procedure will be the responsibility of the STP Procedure Contact. ~~Copies of STP procedures will be distributed for information.~~



Procedure Title:
*Reviewing the Non-Common Performance Indicator -
Sealed Source & Device (SS&D) Evaluation Program*
Procedure Number: SA-108

Page: 1 of 6

Issue Date:

I. INTRODUCTION

This document describes the procedure for conducting reviews of the U.S. Nuclear Regulatory Commission (NRC) and Agreement State sealed source and device (SS&D) evaluation activities using the Non-Common Performance Indicator: *Sealed Source and Device Evaluation Program* [NRC Management Directive (MD) 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*].

II. OBJECTIVES

To verify the **adequate** implementation of the three subelements under this indicator - (a) Technical Staffing and Training, (b) Technical Quality of the Product Evaluation Program, and (c) Evaluation of Defects and Incidents Regarding SS&Ds.

III. BACKGROUND

Adequate technical evaluations of SS&D designs are essential to ensure that SS&Ds will maintain their integrity and that the design is adequate to protect public health and safety. NUREG-1556, Volume 3, *Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration*, provides information on conducting SS&D reviews that may provide and establishes useful guidance for review teams. Three subelements, noted above, will be evaluated to determine if the SS&D program is **adequate/satisfactory**. Agreement States with authority for SS&D evaluation programs who are not performing SS&D reviews are required to commit in writing to having an SS&D evaluation program in place before performing evaluations.

IV. ROLES AND RESPONSIBILITIES

A. Team Leader

~~The team leader d~~Determines which team member(s) is assigned review responsibility for this performance indicator. The reviewer(s) should meet the applicable requirements specified in MD 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*. ~~Assists in developing a plan to further review or identify root causes for any potential health and safety issues identified by SS&D reviewer.~~

B. SS&D Reviewer

~~The reviewer is responsible for~~ **Selecting** documents for review for each of the three sub-elements; (e.g., training records, SS&D evaluations, event reports); ~~for reviewing~~ **s** relevant documentation; ~~for conducting~~ **s** staff discussions., and ~~for maintaining~~ **s** a summary of the review for this indicator. ~~The reviewer is responsible for writing the relevant sections in the IMPEP report.~~

~~If a significant issue is identified, the reviewer should immediately discuss it with the team leader.~~

V. GUIDANCE

A. Scope

This guidance applies to the three subelements to be reviewed under this indicator.

1. Evaluation of SS&D staffing and training should be conducted in ~~the same manner and as part~~ **a manner similar to, but not necessarily a part of,** of the Common Performance Indicator: Technical Staffing and Training, focusing on the training and experience necessary to conduct SS&D activities. The minimum qualifying criteria for SS&D staff authorized to sign registration certificates should be specified by the program and should be used in the review.

2. Review for adequacy, accuracy, completeness, clarity, specificity, and consistency of the technical quality of completed SS&D evaluations issued by the NRC or the Agreement State.

3. Reviews of SS&D incidents should be conducted in ~~the same manner and as part~~ **a manner similar to, but not necessarily a part of,** the Common Performance Indicator: *Technical Quality of Incident and Allegation Activities*, to detect possible manufacturing defects and the root causes of these incidents. The incidents should be evaluated to determine if other products may be affected by similar problems. Actions and notifications to NRC, Agreement States, and others should be conducted as specified in **the Office of State and Tribal Programs (STP) Procedure SA-300, Reporting Material Events.**

~~4. This review should cover the period of time since the last IMPEP review. This time frame is defined as the “review period.”~~

54. This guidance specifically excludes SS&D evaluations of non-Atomic Energy Act materials.

B. Evaluation Procedures

The reviewer should refer to **MD 5.6**, Part III, Evaluation Criteria, Non-Common Performance Indicator: Sealed Source and Device **Evaluation Program**, ~~Handbook 5.6~~ for the SS&D evaluation program criteria, in accordance with the subelements for this indicator.

1. The minimum training and qualification requirements for reviewers should be documented and be in compliance with **MD 5.6**, Part II, Non-Common Performance Indicator: Technical Staffing and Training, ~~Handbook 5.6~~. The reviewer should determine whether the training and experience of all SS&D personnel meet these or equivalent requirements.
 - a. **For NRC, SS&D training and qualification requirements are documented in NRC Manual Chapter (MC) 1246, Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area.**
 - b. **Agreement States should have established, documented training and qualification requirements that are either equivalent to IMC 1246 or have implemented Appendix A of STP Procedure SA-103, Reviewing the Common Performance Indicator, Technical Staffing and Training.**
2. All SS&D evaluations completed since the last IMPEP **review** are ~~potential~~ candidates for review.
3. The reviewer should select a representative sample based on the number and the type of evaluations performed during the review period. The selected sample should represent a cross-section of the **Agreement State's** or NRC's evaluations completed and include as many different reviewers and categories (**e.g., new registrations, amendments, inactivations, or reactivations**) as practical.
4. If the initial review indicates an ~~appearance of a~~ **apparent** weakness on the part of a reviewer(s), or problems with respect to one or more type(s) of SS&D or event evaluations, additional samples should be reviewed to determine the extent of the problem or **to** identify a systematic weakness. The findings, if any, should be documented in the report. **If previous reviews indicated a programmatic weakness**

in a particular area, additional casework in that area should be evaluated to assure that the weakness has been addressed.

5. The reviewer should determine whether or not a backlog exists, based on the criteria established by the program, and if the backlog has any impact on **health and safety**.
6. The review of incidents involving SS&Ds should be conducted in accordance with the guidance provided in Section V; of **STP Procedure SA-105, *Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities***.
7. **For Agreement States, the reviewer should also determine if the program has received notification from the NRC about potential generic SS&D issues discovered during trend analysis of NMED events and identified in accordance with NRC in Policy and Procedure Letter 1.57, NMSS Generic Assessment Process. The reviewer would determine if such notifications had been received under this process; the effectiveness of the State's response to these notifications; 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; Policy and Procedure Letter 1.57; and, the program's effort to notify NRC and Agreement States of the corrective actions by the issuance of a revised certificate.**
8. In cases where an Agreement State may have SS&D evaluation authority but is not performing SS&D reviews, the reviewer should verify that the program has committed in writing to having an evaluation program, as described in Section (C)(2) of Part II, MD 5.6, in place before performing evaluations.

C. Review Guidelines.

1. The response ~~provided to SS&D questions~~ **relevant to this indicator** in the IMPEP Questionnaire should be used ~~as the basis for~~ **to focus** the review.
2. The reviewer should be familiar with NUREG 1556, Vol. 3, ~~Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration~~, which provides guidance for SS&D evaluations.
3. Any issues identified in the last IMPEP review should be resolved in accordance with ~~Part 4, Section V.H.4,~~ **STP Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)***.

D. Review Details.

For SS&D evaluations, the reviewer should evaluate **the following**:

1. Technical correctness with regard to all aspects of evaluations. The checklist in NUREG 1556, Vol. 3, or equivalent document, may be used to verify the full range of considerations;
2. Completeness of applications and proper signature by an authorized official;
3. Records to document significant errors, omissions, deficiencies or missing information; (e.g., documents, letters, file notes, and telephone conversation records). The decision making process, including any significant deficiencies related to health and safety is noted during the evaluation, and adequately documented in the records;
4. The adequacy of the limitations and/or other considerations of use;
5. The conduct of the concurrence review, as defined in the Glossary, ~~NRC~~MD 5.6;
6. Acceptance of variances or exceptions to industry standards in accordance with NUREG 1556 Vol. 3, or equivalent guidance;
7. Guidance, checklists, regulations, and policy memoranda to ensure consistency with current accepted practice, standards and guidance.
8. Appropriate use of signature authority for the registration certificates.

E. Review Information Summary

The summary maintained by the reviewer for preparation of ~~Appendix F~~ of the final report will include, at a minimum:

1. The applicant's name, ~~city, and state~~;
2. The registration certificate number;
3. ~~The initials of the staff responsible for the evaluation for identification~~;
4. The type of action, e.g., new registration, amendment, inactivation, or reactivation;
5. The date of issuance;

65. The “use code” of the registration certificate, re: NUREG 1556, Vol. 3;
7. Narrative of the comments if any.

This summary of the review information usually, but not always, appears in Appendix F. The summary should follow the guidance in STP Procedure SA-100 and should be limited only to significant findings. Also, the information should be prepared in a redacted fashion, if necessary, in order not to compromise to protect individual confidentiality. In addition, any comments on a particular file should not be detailed enough to link source, type, and quantity of radioactive material to a specific licensee.

F. Discussion of Findings with the NRC or the Agreement State.

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

VI. APPENDICES [RESERVED]

Not Applicable.

VII. REFERENCES

1. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program*.
2. NRC Management Directive 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*.
3. NRC Manual Chapter 1246, *Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area*
4. NUREG 1556 Volume 3, **Rev. 1**, *Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration*
5. **Policy and Procedure Letter 1.57, NMSS Generic Assessment Process**
6. STP Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*.
7. STP Procedure SA-103, *Reviewing the Common Performance Indicator, Technical Staffing and Training*.

8. STP Procedure SA-104, *Reviewing the Common Performance Indicator, Technical Quality of Licensing Actions.*
9. STP Procedure SA-105, *Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities.*
10. STP Procedure SA-300, *Reporting Material Events.*

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.