FSME Procedure Approval

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

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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 the FSME procedures will be available through the NRC website.

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)*]. Agreement States have the option of maintaining their own SS&D program. This option has been listed as a line item in the most recently signed Agreements.

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, but focused 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 (FSME) 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 Inspection Manual Chapter (IMC) 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 FSME 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. The reviewer should include any work performed on behalf of the program under review by others, i.e. NRC, an Agreement State, or a contractor, to ensure the technical quality of the work. The reviewer should also ensure that any individuals performing work on a program's behalf meet the program's training and qualification requirements.

   NOTE: Because the work is being performed at the discretion of the program under review, any weaknesses or deficiencies that the review team identifies will affect the appropriate subelement rating(s) and could ultimately affect the overall indicator rating for the program under review.

5. 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.

6. 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.

7. The review of incidents involving SS&Ds should be conducted in accordance with the guidance provided in Section V of FSME Procedure SA-105, *Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities*.

8. 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 Material 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.

9. 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, FSME 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. SS&D Type;

6. 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 FSME 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 FSME Procedure SA-100 for discussing technical findings with reviewers, supervisors, and management.

VI. APPENDICES

Not Applicable.

VII. REFERENCES

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

VIII. ADAMS REFERENCE DOCUMENTS

For knowledge management purposes, all previous revisions of this procedure, as well as associated correspondence with stakeholders that have been entered into NRC's Agencywide Documents Access and Management System (ADAMS) are listed below.

No.	Date	Document Title/Description	Accession Number
1	2/27/04	STP-04-011, Opportunity to Comment on Draft STP Procedure SA-108	ML061640162
2	6/20/05	STP Procedure SA-108, Reviewing the Non-Common Performance Indicator, Sealed Source and Device Evaluation Program, Redline/Strikeout Version	ML061640169
3	6/20/05	Summary of Comments on SA-108	ML061640173
4	6/20/05	STP Procedure SA-108, Reviewing the Non-Common Performance Indicator, Sealed Source and Device Evaluation Program	ML040620291
5	6/30/05	STP-05-049, Final STP Procedure SA-108	ML051810473
6	7/14/09	FSME-09-051, Opportunity to Comment on Draft Revision of FSME Procedures SA-108 and SA-109	ML091330602
7	7/14/09	FSME Procedure SA-108, Draft Revision with tracked changes	ML091330103