Office of Nuclear Material Safety and Safeguards Procedure Approval

Reviewing the Non-Common Performance Indicator, Sealed Source and Device Evaluation Program, State Agreements (SA) Procedure SA-108

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NOTE

Any changes to the procedure will be the responsibility of the NMSS Procedure Contact. Copies of NMSS procedures are available through the NRC Web site at https://scp.nrc.gov.

I. INTRODUCTION

This document describes the procedure for conducting reviews of Agreement State and U.S. Nuclear Regulatory Commission (NRC) radiation control programs as specified in NRC Management Directive (MD) 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*.

II. OBJECTIVES

To verify the adequate implementation of the three sub-elements under this indicator:

A. Technical Staffing and Training,

B. Technical Quality of the Product Evaluation Program, and

C. Evaluation of Defects and Incidents Regarding Sealed Source & Devices.

III. BACKGROUND

Adequate technical evaluations of Sealed Source & Device (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. The three sub-elements, noted above, are 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. IMPEP Review Team Leader (Team Leader)

1. In coordination with the IMPEP Program Manager, the Team Leader determines which team member is assigned lead review responsibility for this performance indicator.

2. Communicates the team's findings to Program Management and ensures that the team's findings are in alignment with MD 5.6.

3. This procedure allows for the option to not review a SS&D Evaluation Program that has not performed any evaluations since the last IMPEP review and that there have been no changes or issues since the last IMPEP review that would impact safety of the SS&Ds within the Program's oversight.

B. SS&D Reviewer

1. Selects documents for review for each of the three sub-elements (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.

2. Coordinates the review of the indicator with other reviewers, if needed.

3. Informs the Team Leader of the team's findings throughout the onsite review.

4. Presents the team's findings to the Program at the staff exit meeting.

5. Completes their portion of the IMPEP report for the Sealed Source and Device Evaluation Program performance indicator.

6. Attends the Management Review Board meeting for the IMPEP review; presents and discusses the team's findings for the Sealed Source and Device Evaluation Program performance indicator (this can be done either in person or remotely).

V. GUIDANCE

A. Scope

Guidance applies to the three sub-elements to be reviewed under this indicator.

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

3. Review the SS&D incidents 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 Agreement States, NRC, and others should be conducted as specified in the Office of Nuclear Material Safety and Safeguards (NMSS) State Agreements (SA) Procedure SA-300, *Reporting Material Events*.

4. Review of SS&D evaluations of non-Atomic Energy Act materials (e.g., naturally occurring radioactive material (NORM)) will be specifically excluded.

B. Review Guidelines

1. Evaluate the response generated by the Program to relevant questions in the IMPEP questionnaire. Depending on the level of detail of the information provided, the response to the questionnaire relative to this indicator may be useful to focus the review.

2. Identify any issues in the last IMPEP review that should be resolved in accordance with Section V.H.4, NMSS Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*.

3. All SS&D evaluations completed since the last IMPEP review are candidates for review.

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

   a. 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.

   b. Select work performed on behalf of the program under review by others, (i.e., an Agreement State, NRC, 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 sub-element rating(s) and could ultimately affect the overall indicator rating for the program under review.

   c. Identify if the initial review indicates an apparent weakness on the part of SS&D personnel, 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. 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. Review the technical correctness with regard to all aspects of evaluations. The checklist in the latest revision of NUREG–1556, Volume 3, or equivalent document, may be used to verify the full range of considerations.

7. Review the completeness of applications and proper signature by an authorized official.

8. Review 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.

9. Review the adequacy of the limitations and other considerations of use.

10. Evaluate the method used for the concurrence review with regard to SS&D reviewers who may not be fully qualified SS&D reviewers and may not have full signature authority.

11. Review the acceptance of variances or exceptions to industry standards in accordance with NUREG–1556, Volume 3, or equivalent guidance.

12. Review the guidance, checklists, regulations, and policy memoranda to ensure consistency with current accepted practice, standards and guidance.

13. Ensure the appropriate use of signature authority for the registration certificates.

14. Ensure the thorough technical evaluations of the SS&D designs are conducted because the SS&Ds design must be 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 the SS&D reviews and establishes useful guidance for IMPEP teams.

15. Reviews of Technical Staffing and Training should focus on the following:

    a. Review the minimum training and qualification requirements for the Program's SS&D personnel. The qualifications should be documented and compatible 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.

    b. Agreement States should have established, documented training and qualification requirements that are either equivalent to NRC Inspection Manual Chapter (IMC) 1248, *Formal Qualification Programs for Federal and State Material and Environmental Management Programs* or have implemented NMSS Procedure SA-103, *Reviewing the Common Performance Indicator, Technical Staffing and Training*.

c. NRC should follow the SS&D training and qualification requirements documented in NRC IMC 1248.

16. Reviews of Technical Quality of the Product Evaluation Program should focus on the following:

    a. Review the technical evaluations of the SS&D designs to ensure that the SS&Ds used by both licensees and persons exempt from licensing will maintain their integrity and that the design features are adequate to protect public health and safety. The technical quality of the product evaluation program should be assessed by the IMPEP review team on the basis of an in-depth review of a representative cross-section of evaluations performed on various types of products and actions. To the extent possible, the review team should capture a representative cross-section of completed actions by each of the Agreement State or NRC SS&D reviewers.

17. Reviews of Evaluation of Defects and Incidents Regarding SS&Ds should focus on the following:

    a. Review incidents involving SS&Ds in accordance with the guidance provided in Section V of NMSS Procedure SA-105, *Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities*.

       This review is used to detect possible manufacturing defects and the root causes for these incidents with regard to potential generic SS&D issues. The incidents should be evaluated to determine if other products may be affected by similar problems. Appropriate action should be taken, and notifications made to the Agreement States, NRC, and others, as appropriate.

    b. The reviewer will evaluate the Agreement States response to notifications from the NRC with regard to generic SS&D issues related to the effectiveness of the States 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; and the programs effort to notify Agreement States and NRC of the corrective actions by the issuance of a revised certificate.

    c. Verify the 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 Information Summary

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

1. The applicants 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; and

6. Narrative of the comments, if any.

The summary of review information will not appear in the final IMPEP report. However, it is a good practice for the reviewer to maintain this information to support the reviewer's presentation to the MRB.

D. Evaluation Process

1. The principle reviewer should refer to MD 5.6, Part II, Performance Indicators, and Part III, Evaluation Criteria, Non-Common Performance Indicator: Sealed Source and Device Evaluation Program, for the SS&D evaluation program criteria. These criteria should apply to program data for the entire review period. A finding of "satisfactory" is appropriate when a review demonstrates the presence of the following conditions:

   a. The SS&D program meets the criteria for a "satisfactory" finding for the performance indicator, Technical Staffing and Training, as described in Section III.B.1 of the MD 5.6 Directive Handbook.

   b. Procedures compatible with NMSS Procedure SA-108, "Reviewing the Non-Common Performance Indicator, Sealed Source and Device Evaluation Program."

   c. Concurrence review of the technical reviewer's evaluation is performed by management or staff having proper qualifications and training.

   d. Product evaluations address health and safety issues; are thorough, complete, consistent, and of acceptable technical quality; and adequately address the integrity of the products under normal conditions of use and likely accident conditions.

e. Registrations clearly summarize the product evaluation and provide license reviewers with adequate information with regard to license possession and use of the product.

f. Deficiency letters clearly state regulatory positions and are used at the proper time.

g. Completed registration certificates, and the status of obsolete registration certificates, are clear and are promptly transmitted to the Agreement States, NRC, and others, as appropriate.

h. The SS&D reviewers ensure that registrants have developed and implemented adequate quality assurance and control programs.

i. There is a means for enforcing commitments made by registrants in their applications and referenced by the program in the registration certificates.

j. There are no potentially significant health and safety issues identified from the review, that were linked to a specific product evaluation.

k. The SS&D reviewers routinely evaluate the root causes of defects and incidents involving the devices subject to the SS&D program and take appropriate actions, including modifications of the SS&D sheets and notifications to the Agreement States, NRC, and others, as appropriate.

Note: *Examples of Less than Satisfactory Findings of Program Performance* can be found in the IMPEP Toolbox on the State Communications Portal Web site. These examples may assist the reviewer in identifying less than fully satisfactory findings of a Program's performance.

E. Discussion of Findings with the Radiation Control Program

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

2. If the IMPEP review team identifies programmatic performance issues, the IMPEP review team should seek to identify the root cause(s) of the issues, which can be used as the basis for developing recommendations for corrective actions. The NMSS procedure SA-100 contains criteria regarding the development of recommendations by the IMPEP team.

VI. REFERENCES

Management Directives (MD) available at https://scp.nrc.gov

NMSS SA Procedures available at https://scp.nrc.gov

NUREG–1556 Volume 3, *Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration available at* https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v3/
Policy and Procedure Letter 1.57, *NMSS Generic Assessment Process* (Agencywide Documents Access and Management System (ADAMS) Accession No. ML020170155)

NRC Inspection Manual Chapters available at https://www.nrc.gov/reading-rm/doc-collections/insp-manual/manual-chapter/

IMPEP Toolbox (e.g., examples of a less than satisfactory program) on the State Communications Portal Web site available at https://scp.nrc.gov/impeptools.html

VII. 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 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
8	1/22/10	Final FSME Procedure SA-108	ML092740005
9	1/22/19	FSME Procedure SA-108, Resolution of Comments	ML092740069
10	1/22/19	FSME Procedure SA-108, Draft Revision with tracked changes	ML092740014

11	12/20/19	Interim Procedure SA-108: Reviewing the Non-Common Performance Indicator, Sealed Source & Device Evaluation Program	ML19324F028
12	7/6/20	Resolution of Comments	ML20188A165
13	9/15/20	Final NMSS Procedure SA-108	ML20244A280