STP Procedure Approval

Non-Common Performance Indicator - Sealed Source & Device (SS&D) Reviews SA-108

Issue Date:

Review Date:

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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.

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 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 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 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, provides information on conducting SS&D reviews that may provide useful guidance for review teams. Three subelements, noted above, will be evaluated to determine if the SS&D program is adequate. 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 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 Team Members*.

Assists in developing a plan to further review or identify root causes for any potential health and safety issues identified by review.

B. SS&D Reviewer

The reviewer is responsible for selecting documents for review for each of the three subelements, e.g., training records, SS&D evaluations, event reports; for reviewing relevant documentation; for conducting staff discussions, and for maintaining 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 Sub-elements to be reviewed under this indicator.

1. Evaluation of SS&D staffing and training should be conducted in the same manner and as 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 the same manner and as 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 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.”

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

B. Evaluation Procedures

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

1. The minimum training and qualification requirements for reviewers should be documented and be in compliance with 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.

2. All SS&D evaluations completed since the last IMPEP 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 State's or NRC's evaluations completed and include as many different reviewers and categories as practical.

4. If the initial review indicates an appearance of a 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 identify a systematic weakness. The finding, if any, should be documented in the report.

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 safety.

6. The review of incidents involving SS&Ds should be conducted in accordance with the guidance provided in Section V, SA-105, "Response to Incidents and Allegations." The reviewer should examine a representative number of such incidents.

7. 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 in the IMPEP Questionnaire should be used as the basis for 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 H, SA-100, Implementation of the Integrated Materials Performance Evaluation Program (IMPEP).

D. Review Details.

For SS&D evaluations, the reviewer should evaluate:

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;

6. The "use code" of the registration certificate, re: NUREG 1556, Vol. 3;

7. Narrative of the comments if any.

This information should be prepared in a sanitized fashion, if necessary, in order not to compromise confidentiality.

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

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

VI. APPENDICES [RESERVED]

VII. REFERENCES

1. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program.*
2. NRC Management Directive 5.10, *Formal Qualifications for IMPEP Team Members*.
3. STP Procedure SA-100, *Integrated Materials Performance Evaluation Program.*
4. STP Procedure SA-103, *Reviewing Common Performance Indicator, Technical Staffing and Training.*
5. STP Procedure SA-104, *Reviewing Common Performance Indicator, Technical Quality of Licensing*.
6. STP Procedure SA-105, *Reviewing Common Performance Indicator, Response to Incidents and Allegations.*
7. STP Procedure SA-300, *Reporting Material Events*
8. Volume 3, NUREG 1556 *Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration*
9. NRC Manual Chapter 1246, *Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area*