Office of Nuclear Material Safety and Safeguards
Procedure Approval

Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities
State Agreements (SA) Procedure SA-105

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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 for the common performance indicator, Technical Quality of Incident and Allegation Activities in accordance with Management Directive (MD) 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*.

A. The term "incident" means an event or condition that has the possibility of affecting public health and safety such as overexposure, damage to equipment or facility, release of radioactive material, equipment or procedure failure, lost/stolen/abandoned radioactive material, leaking source, contamination event, transportation, loss of control, medical event, etc. In accordance with provisions contained in the Atomic Energy Act and the Energy Reorganization Act, and compatible Agreement State regulations, Agreement State and NRC licensees are required to report the occurrence of incidents and events involving the use of nuclear materials to the appropriate regulatory agency. For purposes of compatibility, the Agreement States report to NRC those incidents and events reported to them by their licensees or non-licensees that involve the use of nuclear materials. If an Agreement State defines this term in a different fashion, this should be noted during the review.

B. The term "allegation" means a declaration, statement, or assertion of impropriety or inadequacy associated with regulated activities within the scope of this procedure, the validity of which has not been established. For this procedure, this term also includes all concerns identified by external sources such as the media, individuals, or organizations. Excluded from this definition are matters being handled by more formal processes, such as Title 10 *Code of Federal Regulations* (10 CFR) 2.206 petitions, hearing boards, and appeal boards. If an Agreement State program defines this term in a different fashion, this should be noted during the review.

II. OBJECTIVES

A. To ensure that actions taken in response to incidents and allegations are appropriate and well-coordinated.

B. To verify that the radiation control program has appropriate incident and allegation response procedures in place and that the procedures are followed.

C. To confirm that the radiation control program takes appropriate measures to follow-up on licensee corrective actions that were implemented in response to incidents and allegations to ensure compliance.

D. To confirm notification by the Agreement States to the NRC is performed, as appropriate, in accordance with the Handbook on Nuclear Material Event Reporting in the Agreement States (SA-300, *Reporting Material Events*).

E. To verify that the information provided by the radiation control program on incidents for inclusion in the Nuclear Material Events Database (NMED) is complete.

F. To confirm that the alleger is informed of the findings within 30 days following the completion of all actions necessary to close the allegation, as appropriate, if the identity of the alleger is known.

III. BACKGROUND

The regulator's response to incidents and allegations can have a direct impact on public health, safety, and security. A careful assessment of incident response and allegation investigation, including internal and external coordination and investigative and follow-up actions, is an indication of the overall quality of the program.

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 and assigns other team members to provide support, as necessary.

2. The Team Leader ensures that the team's findings are in alignment with MD 5.6 and communicates the team's findings to Program Management.

3. The Team Leader should request that the Program notify the IMPEP Team Leader if an incident or allegation is received during the on-site review. This may be an opportunity to conduct a performance-based review of this indicator.

B. Principal Reviewer

1. Evaluates the Program's actions as outlined in this procedure.

2. Ensures that the allegation information recorded as part of this review does not reveal the identities of the allegers.

3. Informs the Team Leader of the team's findings throughout the on-site 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 Technical Quality of Incident and Allegation Activities performance indicator.

6. Attends the Management Review Board (MRB) meeting for the IMPEP review; presents and discusses the team's findings for the Technical Quality of Incident and Allegation Activities performance indicator (this can be done either in-person or remotely).

V. GUIDANCE

A. Scope

1. This procedure applies to all incident response and allegation activities that were received, reported, and completed during the review period.

2. This procedure specifically excludes incident response and allegations activities with non-Atomic Energy Act material (e.g., naturally occurring radioactive material (NORM)).

B. Preparation

1. Review the NRC guidance related to incidents and allegations.

2. Obtain relevant documentation prior to the on-site review by performing the following:

   a. Perform an NMED search for all events since the last IMPEP. Guidance for performing NMED searches for IMPEP reviews is available in the Help Section of the NMED Web site; [Note: Be alert for searches indicating "pending" or "not completed," because this means information is still needed.];

   b. Contact the Regional State Agreements Officer and Headquarters Allegations Team (HQAT), to obtain a list of allegations that have been referred to the Agreement State since the last IMPEP; and

   c. Obtain the last audit of the allegation program, if available. For an NRC IMPEP review, contact the HQAT to obtain their last audit of the allegation program.

C. Review Guidelines

1. The response generated by the Program to relevant questions in the IMPEP questionnaire should be used to focus the review.

2. The reviewer should request the IMPEP Team Members who are reviewing license and inspection files be alert to any documentation of any incidents or allegations in the files and share these findings with this principal reviewer.

3. For incident response, the reviewer should:

   a. Obtain a detailed printout of all NMED data for the review period;

   b. Select a sampling of radioactive materials events received by the radiation control program that meet the NRC's criteria of a reportable event (if there are less than 10 events for the review period, the reviewer should review all reportable events). The sample should represent a cross-section of the type of events reported during the review period. Additional cases can be reviewed as necessary to evaluate the severity of a potential performance issue;

   c. Select a small sample of radioactive materials events that were deemed not reportable to determine if the events should have been reported. This sample of events should primarily be evaluated with respect to the reporting criteria in SA-300;

   d. Ensure responses are appropriate for the risk-significance of the incident;

e. Ensure timeliness of notifications to the NRC Headquarters Operations Center and to NMED for reportable events;

f. Ensure inquiries made to evaluate the need for on-site investigations are conducted in accordance to the Program's procedure. Inspectors need to obtain information that will aid in the assessment for the type of response necessary;

g. Ensure performance, including timeliness of on-site investigations, and justification if on-site investigation is delayed, when appropriate. For example, the radiation control program response to an overexposure incident or allegation, a loss of a Category 1 or 2 radioactive source, or radioactive material found in the public domain should be commensurate with the risk. If the incident or allegation deals with risk-significant health, safety, or security matters for a radiation worker, a member of the public or the environment, the response needs to be prioritized;

h. Ensure follow-up of incidents is conducted during the next scheduled inspection;

i. Ensure inclusion of in-depth reviews of incidents during inspections on a high- priority basis, as warranted. When appropriate, follow-up activities should include re-enactments and time-study measurements. Inspection results should be documented;

j. Ensure information on incidents involving equipment failure (including make, model, and serial number) is provided to the regulatory agency responsible for evaluation of the device for an assessment of possible generic design deficiency;

k. Determine that the number, type of event reports, and technical quality of information recorded in NMED and the number, type of event reports, and technical quality of information on record at a radiation control program are consistent and complete;

l. Ensure information obtained during the Program's investigation is compared with information obtained from the licensee to identify and resolve any differences;

m. Determine whether or not the public is provided access to the radiation control program and licensee records on the incident, as permitted within the constraints of laws for protection of personal, private, and proprietary information;

n. Verify that the written procedure for handling incidents is available to staff, implemented appropriately with any deviations from the written procedure justified, and is effective in addressing the above review detail criteria;

o. Review the Agreement State's written procedure to ensure it is compatible with the NRC's SA-300, *Reporting Materials Events,* and verify that staff are aware of the procedure and use it accordingly;

p. Observe the performance-based actions (e.g., receipt, disposition, and inspection) of a new incident, should one occur during the on-site review (if approved by Program management);

q. Ensure the licensee's written response, if required, was reviewed for adequacy, completeness, and verification that the corrective actions correspond to the root cause or mitigating factors to prevent recurrence;

r. Ensure that items of noncompliance that led to an event are being identified and dispositioned in accordance with the Agreement State's or NRC's radiation control program; and

s. Assess whether the reportable incident has the potential for meeting the Abnormal Occurrence (AO) criteria and has been correctly identified in NMED.

4. For allegations, the reviewer should:

a. Select a sampling of allegation cases (if there are less than 10 allegations for the review period, the reviewer should review all allegations). Additional cases can be reviewed as necessary to evaluate the severity of a potential performance issue. All cases referred to the Agreement State from the NRC should be reviewed. [NOTE: The principal reviewer may choose to review the latest audit conducted by the Headquarters Allegation Team (for the NRC) or conducted by the Agreement State to supplement the review.];

b. Consult with the Agreement State radiation control program, on the existence of confidentiality agreements (or other similar mechanisms) in place that may limit the review of specific files. The State may have to remove certain information from documents to protect the identity of allegers;

c. Ensure responses are appropriate for the risk-significance of the allegation;

d. Ensure priority is given to allegations with potential safety or security significance;

e. Ensure receipt of an allegation is acknowledged to the alleger;

f. Ensure the Program conducts discussions with the alleger, if any, to obtain additional information;

g. Ensure protection of alleger's identity in accordance with the Agreement State's or NRC's rules and policy relating to alleger identity protection;

h. Ensure adequacy of the evaluation and inspection of the allegation to assess its validity and if health, safety and security issues are present;

i. Ensure the alleger has been notified of the results of the review of each allegation, describing the scope and depth of the review performed and indicating the staff's conclusion as to the validity of the allegation, and that allegers are informed of the progress of unresolved allegations consistent with the Agreement State's or Region's policy;

j. Ensure closure of allegations is conducted in accordance with the Program's procedure;

k. Ensure Agreement State allegation procedures are compatible to Section I (A, B and C) and Section II (A, B, F, H, J and L) of the Handbook to MD 8.8, *Management of Allegations*;

l. Verify whether the program for processing allegations encourages those with safety concerns to express those concerns;

m. Verify that the written procedure for handling allegations (e.g., MD 8.8) is available to staff, implemented appropriately with any deviations from the written procedure justified and is effective in addressing the above review detail criteria;

n. Observe the performance-based actions (e.g., receipt, disposition, and inspection) of any new allegations received during the on-site review to the extent practicable (if approved by Program management);

o. Verify that letters referring allegations to licensees are written in appropriate regulatory language and that each letter specifies the date for the licensee's response indicating findings, corrective actions, and actions taken to prevent recurrence; and

p. Verify the licensee's response to an allegation referral was reviewed for adequacy and completeness.

D. Review Information Summary

1. At a minimum, the principal reviewer should retain the following information for all incident and allegation casework evaluated during the on-site review:

a. Licensee's name,

b. A numerical file reference (such as license number, inspection report number, or NMED number),

c. The lead inspector's initials (if on-site investigation was conducted),

d. Date the incident or allegation was received and date of incident (if different),

e. Type of incident or allegation (such as medical event, transportation, loss of control, etc.),

f. Date of investigation, and

g. Type of investigation (such as inspection, telephone, licensee report, etc.).

2. The Incident Casework Review Summary Sheet can be found in the IMPEP Toolbox on the state communications portal Web site. This summary sheet provides a template for recording the necessary information that should be maintained by the principal reviewer. The principal reviewer should not feel obligated to use the summary sheet but may find it as a useful means of recording the necessary information. The principal reviewer should retain the records until after the MRB meeting, as case-specific questions may be asked by MRB members.

3. The Allegation Casework Review Summary Sheet can be found in the IMPEP Toolbox on the state communications portal Web site. This summary sheet provides a template for recording information specific to allegation casework reviews. Information on allegation casework reviews is not published in IMPEP reports. The principal reviewer should retain the records until after the MRB meeting, as case-specific questions may be asked by MRB members.

    a. The completed summary sheet cannot include any information on the identity of the concerned individual (aka the alleger), personally identifiable information (PII), Privacy Act information, or other sensitive information. The reviewer cannot photocopy any information from the allegation file. Documentation needed for the IMPEP report should be retained on the summary sheet.

E. Evaluation Process

The principal reviewer should refer to Part III, Evaluation Criteria of MD 5.6 for specific evaluation criteria. As noted in MD 5.6, the criteria for a satisfactory program is as follows:

1. Incident response and allegation procedures are compatible with the criteria specified in this procedure.

2. Incident response and allegation procedures are implemented for the type of incident or allegation as specified in this procedure or compatible Agreement State procedure.

3. Level of effort is commensurate with the potential health, safety, and security significance of an incident or allegation, including on-site investigation of incidents.

4. Actions taken are focused, coordinated, and timely for incidents and allegations involving health, safety, and security issues.

5. Corrective (e.g., enforcement) actions are taken to achieve compliance and prevent recurrence.

6. Program responses to incidents and allegations are conducted by inspectors knowledgeable of the license type and radioactive material involved.

7. Follow-up inspections are scheduled and completed, if necessary.

8. Notifications to the NRC Headquarters Operations Center, with follow-up to NMED, as necessary, are performed in accordance with the time frames established in SA- 300 or compatible Agreement State procedure.

9. Results of allegation investigations are provided to allegers, and alleger identities are protected in accordance with the applicable State or Federal laws or policies.

10. Responses to incidents or allegations are complete, coordinated, and timely for cases that could have resulted in an overexposure, or loss of risk-significant radioactive material.

These examples are maintained in the IMPEP Toolbox on the state communications portal Web site. These examples can assist the reviewer in identifying less than satisfactory findings of a program performance.

F. 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

NMED is available at https://nmed.inl.gov/

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

NRC Allegation Manual available at https://www.nrc.gov/docs/ML1700/ML17003A227.pdf

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

NUREG-0090 *Report to Congress on Abnormal Occurrences* available at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/

Title 10 Code of Federal Regulations available at https://www.nrc.gov/reading-rm/doc- collections/cfr/

IMPEP Toolbox (e.g., casework summary sheets and examples of a less than satisfactory program) available at https://scp.nrc.gov/impeptools.html

VII. AGENCYWIDE DOCUMENTS ACCESS AND MANAGEMENT SYSTEM (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	12/15/06	FSME-06-112, Opportunity to Comment on Draft Revisions to FSME Procedure SA-105	ML063480642
2	12/15/06	FSME Procedure SA-105, Draft Revision	ML063480651
3	6/13/07	FSME-07-057, Final FSME Procedure SA-105	ML071880003
4	6/13/07	FSME Procedure SA-105	ML071880005
5	6/13/07	Redline/Strikeout Copy	ML071880006
6	6/13/07	Resolution of Comments	ML071880007
7	10/8/09	FSME-09-092, Opportunity to Comment on Draft Revisions to FSME Procedure SA-105	ML092750465
8	3/28/16	NMSS Procedure SA-105, Draft Revision	ML16034A472
9	10/20/17	Resolution of Comments	ML17293A203
10	12/20/19	NMSS Procedure SA-105, Revision	ML1793A201
11	12/20/19	Redline/Strikeout Copy	ML17923A202
12	08/06/20	Resolution of Comments	ML20183A152
13	9/15/20	Final NMSS Procedure SA-105	ML20196L417