Office of Nuclear Material Safety and Safeguards Procedure Approval

Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities

Interim 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 as (NRC)) 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. An incident applies to an event that may have caused, or threatens to cause, conditions described in *Title 10 Code of Federal Regulations* (10 CFR) or the equivalent Agreement State regulations, or other regulatory reporting requirements imposed by order or license condition. 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 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 or 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/or allegations to ensure compliance.

D. To confirm notification to the NRC by the Agreement States 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. Team Leader

1. In coordination with the IMPEP Program Manager, the Team Leader determines which team member is assigned lead review responsibility and also 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 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 (e.g., observe intake, disposition, inspection, etc.).

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 any findings throughout the on-site review.

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

5. Completes the portion of the IMPEP report for Technical Quality of Incident and Allegation Activities.

6. Participates in the Management Review Board meeting for the review and discusses the team's findings for this 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/or 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. Be familiar with this procedure and the list of references listed in Section V of this procedure.

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.] and

   b. For an Agreement State IMPEP review, 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.

3. Conduct staff discussions, as necessary; review internal written procedures; review incident and allegation files; accompany a staff member into the field, if appropriate; and maintain a reference summary of all casework reviewed and any personnel interviewed during the on-site review.

C. 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/or radioactive material involved.

7. Followup inspections are scheduled and completed, if necessary.

8. Notifications to the NRC Headquarters Operations Center, with followup 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.

Appendix A contains examples to assist the reviewer in identifying less than satisfactory findings of a program performance.

D. 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 principal 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 receipt, disposition, and/or inspection of a new incident, should one occur during the on-site review;

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 NRC) or 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 evaluation/inspection of the allegation to assess its validity and if health, safety and security issues are present;

i. Ensure the alleger(s) is/are 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 receipt, disposition, and/or inspection of any new allegations received during the on-site review to the extent practicable;

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.

E. 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. Appendix B of this procedure, Incident Casework Review 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 Appendix B but may find it as a useful means of recording the necessary information. The principal reviewer should retain the records until after the Management Review Board (MRB) meeting, as case-specific questions may be asked by MRB members.

3. Appendix C of this procedure, Allegation Casework Review 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.

F. Discussion of Findings with the Radiation Control Program

1. The IMPEP team should follow the guidance given in SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP),* for discussion of technical findings with inspectors, supervisors, and managers. If performance issues are identified that lead to programmatic weaknesses, the 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. Appendix D of SA-100 contains criteria regarding the development of recommendations by the IMPEP team.

2. In terms of general guidance for the IMPEP review team, a finding of "satisfactory" should be considered when none or only a few or small number of the cases or areas reviewed involve performance issues/deficiencies (e.g., inspection, licensing, staffing, etc.) ; an "unsatisfactory" finding should be considered when a majority or a large number of cases or areas reviewed involve performance issues/deficiencies, especially if they are chronic, programmatic, and/or of high-risk significance; and a finding of "satisfactory, but needs improvement" should be considered when more than a few or a small number of the cases or areas reviewed involve performance issues/deficiencies in high-risk-significant regulatory areas, but not to such an extent that the finding would be considered unsatisfactory.

IV. APPENDICES

Appendix A – Examples of Less than Satisfactory Findings of Program Performance

Appendix B – Incident Casework Review Summary Sheet

Appendix C – Allegation Casework Review Summary Sheet

V. 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. 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.*

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

VI. 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

Appendix A

EXAMPLES OF LESS THAN SATISFACTORY FINDINGS OF A PROGRAM PERFORMANCE

The effectiveness of a program is assessed through the evaluation of the criteria listed in Section III, Evaluation Criteria, of MD 5.6. These criteria are NOT intended to be exhaustive but provide a starting point for the IMPEP review team to evaluate this indicator. The review team should also take into consideration other relevant mitigating factors that may have an impact on the program's performance under this performance indicator. The review team should consider a less than satisfactory finding when the identified performance issue(s) is/are programmatic in nature, and not isolated to one aspect, case, individual, etc. as applicable.

This list is not all inclusive and will be maintained and updated in the IMPEP Toolbox on the state communications portal website.

The following are examples of review findings that resulted (or could result) in a program being found "**satisfactory, but needs improvement**" for this indicator:

1. In more than a few cases, incidents received by the Program were not reported to the NRC's Headquarters Operations Center in accordance with the time frames established in SA-300, "Reporting Material Events" of the overall incidents reviewed.

2. The review team's evaluation of selected incident case files found that the Program's responses to reported incidents were not well coordinated, not consistent, and in some cases, not thorough. In more than a few cases, the Program lacked a systematic approach to determine what type of response was warranted for reported events. There was no determination as to whether an onsite response was warranted regarding the safety or security significance of an event, and if so, the time frame and scope of the response.

3. The review team found that the Program did not perform an onsite response to a potential overexposure of a radiation worker that resulted in deterministic radiation effects. The failure to perform an onsite inspection resulted, among other things, in no evaluation of other workers and members of the public in the vicinity of the event.

4. In more than a few cases, the Program failed to followup on allegations reported to them. The review team determined that the cases where no followup was conducted, included the failure to file reciprocity on the part of a licensee working in multiple jurisdictions and use of a worker not deemed trustworthy and reliability.

5. In more than a few cases, the Program did not close out the allegations including providing allegation followup results to the allegers.

The following are examples of review findings that resulted (or could result) in a program being found "**unsatisfactory**" for this indicator:

1. In most cases, incidents received by the Program were not reported to the NRC's Headquarters Operations Center in accordance with the time frames established in SA-300, "Reporting Material Events" of the overall incidents reviewed.

2. The review team's evaluation of incident case files found that the Program's responses to reported incidents were not well coordinated, not consistent, and not thorough. In most cases, the Program lacked a systematic approach to determine what type of response was warranted for reported events. There was no a determination as to whether an onsite response was warranted regarding the safety or security significance of an event, and if so, the time frame and scope of the response.

3. The review team found that the Program did not perform onsite responses to multiple events involving potential overexposure cases of radiation workers that resulted in deterministic radiation effects. The failure to perform onsite inspections resulted in no evaluation of other workers and members of the public in the vicinity of the event and no independent determinations of the root cause of the events.

4. In most cases, the Program failed to followup on allegations reported to them. The review team determined that the cases where no followup was conducted, included safety and security related activities for licensees who possess category 1 and category 2 materials, failure to file reciprocity on the part of a licensee working in multiple jurisdictions, and use of a worker not deemed trustworthy and reliability.

5. In most cases, the Program did not close out the allegations and did not provide allegation followup results to the alleger.

APPENDIX B

INCIDENT CASEWORK REVIEW SUMMARY SHEET

A/S or NRC Office:_____ Reviewer_____:_____ Date:_____

State Incident Number or Other File_____

Licensee_____License_____

Date of Incident _____Date of 1st Contact_____

Date of Investigation _____

Investigation Type ☐ Site ☐ Phone ☐ Next Insp. ☐ None

☐ Overexposure	☐ Damage to Equipment or Facility
☐ Release of RAM	☐ Equipment or procedure Failure
☐ Lost/Stolen/Abandoned RAM	☐ Leaking Source
☐ Contamination Event	☐ Transportation
☐ Loss of Control	☐ Medial Event
☐ Other	

Brief Summary of Event

_____

_____

_____

Event Properly Reported to the NRC Headquarters Operation Center ☐ Yes ☐ No
Event Added to NMED ☐ Yes ☐ No Event Met AO Reporting Requirements ☐ Yes ☐ No
Possible Generic Problem ☐ Yes ☐ No

State/NRC's Action

_____

Final Disposition

_____

No	Comments

Inspector/Investigator_____

Supervisory Review By__ _____ Date_____

Findings Discussed With :_____Date_____

APPENDIX C

ALLEGATION CASEWORK REVIEW SUMMARY SHEET

A/S or NRC Office:_____ Reviewer:_____ Date:_____

Allegation Number or Other File Identification

_____

Licensee_____License_____

Date of Alleged Event _____Date of 1st Contact_____

Date of Investigation _____

Investigation Type ☐ Site ☐ Phone ☐ Next Insp. ☐ None

Allegation Pertaining to Possible

- ☐ Unreported Overexposure
- ☐ Unreported Release of RAM
- ☐ Unqualified Users or Inadequate Training
- ☐ Inadequate Procedures or Postings
- ☐ Other
- ☐ Faulty Equipment
- ☐ False Statement or Records
- ☐ Deliberate Violation
- ☐ Discrimination

Brief Summary of Allegation

_____

_____

_____

Rule or License Condition Allegedly Violated

_____

State/NRC's Action(s) and Respective Date(s)

_____

Final Disposition and Date of Completion

_____

No	Comments

Inspector/Investigator _____

Supervisory Review By_____ Date_____

Findings Discussed With :_____Date_____