FSME Procedure Approval

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

SA-105

Issue Date:

Review Date:

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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.

	Procedure Title: ***Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities*** ***Procedure Number: SA-105***	**Page: 1 of** **Issue Date:**

I. INTRODUCTION

A. This document describes the procedure for conducting reviews of U.S. Nuclear Regulatory Commission (NRC) Regional and Agreement State radioactive materials programs using the common performance indicator, Technical Quality of Incident and Allegation Activities [NRC Management Directive (MD) 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*.]

B. As used in this procedure, the term "incident" applies to an event that may have caused, or threatens to cause, conditions described in Title 10 Code of Federal Regulations (CFR) 20.1906, 20.220~~2~~1 through 20.2204~~3~~, 10 CFR 30.50, 10 CFR 31.5~~4~~, 10 CFR 34.27, 10 CFR 34.101, ~~10 CFR 35.67,~~ 10 CFR 35.3045, 10 CFR 35.3047, 10 CFR 35.3067, 10 CFR 36.83, 10 CFR 39.35, 10 CFR 39.77, 10 CFR 40.60, 10 CFR 70.50, 10 CFR 71.95, 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 course of the review.

C. As used in this procedure, the term "allegation" means a declaration, statement, or assertion of impropriety or inadequacy associated with regulated activities, the validity of which has not been established. This term includes all concerns identified by 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 defines this term in a different fashion, this should be noted during the course of the review.

II. OBJECTIVES

A. To assure that actions taken in response to incidents or allegations are appropriate, well-coordinated, and timely.

B. To verify that NRC Regions and Agreement States have appropriate incident and allegation response procedures in place and that the procedures are followed.

C. To confirm that NRC Regions and Agreement States take ~~corrective actions in response to incidents and allegations are adequately identified by NRC Regions and Agreement States and implemented by licensees and that~~ appropriate ~~followup~~ measures to follow up on licensee corrective actions that were implemented in response to incidents and/or allegations ~~are taken~~ to ensure compliance.

D. For incidents:

1. To ~~assure~~ensure that the level of effort in responding to an incident is commensurate

with potential health and safety significance.

2. To confirm that followup inspections are scheduled and completed, if necessary.

3. For Regional reviews, to confirm that notification to the Office of Federal and State Materials and Environmental Management Programs (FSME) and the NRC Headquarters Operations Center, as appropriate, is ~~usually~~ performed in a timely fashion.

4. For Agreement State reviews, to confirm that notification to the NRC, as appropriate, is ~~usually~~ performed in a timely manner and in accordance with the Handbook on Nuclear Material Event Reporting in the Agreement States (STP Procedure SA-300, *Reporting Material Events*.)

5. To verify that the information provided by the Agreement States on incidents for inclusion in the Nuclear Material Events Database (NMED) is complete and accurate.

E. For allegations:

1. To ~~assure~~ensure that the level of effort in responding to an allegation is commensurate with potential health and safety significance.

2. To confirm that allegations are addressed in a timely manner.

~~2~~3. To verify that Agreement States are properly handling all allegations referred to the State from ~~the~~ NRC (e.g., that safety issues are properly addressed, length of time to close an allegation is appropriate, and feedback is provided to allegers;) in addition to the general sampling of allegations involving 274b. radioactive materials.

III. BACKGROUND

The effectiveness, thoroughness, and timeliness of a regulator's response to incidents and allegations can have a direct impact on public health and safety. A careful assessment of incident response and allegation investigation, including internal and external coordination and investigative and followup actions, is a significant indication of the overall quality of the program.

IV. ROLES AND RESPONSIBILITIES

A. Team Leader:

Determines which team member(s) is assigned lead review responsibility for this performance indicator. In order to limit knowledge of allegers' identities, only NRC staff should review NRC Regional Office allegations.

B. Principal Reviewer:

1. Reviews relevant documentation, conducts staff discussions, and maintains a reference summary of all casework reviewed and any personnel interviewed.

2. Meets the appropriate requirements specified in MD 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*.

3. Is familiar with MD 8.8, *Management of Allegations*; STP Procedure SA-300; STP Procedure SA-400, *Management of Allegations*; NRC Inspection Manual Chapter 2800, *Materials Inspection Program*; applicable NRC and/or Agreement State regulations; and the operation of NMED.

V. GUIDANCE

A. Scope

1. This procedure applies to all incident response and allegation activities ~~centered primarily~~ that occurred in the period of time since the last IMPEP review. Incidents and allegations that began in ~~periods prior to~~ the previous review ~~cycle~~ period ~~should be included~~ are eligible for review if significant activity continued into the current review period.

2. This procedure specifically excludes incident response and allegations activities with non-Atomic Energy Act material. Incident response or allegation followup actions conducted by or referred to NRC Headquarters personnel for decisions are also excluded from IMPEP reviews.

B. Evaluation Procedures

1. The principal reviewer should refer to Part III, Evaluation Criteria, of MD 5.6 for specific evaluation criteria. The definitions of the terms "Incident" and "Allegation" can be found in the Directive's Glossary.

2. ~~The reviewer should be familiar with or have access to copies of MD 8.8, *Management of Allegations*, the inspector field notes, report forms for inspections and investigations, and appropriate NRC/Agreement State regulations. In particular, the reviewer should be familiar with the contents of STP Procedure SA-300, *Reporting Material Events*, STP Procedure SA-400, *Management of Allegations*, and Inspection Manual Chapter 2800, *Materials Inspection Program*. A printout of the NMED data should be obtained for each Region and State.~~

~~3.~~ The reviewer should ~~examine a representative number~~ select a sample of incident responses (approximately 10 ~~each~~cases) ~~of significant materials program incident response and allegation activities~~ to radioactive materials events conducted by the NRC Region or Agreement State that were reported to the NRC Headquarters Operations Center. ~~For Agreement States, priority should be given to evaluating in~~

~~detail all allegations referred to the State by the NRC.~~The sample should represent a cross-section of the type of events reported during the review period (i.e., medical, lost/stolen material, transportation, etc.). Particular attention should be given to thefts, diversions, or sabotages of risk-significant quantities of radioactive materials reported under the requirements of the Increased Controls (see NRC Order EA-05-090 or equivalent Agreement State requirements).

3. The reviewer should also select a smaller sample of incident responses to radioactive materials events that were not reported to the NRC Headquarters Operations Center to determine if the events should have been reported.

4. The reviewer should select a sample of allegations activities (approximately 10 cases) that the NRC Region or Agreement State conducted during the review period. The review should select all allegations referred to an Agreement State by NRC for evaluation.

~~4~~5. For Agreement States, the reviewer will need to consult with the State 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.

~~5~~6. For Regions, the latest audit conducted by the NRC's Agency Allegation Advisor (AAA) should be obtained in preparation for the review. The annual AAA audit may be conducted at the same time as the IMPEP review for a particular Region. In appropriate cases, the principal reviewer may adopt a portion of the AAA audit to augment the IMPEP report; however, the principal reviewer must perform his/her own independent review of the NRC Region's response to allegations.

C. Review Guidelines

1. The response generated by the NRC Region or Agreement State radioactive materials program to relevant questions in the IMPEP questionnaire should be used to focus the review.

2. ~~For Regional reviews, FSME's Medical Safety and Event Assessment Branch and Intergovernmental Liaison Branch should be contacted for lists of incidents or allegations to be included in the review. NRC's Office of Enforcement and the Headquarters Operations Center are also potential sources for this information.~~

~~3.~~ A detailed printout of all NRC Region and Agreement State NMED data for the review period should be obtained. Guidance for performing NMED searches for IMPEP reviews is available in the Help Section of the NMED website.

~~4~~3. For Agreement States, the principal reviewer should work with the Regional State Agreements Officer and the FSME Allegation Coordinator to obtain the listing of allegations referred to the State by ~~the~~ NRC.

4. For Regional reviews, FSME's Medical Safety and Event Assessment Branch and the FSME Allegation Coordinator should be contacted for lists of incidents or allegations to be included in the review. NRC's Office of Enforcement and the Headquarters Operations Center are also potential sources for this information.

5. Any incidents or allegations identified for followup from any periodic meetings held during the review period should be selected for review.

D. Review Details

1. For incident response, the principal reviewer should evaluate the following:

   a. Timeliness of ~~reporting "significant" events~~notifications to the NRC Headquarters Operations Center for reportable events;

   b. Promptness of inquiries made to evaluate the need for on-site investigations;

   c. ~~Promptness~~Performance, including timeliness, of on-site investigations~~ of incidents requiring reporting to the Agency in less than 30 days~~, when appropriate;

   d. Appropriate followup of incidents during the next scheduled inspection, including ensuring the adequacy, accuracy, and completeness of licensee-provided information;

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

   f. Pertinent information about incidents that could be relevant to other licensed operations (e.g., equipment failure, improper operating procedures) is provided to licensees, ~~the~~ NRC, and/or Agreement States;

   g. 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;

   h. Determination 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 an NRC Region or Agreement State are consistent;

   i. Information obtained during the NRC Region's or Agreement State's investigation is compared with information obtained from the licensee to identify and resolve

any differences; and,

j. Whether or not the public is provided access to NRC/Agreement State and licensee records on the incident, as permitted within the constraints of laws for protection of personal, private, and proprietary information.

2. For allegations, the reviewer should evaluate the following:

   a. Priority given to allegations with potential safety significance;

   b. Receipt of an allegation is acknowledged to the alleger;

   c. Discussions with the alleger, if any, conducted to obtain additional information;

   d. State rules and policy relating to alleger identity protection;

   e. Adequa~~te~~cy of evaluation/inspection of the allegation to assess its validity and if health and safety issues are present;

   f. Notification to allegers that the allegation is closed, and that allegers are informed of the progress of unresolved allegations consistent with the State's or Region's policy;

   g. Timeliness of closure of allegations;

   h. When concerns are raised regarding Agreement State performance with respect to allegations, that the State's procedures for handling allegations compare to guidance in MD 8.8, documenting any significant differences and determining if the State's procedures are equally as effective as NRC's; and,

   i. For Agreement State reviews, whether the program for processing allegations encourages those with safety concerns to express those concerns to the Agreement State program.

3. In addition to other items mentioned above, the reviewer should determine, for incidents and allegations, that:

   a. Appropriate regulatory action was taken for items of noncompliance;

   b. Letters to licensees are written in appropriate regulatory language and that they specify the time period for licensee response indicating corrective actions and actions taken to prevent recurrence;

   c. The licensee's response was reviewed for adequacy and/or what subsequent action was taken by compliance supervision.

E. Review Information Summary

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

   a. Licensee's name~~, city, and state~~;
   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 of incident;
   e. Locaton of incident (city and state);
   ~~e~~f. Type of incident (such as medical event, transportation, loss of control, etc.);
   ~~f~~g. Date of investigation;
   ~~g~~h. Type of investigation (such as inspection, telephone, licensee report, etc.).

2. Appendix A, 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 A, but may find it as a useful means of recording the necessary information.

   a. Due to the NRC policies on sensitive information, not all the information maintained in the reviewer's summary will appear in the list of incident casework review in the IMPEP report's appendix. Please contact the IMPEP Project Manager for the current guidance and format on the report's incident casework appendix.

   b. Comments in regard to incident casework that will appear in the report's appendix should be factual, concise, and concentrate on casework deficiencies and their root cause(s).

3. Appendix B, 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.

F. Discussion of Findings with NRC Regions or Agreement States

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

VI. APPENDIXES

Appendix A - Incident Casework Review Summary Sheet
Appendix B - Allegation Casework Review Summary Sheet
Appendix C - Frequently Asked Questions

VII. REFERENCES

1. FSME Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*.
2. NRC Inspection Manual Chapter 2800, *Materials Inspection Program*.
3. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program.*
4. NRC Management Directive 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*.
5. NRC Management Directive 8.8, *Management of Allegations*.
6. STP Procedure SA-300, *Reporting Material Events*.
7. STP Procedure SA-400, *Management of Allegations*.

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 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

Appendix A

INCIDENT CASEWORK REVIEW SUMMARY SHEET

NRC REVIEW BY: _____ DATE: _____ A/S OR REGION: _____

STATE INCIDENT NUMBER OR OTHER FILE IDENTIFICATION: _____

LICENSEE: _____ LICENSE # _____

LOCATION OR SITE OF EVENT: _____

DATE OF INCIDENT: _____ DATE OF 1ST CONTACT: _____

DATE OF INVESTIGATION: _____ INVESTIGATION TYPE: SITE ☐ PHONE ☐ NEXT INSP ☐ NONE ☐

☐ OVEREXPOSURE
☐ RELEASE OF RAM
☐ LOST/STOLEN/ABANDONED RAM
☐ CONTAMINATION EVENT
☐ LOSS OF CONTROL
☐ OTHER: _____
☐ DAMAGE TO EQUIPMENT OR FACILITY
☐ EQUIPMENT OR PROCEDURE FAILURE
☐ LEAKING SOURCE
☐ TRANSPORTATION
☐ MEDICAL EVENT

BRIEF SUMMARY OF INCIDENT _____

EVENT MET AO REPORTING REQUIREMENTS? Y N POSSIBLE GENERIC PROBLEM? Y N

STATE'S ACTION: _____

FINAL DISPOSITION: _____

NO.	COMMENTS FOR REPORT APPENDIX

INVESTIGATOR _____

SUPERVISORY REVIEW BY: _____ DATE: _____

FINDINGS DISCUSSED WITH: _____ ON: _____

Appendix B

ALLEGATION CASEWORK REVIEW SUMMARY SHEET

NRC REVIEW BY: _____ DATE: _____ A/S OR REGION: _____

STATE INCIDENT NUMBER OR OTHER FILE IDENTIFICATION: _____

LICENSEE: _____ LICENSE # _____

LOCATION: _____

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
- ☐ FAULTY EQUIPMENT
- ☐ FALSE STATEMENTS OR RECORDS
- ☐ DELIBERATE VIOLATION
- ☐ DISCRIMINATION
- ☐ OTHER: _____

BRIEF SUMMARY OF ALLEGATION _____

RULE OR LICENSE CONDITION ALLEGEDLY VIOLATED: _____

STATE'S ACTION: _____

FINAL DISPOSITION: _____

NO.	COMMENTS FOR REPORT

INVESTIGATOR _____

SUPERVISORY REVIEW BY: _____ DATE: _____

FINDINGS DISCUSSED WITH: _____ ON: _____

Appendix C

FREQUENTLY ASKED QUESTIONS

Q. What is the Nuclear Material Events Database (NMED)?

A. NMED is a historical collection of information on the occurrence, description, and resolution of events involving radioactive material in the United States. NMED accommodates the sharing of material event data submitted by Agreement and non-Agreement States and ~~the~~ NRC. The data includes information on material events from January 1990 through the present. The database is maintained by the NRC's Office of Federal and State Materials and Environmental Management Programs through a contractor, Idaho National Laboratory (INL).

Q. Where is the NMED data located and how is it accessed?

A. The data is located at the NMED homepage (https://nmed.inl.gov). A password is required for access and can be obtained by an e-mail request to NMED@inl.gov or to the NRC's NMED Project Manager (NMEDNRC@nrc.gov).

Q. Should the principal reviewer assigned this indicator obtain the NMED printout for the NRC Region or Agreement State prior to the IMPEP review?

A. Yes, a printout of NMED data for the review period for the respective program should be obtained prior to the on-site portion of the IMPEP.

Q. Does a Potential "P" classification shown for a specific event on the NMED report mean that a Abnormal Occurrence (AO) event has occurred in the State?

A. The Agreement States support the NRC in their effort to keep Congress apprised of any significant events that may directly affect public health or safety by providing information to ~~the~~ NRC on potential AOs that have occurred in their State. Any events identified as potential AOs should be reported to NRC and will show up on the NMED report once they have been reported. The Commission makes the final determination of whether or not an AO occurred and all potential AOs are in fact potential until such a determination is made by the Commission. As such, a *potential* classification does not necessarily mean an AO actually occurred.

Q. Is the Agency's event notifications (ENs) system received and maintained by the Headquarters Operations Center a potential source of information specific to events?

A. Yes, the Agency's EN system is accessible through the NRC's public website and could be used as a source of information for events for a particular program. The EN system contains reports of significant events received from Agreement States reported by phone to a Headquarters Operations Officer. NMED should be used as the primary means for obtaining incident data for a particular program. The NMED report, used in conjunction with the EN system, will provide the greatest amount of event information in preparation for an IMPEP review.

Q. What processes does the Agency use to evaluate Agreement State performance relative to allegations?

A. The Agency has established ~~two~~ several tools relative to the handling of Agreement State allegations: IMPEP, which is dictated by Management Directive 5.6 and other associated implementing procedures; Management Directive 8.8; and STP Procedure SA 400, *Management of Allegations*.

Q. Is it appropriate to discuss the merits of an allegation during a Management Review Board (MRB) meeting for an IMPEP review?

A. Although the MRB meeting provides a senior-level review of the IMPEP team's findings and recommendations, it is not appropriate to discuss the merits of an allegation during the MRB. The Allegation Review Board (ARB) is a more appropriate forum for discussing allegations. One reason is that the MRB is a public meeting. The ARB is not a public meeting and includes discussions regarding allegations that may or may not be proven to be true.