



**Office of Federal and State Materials and Environmental
Management Programs (FSME) STP Procedure Approval**

***Reviewing Technical Quality of Incident and Allegation
Activities - SA-105***

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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. 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 STP-FSME Procedure Contact as of October 1, 2006. Copies of STP FSME procedures will be distributed for information available through the NRC website.



Procedure Title:
Reviewing Technical Quality of Incident and Allegation Activities
Procedure Number: SA-105

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I. INTRODUCTION

- A. This document describes the procedures for conducting reviews of NRC Regional offices and Agreement States using Common Performance Indicator #5, **Response Technical Quality of** Incidents and Allegations **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 10 CFR 20.2202 through 20.2204, 10 CFR 30.50, 10 CFR 34.24, CFR 34.30, 10 CFR 35.33, 10 CFR 36.83, 10 CFR 39.77, 10 CFR 40.60, 10 CFR 70.50, or the equivalent State regulations. If a 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, for example. If a 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 Regions and Agreement States have in place appropriate incident and allegation response procedures.
- C. To confirm that corrective actions in response to incidents and allegations are adequately identified and implemented by licensees and that appropriate follow-up measures are taken to ensure compliance.
- D. For incidents:
 - 1. To assure that the level of effort in responding to an incident is commensurate with potential health and safety significance.

2. To confirm that follow-up inspections are scheduled and completed, if necessary.
 3. For Regional reviews, to confirm that notification to the Office of Nuclear Material Safety and Safeguards (NMSS) of **Federal and State Materials and Environmental Management Programs (FSME)** and NRC Headquarter 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 accordance with the Handbook on Nuclear Material Event Reporting in the Agreement States (**FSME** Procedure SA-300, *Reporting Material Events*).
 5. To verify that the information provided by the Agreement States on incidents and events for Nuclear Materials Event Database (NMED) is complete and accurate.
- E. For allegations:
1. To assure that the level of effort in responding to an allegation is commensurate with potential health and safety significance.
 2. 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, feedback is provided to allegers, etc.), in addition to the general sampling of allegations involving 274b materials.

III. BACKGROUND

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

IV. ROLES AND RESPONSIBILITIES

A. Team Leader.

The team leader for the Regional or State review will determine which team member(s) is assigned lead review responsibility for this performance indicator. The principal reviewer should meet the appropriate

requirements specified in MD 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*. In order to limit knowledge of allegers' identities, only NRC staff will review NRC Regional Office allegations.

B. Principal Reviewer.

The principal reviewer is responsible for reviewing relevant documentation, conducting staff discussions, and maintaining a reference summary of all licensing or inspection files reviewed and Regional or State personnel interviewed.

V. **GUIDANCE**

A. Scope.

1. This procedure applies to all incident response and allegation activities centered primarily in the period of time since the last Regional or State review. Incidents and allegations that began in periods prior to the review cycle should be included, but only 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 follow-up 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 Directive's Glossary defines the terms "Incidents" and "Allegations."
2. The reviewer should be familiar with, or have available, copies of NRC MD 8.8, *Management of Allegations*, and the Region's or State's inspector field notes, report forms for inspections and investigations, and appropriate NRC/State regulations. In particular, the reviewer should be familiar with the contents of **OSP FSME** Procedure SA-300, *Reporting Material Events*, **OSP FSME** Procedure SA-400, *Management of Allegations*, and related NRC 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 (approximately 10 each) of significant materials program incident response and allegation activities conducted by Regions or Agreement States. For Agreement States, priority should be given to evaluating in detail all allegations referred to the State from the NRC within the constraints of Section III. A. and B., above.
4. For Agreement States, the reviewer will need to consult with the State as to 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 allegeders.
5. For Regions, the latest audit conducted by the NRC's Agency Allegation Advisor (AAA) should be obtained in preparation for the review. Normally, the annual AAA review will be conducted at the same time as the IMPEP review for a particular Region. In order to increase flexibility and efficiency, the principal reviewer may, in appropriate cases, adopt a portion of the AAA audit to augment the IMPEP report for the Regions.

C. Review Guidelines

1. The responses generated by the Regions or States to relevant questions in the IMPEP questionnaire should be used to focus the review.
2. For Regional reviews, the ~~Materials Safety Branch in the NMSS² Division of Industrial and Medical Nuclear Safety~~ **the Intergovernmental Liaison and Medical Safety and Event Assessment Branches in FSME** should be contacted for lists of incidents or allegations to be included in the review. NRC's Offices of Enforcement and ~~HO~~ **the Agency's event notifications (ENs) received by the Headquarters Operations Center** are also potential sources for this information.
3. A detailed printout of all State NMED data for the review period should be obtained.
4. For the States, the principal reviewer should work with the Regional State Agreements Officer in obtaining the listing of allegations transferred from the NRC to the Agreement State for response in selecting the appropriate files for review.

5. Any incidents or allegations identified for follow up from the last periodic meeting should be reviewed.

D. Review Details

1. The review of each file should be made in conjunction with the reference and resource materials specified in Paragraph E., below.
2. For incident response, the principal reviewer should evaluate the following:
 - a. “Significant” events reported within 24 hours or less;
 - b. Promptness of inquiries made to evaluate the need for on-site inspections;
 - c. Promptness of on-site inspections of incidents requiring reporting to the Agency in less than 30 days;
 - d. Appropriate follow up 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, follow-up activities should include re-enactments and time-study measurements. Inspection results should be documented and enforcement action taken in accordance with NRC or State policy and procedures;
 - f. Pertinent information about incidents which could be relevant to other licensed operations (e.g., equipment failure, improper operating procedures) is provided to licensees, the NRC (for Agreement States), and/or Agreement States (for NRC Regions or Agreement States, as appropriate);
 - g. Information on incidents involving equipment failure (including make, model, and serial number) is provided to the 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 Region's or State's review is compared with other information obtained from the licensee to identify and resolve any differences;
 - j. The public is provided access to NRC/State and licensee records on the review as permitted within the constraints of laws for protection of personal, private, and proprietary information;
 - k. Appendix A, IMPEP Incident Reviewer Guidance, was developed to assist the principal reviewer in reviewing completed incident casework. However, the principal reviewer should not feel compelled to address every item in the guidance.
3. 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 allexer;
 - c. ~~The allegation is discussed with the allexer, if any known, conducted~~ **Discussions** to obtain additional information;
 - d. ~~In accordance with State rules and policy, relating to allexers' identities are successfully protectioned;~~
 - e. Adequate evaluation/inspection of the allegation to assess its validity and whether licensee health and safety issues are present;
 - f. Appropriate regulatory action taken;
 - g. Notification to allexers that the allegation is closed, and that allexers are informed of the progress of unresolved allegations consistent with the State's or Region's policy;

- h. Appropriate length of time to close allegations;
 - i. When concerns are raised regarding State performance with respect to allegations, that the State's procedures for handling allegations compare to guidance in Management Directive 8.8, documenting any significant differences and determining if the State's procedures are equally as effective as NRC's;
 - j. For Agreement State reviews, whether the program for processing allegations encourages those with safety concerns to express those concerns to the Agreement State program;
 - k. Appendix B, IMPEP Allegation Reviewer Guidance, was developed to assist the principal reviewer in reviewing completed allegation casework. However, the principal reviewer should not feel compelled to address every item in the guidance.
4. In addition to other items mentioned above, the reviewer should determine that:
- a. Appropriate regulatory action was taken for items of noncompliance;
 - b. Letters to licensees are written in appropriate regulatory language, and 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.

At a minimum, the principal reviewer should retain the following information of all licensing/inspection files for incidents or allegation files reviewed during the IMPEP site visit:

- 1. Licensee name;
- 2. Licensee **location** address;

3. A numerical file reference (such as license number, or inspection report number);
4. Inspection priority of the license;
5. The lead inspector (if any);
6. Type of inspection (i.e., reactive, closeouts, announced, unannounced, team, other, etc.);
7. Date of inspection;
8. Date inspection or allegation report issued;
9. Type of license operation (i.e., portable gauge or diagnostic nuclear medicine program code or license category).

This information should be prepared in a sanitized fashion, if necessary, in order not to compromise the confidentiality of alleged, or others. (Note: The information for incidents will be part of the IMPEP report, however, the information from the allegation reviews will not be part of the IMPEP review report.)

- F. Discussion of Findings with Region or State.

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 reviewers, supervisors, and management.

VI. APPENDICES

- Appendix A - IMPEP Incident Reviewer Guidance
- Appendix B - IMPEP Allegation Reviewer Guidance

VII. REFERENCES

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

Appendix A

IMPEP INCIDENT REVIEWER GUIDANCE

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

STATE INCIDENT NUMBER OR OTHER FILE IDENTIFICATION: _____	
LICENSEE: _____	LICENSE # _____
LOCATION OR SITE OF EVENT: _____	
DATE OF 1ST CONTACT: _____	DATE OF INCIDENT: _____
DATE OF INVESTIGATION: _____	INVESTIGATION TYPE: SITE <input type="checkbox"/> PHONE <input type="checkbox"/> NEXT INSP <input type="checkbox"/> NONE <input type="checkbox"/>
<input type="checkbox"/> OVEREXPOSURE	<input type="checkbox"/> DAMAGE TO EQUIPMENT OR FACILITY
<input type="checkbox"/> RELEASE OF RAM	<input type="checkbox"/> EQUIPMENT OR PROCEDURE FAILURE
<input type="checkbox"/> LOST/STOLEN/ABANDONED RAM	<input type="checkbox"/> LEAKING SOURCE
<input type="checkbox"/> CONTAMINATION EVENT	<input type="checkbox"/> TRANSPORTATION
<input type="checkbox"/> LOSS OF CONTROL	<input type="checkbox"/> MEDICAL EVENT
<input type="checkbox"/> OTHER: _____	

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

IMPEP ALLEGATION REVIEWER GUIDANCE

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

STATE INCIDENT NUMBER OR OTHER FILE IDENTIFICATION: _____	
LICENSEE: _____	LICENSE # _____
LOCATION: _____	
DATE OF 1ST CONTACT: _____	DATE OF ALLEGED EVENT: _____
DATE OF INVESTIGATION: _____ INVESTIGATION TYPE: SITE <input type="checkbox"/> PHONE <input type="checkbox"/> NEXT INSP <input type="checkbox"/> NONE <input type="checkbox"/>	
ALLEGATION PERTAINING TO POSSIBLE:	
<input type="checkbox"/> UNREPORTED OVEREXPOSURE	<input type="checkbox"/> FAULTY EQUIPMENT
<input type="checkbox"/> UNREPORTED RELEASE OF RAM	<input type="checkbox"/> FALSE STATEMENTS OR RECORDS
<input type="checkbox"/> UNQUALIFIED USERS OR INADEQUATE TRAINING	<input type="checkbox"/> DELIBERATE VIOLATION
<input type="checkbox"/> INADEQUATE PROCEDURES OR POSTINGS	<input type="checkbox"/> DISCRIMINATION
<input type="checkbox"/> 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 B (Continued)

ITEM	O.K.	COMMENTS
INITIAL RESPONSE		
ALLEGATION HANDLED PROFESSIONALLY		
PROMPTNESS (PRIORITY GIVEN TO SERIOUS ALLEGATIONS)		
APPROPRIATE TYPE OF RESPONSE (ON-SITE, TELCON, NEXT INSPECTION, ETC.)		
DOCUMENTATION OF ALLEGATION		
DETAILS OF ALLEGATION (WHAT, WHERE, WHERE, WHO?)		
CONFIDENTIALITY OF ALLEGER PRESERVED		
INVESTIGATION		
DEPTH OF INVESTIGATION		
DOCUMENTATION OF INVESTIGATION REPORTS, TELCON DOCUMENTATION, ETC)		
DESCRIPTION OF EVIDENCE EXAMINED		
REGULATORY ACTIONS (CITATIONS, LICENSE RESTRICTIONS, CORRECTIVE REQUIREMENTS)		
SUPERVISORY OVERSIGHT OF INVESTIGATION		
FOLLOW THROUGH AND CLOSE OUT		
ALLEGER PROVIDED WITH RESULTS OF INVESTIGATION		
INVESTIGATION ENTERED AND CLOSED OUT IN STATE'S TRACKING SYSTEM		
LICENSEE'S REPORTS AND CORRECTIVE ACTIONS REVIEWED AND/OR VERIFIED		
CLOSE-OUT DOCUMENTATION COMPLETE WITH DATE AND SIGNATURE		
SUBSTANTIATED ALLEGATION REVIEWED AT NEXT INSPECTION		
ALLEGATION OR INCIDENT REPORT CROSS REFERENCED TO LICENSE/COMPLIANCE FILE		
MEDIA HANDLING		
INCIDENT REPORTING REQUIREMENTS MET		
OTHER:		
QUESTIONS FOR INVESTIGATOR OR SUPERVISOR:		

Appendix C

FREQUENTLY ASKED QUESTIONS

- Q. Should the principal reviewer assigned oversight of the *Technical Quality of Incident and Allegation Activities* indicator obtain the Nuclear Material Event Database (NMED) printout prior to IMPEP State review.
- A. Yes, a printout of NMED data for the assigned State’s review period should be obtained prior to the onsite IMPEP for efficiency.
- Q. What is NMED?
- A. NMED is a historical collection of information on the occurrence, description, and resolution of events involving the use of radioactive material in the United States (source, byproduct, special nuclear material, and a limited number of events involving naturally occurring, and, in some cases, accelerator-produced radioactive material that was initially identified as “unknown radioactive material” and later found to be non-AEA material). 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 NMSS 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 through NMED@inl.gov or the NRC NMED Project Manager NMEDNRC@nrc.gov.
- 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 if they are will show up on the NMED report. However, the Commission has 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 at <http://www.nrc.gov/reading-rm/doc-collections/event-status/event/> and should be reviewed prior to conducted the onsite IMPEP. The EN system contains reports of significant event received from Agreement States reported by phone to a Headquarters Operations Officer.
- Q. What processes does the Agency use to evaluate Agreement State performance relative to allegations?
- A. The Agency has established two tools relative to the handling of Agreement State allegations – the IMPEP, which is guided by Management Directive 5.6 and other associated implementing procedures, and the Allegation Review Board (ARB) process which is guided by Management Directive 8.8 and FSME Procedure, SA 400-Management of Allegation
- Q. Its is appropriate to discuss the merits of an allegation during an Agreement State Management Review Board (MRB) meeting?
- 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 ARB is a more appropriate forum for discussing allegations. One reason is that the MRB is a public meeting whereas the ARB is not. And allegation files reviewed during IMPEP are not included in the publicly available IMPEP Report. Alternatively, the ARB is not a public meeting and includes discussions regarding allegations that may or may not be proven to be true.