

MANAGEMENT MEASURES

11.8 INCIDENT INVESTIGATIONS

11.8.1 PURPOSE OF REVIEW

The purpose of this review is to establish, with reasonable assurance, that the applicant will have a system in place for the systematic investigation of incidents, assignment and acceptance of corrective actions, and follow-up to ensure completion of the actions. The review should confirm that incidents will be investigated and corrective action taken to prevent (or minimize) their recurrence or their leading to more serious consequences. Furthermore, the review should find that the results of incident investigations will be compared against the integrated safety analysis summary (ISA - see SRP Chapter 3.0) to provide assurance that there is continued compliance with the performance requirements contained in 10 CFR Part 70, as revised.¹

11.8.2 RESPONSIBILITY FOR REVIEW

<u>Primary:</u>	Licensing Project Manager
<u>Secondary:</u>	Quality Assurance Engineer/Specialist and ISA Reviewers
<u>Supporting:</u>	Site Representative/Facility Inspector

11.8.3 AREAS OF REVIEW

The review should encompass the following areas:

1. The description of the functions, qualifications, and responsibilities of the management person who would lead the investigation team and those of the other team members, the scope of the team's authority and responsibilities, and assurance of cooperation of management.
2. The team's ability to obtain all the information considered necessary and independence from responsibility for or to the functional area involved in the incident under investigation.
3. The maintenance of documentation consistent with Section 11.9, "Records Management."
4. Guidance for the team conducting the investigation on how to apply a reasonable, systematic, structured approach to determine the root cause(s) of the problem.
5. The system for comparing the results of the investigation against the ISA.

¹Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)." *Federal Register*: Vol. 64, No. 146. pp. 41338--41357. July 30, 1999.

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6. The system for monitoring to ensure completion of any corrective measures specified -- including revisions to the ISA.

11.8.4 ACCEPTANCE CRITERIA

The regulatory requirements, regulatory guidance, and regulatory review criteria applicable to this SRP are listed in the following sections.

11.8.4.1 Regulatory Requirements

Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)." *Federal Register*: Vol. 64, No. 146. pp. 41338–41357. July 30, 1999.

Specific references are as follows:

1. In § 70.4, "Definitions," the term management measures is defined. Incident investigations are included as a management measure.
2. In § 70.62(d), the applicant or licensee is required to establish management measures to provide continuing assurance of compliance with the performance requirements.
3. In § 70.64(a)(1), the design of new facilities or the design of new processes at existing facilities is required to be developed and implemented in accordance with management measures.
4. In § 70.65(a), the application is required to include a description of the management measures.

11.8.4.2 Regulatory Guidance

There is no specific regulatory guidance for the overall conduct of incident investigation. See the References at the end of this section for guidance on specific aspects of incident management such as corrective action and root cause analysis.

11.8.4.3 Regulatory Acceptance Criteria

The NRC reviewers should find the applicant's submittal regarding incident investigations provides reasonable assurance that the regulatory review criteria below are adequately addressed and satisfied. Some of the information may be referenced to other sections of the SRP, or incorporated by reference, provided that these references are clear and specific.

1. Acceptability should be based on commitments for the prompt investigation of incidents that include the following elements:

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- a. The establishment of teams to investigate incidents that may occur during operation of the facility, to determine the root cause(s) of the event, and to recommend corrective actions. These teams should be independent from the line function(s) involved with the incident under investigation.
 - b. The monitoring and documenting of corrective actions (including effectiveness) through completion.
 - c. The maintenance of documentation so that "lessons learned" may be applied to future operations of the facility. Details of the incidents should be compared to incidents already considered in the ISA, and actions should be taken to ensure that the ISA includes the evaluation of the risk associated with incidents of the type actually experienced.
2. Acceptability should be based on the adequacy of the applicant's commitments to establish and use a plan for the investigation of incidents. Acceptability should also be based upon the following acceptance criteria:
- a. The licensee has described the overall plan and method for investigating incidents.
 - b. The functions, responsibilities, and scope of authority of investigation teams are documented in the plan.
 - c. Qualified internal or external investigators are appointed to serve on investigation teams. Each team should include at least one process expert and one team member trained in root cause analysis.
 - d. There is a commitment to undertake prompt investigation of any incidents.
 - e. The investigation process and investigation team are independent of the line management, and participants are assured of no retribution from participating in investigations.
 - f. A reasonable, systematic, structured approach is used to determine the root cause(s) of incidents. The level of investigation should be based on a graded approach relative to the severity of the incident.
 - g. Auditable records and documentation related to incidents, investigations, and root cause analysis are maintained. For each incident, the incident report should include a description, contributing factors, root-cause analysis, findings, and recommendations. Relevant findings are reviewed with all affected personnel. These reports should be made available to the NRC on request.
 - h. Documented corrective actions are taken within a reasonable period to resolve findings from incident investigations.

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11.8.5 REVIEW PROCEDURES

11.8.5.1 Acceptance Review

The primary reviewer should evaluate the application to determine whether it addresses the “Areas of Review” discussed in Section 11.8.3, above. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation.

11.8.5.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with Section 11.8.5.1, above, the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 11.8.4. If during the course of the safety evaluation the primary reviewer determines the need for additional information, the primary reviewer should coordinate a request for additional information with the licensing project manager. The review should determine if the applicant and principal contractors have adequately planned for incident investigations to be conducted with resulting corrective actions to be appropriately implemented.

The primary reviewer should review the applicant's plan and procedures for investigating incidents. The review should include the organizational structure, provisions for establishing investigating teams, methods for determining root causes, and procedures for tracking and completing corrective actions and for documenting the process for the purpose of applying the “lessons learned” to other operations as well as validating the ISA. The organizational structure and procedures should be consistent with the relevant sections of other SRP Chapter 11, “Management Measures.” This plan should be separate from any required Emergency Plan.

The quality assurance secondary reviewer should review the methods used for determining root causes, the procedures for tracking and implementing the corrective actions, and the process of applying the “lessons learned” to the other operations.

The ISA reviewers should review the procedure that ensures the results of the investigation are compared against the ISA and the necessary follow-up actions occur.

The secondary and supporting reviewers should become familiar with these procedures and determine whether planned future and ongoing activities are consistent with them.

11.8.6 EVALUATION FINDINGS

The primary reviewer should write an SER section that addresses each topic reviewed under this SRP Section and that explains why the NRC staff has reasonable assurance that the incident investigation system is acceptable. License conditions may be proposed to impose requirements where the application is deficient. The primary reviewer should also describe the applicant's organization, methodology, and support to ensure the quality and reliability of the

incident investigation program. The SER should include a summary statement of what was evaluated and the basis for the reviewers' conclusions.

The staff can document the evaluation as follows:

Based on its review of the license application, [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable,] the NRC staff has concluded that the applicant has performed the following:

1. The applicant has committed to and established an organization responsible for performing incident investigations of incidents that may occur during operation of the facility, determining the root cause(s) of the event, and recommending corrective actions for ensuring a safe facility and safe facility operations in accordance with the acceptance criteria of Subsection 11.8.4 of the SRP. As part of the review, the applicant has committed to review the results of the investigation against the ISA.

2. The applicant has committed to monitoring and documenting corrective actions through completion.

3. The applicant has committed to the maintenance of documentation so that "lessons learned" may be applied to future operations of the facility.

Accordingly, the staff concludes that the applicant's description of the incident investigation process complies with applicable NRC regulations and is adequate.

11.8.7 REFERENCES

1. Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)." *Federal Register*: Vol. 64, No. 146. pp. 41338–41357. July 30, 1999.
2. Department of Energy (U.S.) (DOE). DOE-STD-1010-92, "Guide to Good Practices for Incorporating Operating Experiences." DOE: Washington, D.C. July 1992.
3. Department of Energy (U.S.) (DOE). DOE-NE-STD-1004-92, "Root Cause Analysis Guidance Document." DOE: Washington, D.C. February 1992.
4. Nuclear Regulatory Commission (U.S.) (NRC). NUREG/CR-4616, "Root Causes of Component Failures Program: Methods and Applications." NRC: Washington, D.C. December 1986.
5. Nuclear Regulatory Commission (U.S.) (NRC). NUREG/CR-5665, "A Systematic Approach to Repetitive Failures." NRC: Washington, D.C. February 1991.

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6. Nuclear Regulatory Commission (U.S.) (NRC), NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action." NRC: Washington, D.C. May 1996.