

NRC INSPECTION MANUAL

FCSE

INSPECTION MANUAL CHAPTER 2601

REACTIVE INSPECTION DECISION MAKING PROCESS FOR FUEL FACILITIES

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2601-01 PURPOSE

01.01 Provide guidance to the Division of Fuel Cycle Safety, Safeguards, and Environmental Review (FCSE) in the Office of Nuclear Material Safety and Safeguards (NMSS) and the Division of Fuel Facility Inspection (DFFI) in the Region II Office staff for implementing the requirements prescribed in Management Directive (MD) 8.3, "NRC Incident Investigation Program."

01.02 Provide detailed guidance consisting of both deterministic criteria and risk-informed insights that can be used as a decision basis for implementing Incident Investigation Teams (IITs), Augmented Inspection Teams (AITs), and Special Inspection Teams (SITs).

01.03 Provide the availability of various tools to communicate with internal and external stakeholders on event response and assessment.

01.04 Provide a sample format to use when documenting reactive inspection decisions.

2601-02 BACKGROUND

MD 8.3 is the Agency-level governing document for this Inspection Manual Chapter (IMC) that includes deterministic and risk-informed criteria for determining the agency's appropriate event response and delineates organizational responsibilities for event response. A significant operational event is any radiological, safeguards, or other safety-related operational event at an NRC-licensed facility that poses an actual or potential hazard to public health and safety, property, or the environment. In this IMC, a significant operational event may also be referred to as "an event." This manual chapter provides specific roles and responsibilities for the staff involved in the reactive inspection decision-making process as well as guidance for developing cooperative staff-level relationships among the participating offices. Furthermore, it provides guidance on the use of both deterministic and risk insights to assess the significance of an event. Inspection Procedure (IP) 88075, "Event Follow-up," provides inspection guidance for evaluating licensee events and communicating event information to management, risk analysts, and staff in both Region II and headquarters as input to the reactive inspection decision-making process. IP 88003, "Reactive Inspections," provides implementing guidance for AIT and SIT responses. NUREG-1303 provides guidance for conducting an IIT.

2601-03 RESPONSIBILITIES

03.01 Region II, Regional Administrator (RA)

1. Decide the appropriate level of reactive inspection given the available information and the need to make a timely regulatory response to the operational event.
2. Coordinate with the Office Directors of NMSS and NSIR, as appropriate.

03.02 Region II, Division of Fuel Facility Inspection (DFFI).

1. Responsible for the initial follow-up of a significant operational event at a fuel facility.

2. Formulate the recommendation to the Regional Administrator (RA) regarding the appropriate response in the form of an SIT, AIT, or IIT with support from PORS and other FCSE staff as needed.
3. Provide the basis for a reactive inspection decision in the inspection charter, to include a description of the specific deterministic criteria and other risk insights, as applicable, that served as a basis for deciding on the particular reactive inspection.
4. Coordinate with staff in NMSS and NSIR as appropriate for technical support and assistance in the decision-making process.

03.03 Programmatic Oversight and Regional Support Branch (PORSB).

1. Identify appropriate technical staff in FCSE to address relevant technical and regulatory issues and coordinate their support.
2. Support DFFI in evaluating the risk associated with significant operational events at fuel facilities.

03.04 Division of Fuel Cycle Safety, Safeguards, and Environmental Review (FCSE).

1. Provide technical support and expertise for resolving issues identified during the follow-up of significant operational events.
2. Coordinate support for DFFI and other FCSE staff during the short-term event response to ensure that all the appropriate technical and management staff are involved in the process.

03.05 Office of Nuclear Security and Incident Response, Division of Preparedness and Response (NSIR/DPR).

1. Participate in the reactive inspection decision-making process when headquarters involvement is needed to support the reactive inspection effort.

2601-04 REQUIREMENTS

04.01 Initial Event Notification and Follow-up. DFFI receives the initial event notification and performs the initial follow-up communications with the licensee and implements the inspection guidance in IP 88075, "Event Follow-up". If the event meets applicable reporting requirements, headquarters receives a formal notification via the Operations Center staff. DFFI requests technical and logistical support from FCSE, as needed, by contacting PORS staff and the Project Manager (PM). The PM is kept informed of the event and coordinates appropriate event follow-up activities on behalf of FCSE.

04.02 Deterministic Criteria. The following list of deterministic criteria is used as the initial screening criteria to evaluate the appropriate level of response for a significant event. The IIT

and AIT deterministic criteria below is a combination of criteria from MD 8.3 and additional criteria applicable to fuel cycle facilities.

1. An IIT should be considered for a significant event with one or more of the following characteristics:
 - a. Led to a significant radiological release (levels of radiation or concentrations of radioactive material in excess of 10 times any applicable limit in the license or 10 times the concentrations specified in 10 CFR Part 20, Appendix B, Table 2, "Effluent Concentrations," when averaged over a year) of byproduct, source, or special nuclear material to unrestricted areas.
 - b. Involved an inadvertent criticality.
 - c. Led to a high consequence event as defined by 10 CFR 70.61(b).
 - d. Led to a significant occupational exposure or significant exposure to a member of the public. In both cases, "significant" is defined as five times the applicable regulatory limit (except for shallow-dose equivalent to the skin or extremities from discrete radioactive particles).
 - e. Led to a site area emergency.
 - f. Involved the commercial use of source or special nuclear material and resulted in the potential exposure of a significant number of individuals above occupational or public dose limits.
 - g. Involved the deliberate misuse of source or special nuclear material from its intended or authorized use, which resulted in the exposure of a significant number of individuals.
 - h. Involved source or special nuclear material, which may have resulted in a fatality.
 - i. Involved circumstances sufficiently complex, unique, or not well enough understood, or involved safeguards concerns, or involved characteristics the investigation of which would best serve the needs and interests of the Commission.
 - j. Actual intrusion into the protected area or controlled access area or the established first-line physical barrier for controlling personnel access to the facility.
 - k. Involved a willful disclosure of classified information with potential damage to national security.

2. An AIT should be considered for a significant event with one or more of the following characteristics:
 - a. Led to a radiological release of source or special nuclear material to unrestricted areas that resulted in occupational exposure or exposure to a member of the public in excess of the applicable regulatory limit (except for shallow-dose equivalent to the skin or extremities from discrete radioactive particles).
 - b. Led to an intermediate consequence event as defined by 10 CFR 70.61(c).
 - c. Involved a high consequence event that was not unlikely or a very substantial increase in its likelihood.
 - d. Involved a fire or explosion involving licensed material or hazardous chemicals produced from licensed materials.

- e. Involved the deliberate misuse of source or special nuclear material from its intended or authorized use and had the potential to cause an exposure of greater than 5 rem to an individual or 500 mrem to an embryo or fetus.
 - f. Involved a significant infraction or repeated instances of safeguards infractions that demonstrate the ineffectiveness of facility security provisions.
 - g. Involved repeated instances of inadequate nuclear material control and accounting provisions to protect against theft or diversions of nuclear material.
 - h. Involved the failure of radioactive material packaging that resulted in external radiation levels exceeding 10 rads/hr or contamination of the packaging exceeding 1000 times the applicable limits specified in 10 CFR 71.87, "Routine Determinations."
 - i. Involved a loss of classified or safeguards information with potential disclosure to unauthorized individuals affecting national security or the common defense and security.
 - j. Involved an a failure to control unauthorized disclosure of other classified information or safeguards information that results in the removal of material from a controlled area and disclosure to an unauthorized individual.
3. An SIT should be considered for a significant event with one or more of the following characteristics:
- a. Involved safety function(s) that have been lost or significantly degraded such that the performance requirements of 70.61(b), (c), or (d) are not being met.
 - b. Involved repetitive failures or events involving items relied on for safety (IROFS) or deficiencies in operations.
 - c. Involved a high consequence event that was unlikely or a substantial increase in its likelihood.
 - d. Involved an intermediate consequence event that was not unlikely or a significant increase in its likelihood.
 - e. Led to a radiological release of source or special nuclear material or a chemical release that had a reasonable potential in exceeding an occupational or public radiation regulatory limit.
 - f. Led to an Alert in accordance with the facility Emergency Plan.
 - g. Involved a significant instance of inadequate nuclear material control and accounting provisions to protect against theft or diversions of nuclear material.
 - h. Involved a safeguards infraction that significantly weakens the effectiveness of the facility security provisions.
 - i. Involved a major deficiency in design, construction, or operation having potential generic safety or safeguards implications.
 - j. Involved an unanalyzed condition or unexpected system interactions that could reasonably lead to a significant safety or safeguards concern.
 - k. Involved a significant failure to obtain NRC approval to implement a facility change or change process in accordance with 10 CFR 70.72.
 - l. Involved a failure to control safeguards information with substantial potential for disclosure to unauthorized individuals.

04.03 Consideration of Risk Insights. Fuel facility events meeting one or more of the deterministic criteria associated with the safety operations performance area are further evaluated based on additional risk insights, as applicable. DFFI staff, with the support of staff in FCSE, will promptly consider risk insights associated with the event based on the best available information (e.g., the facility ISA, realistic assumptions regarding IROFS, other safety controls, operator actions, etc.) Given the relatively short time frame to decide whether or not to initiate a reactive inspection, some event information will most likely be missing or incomplete, which can inevitably add an appreciable level of uncertainty to be addressed in the decision-making process. This lack of complete event information focuses attention on the uncertainty of influential assumptions and their effect on the risk significance. Overall, the consideration of risk insights should be as realistic as possible given all of the information available at the time while balancing the need to make a timely decision. Inspection Procedure 88075, "Event Follow-up," discusses inspector inputs to can support the consideration of risk insights.

04.04 Event Management Screening. An event is additionally evaluated on how well it is understood by the NRC and how it is being managed by the fuel facility. The staff shall determine if the event is terminated and if the applicable facility processes and/or systems are in a safe condition. The staff shall assess if the licensee is exercising conservative operational decision making, has implemented effective immediate corrective actions, is conducting an appropriately scaled event investigation, and evaluating the extent of condition and generic implications. Based upon the results of this evaluation the option exists to reduce the level of inspection.

04.05 Recommendation to Management. Based on the initial event notification and follow-up, the deterministic criteria screening, the consideration of risk insights (for the safety operations performance area), and the event management screening, the staff will propose a reactive inspection recommendation to the DFFI Division Director using Enclosure 1 as a guide. The recommendation should be considered a risk-informed and integrated assessment that incorporates all of the relevant information into a recommendation to support a management decision.

If the initial review of the event significance, based on the information from sections 04.02, 04.03, and 04.04, suggests at most the consideration of a SIT, the RA will make the decision whether or not to initiate the SIT. In this case, regional management may consult with NRR and NSIR, but is not required to do so.

If the initial review of the event significance, based on the information from sections 04.02, 04.03, and 04.04, suggests more resources and effort beyond a SIT, regional management should promptly coordinate with FCSE and NSIR/DPR to discuss whether a SIT or AIT is more appropriate. In such cases, the RA, in consultation with the NMSS Office Director, makes the final decision on whether to proceed with an AIT or SIT.

For events that may warrant an IIT, the Directors of NMSS and NSIR will consult with the RA and provide a recommendation to the EDO. In such cases, the EDO, in consultation with the RA, will make the ultimate decision on whether to proceed with an IIT.

04.06 Communications with Internal and External Stakeholders on Event Response and Assessment. For significant operational events, the staff should be cognizant of the communication tools that are available to enhance the effectiveness and efficiency of the agency's communications with its stakeholders. The NRC has developed the Event Response and Assessment Communications Plan. The plan is available in the ADAMS Main Library internal folder entitled "Communication Plans," and should be consulted following a significant operational event or discovery of a significant degraded plant condition.

The communication tools available for event response and assessment include:

- a communications team
- central tracking of controlled correspondence
- a notification sequence for significant regulatory documents
- formalized questions and answers (Q&A) for common and expected significant events for use by the Office of Public Affairs (OPA) during initial event response
- a dedicated Web page for each event

If it is determined that a communications team is warranted, the FCSE PM typically plays the key headquarters role in developing and coordinating the communications team and subsequent communications activities. Specific communication activity assignments are determined by the communications team. Communication activities typically continue beyond the initial phase of investigative response until their goals have been accomplished.

Reactive inspections may generate high public interest. The RA in consultation with the OPA may elect to open a reactive inspection exit meeting to the public. Alternately, the RA may decide it is more appropriate to have a separate public meeting and/or press conference in lieu of a public meeting with the licensee.

2601-05 REFERENCES

1. [Management Directive 8.2](#), "NRC Incident Response Program"
2. [Management Directive 8.3](#), "NRC Incident Investigation Program"
3. NUREG 1303, "Incident Investigation Manual"
4. Inspection Procedure 88075, "Event Follow-up"
5. Inspection Procedure 88003, "Reactive Inspections"
6. Inspection Manual Chapter 2606, "Risk for Potential Non-compliances"
7. Event Response and Assessment Communications Plan, dated 10/3/2000 (ML003774969)

END

Enclosures:

1. Decision Documentation for Reactive Inspection (Deterministic and Risk Criteria Analyzed)
2. Reserved

Enclosure 1 – Decision Documentation for Reactive Inspection
(Deterministic and Risk Criteria Analyzed)

<u>Decision Documentation for Reactive Inspection</u> (Deterministic and Risk Insights)	
FACILITY:	EVENT DATE:
EVALUATION DATE:	
Brief Description of the Significant Operational Event:	
<u>Type</u>	<u>DETERMINISTIC CRITERIA</u>
	List the screening criteria that were met
	Remarks:
	List the screening criteria that were met
	Remarks:
	List the screening criteria that were met
	Remarks:
	List the screening criteria that were met
	Remarks:
	List screening criteria that were met
	Remarks:

<u>RISK INSIGHTS</u>
Brief description of the additional Risk Insights to consider (may include influential assumptions, uncertainties, calculations, complexities, areas with lack of information, references, and any risk insights provided by the licensee):

<u>RESPONSE DECISION</u>	
USING THE ABOVE INFORMATION AND OTHER KEY ELEMENTS OF CONSIDERATION AS APPROPRIATE, DOCUMENT THE RESPONSE DECISION TO THE EVENT AND THE BASIS FOR THAT DECISION.	
DECISION AND DETAILS OF THE BASIS FOR THE DECISION:	
BRANCH CHIEF REVIEW:	DATE:
DIVISION DIRECTOR REVIEW:	DATE:
ADAMS ACCESSION NUMBER:	
EVENT NOTIFICATION REPORT NUMBER (as applicable):	

Note: The above tables are provided as examples only. The regions have discretion to modify these tables in their implementing procedures or office instructions.

Enclosure 2 – Reserved

Attachment 1 – Revision History for IMC 2601

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment and Feedback Resolution Accession Number (Pre-Decisional, Non-Public Information)
N/A	ML16160A407 09/20/16 CN 16-023	Initial Issue. Provides guidance for implementing Management Directive 8.3, "NRC Incident Investigation Program," at fuel cycle facilities and describes the reactive inspection decision-making process.	None	ML16232A188