

U.S. NUCLEAR REGULATORY COMMISSION MANAGEMENT DIRECTIVE (MD)

MD 8.5		NONREACTOR OPERATIONAL SAFETY	DT- 18-15
		DATA REVIEW	
Volume 8	Licensee Oversight Programs		
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<i>Issuing Office:</i>	Office of Nuclear Material Safety and Safeguards Division of Fuel Cycle Safety, Safeguards and Environmental Review		
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EXECUTIVE SUMMARY			
Management Directive 8.5, “Nonreactor Operational Safety Data Review,” is revised to reflect organizational changes that have occurred since the last revision, and to update the referenced documents.			

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For updates or revisions to policies contained in this MD that were issued after the MD was signed, please see the Yellow Announcement to Management Directive index ([YA-to-MD index](#)).

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I. POLICY

It is the policy of the U.S. Nuclear Regulatory Commission to have an effective, coordinated program to systematically review nonreactor operating experience with regard to licensed material, assess its significance, provide timely and effective communication to stakeholders, and apply the lessons learned to regulatory decisions and programs.

II. OBJECTIVES

- Establish a nonreactor operating experience program, focused on the unique needs of materials and radiation safety areas, independent from the reactor program described in Management Directive (MD) 8.7, “Reactor Operating Experience Program,” managed by the Office of Nuclear Reactor Regulation.
- Ensure that the immediate and long-term safety, security, and safeguards concerns identified from nonreactor operating experience are documented, analyzed, resolved, and disseminated so that the margin of safety is maintained.
- Ensure that program and regional offices maintain a coordinated and efficient capability to effectively collect, review, and analyze nonreactor operational and occupational data as related to radiation safety, including identification of potential generic concerns and generic issues.
- Establish responsibilities for tracking and resolving potential generic concerns and generic issues, as they relate to the functional responsibilities of each office.
- Increase the effectiveness of NRC regulatory programs and licensee operations to ensure safety, security, and safeguards by prompt dissemination of concerns and lessons learned from nonreactor operating experience.
- Ensure that Congress, the public, Agreement States, and the nuclear industry are provided with current information regarding nonreactor operational and occupational experience, including the actual or potential hazards to health and safety that have been inferred from operational data.

- Increase coordination among the offices to prevent unwarranted duplication of effort and to increase the effectiveness of nonreactor operational safety data review.

III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY

A. The Commission

Acts on the most serious operational and occupational events that are brought to its attention after a nonreactor operational safety data review determines that the significance of an event to public health and safety requires the immediate attention of the Commission.

B. Advisory Committee on the Medical Uses of Isotopes (ACMUI)

Reviews medical events and safety studies from the operational safety data reviews of medical and pharmacy facilities, as directed, and advises the staff.

C. Advisory Committee on Reactor Safeguards (ACRS)

1. Advises the Commission on the hazards of proposed and existing nuclear materials and fuel cycle facilities and the adequacy of proposed safety standards.
2. Initiates reviews of specific generic matters or nuclear facilities safety-related items.

D. Director, Office of International Programs (OIP)

1. Serves as the principal contact for the establishment and administration of formal arrangements between the NRC and the agencies of foreign countries and international organizations for the exchange and collection of nonreactor operational safety data.
2. Serves as the formal contact for obtaining international operating safety data information and transferring to internal systems for further processing.
3. Coordinates U.S. participation in the Nuclear Energy Agency's incident reporting system and the International Atomic Energy Agency's reporting system and distributes foreign reports to applicable offices.

E. Executive Director for Operations (EDO)

Oversees NRC responses to significant operational and occupational events and safety studies from nonreactor operational safety data reviews and directs the required action to the appropriate offices.

F. Director, Office of Nuclear Material Safety and Safeguards (NMSS)

1. Conducts reviews and analyses of operational and material safety, security, and safeguards data related to the Office of Nuclear Material Safety and Safeguards (NMSS) regulated activities, including information on foreign nuclear-related activities for the identification, processing, and closure of generic concerns and generic issues.
2. Refers generic issues and significant events to the appropriate lead office when that office is responsible for a regulatory area affected by the issue or event.
3. Takes licensing-related action (except where specific licensing authority has been delegated to the regional administrators) when potential operational and occupational safety and security issues are determined to affect the current basis of licenses or certificates of compliance issued by NMSS.
4. Manages and maintains the Nuclear Materials Events and Fuel Cycle Operating Experience Database used to store operational safety data.
5. Provides technical support to regional offices, as requested, for events with generic or licensee-specific health and safety or safeguards implications related to nonreactor operational safety data reviews.
6. Tracks and directs the prompt review and analyses of significant operational safety, security, and safeguards events related to NMSS regulated activities.
7. Provides event reporting guidance to the Agreement States to enable NRC staff to conduct reviews and analysis of operational safety and security-related information under the purview of Agreement State-regulated materials activities.

G. Director, Office of Nuclear Regulatory Research (RES)

Directs the Generic Issues Program and classifies, prioritizes, and tracks the resolution of selected generic issues.

H. Director, Office of Enforcement (OE)

Oversees, manages, and directs the development of policies and programs for enforcement of NRC requirements.

I. Director, Office of Nuclear Security and Incident Response (NSIR)

1. Manages the agency's incident response function, which provides the program that receives and disseminates operational data information to the agency's Headquarters Operations Center.

2. Coordinates with other NRC program offices, as necessary, to identify security-related issues for nonreactor operational safety data reviews.
3. Supports program offices in the assessment of operational security-related data relative to the effectiveness of core programs such as licensing, oversight, rulemaking, and incident response.
4. Assists program offices in the review of security-related data for generic implications that could have an adverse impact on security requirements, security program implementation, or security program oversight.
5. Provides guidance to program offices in the development of generic communications for security-related infractions, security-related near-misses, or security-related events.

J. Chief Information Officer, Office of the Chief Information Officer (OCIO)

Supports, as necessary, NMSS, the Office of Nuclear Security and Incident Response (NSIR), and NRC regional offices in providing efficient information technology solutions for the nonreactor operational safety data review process.

K. Regional Administrators

1. Take licensing-related action, where the authority has been delegated to them, when potential operational and occupational radiation safety issues are determined to affect the current basis of licenses or certificates of compliance.
2. Conduct prompt review of specific events related to NRC-regulated facilities and activities, including onsite followup and the identification of violations of NRC requirements for enforcement purposes.
3. Assess events with generic or licensee-specific health and safety or safeguards implications related to nonreactor operational safety data reviews and communicate potential generic implications to the appropriate program office.
4. Coordinate regional efforts with other NRC offices that share responsibility for nonreactor operational safety data reviews.

IV. APPLICABILITY

The policy and guidance in this directive apply to all NRC employees.

V. HANDBOOK

- A. There is no handbook associated with MD 8.5. Instead, each office reviews, updates, and maintains its office procedures relevant to this directive to ensure that applicable agency objectives identified in Section II of this directive are met. Office procedures address the following topics, as appropriate:
1. Receipt of data,
 2. Preliminary analysis,
 3. Dissemination of data,
 4. Management and tracking of data,
 5. Screening of operational data,
 6. Detailed analysis and evaluation,
 7. Identification of generic issues and/or generic concerns,
 8. Feedback to stakeholders, and
 9. Followup actions.
- B. Although a list of existing office procedures is provided in Section VI of this directive under “Other Documents,” those procedures are likely to change as individual offices conduct periodic reviews and updates.

VI. REFERENCES

Code of Federal Regulations

Title 10, “Energy.”

Nuclear Regulatory Commission Documents

Inspection Manual Chapters

0970, “Potential Generic Items Identified by Regional Offices.”

1120, “Preliminary Notifications.”

Management Directives—

6.4, “Generic Issues Program.”

8.1, “Abnormal Occurrence Reporting Procedure.”

8.2, “NRC Incident Response Program.”

8.3, "NRC Incident Investigation Program."

8.7, "Reactor Operating Experience Program."

8.9, "Accident Investigation."

12.1, "NRC Facility Security Program."

12.2, "NRC Classified Information Security Program."

12.3, "NRC Personnel Security Program."

12.4, "NRC Communications Security (COMSEC) Program."

12.5, "NRC Cybersecurity Program."

12.6, "NRC Sensitive Unclassified Information Security Program."

12.7, "NRC Safeguards Information Security Program."

NRC "Statement of Agreement State Program Policy," 82 FR 46840,
October 6, 2017.

NRC "Statement of Agreement State Program Policy; Correction," 82 FR 48535,
October 18, 2017.

Office of Federal and State Materials and Environmental Management Programs
(FSME) (currently Nuclear Material Safety and Safeguards (NMSS)) Procedures—

FSME Procedure Approval, SA-300, "Reporting Materials Events,"
March 27, 2013 ([ML13053A346](#)).

NUREG-0933, Main Report with Supplements 1–34, "Resolution of Generic Safety
Issues" (formerly entitled "A Prioritization of Generic Safety Issues").

Other Documents—

NMSS Office Procedures—

Policy and Procedure 6-6, Rev. 1, "NMSS Operating Experience Assessment
and Processing" ([ML15225A045](#)).

Policy and Procedure 6-14, Rev. 1, "Fuel Cycle Operating Experience Program"
([ML16188A156](#)).

Policy and Procedure 8-1, Rev. 2, "Process Overview for the Regional
Coordination of Events" ([ML16158A391](#)).

Policy and Procedure 8-2, "Abnormal Occurrence Identification and Reporting
Procedure" ([ML072340473](#)).

Policy and Procedure 8-3, "Reporting Materials Events to the International Nuclear and Radiological Events Scale" ([ML15328A063](#)).

NMSS Office Procedures—

NMSS-LIC-155, "NMSS Event Coordination and Evaluation" ([ML13121A177](#)).

Region III Regional Procedures and Divisional Instructions—

DI-IMC-2800, "Identification and Closure of Nuclear Material Events" ([ML14114A707](#)).

RP 8.1, "Preparation and Updating of Abnormal Occurrence Reports" ([ML14216A726](#)).

RES Office Instructions—

TEC-001, "Coordination of RES Operating Experience Information with the NRC Operating Experience (OpE) Program" ([ML16068A313](#)).

TEC-002, "Procedure for Processing Generic Issues" ([ML11242A033](#)).

United States Code

Atomic Energy Act of 1954, as amended, (42 U.S.C. 2011 et. seq.).

Energy Reorganization Act of 1974, as amended, Section 208, Abnormal Occurrence Reporting (42 U.S.C. 5801 et. seq.).