



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

(FSME-10-002, January, Program, SA-300)

January 11, 2010

ALL AGREEMENT STATES, MICHIGAN

OPPORTUNITY TO COMMENT ON DRAFT REVISION TO FSME PROCEDURE SA-300,  
"REPORTING MATERIAL EVENTS" (FSME-10-002)

**Purpose:** To provide the Agreement States with the opportunity to comment on the proposed revisions to the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300, *Reporting Material Events*.

**Background:** Proposed revision of FSME Procedure SA-300 with tracked changes.

**Discussion:** Enclosed for your review and comment are the draft revisions to the FSME Procedure SA-300, *Reporting Material Events*. The SA-300 procedure describes the process for the collection, control, and preliminary review of material events that have been reported to NRC by Agreement States. We would appreciate receiving your **comments\* within 60 days from the date of this letter.**

If you have any questions regarding this communication, please contact me at 301-415-3340 or the individual named below.

POINT OF CONTACT: Duane White  
TELEPHONE: (301) 415-6272

EMAIL: Duane.White@nrc.gov  
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Robert J. Lewis, Director **/RA/ Terrence Reis** for  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

Enclosure:  
FSME SA-300 Proposed Revised Procedure  
with tracked changes

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\*This information request has been approved by OMB 31 50-0029, expiration 08/31/2010. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and FOIA/Privacy Services Branch (T-5F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to [infocollects@nrc.gov](mailto:infocollects@nrc.gov), and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0029), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.



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

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***Reporting Material Events - SA-300***

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Issue Date:

Review Date:

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Robert J. Lewis  
*Director, MSSA*

*Date:*

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Christian Einberg  
*Branch Chief, MSSA*

*Date:*

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Duane E. White  
*Procedure Contact, MSSA*

*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 are the responsibility of FSME as of October 1, 2006. Copies of FSME procedures will be available through the NRC website.***



**I. INTRODUCTION**

This procedure establishes a process for the collection, control, and preliminary review of material events that have been reported to NRC by the Agreement States.

**II. OBJECTIVES**

- A. To provide guidance for use by the Agreement States on reporting material events to NRC.
- B. To provide guidance to NRC staff in the collection, coordination, and preliminary review of material events reported by the Agreement States.

**III. BACKGROUND**

- A. The Atomic Energy Act (AEA) allows the Commission to enter an Agreement with a State to transfer regulatory authority over certain nuclear materials. In accordance with provisions contained in the AEA and the Energy Reorganization Act, and compatible Agreement State regulations, NRC and Agreement State licensees are required to report the occurrence of incidents and events involving the use of nuclear materials to the appropriate regulatory agency. For purposes of compatibility, the Agreement States report, **to NRC those incidents and events reported to them by their licensees that involve** the use of nuclear materials.
- B. The information collected on exposures, medical events, lost material, equipment failures, etc., that have occurred involving the licensed and unlicensed use of nuclear materials is invaluable in assessing trends or patterns, identifying generic issues **or generic concerns**, and recognizing any inadequacies or unreliability of specific equipment or procedures. The reported information is critical for initiating a timely and effective response to security-related events and will significantly aid in understanding why the event occurred and identifying any actions necessary to improve the effectiveness of NRC and Agreement State regulatory programs. The information is also used in preparation of NRC's annual performance report to Congress, **the NRC's annual report to Congress on abnormal occurrences, and to support the United States commitment to report to the International Atomic Energy Agency (IAEA) international database of significant events.**

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C. Nuclear Material Events Database (NMED)

NMED contains an 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). NMED accommodates the sharing of material event data submitted by Agreement States, NRC licensees, and other non-licensed entities. NMED is maintained by FSME. The NMED contractor is responsible for coding and quality control of information with general oversight from the NRC NMED Project Manager.

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Deleted: is responsible for the collection, coordination and, in cooperation with NMSS and the Office of Nuclear Regulatory Research (RES), the review of reports of incidents and events that have occurred involving the use of nuclear materials received from the Agreement States. NMSS is the designated agency lead office for review and evaluation of material events. NRC's Nuclear Security and Incident Response (NSIR) Operations Center receives notifications of significant events. NSIR staff participates in the review and evaluation of security-related material events.

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C. The Deputy Director, STP, is responsible for assigning a staff member to serve as lead material events project manager.¶

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D. The STP-designated Project Manager for events [Event Project Manager] is responsible for coord( ... [1]

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IV. ROLES AND RESPONSIBILITIES

A. The Director, Division of Materials Safety and State Agreements (MSSA), or designee, participates in NRC management review and evaluation of Agreement State response to material events that have been identified by NRC as requiring notification to the NRC within 24 hours of the State's discovery of the event.

B. The Branch Chief of the Radioactive Materials Safety Branch (RMSB), which is within MSSA, or designee, is responsible, in cooperation with the Office of Nuclear Material Safety and Safeguards (NMSS); Nuclear Security and Incident Response (NSIR); Nuclear Regulatory Research (RES); and the NRC Regions, for the collection, coordination and review of reports of incidents and events reported to the NRC by the Agreement States. This includes the identification and review of events that may: 1) meet the abnormal occurrence (AO) criteria; 2) constitute a generic issue or concern; and 3) require notification to another entity such as the IAEA, or be reportable to Congress. The NRC Operations Center receives notifications of events requiring notification to NRC within 24 hours. NSIR staff participates in the review and evaluation of security-related material events.

C. The Regional State Agreements Officer (RSAO) is a designated staff member, in an NRC regional office, who serves as the point of contact for the region and MSSA regarding Agreement State radiation control programs. RMSB staff should coordinate with the appropriate RSAO, regarding the receipt of a reportable event(s) requiring NRC notification within 24 hours.

**V. GUIDANCE**

**A. Guidance for Agreement States**

Agreement States should follow the guidance presented in the Appendix to this procedure entitled, *Handbook on Nuclear Material Event Reporting in the Agreement States*.

**Deleted:** G. STP staff should coordinate with the appropriate ASPO, responsible for providing back-up staff support to the RSAO (see STP Procedure SA-117), regarding the receipt of a *significant* event report.¶

**B. Guidance for NRC Staff upon Receipt of an Event Report directly from the Agreement State**

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**1. Reports of Events Requiring Notification Within 24 Hours from Agreement States**

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The following actions should be taken upon receipt of a report of an event requiring notification within 24 hours from an Agreement State. Receipt of such reports should occur infrequently since guidance to the Agreement States stipulates that reports for these events should be provided directly to the NRC Operations Center at (301) 816-5100.

**a. For reports received via phone, direct the Agreement State representative to call the NRC Operations Center’s Headquarters Operations Officer (HOO) to report the event. If staff has reason to believe that the HOO was not informed, the Branch Chief, RMSB, should be contacted for follow-up.**

**Deleted:** Dial the NRC Operations Center Headquarters Operations Officer (HOO) if the State has contacted you by phone and have the State representative calling in provide the event notification information directly to the HOO.

- b. For reports received via other means (e.g., fax, email, hard copy), immediately forward to the HOO.

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2. Reports of Events Requiring 5 - 60 Day Notification from Agreement States

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- a. A copy of the event report should be provided to the RMSB Branch Chief or designee. This can be accomplished by providing the report directly to the Branch Chief, RMSB or designee, or by placing the report in NRC's Agencywide Documents Access and Management System (ADAMS) (using NRC's guidance on handling sensitive unclassified non-safeguards information (SUNSI), to ensure appropriate public availability) and providing the RMSB Branch Chief or designee with the ADAMS Accession Number. A copy of the event report should also be provided to the NMED contractor through the NRC NMED Project Manager.

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**Deleted:** A copy should also be sent to the NMED contractor, INL, through the STP Director's Secretary.

- b. If it is not clear whether the report involves an event that requires notification within 24 hours, follow the procedure for reporting an event that requires reporting to the NRC within 24 hours.

C. Additional Guidance for RMSB Staff and RSAOs

1. NRC Regional and RMSB Event Review

- a. Regional Review: Event Reports shall be reviewed by the RSAO in accordance with regional procedures.
- b. RMSB Review: Event Reports shall be reviewed by the RMSB staff in accordance with RMSB procedures. Events are reviewed to identify:
  - (i) Any concerns or issues that, in accordance with the NRC Strategic Plan performance goals and measures, could have significant impact on health and safety, security and/or the environment; (and as required by Congress under the Government Performance Results Act (GPRA).
  - (ii) Events that may be reportable to another entity such as IAEA.
  - (iii) Events that meet the AO criteria, for inclusion in the annual AO report to Congress. Draft AO reports and draft reports to other entities will be coordinated with the Agreement States.

**Deleted:** Agreement State event reports shall be reviewed by the Events Project Manager to identify any events that may be **significant** from the standpoint of health and safety. If the event is identified as **significant** and it was not previously reported to the NRC by the Agreement State under the 24-hour reporting requirement, the Event Project Manager should notify the HOO and the appropriate RSAO. If an event indicates the possibility of a generic concern or issue, the Event Project Manager will provide notification to the Deputy Director, Division of Industrial and Medical Nuclear Safety, NMSS. NOTE: Hard copy event reports received by the RSAO shall be reviewed by the RSAO in accordance with regional procedures. The RSAO should provide a copy of the event report to the Event Project Manager. The RSAO will keep the Event Project Manager informed of the status of events that have been identified as **significant.**

- (iv) Events that should be forwarded to other Branches or Divisions within FSME for awareness and further assessment as warranted.
- 2. Reports of Events Requiring Notification Within 24 Hours
  - a. Reports to NRC from Agreement States
    - (i) Events reported to the HOO shall be reviewed by RMSB, using RMSB's standard procedures for event coordination and assessment.
    - (ii) If an event is identified that was not previously reported to the NRC by the Agreement State within the 24-hour reporting requirement, RMSB should notify the appropriate RSAO. The RSAO will contact the Agreement State to obtain information and, if determined to be reportable, direct the Agreement State to report the event to the NRC Operations Center. Conversely, the RSAO will notify RMSB if they identify such an event.
    - (iii) If an event is identified as a potential AO; and/or is reportable to the International Nuclear and Radiological Event Scale (INES); or if an event indicates the possible presence of a generic concern or issue, RMSB should notify the appropriate RSAO. Conversely, the RSAO will notify RMSB if they identify such an event. The RSAO will be the primary contact for resolving with the Agreement State any issues or necessary follow-up actions related to the event. RMSB will be the primary contact for coordination of the issues at NRC Headquarters.
- 3. Reports of events requiring 5 - 60 day reporting to NRC will be placed in ADAMS in accordance with NRC's SUNSI guidance regarding public availability; and NRC's NMED Project Manager will be notified of all non-public documents.
- 4. Requests for Additional Information
  - a. NRC staff may contact Agreement States for additional information on events that pose or could pose risks to health and safety, security and/or the environment. Such requests, normally initiated by the RSAO, would occur on an as needed basis,

possibly within hours to a few days of notification of the occurrence of the event, based on the safety significance.

- b. The RSAO, or a designee, may contact Agreement States for additional event information for events not considered to pose risks to health and safety, security and/or the environment. Standard procedure is to allow at least 30 days before making such requests to provide reasonable time for State review and evaluation, and submission of follow-up information. A request for follow-up information may also be sent routinely via email by the NMED contractor, (e.g., when the NMED record is incomplete after 60 days from the date reported to the regulatory agency).
5. Agreement States Updates to NMED
- a. Agreement States are requested to update the NMED event record in a timely manner until the event has been resolved and closed.
  - b. Periodically, NRC staff may be requested by management to provide information regarding the status of event reporting by the Agreement States. Information provided by the Agreement State and collected and maintained in NMED should be used by staff to evaluate the effectiveness and completeness of Agreement State event information. See FSME Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)* and SA-105, *Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities*.

## VI. APPENDIX

*Handbook on Nuclear Material Event Reporting in the Agreement States.*

## VII. REFERENCES

1. *Policy Statement on Adequacy of and Compatibility of Agreement State Programs*, published in the Federal Register, 62 FR 46517 (September 3, 1997).
2. NRC Management Directive 5.6 *Integrated Material Performance Evaluation Program (IMPEP)*, February 26, 2004.
3. NRC Management Directive 6.4, *Generic Issues Program*, July 29, 2005.
4. NRC Management Directive 8.1, *Abnormal Occurrence Reporting Procedure*, June 11, 2001.
5. NRC Management Directive 8.5, *Operational Safety Data Review*, December 23, 1997.

**Deleted:** 3. Electronic Event Reports (E-mail or Electronic Storage Media)

The Agreement States send electronic copies of event reports (via Internet e-mail, PC diskette, fax or CDs) directly to the NMED contractor, INL, for entry into NMED. INL, in coordination with NMSS, conducts reviews of Agreement State material event reports that have been electronically provided to INL for safety significance. Information on any events identified as *significant* that were not previously identified by the Agreement State under the 24-hour reporting requirement or events that could pose possible generic issues are provided to STP and NMSS by INL.

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<#>Event Review for Safety Significance and Identification of Possible Generic Concerns

a. The NMSS materials staff conducts a daily review of new material event notifications (ENs) received by the Headquarters Operations Center. Events are reviewed to identify any events that may involve generic safety concerns, issues (GSI) or trends, that could have significant impact on health, safety and/or security concerns, relative to the NRC Strategic Plan performance goals and measures that have been linked to agency programs and activities, as required by Congress under the Government Performance Results Act (GPRA). Events are also evaluated by NRC and Agreement State staff to identify any events that meet the abnormal occurrence (AO) criteria, for inclusion in the annual AO Report to Congress. Similar event reviews to identify health, safety and security significance and generic concerns are conducted by the Agreement States. Information on any possible generic concerns identified by NRC or the Agreement States will be coordinated and shared with NMSS, STP and the Agreement States. A quarterly analysis is also performed on the information contained in NMED for each major event type to identify any statistically significant trends.

b. Based on the results of the review, it may be necessary to request additional clarifying information. Agreement State staff may be contacted by the RSAO, or a designee, when the event has been identified as safety significant and meet the AO criteria.

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- 6. ~~FSME~~ Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*.
- 7. ~~FSME~~ Procedure SA-105, *Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities.*

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**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	03/08/06	Reporting Materials Events, Rev. 2	ML081690879
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# Handbook on Nuclear Material Event Reporting in the Agreement States

Final Report

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Management Programs**  
U.S. Nuclear Regulatory Commission

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## AVAILABILITY OF REFERENCE MATERIAL

NRC documents: Event Notifications, Preliminary Notifications, Inspection Manuals and Procedures, NUREG Series technical reports, Regulatory Guides, etc. are available at the NRC external Website under References at: <http://www.nrc.gov/reading-rm/doc-collections/>. The FSME, State Agreement (SA) policies and procedures are available at: <http://nrc-stp.ornl.gov/procedures.html>.

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## Paperwork Reduction Act Statement

The information collections contained in this handbook have been approved under Office of Management and Budget approval number 3150-0178, which expires 10/31/2009. The burden to the public for these mandatory information collections is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of these information collections, including suggestions for reducing the burden, to the U.S. Nuclear Regulatory Commission, FOIA/Privacy Officer, Mail Stop T-5-F09, Washington, DC 20555-0001, or by email to [FOIA\\_resource@nrc.gov](mailto:FOIA_resource@nrc.gov); and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0178), Office of Management and Budget, Washington DC 20503.

The information collections contained in this report are covered by the requirements of NRC regulations contained in Title 10 of the U.S. Code of Federal Regulations. The Agreement States collect this information under compatible Agreement State regulations.

## Public Protection Notification

If a document does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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The collection of event information has been approved by the U.S. Office of Management and Budget, as follows.¶  
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"This information request has been approved by OMB 3150-0178, expiration date 09/03/2006. The estimated burden per response to comply with this collection request is 2 hours. Forward any comments regarding the burden estimate to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0052), Office of Management and Budget, Washington, DC 20503." ... [4]

# Abstract

The review and analysis of operational event information increases the effectiveness of the U.S. Nuclear Regulatory Commission (NRC) and Agreement State regulatory programs by identifying safety and security significant events and concerns, and their causes. The information from reports of medical events, overexposures, equipment failures, and other events that have occurred involving the use of nuclear materials licensed by either the NRC or the Agreement States is invaluable in assessing trends or patterns and identifying possible inadequacies or unreliability of specific equipment or procedures. The reported information will significantly aid in understanding why the events occurred and identifying any actions necessary to improve the effectiveness of NRC and Agreement States regulatory programs. The information is also used in preparation of NRC's performance report to Congress.

This handbook, which supercedes the previous ~~March 2006~~ version, has been developed to provide information to the staff of the Agreement States that are responsible for the preparation of reports for incidents and events involving the use of nuclear materials that occurred in their State. Reporting of Agreement State material events to NRC is mandatory for purposes of compatibility. The handbook describes the procedure to be followed in reporting material events to NRC. Guidance is provided on what information should be reported, the level of detail, and where to report. Information is also provided on obtaining Federal assistance for radiological emergencies. Procedures for identifying and reporting ~~abnormal occurrences~~ (AOs) are also included. The objective of the handbook is to:

- Improve technical information
- Standardize format
- Ensure consistency
- Facilitate information retrieval

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# 1. Introduction

This handbook contains guidance for Agreement States on reporting material event information to the Nuclear Regulatory Commission (NRC) for events that occurred in their State. It also provides guidance for use by non-Agreement States and non-licensees when voluntarily reporting events involving lost, stolen or found sources. At the request of the Conference of Radiation Control Program Directors (CRCPD), the Nuclear Material Events Database (NMED) captures voluntary reports on lost and stolen events, for any type of material, as well as situations that can not be specifically tied to a reporting requirement, such as “found sources, materials contaminated with radioactive material, and landfill alarm trips. The reported information aids in understanding why the events occurred and in identifying actions to help ensure public and occupational safety and security, and improves the overall effectiveness of the NRC and Agreement State regulatory programs. Guidance is provided on (1) reporting events requiring notification within 24 hours to the NRC Operations Center; (2) providing 5 - 60 day notification and follow-up event information; (3) schedule for event reporting; (4) reporting formats; and (5) reporting event information for events meeting the abnormal occurrence (AO) criteria. NOTE: This procedure does not contain guidance on NMED data entry (e.g., coding). For guidance on data entry, an electronic copy of the NMED users guide has been included with the local NMED Agreement State software, and the NMED website under “Help”. The NMED website is located at <https://nmed.inl.gov>. The local Agreement State software may be downloaded from the NMED website.

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## 1.1 Why do we collect event information?

Operating experience is an essential element in the regulatory process for ensuring that licensed activities are conducted safely. Reporting operating incidents and events helps to identify deficiencies in the safe use of Atomic Energy Act (AEA) radioactive material and to ensure that corrective actions are taken to prevent recurrence. A 1993 General Accounting Office (GAO) report identified the compilation and presentation of national materials data as an area for improvement and recommended that NRC take appropriate action to ensure that the information on radiation events is reported completely and accurately. Further, reliable information should be available to NRC, the Congress, and the States to identify patterns and trends and determine appropriate changes for the programs.<sup>1</sup> Event information is reported to Congress annually and used to demonstrate that the Agency and the States are meeting the safety and security goals and the corresponding strategic outcomes in the NRC's strategic plan. NRC conducts reviews of

<sup>1</sup> Nuclear Regulation: Better Criteria and Data Would Help Ensure Safety of Nuclear Materials, GAO/RCED-93-90.



all operating experience reports, from both NRC licensees and Agreement States, to identify safety concerns early, and to further evaluate individual **events for the possible presence of generic** safety concerns **or generic issues**, that could apply to a broader class of licensees. Prompt reporting of event information, including **5 - 60** day report information, and updates to events, helps the staff identify or detect possible safety concerns **or issues** as early as possible. An event or condition could, by itself appear insignificant, but when compared with national information, could become a generic concern **or issue**. In-depth analysis of event report data may result in the identification of actions that could lead to improvements in the effectiveness of NRC and Agreement State regulatory programs. Event analysis may also result in the issuance of **generic communications to provide information and guidance regarding safety concerns and issues**, and/or **an** assessment of the need for regulatory changes or revisions. Feedback is provided to Agreement State regulators, the industry, and the public.

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NRC publishes an **annual** report that presents information on the results of statistical analysis of event data and any **safety** significant or generic issues or concerns. The *Nuclear Material Events Database Annual Report* is available in electronic form at the NMED Internet Website: <https://nmed.inl.gov>. Also, NRC publishes a nuclear material newsletter, *Office of Federal and State Materials and Environmental Management Programs (FSME) Licensee Newsletter*, NUREG/BR-0117, that includes information on safety concerns identified during that quarter.

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**1.2 What is the governing regulatory authority?**

-- Under Section 274 of the AEA, Agreement States have assumed regulatory authority over byproduct, source and certain quantities of special nuclear materials. The AEA directs NRC to cooperate with the States in the formulation of standards to protect employees or the general public against hazards of radiation and to assure that State and Commission programs will be coordinated and compatible. Article VI of the Agreement between the State and the NRC states that "the State and the Commission agree to keep each other informed of events, accidents, and licensee performance that may have generic implications or otherwise be of regulatory interest."

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-- Under the AEA and the Energy Reorganization Act of 1974 (ERA), as amended, the NRC evaluates material event reports for both NRC and Agreement State licensees, and AOs that have occurred in licensed facilities. In addition, the ERA requires NRC to provide to Congress on an annual basis, information on **events** that meet the AO criteria.

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- Under the Government Performance Results Act of 1994 (GPRA), Federal agencies are required to establish measurable outcome oriented performance goals linked to Agency programs and activities in a strategic plan. An annual performance report to Congress is prepared that evaluates the NRC materials program against the metric performance goals. The metric goals are based on current and historical event reporting data. Due to the importance of nationwide operating experience as an essential element in the regulatory process for ensuring that licensed activities are conducted safely, the Commission directed the staff to make Agreement State reporting of events to NRC's NMED database an item of compatibility (See Reference section, June 30, 1997, [Staff Requirements Memorandum](#)).
- The guidance contained in this handbook is to assist NRC and Agreement State staff in the joint sharing and analysis of event information. It does not address evaluation of Agreement State programs. The AEA directs the Commission to periodically review actions taken by the States under the Agreements to ensure adequacy and compatibility with the provisions of the Act. NRC conducts periodic evaluations of Agreement State programs under the *Integrated Materials Performance Evaluation Program (IMPEP)*, which includes an evaluation of event response, reporting, follow-up, and close-out. (See Reference for [FSME Procedures SA-100](#), [Implementation of the Integrated Performance Evaluation Program \(IMPEP\)](#) and SA-105), *Reviewing Common Performance Indicator #5, Response to Incidents and Allegations*.

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### 1.3 How do you determine if an event is reportable?

Agreement States should report to NRC all events reported to their State by State licensees under State regulations equivalent to NRC's reporting requirements. [Section 2 of this document provides additional details regarding reporting events.](#) [Appendix A](#) of this guide contains a listing of the [most commonly encountered NRC regulatory reporting requirements for material event information](#). The reporting requirements form the basis for equivalent reporting requirements in Agreement State regulations. The listing references the specific [regulatory requirement](#), followed by a brief description of the types of events that fall under the reporting requirement, and the periodicity for reporting. [Appendix B](#) provides examples of reportable material events or occurrences that are required to be reported by both NRC and Agreement State material licensees.

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The States are encouraged to voluntarily report an occurrence that [the State believes might be of safety significance, generic interest or concern, or involves media interest, even if that occurrence is not able to be tracked to a specific reporting requirement](#). These can be [occurrences that actually happened \(event\) or something that may happen \(condition\) that does not meet the regulatory reporting criteria](#). [For voluntary reports of this type, the State should identify the situation and provide any explanation of the safety significance, generic interest or concern, or media interest generated.](#)

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## 1.4 What is the Nuclear Material Events Database (NMED)?

NMED contains a historical collection of information on the occurrence, description, and resolution of events involving the use of radioactive material in the United States. NMED accommodates the sharing of material event data submitted by Agreement States and the NRC. The data includes information on material events from January 1990 through the present. The States will be notified of any changes made to NMED. The database is maintained by FSME through a contractor. NMED is a tool available to both NRC and the States to support evaluation of specific events, as well as assessment of event types, and identification of generic issues and concerns. NRC posts its annual events assessment on the NMED website. States are encouraged to share with NRC and the other States any assessments or trending studies they have performed. These can be forwarded to the NMED Project Manager for posting on the NMED website, or distribution as an all Agreement State Letter.

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1.5 Reporting Lost, Stolen and Abandoned Sources ... [5]

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1.6 Reporting Theft or Terrorist Activity Events (reportable within 4 hours) ... [6]

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## 2. Reporting Material Events

In accordance with the provisions of compatible Agreement State regulations, Agreement State licensees are required to report the occurrence of material incidents and events to the Agreement State regulatory agency. As an item of compatibility, the Agreement States provide reports of incidents and events involving the use of nuclear materials by Agreement State licensees to NRC. This section presents information on reporting (1) immediate or 24-hour reportable events to the NRC Operations Center, (2) 5 - 60 day reportable events, and (3) follow-up event information. As a general rule, Agreement States must report events to NRC on the same timeframe that licensees must report to the Agreement State. For example, if a report is due from the licensee to the Agreement State in 24 hours, the Agreement State report is due to the NRC within 24 hours of receipt. Appendix A contains a summary table of event reporting requirements. Appendix C contains a summary table of the event reporting schedule.

### 2.1 Reporting Events Requiring Notification Within 24 Hours

Agreement States should report events requiring notification within 24 hours to the NRC Operations Center. Information should be initially reported to the NRC Operations

Center by telephone at (301) 816-5100. Follow-up information for the event may also be provided to the NRC Operation Center by fax at (301) 816-5151 or by email at HOO.HOC@nrc.gov. An example of a fax page has been included in Appendix D. States should assign an Event Report Identification Number to each reportable event. The format for this number is described in Section 2.4.a. “Assign Event Report Identification Number.” Appendix E provides a listing of minimum event information that should be provided to complete an event report. When submitting an initial event report, please provide as much information as is known at the time the report is prepared regarding the items indicated in Appendix E. However, it is understood that this information may be incomplete or preliminary. Updated information should be subsequently provided in follow-up reports (see Section 2.5).

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**2.2 NMED Record for Events Reported Within 24 Hours**

The NMED contractor uses the initial event notification (EN) information, which was provided to the NRC Operations Center from an Agreement State, to establish a record in the national NMED database. The NMED contractor will reference the Agreement State Event Report Identification Number (See Section 2.4.a for generating Agreement State Event Report Identification Number) in the record. The Agreement State Event Report Identification Number will be reflected in the “Reference” field of the NMED record and will be used to ensure any subsequent updates are correctly associated with the initial event record. (See Section 2.5, of this Handbook for guidance on reporting follow-up event information to NMED). In addition, each event entered into NMED is assigned a unique NMED item number.

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### **2.3 Radiological Emergency Response Assistance Available to the States**

States may request Federal assistance through the NRC Operations Center staff. The Federal government, upon request, has the capability to provide assistance to States in responding to radiological emergencies. Under the National Response Plan (NRP), NRC is the lead Federal agency (LFA) for radiological emergencies involving AEA material where the material can be traced back to an individual, NRC or Agreement State licensee. As the LFA, NRC is responsible for coordination of the Federal response, including providing assistance from NRC and arranging for assistance from other agencies, e.g., FEMA, DOE, etc., as requested by the States. Federal assistance is available to provide ground and aerial radiological monitoring (e.g., missing source), medical advice on radiation effects and treatment, consequence projection, and protective action assessment

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## 2.4 5 - 60 Day Event Reporting

Within 5 - 60 days, and in accordance with Agreement State regulations, Agreement States must forward, to NRC, reports from its licensees of those events that are not reportable within 24 hours. These reports may be provided in writing to the Branch Chief of NRC's Radioactive Materials Safety Branch (RMSB) or electronically to the NMED contractor as described below. NRC staff encourages Agreement States to electronically report these events using the local NMED Agreement State software.

The following paragraphs provide additional information on reporting events. For guidance on data entry, an electronic copy of the NMED users guide has been included in the local NMED Agreement State software.

### a. Assign Event Report Identification Number

This number should appear on all reports, including preliminary, initial notification reports, and any follow-up reports. The Event Report Identification Number should consist of the two letter State agency ID, two digit year corresponding to the reporting year, and a sequentially assigned four digit ID number. The Event Report Identification Number should be referenced by the State for all telephone, electronic or written notification involving each specific event.

### b. Basic Event Information

Appendix E provides a listing of the minimum event information that should be provided. When submitting an initial event report, please provide as much information as is known at the time the report is prepared regarding the items indicated in the Appendix. It is understood that this initial information may be incomplete or preliminary. Updated information should be subsequently provided in follow-up reports (see Section 2.5).

### c. Electronic Reporting to NMED

States may provide an electronic NMED report to the NMED contractor by using the local NMED Agreement State software, which may be downloaded from the NMED website, or by using the "Upload" function on the NMED website. If you need additional help, you may contact the NMED contractor via email at [NMED@inl.gov](mailto:NMED@inl.gov), or the NRC NMED Project Manager via e-mail at [NMEDNRC@nrc.gov](mailto:NMEDNRC@nrc.gov). For contact via telephone or mail, refer to the contact information on the homepage of the NMED website at <https://nmed.inl.gov>.

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d. **Internet Access to NMED**

An NMED search of the nationally collected data is available on the website with several drop-down point-and-click menus available. Internet access to the NMED is controlled through the NRC NMED Project Manager. If access is required, contact the NRC NMED Project Manager by email at NMEDNRC@nrc.gov. Access to the NMED is only provided to NRC, Agreement States and other federal government agencies and/or government contractors with the need to use the event information in NMED.

e. **Written Event Reports**

Written event reports should be sent to the Branch Chief, RMSB, at the address listed on the NMED website (e.g., https://nmed.inl.gov). Written report information should address the basic information identified in Appendix E. Reports should be provided in an optical character recognition (OCR) scannable format. Please include an event report cover page for all written event information provided to NRC. Use of an event report cover page helps ensure our document control staff can readily identify, classify and appropriately record the document. A sample event report cover page is provided in Appendix F of this Handbook.

**2.5 Reporting Follow-up Event Information**

Follow-up information for material event reports (e.g., providing the results of investigations into what, where, when and how the event or conditions occurred) should be provided for all events. Agreement States should provide the items below when reporting follow-up information:

- a. Follow-up reports through the closeout of the event should be provided in writing to the RMSB Branch Chief at the address listed on the NMED website, or electronically to the NMED contractor via the NMED website (e.g., https://nmed.inl.gov). A complete event report should include all investigative and/or medical information obtained through closeout of the event.
- b. When providing follow-up event information, provide the document(s) or clear reference to documents on file that the State used to generate the NMED event report (e.g., a licensee inspection report dated mm/dd/yy), if applicable and appropriate.
- c. Any follow-up event information that revises earlier information or provides additional information on a given event should be provided to ensure a complete historical record.

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## ***2.6 Voluntary Reporting of Lost, Stolen and Abandoned Sources***

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Although NMED typically contains only events involving AEA material, the NMED database was expanded in 1998 to include voluntary reports of non-AEA orphan discrete sources (sources that are found but where the owner could not be identified), and expanded again in 2002 to capture voluntary reports of lost or stolen non-AEA discrete sources. This was done at the request of CRCPD to support their national effort to track lost, stolen and recovered radioactive material of all types (including non-AEA and unlicensed material) found in both Agreement and non-Agreement States. (Note that in 2007, the definition of byproduct material under the AEA was expanded to include some of this material that had been “non-AEA.”) The reportable as well as voluntary data on lost, stolen, and abandoned sources will be collected from Agreement and non-Agreement States, and in some cases non-licensee organizations and members of the public. Agreement and Non-Agreement States should follow the guidance provided in Section 2, “Reporting Material Events,” to report any lost, stolen and abandoned non-AEA and unlicensed material.



### 3. Closing and Completing Events

#### 3.1 Event Closed in NMED

At the request of the Agreement States, a field was added to the NMED web site to enable a search for records that have been closed by the applicable regulatory agency under “Event Closed by Region/State.” Agreement States should notify the NMED contractor when the event record has been officially closed (i.e., no further follow-up planned and/or no additional information expected). The State should ensure that the record contains all pertinent technical information, including follow-up information before closing the record.

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#### 3.2 Record Complete in NMED

A “complete record” refers to an NMED record that contains a specified minimum set of information. This minimum set of information is defined in Appendix E of this Handout and may also be found on the NMED website under “Help.” A “complete record” indicates that the event notification includes the *minimum* basic information to receive a “complete” determination from the NMED contractor.

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NOTE IMPEP Review: The contractor is unable to determine if pertinent subsequent followup information that may have been provided by the licensee to the State has also been provided to NMED. Therefore, the abstract may or may not include sufficient technical information on followup activities such as root cause, dose assessment, licensee and State corrective actions, etc. A technical quality completeness review is conducted during periodic IMPEP reviews. (For additional information see *NMED Newsletter*, January 2002, January 2003, and January 2005 available at the NMED website.)

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## 4. NRC Publication and Distribution of Event Notifications

### 4.1 Event Notifications (ENs) are Available on Internet

All events reported to the NRC Operations Center are currently entered into the NRC Event Notification (EN) database. Most ENs are publicly available on NRC's external website at <http://www.nrc.gov/reading-rm/doc-collections/>, under "Event Reports", within one to five working days of notification. As a result of public access to this information, Agreement States may receive contacts from the public or media regarding events and requesting additional information. The NRC will withhold Agreement State reports from public release for at least 48 hours. Information regarding copies of non-public ENs may be obtained by contacting the appropriate Regional State Agreements Officer (RSAO).

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### 4.2 Preliminary Notifications (PNs) are Used to Distribute Event Information

Preliminary Notifications (PNs) are brief summary reports issued by the NRC staff to notify the Commission of the occurrence of a significant event. PNs are based on information provided by State radiation control program staff. PNs are usually issued within the same business day of the notification (or the next business day if the event is reported after hours on the weekend). Most PNs will be publicly available on NRC's external home page under "Event Reports" at <http://www.nrc.gov/reading-rm/doc-collections/>. Updates to PNs occur when significant additional information about an event is provided to NRC. When preparing PNs, NRC staff may contact the State for additional information on the event. Information regarding copies of non-public PNs may be obtained by contacting the appropriate RSAO.

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## 5. NRC Safety Reviews of Material Event Reports

### 5.1 NRC Review of Material Events for Safety Significance and Generic Assessment

A review of all new and updated material ENs received by the NRC Operations Center is conducted by NRC staff. The objective of the review is to identify any events that may involve generic concerns or issues, or could have significant impact on health and safety, security, and/or the environment. Events would include:

- a. Multiple occurrences of the events tracked as performance measures in the Strategic Plan (e.g., medical events, overexposures, lost or stolen sources of concern), or
- b. A single occurrence of an event tracked as a strategic goal in the Strategic Plan (e.g., deaths, loss of organ function, significant release to the environment), or
- c. Events involving possible generic concerns or issues (e.g., equipment malfunctions, equipment failures, inadequate user procedures, software problems), or
- d. Consequences or causal factors not previously seen in the event assessment process.

**Requests for additional information:** Based on the results of the materials event safety and generic assessment review and periodic audits, Agreement State staff may be contacted by the RSAO by phone or email to discuss the event. Additional information may be requested to help determine the safety significance and any possible generic implications (e.g., equipment malfunction or failure, significant exposures). Specific issues identified as a result of the review are tracked by NRC through close-out of the event.

If necessary, NRC staff may contact Agreement States for additional information on events that pose risks to health and safety, security, and/or the environment. Such requests, normally initiated by the RSAO, would occur on an as needed basis, possibly within hours to a few days of notification of the occurrence of the event, based on the safety significance.

The RSAO, or a designee, may contact Agreement States for additional event information for events not considered to be reportable within 24 hours. Standard procedure is to allow at least 30 days before making such requests to provide reasonable time for State review and evaluation, and submission of follow-up information. A request for follow-up information may also be sent routinely via email by the NMED contractor, (e.g., when the NMED record is incomplete after 60 days from the date reported to the regulatory agency).

### 5.2 Actions NRC May Take after Review of "Significant" Events

Events identified as having a significant potential risk to health and safety, security, and/or

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NOTE: GSI's are defined as a safety concern that may affect the design, construction, operation, or decommissioning of all, several, or a class of regulated operations, and may have the potential to require licensees or certificate holders to make safety improvements and/or require new or revised requirements or guidance.

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**the environment** may receive additional NRC management review. NRC headquarters and region staff continue to follow-up and review material events through closure of the event, which includes checking to see that the final report information has been entered into NMED. Based on potential risks identified as a result of event review and analyses, NRC may take actions to reduce potential risks by issuing safety-related notifications to licensees, (e.g., Information Notices (IN), concerning software problems, equipment modifications, etc.) Further research and analysis may result in regulatory or programmatic changes.

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## 6. Agreement State Safety Reviews of Material Event Reports

### 6.1 *Agreement State Review of Material Events for Safety Significance and Generic Assessment*

Agreement States should review events occurring within their jurisdiction, or related to products registered in their jurisdiction, to identify any events that may involve generic concerns or issues, or could have significant impact on health and safety, security, and/or the environment. Events would include:

- a. Multiple occurrences of the events (e.g., medical events, overexposures, lost or stolen sources of concern), or Formatted: Bullets and Numbering
- b. A single occurrence of a significant or serious event (e.g., deaths, loss of organ function, significant release to the environment), or Formatted: Bullets and Numbering
- c. Events involving possible generic concerns or issues (e.g., equipment malfunctions, equipment failures, inadequate user procedures, software problems), or Formatted: Bullets and Numbering
- d. Consequences or causal factors not previously seen in the event assessment process. Formatted: Bullets and Numbering

### 6.2 *Actions Agreement States May Take after Review of Significant Events*

Events identified as having a significant potential risk to health and safety, security, and/or the environment may receive additional State or NRC management review. Staff should continue to follow-up and review material events through the closure of the event, which includes checking to see that the final report information has been entered into NMED. Based on potential risks identified as a result of event review and analyses, States may take actions to reduce potential risks by issuing safety-related notifications to licensees. States are encouraged to share with NRC and the other States any findings, assessments, or trending studies. These can be forwarded to the NMED Project Manager for posting on the NMED website, or distribution as an all Agreement State Letter.

## 7. Abnormal Occurrence Guidelines and Criteria

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### 7.1 Introduction

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This section presents the guidelines and criteria to be followed when assessing the significance of an event or occurrence to see if it meets the criteria established to identify an abnormal occurrence (AO). Section 208 of the Energy Reorganization Act of 1974 (ERA) (Public Law 93-438, 42 USC 5848) identifies an AO as an unscheduled incident or event that the Commission determines to be significant from the standpoint of health and safety, security, and/or the environment. Section 208 of the Act also requires that the Commission inform Congress of any AOs. The Agreement States support the NRC in their effort to keep Congress apprised of any significant events that may directly affect health and safety, security, and/or the environment by providing information to the NRC on proposed AOs that have occurred in their State.

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### 7.2 AO Policy Information

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The Commission submits a report to Congress identifying any AOs. The Federal Reports Elimination and Sunset Act of 1995 require that AOs be reported to Congress on an annual basis. Section 208 of the ERA indicates that each report shall contain:

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- (1) The date and place of each occurrence;
- (2) The nature and probable consequence of each occurrence;
- (3) The cause or causes of each; and
- (4) Any action taken to prevent recurrence.

As specified in Section 208, within 15 days of receiving information of each AO, the Commission shall provide as wide dissemination to the public as reasonably possible as soon as such information becomes available.

An incident or event will be considered an AO if it involves a major reduction in the degree of protection of the health and safety, security, and/or the environment. This type of incident or event would have a moderate or severe impact and could include, but need not be limited to the following:

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- (1) Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission or an Agreement State;
- (2) Major degradation of essential safety-related equipment; or
- (3) Major deficiencies in design, construction, use of, or management controls for facilities or radioactive material licensed by or otherwise regulated by the Commission or an Agreement State.

The annual AO Report to Congress is published in NUREG-0090 and can be accessed at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0090/>.

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The AO Report to Congress is also used to provide information on significant materials issues and on adverse licensee performance. In accordance with SECY-02-216, “Proposed Process for Providing Information on Significant Nuclear Materials Issues and Adverse License Performance,” Agreement State events will be considered, along with other materials licensees, for discussion during the Annual Agency Action Review Meeting (AARM). The revised Management Directive and Handbook 8.14, “Agency Action Review Meeting,” describes FSME’s participation in the AARM and its role as the leader of discussion on Agreement State licensees, as necessary.

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### 7.3 AO Criteria

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Agreement State staff should routinely screen events against the AO criteria as part of their routine program. Any events identified as potential AOs should be reported to NRC. Additionally, upon request from NRC, Agreement States are requested to prepare a special written report for potential AOs. Agreement State staff should follow the guidelines for preparing AO write-ups contained in Section 7.4 of this Handbook. When questions arise on a given event, it may sometimes be necessary for NRC to directly contact an Agreement State representative and request additional information.

The AO criteria are listed in Appendix A of NUREG-0090. The current criteria should be used when evaluating any event. For reference, Appendix H of this Handbook contains a copy of the criteria as of the publication of this document, however when assessing an event to determine if it is an AO, the State must reference the most current criteria. The current AO criteria may be found at the NMED website (i.e., <https://nmed.inl.gov/>) under “Help” or the State may contact their RSAO.

**Deleted:** The criteria for determining an AO and the guidelines for “Other Events of Interest” were stated in an NRC Policy Statement. The following AO criteria was published in the *Federal Register* on December 19, 1996, (61 FR 67072). The policy statement was revised to include criteria for gaseous diffusion plants and published in the *Federal Register* on April 17, 1997, (62 FR 18820).

**Deleted:** The guidelines were revised for Appendix C “Other Events of Interest” by the Commission in a Staff Requirements Memorandum, SECY-98-175, dated September 4, 1998.¶

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AO Criteria

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## 7.4 Guidelines for AO Write-ups

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All AO write-ups should be complete, up-to-date, and written using text that is understandable to non-technical readers. Please do not use **bold** or *italics* in write-ups; use underline instead. Any special fonts will be added during the final publishing stage of the AO write-up.

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**NOTE: Agreement States should send their AO write-ups to their RSAOs.**

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First paragraph - State the AO criteria for the event by citing the appropriate section of the AO criteria.

Date and Place - Provide the date the event occurred, the licensee's name, and the city and State address of the licensee.

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Nature and Probable Consequences - Briefly explain the event and the circumstances surrounding the occurrence. Provide the specific details of the event to include the: exposure (where applicable), source, specific radionuclide(s), quantity, dose (where applicable), treatment plan (where applicable), equipment/devices with the manufacturer and model number. Describe any immediate actions taken by the licensee and the State (e.g., decontaminated the facility, evacuated the staff, special inspection performed, enforcement action(s) taken, etc.). The write-up should answer where, when, how, why, and efforts to prevent recurrence.

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For occupational or public overexposures identify whether the person was notified.

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For medical events, include the intended and actual treatment plan. For example, as applicable; state the prescribed dose and the actual delivered dose to the intended treatment site; state any doses to unintended sites (include the dose and the site); state the prescribed radioisotope and/or radiopharmaceutical and the radioisotope/radiopharmaceutical actually administered; and describe the prescribed mode of treatment and the actual mode of treatment delivered. Identify any health effects, including a statement of "no health effects," where applicable, and a statement whether the patient and referring physician were informed of the event. State whether a medical consultant has been contracted to review the event. Include the consultant's conclusions and identify the effects to the patient. Never mention any health effects to a patient without attributing the statement to the licensee or medical consultant. Indicate whether the primary physician was notified.

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**NOTE:** NRC's NUREG publication policy states that all documents must be published in dual units (Metric and English).

Cause or Causes - Explain what the causes of the event were determined or estimated to be, including any contributing factors leading up to the event.

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Action(s) taken to prevent recurrence - Briefly explain what corrective actions (e.g., developed new procedures, hired more staff,) were taken to prevent recurrence by the licensee, and indicate whether or not the State was satisfied with the licensee's corrective actions. State whether there were any enforcement actions, penalties given to the licensee and/or individual(s).

Last paragraph - Indicate the status of the AO event by stating whether the event is closed or remains open pending additional information from the Agreement State licensee. An item should only be identified as open if the State expects additional action(s) may take place that will be covered in a follow-up report. The new information contained in the follow-up report should be provided to NRC for inclusion in the AO report under the section entitled "Update to Previously Reported AOs."

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Appendix I contains three examples of an AO write-up. Also, see NUREG-0090 for recent examples of AO write-ups.

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**Example 1: Radiopharmaceutical  
Overexposure Write-up** [26]

# *Appendix A*

## *NRC Regulatory Reporting Requirements*

## NRC Regulatory Reporting Requirements

The following provides a listing of the most commonly encountered material reporting requirements for which Agreement States should have compatible regulations. This table does not contain all of NRC's regulatory reporting requirements.

Regulatory Requirement	Reporting Category		Brief Summary of Reporting Requirement	Notification
	Within 24 hours	5 - 60 Days		
10 CFR <b>Part 20</b> , Standards for Protection Against Radiation	<a href="#">20.1906(d)(1)</a>		Reports of removable contamination on package >limits in <a href="#">10 CFR 71.87</a> .	Immediate
	<a href="#">20.1906(d)(2)</a>		Radiation levels on package > limits in <a href="#">10 CFR 71.47</a>	Immediate
	<a href="#">20.2201(a)(1)(i)</a>		Reports of theft or loss of licensed material $\geq 1000 \times$ <a href="#">App C</a> value	Immediate
		<a href="#">20.2201(a)(1)(ii)</a>	Reports of theft or loss of licensed material $> 10 \times$ <a href="#">App C</a> value	30 days
	<a href="#">20.2202(a)(1)</a>		Exposure (real or threatened) $\geq$ TEDE of 25 rem (.25 Sv), or eye or lens dose equiv. of 75 rem (.75 Sv) or shallow dose equiv. (skin/extremities) of 250 rads (2.5 Gy).	Immediate
	<a href="#">20.2202(b)(1)</a>		Exposure (real or threatened) $\geq$ TEDE of 5 rem (.05 Sv), or eye or lens dose equiv. of 15 rem (.15 Sv), or shallow dose equiv. (skin/extremities) of 50 rems (.5 Sv).	24 hours
	<a href="#">20.2202(a)(2)</a>		Release where individual could have intake $\geq 5 \times$ ALI over 24 hours.	Immediate
	<a href="#">20.2202(b)(2)</a>		Release where individual could have intake $> 1 \times$ ALI over 24 hours	24 hours
		<a href="#">20.2203(a)</a>	Radiation doses, releases or concentrations of radioactive material that exceed the limits.	30 days
10 CFR <b>Part 30</b> , Rules of General Applicability to Domestic Licensing of Byproduct Material	<a href="#">30.50(a)</a>		Events involving prevention of immediate protective actions, necessary to avoid exposures to radiation, radioactive materials or releases of radioactive material that could exceed regulatory limits	Immediate
	<a href="#">30.50(b)(1)</a>		Events involving an unplanned contamination (Under <a href="#">30.50(b)(1)</a> , see items (i)-(iii) for other conditions that apply).	24 hours
	<a href="#">30.50(b)(2)</a>		Events in which equipment is disabled or fails to function as designed. (Under <a href="#">30.50(b)(2)</a> , see items (i)-(iii) for other conditions that apply).	24 hours
	<a href="#">30.50(b)(3)</a>		Events involving unplanned medical treatment of contaminated person	24 hours

## NRC Regulatory Reporting Requirements

The following provides a listing of the most commonly encountered material reporting requirements for which Agreement States should have compatible regulations. This table does not contain all of NRC's regulatory reporting requirements.

Regulatory Requirement	Reporting Category		Brief Summary of Reporting Requirement	Notification
	Within 24 hours	5 - 60 Days		
	<a href="#">30.50(b)(4)</a>		Events involving unplanned fire, or explosion affecting integrity of material, device or container, or equipment containing licensed material. (Under <a href="#">30.50(b)(4)</a> , see items (i)-(ii) for other conditions that apply).	24 hours
10 CFR <a href="#">Part 31</a> , General Domestic Licenses for Byproduct Material		<a href="#">31.5(c)(5)</a>	Shall immediately suspend operation of a device if there is a failure of or damage to the shielding or an indication of a failure of or damage to the shielding, or the on-off mechanism or indicator, or upon detection of 185 becquerel (0.005 microcurie) or more of removable radioactive material, and submit a written report within 30 days. (See the rest of Paragraph (c)(5) for other conditions and restrictions that apply).	30 days
10 CFR <a href="#">Part 34</a> , Licenses for Radiography & Radiation Safety Requirements for Radiographic Operations		<a href="#">34.27(d)</a>	Reporting of leaking sources, leak test results $\geq 0.005$ microcurie (185 Bq).	5 days
		<a href="#">34.101(a)</a>	Radiography source disconnection, inability to retract source, or component failure (critical to safe operation of device).	30 days
10 CFR <a href="#">Part 35</a> , Medical Use of Byproduct Material	<a href="#">35.3045</a>		Notifications and reports of medical events involving administration and use of byproduct materials, with the exception of patient intervention events <sup>1</sup>	Next calendar day
		<a href="#">35.3067</a>	Reports of leak test results that demonstrate the presence of 185 becquerel (0.005 microcurie) or more of removable contamination.	5 days
	<a href="#">35.3047</a>		Events involving an unauthorized dose of 50 mSv (5 rem) to an embryo/fetus or a nursing child, or an unintended functional damage to an organ or a physiological system of the child..	Next calendar day
10 CFR <a href="#">Part 36</a> , Licenses & Radiation Safety Requirements for Irradiators	<a href="#">36.83</a>		The following events are reportable under 36.83 if not reported under other NRC reporting requirements: stuck sources, fire/explosions, damage to source racks, cable or drive mechanism failure, access control system failure, detection of source by the product exit monitor, contamination from licensed material, etc. (See items (1)-(10) under <a href="#">36.83</a> for specific descriptions of reportable events.	24 hours
10 CFR <a href="#">Part 39</a> , Licenses & Radiation Safety Requirements for Well-Logging	<a href="#">39.35</a>		Report of leak test results (of sources leak tested at intervals not greater than every 6 months) when the presence of 185 becquerel (0.005 microcurie) or more of contamination is detected. (See remaining paragraphs under <a href="#">39.35</a> for other	5 days

## NRC Regulatory Reporting Requirements

The following provides a listing of the most commonly encountered material reporting requirements for which Agreement States should have compatible regulations. This table does not contain all of NRC's regulatory reporting requirements.

Regulatory Requirement	Reporting Category		Brief Summary of Reporting Requirement	Notification
	Within 24 hours	5 - 60 Days		
			conditions, including exemptions, that apply)	
	<a href="#">39.77(a)</a>		Well logging source rupture	Immediate
	<a href="#">39.77(b)</a>		Theft or loss, exposures, excessive concentration of radioactive material	Immediate
		<a href="#">39.77(c) and (d)</a>	Reports of well-logging source abandonment	30 days
10 CFR <a href="#">Part 40</a> , Domestic Licensing of Source Material	<a href="#">40.60(a)</a>  <a href="#">(b)(1)-(b)(4)</a>		Events involving immediate protective actions, unplanned contamination in accessible areas; disabled or malfunctioning equipment; unplanned medical treatments; and unplanned fires or explosions. (Note: Same as <a href="#">30.50</a> above except that this is reporting that is required concerning source materials)	a. Immediate b. 24 hours
10 CFR <a href="#">Part 70</a> , Domestic Licensing of Special Nuclear Material	<a href="#">70.50(a)</a>  <a href="#">(b)(1)-(b)(4)</a>		Events involving immediate protective actions; unplanned contamination in accessible areas; disabled or malfunctioning equipment; unplanned medical treatments; and unplanned fires or explosions. Essentially the same as <a href="#">30.50</a> and <a href="#">40.60</a> except that this is reporting that is required concerning special nuclear material (SNM) and there are some small variations in reporting details following Paragraph (c). See <a href="#">70.4</a> , "Definitions," for a definition of SNM	a. Immediate b. 24 hours
10 CFR <a href="#">Part 71</a> , Packaging and Transportation of Radioactive Material	<a href="#">71.5</a>  <a href="#">49 CFR 171.15 (b)(1) and (2)</a>		10 CFR 71.5 provides that licensees shall comply with the applicable requirements of the Department of Transportation regulations in 49 CFR.  49 CFR 171.15 (b)(1) events involving hazardous materials (which include radioactive materials) requires the immediate reporting of incidents involving hazardous materials (which include radioactive materials) that result in an individual's death, injury requiring hospitalization, evacuation of the general public for at least one hour, The operational flight pattern or routine of an aircraft is altered and the closure of one or more major transportation facility or roadway for at least one hour.  49 CFR 171.15(b)(2) requires the immediate reporting of fire, breakage, spillage, or	Immediate

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### NRC Regulatory Reporting Requirements

The following provides a listing of the most commonly encountered material reporting requirements for which Agreement States should have compatible regulations. This table does not contain all of NRC's regulatory reporting requirements.

Regulatory Requirement	Reporting Category		Brief Summary of Reporting Requirement	Notification
	Within 24 hours	5 - 60 Days		
			suspected radioactive contamination occurs involving the shipment of radioactive material	
<u>Orders Imposing Increased Controls (IC) (EA-05-090, Attachment B)</u>	<u>IC.2.d</u>		After initiating an appropriate response to any actual or attempted theft, sabotage, or diversion of radioactive material, licensees shall notify the NRC Operations Center.	Immediate

# *Appendix B*

## *Examples of Reportable Events*



## EXAMPLES OF REPORTABLE EVENTS

This Table provides examples of reportable material events or occurrences that are required to be reported by both NRC and Agreement State material licensees. The Table addresses specific reporting requirements for either immediate notification (within 24 hours or less) or 30 day written reports.

<p>Immediately reportable under 10 CFR 20.2201(a)(1)(i)</p>	<p><b>Stolen Portable Moisture Density Gauge</b></p> <p>Licensee [Name][License Number] reported that a [Manufacturer] [Model #] [serial #] portable gauge containing 10 millicuries of Cesium-137 and 50 millicuries of Americium-241: Beryllium was stolen from the licensee's vehicle parked at the licensee's facility [Address]. The gauge was padlocked in its original carrying case. The State is following the incident and working with local authorities to develop a press release. Local law enforcement and the FBI have been notified. Follow-up information will be provided to NRC on the recovery of the stolen gauge and entered into NMED.</p>
<p>Reportable within 24 hours under 10 CFR 30.50(b)(2)</p>	<p><b>Possible Loss of Control and Damage to Portable Gauge</b></p> <p>Licensee [Name][License Number] reported that a [Manufacturer] [Model #] [serial #] moisture density gauge had been damaged on March 28, 2001. The gauge contained 7.9 millicuries of Cesium-137 and 40 millicuries of Americium-241. A technician left the gauge unattended [Location Address] for a brief time and upon returning found that a construction vehicle had run over the gauge. The source rod was broken but the source was not damaged. However, the source was in an unshielded position. Wipe tests and instrument survey verified leakage. The gauge was returned to the manufacturer for repair. The licensee was cited for not keeping licensed material under constant surveillance in an unrestricted area. Follow-up information will be provided to NRC.</p>
<p>Immediately reportable under 20.1906(d)(2)</p>	<p><b>Shipment of Brachytherapy Sources Received with Radiation Levels Exceeding Regulatory Limits</b></p> <p>A medical licensee [Name][License Number] reported receiving a shipment of two packages containing cesium-137 brachytherapy sources. Radiation surveys of the packages found radiation levels of 250 millirem per hour on one package, which exceeds the State and Federal limit at the external surface of a package of 200 millirem per hour. The third and final package was received two days later with radiation levels of 400 millirem per hour at the surface of the package. The shipper has retained a consultant to determine the cause of the elevated radiation levels. The State will keep NRC informed of the results of the consultants review of the event, and the information will be entered into NMED.</p>

<p>Reportable within 24 hours under 10 CFR 20.2202 (b)(1)(i)</p>	<p><b>Exposure to Non-radiation Worker at a Licensed Facility</b></p> <p>A licensee [Name][License Number] reported to the State that a non-radiation worker had received an exposure as a result of picking up a 5 curie Americium-241-Beryllium neutron source used for well logging and placing it in his pocket. The worker, a temporary contractor employee, was cleaning a well logging tool at the licensee facility [Address]. (The licensee was under the assumption that all of the source material had been removed from the equipment.) While cleaning the tool, the source fell out, and the worker picked it up and placed it his pocket. The worker was not a radiation worker and had no knowledge of what the object was. Preliminary calculations performed by [identify Consultant/Contractor] indicate that the individual may have received a dose of 4-6 Rem. The licensee's RSO is investigating the incident. The State plans to keep NRC informed of the ongoing results of the investigation, and the information will be entered into NMED.</p>
<p>Reportable by next calendar day under 10 CFR Parts 35.3045 and within 24 hours under 30.50(b)(2)</p>	<p><b>Possible Medical Event involving a Teletherapy Unit Malfunction</b></p> <p>A patient undergoing a Cobalt-60 Teletherapy treatment with a [Manufacturer][Model #] received an unintended exposure (<b>identify organ</b>). The RSO estimated that the patient received an exposure of 138 centiGray (rads) to a depth of 0.5 centimeters to the wrong treatment site, based on a possible total treatment time of 1.5 minutes. The exposure occurred as a result of two power disruptions during a thunderstorm. The loss of electrical power caused the unit table to move which resulted in treatment to the wrong site. The patient received 0.35 minutes of the intended fractionated treatment time of 1.5 minutes. The patient was prescribed a total dose of 5,040cGy (rads) to be given in 28 fractions of 180 cGy (rads) per day at the rate of 5 fractions per week. The prescribing physician elected not to make up the missed dose. The prescribing physician indicated that the patient is not expected to have any adverse effects from the medical administration. The patient and referring physician were notified of the event. The licensee [Name][License Number] was able to recreate the event to demonstrate how the event occurred. The licensee has contacted the manufacturer. The State will keep NRC informed of the results of the review for any generic implications.</p>
<p>Reportable by next calendar day under 10 CFR Part 35.3045</p> <p>Note: May be classified as a potential AO.</p>	<p><b>Medical Event high dose rate (HDR) afterloader device</b></p> <p>A cancer patient undergoing therapeutic radiation treatment at [Licensee Name][License Number] for prostate cancer received 18 Gy (1,800 rads) to the wrong treatment site. This error occurred using a HDR afterloader device with a radioactive source containing 270.7 GBq (7.32 Ci) of Ir-192. The event occurred after the dosimetrist made an error while inputting data into the afterloader's dosimetry software program. Although the dosimetrist appropriately clicked the "catheter tip" selection, the dosimetrist did not highlight and choose "catheter tip." Therefore, the computer cursor stayed on the "connector end" selection. This resulted in a 2-cm positioning error, which caused the source to stop short of the target so that the total prescribed dose was not delivered. The patient was informed of the event, and the remaining dose was delivered by external beam therapy. The State accepted the licensee's implementation of new procedures and its corrective actions, which are described in the attached document, as appropriate.</p>

<p>Reportable by next calendar day under 10 CFR Part 35.3045</p> <p>Note: May be classified as a potential AO.</p>	<p><b>Medical event involving the wrong treatment site</b></p> <p>Licensee notified the State that a patient received greater than 1000 cGy (rads) to the wrong treatment site during an I-125 prostate gland treatment involving 88 I-125 seeds with an activity of 11.1 MBq (0.3 mCi) per seed with a total activity of 1.0 Gbq (26.8 mCi). The prescribed treatment was for 14,500 cGy (rads) to the prostate gland. Due to a coordinate error, the administration resulted in a partial treatment of the intended site and greater than 1,000 cGy (rads) to the rectum. The patient was notified of the error and the treatment was re-administered correctly. The State plans to update the NMED record with details of licensee corrective actions to prevent recurrence.</p>
<p>Reportable within 24 hours under 10 CFR Parts 36.83(a)(9), 30.50(b)(2)</p> <p>(Note: since water level was later verified to be normal, this is no longer a 36.83 issue)</p>	<p><b>Possible Loss of Water or Leakage from Source Water Pool at Irradiator Facility</b></p> <p>Licensee [Name][License Number] notified the State that the controls at a Co-60 irradiator facility were indicating that the water level was low, circulating pump off, and fill valves were open. The pool water level gauge indicated pool water level of 93 inches, well below the normal level of 137 inches. Previous incidents indicated that a loss of compressed air pressure to the water level gauge could result in an erroneously low water level gauge reading, causing the automatic pool fill valves to open, and the pool water circulating pump to turn off. The compressed air system pressure was found to be in the normal range, but the operator found water and congealed oil in the air line supplying the pool water level gauge, and the air line supplying the elevator control valve. Further investigation found that the compressed air line water traps were full of water. A past similar incident resulted in a failure to raise the elevator. The operator then verified that the pool water level was in fact normal. The licensee requested the building maintenance personnel to diagnose and repair the compressed air supply immediately, to prevent the conductivity in the pool water from reaching abnormal levels as a result of the resin filter circulating pump being automatically turned off by the false low pool water level meter reading. Maintenance personnel responded and replaced a failed compressed air dryer, and monitored the open air lines to clear the lines of water. A float activated automatic water drain was installed in the air line to prevent a possible recurrence by allowing any water to automatically drain from the air line.</p>

# *Appendix C*

## *Event Reporting Schedule*

(Take Out Pages for Handy Reference)

<b>Event Reporting Schedule for Agreement States</b>			
	<b>REPORTABLE EVENT NOTIFICATION<sup>1</sup></b>	<b>AGREEMENT STATE REPORTING SCHEDULE TO NRC</b>	<b>REPORTING METHODS TO NRC<sup>4</sup></b>
<b>IMMEDIATE</b>	<b>Significant</b> reportable events requiring <b>immediate notification (i.e., within 4 hours or less<sup>2</sup>)</b> by Agreement State licensees.	Agreement States should report to NRC immediately of notification by an Agreement State licensee.	Report initial information to the <b>NRC Operations Center<sup>5</sup> (301) 816-5100</b> FAX #: (301) 816-5151 Email: HOO.HOC@nrc.gov
<b>24 HOURS</b>	<b>Significant</b> reportable events requiring notification within <b>24 hours or less, or next calendar day</b> , by Agreement State licensees.	Agreement States should report to NRC within 24 hours of notification by an Agreement State licensee.	
	Events involving <b>theft or terrorist</b> activities should be reported to the <b>FBI<sup>3</sup></b> .	Agreement States should report to the FBI within 24 hours of notification.	
<b>5 - 60 DAYS</b>	<b>5 – 60 day reportable events</b> requiring <b>greater than 24 hour</b> notification by Agreement State licensee and event follow-up reports.	Agreement States should provide 5 - 60 day notification within the same timeframe licensees must report the event to the Agreement States, and any follow-up reports should be provided in a timely manner <sup>6</sup> .	Email: <a href="mailto:NMED@INL.GOV">NMED@INL.GOV</a> Telephone: 208-526-6904 Fax: 208-526-0990 or Mail: INL, P.O. Box 1625, MS 3870, Idaho Falls, ID 83415 Attn: Thomas W. Smith or Mail: U.S. NRC, Branch Chief of RMSB/MSSA, Mail Stop T-8-E24, Washington, DC 20555
<b>VOLUNTARY</b>	Lost, stolen, or abandoned sources reported to the Agreement State that are non-AEA or unlicensed material and not covered by the above two categories.	Voluntary reporting by the Agreement States and non-Agreement States. <sup>7</sup>	Email: <a href="mailto:NMED@INL.GOV">NMED@INL.GOV</a> or <a href="mailto:NMEDNRC@NRC.GOV">NMEDNRC@NRC.GOV</a>

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- <sup>1</sup> Privacy Act Information - Personal or sensitive information should not be included in event descriptions (e.g., names, personal addresses, or-social security-numbers).
- <sup>2</sup> For example, events involving lost, actual or attempted theft, sabotage, or diversion of radioactive materials or devices containing "high-risk" sources in quantities greater than or equal to the *quantities of concern* (i.e., quantities greater than or equal to Category 2 sources listed in the International Atomic Energy Agency 's Code of Conduct and as outlined in reporting requirements in 10 CFR Part 20.2201
- <sup>3</sup> A revision to the U.S. Code assigns lead responsibility for material events involving possible theft or terrorist activities to the Federal Bureau of Investigation (FBI).
- <sup>4</sup> A sample fax to the NRC Operations Center is available in Appendix D of FSME procedure SA-300.
- <sup>5</sup> The NRC Operations Center staff will promptly notify the appropriate Region Duty Officer (RDO) and Headquarters staff of Agreement State events. Therefore, no separate notification to other NRC staff by an Agreement State is necessary.
- <sup>6</sup> An example of the minimum basic event information required for a complete record is provided in Appendix E of SA-300.
- <sup>7</sup> Voluntary reporting is a joint national effort of the NRC and the Conference of Radiation Control Program Directors (CRCPD) to track certain non-AEA, unlicensed or non-reportable AEA lost and found radioactive material. More information about the national program may be found in SA-300.

# *Appendix D*

## *Sample Fax Sheet to NRC Operations Center*

## FAX TO: NRC OPERATIONS CENTER

<b>Agreement State Agency:</b>	[State] Dept. of Health, Division of Radiation Protection
<b>Event Report ID No.:</b>	State ID, YY, No., e.g. TN-06-0001
<b>License No.:</b>	CL-Z00X-1
<b>Licensee:</b>	County Inspection Inc.
<b>Event date and time:</b>	Month XX, YYYY, between 4:00 and 5:00 am
<b>Event location:</b>	City, State
<b>Event type:</b>	Stolen Radiography Device
<b>Notifications:</b>	[State] Dept. of Health has notified local police, and the FBI due to possibility of unlawful criminal activity. Press release has not been issued at this time.
<b>Event description:</b>	<p>[State] Dept. of Health was notified on [date], by a representative from [licensee], of the theft of a radiography exposure device [camera] from a locked equipment trailer on Thursday morning, April 6, 2006. The locked camera and the keys to the camera were stolen. The radiography camera is identified as XYZ Company, Model 160B, serial No. B-3333, containing [radionuclide] [activity, when known] 88.3 curies of Iridium-192. The device cables were not stolen.</p> <p>The State has an inspector on site and will continue to keep NRC informed of the status of our investigation.</p>
<b>Transport vehicle description:</b>	N/A
<b>Media attention:</b>	[State] Dept. of Health has received inquiries from the media
<b>Point of contact:</b>	Minnie C. Gauges, 301-415-0001



# *Appendix E*

## *Minimum Required Event Information*

<b>Minimum Required Information for a Complete Event Report</b>	
<b>1. Essential Details (Provide)</b>	<b>3. Device/Associate Equipment</b>
a. Narrative event description (e.g., Event circumstances and details including source radionuclide and activity)	For equipment/device involved indicate the manufacturer, model and serial number, and provide clear description of any equipment problems.
b. Report identification number	<b>4. Release of Licensed Material or Contamination</b>
c. Event date and notification date	Release type (air or water); contamination (person or surface); isotope and activity released
d. Licensee/reporting party information (i.e., name license number, and address).	<b>5. Medical Event</b>
e. Location (site) of event.	a. Procedure administered; dose intended and actual dose administered; isotope and activity administered; target organ.
f. Whether the event is NRC reportable and the applicable reporting requirement.	b. Patient and Referring Physician notified?
g. Cause and corrective actions (States and licensees actions)	<b>6. Overexposure</b>
h. Notifications: local police, FBI, and other States; as needed.	a. Radiation source and activity
i. Indicate if there are any generic implications (i.e., generic issues or concerns).	b. Exposure dose and exposure type (e.g., whole body, extremity, etc.)
<b>2. Source/Radioactive Material</b>	<b>7. Transportation</b>
Isotope and activity; manufacturer, model and serial number, and leak test results, if applicable.	Type of transport; identity of shipper; package type and ID number (if available)

*Appendix F*

*Sample Event Report Cover Page*

**AGREEMENT STATE**

**EVENT REPORT ID NO. \_\_ - \_\_ - \_\_**

**(State\YY\No.)**

**DATE:**

**TO:                   Branch Chief  
                          Radioactive Materials Safety Branch**

**SUBJECT:**

**STATE:**

**Signature and Title:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Public Availability of Event Information:** Any event information that is considered preliminary pre-decisional information by the State should be clearly identified on the cover page as follows: "Preliminary, **Not for Public Disclosure.**" For event information in NRC's possession, the final determination on whether to withhold from public disclosure will be made by NRC on a case by case basis in accordance with the requirements of 10 CFR Part 9.

# *Appendix G*

## *Radionuclides of Concern*

## Radionuclides of Concern

Radionuclide	Quantity of Concern <sup>1</sup> (TBq)	Quantity of Concern <sup>2</sup> (Ci)
Am-241	0.6	16
Am-241/Be	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14
Co-60	0.3	8.1
Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pm-147	400	11,000
Pu-238	0.6	16
Pu-239/Be	0.6	16
Ra-226	0.4	11
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations of radioactive materials listed above <sup>3</sup>	See Footnote Below <sup>4</sup>	

<sup>1</sup> The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity equals or exceeds the quantity of concern.

<sup>2</sup> The primary values used for compliance with this Order are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

<sup>3</sup> Radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

<sup>4</sup> If several radionuclides are aggregated, the sum of the ratios of the activity of each source,  $i$  of radionuclide,  $n$ ,  $A_{(i,n)}$ , to the quantity of concern for radionuclide  $n$ ,  $Q_{(n)}$ , listed for that radionuclide equals or exceeds one.  $[(\text{aggregated source activity for radionuclide A}) \div (\text{quantity of concern for radionuclide A})] + [(\text{aggregated source activity for radionuclide B}) \div (\text{quantity of concern for radionuclide B})] + \text{etc.} \dots \geq 1$

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# *Appendix H*

## *AO Criteria*

# AO Criteria

*As published in the Federal Register on October 12, 2006 (71 FR 60198). This is a summary of the current criteria at the time of publication of the document, and is included as reference. Agreement States assessing events should obtain the current version of this criteria at the NMED website under "Help" or by contacting their RSAO.*

Criteria by types of events used to determine which events will be considered for reporting as AOs are as follows:

I. For All Licensees

A. Human Exposure to Radiation from Licensed Material

1. Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 mSv (25 rem) or more; or an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ other than the lens of the eye, the bone marrow, and the gonads of 2,500 mSv (250 rem) or more; or an annual dose equivalent to the lens of the eye of 1 Sv (100 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow of 1 Sv (100 rem) or more; or a committed dose equivalent to the gonads of 2,500 mSv (250 rem) or more; or an annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more.
2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.
3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

B. Discharge or dispersal of radioactive material from its intended place of confinement which results in the release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceeds 5,000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20, unless the licensee has demonstrated compliance with §20.1301 using §20.1302(b)(1) or §20.1302(b)(2)(ii). This criterion does not apply to transportation events.

C. Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach<sup>1,2</sup>

<sup>1</sup> Information pertaining to certain incidents may be either classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Section 208 of the ERA of 1974, as amended. Any classified details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

<sup>2</sup> Due to increased terrorist activities worldwide, the AO report would not disclose specific classified information and sensitive information, the details of which are considered useful to a potential terrorist. Classified information is defined as information that would harm national security if disclosed in an unauthorized manner.



1. Any unrecovered lost, stolen, or abandoned sources that exceed the values listed in Appendix P to Part 110, "High Risk Radioactive Material, Category 2." Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur while the source was missing; and unrecoverable sources (sources that have been lost and for which a reasonable attempt at recovery has been made without success) lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 are not known to have occurred and the agency has determined that the risk of theft or diversion is acceptably low.
2. A substantiated<sup>3</sup> case of actual theft or diversion of licensed, risk-significant radioactive sources or a formula quantity<sup>4</sup> of special nuclear material; or act that results in radiological sabotage<sup>5</sup>.
3. Any substantiated<sup>3</sup> loss of a formula quantity<sup>4</sup> of special nuclear material or a substantiated<sup>3</sup> inventory discrepancy of a formula quantity<sup>4</sup> of special nuclear material that is judged to be caused by theft or diversion or by a substantial breakdown<sup>6</sup> of the accountability system.
4. Any substantial breakdown<sup>6</sup> of physical security or material control (i.e., access control containment or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.
5. Any significant unauthorized disclosures (loss, theft, and/or deliberate) of classified information that harms national security or safeguards information that harms the public health and safety.

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D. Initiation of High-Level NRC Team Inspections<sup>7</sup>

II. For Commercial Nuclear Power Plant Licensees

A. Malfunction of Facility, Structures, or Equipment

1. Exceeding a safety limit of license technical specification (TS) [10 CFR 50.36(c)].
2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

<sup>3</sup> "Substantiated" means a situation where an indication of loss, theft, or unlawful diversion such as: an allegation of diversion, report of lost or stolen material, statistical processing difference, or other indication of loss of material control or accountability cannot be refuted following an investigation; and requires further action on the part of the Agency or other proper authorities.

<sup>4</sup> A formula quantity of special nuclear material is defined in 10 CFR 70.4.

<sup>5</sup> Radiological sabotage is defined in 10 CFR 73.2.

<sup>6</sup> A substantial breakdown is defined as a red finding in the security inspection program, or any plant or facility determined to have overall unacceptable performance, or in a shutdown condition (inimical to the effective functioning of the Nation's critical infrastructure) as a result of significant performance problems and/or operational events.

<sup>7</sup> Initiation of any Incident Investigation Teams, as described in NRC Management Directive (MD) 8.3, "NRC Incident Investigation Program," or initiation of any Accident Review Groups, as described in MD 8.9, "Accident Investigation."

3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).
- B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy
1. Discovery of a major condition not specifically considered in the safety analysis report (SAR) or TS that requires immediate remedial action.
  2. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions so that a release of radioactive materials which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, GDC 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod drive mechanism).
- C. Any reactor events or conditions that are determined to be of high safety significance<sup>8</sup>
- D. Any operating reactor plants that are determined to have overall unacceptable performance or that are in a shutdown condition as a result of significant performance problems and/or operational event(s)<sup>9</sup>

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### III. Events at Facilities Other than Nuclear Power Plants and all Transportation Events

- A. Events Involving Design, Analysis, Construction, Testing, Operation, Transport, Use, or Disposal of Licensed Facilities or Regulated Materials
1. An accidental criticality [10 CFR 70.52(a)].
  2. A major deficiency in design, construction, control, or operation having significant safety implications that require immediate remedial action.
  3. A serious safety-significant deficiency in management or procedural controls.
  4. A series of events (in which the individual events are not of major importance), recurring incidents, or incidents with implications for similar facilities (generic incidents) that raise a major safety concern.

<sup>8</sup> The NRC ROP uses four colors to describe the safety significance of licensee performance. As defined in NRC Management Directive 8.13, "Reactor Oversight Process," green is used for very low safety significance, white is used for low to moderate safety significance, yellow is used for substantial safety significance, and red is used for high safety significance. Reactor conditions or performance indicators evaluated to be red are considered Abnormal Occurrences. Additionally, Criterion II.C also includes any events or conditions evaluated by the NRC ASP program to have a conditional core damage probability (CCDP) or change in core damage probability ( $\Delta$ CDP) of greater than  $1 \times 10^{-3}$ .

<sup>9</sup> Any plants assessed by the ROP to be in the unacceptable performance column, as described in NRC Inspection Manual Chapter 0305, "Operating Reactor Assessment Program." This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

B. For Fuel Cycle Facilities

1. Absence or failure of all safety-related or security-related controls (engineered and human) for a NRC-regulated lethal hazard (radiological or chemical) while the lethal hazard is present.
2. An NRC-ordered safety-related or security-related immediate remedial action.

C. For Medical Licensees

A medical event that:

1. Results in a dose that is
  - a. equal to or greater than 1 Gy (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal or greater than 2.5 Gy (250 rad) to the gonads; or
  - b. equal to or greater than 10 Gy (1,000 rad) to any other organ or tissue; and
2. Represents either
  - a. a dose or dosage that is at least 50 percent greater than that prescribed, or
  - b. a prescribed dose or dosage that
    - (i) Uses the wrong radiopharmaceutical or unsealed byproduct material; or
    - (ii) Is delivered by the wrong route of administration; or
    - (iii) Is delivered to the wrong treatment site; or
    - (iv) Is delivered by the wrong treatment mode; or
    - (v) Is from a leaking source or sources; or
    - (vi) Is delivered to the wrong individual or human research subject.

IV. Other Events of Interest

The Commission may determine that events other than AOs may be of interest to Congress and the public and should be included in an appendix to the AO report as "Other Events of Interest." Such events may include, but are not necessarily limited to, events that do not meet the AO criteria but that have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.

# *Appendix I*

## *Sample AO Write-Ups*

## Example 1: Radiopharmaceutical Overexposure Write-up

**Criteria** In accordance with the AO criteria I.A.1, "Human Exposure to Radiation from Licensed Material" any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual shallow-dose equivalent to the skin or extremities greater than 2,500 mSv (250 rem).

**Date and Place**- [Date]; [Facility/Licensee]; [location] City, State.

**Exposure** **Nature and Probable Consequences**- A pharmacist trainee received an extremity exposure resulting in a shallow dose equivalent to the hand of 7,402 mSv (742 rem); a deep dose equivalent of 70 mSv (7.02 rem) to the hand; and a dose of 0.9 mSv (0.09 rem) to the thyroid, based on licensee's consultation with several external and internal dosimetry specialists. The exposures to the pharmacist trainee's hand and forearm occurred when a spill took place while compounding I-131 from a vial. The pharmacist failed to notify anyone of the event, cleaned up the area and decontaminated his skin. The following day, the pharmacist reported the I-131 spill to the Imaging Manager, who conducted a second survey of the area that revealed no remaining contamination. Upon return from a one week vacation, the pharmacist informed the Radiation Safety Officer that skin on the forearm had been contaminated as a result of an earlier I-131 spill received prior to vacation. Immediate action was taken to determine if any contamination still remained on his arm. Elevated levels were discovered on his right forearm and left fingertips. The appropriate hospital/nuclear medicine personnel were notified. The contaminated individual was suspended from any and all duties involving radioactive material during the investigation.

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**Source/Quantity**

**Cause or Causes** - The event occurred due to human error and failure to follow established procedures. An initial crimp failure on the vial may have contributed to the spill.

### **Actions Taken to Prevent Recurrence**

**Licensee** - The licensee retrained all staff in spill procedures and proper supervisory notification. Additionally, at the prompting of the licensee, the vial supplier, re-evaluated the process of ensuring that each crimp is acceptable for shipment, although the supplier believed it was more likely an isolated incident.

**State Agency** - The State agency conducted inspections and reviewed licensee corrective actions. The licensee was cited for violations of State Regulations for Control of Radiation.

**Status** This event is (open\closed) in (State).

## Example 2: Diagnostic Medical Event AO Write-up

**Criteria** In accordance with the AO criteria IV, "For Medical Licensees," administering a dose that is (1) equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than the bone marrow, lens of the eye or the gonads) and (2) represents a prescribed dose or dosage that is delivered to the wrong treatment site.

**Date and Place** - [Date]; [Facility/Licensee], [City, State]

**Procedure/dose**  
(actual vs. intended)

**Nature and Probable Consequences** - A patient was prescribed a dose of 0.93 megabecquerel (MBq) (25 microcurie [ $\mu$ Ci]) of Iodine-131 (I-131) for a diagnostic scan to assess a thyroid nodule. However, the patient was administered a dosage of 111 MBq (3,000  $\mu$ Ci) of I-131. The licensee discovered the event on [date], when the patient returned for the whole body scan 48 hours later. The technologist misunderstood the order by assuming that the referring physician wanted a whole body scan to assess thyroid cancer, and administered 111 MBq (3,000  $\mu$ Ci) of I-131 without requesting clarification or approval from the authorized users. As a result the patients thyroid received a dose of about 43 Gy (4,300 rads) instead of the prescribe

**Notifications**

dose of about 32.5 Gy (3,250 rads). The referring physician and patient were properly notified.

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**Health effect**  
to patient

Two authorized users determined that the administered dose of I-131 may induce a hypothyroid state requiring the patient to take thyroid hormone. A patient followup assessment included thyroid profiles and thyroid uptakes to determine thyroid function.

**Cause or causes** - The event was attributed to human error. The technologist misunderstood the treatment ordered by the referring physician and failed to verify the written directive.

### **Actions taken To Prevent Recurrence**

**Licensee** - The licensee implemented corrective measures to ensure that authorized users approve all procedures involving the administration of radiopharmaceutical and re- instructed nuclear medicine personnel.

**State Agency** - The State agency conducted a follow-up inspection to ensure that the licensee's actions taken to prevent recurrence had been implemented.

This event is closed for the purpose of this report.

### **Example 3: Gamma Stereotactic Radiosurgery (Gamma Knife )Write-up**

**Criteria** In accordance with the AO criteria IV, “For Medical Licensees,” administering a dose that is (1) equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than the bone marrow, lens of the eye or the gonads) and (2) represents a prescribed dose or dosage that is delivered to the wrong treatment site.

**Date and Place** - [Date]; [Facility/Licensee], [City, State]

**Procedure/dose** **Nature and Probable Consequences** - A patient undergoing Gamma (intended vs. actual) Stereotactic Radiosurgery (Gamma Knife) was prescribed treatment of 20 Gy (2,000 rads) to a portion of the brain. However, the patient received a dose of 12.8 Gy (1,280 rads) to an unintended portion of the brain, (i.e. wrong treatment site).

**What occurred?** During the treatment, the licensee completed three and one-half fractions of eight treatments before the medical physicist and radiation therapist realized that the administered treatment utilized the treatment parameters for another patient. The licensee’s medical physics staff had prepared treatment plan for two patients, to be treated on the same day. The treatment plan for Patient A consisted of a prescribed dose of 18 Gy (1,800 rads). Prior to initiating treatment of Patient A, a licensee staff member handed the plan of treatment for Patient B to the licensee’s radiation therapist; later, the therapist could not recall from whom the plan had been received. Using Patient B’s treatment plan, the treatment team set up and delivered the first three fractions to Patient A and began delivery of the fourth fraction when the error was discovered by the medical physicist. Once notified of the error, the radiation oncologist terminated treatment.

The medical physicist determined that the treatment delivered a dose of 12.8 Gy (1,280 rads) to an unintended region of the patient's brain. The radiation oncologist determined that the location of the unintended site was far enough away from the intended site to proceed with the intended treatment. The licensees subsequently administered the intended treatment without incident.

**Notifications** The licensee notified the patient's referring physician and the radiation oncologist notified the patient of the event.

**Health effect to patient** The radiation oncologist did not anticipate any immediate adverse effect to the patient, and was not certain of the potential for any long-term effects as a result of the administration.

***Consultant report,  
where applicable***

The licensee consultant agreed with the assessment. With regard to long-report term affects, the consultant concluded that this administration may be at the threshold of late central nervous system injury and may produce symptoms. The consultant further stated that long-term follow-up was indicated for the patient and that the patient was eligible for inclusion in the Department of Energy's Office of Epidemiology and Health Surveillance voluntary life-time morbidity study. The licensee conducted medical follow-up of the patient to identify and respond to potential adverse medical consequences resulting from this administration. However during further attempted follow-ups on the patient the licensee lost contact with the patient.

**Cause or causes** -The misadministration was caused by human error, as a result of the licensee's failure to verify that the treatment plan used was for the patient being treated. Contributing factors included inadequate labeling of the patient's name on the computer treatment plan and other medical recording information.

**Actions Taken to Prevent Recurrence**

**Licensee** -The licensee immediately implemented revised procedural measures and conducted retraining of applicable staff to ensure that patient - specific parameters are confirmed and verified prior to initiation of treatment, and that all medical record information is adequately labeled.

**State Agency** - The State conducted an investigation and reviewed the licensee's corrective actions, which were found adequate by the State.

This event is closed for the purposes of this report.



# *Appendix J*

## *Glossary of Terms and References*



## *Glossary*

<b>ADAMS</b>	Agencywide Documents Access and Management System, NRC's official record electronic recordkeeping system, approved by the National Archives and Records Administration on April 1, 2000.
<b>AO</b>	Abnormal Occurrence. As published in the Federal Register on October 12, 2006 (71 FR 60198).
<b>CRCPD</b>	Conference of Radiation Control Program Directors. A non-profit entity representing the radiation control programs of each States (not limited to Agreement States)
<b>EN</b>	The Event Notification (EN) system is an internal NRC automated event tracking system used by the NRC Operations Center to track information on incoming notifications of the occurrence of significant material events that have or may affect public health and safety. Significant material events are reported to the NRC Operations Center by NRC licensees, staff of the Agreement States, other Federal agencies, and the public. The EN's are published each work day through the Internet.
<b>FSME</b>	NRC's Office of Federal State and Materials and Environmental Management Programs develops, implements and oversees the regulatory framework for industrial, commercial, and medical uses of radioactive materials, uranium recovery activities and the decommissioning of previously operating nuclear facilities and power plants.
<b>Gray</b>	Gray (Gy) is the SI unit of absorbed dose. One Gray is equal to an absorbed dose of 1 joule/kilogram (100 rads).
<b>Generic Concern</b>	Generic concerns are events of a general safety concern, but do not rise to the level of generic issues. Generic concerns may involve an issue of ongoing concern with one or more licensees.
<b>Generic Issues</b>	Generic issues are complex safety or security issues that require extensive NRC staff and industry involvement to resolve. Several criteria must be met for an event to be identified as a generic issue. These criteria include: 1) the event is a well-defined, discrete, technical or security issue, of which the risk or safety significance can be adequately determined; 2) the involves an issue that affects two or more facilities and/or licensees, or holders of other regulatory approvals; 3) the event affects the public health and safety, the common defense and security, or the environment; 4) the event involves an issue not already being processed under an existing NRC program or process; and 5) the event involves an issue that cannot be readily addressed

through existing regulations, policies, or guidance; or voluntary industry initiatives. Once an event is suspected to be a generic issue, NRC uses the process outlined in Management Directive 6.4, "Generic Issues," to formally identify process and resolve the generic issue. Agreement State regulators may process generic issues under their jurisdiction through State processes, or may request NRC assistance.

**Metric System**

The metric system is now included in all Federal documents. All event reports should include the dual system of Units (SI) in the following order. First use the International System of Units (SI) with the English System unit equivalent following in parentheses. Spell out the first time it appears, continue with an abbreviation. (e.g., 1000 centigray (cGy) (1000 rad) the first time, and continue with 1000 cGy (1000 rad), 50 millisieverts (mSv) (5 rem), 730 megabecquerel (MBq) (20.4 mCi))

**NMED**

The Nuclear Material Events Database (NMED), maintained by NRC, is a historical collection of incidents and events that have occurred throughout the United States involving the use of radioactive material covered under the Atomic Energy Act. This excludes events occurring at nuclear power plants.

**NRC Ops Center**

The NRC Operations Center in Rockville, Maryland, serves as the focal coordination point for communicating with NRC licensees, State agencies, and other Federal agencies about operating events in both the nuclear reactor and nuclear material industry. The Operations Center is staffed 24 hours a day by an NRC Headquarters Operations Officer (HOO), who is trained to receive, evaluate, and respond to events reported to the Operations Center.

**PN**

Preliminary Notifications (PN) are brief summary reports of significant events issued by the NRC staff to notify the Commission of the occurrence of a significant event that appears to have health and safety significance or major public or media interest. PNs are based on information

provided by State radiation control program staff. These reports are publicly available through Internet on NRC's external home page under PN Reports at (<http://www.nrc.gov>).

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¶ Glossary of Terms Event Reporting Handbook¶

**RMSB**

The Radioactive Materials Safety Branch (RMSB) is responsible for the programmatic direction of materials uses associated with medical uses of byproduct materials including direction to the Regions and technical assistance to Agreement States, and to medical licensees across the country regarding these activities including any new licensees under the expanded definition of byproduct material.

**RSOA**

The Regional State Agreements Officer (RSOA) is a designated staff

member, in an NRC regional office, who serves as the point of contact for the region and the Office of State and Tribal Programs regarding Agreement State radiation control programs, and who participates in technical reviews of Agreement State radiation control programs.

- Rad** Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/grams or 0.01 joule/kilogram (0.01 gray)
- Rem** Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert).
- Sievert** Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rem.).

## References

The following is a list of NRC documents, manuals and procedures that contain additional information on event response and AOs.

### NRC Policy

June 30, 1997 Staff Requirements Memorandum, Procedures for *Statement of Principles and Policy for the Agreement State Program and Policy Statement on Adequacy and Compatibility of Agreement State Programs*.

### NRC Report

Report to Congress on Abnormal Occurrences - Fiscal Year 2008, NUREG-0090, Volume 31

Performance Budget FY2010, NUREG-1100, Vol. 25, May 2009, annual report to Congress required by GPRA.

FSME Licensee Newsletter, NUREG/BR-0017

### NRC Management Directives

6.4 Generic Issues Program

8.1 Abnormal Occurrence Reporting Procedure

8.10 NRC Medical Event Assessment Program

### NRC Inspection Manual

1301 Response to Radioactive Material Incidents That Do Not Require Activation of the NRC Incident Response Plan

1302 Follow-up Actions and Action Levels for Radiation Exposures Associated with Material Incidents Involving Members of the Public

1303 Requesting Emergency Acceptance of Radioactive Material by the

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	U.S. Department of Energy (DOE)	Deleted: (95-009)
1330	Response to Transportation Accidents Involving Radioactive Materials	Deleted:
1360	Use of Physician and Scientific Consultants in the Medical Consultant Program	Deleted: (84-22)
2800	Materials Inspection Program	Deleted:
		Deleted: (94-013)
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		Deleted: 87103 Inspection of Materials Licensees Involved in an Incident Bankruptcy Filing (97-008)
	<b>FSME Procedures</b>	Deleted: NRC Emergency Response Manuals¶
SA-100	Implementation of the Integrated Materials Performance Evaluation Program	¶ NUREG/BR-0230 Response Coordination Manual - Contains procedures for requesting Federal assistance during an emergency.¶
SA-200	Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements	¶ NUREG/BR-0150 Contains procedures for assessing the consequences of an emergency. ¶
	<b>Event Notification and Response</b>	Deleted: STP Correspondences¶
<b>FBI</b>	A revision to Section 831 of Chapter 39 of Title 18 of the U.S. Code regarding criminal activity, includes a significant expansion of Federal Bureau of Investigation jurisdiction to initiate criminal investigations and pursue prosecutions when radioactive materials are involved. In instances involving the suspected criminal misuse of nuclear material and byproduct material, your notification of the FBI is warranted. However, the U.S. Attorney's Office and the FBI will determine whether or not a criminal investigation is to be	¶ STP All Agreement State Letter (SP-98-018), dated March 17, 1998, "Use of the Nuclear Material Events Database (NMED) As a Central Listing Of Lost or Stolen Sealed Sources and Devices."¶
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conducted by the FBI or deferred to State or local authorities for investigation and prosecution. The Commission also requests that Agreement States inform NRC of reports of events involving theft or terrorist activities warranting FBI notification.

**NRF**

The *National Response Framework* is a guide that details how the Nation conducts all-hazards response— from the smallest incident to the largest catastrophe. This document establishes a comprehensive, national, all-hazards approach to domestic incident response. The Framework identifies the key response principles, as well as the roles and structures that organize national response. It describes how communities, States, the Federal Government and private-sector and nongovernmental partners apply these principles for a coordinated, effective national response. The NRC is the lead Federal agency (LFA) for response to any event involving NRC and Agreement State-licensed Atomic Energy Act material.

Deleted: NRP The Commission is the lead Federal agency (LFA) for response to any event involving NRC and Agreement State-licensed Atomic Energy Act material under the National Response Plan (NRP), which includes other Federal agencies, i.e., Department of Energy (DOE), Environmental Protection Agency (EPA), Federal Emergency Response Administration (FEMA). NRP covers any peacetime radiological emergency that has actual, potential or perceived radiological consequences within the United States.

**DOT/NRC**

The National Response Center is a Department of Transportation, Pipeline and Hazardous Materials Safety Administration service that serves as a national point of contact for reporting hazardous materials transportation and pipeline accidents (e.g., oil, chemical, non-AEA radiological, biological, and etiological discharges). The Center maintains a 24 hour call line at 1-800-424-8802.

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**REACTS**

The Radiation Emergency Assistance Center/Training Site (REACTS), is a Department of Energy (DOE) resource headquartered in Oak Ridge, Tennessee, telephone (865) 576-1005. REACTS is available 24 hours a day to provide medical and radiological assistance either from the REACTS facility or the accident site. Additionally, REACTS maintains a listing of other professionals throughout the country who are recognized as having highly specialized expertise and equipment to manage a particular area of concern.

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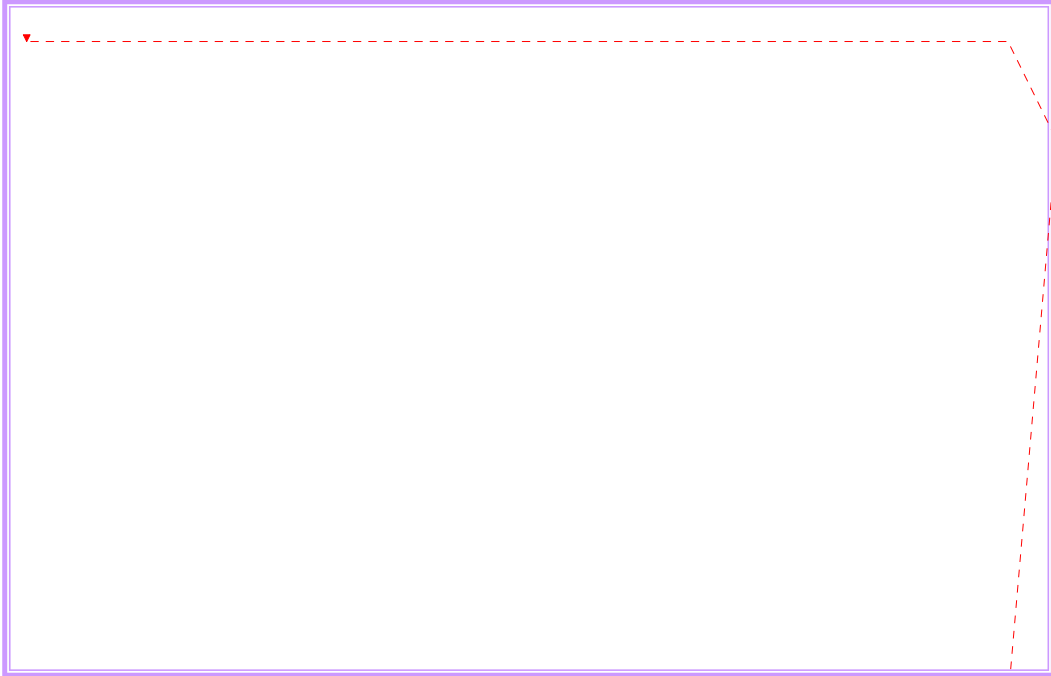
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AVAILABILITY OF REFERENCE MATERIAL
NRC documents: Event Notifications, Preliminary Notifications, Inspection Manuals and Procedures, NUREG Series technical reports, Regulatory Guides, etc., are available at the NRC's <u>electronic reading room website</u> at: <a href="http://www.nrc.gov/reading-rm/doc-collections/">http://www.nrc.gov/reading-rm/doc-collections/</a> . The Office of <u>Federal and State Materials and Environmental Management Programs (FSME)</u> documents are available at the <u>FSME external website</u> at: <a href="http://nrc-stp.ornl.gov/">http://nrc-stp.ornl.gov/</a> .



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Event Reporting Schedule for  
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Deleted: <sup>1</sup> Personal or sensitive information should not be included in event descriptions (e.g., names,¶ personal addresses, or-- social security-- numbers).¶

¶

<sup>2</sup> Events involving lost, actual or attempted theft, sabotage, or diversion of radioactive materials or¶ devices containing "high-risk" sources in quantities greater than or equal to the *quantities of*¶ *concern* (i.e., quantities greater than or equal to Category 2 sources listed in the International¶

Atomic Energy Agency 's Code of Conduct and as outlined in reporting requirements in 10 CFR ¶

Part 20.2201 ¶

¶

<sup>3</sup> A revision to the U.S. Code assigns lead responsibility for material events involving possible theft ¶ or terrorist activities to the Federal Bureau of Investigation (FBI).¶

¶

<sup>4</sup> A sample fax to the NRC Operations Center is available in Table 1 of STP procedure SA-300.¶

¶

<sup>5</sup> The NRC Operations Center staff will promptly notify the appropriate Region Duty Officer (RDO) ¶ and Headquarters staff of Agreement State events. Therefore, no separate notification to other ¶ NRC staff by an Agreement State is necessary.¶

¶

<sup>6</sup> An example of the minimum basic event information required for a complete record is provided in¶ Section 3 of SA-300.¶

¶

<sup>7</sup> Voluntary reporting is a joint national effort of the NRC and the Conference of Radiation Control¶ Program Directors (CRCPD) to track all types of non-AEA, unlicensed or non-reportable AEA lost ¶ and found radioactive material. More information about the national program may be found in¶ SA-300.

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- C. The Deputy Director, STP, is responsible for assigning a staff member to serve as lead material events project manager.
- D. The STP-designated Project Manager for events [Event Project Manager] is responsible for coordination with the Agreement States and, in collaboration with NMSS and RES, the review of material event reports submitted to STP. Additionally, the Event Project Manager and the Regions participate in cooperation with NMSS and RES, in the identification and review of events that may meet the AO criteria in cooperation with NMSS, RES, and the Agreement States, and coordinates Agreement State review of the draft AO report.

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- E. The STP Director's Secretary is responsible for controlling STP distribution of Agreement State material event reports.

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- 3. Electronic Event Reports (E-mail or Electronic Storage Media)

The Agreement States send electronic copies of event reports (via Internet e-mail, PC diskette, fax or CDs) directly to the NMED contractor, INL, for entry into NMED. INL, in coordination with NMSS, conducts reviews of Agreement State material event reports that have been electronically provided to INL for safety significance. Information on any events identified as *significant* that were not previously identified by the Agreement State under the 24-hour reporting requirement or events that could pose possible generic issues are provided to STP and NMSS by INL.

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Event Review for Safety Significance and Identification of Possible Generic Concerns

- a. The NMSS materials staff conducts a daily review of new material event notifications (ENs) received by the Headquarters Operations Center. Events are reviewed to identify any events that may involve generic safety concerns, issues (GSIs) or trends, that could have significant impact on health, safety and/or security concerns, relative to the NRC Strategic Plan performance goals and measures that have been linked to agency programs and activities, as required by Congress under the Government Performance Results Act (GPRA). Events are also evaluated by NRC and Agreement State staff to identify any events that meet the abnormal occurrence (AO) criteria, for inclusion in the annual AO Report to Congress. Similar event reviews to identify health, safety and security significance and generic concerns are conducted by the Agreement States. Information on any possible generic concerns identified by NRC or the Agreement States will be coordinated and shared with NMSS, STP and the Agreement States. A quarterly analysis is also performed on the information contained in NMED for each major event type to identify any statistically significant trends.
- b. Based on the results of the review, it may be necessary to request additional clarifying information. Agreement State staff may be contacted by the RSAO, or a designee, when the event has been identified as safety significant and meet the AO criteria.
- c. For events that have not been identified as safety significant, when necessary, the RSAO, or a designee, may contact Agreement States for additional information within 30 days for a 15-day Event Report and within 60 days for a 30-day Event Report after NRC receipt of the initial notification of the occurrence of the event from the State. This schedule provides reasonable time for State review and evaluation, and voluntary submission of the follow-up information by the State. A request for follow-up information may also be sent routinely via email by the NMED contractor, (e.g., when the NMED record is incomplete after 60 days from the date it was reported to the regulatory agency). Agreement States are

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also requested to update NMED on a monthly basis until the event has been resolved and closed.

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- d. The designated STP Project Manager and the Regions participate in cooperation with NMSS and RES, in the identification and review of events that may meet the AO criteria in cooperation with NMSS, RES, and the Agreement States, and coordinates Agreement State review of the draft AO report.
- e. Periodically, the Project Manager may be requested by management to provide statistical information regarding the status of event reporting by the Agreement States. Information provided by the Agreement State and collected and maintained in NMED, should be used by the Project Manager, the ASPO, the RSAO, and the designated IMPEP reviewer to evaluate the effectiveness and completeness of Agreement State event information provided for entry into the NMED database. See STP Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)* and SA-105, *Reviewing Common Performance Indicator #5, Response to Incidents and Allegations*.

The collection of event information has been approved by the U.S. Office of Management and Budget, as follows.

"This information request has been approved by **OMB 3150-0178**, expiration date 09/03/2006. The estimated burden per response to comply with this collection request is 2 hours. Forward any comments regarding the burden estimate to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0052), Office of Management and Budget, Washington, DC 20503."

**1.5 Reporting Lost, Stolen and Abandoned Sources**

Title 10 CFR 20.2201 mandates that each licensee report, by telephone, its discovery of any lost, stolen, or missing licensed material that exceeds specified quantities. Specifically, 10 CFR 20.2201(a)(1)(i) requires an immediate call if the licensed material is equal to or greater than 1000 times the quantity specified in Appendix C to 10 CFR Part

20, under such circumstances that an exposure could result to persons in unrestricted areas. Title 10 CFR 20.2201(a)(1)(ii) requires a call, within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, in a quantity greater than 10 times the quantity specified in Appendix C to 10 CFR Part 20, that is still missing at the time. Title 10 CFR 20.2201(b) requires a written report within 30 days after making the telephone call required by 10 CFR 20.2201(a). Title 10 CFR 20.2201(d) requires that, subsequent to filing the written report, the licensee report any additional substantive information on the loss or theft of the licensed material within 30 days of the knowledge of the substantive information.

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The terrorist attacks on September 11, 2001, alerted regulators, licensees, and the public to the possible use of radioactive material as a terrorist weapon. Because of this possibility, it is important that any event, including transportation, involving sources in quantities greater than or equal to the *quantities of concern* (See Table 3, Radionuclides of Concern) that are lost, stolen or abandoned must be reported to the NRC Headquarters Operations Center immediately. The Commission has since codified these requirements in Appendix P to 10 CFR Part 110, "High-Risk Radioactive Material, Category 2." "High-Risk" describes sources that could be used for malicious purposes to cause harmful effects. "Immediately" is interpreted as 4 hours after an Agreement State has been notified of the event by a licensee. The International Atomic Energy Agency (IAEA) described these high-risk sources and their activity thresholds in its draft TECDOC-1344, entitled "Categorization of Radioactive Sources." That document provides the supporting technical basis for the IAEA's Code of Conduct [the Code] on the Safety and Security of Radioactive Sources, as listed in Categories 1 and 2 of Table 3 to the Code. The rationale for this immediate notification standard is to facilitate prompt coordinated Federal response in situations involving lost, stolen, or abandoned sources involving quantities of concern.

In order to ensure the safe handling, use, and control of licensed material in transportation for domestic highway and rail shipments by a carrier other than the licensees, for quantities that equal or exceed those in Table 3 but are less than 100 times Table 3 quantities, per consignment, the licensee shall confirm receipt of the shipment; and initiate an investigation to determine the location of the licensed material if the shipment does not arrive on or about the expected arrival time. When, through the course of the investigation, it is determined that the shipment has become lost, stolen, or missing, the licensee shall immediately notify the appropriate Agreement State regulatory agency. If, after 24 hours of investigation, the location of the material still cannot be determined, the radioactive material shall be deemed missing and the Agreement State licensee shall immediately notify the appropriate Agreement State regulatory agency.

Although NMED typically contains only events involving AEA material, the NMED database was expanded in 1998 to include voluntary reports of non-AEA orphan discrete sources (sources that are found but where the owner could not be identified), and expanded again in 2002 to capture voluntary reports of lost or stolen non-AEA discrete sources. This was done at the request of CRCPD to support their national effort to track lost stolen and recovered radioactive material of all types (including non-AEA and unlicensed material) found in both Agreement and non-Agreement States. The reportable as well as voluntary data on *lost, stolen, and abandoned sources* will be collected from Agreement and non-Agreement States, and in some cases non-licensee organizations and

members of the public. Agreement and Non-Agreement States should follow the guidance provided in Section 2, "Reporting Material Events," to report any lost, stolen and abandoned non-AEA and unlicensed material. (See All Agreement State Letter SP-98-018, March 17, 1998).

**1.6 Reporting Theft or Terrorist Activity Events**  
(reportable within 4 hours)

FBI notification should be considered if an event involves the possibility of *theft or terrorist activities*. Agreement States are required to notify the NRC Headquarters Operations Center immediately in cases involving actual or attempted theft, sabotage, or diversion of radioactive material containing quantities greater than or equal to the quantities of concern of radioactive material as defined in Table 3. Agreement State Regulatory Agencies should notify the FBI or Local Law Enforcement Agency (LLEA) in all cases of actual theft, sabotage, diversions and possible terrorism of radioactive material, regardless of the quantity of radioactive material involved. This includes intentional use of radioactive materials that could be used in an unauthorized malevolent manner that could lead to serious consequences. In cases of theft or terrorist activities, after initial appropriate responses are made to the FBI or LLEA, Agreement States Regulatory Agencies shall promptly as possible, notify the NRC Operations Center. Agreement States should coordinate with the NRC, their communications with other local, Federal and State Agencies, to ensure that shared information is accurate and consistent. Based on health and safety significance the issuance of a press release should also be considered. (See All Agreement State Letter SP-98-038, dated May 5, 1998, regarding expansion of the FBI criminal investigative jurisdiction to include byproduct material. A revision to the U.S. Code assigns lead responsibility for material events involving *theft or terrorist activities* to the FBI.)

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Radionuclide	Quantity of Concern <sup>1</sup> (TBq)	Quantity of Concern <sup>2</sup> (Ci)
Am-241	0.6	16
Am-241/Be	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14
Co-60	0.3	8.1
Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pm-147	400	11,000
Pu-238	0.6	16
Pu-239/Be	0.6	16
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations of radioactive materials listed above <sup>3</sup>	See Footnote Below <sup>4</sup>	

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<sup>1</sup> The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity equals or exceeds the quantity of concern.

<sup>2</sup> The primary values used for compliance with this Order are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

<sup>3</sup> Radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

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<sup>4</sup> If several radionuclides are aggregated, the sum of the ratios of the activity of each source,  $i$  of radionuclide,  $n$ ,  $A_{(i,n)}$ , to the quantity of concern for radionuclide  $n$ ,  $Q_n$ , listed for that radionuclide equals or exceeds one.

$[(\text{aggregated source activity for radionuclide A}) \div (\text{quantity of concern for radionuclide A})] + [(\text{aggregated source activity for radionuclide B}) \div (\text{quantity of concern for radionuclide B})] + \text{etc.} \dots \geq 1$

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Non-Agreement States have been requested by CRCPD to voluntarily report any lost, stolen and abandoned non-AEA and unlicensed material.

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within 24 hours of notification by an Agreement State licensee. Significant events are those requiring prompt notification as determined under applicable Agreement State regulations.

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, based on the information provided by the Agreement State licensee in the 5, 15, 30 or 60 day report to **NMED@INL.GOV**.

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NMED Project Manager, electronically via Internet email at: [NMED@inl.gov](mailto:NMED@inl.gov),

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**Table 4. Minimum Basic Event Information for a Complete Report**

<b>1. Essential Details (Provide)</b>	<b>2. Source/Radioactive Material/Devices</b>
a. State Event Report Identification No.	a. Isotope and activity; manufacturer, model and serial number, leak test results, if applicable.
b. Licensee name and location, including licensing State.	b. For events involving lost, stolen or abandoned material does source exceed IAEA Category 2 quantity? Provide monthly event update through closure of event.
c. License No. or identify as General Licensee, (if applicable).	c. For equipment/device involved indicate the make, model and serial no. and provide clear description of any equipment problems.
d. Event date, time of occurrence and location (site) of event.	<b>3. Release of Licensed Material or Contamination</b>
e. Event circumstances and details including source radionuclide and activity.	Release type (air or water); contamination (person or surface); isotope and activity released
f. Date State Agency was notified of event by licensee or non-licensee.	<b>4. Medical Event</b>
g. Notifications: local police, FBI, and other States; as needed.	a. Procedure administered; dose intended and dose administered; isotope and activity administered; target organ.

**Table 4. Minimum Basic Event Information for a Complete Report**

<b>1. Essential Details (Provide)</b>	<b>2. Source/Radioactive Material/Devices</b>
a. State Event Report Identification No.	a. Isotope and activity; manufacturer, model and serial number, leak test results, if applicable.
b. Licensee name and location, including licensing State.	b. For events involving lost, stolen or abandoned material does source exceed IAEA Category 2 quantity? Provide monthly event update through closure of event.
h. Whether the event is NRC reportable and the applicable State reporting requirement.	b. Patient and Referring Physician notified?
i. Persons involved. Note: include position title(s) but do not submit personal or privacy information.	<b>5. Overexposure</b>
j. Licensee corrective actions and what actions were performed to prevent recurrence?	a. Indicate short and long-term health effects and exposure type (e.g., whole body or extremity)
k. Possible generic safety concerns.	b. Is event a potential Abnormal Occurrence?
l. Root cause(s) and contributing factors	<b>6. Transportation</b>
m. Actions the State took? Onsite inspections, any enforcement actions?	Type of transport; identity of shipper; package type and ID number (if available)

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: NMED@inl.gov or the NRC NMED Project Manager by email message at:		
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<i>NOTE: Agreement States should continue to use the Microsoft Access data entry program for maintaining a local events database and for submitting NMED event reports to INL.</i>		
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or directly to the INL Project Manager		
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be comparable to the minimum		
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--through resolution and close out,		
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, both significant (24 hr. reportable) and 30-60 day reportable events.		
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Enter any new or supplemental information to the initial NMED record.		
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NOTE IMPEP Review: The contractor is unable to determine if pertinent subsequent followup information that may have been provided by the licensee to the State has also been provided to NMED. Therefore, the abstract may or may not include sufficient technical information on followup activities such as root cause, dose assessment, licensee and State corrective actions, etc. A technical quality completeness review is conducted during periodic IMPEP reviews. (For additional information see *NMED Newsletter*, January 2002, January 2003, and January 2005 available at the NMED website.)

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## ***AO Criteria***

***As published in the Federal Register on December 19, 1996 (61 FR 67072) and as revised and published on April 17, 1997 (62 FR 18820) to incorporate gaseous diffusion plants.***

Criteria by types of events used to determine which incidents or events will be considered for reporting as AOs are as follows:

***I. For All Licensees.***

***A. Human Exposure to Radiation from Licensed Material.***

1. Any unintended radiation exposure<sup>1</sup> to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more; or an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ or tissue other than the lens of the eye, bone marrow and the gonads, of 2500 mSv (250 rem) or more; or an annual dose

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<sup>1</sup> An “unintended radiation exposure” includes any occupational exposure, exposure to the general public, or exposure as a result of a medical misadministration (as defined in §35.3045) involving the wrong individual that exceeds the reporting values established in the regulations.

All other reported medical events will be considered for reporting as an AO under the criteria for medical licensees. In addition, unintended radiation exposures include any exposure to a nursing child, fetus, or embryo as a result of an exposure (other than an occupational exposure to an undeclared pregnant woman) to a nursing mother or pregnant woman above specified values.



equivalent to the lens of the eye, of 1 Sv (100 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow, and the gonads, of 1 Sv (100 rem) or more; or an annual shallow-dose equivalent to the skin or extremities of 2500 mSv (250 rem) or more.

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2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.
3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

***B. Discharge or Dispersal of Radioactive Material from its Intended Place of Confinement.***

1. The release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20, unless the licensee has demonstrated compliance with §20.1301 using §§20.1302(b)(1) or 20.1302(b)(2)(ii).
2. Radiation levels in excess of the design values for a package, or the loss of confinement of radioactive material resulting in one or more of the following:
  - (a) a radiation dose rate of 10 mSv (1 rem) per hour or more at 1 meter (3.28 feet) from the accessible external surface of a package containing radioactive material;
  - (b) a radiation dose rate of 50 mSv (5 rem) per hour or more on the accessible external surface of a package containing radioactive material and that meet the requirements for "exclusive use" as defined in 10 CFR 71.47; or
  - (c) release of radioactive material from a package in amounts greater than the regulatory limits in 10 CFR 71.51(a)(2).

**C. *Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach.***<sup>2</sup>

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<sup>2</sup> Information pertaining to certain incidents may be either classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Section 208 of the Energy Reorganization Act of 1974, as amended. Any classified details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

1. Any lost, stolen, or abandoned sources that exceed 0.01 times the  $A_1$  values, as listed in 10 CFR Part 71, Appendix A, Table A-1, for special form (sealed/nondispersible) sources, or the smaller of the  $A_2$  or 0.01 times the  $A_1$  values, as listed in Table A-1, for normal form (unsealed/dispersible) sources or for sources for which the form is not known. Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur during the time the source was missing; and unrecoverable sources lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 were not known to have occurred.
  2. A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.
  3. Any substantiated loss of special nuclear material or any substantiated inventory discrepancy that is judged to be significant relative to normally expected performance, and that is judged to be caused by theft or diversion or by substantial breakdown of the accountability system.
  4. Any substantial breakdown of physical security or material control (i.e., access control containment or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.
- D. *Other Events (i.e., those concerning design, analysis, construction, testing, operation, use, or disposal of licensed facilities or regulated materials).***
1. An accidental criticality [10 CFR 70.52(a)].
  2. A major deficiency in design, construction, control, or operation having significant safety implications requiring immediate remedial action.

3. A serious deficiency in management or procedural controls in major areas.

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Series of events (where individual events are not of major importance), recurring incidents, and incidents with implications for similar facilities (generic incidents) that create a major safety concern.

**II. For Commercial Nuclear Power Plant Licensees.**

**A. Malfunction of Facility, Structures, or Equipment.**

1. Exceeding a safety limit of license technical specification (TS) [§50.36(c)].
2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.
3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

**B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy.**

1. Discovery of a major condition not specifically considered in the safety analysis report (SAR) or TS that requires immediate remedial action.
2. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50,

Appendix A, GDC 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

**III. For Fuel Cycle Facilities.**

1. A shutdown of the plant or portion of the plant resulting from a significant event and/or violation of a law, regulation, or a license/certificate condition.
2. A major condition or significant event not considered in the license/certificate that requires immediate remedial action.

A major condition or significant event that seriously compromises the ability of a safety system to perform its designated function that requires immediate remedial action to prevent a criticality, radiological or chemical process hazard.

**IV. For Medical Licensees.**

A medical event that:

- (a) Results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1000 rad) to any other organ; and
- (b) Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive or (2) a prescribed dose or dosage that (i) is the wrong radiopharmaceutical,<sup>3</sup> or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source.

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<sup>3</sup> The wrong radiopharmaceutical as used in the AO criterion for medical events refers to any radiopharmaceutical other than the one listed in the written directive or in the clinical procedures manual.

V. Guidelines for "Other Events of Interest"

The Commission may determine that events other than AOs may be of interest to Congress and the public and should be included in an Appendix to the AO report as Other Events of Interest. Guidelines for events to be included in the AO report for this purpose may include, but not necessarily be limited to, events that do not meet the AO criteria but that have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.<sup>4</sup>

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<sup>4</sup> Staff Requirements Memorandum, SECY-98-175, dated September 4, 1998.



**Example 1: Radiopharmaceutical Overexposure Write-up**

*Criteria* In accordance with the AO criteria I.A.1, “Human Exposure to Radiation from Licensed Material” any unintended radiation exposure to an adult (any individual 18 years of age or older resulting in an annual shallow-dose equivalent to the skin or extremities greater than 2,500 mSv (250 rem) is considered an AO.

**Date and Place-** [Date]; [Facility/Licensee]; [location] City, State.

*Exposure* **Nature and Probable Consequences-** A pharmacist trainee received an extremity exposure resulting in a shallow dose equivalent to the hand of 7,402 mSv (742 rem); a deep dose equivalent of 70 mSv (7.02 rem) to the hand; and a dose of 0.9 mSv (0.90 rem) to the thyroid, based on licensee consultation with several external and internal dosimetry specialists. The exposures to the pharmacist trainees hand and forearm occurred when a spill took place while compounding I-131 from a vial. The pharmacist failed to notify anyone of the event, cleaned up the area and decontaminated his skin. The following day, the pharmacist reported the I-131 spill to the Imaging Manager , who conducted a second survey of the area that revealed no remaining contamination. Upon return from a one week vacation, the pharmacist informed the Radiation Safety Officer that skin on the forearm had been contaminated as a result of an earlier I-131 spill received prior to vacation. Immediate action was taken to determine if any contamination still remained on his arm. Elevated levels were discovered on his right forearm and left fingertips. The appropriate hospital/nuclear medicine personnel were notified. The contaminated individual was suspended from any and all duties involving radioactive material during the investigation.

*Source/Quantity*

**Cause or Causes** - The event occurred due to human error and failure to follow established procedures. An initial crimp failure on the vial may have contributed to the spill.

**Actions Taken to Prevent Recurrence**

**Licensee** - The licensee retrained all staff in spill procedures and proper supervisory notification. Additionally, at the prompting of the licensee, the vial supplier, re-evaluated the process of ensuring that each crimp is acceptable for shipment, although the supplier believed it was more likely an isolated incident.

**State Agency** - The State agency conducted inspections and reviewed licensee corrective actions. The licensee was cited for violations of State

Regulations for Control of Radiation.

*Status*

This event is (**open\closed**) in (**State**).

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**Example 2: Diagnostic Medical Event AO Write-up**

**Criteria**

In accordance with the AO criteria IV, “For Medical Licensees,” administering a dose that is (1) equal to or greater than 1 gray (Gy) (100 rads) to a major portion of the bone marrow, the lens of the eye, or to the gonads; or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an abnormal occurrence.

**Date and Place** - [Date]; [Facility/Licensee], [City, State]

**Procedure/dose**  
**(actual vs. intended)**

**Nature and Probable Consequences** - A patient was prescribed a dose of 0.93 megabecquerel (MBq) (25 microcurie [ $\mu$ Ci]) of Iodine-131 (I-131) for a diagnostic scan to assess a thyroid nodule. However, the patient was administered a dosage of 111 MBq (3,000  $\mu$ Ci) of I-131. The licensee discovered the event on [date], when the patient returned for the whole body scan 48 hours later. The technologist misunderstood the order by assuming that the referring physician wanted a whole body scan to assess thyroid cancer, and administered 111 MBq (3,000  $\mu$ Ci) of I-131 without requesting clarification or approval from the authorized users. As a result the patients thyroid received a dose of about 43 Gy (4,300 rads) instead of the prescribe

**Notifications**

dose of about 32.5 Gy (32.5 rads). The referring physician and patient were properly notified.

**Health effect**  
**to patient**

Two authorized users determined that the administered dose of I-131 may induce a hypothyroid state requiring the patient to take thyroid hormone. A patient followup assessment included thyroid profiles and thyroid uptakes to determine thyroid function.

**Cause or causes** - The event was attributed to human error. The technologist misunderstood the treatment ordered by the referring physician and failed to verify the written directive.

**Actions taken To Prevent Recurrence**

**Licensee** - The licensee implemented corrective measures to ensure that authorized users approve all procedures involving the administration of radiopharmaceutical and re- instructed nuclear medicine personnel.

**State Agency** - The State agency conducted a follow-up inspection to ensure that the licensee’s actions taken to prevent recurrence had been implemented.

This event is closed for the purpose of this report.

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**Example 3: Gamma Stereotactic Radiosurgery (Gamma Knife ) Write-up**

**Criteria** In accordance with the AO criteria IV, "For Medical Licensees," administering a dose that is (1) equal to or greater than one gray (Gy) (100 rads) to a major portion of the bone marrow, the lens of the eye, or to the gonads; or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an abnormal occurrence.

**Date and Place - [Date]; [Facility/Licensee], [City, State]**

**Procedure/dose** **Nature and Probable Consequences** - A patient undergoing Gamma (intended vs. actual) Stereotactic Radiosurgery (Gamma Knife) was prescribed treatment of 20 Gy (2,000 rads) to a portion of the brain. However, the patient received a dose of 12.8 Gy (1,280 rads) to an unintended portion of the brain, (i.e. wrong treatment site).

**What occurred?** During the treatment, the licensee completed three and one-half fractions of eight treatments before the medical physicist and radiation therapist realized that the administered treatment utilized the treatment parameters for another patient. The licensee's medical physics staff had prepared treatment plan for two patients, to be treated on the same day. The treatment plan for Patient A consisted of a prescribed dose of 18 Gy (1,800 rads). Prior to initiating treatment of Patient A, a licensee staff member handed the plan of treatment for Patient B to the licensee's radiation therapist; later, the therapist could not recall from whom the plan had been received. Using Patient B's treatment plan, the treatment team set up and delivered the first three fractions to Patient A and began delivery of the fourth fraction when the error was discovered by the medical physicist. Once notified of the error, the radiation oncologist terminated treatment.

The medical physicist determined that the treatment delivered a dose of 12.8 Gy (1,280 rads) to an unintended region of the patient's brain. The radiation oncologist determined that the location of the unintended site was far enough away from the intended site to proceed with the intended treatment. The licensee subsequently administered the intended treatment without incident.

**Notifications** The licensee notified the patient's referring physician and the radiation oncologist notified the patient of the event.

***Health effect to patient***

The radiation oncologist did not anticipate any immediate adverse effect to the patient, and was not certain of the potential for any long-term effects as a result of the administration.

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*Consultant report,*  
*where applicable*

The licensee consultant agreed with the assessment. With regard to long-report term affects, the consultant concluded that this administration may be at the threshold of late central nervous system injury and may produce symptoms. The consultant further stated that long-term follow-up was indicated for the patient and that the patient was eligible for inclusion in the Department of Energy's Office of Epidemiology and Health Surveillance voluntary life-time morbidity study. The licensee conducted medical follow-up of the patient to identify and respond to potential adverse medical consequences resulting from this administration. However during further attempted follow-ups on the patient the licensee lost contact with the patient.

**Cause or causes** -The misadministration was caused by human error, as a result of the licensees failure to verify that the treatment plan used was for the patient being treated. Contributing factors included inadequate labeling of the patient's name on the computer treatment plan and other medical recording information.

**Actions Taken to Prevent Recurrence**

**Licensee** -The licensee immediately implemented revised procedural measures and conducted retraining of applicable staff to ensure that patient - specific parameters are confirmed and verified prior to initiation of treatment, and that all medical record information is adequately labeled.

**State Agency** - The State conducted an investigation and reviewed the licensees corrective actions, which were found adequate by the State.

This event is closed for the purposes of this report.

NOTE: Emphasis added [**bold**] to clarify specific information that should be included in the report

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**Event Reporting**

**Handbook**

(Cut Out Page for Handy Reference)

<b>Event Reporting Schedule for Agreement States</b>			
	<b>REPORTABLE EVENT NOTIFICATION<sup>1</sup></b>	<b>AGREEMENT STATE REPORTING SCHEDULE TO NRC</b>	<b>REPORTING METHODS TO NRC<sup>4</sup></b>
<b>4 HOURS</b>	<b>Significant</b> reportable events requiring <b>4 hours or less<sup>2</sup></b> notification by Agreement State licensees.	Agreement States should report to NRC within 4 hours of notification by an Agreement State licensee.	Report initial information to the <b>NRC Operations Center<sup>5</sup></b> (301) 816-5100 or (301) 951-0550 FAX #: (301) 816-5151
<b>24 HOURS</b>	<b>Significant</b> reportable events requiring <b>24 hours or less</b> notification by Agreement State licensees.  Events involving <b>theft or terrorist</b> activities should be reported to the <b>FBI<sup>3</sup></b> .	Agreement States should report to NRC within 24 hours of notification by an Agreement State licensee.  Agreement and non-Agreement States should report to the FBI within 24 hours of notification.	
<b>30-60 DAYS</b>	<b>30 – 60 day reportable events</b> requiring <b>greater than 24 hour</b> notification by Agreement State licensee and event follow-up reports.	Agreement State should provide 30-60 day notification and any follow-up reports to NRC-NMED on a monthly basis. NOTE: Licensee reports received within less than 30 days of the date of the monthly report may be included in the next month's report. <sup>6</sup>	Email: NMED@INL.GOV Telephone: 208-526-6904 or 208-526-0990-fax Disk/CD: INL, P.O. Box 1625, Idaho Falls, ID 83415 Attn: Thomas W. Smith or Written: Director of STP US NRC, Washington, DC 20555



**SA-300 Reporting Material Events**

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**Issue Date:**  
**03/08/06**

<b>VOLUNTARY</b>	Lost, stolen, or abandoned sources reported to the Agreement State that are non-AEA or unlicensed material and not covered by the above two categories.	Voluntary reporting by the Agreement States and non-Agreement States. <sup>7</sup>	Email: NMED@INL.GOV
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Rev. 3, December 2005