



## STP Procedure Approval

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

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#### **NOTE**

*The STP Director's Secretary is responsible for the maintenance of this master copy document as part of the STP Procedure manual. Any changes to the procedure will be the responsibility of the STP Procedure Contact. Copies of STP procedures will be distributed for information.*



***Procedure Title: Reporting Material Events***  
***Procedure Number: SA-300***

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**Issue Date: 5/23/01**

## **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 incidents and events involving the use of nuclear materials that have been reported by Agreement State licensees, to NRC.
- 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, and recognizing any inadequacies or unreliability of specific equipment or procedures. The reported information 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.
- C. Nuclear Materials Events Database (NMED)  
  
NMED contains the official agency 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, naturally occurring, and accelerator-produced radioactive material). NMED accommodates the sharing of material event data submitted by Agreement States, non-Agreement States, and NRC licensees. NMED is maintained by the NRC's

Office of Nuclear Material Safety and Safeguards (NMSS). The NMSS contractor, Idaho National Engineering and Environmental Laboratory (INEEL), is responsible for coding and quality control of information.

#### **IV. ROLES AND RESPONSIBILITIES**

- A. The Director, Office of State and Tribal Programs (STP), is responsible for the collection, coordination and, in cooperation with NMSS and the Office of 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.
- B. The Director, STP, participates in NRC management review and evaluation of Agreement State response to material events that have been identified by NRC as **significant** in relation to public health and safety.
- 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 is responsible for coordination with the Agreement States and, in collaboration with NMSS and RES, review of material event reports submitted to STP.
- E. The STP Director's Secretary is responsible for controlling STP distribution of Agreement State material event reports.
- F. 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 STP regarding Agreement State radiation control programs. STP staff should coordinate with the appropriate Regional State Agreement Officer (RSAO), regarding the receipt of a **significant** event report.
- G. STP staff should coordinate with the appropriate STP Agreement State Project Officer (ASPO), responsible for providing back-up staff support to the RSAO (see STP Procedure SA-117), regarding the receipt of a **significant** event report.

## 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*.

### B. Guidance for STP Staff and Regional State Agreements Officers (RSAOs)

#### 1. Reports of Significant Events Received from Agreement States by Phone.

- a. The following actions should be taken upon receipt of a report of a significant event from an Agreement State (i.e., events requiring 24-hour notification to the Operations Center by Agreement States). Receipt of such reports should occur infrequently since guidance to the Agreement States stipulates that reports of **significant** events should be provided directly to the NRC Operations Center.
- b. If the State has contacted you by phone, dial in the NRC Operations Center Headquarters Operations Officer (HOO) and have the State representative calling in -- provide the event notification information directly to the HOO.
- c. Inform the Project Manager, or the Project Manager backup, the STP Director and Deputy Director. STP staff should inform the RSAO.

#### 2. E-mail, FAX, or Written (Hard Copy) Event Reports

- a. A copy of the event report should be provided to the Director and Deputy Director, STP, the appropriate Agreement State Project Officer (ASPO), and the Project Manager. A copy should also be sent to the NMED contractor, INEEL, through the STP Directors Secretary.
- b. Agreement State event reports shall be reviewed by the Project Manager, to identify any events that may be **significant** from the standpoint of health and safety (i.e., reportable by the licensee within 24 hours). 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 Project Manager should notify the NRC Operations Center (HOO), and the appropriate regional RSAO. If an event indicates the possibility of a generic issue, the 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 STP Project Manager. The RSAO will keep the STP Project Manager informed of the status of events that have been identified as *significant*.

3. Electronic Event Reports (E-mail or PC diskette)

The Agreement States send electronic copies of event reports (via Internet e-mail or PC diskette) directly to the NMED contractor, INEEL, for entry into NMED. INEEL, in coordination with NMSS, conducts reviews of Agreement State material event reports that have been electronically provided to INEEL 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 INEEL.

4. NMSS Generic Assessment Panel (GAP)

- a. The NMSS materials staff conduct a weekly GAP review of all material events received and entered into NMED from both Agreement States and NRC licensees. Events are reviewed for safety significance and generic implications, against the abnormal occurrence criteria, and as candidates for the quarterly Operational Events Briefing. Information on any possible generic issues identified in Agreement State events will be shared with the STP Project Manager. Any safety significant concerns and possible generic issues will also be shared with the Agreement States.
- 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.
- 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 LER<sup>1</sup>, and within 60 days for a 30 day LER 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 receipt of the initial record).

5. NMSS Operational Events Briefing
  - a. The Deputy Director, STP, and the Project Manager, or a designee, serve as the designated STP representatives for reporting on Agreement State events at the interoffice quarterly NMSS Operational Events Briefing. In some cases, Agreement State staff also participate and report on events that have occurred in their State. Staff of NMSS, STP, RES, the Regions, and the Office of the General Counsel, meet quarterly to discuss any NRC or Agreement State licensee material events that have occurred during the period covered that NRC has identified for review based on the “significance of the event and/or possible generic implications.” The quarterly briefings track **significant** events, that have been identified for review, through closure and entry of the final complete record into NMED.
  - b. The Project Manager is responsible for coordinating telephone (bridge) participation of an Agreement State in the briefing, when necessary, for discussion of **significant** events that have occurred in their respective State, and coordinates with the States on requests for additional information.
6. The designated Project Manager coordinates with the Agreement States, and participates, in cooperation with NMSS and RES, in the identification and review of Agreement State abnormal occurrence reports.
7. 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

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<sup>1</sup>Licensee Event Report (LER)

Manager, the ASPO, the RSAO, and the designated IMPEP<sup>2</sup> reviewer, to evaluate the effectiveness and completeness of Agreement State event information provided for entry into the NMED database.

## **VI. APPENDIX**

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

## **VII. REFERENCES**

NRC Management Directive 8.1, *Abnormal Occurrence Reporting Procedure*, August 21, 1997.

*Policy Statement on Adequacy of and Compatibility of Agreement State Programs*, published in the Federal Register, 62 FR 46517 (September 3, 1997).

NRC Management Directive 5.6 *Integrated Material Performance Evaluation Program (IMPEP)*.

STP Procedure SA-100, *Implementation of the Integrated Performance Evaluation Program (IMPEP)*

STP Procedure SA-105, *Reviewing Common Performance Indicator #5 Response to Incidents and Allegations*

STP Procedure SA-117, *Agreement State Project Officers (ASPO)*

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<sup>2</sup>See STP Procedure SA-100, *Implementation of the Integrated Materials Evaluation Program (IMPEP)* and SA-105, *Reviewing Common Performance Indicator #5 Response to Incidents and Allegations*



**SA-300 Reporting Material Events  
Appendix (Rev. 1)**

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

**Final Report**

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**April 24, 2001**

**Office of State and Tribal Programs  
U.S. Nuclear Regulatory Commission**

**Contact: Patricia M. Larkins**



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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/NRC/reference.html>. The Office of State and Tribal Programs (STP) documents are available at the STP external Website at: <http://www.hsrdoornl.gov/nrc/>.

### **Paperwork Reduction Act Statement**

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.

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 08/31/2003. The estimated burden per response to comply with this collection request is 1.25 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."

### **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.

## *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-significant events and concerns, and their causes. The information from reports of medical misadministrations, 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 February 20, 1998-version, has been developed to provide information to the staff of the Agreement and non-Agreement States that are responsible for the preparation of event reports for incidents and events involving the use of nuclear materials that have 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 have occurred in their State. It also provides guidance for use by non-Agreement States when reporting events involving lost, stolen or found sources of naturally occurring and accelerator-produced radioactive materials. The reported information aids in understanding why the events occurred and in identifying actions to help ensure safety and improve the overall effectiveness of the NRC and Agreement State regulatory programs. Guidance is provided on (1) reporting significant events to the NRC Operations Center; (2) providing 30-60 day notification and follow-up event information; (3) schedule for event reporting; (4) reporting formats (i.e., electronic reporting to the Nuclear Materials Events Database (NMED) or written reports (mail, Fax, or email) to the Director, Office of State and Tribal Programs (STP); and (5) reporting event information for events meeting the abnormal occurrence (AO) criteria. An appendix to the Handbook contains (1) a glossary of terms, and (2) a listing of reference materials. NOTE: This procedure does not contain guidance on NMED data entry (coding). For guidance on data entry, an electronic copy of the NMED users guide has been included under the *Help* support icon in the upgraded Microsoft Access 97/2000 version of the NMED software program.

### 1.1 Why do we collect event information?

Operating experience is an essential element in the regulatory process for insuring that licensed activities are conducted safely. Reporting operating incidents and events helps to identify deficiencies in the safe use of AEA radioactive material and to ensure that corrective actions are taken to prevent recurrence. The *Government Performance Results Act of 1994 (GPRA)*, required the Agency 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 materials program against the metric performance goals. The metric goals are based on current and historical event reporting data. 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>3</sup> NRC conducts reviews of all operating experience reports, from both NRC licensees and Agreement States, to identify safety concerns early, and to further evaluate individual safety concerns for any *generic safety issues (GSIs)* that could apply to a broader class of licensees. Prompt reporting of event information, including 30 day report information, helps the staff

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<sup>3</sup> Nuclear Regulation: Better Criteria and Data Would Help Ensure Safety of Nuclear Materials, GAO/RCED-93-90.

identify or detect possible safety concerns as early as possible. An event or condition could, by itself appear insignificant, but when compared with national information, could become a generic concern. 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 information notices warning of possible safety concerns and assessment of the need for regulatory changes or revisions. Feedback is provided to Agreement State regulators, the industry, and the public.

NRC publishes a quarterly report that presents information on the results of statistical analysis of event data and any significant or generic issues or concerns. The *Nuclear Materials Events (NMED) Database Quarterly Report* is available in electronic form at the NMED Internet Website: <http://nmed.inel.gov>. A nuclear material newsletter is also published quarterly by NRC's Office of Nuclear Material Safety and Safeguards (NMSS) that includes information on safety concerns identified during that quarter.

## **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 USNRC 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."
- 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 significant events that meet the AO criteria.
- Due to the importance of 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, SECY-97-054). The implementing procedures are contained in STP Procedure SA-200 (See Reference section).
- 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 insure 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 STP Procedure SA-100 (IMPEP))

### 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 4 of this guide contains a listing of the *U.S. Code of Federal Regulations (10 CFR)* regulatory reporting requirements for material event information. The 10 CFR reporting requirements form the basis for equivalent reporting requirements in Agreement State regulations. The listing references the specific 10 CFR reporting requirements, followed by a brief description of the types of events that fall under the reporting requirement, and the periodicity for reporting. This list begins on page 11 of the "Handbook."

*New* Please note the new reference in All Agreement State Letter SP-98-038, dated May 5, 1998, regarding expansion of the Federal Bureau of Investigation (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.

The States are encouraged to voluntarily report an occurrence that actually happened (event) or something that may happen (condition) that does not meet the regulatory reporting criteria that the State believes might be of safety significance or of generic interest or concern, or involves media interest.

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

The NMED database contains a historical collection of information on the occurrence, description, and resolution of events involving the use of radioactive material in the United States (source, byproduct, special nuclear material, naturally occurring, and accelerator-produced radioactive material). NMED accommodates the sharing of material event data submitted by Agreement and non-Agreement States and the NRC. The data includes information on material events from January 1990 through the present. The database is maintained by NMSS through a contractor, Idaho National Engineering and Environmental Laboratory (INEEL).

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

*New* The NMED database has been expanded to include additional information on *lost, stolen, and abandoned sources* in coordination with a national effort led by the *Conference of*



*Radiation Control Program Directors, Inc., (CRCPD)* to track lost and found radioactive material (including non-AEA and unlicensed material) found in both Agreement and non-Agreement States. The data will be collected from all States, and in some cases non-licensee organizations and members of the public. 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).

NOTE: FBI notification should be considered if the event involves the possibility of theft or terrorist activities. Based on health and safety significance the issuance of a press release should also be considered.

## **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. Non-Agreement States have been requested by CRCPD to voluntarily report any lost, stolen and abandoned non-AEA and unlicensed material. This section presents information on reporting (1) significant events to the NRC Operations Center, (2) 30-60 day reportable events, and (3) follow-up event information.

### **2.1 Reporting Significant Events (Reportable within 24 hrs. by Agreement State licensee)**

Agreement States should report significant events to the NRC Operations Center within 24 hours of notification by an Agreement State licensee. Significant events are those requiring prompt notification as determined under applicable Agreement State regulations. Information should be reported to the NRC Operations Center via voice at (301) 816-5100 or (301) 951-0550 or by FAX at (301) 816-5151. A Sample FAX page has been included at the end of Section 2, see Table 1. (For reference, NRC reporting requirements for significant events are presented in Section 4.)

### **2.2 Initial NMED Record for Significant Events**

A copy of the initial event notification information received from an Agreement State on significant events is used by INEEL to establish an initial record in the national NMED database. INEEL will use the *Event Report Identification No.*, consisting of the State ID, year, and a sequential ID No., e.g., (TN-00-001) when entering the initial event record

into NMED. The State should use that Event Report Identification number when providing updates to the initial NMED event record using the State's local Microsoft Access, NMED database. (See Section 2.5, of this Handbook for guidance on reporting follow-up event information to NMED.)

**2.3 *Radiological Emergency Response Assistance Available to the States for Significant Material Events***

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 Federal Radiological Emergency Response Plan (FRERP), 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.

**FAX TO: NRC OPERATIONS CENTER**

**Agreement State Agency:** [State] Dept. of Health, Division of Radiation Protection

**Event Report ID No.:** State ID, YR, No., e.g. WA-00-002

**License No.:** CL-Z00X-1  
**Licensee:** County Inspection Inc.

**Event date and time:** April 6, 2001, between 4:00 and 5:00 am

**Event location:** City, State

**Event type:** Stolen Radiography Device  
**Notifications:** [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.

**Event description:** [State] Dept. of Health was notified on [date], by a representative from [licensee], of the theft of a radiography camera from a locked equipment trailer on Thursday morning, April 6, 2001. 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 [isotope] [activity, when known] 88.3 curies of Iridium-192. The device cables were not stolen.

The State has an inspector on site and will continue to keep NRC informed of the status of our investigation.

**Transport vehicle description:** N/A

**Media attention:** [State] Dept. of Health has received inquiries from the media

**Point of contact:** Bob Brown, 301-415-0001

**Table 1. Sample FAX Sheet to NRC Operations Center**

**2.4 30 - 60 Day Event Notification**

Agreement States should report events requiring greater than 24 hours notification by Agreement States licensees, as determined under applicable Agreement State regulations, to NRC on a monthly basis. (For reference, NRC reporting requirements for events are presented in Section 4.) Reports may be made either electronically or in written form. NRC staff encourages Agreement States to electronically report all events using the NMED database software and entry screens.

The following paragraphs provide additional information on reporting events and NMED. For guidance on data entry (coding), an electronic copy of the NMED users guide has been included under the *Help* support icon in the upgraded Microsoft Access 97/2000 version of the NMED software program. The upgrade NMED software program also contains downloadable sample NMED data entry screen (previously included in this Handbook).

a. ***Assign Event Report Identification No.***

This number should appear on all reports, including preliminary, initial notification reports, and any follow-up reports. The Event Report Notification No. should consist of the State or State agency ID, year, and a sequentially assigned ID number, e.g., (NYDOL-99-001), (NYC-99-001), (TX-00-001), (GA-00-001), (NE-00-001), (CA-00-001) for each agency in your State. NOTE: The Agreement State ID number field in NMED can accommodate up to four characters for the State or agency identifier. The "Agreement State ID No." should be specified by the State for all telephone, electronic or written notification involving each specific event.

b. ***Basic Event Information***

Section 3 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 Section 3. Updated information should be subsequently provided in follow-up reports (see Section 2.5).

c. ***Electronic Reporting to NMED***

Provide an electronic NMED report via E-mail or PC diskette to the NMED contractor, based on the information provided by the Agreement State licensee in the 5, 15, 30 or 60 day report. If you need additional help, you may contact the INEEL NMED Project Manager, Dante Huntsman, electronically via Internet email at: [dhun@inel.gov](mailto:dhun@inel.gov), or by telephone at 208-526-2741, or the NRC NMED Project Manager, Sam Pettijohn, via e-mail [SLP@nrc.gov](mailto:SLP@nrc.gov) or telephone: 301-415-6822.

d. **Internet Access to NMED**

An Internet (query only) version of NMED with several drop-down point-and-click menus is available. The Internet version of the NMED program eliminates the need for INEEL to provide users with periodic diskette updates of the national NMED data. Users may download the latest NMED national database information via Internet file transfer. Internet access to the NMED is currently controlled either by a user -ID and password, or a user -ID and Internet Protocol (IP) Addresses. If passwords are required contact Dante Huntsman, INEEL by e-mail message at: [dhun@inel.gov](mailto:dhun@inel.gov) or by telephone at 208-526-2741. Future plans include upgrading the Internet version of NMED to provide open public access to material event information. *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 INEEL.*

e. **Written Event Reports**

Written event reports, including e-mail or fax, should be sent to the Director, STP. Written report information should be comparable to the minimum basic information identified in Section 3. Reports should be provided in an optical character recognition (OCR) scannable format. Please include an **Event Report Cover Page** for all written form event information provided to NRC. Use of the Event Report Cover Page helps ensure our Document Control staff can readily identify, classify and appropriately record the document. A sample cover page is provided on page 10 of this Handbook.

**2.5 Reporting Follow-up Event Information**

Follow-up material event reports--providing the results of investigations into what, where, when and how the event or conditions occurred--through resolution and close out, should be provided for all events, both significant (24 hr. reportable) and 30-60 day reportable events.

- a. Follow-up reports through a closeout of the event should be provided electronically or in writing to NRC on a monthly basis. Enter any new or supplemental information to the initial NMED record. A complete event report should include all investigative and medical information through closeout. (See minimum basic event information in Section 3.)
- b. The initial event report identification number (**State\Yr.\No.**) should be included whenever additional follow-up event information is provided. Indicate that it is a follow-up report.
- c. Additionally, when providing follow-up NMED event information, provide 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/yr., if applicable and appropriate.

- d. Any follow-up information that revises earlier information or provides additional information on a given event should be provided to ensure a complete historical NMED record.

### **3. Minimum Basic Event Information for a Complete Report**

The following listing identifies the minimum basic information that should be provided for all events.

<b>a. What happened, and when?</b>	
1. Agreement State, Event Report ID No.	7. Sealed source, device, etc, (make, model #, serial #)
2. Licensee (Name, address), License No.	8. Leak test information, when applicable
3. Event date and time of occurrence	9. Equipment (make, model #, serial #), and clear description of any equipment problems.
4. Date notified of event by licensee or non-licensee	10. Persons involved, consequences
5. Radionuclide, activity	11. Transportation, identify shipper, package type and ID No.
6. Any exposures (indicate short and long-term effects.)	12. Abnormal occurrence (Y/N)
<b>b. Why did it happen?</b>	
13. Cause, and contributing factors	
<b>c. What actions did the licensee take to prevent recurrence?</b>	
14. Notifications: patient, physician	15. Licensee corrective actions
<b>d. Events involving lost, stolen or abandoned material</b>	
16. Provide status through resolution (update record when found)	
<b>e. What actions did the State take?</b>	
17. Notifications: local police, FBI, and other States; as needed	18. Enforcement actions
<b>f. Describe any generic implications</b>	
19. Identify any possible generic safety concerns	20. Potential for others to experience the same event

# EVENT REPORT COVER PAGE

## AGREEMENT STATE

EVENT REPORT ID NO. \_\_\_ - \_\_\_ - \_\_\_\_  
(State\Yr.\No.)

DATE:

TO:

Director  
Office of State and Tribal Programs

SUBJECT:

STATE:

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

**Public Availability of Event Information:** Any event information that is considered preliminary predecisional 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.

Table 2. Event Report Cover Page

**Event Reporting Handbook**

**4. Regulatory Reporting Requirements**

NRC reporting requirements are contained in multiple Parts of Title 10 of the Code of Federal Regulations (10 CFR). The following provides a complete listing of the current 10 CFR material reporting requirements for which Agreement States should have compatible regulations.

10 CFR Part	Reporting Category		Reporting Requirement	Notification
	Significant	30-60 Day		
20, Standards for Protection Against Radiation	20.1906(d)(1)		reports of removable contamination on package >limits in 10 CFR 71.87.	Immediate
	20.1906(d)(2)		radiation levels on package > limits in 10 CFR 71.47	Immediate
	20.2201(a)(1)(i)		reports of theft or loss of licensed material > 1000 X App C value	Immediate
		20.2201(a)(1)(ii)	reports of theft or loss of licensed material > 10 X App. C value	30 days
	20.2202(a)(1)		exposure (real or threatened) ≥ 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
	20.2202(b)(1)		exposure (real or threatened) ≥ 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 rads (.5 Gy).	24 hours
	20.2202(a)(2)		release where individual could have intake > 5 X ALI over 24 hours.	Immediate
	20.2202(b)(2)		release where individual could have intake > 1 X ALI over 24 hours	24 hours
		20.2203(a), (b)	radiation exposures, releases or concentrations of radioactive material that exceed the limits.	30 days
	21, Reporting of Defects & Noncompliance		21.21(a)(1-2)	reporting of defect in basic component, structure or system. <sup>4</sup>
30, Rules of General Applicability to Domestic Licensing of Byproduct Material	30.50(a)		events involving prevention of immediate protective action, involving exposures or releases that could exceed regulatory limits	4 hours

<sup>4</sup> Not a compatibility requirement for Agreement States, but States voluntarily provide information on equipment failure and defects.



## Event Reporting Handbook

### 4. Regulatory Reporting Requirements

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10 CFR Part	Reporting Category		Reporting Requirement	Notification
	Significant	30-60 Day		
	30.50(b)(1)		event involving unplanned contamination restricting access >24 hours (no isotopes with half-lives <24 hrs)	24 hours
	30.50(b)(2)		event involving equipment failure or disability to function as designed when equipment is required to be available and operable and no redundant equipment is available and operable	24 hours
	30.50(b)(3)		event involving unplanned medical treatment of contaminated person	24 hours
	30.50(b)(4)		event involving fire, explosion affecting integrity of material, device or container, and material exceeds 5Xs ALI	24 hours
31, General Domestic Licenses for Byproduct Material		31.5(c)(5)	failure or damage to shielding, on-off mechanism or indicator, or $\geq 0.005$ microcuries (185 Bq) removable radioactive material for generally licensed device	30 days
34, Licenses for Radiography & Radiation Safety Requirements for Radiographic Operations	34.27(d)		reporting of leaking sources, leak test results $\geq 0.005$ microcurie (185 Bq)	5 days
		34.101(a)	radiography source disconnect, inability to retract source, or component failure (critical to safe operation of device)	30 days
35, Medical Use of Byproduct Material	35.33(a)		notifications and reports of misadministrations <sup>5</sup>	Next day (24 hours)
	35.59(e)(2)		leak testing sealed sources and brachytherapy sources	5 days

<sup>5</sup> Misadministration events require 15 day licensee event report and 24 hour notification to referring physician and patient.

**Event Reporting Handbook**

**4. Regulatory Reporting Requirements**

NRC reporting requirements are contained in multiple Parts of Title 10 of the Code of Federal Regulations (10 CFR). The following provides a complete listing of the current 10 CFR material reporting requirements for which Agreement States should have compatible regulations.

10 CFR Part	Reporting Category		Reporting Requirement	Notification
	Significant	30-60 Day		
36, Licenses & Radiation Safety Requirements for Irradiators	36.83		irradiator events, release of material, defective components, systems or structures; (if not reported under other 10 CFR reporting requirements)	24 hours
39, Licenses & Radiation Safety Requirements for Well-Logging	39.35		leaking sealed sources found during periodic leak testing requirement	5 days
	39.77 (a)		well logging source rupture	Immediate
		39.77(b)	theft or loss, exposures, excessive concentration of rad material	30 days
		39.77(c) and (d)	when apparent recovery impossible, irretrievable source, abandonment	60 days
40, Domestic Licensing of Source Material	40.26(c)(2)		tailings or waste retention system failure that results in a release of material into unrestricted areas, or unusual conditions	Immediate
	40.60(a) (b)(1)-(b)(4) (c)(1)-(c)(2)		requirements for domestic licensing of source material to receive, possess, use, transfer, or deliver source and byproduct material (NOTE: Same as 30.50 above)	
70, Domestic Licensing of Special Nuclear Material	70.50(a)	70.50 (b) (c)	events involving special nuclear material (SNM)	(a) 24 hours (b) 30 days (c) 60 days

**Table 3. 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</p>	<p><b>Stolen Portable Moisture Density Gauge</b></p> <p>Licensee 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. 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) and 20.2201</p>	<p><b>Possible Loss of Control and Damage to Portable Gauge</b></p> <p>Licensee 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 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 undamaged and remained in the shielded position. Wipe tests and instrument survey verified no 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. Report has been entered in NMED.</p>
<p>Reportable within 30 days under 20.1906</p>	<p><b>Shipment of Brachytherapy Sources Received with Radiation Levels Exceeding Regulatory Limits</b></p> <p>A medical licensee reported receiving a shipment of two packages containing cesium-137 brachytherapy sources. Radiation surveys of the packages with an ion chamber detector 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 20.1301, 20.2203</p>	<p><b>Exposure to Nonradiation Worker at a Licensed Facility</b></p> <p>A licensee reported to the State that a nonradiation 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. (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>

## Event Reporting Handbook

<p>Reportable within 24 hours under 10 CFR Part 35 and 30.50(b)(2)</p>	<p><b>Possible Misadministration involving a Teletherapy Unit Malfunction</b></p> <p>A patient undergoing a Cobalt-60 Teletherapy treatment with a [Manufacturer][Model #] received an unintended exposure. 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 5040cGy to be given in 28 fractions of 180 cGy 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 misadministration. The patient and referring physician were notified of the event. The licensee 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 within 24 hours under 10 CFR 36.83(a)(9)</p>	<p><b>Possible Loss of Water or Leakage from Source Water Pool at Irradiator Facility</b></p> <p>Licensee 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 a 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>

## 5. NRC Publication and Distribution of Event Notifications

### 5.1 *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. ENs are publicly available through Internet on NRC's external home page at (<http://www.nrc.gov/opa>) under *Event Reports*, within one work day of notification. As a result of public access to this information, Agreement and non-Agreement States may receive contacts from the public or media regarding events and requesting additional information.

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

Preliminary Notifications (PNs) are brief summary reports of significant events 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 approximately two hours of notification of the occurrence of a significant event. The PN will be publicly available through Internet on NRC's external home page under PN Reports at (<http://www.nrc.gov/opa>). 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.

## 6. NRC Safety Reviews of Material Event Reports

### 6.1 *NRC Review of Material Events for Safety Significance and Generic Issues (New)*

- A. A *Generic Assessment Panel (GAP)* has been established within NRC to review all material event information. A weekly review of all new NRC or Agreement State licensee event information that has been entered into NMED is conducted by NRC staff. The objective of the review is to identify any events that may be safety significant or may involve GSIs, i.e., equipment malfunction or failure, significant exposures, etc. 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.

**B. *Requests for additional information:*** Based on the results of the GAP review, Agreement State staff may be contacted by the Regional State Agreements Officer (RSAO) by voice 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 through close-out of the event. To provide the States reasonable time for review and investigation of reported events, any requests for additional information to States will be conducted within the following schedule.

1. Schedule for requesting additional information:

If necessary, NRC staff may contact Agreement States for additional information on *significant events* that pose or could pose public health and safety risks. Such requests 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.

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 notification)) and within 60 days for a (30 day event notification) after NRC's receipt of the initial notification from 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 receipt of the initial record).

**6.2 *Quarterly Operational Events Briefing  
Review of "Significant" Events***

**A.** Events identified as having a "significant" potential risk to public health and safety may receive additional NRC management review at the quarterly NRC Operational Events Briefing. The quarterly briefing, attended by managers and staff from the offices of NMSS, STP, Incident Response Operations (IRO), Nuclear Regulatory Research (RES), and the Regions is convened to review and assess health and safety-related issues, e.g., cause, effects, generic implications, mitigating actions, etc. NRC headquarters and region staff continue to follow-up and review material events discussed at the *operational events briefing* through closure of the event, which includes checking to see that the final report information has been entered into NMED. Based on potential safety risks identified as a result of event review and analyses, NRC may take actions to reduce potential health and safety risks to the public by issuing safety-related notifications to licensees, concerning software problems, equipment modifications, etc. Further research and analysis may result in regulatory or programmatic changes.

- B. Agreement State staff may be requested to participate in the briefings by telephone to discuss specific events, the status, results of licensee or State investigation activities and licensee corrective actions, and the potential generic significance of the event. Agreement State participation helps in the exchange of event information and in follow-up actions if generic implications are identified.

## **7. Abnormal Occurrence Guidelines and Criteria**

### **7.1 Introduction**

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 abnormal occurrence as an unscheduled incident or event that the Commission determines to be significant from the standpoint of public health or safety. Section 208 of the Act also requires that the Commission inform Congress of any abnormal occurrences. The Agreement States support the NRC in their effort to keep Congress apprised of any significant events that may directly affect public health or safety by providing information on proposed AOs that have occurred in their State.

### **7.2 AO Policy Information**

The Commission submits a report to Congress identifying any AOs. The Federal Reports Elimination and Sunset Act of 1995 requires that AOs be reported to Congress on an annual basis (see "Report to Congress on Abnormal Occurrences, Fiscal Year 1996," NUREG-0090, Vol. 19). Section 208 of the ERA indicates that each report shall contain:

- (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.

A final AO policy statement containing criteria for determining an AO was published in the *Federal Register* on December 19, 1996, (61 FR 67072). Revised AO criteria were published in the *Federal Register* on April 17, 1997 (62 FR 18820) to incorporate minor changes and to revise criterion III covering Fuel Cycle Licensees.

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

- (1) Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission;
- (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.

### 7.3 AO Criteria

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, 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 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 76072). 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).

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.



## 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>6</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 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.
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**

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<sup>6</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 §35.2) involving the wrong individual that exceeds the reporting values established in the regulations.

All other reported medical misadministrations 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.

*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>7</sup>*

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

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<sup>7</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.

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.
4. 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.
3. 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 misadministration 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>8</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(s).

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<sup>8</sup> The wrong radiopharmaceutical as used in the AO criterion for medical misadministrations refers to any radiopharmaceutical other than the one listed in the written directive or in the clinical procedures manual.

New, revised:

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>9</sup>

\* \* \* \* \*

**7.4 Guidelines for AO Write-ups**

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 writeups; use underline instead. Any special fonts will be added during the publishing stage by the NRC Technical Publications Specialist using the Kodak Ektaprint Electronic Publishing System.

**NOTE: Agreement States may use INTERNET E-Mail capability to electronically send their AO information to STP via Internet using WordPerfect or an ASCII text file. NRC is currently using WordPerfect 8. The file may be attached to an e-mail transmission. The STP AO coordinator, Patricia Larkins, may be reached at (PML@NRC.GOV).**

Margin notation - Include at the beginning of the report the Original Event Report Identification No., State ID-YR., - ITEM NO. (XX-00-01).

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.

Nature and Probable Consequences - Briefly explain what happened and what were the circumstances. Provide the specific details of the event, i.e., exposure (where applicable), source, indicate the specific isotope(s), quantity, dose (where applicable), treatment plan (where applicable), equipment, manufacturer and Model No. Describe any immediate actions taken by the licensee or the State (confirmatory action

<sup>9</sup>Staff Requirements Memorandum, SECY-98-175, dated September 4, 1998.

letter, special inspection, enforcement conference, enforcement action(s), etc.). The write-up should answer where, when, how, why, and efforts to prevent recurrence.

For occupational, medical, or public overexposures identify whether the person was notified. For medical misadministrations, include the intended and actual treatment plan, identify any health effects. Mention if a medical consultant has been contracted to review the event. Include the consultant's conclusions and identify the effects on the patient. Never mention any health effects on a patient without attributing the statement to the licensee or medical consultant. Indicate whether the primary physician was notified.

NRC policy states that all documents must be published in dual units (Metric and English).

Cause or Causes - Self explanatory

Action(s) taken to prevent recurrence - Briefly explain what actions were taken to prevent recurrence by the licensee, and indicate whether or not the State was satisfied with the licensee's corrective actions. Were there any enforcement actions, penalties, etc.?

Last paragraph - Indicate the status by stating whether the AO is closed or remains open waiting for additional significant information from the Agreement State licensee. An item should only be identified as open if the State expects additional significant action 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."

The following pages contain two sample AO write-ups.

<b>Table 4. Sample Industrial Radiography AO Report</b>
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*State ID-Yr.-No*  
*(XX-00-001)*

Industrial radiography exposure at (**Name of facility, City, State**).

In accordance with the AO criteria an annual shallow-dose equivalent to the skin or extremities greater than 2500 mSv (250 rem) is considered an AO.

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

*Exposure*  
*Source/Quantity*  
*Equipment/Device*  
*(Manuf./Model #)*

Nature and Probable Consequences: A radiography trainer (#2) received an extremity exposure of at least 500 rem to the left-hand thumb and index finger during a source disconnect involving a 96 curie iridium-192 radiography source, contained in the licensee's Gamma Century radiography camera. While radiographing welds on a 12 inch pipe line in a five foot deep ditch, the trainer began experiencing difficulty with the source exiting from and retracting into the camera. Survey meter readings indicated a source disconnect. Radiographer (#1 ) shielded the source in the guide tube with a one inch thick lead sheet while the radiographer helper (#2) roped off a larger area and stayed a distance from the source. The radiographer trainee (#2) (employee of the radiography manufacturer) asked the (**Licensee**) radiographer to notify the radiography company RSO, and indicate everything was under control. As the trainer disconnected the guide tube, the source assembly fell into the mud at the bottom of a ditch. While picking up the source assembly from the mud with channel lock pliers, the source slipped. He instinctively reached for and straightened the source assembly (pigtail) with his hand, apparently touching the source in the process. He placed the pigtail into the camera, intending to place the source capsule in first. He noticed the survey meter reading high, indicating the source was outside of the camera. Radiographer (#2) then removed the source from the camera and placed it under the lead sheet. He then secured the source in the shielded position. The company did not notify the Agency of the disconnect.

About 10 days later, the radiographer started experiencing discomfort in his left thumb and index finger and made several visits to a doctor for treatment. Approximately 30 days later the RSO and the radiographer reported the incident to the State. An Agency investigation found the radiographer's film badge read 1.06 rem whole body. An inspection of the camera was performed by the company RSO the day after the incident. The Licensee and the State Agency determined that the company had ordered

two model #22 pigtails and sources from (Manufacturer, City, State), for the Century radiography cameras, and the (Manufacturer) inadvertently sent an incorrect Model #23 pigtail instead of the two model #22's ordered. The two models appear similar, but the model #22 is manufactured with 1/8 inch aircraft cable and a 3/4 inch connector, and the model #23 is manufactured with teleflex cable, the same as the drive cable material, and a one inch connector. The radiography company assumed the two pigtails sent to them were model #22's. The #23 was mistakenly placed in the Gamma century camera and is apparently the cause of the disconnect. The Agency investigation determined that the trainer had received at least a 1500 rem exposure to the thumb and index finger of the left hand. The (State) Radiation Control Program, in which the manufacturer was licensed, was informed of the incident and investigated the manufacturer's (Licensee) error in sending the two different pigtails to the radiography company.

**Cause or Causes** - The manufacturer's mistaken delivery of a pigtail model number different than the one ordered and the radiography company's assumption that the pigtails they received were the models they ordered, resulted in a pigtail being used in a camera for which it was not manufactured. The disconnect resulted from the difference in the length of the connectors between the two models. Also, the radiographer attempted an unauthorized recovery of the disconnected source. The radiographer was not trained in source recovery and had no previous experience with source disconnects.

Actions Taken to Prevent Recurrence

**Licensee** - Actions will be given at the enforcement conference.

**State Agency** - The Licensee and radiographer were cited for violations of the (State) Regulations for Control of Radiation. The Licensee was cited for the extremity exposure, unauthorized retrieval of a disconnected source, failure to immediately notify the Agency of the incident, and failure to notify the Agency in writing within thirty days of the incident. The radiographer was cited for unauthorized retrieval of a disconnected source. The incident has been referred for escalated enforcement.

**Status**

This file is (**open**/**closed**) in (State). The event will remain open for additional information from the State of (State).

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



**Table 5. Sample Medical AO Report**

<b>State ID-YR.-NO.</b> (XX-00-002)	Radiopharmacy Medical Misadministration at (Name of Facility, City, State) location.
<b>Criteria</b>	In accordance with the AO criteria, administering a dose equal to or greater than 10 gray (Gy) (1000 rad) to any organ (other than a major portion of the bone marrow, the lens of the eye, or to the gonads) and, the administered dose or dosage is at least 50 percent greater than that prescribed in a written directive is considered an abnormal occurrence.
	<b>Date and Place</b> - [Date]; [Facility/Licensee], [City, State]
<b>Procedure/dose</b> (actual vs. intended)	Nature and Probable Consequences - a patient was prescribed a dose of 3.7 megabecquerel (MBq) (0.1 millicurie [mCi]) of Iodine-131 (I-131) for a thyroid scan and uptake procedure. However, the patient was administered a dosage of 262.7 MBq (7.1 mCi) of I-131. As a result the patients thyroid received a dose of about 9100 centigray (cGy) (9100 rad) instead of the prescribe dose of 130Gy (130 rad).
<b>Health effect</b> <i>to patient</i>	Licensee stated that the administered dose of I-131 may induce a hypothyroid state requiring the patient to take thyroid hormone.
	<b>Cause or causes</b> - the wrong dosage was administered on the assumption that the patient was prescribed a whole body thyroid scan for a cancer metastatic disease evaluation.
	Actions taken To Prevent Recurrence
	<b>Licensee</b> - Procedures for scheduling a whole body scan for thyroid cancer and metastasis were revised to include a detailed patient preparation and history. The revised procedures required that the approving radiologist sign the Iodine-131 administration policy before ordering a radiopharmaceutical. The nuclear medicine technologist attended a continuing education program at a local hospital, which included a session on the effects of studies involving therapy dosages.
	<b>State Agency</b> - The State agency conducted numerous follow-up inspections to ensure that the licensee's actions taken to prevent recurrence had been implemented.
	This event is closed for the purpose of this report.

# *Appendix*

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## *Glossary*

- DPC** The Document Processing Center (DPC) is an internal NRC automated document search and retrieval system, indexed by a unique identification (Accession) No. for use by the staff of the NRC.
- EN** 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.
- Gray** Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule/kilogram (100 rads).
- 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, (see examples below). 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 Materials 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/opa>).

- RSAO** 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 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 manuals and procedures that contain additional information on event response and AOs. Additionally information is provided on the NRC Region contact for Agreement State issues, the Federal Radiological Emergency Response Plan (FRERP), the Federal Bureau of Investigations (FBI) expansion into byproduct material, and the Radiation Emergency Assistance Center/Training Site (REACTS) along with a telephone number.

### *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 Management Directives*

8.1 Abnormal Occurrence Reporting Procedures

8.10 NRC Medical Event Assessment Program

### *NRC Inspection Manual (Series 1300, Incident Response)*

1300 Incident Response Actions - Responsibility and Authority (84-080)

1301 Response to Non-Emergency Incidents Involving Radioactive Material (96-022)

1302 Action Levels for Radiation Exposures and Contamination Associated with Material Events Involving Members of the Public (94-004)

1303 Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE) (95-009)

1330 Response to Transportation Accidents Involving Radioactive Materials (84-22)

1360 Use of Physician and Scientific Consultants in the Medical Consultant Program (94-013)

***NRC Inspection Procedures Manual*** (Series 8700, Material Safety Inspection)

87103      Inspection of Materials Licensees Involved in an Incident Bankruptcy Filing (97-008)

***NRC Emergency Response Manuals***

NUREG/BR-0230      Response Coordination Manual - Contains procedures for requesting Federal assistance during an emergency.

NUREG/BR-0150      Contains procedures for assessing the consequences of an emergency.

***STP Procedures***

SA-100              Implementation of the Integrated Materials Performance Evaluation Program

SA-200              Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements

***Event Notification and Response***

**FBI**              A recent 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 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.

**FRERP**              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 Federal Radiological Emergency Response Plan (FRERP), which includes other Federal agencies, i.e., Department of Energy (DOE), Environmental Protection Agency (EPA), Federal Emergency Response Administration (FEMA). FRERP covers any peacetime radiological emergency that has actual, potential or perceived radiological consequences within the United States. The FRERP is reproduced in Section V of NUREG/BR-0230.

**References**

**Event Reporting Handbook**

**DOT/NRC**

The National Response Center is a Department of Transportation, Coast Guard service that serves as a national point of contact for reporting all oil, chemical, non-AEA radiological, biological, and etiological discharges into the environment

anywhere in the United States and its territories. In addition to gathering and distributing spill data for Federal On-Scene Coordinators and serving as the communications and operations center for the National Response Team, the Center maintains agreements with a variety of federal entities to make additional notifications regarding incidents meeting established trigger criteria. The Center maintains a 24 hour call line at 1-800-424-8802. The Center's Website address is: [www.nrc.uscg.mil/services](http://www.nrc.uscg.mil/services).

**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.

**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/NRC/reference.html>. The Office of State and Tribal Programs (STP) documents are available at the STP external Website at: <http://www.hsrdo.ornl.gov/nrc/>.



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***Event Reporting Schedule Reference Sheet***

<b>Reportable Event Notification</b>	<b>Reporting Schedule</b>	<b>Reporting Method</b>
<p>Events requiring 24 hours or less notification by Agreement State licensees (<b>significant</b> reportable event).</p>	<p>Agreement State should report to NRC within 24 hours of notification by an Agreement State licensee.</p> <p>(See Hndbk. Table 1, Sample FAX to Ops. Center) for sample initial information to be reported.</p>	<p>Initial information should be reported to NRC Operations Center* Telephone (voice): (301) 816-5100 or (301) 951-0550</p> <p>NRC Operations Center FAX # (301) 816-5151</p>
<p>Events requiring greater than 24 hour notification by Agreement State licensees (e.g., <b>30-60 days</b>) and follow-up reports.</p>	<p>Agreement State should provided 30-60 day notification and any follow-up reports to NRC-NMED on a monthly basis.</p> <p>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.</p> <p>See Section 3. "Minimum Basic Event Information for a Complete NMED Report" for sample information needed.</p>	<p><b>Information may be reported by:</b></p> <p>Email: <a href="mailto:DHUN@INEL.GOV">DHUN@INEL.GOV</a> Tel. 208-526-2741</p> <p>Disk: INEEL Attn: Dante Huntsman P.O. Box 1625 Idaho Falls, ID 83415</p> <p>Written: Director of STP US NRC Washington, DC 20555</p>
<p><b>Personal or sensitive information, e.g., names, personal address, social security #, should not be included in event descriptions.</b></p>		
<p><b>*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.</b></p>		