(STP-05-064, August, Program, SA-300)

August 30, 2005

ALL AGREEMENT STATES, MINNESOTA, PENNSYLVANIA

**OPPORTUNITY TO COMMENT ON DRAFT REVISION TO STP PROCEDURE SA-300, "REPORTING MATERIALS EVENTS" (STP-05-064)**

Enclosed for your review and comment is the draft revision to the Office of State and Tribal Programs Procedure SA-300*, Reporting Materials Events*. This procedure describes the process to be used by the Agreement States to report and collect information on radiation exposures, medical events (including Abnormal Occurrences), lost material, and equipment failures to the NRC. Changes are in redline/strikeout format. We would appreciate receiving your comments* within 30 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: Andrea Jones INTERNET: ARJ@NRC.GOV
TELEPHONE: (301) 415-2309 FAX: (301) 415-3502

***/RA by Dennis K. Rathbun for/***

Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosure:
As stated

* This information request has been approved by OMB 3150-0029, expiration 06/30/07. 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, 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.

# STP Procedure Approval

## *Reporting Material Events - SA-300*

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Issue Date:

Review Date:

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Paul H. Lohaus
*Director, STP* *Date: / /05*

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Dennis Rathbun
*Deputy Director, STP* *Date: / /05*

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Andrea Jones
*Procedure Contact, STP* *Date: / /05*

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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.~~***

## 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 an ~~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, and in some cases, 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 (IN~~EE~~L), 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, IN~~EE~~L, 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 concern or 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, IN~~EE~~L, for entry into NMED. IN~~EE~~L, in coordination with NMSS, conducts reviews of Agreement State material event reports that have been electronically provided to IN~~EE~~L 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. Event Review for Safety Significance and Identification of Possible Generic Concerns

a. The NMSS materials staff conducts a weekly review of new material event notifications (ENs) received by the Headquarters Operations Office, and event notifications and follow-up event reports ~~received and entered into NMED from both Agreement States and NRC licensees~~. Events are reviewed to identify any events that may involve generic safety concerns, issues (GSIs) or trends, or may or 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/or may meet the AO criteria.

5. 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 ( Licensee Event Report), 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).

6. The designated STP Project Manager participates in cooperation with NMSS and RES, in the identification and review of events that may meet the abnormal occurrence criteria in cooperation with NMSS, RES, and the Agreement States, and coordinates Agreement State review of the draft AO report.

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 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 Evaluation Program (IMPEP) and SA-105, Reviewing Common Performance Indicator #5 Technical Quality of Incidents and Allegations.

## VI. APPENDIX

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

## VII.REFERENCES

*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).*

NRC Management Directive 6.4, *Generic Issues Program*, December 4, 2001.

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

NRC Management Directive 8.5, *Operational Safety Data Review*, December 23, 1997

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

STP Procedure SA-105, *Reviewing Common Performance Indicator #5 Technical Quality of Incidents and Allegations*

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

New text redlined

*SA-300* **Reporting Material Events Appendix (Rev. 2)**

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

## Draft Report

**May 2005**

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

**Contact: Andrea Jones**

## 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.hsrd.ornl.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 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."

## 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~~ 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 May 23, 2001 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

# *Table of Contents*

# *List of Tables*

# 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. At the request of the Conference of Radiation Control Program Directors (CRCPD), NMED captures voluntary reports on lost and stolen events involving naturally occurring (NARM) and accelerator-produced radioactive material (NARM). The reported information aids in understanding why the events occurred and in identifying actions to help ensure public and occupational safety and security, 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~~ with local Microsoft Access software program.

## *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 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.[1] 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,

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

and updates to events, helps the staff 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.~~ http://nmed.inl.gov. A nuclear material newsletter, *NMSS Licensee Newsletter*, NUREG/BR-0117, 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.

-- 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 important 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) and SA-105, Technical Quality of Incidents and Allegations.

## *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."

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, and a limited number of events involving naturally occurring, and, in some cases, accelerator-produced radioactive material that was initially identified as 'unknown radioactive material" and later found to be non-AEA 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 (IN~~EE~~L).

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

***New*** 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, any event involving "risk-significant" sources that are lost, stolen or abandoned must be reported to the NRC Headquarters Operations Center immediately. "Risk-significant" 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 1 to the Code. The rational for this immediate notification standard is to facilitate prompt coordinated Federal response in situations involving lost, stolen, or abandoned sources, in excess of the category 2 values in the IAEA's Code of Conduct.

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.

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 (FBI notification)*

FBI notification should be considered if an event involves the possibility of ***theft or terrorist activities***. The States are responsible for notifying the Federal Bureau of Investigations (FBI) of the occurrence of events involving possible theft or terrorist activities. 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.)

## 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 hours 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 IN~~EE~~L to establish an initial record in the national NMED database. IN~~EE~~L will use the *Event Report Identification No.*, consisting of the two letter State ID, two year, and a four digit sequential ID No., e.g., TN0001, when entering the initial event record into NMED. This number, the Event Report Identification number, is reflected in the "Reference" field of the NMED record~~. The State~~ and should be used ~~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.) In addition, each event entered into NMED is assigned an unique NMED item number.

## *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 National Response Plan (NRP) ~~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. WA00001 |
| **License No.:** | CL-Z00X-1 |
| **Licensee**: | County Inspection Inc. |
| **Event date and time:** | April 6, 2001~~1~~5 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 exposure device [camera] from a locked equipment trailer on Thursday morning, April 6, 2005. 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.<br><br>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 local ~~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 two letter ~~State or~~ State agency ID, two digit year, and a sequentially assigned four digit 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 "Event Report ~~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 to **NMED@INL.GOV**. If you need additional help, you may contact the INL NMED Project Manager, ~~Thomas Smith~~, electronically via Internet email at: NMED@inl.gov., ~~Thomas.Smith@inl.gov., or by telephone at 208-526-6904~~, or the NRC NMED Project Manager, ~~Michele Burgess~~, via e-mail NMEDNRC@nrc.gov ~~MLB5@nrc.gov or telephone: 301-415-5868.~~ For contact via telephone, refer to the contact information on the homepage of the NMED website.

d. ***Internet Access to NMED***

An Internet (query only) version of NMED with several drop-down point-and-click menus is available. 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 access is ~~passwords are~~ required, contact the INL NMED Project Manager by email message at: NMED@inl.gov ~~Thomas W. Smith, INEEL by e-mail message at: NMED@inl.gov or by telephone at 208-526-6904~~ or the NRC NMED Project Manager by email message at: NMEDNRC@nrc.gov. *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 IN~~EE~~L.*

e. ***Written Event Reports***

Written event reports, including e-mail or fax, should be sent to the Director, STP or directly to the INL Project Manager at the address listed at the NMED homepage at http:/nmed.inl.gov. 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 12 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 the Director, STP or directly to the INL Project Manager at the address listed at the NMED homepage at http:/nmed.inl.gov. 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.

| | |
|---|---|
| **a. What happened, and when?** | |
| 1. Reporting requirement | 8. Sealed source, device, etc, (make, model #, serial #) |
| 2. Agreement State, Event Report ID No. | |
| 3. Licensee (Name, address), License No. | 9. Leak test information, when applicable |
| 4. Event date and time of occurrence | 10. Equipment (make, model #, serial #), and clear description of any equipment problems. |
| 5. Date notified of event by licensee or non-licensee | 11. Persons involved, consequences |
| 6. a.. Radionuclide, activity<br>b. Medical isotope, activity, dose assessment | 12. Transportation, identify shipper, package type and ID No. |
| 7. Any exposures, intended and actual, as applicable (indicate short and long-term effects.) | l3. Abnormal occurrence (Y/N) |
| **b. Why did it happen?** | |
| 14. Cause: Root cause and contributing factors | |
| **c. What actions did the licensee take to prevent recurrence?** | |
| 15. Notifications: patient, physician | 16. Licensee corrective actions |
| **d. Events involving lost, stolen or abandoned material** | |
| 17. Provide status through resolution (update record when found) | |
| **e. What actions did the State take?** | |
| 18. Notifications: local police, FBI, and other States; as needed | 19. Enforcement actions |
| **f. Describe any generic implications** | |
| 20. Identify any possible generic safety concerns | 21. 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**

## *3.1 Events 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 agency under "Events Closed by Region/State." Agreement States should notify NRC, through the NMED contractor, INEL, when the event record has been officially closed (i.e., no further follow-up planned and/or no additional information expected). For the purposes of NMED "event record closed" refers to an event that has been closed by the applicable Agreement State or NRC Region Office. The State should ensure that the record contains all pertinent technical information, including followup information.

## *3.2 Record Complete in NMED*

A "complete record" refers to an NMED record that contains the basic *minimum* information defined in Section 3 of this guide, (STP Procedure SA-300, *Handbook on Nuclear Material Event Reporting in the Agreement States*, for a complete event report. A "complete record" indicates that the event notification included the *minimum* basic information to receive a "complete" determination from the contractor, INL.

NOTE-IMPEP: 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.)

## 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.[2] | 60 days |
| 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 |

[2] Not a compatibility requirement for Agreement States, but States voluntarily provide information on equipment failure and defects.

## 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 | | |
| | 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**,** includes source disconnect and failure to retract source | 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 ≥ 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.~~27d~~101 | reporting of leaking sources, leak test results ≥ 0.005 microcurie (185 Bq), includes source disconnect and failure to retract source | 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.~~33a~~ 3045 | | notifications and reports of medical events involving administration and use of byproduct material, with the exception of patient intervention events[3] | Next day (24 hours) |
| | 35.~~59e2~~ 67 and 3067 | | leak testing sealed sources and brachytherapy sources | 5 days |

[3] Medical ~~administration and use~~ events require 15 day licensee event report and 24 hour notification to referring physician and patient.

## 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 | | |
| | 35.3047 | | event involving a dose to an embryo/fetus or a nursing child | Next day 24 hours |
| 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 | 360 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)<br>(b)(1)-(b)(4)<br>(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)<br>(c) | events involving special nuclear material (SNM) | (a) 24 hours<br>(b) 30 days<br>(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. | |
| Immediately reportable under 10 CFR 20.2201(a)(i) | **Stolen Portable Moisture Density Gauge**<br><br>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. |
| Reportable within 24 hours under 10 CFR 30.50(b)(2) and 201801.~~2201~~ | **Possible Loss of Control and Damage to Portable Gauge**<br><br>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. |
| Reportable within 30 days under 20.1906 | **Shipment of Brachytherapy Sources Received with Radiation Levels Exceeding Regulatory Limits**<br><br>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. |
| Reportable within 24 hours under 10 CFR 20.1301,20,2203 20.2203 | **Exposure to Nonradiation Worker at a Licensed Facility**<br><br>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. |

| | |
|---|---|
| Reportable within 24 hours under 10 CFR Parts 35.3045 and 30.50(b)(2) | **Possible Medical Event ~~Misadministration~~ involving a Teletherapy Unit Malfunction**<br><br>A patient undergoing a Cobalt-60 Teletherapy treatment with a [Manufacturer][Model #] received an unintended exposure (**identify organ**). 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 medical ~~mis~~administration. 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.INI |
| Reportable within 24 hours under 10 CFR Parts 36.83(a)(9), 30.50(b)(2) | **Possible Loss of Water or Leakage from Source Water Pool at Irradiator Facility**<br><br>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 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. |
| Reportable within 24 hours under 10 CFR Part 35.3045<br><br>Note: May be classified as a potential AO. | **Medical event involving the wrong treatment site**<br><br>Licensee notified the State that a patient received greater than 1000 cGy(rad) to the wrong treatment site during an I-125 prostrate 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(rad) to the prostrate gland. Due to a coordinate error, the administration resulted in a partial treatment of the intended site and greater than 1,000 cGy(rad) 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. |

# 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. Most ENs are publicly available ~~through Internet~~ on NRC's external home page at (http://www.nrc.gov ~~/opa~~) under *Event Reports*, within one to five working days 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. Most ~~The~~ PNs will be publicly available ~~through Internet~~ on NRC's external home page under ~~PN~~ Event 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 Assessment* **(New)**

A weekly review all of new material event notifications (ENs) received by the Headquarters Operations Office (HOO) and event notifications and follow-up reports, received and entered into NMED from the Agreement States or NRC licensees, is conducted by NRC materials staff. The objective of the review is to identify any events that may ~~be~~ involve generic safety concerns (GSIs) or may or could have significant impact on public health, safety or security. Events will be considered to have safety

significance if they are covered by existing requirements and guidance, and have the potential to cause:

1. 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

2. A single occurrence of an event tracked as a strategic goal in the Strategic Plan (e.g. deaths, loss of organ function), or

3. Events involving possible generic concerns or issues, i.e., equipment malfunctions, equipment failures, etc., or

4. Consequences or causal factors not previously seen in the event assessment process.

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.

***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 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 by NRC 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 or security 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 the date reported to the regulatory agency ~~receipt of the initial record~~).

### *6.2 Followup Review of "Significant" Events*

Events identified as having a "significant" potential risk to public health, ~~and~~ safety and security 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 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, i.e. Information Notices (IN), concerning software problems, equipment modifications, etc. Further research and analysis may result in regulatory or programmatic changes.

# 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 2004," NUREG-0090, Vol. 27). 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[4] 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 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

[4] 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 ~~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.

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.[5]*

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)].

[5] 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.

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 event ~~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,[6] 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).

**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.[7]

* * * * * * * * * *

## *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.

[6] 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.

[7] Staff Requirements Memorandum, SECY-98-175, dated September 4, 1998.

**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, Andrea Jones ~~Patricia Larkins~~, may be reached at (ARJ~~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 licensees name, and the city and State address of the licensee.

Nature and Probable Consequences - Briefly explain the event ~~what happened~~ and ~~what were~~ the circumstances surrounding the occurrence. Provide the specific details of the event to include the:~~, i.e.~~, exposure (where applicable), source, ~~indicate the~~ specific isotope(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 or the State (confirmatory action 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 events ~~misadministrations~~, include the intended and actual treatment plan, 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. 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 corrective actions 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 ~~Were~~ there were 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.

## Table 4. Sample Radiopharmaceutical Exposure AO Report

***State ID-Yr.-No*** (***XX-00-001)***

Occupational Radiopharmacy 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***

Nature and Probable Consequences: A pharmacist trainee received an extremity exposure resulting in a shallow dose equivalent of 742 centiGray (742 rads) to the hand; a deep dose equivalent of 7.02 centiSeiverts (7.02 rem) to the hand; and a dose of 0.9 milliSievents (90 millirem) to the thyroid, based on licensees 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 (IM), 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 (RSO) 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 many 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**).

# *Table 5. Sample Medical AO Report*

| | |
|---|---|
| ***State ID-YR.-NO. (XX-00-002)*** | Medical Misadministration at (**Name of Facility, City, State**) location. |
| ***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 [µCi]) of Iodine-131 (I-131) for a diagnostic scan to assess a thyroid nodule. However, the patient was administered a dosage of 111 MBq (3000 µCi) 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 (3000 µCi) of I-131 without requesting clarification or approval from the authorized users. As a result the patients thyroid received a dose of about 4300 centiGray (cGy) (4300 rad) instead of the prescribe dose of about 32.5 Gy (32.5 rad). The referring physician and patient were properly notified. |
| ***Notifications*** | |
| ***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. |

## *Table 6. Sample Gamma Knife Medical AO Report*

| | |
|---|---|
| ***State ID-Yr.-No.*** (XX-00-005) | Medical Misadministration at (**Name of Facility, City, State)** location. |
| ***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 rad) 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 (1000 rad) 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*** (intended vs. actual) | Nature and Probable Consequences - A patient undergoing Gamma Stereotactic Radiosurgery (Gamma Knife) was prescribed treatment of 20 Gy (2000 rad) to a portion of the brain. However, the patient received a dose of 12.8Gy (1280 rad) 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 licensees 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 rad). Prior to initiating treatment of Patient A, a licensee staff member handed the plan of treatment for Patient B to the licensees radiation therapist; later, the therapist could not recall from whom the plan had been received. Using Patient Bs 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.<br><br>The medical physicist determined that the treatment delivered a dose of 12.8 Gy (1280 rad) to an unintended region of the patient's brain. The radiation oncologist determine 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. The licensee notified the patient's referring physician and the radiation oncologist notified the patient of the event. |
| ***Notifications*** | |

***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*** 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.

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

# *Appendix*

# *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).

**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 documents, 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 National Response Plan (NRP) ~~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.*

STP All Agreement State and Non-Agreement State Letter, SP-98-018, March 17, 1998, Reporting of lost stolen and abandoned radioactive material, including non-AEA and unlicensed radioactive material.

## *NRC Report*

Performance Budget FY2006, NUREG-1100, Vol. 21, February 2005, annual report toCongress required by GPRA.

NMSS Licensee Newsletter, NUREG/BR-0017

## *NRC Management Directives*

| | |
|---|---|
| 6.4 | Generic Issues Program |
| 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 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. |

FRP

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) ~~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.

**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.

**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.hsrd.ornl.gov/nrc/. |

(**Cut Out Page for Handy Reference**)

# Event Reporting Schedule for Agreement States

| | Reportable Event Notification[1] | Agreement State Reporting Schedule to NRC | Reporting Methods to NRC [3] |
|---|---|---|---|
| 24 HOURS | **Significant** reportable events requiring **24 hours or less** notification by Agreement State licensees. | Agreement State should report to NRC within 24 hours of notification by an Agreement State licensee. | Report initial information to the **NRC Operations Center** [4] **(301) 816-5100** or **(301) 951-0550** FAX #: (301) 816-5151 |
| 24 HOURS | Events involving **theft or terrorist** activities should be reported to the **FBI.**[2] | Agreement and non-Agreement States should report to the FBI within 24 hours of notification. | |
| 30 – 60 DAYS | **30 – 60 day reportable events** requiring **greater than 24 hour** 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.[5] | Email: NMED@INL.GOV Telephone: 208-526-6904 or 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 |
| VOLUNTARY | 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.[6] | Email: NMED@INL.GOV |

Rev. 2 April 2005

[1] Personal or sensitive information should not be included in event descriptions (e.g., names, personal addresses, or-- social security-- numbers).

[2] 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).

[3] A sample fax to the NRC Operations Center is available in Table 1 of STP procedure SA-300.

[4] 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.

[5] An example of the minimum basic event information required for a complete record is provided in Section 3 of SA-300.

[6] 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.