



Handbook on Nuclear Material Event Reporting in the Agreement States

Final Report

March 2013

**Office of Federal and State Materials and Environmental
Management Programs
U.S. Nuclear Regulatory Commission**

Contact: Robert Sun

AVAILABILITY OF REFERENCE MATERIAL

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

Paperwork Reduction Act Statement

The information collections contained in this handbook have been approved under Office of Management and Budget approval number 3150-0178, which expires March 31, 2016. The burden to the Agreement States for these mandatory information collections is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding the burden estimate to the Records and Information Services Branch (T-5F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0200), Office of Management and Budget, Washington, DC 20503.

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

Public Protection Notification

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

Abstract

The review and analysis of operational event information increases the effectiveness of the U.S. Nuclear Regulatory Commission (NRC) and Agreement State regulatory programs by identifying safety and security significant events and concerns, and their causes. The information from reports of medical events, overexposures, equipment failures, and other events that have occurred involving the use of nuclear materials licensed by either the NRC or the Agreement States is invaluable in assessing trends or patterns and identifying possible inadequacies or unreliability of specific equipment or procedures. The reported information will significantly aid in understanding why the events occurred and identify 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, the annual report to Congress on abnormal occurrences, and to support the United States' commitment to report to the International Atomic Energy Agency's (IAEA) international database of significant events.

This handbook, which supersedes the previous March 2006 version, has been developed to provide information to the staff of the Agreement States that are responsible for the preparation of reports for incidents and events involving the use of nuclear materials that occurred in their State. Reporting of Agreement State nuclear material events to NRC is mandatory for purposes of compatibility. The handbook describes the procedures 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 are also included. The objectives of this handbook are to:

- Improve technical information;
- Standardize format;
- Ensure consistency; and
- Facilitate information retrieval.

Table of Contents

	Page
Abstract	iii
1. Introduction	1
1.1 Why do we collect event information?	1
1.2 What is the governing regulatory authority?	2
1.3 How do you determine if an event is reportable?	3
1.4 What is the Nuclear Material Events Database (NMED)?	3
2. Reporting Material Events	5
2.1 Reporting Events Requiring Notification Within 24 Hours	5
2.2 NMED Record for Events Reported Within 24 Hours	5
2.3 5 - 60 Day Event Reporting	6
2.4 Reporting Follow-up Event Information	7
2.5 Radiological Emergency Response Assistance Available to the States	8
2.6 International Nuclear Event Scale Reporting.....	8
2.7 Voluntary Reporting of Lost, Stolen and Abandoned Sources	9
2.8 Reporting of Thefts or Terrorist Activity	9
3. Closing and Completing Events	10
3.1 Event Closed in NMED.....	10
3.2 Record Complete in NMED	10
4. NRC Publication and Distribution of Event Notifications	11
4.1 Event Notifications (ENs)	11
4.2 Preliminary Notifications (PNs).....	11
5. NRC Safety Reviews of Material Event Reports	12
5.1 NRC Review of Material Events for Safety Significance and Generic Assessment	12
5.2 Actions NRC May Take After Review of “Significant” Events	13
6. Agreement State Safety Reviews of Material Event Reports	14
6.1 Agreement State Review of Material Events for Safety Significance and Generic Assessment	14
6.2 Actions Agreement States May Take After Review of “Significant” Events	14

7.	Abnormal Occurrence Guidelines and Criteria	15
7.1	Introduction.....	15
7.2	AO Policy Information	15
7.3	AO Criteria	16
7.4	Guidelines for AO Write-ups.....	16

Appendices:

Appendix A	NRC Regulatory Reporting Requirements	18
Appendix B	Examples of Reportable Events	24
Appendix C	Event Reporting Schedule.....	29
Appendix D	Sample FAX Sheet to NRC Operations Center.....	32
Appendix E	Minimum Required Event Information	34
Appendix F	Sample Event Report Cover Page.....	36
Appendix G	Radionuclides of Concern	38
Appendix H	Glossary of Terms and References.....	40

1. Introduction

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

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. The reporting and analysis of incidents and events helps to identify deficiencies in the safe use of Atomic Energy Act (AEA) nuclear material and to help 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 Event information is reported to Congress annually and used to demonstrate that the NRC and the Agreement States are meeting the safety and security goals and the corresponding strategic outcomes in the NRC’s strategic plan. NRC conducts reviews of all operating experience reports, from both NRC licensees and

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

Agreement States, to identify safety concerns early, and to further evaluate individual events for the possible presence of generic safety concerns or generic issues that could apply to a broader class of licensees. Prompt reporting of event information, including 5-60 day report information, and updates to events, helps the staff identify or detect possible safety concerns or issues as early as possible. An event or condition could, by itself appear insignificant, but when compared with national information, could indicate a generic concern or issue. In-depth analysis of event report data may result in the identification of actions that could lead to improvements in the effectiveness of NRC and Agreement State regulatory programs. Event analysis may also result in the issuance of generic communications to provide information and guidance regarding safety concerns and issues.

NRC provides a quarterly and annual report that presents information on the results of statistical analysis of event data and any safety significant or generic issues or concerns. This information is published in the NMED Quarterly and Annual Reports, which are available in electronic form at the NMED Website (<http://nmed.inl.gov>). Also, NRC Office of Federal and State Materials and Environmental Management Programs (FSME) publishes a quarterly licensee newsletter (NUREG/BR-0117) that includes information on nuclear material safety concerns.

1.2 What is the governing regulatory authority?

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

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

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 nuclear materials program against the metric performance goals. The metric goals are based on current and historical event reporting data. Due to the importance of nationwide operating experience as an essential element in the regulatory process for ensuring that licensed activities are conducted safely, the Commission directed the staff to make Agreement State reporting of events to NRC an item of compatibility (See Reference section, June 30, 1997, Staff Requirements Memorandum).

The guidance contained in this handbook is to assist NRC and Agreement State staff in the joint sharing and analysis of event information. It does not address evaluation of Agreement State programs. The AEA directs the Commission to periodically review actions taken by the States under the Agreements to ensure adequacy and compatibility with the provisions of the Act. NRC conducts periodic evaluations of Agreement State programs under the *Integrated Materials Performance Evaluation Program (IMPEP)*, which includes an evaluation of event response, reporting, follow-up, and close-out. (See FSME Procedures SA-100, *Implementation of the Integrated Performance Evaluation Program (IMPEP)* and SA-105, *Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities*.)

1.3 How do you determine if an event is reportable?

Agreement States shall report to NRC all events reported to them in accordance with their State regulations that are compatible to NRC's reporting requirements. Section 2 of this document provides additional details regarding reporting events. Appendix A of this handbook contains a listing of the most commonly encountered NRC regulatory reporting requirements for nuclear material events. The reporting requirements in Title 10 of the U.S. Code of Federal Regulations (CFR) form the basis for the compatible reporting requirements in Agreement State regulations. The table in Appendix A provides the specific regulatory requirement, followed by a brief description of the types of events that fall under the reporting requirement, and the periodicity for reporting. It should be noted that the information in Appendix A is only to be used as a reference and does not contain all of the regulatory reporting requirements. You should consult the actual reporting requirements provided in NRC's regulations (10 CFR) to determine if an event is reportable. Appendix B provides examples of reportable nuclear material events or occurrences that are required to be reported by both NRC and Agreement State licensees.

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

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

NMED contains a historical collection of information on the occurrence, description, and resolution of events involving the use of radioactive material in the United States. NMED accommodates the sharing of material event data submitted by Agreement States and the NRC. The data includes information on material events from January 1990 through the present. The Agreement States will be notified of changes made to NMED. The

database is maintained by FSME through a contractor. NMED is a tool available to both NRC and the Agreement States to support evaluation of specific events, as well as assessment of event types, and identification of generic issues and concerns. NRC performs event assessments on a quarterly and annual basis, and these assessments can be found on the NMED website. To gain access to the NMED website, contact the NRC NMED Project Manager at NMEDNRC@nrc.gov. Also, Agreement States are encouraged to share with NRC and the other Agreement States any assessments or trending studies they have performed. These assessments or studies can be forwarded to the NRC NMED Project Manager for posting on the NMED website, or distributed as an all Agreement State Letter.

2. Reporting Material Events

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

2.1 Reporting Events Requiring Notification Within 24 Hours

Agreement States shall report events requiring notification within 24 hours to the NRC Operations Center's Headquarters Operations Officer (HOO). Information should be initially reported to the HOO by telephone at (301) 816-5100. Follow-up information for the event may also be provided to the HOO by fax at (301) 816-5151 or by email at HOO.HOC@nrc.gov. An example of a fax page has been included in Appendix D of this handbook. Agreement States should assign and provide an Event Report Identification Number for each reported event. The format for this number is described in Section 2.3.a. **"Assign Event Report Identification Number."** Appendix E provides a listing of minimum event information that should be provided to complete an event report. When submitting an initial event report, please provide as much information as is known at the time the report is prepared regarding the items indicated in Appendix E. However, it is understood that this information may be incomplete or preliminary. Updated information should be subsequently provided in follow-up reports (see Section 2.4).

2.2 NMED Record for Events Reported Within 24 Hours

The NMED contractor uses the initial event notification (EN) information, which was provided to the NRC Operations Center from an Agreement State, to establish a record in the national NMED database. The NMED contractor will reference the Agreement State Event Report Identification Number (See Section 2.3.a for generating an Agreement State Event Report Identification Number) in the record. The Agreement State Event Report Identification Number will be reflected in the "Reference" field of the NMED record and will be used to ensure any subsequent updates are correctly associated with the initial event record (See Section 2.4 of this Handbook for guidance on reporting follow-up event information to NMED). In addition, each event entered into NMED is assigned a unique NMED item number.

2.3 5 - 60 Day Event Reporting

Agreement States shall report events that require reporting within 5 to 60 days to the NRC. These reports may be provided in writing by mail or electronically. NRC staff encourages Agreement States to electronically report these events using the local NMED Agreement State software or the document "Upload" program on the NMED website. However, if the Agreement State prefers to send the event report via mail, then the report should be mailed to NRC's Radioactive Materials Safety Branch (RMSB) (See Appendix C for mailing address).

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

a. Assign Event Report Identification Number

The Agreement State event report identification number should appear on all event reports, including preliminary, initial notification reports (e.g., ENs), and any follow-up reports. The event report identification number should consist of the two letter State agency ID, two digit year corresponding to the reporting year, and a sequentially assigned four digit ID number. The event report identification number should be referenced by the Agreement State for all telephone, electronic or written notifications involving each specific event.

b. Basic Event Information

Appendix E of this handbook provides a listing of the minimum event information that should be provided. When submitting an initial event report, please provide as much information as is known at the time the report is prepared regarding the items indicated in the Appendix. It is understood that this initial information may be incomplete or preliminary. Updated information should be subsequently provided in follow-up reports (see Section 2.4).

c. Electronic Reporting to NMED

Agreement States may provide an electronic NMED report to the NMED contractor by using the local NMED Agreement State software, which may be downloaded from the NMED website, or by using the document "Upload" function on the NMED website. If you need additional help, you may contact the NMED contractor or the NRC NMED Project Manager. For contact via telephone, email or mail, refer to the contact information on the NMED website.

d. Access to NMED

A search of the nationally collected data is available on the NMED website with several drop-down, point-and-click menus available. Access to the NMED is controlled through the NRC NMED Project Manager. If access is required, contact the NRC NMED Project Manager by email at NMEDNRC@nrc.gov. Access to NMED is only provided to NRC,

Agreement States, other federal government agencies, and/or federal government contractors who have the need to use the event information in NMED.

e. **Written Event Reports**

Written event reports should be sent to the Branch Chief, RMSB at the address listed in Appendix C. Reports should be provided in an optical character recognition (OCR) format. Please include an event report cover page for all written event information provided to NRC. Use of an event report cover page helps ensure our document control staff can readily identify, classify and appropriately record the document. A sample event report cover page is provided in Appendix F of this Handbook.

Also, the Agreement States should refrain from providing information that is considered sensitive (e.g., personal privacy, proprietary, and/or security related information (e.g., sensitive unclassified non-safeguards information (SUNSI))). If such information is required to describe the event, the Agreement State should provide a bracketed copy of the information that identifies the information that should be protected and a redacted copy of the information that deletes such information.

2.4 Reporting Follow-up Event Information

Follow-up information for nuclear material event reports (e.g., providing additional information regarding initial event reports) should provide the results of investigations as to what, where, when and how the event or conditions occurred. Agreement States should provide the items below when reporting follow-up information:

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

2.5 Radiological Emergency Response Assistance Available to the States

Agreement States may request radiological emergency response assistance by contacting the NRC's Operations Center. The Federal government, upon request, has the capability to provide assistance to States in responding to radiological emergencies. Under the National Response Framework, NRC is the coordinating agency for domestic incident management for incidents involving nuclear materials or facilities licensed by the NRC or Agreement States. As the coordinating agency, NRC may request assistance from other agencies, (e.g., Department of Homeland Security, Department of Energy, etc.) which could also include the Agreement States. Federal assistance could include ground and aerial radiological monitoring (e.g., missing source), medical advice on radiation effects and treatment, consequence projection, and protective action assessment.

2.6 International Nuclear Event Scale Reporting

Since 2004, the NRC and the Agreement States have shared event information with the international community for the rating and reporting of nuclear, transportation and radiation source events, using the International Atomic Energy Agency (IAEA) International Nuclear Event Scale (INES). INES is a scale that is used for rating safety significance of events associated with the use of nuclear or radioactive materials.

INES events involve those which are regulated by NRC or the Agreement States, and are eligible for rating. The NRC does not require the States to classify events or to provide direct notifications to IAEA using the INES scale. The NRC will use information provided by the States during their initial reporting and updates of the event for classifying the event and notifying IAEA. The NRC has committed to transmit to the IAEA an INES-based rating for an applicable event that is rated at an INES Level 2 or higher. The NRC will notify the IAEA within 2 business days when it has been determined that an event has a provisional or final INES rating of Level 2 or higher. For events that occur in an Agreement State, the NRC Regional State Agreement Officer (RSAO) will provide the State with the draft INES event report within 24 hours of its generation. The States are asked to concur that the information in the report is factual. If the State cannot review the draft INES event report in time to meet the two business day reporting deadline, NRC will provide the report to INES, and mark the event Provisional.

For further information on INES reporting procedures and rating criteria, please see NRC Management Directive 5.12, "International Nuclear Event Scale Participation," which may be found at <http://www.nrc.gov/reading-rm/doc-collections/management-directives/volumes/vol-5.html>.

2.7 Voluntary Reporting of Lost, Stolen and Abandoned Sources

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 the owner could not be identified), and expanded again in 2002 to capture voluntary reports of lost or stolen non-AEA discrete sources. This was done at the request of CRCPD to support their national effort to track lost, stolen and recovered radioactive material of all types (including non-AEA and unlicensed material) found in both Agreement and non-Agreement States. (Note that in 2007, the definition of byproduct material under the AEA was expanded to include some of this material that had been “non-AEA.”) The reportable as well as voluntary data on lost, stolen, and abandoned sources will be collected from Agreement and non-Agreement States, and in some cases non-licensee organizations and members of the public. Agreement and Non-Agreement States should follow the guidance provided above in Section 2.3 “5 – 60 Day Event Reporting” to report any lost, stolen and abandoned non-AEA and unlicensed material.

2.8 Reporting Theft or Terrorist Activity

The U.S. Federal Bureau of Investigation (FBI) notification should be considered if an event involves the possibility of *theft or terrorist activities*. Agreement States shall promptly notify the NRC Operations Center (i.e., the HOO) after contacting the appropriate Local Law Enforcement Agency (LLEA) and/or the FBI in cases involving actual or attempted theft, sabotage, or diversion of radioactive material containing quantities greater than or equal to the quantities of concern of radioactive material as indicated in Appendix G of this handbook. Agreement State Regulatory Agencies should consider notifying the FBI or LLEA in all cases of actual theft, sabotage, diversions and possible terrorism of radioactive material, regardless of the quantity of radioactive material involved. This includes intentional use of radioactive materials that could be used in an unauthorized malevolent manner that could lead to serious consequences. Agreement States should coordinate with the NRC, their communications with other local, Federal and State Agencies, to ensure that shared information is accurate and consistent. Based on health and safety significance the issuance of a press release should also be considered. (See All Agreement State Letter SP-98-038, dated May 5, 1998, regarding expansion of the FBI criminal investigative jurisdiction to include byproduct material. A revision to the U.S. Code assigns lead responsibility for material events involving ***theft or terrorist activities*** to the FBI.) If it is not clear whether an event should be categorized as a possible theft or terrorist activity, the Agreement State should contact the NRC Headquarters Operations Center for assistance in determining if the event should be reported.

3. Closing and Completing Events

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 regulatory agency under “Event Closed by Region/State.” Agreement States should notify the NMED contractor when the event record has been officially closed (i.e., no further follow-up planned and/or no additional information expected). The State should ensure that the record contains all pertinent technical information, including follow-up information before closing the record.

3.2 *Record Complete in NMED*

A “complete record” refers to an NMED record that contains a specified minimum set of information. This minimum set of information is defined in Appendix E and may also be found on the NMED website under “Help.” Once the minimum information is provided, the NRC/NMED contractor marks the NMED record as “complete.” It should be noted that a “complete” record still remains open in NMED until the State has indicated the record should be closed.

4. NRC Publication and Distribution of Event Notifications

4.1 *Event Notifications (ENs)*

All events that are required to be reported to the NRC Operations Center are currently entered into the NRC Event Notification database. Most ENs are publicly available on NRC's public website at <http://www.nrc.gov/reading-rm/doc-collections/>, under "Events, Reports", within five business days of notification. As a result of public access to this information, Agreement States may be contacted by the public or media regarding events. Typically, the NRC will withhold Agreement State reports from public release for at least three business days.

4.2 *Preliminary Notifications (PNs)*

Preliminary Notifications (PNs) are brief summary reports issued and prepared by the NRC staff to notify the Commission of the occurrence of a significant event. PNs are based on information provided by the Agreement State radiation control program staff. PNs are usually issued within the same business day of the notification (or the next business day if the event is reported after hours or on the weekend). PNs will be available on NRC's public website under "Events, Reports" at <http://www.nrc.gov/reading-rm/doc-collections/>. Updates to PNs occur when significant additional information about an event is provided to NRC. When preparing PNs, NRC staff will generally contact the Agreement State.

5. NRC Safety Reviews of Material Event Reports

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

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

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

Requests for additional information: Based on the results of the nuclear material event safety and generic assessment review, Agreement State staff may be contacted by the RSAO by phone or email to discuss the event. Additional information may be requested to help determine the safety significance and any possible generic implications (e.g., equipment malfunction or failure, significant exposures). For significant events (i.e., immediate or 24 hour reportable events) such requests, normally initiated by the RSAO or NRC's Operation Center staff, would occur on an as needed basis, possibly within hours to a few days of notification of the occurrence.

For events not considered to be significant (i.e., not required to be reported within 24 hours), the standard procedure is to allow at least 30 days before making such requests to provide reasonable time for Agreement State review and evaluation, and submission of follow-up information. A request for follow-up information may also be sent routinely via email by the NMED contractor, (e.g., when the NMED record is incomplete after 60 days from the date reported to the regulatory agency).

5.2 *Actions NRC May Take after Review of “Significant” Events*

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

6. Agreement State Safety Reviews of Material Event Reports

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

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

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

6.2 Actions Agreement States May Take after Review of Significant Events

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

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 AO 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 AOs. 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 to the NRC on potential AOs that have occurred in their State. For more information on AO reporting please see NRC's Management Directive 8.1.

7.2 AO Policy Information

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

- (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 of the ERA, within 15 days of receiving information of each AO, the Commission shall widely disseminate AO information to the public.

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, security, and/or the environment. This type of incident or event would have a moderate or severe impact and could include, but need not be limited to the following:

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

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

The AO Report to Congress is also used to provide information on significant materials issues and on adverse licensee performance. In accordance with SECY-02-216, "Proposed Process for Providing Information on Significant Nuclear Materials Issues and Adverse License Performance" and SECY-11-0132, "Revision of the Criteria for Identifying Nuclear Materials Licensees for Discussion at the Agency Action Review Meeting," Agreement State licensees will be considered, along with NRC nuclear material licensees, for discussion during the Annual Agency Action Review Meeting (AARM). NRC's Management Directive and Handbook 8.14, "Agency Action Review Meeting," describes FSME and the NRC Region's participation in the AARM and its role as the lead for the discussion on Agreement State licensees, as necessary.

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, the Agreement States are expected to provide a draft special AO report (i.e., write-up) as described below. The NRC will assist the Agreement States in preparing the write-ups for potential AOs. The criteria used to determine if an event is an AO can be found in the most recent version of NUREG-0090, "Abnormal Occurrence Report to Congress" (see Appendix A) at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0090/>. Please note that if the AO criteria changes, the NRC will notify the Agreement States. Also, the Agreement States may contact their RSAO or the NRC NMED project manager to ensure they have the most current AO criteria.

7.4 Guidelines for AO Write-ups

AO write-ups should be complete, up-to-date, and written using text that is understandable to non-technical readers. Also, when preparing the AO write-up, the Agreement States should refrain from providing confidential, personal privacy, and/or security related information unless the information is required to describe the AO. If confidential, personal privacy, and/or security related information is included in the report, the report should be properly marked to indicate such information exist. The AO write-up should be formatted to include the following:

First paragraph - State the AO criteria for the event by citing the appropriate section of Appendix A of NUREG-0090, which contains all of the AO criteria.

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

Nature and Probable Consequences - Briefly explain the event and the circumstances surrounding the occurrence, and what were the consequences. Provide the specific details of the event to include the: exposure (where applicable), source, specific radionuclide(s), quantity, dose (where applicable), treatment plan (where applicable), equipment/devices with the manufacturer and model number. Describe any immediate actions taken by the licensee and the State (e.g., decontaminated the facility, evacuated the staff, special

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

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

For medical events, include the intended and actual treatment plan. For example, as applicable; state the prescribed dose and the actual delivered dose to the intended treatment site; state any doses to unintended sites (include the dose and the site); state the prescribed radioisotope and/or radiopharmaceutical and the radioisotope/radiopharmaceutical actually administered; and describe the prescribed mode of treatment and the actual mode of treatment delivered. Indicate whether the patient and referring physician were notified of the event. Also, state the medical significance of the event to the patient (e.g., The licensee concluded that the medical event would not have a significant medical effect on the patient).

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

Cause(s) - Describe what the causes of the event were determined or estimated to be, including any contributing factors leading up to the event.

Actions taken to prevent recurrence - Briefly explain what corrective actions (e.g., developed new procedures, hired more staff, etc.) were taken to prevent recurrence by the licensee. Also, the Agreement State should indicate the actions they took to prevent recurrence (e.g., any enforcement actions or penalties given to the licensee and/or individual(s)).

Last paragraph - If all the reporting requirements have been met for the AO event, then a statement such as "This event is closed for the purpose of this report" should be included in the last paragraph to indicate that the event has been closed. However, the AO will be kept open if there is a reasonable expectation that currently unavailable information will be obtained shortly. Also, if significant new information becomes available for a closed AO at a later date, the AO will be reopened, the new information will be reported under "Updates of Previously Reported Abnormal Occurrences" (NUREG-0090, Appendix B), and the AO will again be closed out.

For examples of AO write-ups see NRC's NUREG-0090 at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0090/>

Appendix A

NRC Regulatory Reporting Requirements

NRC Regulatory Reporting Requirements

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

Regulatory Requirement	Reporting Category		Brief Summary of Reporting Requirement	Notification
	Within 24 hours	5 - 60 Days		
10 CFR Part 20 , Standards for Protection Against Radiation	<u>20.1906(d)(1)</u>		Reports of removable contamination on package > limits in <u>10 CFR 71.87</u> .	Immediate
	<u>20.1906(d)(2)</u>		Radiation levels on package > limits in <u>10 CFR 71.47</u> .	Immediate
	<u>20.2201(a)(1)(i)</u>		Reports of loss, stolen or missing licensed material ≥ 1000 X Appendix C value under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas.	Immediate
		<u>20.2201(a)(1)(ii)</u>	Reports of loss, stolen or missing licensed material > 10 X Appendix C value and is still missing at this time (i.e., within 30 days it becomes known to the licensee).	30 days
	<u>20.2202(a)(1)</u>		Exposure (real or threatened) \geq TEDE of 25 rem (.25 Sv), or lens dose equiv. \geq 75 rem (.75 Sv) or shallow dose equiv. (skin/extremities) \geq 250 rads (2.5 Gy).	Immediate
	<u>20.2202(b)(1)</u>		Exposure (real or threatened) \geq TEDE of 5 rem (.05 Sv), or lens dose equiv. \geq 15 rem (.15 Sv), or shallow dose equiv. (skin/extremities) \geq 50 rems (.5 Sv).	24 hours
	<u>20.2202(a)(2)</u>		Release where individual could have intake ≥ 5 X ALI over 24 hours.	Immediate
	<u>20.2202(b)(2)</u>		Release where individual could have intake > 1 X ALI over 24 hours.	24 hours
		<u>20.2203(a)</u>	Radiation doses, releases or concentrations of radioactive material that exceed the limits.	30 days

NRC Regulatory Reporting Requirements

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

Regulatory Requirement	Reporting Category		Brief Summary of Reporting Requirement	Notification
	Within 24 hours	5 - 60 Days		
10 CFR Part 30 , Rules of General Applicability to Domestic Licensing of Byproduct Material	<u>30.50(a)</u>		Events involving prevention of immediate protective actions, necessary to avoid exposures to radiation, radioactive materials or releases of radioactive material that could exceed regulatory limits.	Immediate
	<u>30.50(b)(1)</u>		Events involving an unplanned contamination (Under <u>30.50(b)(1)</u> , see items (i)-(iii) for other conditions that apply).	24 hours
	<u>30.50(b)(2)</u>		Events in which equipment is disabled or fails to function as designed. (Under <u>30.50(b)(2)</u> , see items (i)-(iii) for other conditions that apply).	24 hours
	<u>30.50(b)(3)</u>		Events involving unplanned medical treatment of contaminated person.	24 hours
	<u>30.50(b)(4)</u>		Events involving unplanned fire, or explosion affecting integrity of material, device or container, or equipment containing licensed material. (Under <u>30.50(b)(4)</u> , see items (i)-(ii) for other conditions that apply).	24 hours
10 CFR Part 31 , General Domestic Licenses for Byproduct Material		<u>31.5(c)(5)</u>	Shall immediately suspend operation of a device if there is a failure of or damage to the shielding or an indication of a failure of or damage to the shielding, or the on-off mechanism or indicator, or upon detection of 185 becquerel (0.005 microcurie) or more of removable radioactive material, and submit a written report within 30 days. (See the rest of Paragraph (c)(5) for other conditions and restrictions that apply). (See also 10 CFR 30.50 requirements and other sections of the regulations (e.g., 10 CFR 21.21)).	30 days
10 CFR Part 34 , Licenses for Radiography & Radiation Safety Requirements for Radiographic Operations		<u>34.27(d)</u>	Reporting of leaking sources, leak test results ≥ 0.005 microcurie (185 Bq).	5 days
		<u>34.101(a)</u>	Radiography source disconnection, inability to retract source, or component failure (critical to safe operation of device). (See also 10 CFR 30.50 requirements and other sections of the regulations (e.g., 10 CFR	30 days

NRC Regulatory Reporting Requirements

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

Regulatory Requirement	Reporting Category		Brief Summary of Reporting Requirement	Notification
	Within 24 hours	5 - 60 Days		
10 CFR Part 35 , Medical Use of Byproduct Material			21.21)).	Next calendar day
	<u>35.3045</u>		Notifications and reports of medical events involving administration and use of byproduct materials, with the exception of patient intervention events.	
	<u>35.3047</u>	<u>35.3067</u>	Reports of leak test results that demonstrate the presence of 185 becquerel (0.005 microcurie) or more of removable contamination. Events involving an unauthorized dose of 50 mSv (5 rem) to an embryo/fetus or a nursing child, or an unintended functional damage to an organ or a physiological system of the child.	5 days Next calendar day
10 CFR Part 36 , Licenses & Radiation Safety Requirements for Irradiators	<u>36.83</u>		The following events are reportable under 36.83 if not reported under other NRC reporting requirements: stuck sources, fire/explosions, damage to source racks, cable or drive mechanism failure, access control system failure, detection of source by the product exit monitor, contamination from licensed material, etc. (See items (a)(1) through (10) under <u>36.83</u> for specific descriptions of reportable events.	24 hours
10 CFR Part 39 , Licenses & Radiation Safety Requirements for Well-Logging		<u>39.35(d)(2)</u>	Report of leak test results (of sources leak tested at intervals not greater than every 6 months) when the presence of 185 becquerel (0.005 microcurie) or more of contamination is detected. (See remaining paragraphs under <u>39.35</u> for other conditions, including exemptions, that apply.)	5 days
	<u>39.77(a)</u>		Well logging source rupture.	Immediate
	<u>39.77(b)</u>		Theft or loss, exposures, excessive concentration of radioactive material.	Immediate
		<u>39.77(c)</u> and (d)	After notification and classification that a source is irretrievable, a report	30 days

NRC Regulatory Reporting Requirements

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

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

NRC Regulatory Reporting Requirements

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

Regulatory Requirement	Reporting Category		Brief Summary of Reporting Requirement	Notification
	Within 24 hours	5 - 60 Days		
			spillage, or suspected radioactive contamination occurs involving the shipment of radioactive material.	
<u>Orders Imposing Increased Controls (IC) (EA-05-090, Attachment B)</u>	<u>IC.2.d</u>		After initiating an appropriate response to any actual or attempted theft, sabotage, or diversion of radioactive material, licensees shall notify the NRC Operations Center.	Immediate
<u>Orders Imposing Increased Controls (IC) (EA-05-090, Attachment B)</u>	<u>IC.3.a.4</u>		During transportation of licensed material, if a shipment does not arrive on or about the expected arrival time and through the investigation it is determined that the shipment has become lost, stolen, or missing, the licensee shall immediately notify the NRC Operations Center.	Immediate
<u>Orders Imposing Fingerprinting and Criminal History Records Check (IC) (EA-07-305)</u>	<u>III.A.5</u>		Notify the NRC's Operations Center if the results from a FBI identification and criminal history records check indicate that an individual is identified on the FBI's Terrorist Screening Database.	24 hours

Appendix B

Examples of Reportable Events

EXAMPLES OF REPORTABLE EVENTS

This Table provides examples of reportable nuclear material events that are required to be reported by the Agreement States to the NRC.

<p>Immediately reportable under 10 CFR 20.2201(a)(1)(i)</p>	<p>Stolen Portable Moisture Density Gauge</p> <p>Licensee [Name][License Number] reported that a [Manufacturer] [Model #] [serial #] portable gauge containing 10 millicuries of cesium-137 and 50 millicuries of americium-241:beryllium was stolen from the licensee's vehicle parked at the licensee's facility [Address]. The gauge was padlocked in its original carrying case. The State is following the incident and working with local authorities to develop a press release. Local law enforcement and the FBI have been notified. Follow-up information will be provided to NRC on the recovery of the stolen gauge and entered into NMED.</p>
<p>Immediately reportable under 20.1906(d)(2)</p>	<p>Shipment of Brachytherapy Sources Received with Radiation Levels Exceeding Regulatory Limits</p> <p>A medical licensee [Name][License Number] reported receiving a shipment of two packages containing cesium-137 brachytherapy sources. Radiation surveys of the packages found radiation levels of 250 millirem per hour on one package, which exceeds the State and Federal limit at the external surface of a package of 200 millirem per hour. The third and final package was received two days later with radiation levels of 400 millirem per hour at the surface of the package. The shipper has retained a consultant to determine the cause of the elevated radiation levels. The State will keep NRC informed of the results of the consultant's review of the event.</p>
<p>Reportable within 24 hours under 10 CFR 20.2202 (b)(1)(i)</p>	<p>Exposure to Non-radiation Worker at a Licensed Facility</p> <p>A licensee [Name][License Number] reported to the State that a non-radiation worker had received an exposure as a result of picking up a 5 curie americium-241:beryllium neutron source used for well logging and placed it in his pocket. The worker, a temporary contractor employee, was cleaning a well logging tool at the licensee's 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.</p>

<p>Reportable within 24 hours under 10 CFR 30.50(b)(2)</p>	<p>Loss of Control and Damage to Portable Gauge</p> <p>Licensee [Name][License Number] reported that a [Manufacturer] [Model #] [serial #] moisture density gauge had been damaged on [Date]. 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 not damaged. However, the source was in an unshielded position. Wipe tests and instrument survey verified leakage. The gauge was returned to the manufacturer for repair. The licensee was cited for not keeping licensed material under constant surveillance in an unrestricted area. Follow-up information will be provided to NRC.</p>
<p>Reportable within 24 hours under 10 CFR 30.50.(b)(2) and reportable within 30 days under 10 CFR 34.101(a)(2)</p>	<p>Radiography Camera Source unable to Retract</p> <p>A licensee [Name][License Number] reported the inability to retract a 2.072 TBq (56 Ci) Ir-192 source ([Source Model #], [Serial #]) into the radiography exposure device ([Manufacturer][Model#][Serial #]) on [Date]. The radiographers had used a double gear control assembly throughout the day without a problem. Later, the radiographers cranked out the source to conduct an exposure and were unable to retract the source. The radiographers removed the cover plate on the control assembly and pulled the drive cables in order to retract the source into the exposure device. The device was locked and the drive cable was disconnected from the source pigtail. The radiation area was repositioned and maintained throughout the incident. The source had been extended for approximately three minutes. The exposure device was physically inspected and determined to be in good working condition. The double gear control assembly was returned to the manufacturer. The manufacturer stated that they were unable to replicate the failure. However, they did note that the gears offered a large amount of resistance, had impurities, and that the drive cable was out of tolerance.</p>
<p>Reportable by next calendar day under 10 CFR Parts 35.3045(a)(1)(i) and within 24 hours under 30.50(b)(2)</p>	<p>Medical Event involving a Gamma Knife Malfunction</p> <p>A licensee [Name][License Number] reported that a patient only received 5% of the prescribed dose during a gamma knife procedure performed on [Date]. The RSO stated that while conducting a single fraction exposure to the patient, the computer screen froze. The patient was immediately removed from the gamma knife unit ([Manufacturer][Model#][Serial #]), which contained Co-60 sources ([Source Model #], [Serial #]) with a total activity of 102.34 TBq (2,766 Ci). The patient was prescribed to receive 2,000 cGy (rad) to one location and 1,500 cGy (rad) to a second location, both to be delivered simultaneously. The referring physician and patient were notified of the event. The service provider for the gamma knife responded and replaced the control unit. The manufacturer stated that the event occurred due to a computer programming problem. The timer that froze is used to display the total run time of the treatment and does not control any part of the treatment. They also stated that the treatment would have run normally</p>

	had the technician not stopped it and the patient would have received the prescribed dose. The manufacturer is resolving the problem in their latest upgrade to the system.
Reportable by next calendar day under 10 CFR Part 35.3045 Note: May be classified as a potential AO.	<p>Medical Event involving prostate brachytherapy</p> <p>A licensee [Name][License Number] reported a medical event involving a patient treated for prostate cancer. The treatment included implanting 65 I-125 brachytherapy seeds ([Manufacturer][Model #]), containing a total activity of 0.814 GBq (22 mCi), in the patient's prostate for a prescribed therapeutic radiation dose of 14,500 cGy (rad). The prostate gland only received approximately 500 cGy (rad). The seeds were implanted on [Date] using real time dosimetry under ultrasonic guidance. On [Date], the patient returned to the facility for a 30-day post implant CT scan. The scan showed that the implanted seeds, although in an appropriate pattern, were placed outside the intended target. The Licensee's Radiation Oncology group determined that an additional quality assurance review was warranted. The State performed a reactive inspection during the week of [Date]. Initially, a malfunction of the ultrasound unit was suspected. That unit was re-evaluated and was determined to be working properly. The cause was determined to be human error. An unintended dose to the penile bulb of approximately 16,100 cGy (rad) was received, where no dose was anticipated. The Radiation Oncology Department suspended prostate brachytherapy treatments. Corrective actions included changes to the prostate brachytherapy protocol to incorporate an additional step to ensure the urologist and radiation oncologist clearly identifies the prostate gland and the surrounding anatomy. The treatment will be cancelled if the prostate gland and surrounding anatomy cannot be visualized adequately.</p>
Written report within 30 days under 10 CFR Part 31.5(c)(5)	<p>A Leaking Source from a General Licensed Device</p> <p>On [Date], a licensee [Name][License Number] reported that a 555 MBq (15 mCi) Ni-63 source was leaking. The source was part of a Hewlett Packard electron capture detector ([Manufacturer][Model#][Serial #]). A routine wipe test of a gas chromatograph ([Manufacturer][Model#][Serial #]) containing two ECDs was performed on [Date] after receiving the gas chromatograph from another licensee. On [Date], the wipe test results indicated that the ECD had 222 Bq (0.006 uCi) of removable contamination wiped from the outlet port. The result of a second wipe of the same port was approximately 1.85 Bq (0.00005 uCi). The ECD was secured and stored pending disposal. The ECD was sent to the manufacturer for disposal on [Date].</p>

<p>Reportable within 24 hours under 10 CFR Parts 36.83(a)(9), 30.50(b)(2)</p> <p>(Note: since water level was later verified to be normal, this is no longer a 36.83 issue)</p>	<p>Possible Loss of Water or Leakage from Source Water Pool at Irradiator Facility</p> <p>Licensee [Name][License Number] notified the State that the controls at a Co-60 irradiator facility were indicating that the water level was low, circulating pump off, and fill valves were open. The pool water level gauge indicated pool water level of 93 inches, well below the normal level of 137 inches. Previous incidents indicated that a loss of compressed air pressure to the water level gauge could result in an erroneously low water level gauge reading, causing the automatic pool fill valves to open, and the pool water circulating pump to turn off. The compressed air system pressure was found to be in the normal range, but the operator found water and congealed oil in the air line supplying the pool water level gauge, and the air line supplying the elevator control valve. Further investigation found that the compressed air line water traps were full of water. A past similar incident resulted in a failure to raise the elevator. The operator then verified that the pool water level was in fact normal. The licensee requested the building maintenance personnel to diagnose and repair the compressed air supply immediately, to prevent the conductivity in the pool water from reaching abnormal levels as a result of the resin filter circulating pump being automatically turned off by the false low pool water level meter reading. Maintenance personnel responded and replaced a failed compressed air dryer, and monitored the open air lines to clear the lines of water. A float activated automatic water drain was installed in the air line to prevent a possible recurrence by allowing any water to automatically drain from the air line.</p>
---	---

Appendix C

Event Reporting Schedule

Event Reporting Schedule for Agreement States			
	REPORTABLE EVENT NOTIFICATION¹	AGREEMENT STATE REPORTING SCHEDULE TO NRC	REPORTING METHODS TO NRC⁴
IMMEDIATE	Significant reportable events requiring immediate notification (i.e., within 4 hours or less²) by Agreement State licensees.	Agreement States should report to NRC immediately of notification by an Agreement State licensee.	Report initial information to the NRC Operations Center⁵ (301) 816-5100 FAX #: (301) 816-5151 Email: HOO.HOC@nrc.gov
	Significant reportable events requiring notification within 24 hours or less, or next calendar day , by Agreement State licensees.	Agreement States should report to NRC within 24 hours of notification by an Agreement State licensee.	
24 HOURS	Events involving theft or terrorist activities should be reported to the FBI³ .	Agreement States should consider reporting to the FBI within 24 hours of notification.	
	5 – 60 day reportable events requiring greater than 24 hour notification by Agreement State licensee and event follow-up reports.	Agreement States should provide 5 - 60 day notification within the same timeframe licensees must report the event to the Agreement States, and any follow-up reports should be provided in a timely manner ⁶ .	NMED Local Agreement State Software or NMED website at http://nmed.inl.gov/ or Mail: U.S. NRC, Branch Chief of RMSB/MSSA, Mail Stop T-8-E24, Washington, DC 20555
5 - 60 DAYS	Lost, stolen, or abandoned sources reported to the Agreement and non-Agreement States 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. ⁷	NMED website at http://nmed.inl.gov/ or Mail: U.S. NRC, Branch Chief of RMSB/MSSA, Mail Stop T-8-E24, Washington, DC 20555
VOLUNTARY			

- ¹ Privacy Act Information - Personal or sensitive information should not be included in event descriptions (e.g., names, personal addresses, or-social security-numbers).
- ² For example, events involving lost, actual or attempted theft, sabotage, or diversion of radioactive materials or devices containing “high-risk” sources in quantities greater than or equal to the *quantities of concern* (i.e., quantities greater than or equal to Category 2 sources listed in the International Atomic Energy Agency’s Code of Conduct and as outlined in reporting requirements in 10 CFR Part 20.2201).
- ³ 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).
- ⁴ A sample fax to the NRC Operations Center is available in Appendix D of FSME procedure SA-300.
- ⁵ 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.
- ⁶ An example of the minimum basic event information required for a complete record is provided in Appendix E of SA-300.
- ⁷ Voluntary reporting is a joint national effort of the NRC and the Conference of Radiation Control Program Directors (CRCPD) to track certain non-AEA, unlicensed or non-reportable AEA lost and found radioactive material.

Appendix D

Sample Fax Sheet to NRC Operations Center

**FAX TO: NRC OPERATIONS CENTER
(301) 816-5151**

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

Appendix E

Minimum Required Event Information

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

Appendix F

Sample Event Report Cover Page

AGREEMENT STATE

EVENT REPORT ID NO. __ - __ - __

(State\YY\No.) |

DATE:

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

SUBJECT:

STATE:

Signature and Title:

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

Appendix G

Radionuclides of Concern

Radionuclides of Concern

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

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

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

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

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

⁵ On August 31, 2005, the NRC issued a waiver, in accordance to Section 651(e) of the Energy Policy Act of 2005, for the continued use and/or regulatory authority of Naturally Occurring and Accelerator-Produced Material (NARM), which includes Ra-226. The NRC plans to terminate the waiver in phases, beginning November 30, 2007, and ending August 7, 2009. The NRC has authority to regulate discrete sources of Ra-226, but has refrained from exercising that authority until the date of an entity's waiver termination. For entities that possess Ra-226 in quantities of concern, this Order becomes effective upon waiver termination. For information on the schedule for an entity's waiver termination, please refer to the NARM Toolbox website at <http://nrcstp.ornl.gov/narmtoolbox.html>.

Appendix H

Glossary

ADAMS	Agencywide Documents Access and Management System, NRC's official record electronic recordkeeping system, approved by the National Archives and Records Administration on April 1, 2000.
AO	Section 208 of the Energy Reorganization Act of 1974 defines an Abnormal Occurrence (AO) as an unscheduled incident or event which the U.S. Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety.
CRCPD	Conference of Radiation Control Program Directors. A non-profit entity representing the radiation control programs of each States (not limited to Agreement States).
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.
FSME	NRC's Office of Federal State and Materials and Environmental Management Programs develops, implements and oversees the regulatory framework for industrial, commercial, and medical uses of radioactive materials, uranium recovery activities and the decommissioning of previously operating nuclear facilities and power plants.
Gray	Gray (Gy) is the SI unit of absorbed dose. One Gray is equal to an absorbed dose of 1 joule/kilogram (100 rads).
Generic Concern	Generic concerns are events of a general safety concern, but do not rise to the level of generic issues. Generic concerns may involve an issue of ongoing concern with one or more licensees.
Generic Issues	Generic issues are complex safety or security issues that require extensive NRC staff and industry involvement to resolve. Several criteria must be met for an event to be identified as a generic issue. These criteria include: 1) the event is a well-defined, discrete, technical or security issue, of which the risk or safety significance can be adequately determined; 2) the involves an issue that affects two or more facilities and/or licensees, or holders of other regulatory approvals; 3) the event affects the public health and safety, the common defense and security, or the environment; 4) the event involves an issue not already being processed under an existing NRC program or process; and 5) the event involves an issue that cannot be readily addressed through existing regulations, policies, or guidance; or

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

Metric System

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

MSSA

FSME's Division of Material Safety and State Agreements (MSSA) works with the Agreement States, non-Agreement States, NRC Regional Offices, NRC licensees, and the public to provide structure and implement the national materials program to enable the safe and secure use of radioactive materials in medical, industrial, and academic applications for beneficial civilian purposes.

NMED

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

NRC Ops Center

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

PN

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

RMSB

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

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

References

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

NRC Policy

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*, dated June 30, 1997

Final Policy Statement on Adequacy and Compatibility of Agreement State Programs, dated September 3, 1997

NRC Report

Report to Congress on Abnormal Occurrences, NUREG-0090

Congressional Budget Justification FY 2013, NUREG-1100, Vol. 28, February 2012, annual report to Congress required by GPRA.

FSME Licensee Newsletter, NUREG/BR-0017

NRC Management Directives

- 5.9 Adequacy and Compatibility of Agreement State Programs
- 5.12 International Nuclear and Radiological Event Scale (INES) Participation
- 6.4 Generic Issues Program
- 8.1 Abnormal Occurrence Reporting Procedure
- 8.10 NRC Assessment Program for an Event Occurring at a Medical Facility
- 8.14 Agency Action Review Meeting, AARM

NRC Inspection Manual Chapters

- 1301 Response to Radioactive Material Incidents That Do Not Require Activation of the NRC Incident Response Plan
- 1302 Follow-up Actions and Action Levels for Radiation Exposures Associated with Material Incidents Involving Members of the Public
- 1303 Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE)

- 1330 Response to Transportation Accidents Involving Radioactive Materials
- 1360 Use of Physician and Scientific Consultants in the Medical Consultant Program
- 2800 Materials Inspection Program

FSME Correspondences

All Agreement State Letter (SP-98-018), dated March 17, 1998, “Use of the Nuclear Material Events Database (NMED) as a Central Listing of Lost or Stolen Sealed Sources and Devices.”

All Agreement State Letter (SP-98-038), dated May 5, 1998, “Expansion of Federal Bureau of Investigation (FBI) Criminal Investigative Jurisdiction to Include Byproduct Materials.”

FSME Procedures

- SA-100 Implementation of the Integrated Materials Performance Evaluation Program
- SA-105 Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities
- 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.

NRF The *National Response Framework* is a guide that details how the Nation conducts all-hazards response– from the smallest incident to the largest catastrophe. This document establishes a comprehensive, national, all-hazards approach to domestic incident response. The Framework identifies the key response principles, as well as the roles and structures that organize national response. It describes how communities, States, the Federal Government and private-sector and non-governmental partners apply these principles for a coordinated, effective national response. The NRC is the coordinating agency for domestic incident management for incidents involving nuclear materials or facilities licensed by the NRC or Agreement States.

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

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's document collections website at http://www.nrc.gov/reading-rm/doc-collections/ . The Office of Federal and State Materials and Environmental Management Programs (FSME) documents are available at the FSME external website at http://nrc-stp.ornl.gov/ .