Handbook on Nuclear Material Event Reporting in the Agreement States

Final Report

Month 2012

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

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/~~http://www.nrc.gov/NRC/reference.html~~. The Office of Federal and State Materials and Environmental ~~Management Programs~~Management Programs ~~Office of State and Tribal Programs (STP) documents~~ State Agreement (SA) policies and procedures are available ~~at the STP external Website~~ at: ~~http://www.hsrd.ornl.gov/nrc/~~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 January 31, 2013. 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 this burden estimate or any other aspect of these information collections, including suggestions for reducing the burden, to the U.S. Nuclear Regulatory Commission, FOIA/Privacy Officer, Mail Stop T-5-F09, Washington, DC 20555-0001, or by email to FOIA.resource@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0178), Office of Management and Budget, Washington DC 20503.

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

~~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 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~~ing~~ 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 ~~supercedes~~supersedes the previous ~~May 23, 2001~~ March 2006 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 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~~ abnormal ~~Occurrences~~ occurrences ~~(AOs)~~ are also included. The objectives of ~~the~~ this handbook are to:

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

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1. Introduction

This handbook contains guidance for Agreement States on reporting nuclear 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 voluntarily reporting events involving lost, stolen or found sources~~ of naturally occurring and accelerator-produced radioactive materials (NARM)~~. 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 can not 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)~~ involving 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 improves the overall effectiveness of the NRC and Agreement State regulatory programs. Guidance is provided on (1) reporting ~~significant~~ events requiring notification within 24 hours to the NRC Operations Center; (2) providing ~~30~~5 - 60 day notification and follow-up event information; (3) schedule for event reporting; (4) reporting formats~~ (i.e., electronic reporting to the NMED or written reports (mail, Fax, or email) to the Director, Office of State and Tribal Programs (STP)~~; and (5) ~~reporting~~ providing 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 (e.g., coding). For guidance on data entry, an electronic copy of the NMED users guide has been included with the local ~~Microsoft Access~~ NMED Agreement State software ~~program~~ 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 ~~R~~reporting and analysis of ~~operating~~ incidents and events helps to identify deficiencies in the safe use of Atomic Energy Act (AEA) ~~radioactive~~ 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 ~~Agency~~ 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 Agreement States, to identify safety concerns early, and to further evaluate individual events for the possible presence of generic safety concerns or ~~for any~~ generic ~~*safety*~~ issues ~~(GSIs)~~ that could apply to a broader class of licensees. Prompt reporting of event information, including ~~30~~5 - 60 day report information, and updates to events, helps the staff identify or detect possible safety concerns or issues as early as possible. An event or condition could, by itself appear insignificant, but when compared with national information, could ~~become~~ 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 ~~information notices~~ generic communications to provide information and guidance regarding safety concerns and issues. ~~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~~ provides a ~~quarterly~~ 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 ~~is~~are ~~The *Nuclear Material Events (NMED) Database Quarterly and Report* is~~ available in electronic form at the NMED ~~Internet~~ Website~~:~~ ~~https://nmed.inl.gov~~(http://nmed.inl.gov). Also, NRC~~'s~~ Office of ~~Nuclear Material Safety and Safeguards (NMSS)~~Federal and State Materials and Environmental Management Programs (FSME) publishes a quarterly ~~nuclear material~~ licensee newsletter~~,~~ ~~*NMSS Licensee Newsletter*~~, (NUREG/BR-0117)~~,~~ that includes information on nuclear material 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 ~~B~~between the State and the ~~US~~NRC states that "the State and the Commission agree to

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

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.

~~—~~ ~~U~~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~~'s NMED database~~ an item of compatibility (See Reference section, June 30, 1997, ~~SECY-97-054~~Staff Requirements Memorandum). ~~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~~ ensure adequacy and compatibility with the provisions of the Act. NRC conducts periodic evaluations of Agreement State programs under the *Integrated Materials Performance Evaluation Program (IMPEP)*, which includes an evaluation of event response, reporting, follow-up, and close-out. (See ~~Reference for STP~~ FSME Procedures SA-100, ~~,~~ *Implementation of the Integrated Performance Evaluation Program (IMPEP)* and SA-105, *Reviewing the Common Performance Indicator ~~#5, Response to Incidents and Allegations~~ Technical Quality of Incident and Allegation Activities*.

1.3 How do you determine if an event is reportable?

Agreement States ~~should~~ shall report to NRC all events reported to ~~their State~~them ~~by State licensees under~~ in accordance with their State regulations that are ~~equivalent~~ compatible to NRC's reporting requirements. Section 2 of this document provides additional details regarding reporting events. ~~Table 1~~~~Attachment 1~~Appendix A~~, "Regulatory Reporting Requirements,"~~ of this ~~guide~~ handbook contains a listing of the most commonly encountered NRC ~~*U.S. Code of Federal Regulations (10 CFR)*~~ regulatory reporting requirements for nuclear material events ~~information~~. The reporting requirements in Title 10 of ~~T~~the U.S. Code of Federal Regulations (CFR)~~10 CFR reporting requirements~~ form the basis for the ~~equivalent~~ compatible reporting requirements in Agreement State regulations. The ~~listing references~~table in ~~Attachment 1~~Appendix A provides the specific ~~10 CFR reporting requirements~~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 ~~Attachment 1~~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. ~~Table 2~~ Appendix B ~~"Examples of Reportable Events,"~~ provides examples of reportable nuclear material events or occurrences that are required to be reported by both NRC and Agreement State ~~material~~ 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.
~~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 Material 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. ~~NMED is being evaluated with respect to inclusion of events involving NARM or discrete NORM.~~ The Agreement States will be notified of ~~any~~ changes made to NMED. The database is maintained by ~~NMSS~~ FSME through a contractor~~, Idaho National Laboratory (INL).~~ 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.

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

~~Title 10 CFR 20.2201 mandates that each licensee report, by telephone, its discovery of any lost, stolen, or missing licensed material that exceeds specified quantities. Specifically, 10 CFR 20.2201(a)(1)(i) requires an immediate call if the licensed material is equal to or greater than 1000 times the quantity specified in Appendix C to 10 CFR Part 20, under such circumstances that an exposure could result to persons in unrestricted areas. Title 10 CFR 20.2201(a)(1)(ii) requires a call, within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, in a quantity greater than 10 times the quantity specified in Appendix C to 10 CFR Part 20, that is still missing at the time. Title 10 CFR 20.2201(b) requires a written report within 30 days after making the telephone call required by 10 CFR 20.2201(a). Title 10 CFR 20.2201(d) requires that, subsequent to filing the written report, the licensee report any additional substantive information on the loss or theft of the licensed material within 30 days of the knowledge of the substantive information.~~

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

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

~~Although NMED typically contains only events involving AEA material, the NMED database was expanded in 1998 to include voluntary reports of non-AEA orphan discrete sources (sources that are found but where the owner could not be identified), and expanded again in 2002 to capture voluntary reports of lost or stolen non-AEA discrete sources. This was done at the request of CRCPD to support their national effort to track lost stolen and recovered radioactive material of all types (including non-AEA and unlicensed material) found in both Agreement and non-Agreement States. The reportable as well as voluntary data on ***lost, stolen, and abandoned sources*** will be collected from Agreement and non-Agreement States, and in some cases non-licensee organizations and members of the public. Agreement and Non-Agreement States should follow the guidance provided in Section 2, "Reporting Material Events," to report any lost, stolen and abandoned non-AEA and unlicensed material. (See All Agreement State Letter SP-98-018, March 17, 1998).~~

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

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

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
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. [(aggregated source activity for radionuclide A) ÷ (quantity of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) ÷ (quantity of concern for radionuclide B)] + etc..... ≥1

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 immediate or 24-hour reportable events to the NRC Operations Center, (2) 305 - 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. Attachment 1Appendix 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 Significant Events (Reportable within 24 hours by Agreement State licensee)Requiring

Notification Within 24 Hours

Agreement States ~~should~~ shall report ~~significant~~ events requiring notification within 24 hours to the NRC Operations Center's Headquarters Operations Officer (HOO). ~~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 initially reported to the ~~NRC Operations Center~~HOO ~~via voice~~by telephone at (301) 816-5100. Follow-up information for the event may also be provided to the HOO ~~or (301) 951-0550 or~~ by ~~FAX~~ fax at (301) 816-5151 or by email at HOO.HOC@nrc.gov. An ~~S~~example of a ~~FAX~~fax page ~~(Exhibit 1)~~ has been included ~~on page 9~~ in~~-~~ Appendix D of this handbook. Agreement States should assign and provide an Event Report Identification Number ~~[No.]~~ for each reported event. The format for this number is described in Section 2.~~4~~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 ~~Initial~~ NMED Record for ~~Significant~~ Events Reported Within 24 Hours

~~A copy of the initial event notification information received from an Agreement State on significant events is used by INL to establish an initial record in the national NMED database. INL will use the *Event Report Identification No.*, when entering the initial event record into NMED. The Event Report No. is reflected in the "Reference" field of the NMED record and should be used when providing updates to the initial NMED event record using the State's local Microsoft Access, NMED database.~~ 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.~~5~~4~~,~~ of this Handbook for guidance on reporting follow-up event information to NMED). In addition, each event entered into NMED is assigned ~~an~~a unique NMED item number.

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

~~States may request Federal assistance through the NRC Operations Center staff. The Federal government, upon request, has the capability to provide assistance to States in responding to radiological emergencies. Under the National Response Plan (NRP)Framework, 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~~

2.4 ~~3~~ ~~3~~05 - 60 Day Event ~~Notification~~Reporting

~~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 Table 1.~~ Agreement States shall report events that require reporting within 5 to 60 days to the NRC. These ~~R~~reports may be ~~made~~provided ~~either electronically or in written form~~ in writing by mail or electronically. NRC staff encourages Agreement States to electronically report ~~all~~ these events using the local NMED Agreement State software or the document "Upload" program on the NMED website~~database software and entry screens~~. However, if the Agreement State prefers to send the event report via mail, than 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 ~~and NMED~~. For guidance on data entry, an electronic copy of the NMED users guide has been included in the local ~~Microsoft Access~~ NMED Agreement State software ~~program~~. ~~The NMED software program also contains downloadable sample NMED data entry screens.~~

a. ***Assign Event Report Identification Number***

~~This~~ 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 ~~E~~event ~~R~~report identification number ~~No.~~ 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. ~~For events occurring in the State of New York, events should be numbered sequentially following the specific Agency ID and the two digit year (e.g. for New York State Department of Labor, NYDOL-06-001; or New City Department of Health and Mental Hygiene, Office of Radiological, NYC-06-001.)~~ The ~~E~~event ~~R~~report ~~ID~~ identification ~~No.~~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 ~~Table 4, "Minimum Basic Event Information for a Complete Report,"~~ 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 ~~table~~~~Attachment~~Appendix. It is understood that this initial information may be incomplete or preliminary. Updated information should be subsequently provided in follow-up reports (see Section ~~2.5~~2.4).

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

Agreement States may ~~P~~provide an electronic NMED report ~~via E-mail or electronic storage media~~ 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., 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 contractor NMED Project Manager, electronically via Internet email at: NMED@inl.gov, or the NRC NMED Project Manager, Michele Burgess, via e-mail NMEDNRC@nrc.gov. For contact via telephone, email or mail, refer to the contact information on the homepage of the NMED website.

Table 4. Minimum Basic Event Information for a Complete Report	
1. Essential Details (Provide)	**2. Source/Radioactive Material/Devices**
a. State Event Report Identification No.	a. Isotope and activity; manufacturer, model and serial number, leak test results, if applicable.
b. Licensee name and location, including licensing State.	b. For events involving lost, stolen or abandoned material does source exceed IAEA Category 2 quantity? Provide monthly event update through closure of event.
c. License No. or identify as General Licensee, (if applicable).	c. For equipment/device involved indicate the make, model and serial no. and provide clear description of any equipment problems.
d. Event date, time of occurrence and location (site) of event.	**3. Release of Licensed Material or Contamination**
e. Event circumstances and details including source radionuclide and activity.	Release type (air or water); contamination (person or surface); isotope and activity released
f. Date State Agency was notified of event by licensee or non-licensee.	**4. Medical Event**
g. Notifications: local police, FBI, and other States; as needed.	a. Procedure administered; dose intended and dose administered; isotope and activity administered; target organ.
h. Whether the event is NRC reportable and the applicable State reporting requirement.	b. Patient and Referring Physician notified?
i. Persons involved. Note: include position title(s) but do not submit personal or privacy information.	**5. Overexposure**
j. Licensee corrective actions and what actions were performed to prevent recurrence?	a. Indicate short and long-term health effects and exposure type (e.g., whole body or extremity)
k. Possible generic safety concerns.	b. Is event a potential Abnormal Occurrence?
l. Root cause(s) and contributing factors	**6. Transportation**
m. Actions the State took? Onsite inspections, any enforcement actions?	Type of transport; identity of shipper; package type and ID number (if available)

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

~~An NMED~~A search of the nationally collected data is available on the NMED website with several drop-down, point-and-click menus available. ~~Users may download the latest NMED national database information via Internet file transfer.~~ Internet access to the NMED is controlled through ~~INL~~the NRC NMED Project Manager.~~.~~ If access is required, contact the ~~INL~~NRC NMED Project Manager by email ~~message~~ at~~: NMED@inl.gov or the NRC NMED Project Manager by email message 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. ~~*NOTE: Agreement States should continue to use the Microsoft Access data entry program for maintaining a local events database and for submitting NMED event reports to INL.*~~

e. ***Written Event Reports***

Written event reports~~, including E-mail or fax,~~ should be sent to the ~~Director~~Branch Chief, ~~STP~~RMSB ~~or directly to the INL Project Manager~~ at the address listed in ~~at~~ Appendix C~~the NMED homepage at~~. ~~Written report information should be comparable to the minimum basic information identified in Attachment 5.~~ 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~~ an event report cover page helps ensure our ~~Document~~ document ~~Control~~ control staff can readily identify, classify and appropriately record the document. A sample event report cover page is provided ~~as Exhibit 2~~ 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.~~5~~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. ~~—through resolution and close out, should be provided for all events, both significant (24 hr. reportable) and 30-60 day reportable events.~~Agreement States should provide the items below when reporting follow-up information:

a. On a monthly basis, follow-up reports through ~~a~~ the closeout of the event should be provided ~~electronically or~~ in writing to the RMSB Branch Chief at the address listed in Appendix C of this handbook~~Director, STP~~ or ~~directly~~electronically to the ~~INL Project Manager~~ NMED contractor via ~~at the address listed at~~ the NMED ~~homepage~~ website or the

NMED local Agreement State softwareat https://nmed.inl.gov. Enter any new or supplemental information to the initial NMED record. A complete event report should include all investigative and medical information obtained through closeout of the event.

b. Additionally, wWhen providing follow-up NMED 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 NMED 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.

~~1.5~~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~~s~~ Closed by Region/State." Agreement States should notify ~~NRC, through~~ the NMED contractor~~, INL,~~ 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 Regional Office.~~ 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. ~~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, INL, 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 Regional Office. The State should ensure that the record contains all pertinent technical information, including followup information.~~

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

4. NRC Publication and Distribution of Event Notifications

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

All events that are required to be reported to the NRC Operations Center are currently entered into the NRC Event Notification ~~(EN)~~ database. Most ENs are publicly available on NRC's ~~external~~ public~~home page~~ website at ~~(~~) http://www.nrc.gov/reading-rm/doc-collections/, under "Events, Reports", within ~~one to~~ five ~~working~~ business days of notification. As a result of public access to this information, Agreement ~~and non-Agreement~~ States may ~~receive contacts from~~be contacted by the public or media regarding events~~ and requesting additional information~~. Typically, ~~T~~the NRC will withhold Agreement State reports from public release for at least ~~48 hours~~three business days.

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

Preliminary Notifications (PNs) are brief summary reports ~~of significant events~~ 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). ~~Most~~ PNs will be ~~publicly~~ available on NRC's ~~external~~ public ~~home page~~website under -"Events, Reports" at ~~(http//www.nrc.gov)~~ http://www.nrc.gov/reading-rm/doc-collections/. Updates to PNs occur when significant additional information about an event is provided to NRC. When preparing PNs, NRC staff ~~may~~ will generally contact the Agreement State. ~~for additional information on the event.~~

5. NRC Safety Reviews of Material Event Reports

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

A ~~weekly~~ review of all ~~of~~ new and updated nuclear ~~-~~material ~~event notifications (~~ENs~~)~~ received by the ~~Headquarters~~ NRC Operations Center ~~and event notifications and follow-up reports, received and entered into NMED from the Agreement States or NRC licensees,~~ is conducted by NRC staff. The objective of the review is to identify any events that may involve generic ~~safety~~ concerns or issues ~~(GSIs)~~, or could have significant impact on public health and safety, ~~safety or~~ security, and/or the environment. Generic or significant ~~E~~events ~~would include~~that warrant such a review include:

a. ~~1.~~ Multiple occurrences of ~~the~~ an event~~s~~ tracked as performance measures in the Strategic Plan (e.g., medical events, overexposures, lost or stolen sources of concern), or

b. ~~2.~~ 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. ~~3.~~ Events involving possible generic concerns or issues~~,~~ (e.g., equipment malfunctions, equipment failures, inadequate user procedures, software problems), or

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

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

~~The RSAO, or a designee, may contact Agreement States for additional event information~~ For events not considered to be 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. ~~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).

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

Events identified as having a ~~"~~significant~~"~~ potential risk to~~health, safety and security~~ 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 ~~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.~~ 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 ~~all~~ Agreement State Letter.

~~6.~~7. Abnormal Occurrence Guidelines and Criteria

~~6~~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~~ 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 ~~abnormal occurrences~~ 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 ~~proposed~~ potential AOs that have occurred in their State. For more information on AO reporting please see NRC's Management Directive 8.1.

~~6~~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~~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 ~~provide as wide dissemination~~widely disseminate AO information to the public ~~as reasonably possible as soon as such information becomes available~~.

An incident or event will be considered an AO if it involves a major reduction in the degree of protection of the public health or safety, security, and/or the environment. 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 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 ~~AO~~ "Report~~s~~ 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 ~~as 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 ~~events~~ licensees will be considered, along with ~~other~~ NRC nuclear material~~s~~ licensees, for discussion during the Annual Agency Action Review Meeting (AARM). ~~The~~ NRC's ~~revised~~ Management Directive and Handbook 8.14, "Agency Action Review Meeting," describes ~~STP's~~FSME and the NRC Region's participation in the AARM and its role as the lead~~er~~ ~~of~~for the discussion on Agreement State licensees, as necessary.

~~6~~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 ~~are requested to~~ in ~~prepare~~preparing ~~a special written report~~ the write-ups 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 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.

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

~~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[2] 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] An "unintended radiation exposure" includes any occupational exposure, exposure to the general public, or exposure as a result of a medical misadministration (as defined in §35.3045) involving the wrong individual that exceeds the reporting values established in the regulations.~~

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

2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.

3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

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

1. The release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20, unless the licensee has demonstrated compliance with §20.1301 using §§20.1302(b)(1) or 20.1302(b)(2)(ii).

2 Radiation levels in excess of the design values for a package, or the loss of confinement of radioactive material resulting in one or more of the following: (a) a radiation dose rate of 10 mSv (1 rem) per hour or more at 1 meter (3.28 feet) from the accessible external surface of a package containing radioactive material; (b) a radiation dose rate of 50 mSv (5 rem) per hour or more on the accessible external surface of a package containing radioactive material and that meet the requirements for "exclusive use" as defined in 10 CFR 71.47; or (c) release of radioactive material from a package in amounts greater than the regulatory limits in 10 CFR 71.51(a)(2).

C. Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach.[3]

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

1. Any lost, stolen, or abandoned sources that exceed 0.01 times the A_1 values, as listed in 10 CFR Part 71, Appendix A, Table A-1, for special form (sealed/nondispersible) sources, or the smaller of the A_2 or 0.01 times the A_1 values, as listed in Table A-1, for normal form (unsealed/dispersible) sources or for sources for which the form is not known. Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur during the time the source was missing; and unrecoverable sources lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 were not known to have occurred.

2. A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.

3. Any substantiated loss of special nuclear material or any substantiated inventory discrepancy that is judged to be significant relative to normally expected performance, and that is judged to be caused by theft or diversion or by substantial breakdown of the accountability system.

4. Any substantial breakdown of physical security or material control (i.e., access control containment or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.

D. Other Events (i.e., those concerning design, analysis, construction, testing, operation, use, or disposal of licensed facilities or regulated materials).

1. An accidental criticality [10 CFR 70.52(a)].

2. A major deficiency in design, construction, control, or operation having significant safety implications requiring immediate remedial action.

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

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 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,[4] 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.~~

~~***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~~

~~[4] The wrong radiopharmaceutical as used in the AO criterion for medical events refers to any radiopharmaceutical other than the one listed in the written directive or in the clinical procedures manual.~~

~~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.~~[5]

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~~[5] Staff Requirements Memorandum, SECY-98-175, dated September 4, 1998.~~

~~6~~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.~~ 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:

~~**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 10. The file may be attached to an e-mail transmission. The STP AO coordinator, Andrea Jones, may be reached at (ARJ@NRC.GOV).**~~

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 ~~address~~ 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 ~~or~~ and the State (e.g., decontaminated the facility, evacuated the staff, ~~confirmatory action letter,~~ special inspection performed, ~~enforcement conference,~~ 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. ~~, identify any health effects, including a statement of "no health effects," where applicable, and a statement~~ Indicate whether the patient and referring physician were ~~informed~~ notified of the event. Also, ~~S~~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) ~~whether a medical consultant has been contracted to review the event. Include the consultant's conclusions and identify the effects to the patient. Never mention any health effects to a patient without attributing the statement to the licensee or medical consultant. Indicate whether the primary physician was notified.~~

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

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

Action~~(s)~~ 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~~, and indicate whether or not the State was satisfied with the licensee's corrective actions~~. Also, the Agreement State should indicate the actions they took to prevent recurrence (e.g., ~~whether there were~~ any enforcement actions~~,~~ or penalties given to the licensee and/or individual(s)).

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."~~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.

~~The following pages contain three sample AO write-ups.~~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

~~Most Encountered~~ 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	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 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
		20.2201(a)(1)(ii)	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
	20.2202(a)(1)		Exposure (real or threatened) ≥ TEDE of 25 rem (.25 Sv), or lens dose equiv. ≥ 75 rem (.75 Sv) or shallow dose equiv. (skin\extremities) ≥ 250 rads (2.5 Gy).	Immediate
	20.2202(b)(1)		Exposure (real or threatened) ≥ TEDE of 5 rem (.05 Sv), or lens dose equiv. ≥ 15 rem (.15 Sv), or shallow dose equiv. (skin\extremities) ≥ 50 rems (.5 Sv).	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)	Radiation doses, releases or concentrations of radioactive material that exceed the limits.	30 days
10 CFR **Part 30**, Rules of General Applicability to Domestic Licensing of Byproduct Material	30.50(a)		Events involving prevention of immediate protective actions, necessary to avoid exposures to radiation, radioactive materials or releases of radioactive material that could exceed regulatory limits	Immediate
	30.50(b)(1)		Events involving an unplanned contamination (Under 30.50(b)(1), see items (i)-(iii) for other conditions that apply).	24 hours
	30.50(b)(2)		Events in which equipment is disabled or fails to function as designed. (Under 30.50(b)(2), see items (i)-(iii) for other conditions that apply).	24 hours

~~Most Encountered~~ 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		
	30.50(b)(3)		Events involving unplanned medical treatment of contaminated person	24 hours
	30.50(b)(4)		Events involving unplanned fire, or explosion affecting integrity of material, device or container, or equipment containing licensed material. (Under 30.50(b)(4), see items (i)- (ii) for other conditions that apply).	24 hours
10 CFR **Part 31**, General Domestic Licenses for Byproduct Material		31.5(c)(5)	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 bequerel (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		34.27(d)	Reporting of leaking sources, leak test results ≥ 0.005 microcurie (185 Bq).	5 days
		34.101(a)	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 21.21)).	30 days
10 CFR **Part 35**, Medical Use of Byproduct Material	35.3045		Notifications and reports of medical events involving administration and use of byproduct materials, with the exception of patient intervention events.	Next calendar day
		35.3067	Reports of leak test results that demonstrate the presence of 185 becquerel (0.005 microcurie) or more of removable contamination.	5 days
	35.3047		Events involving an unauthorized dose of 50 mSv (5 rem) to an embryo/fetus or a nursing child, or an unintended functional damage to an organ or a physiological system of the child.	Next calendar day
10 CFR **Part 36**,, Licenses & Radiation Safety Requirements for Irradiators	36.83		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)	24 hours

~~Most Encountered~~ 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		
			through (10) under 36.83 for specific descriptions of reportable events.	
10 CFR **Part 39**, Licenses & Radiation Safety Requirements for Well-Logging		39.35(d)(2)	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 39.35 for other conditions, including exemptions, that apply)	5 days
	39.77(a)		Well logging source rupture	Immediate
	39.77(b)		Theft or loss, exposures, excessive concentration of radioactive material	Immediate
		39.77(c) and (d)	After notification and classification that a source is irretrievable, a report shall be made to the NRC Regional Office.	30 days
10 CFR **Part 40**, Domestic Licensing of Source Material	40.60(a) (b)(1)-(b)(4)		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 30.50 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	70.50(a) (b)(1)-(b)(4)		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 30.50 and 40.60 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 70.4, "Definitions" for a definition of SNM.	a. Immediate b. 24 hours
10 CFR **Part 71**, Packaging and Transportation of Radioactive Material	71.5 49 CFR 171.15 (b)(1) and (2)		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	Immediate

~~Most Encountered~~ 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		
			hour, The operational flight pattern or routine of an aircraft is altered and the closure of one or more major transportation facility or roadway for at least one hour. 49 CFR 171.15(b)(2) requires the immediate reporting of fire, breakage, spillage, or suspected radioactive contamination occurs involving the shipment of radioactive material	
Orders Imposing Increased Controls (IC) (EA-05-090, Attachment B)	IC.2.d		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
Orders Imposing Increased Controls (IC) (EA-05-090, Attachment B)	IC.3.a.4		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
Orders Imposing Fingerprinting and Criminal History Records Check (IC) (EA-07-305)	III.A.5		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.	
Immediately reportable under 10 CFR 20.2201(a)(1)(i)	**Stolen Portable Moisture Density Gauge** 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.
Immediately reportable under 20.1906(d)(2)	**Shipment of Brachytherapy Sources Received with Radiation Levels Exceeding Regulatory Limits** A medical licensee [Name][License Number] reported receiving a shipment of two packages containing cesium-137 brachytherapy sources. Radiation surveys of the packages found radiation levels of 250 millirem per hour on one package, which exceeds the State and Federal limit at the external surface of a package of 200 millirem per hour. The third and final package was received two days later with radiation levels of 400 millirem per hour at the surface of the package. The shipper has retained a consultant to determine the cause of the elevated radiation levels. The State will keep NRC informed of the results of the consultants review of the event.
Reportable within 24 hours under 10 CFR 20.2202 (b)(1)(i)	**Exposure to Non-radiation Worker at a Licensed Facility** 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.

Reportable within 24 hours under 10 CFR 30.50(b)(2)	**Loss of Control and Damage to Portable Gauge** 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.
Reportable within 24 hours under 10 CFR 30.50.(b)(2) and reportable within 30 days under 10 CFR 34.101(a)(2)	**Radiography Camera Source unable to Retract** 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 our of tolerance.
Reportable by next calendar day under 10 CFR Parts 35.3045(a)(1)(i) and within 24 hours under 30.50(b)(2)	**Medical Event involving a Gamma Knife Malfunction** 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 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.	**Medical Event involving prostate brachytherapy** 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.
Written report within 30 days under 10 CFR Part 31.5(c)(5)	**A Leaking Source from a General Licensed Device** 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].
Reportable within 24 hours under 10 CFR Parts 36.83(a)(9), 30.50(b)(2) (Note: since water level was later verified to be normal, this is no longer a 36.83 issue)	**Possible Loss of Water or Leakage from Source Water Pool at Irradiator Facility** 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.

Appendix C

Event Reporting Schedule

Event Reporting Schedule for Agreement States

	Reportable Event Notification[1]	Agreement State Reporting Schedule to NRC	Reporting Methods to NRC[4]
IMMEDIATE	**Significant** reportable events requiring **immediate notification (i.e., within 4 hours or less[2])** 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 Center[5]** **(301) 816-5100** FAX #: (301) 816-5151 Email: HOO.HOC@nrc.gov
24 HOURS	**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.	
	Events involving **theft or terrorist** activities should be reported to the **FBI.[3]**	Agreement States should consider reporting to the FBI within 24 hours of notification.	
5 - 60 DAYS	**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
VOLUNTARY	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

[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:	[**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. 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
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. [**State**] Dept. of Health has received inquiries from the media regarding this incident.
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~~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*, $\mathbf{A}_{(i,n)}$, to the quantity of concern for radionuclide *n*, $\mathbf{Q}_{(n)}$, listed for that radionuclide equals or exceeds one. [(aggregated source activity for radionuclide A) ÷ (quantity of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) ÷ (quantity of concern for radionuclide B)] + etc..... ≥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*~~

~~*AO Criteria*~~

AO Criteria

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

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

I. For All Licensees

A. Human Exposure to Radiation from Licensed Material

1. Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 mSv (25 rem) or more; or an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ other than the lens of the eye, the bone marrow, and the gonads of 2,500 mSv (250 rem) or more; or an annual dose equivalent to the lens of the eye of 1 Sv (100 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow of 1 Sv (100 rem) or more; or a committed dose equivalent to the gonads of 2,500 mSv (250 rem) or more; or an annual shallow dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more.

2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.

3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

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

C. Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach[1,2]

1. Any unrecovered lost, stolen, or abandoned sources that exceed the values listed in

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

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

Appendix P to Part 110, "High Risk Radioactive Material, Category 2." Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur while the source was missing; and unrecoverable sources (sources that have been lost and for which a reasonable attempt at recovery has been made without success) lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 are not known to have occurred and the agency has determined that the risk of theft or diversion is acceptably low.

2. A substantiated[3] case of actual theft or diversion of licensed, risk-significant radioactive sources or a formula quantity[4] of special nuclear material; or act that results in radiological sabotage[5].

3. Any substantiated[3] loss of a formula quantity[4] of special nuclear material or a substantiated[3] inventory discrepancy of a formula quantity[4] of special nuclear material that is judged to be caused by theft or diversion or by a substantial breakdown[6] of the accountability system.

4. Any substantial breakdown[6] of physical security or material control (i.e., access control containment or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.

5. Any significant unauthorized disclosures (loss, theft, and/or deliberate) of classified information that harms national security or safeguards information that harms the public health and safety.

D. Initiation of High-Level NRC Team Inspections.[7]

II. For Commercial Nuclear Power Plant Licensees

A. Malfunction of Facility, Structures, or Equipment

1. Exceeding a safety limit of license technical specification (TS) [10 CFR 50.36(c)].

2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

3. Loss of plant capability to perform essential safety functions so that a release of

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

4 A formula quantity of special nuclear material is defined in 10 CFR 70.4.

5 Radiological sabotage is defined in 10 CFR 73.2.

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

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

radioactive materials which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

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

1. Discovery of a major condition not specifically considered in the safety analysis report (SAR) or TS that requires immediate remedial action.

2. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions so that a release of radioactive materials which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, GDC 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod drive mechanism).

C. Any reactor events or conditions that are determined to be of high safety significance.[8]

D. Any operating reactor plants that are determined to have overall unacceptable performance or that are in a shutdown condition as a result of significant performance problems and/or operational event(s).[9]

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

A. Events Involving Design, Analysis, Construction, Testing, Operation, Transport, Use, or Disposal of Licensed Facilities or Regulated Materials

1. An accidental criticality [10 CFR 70.52(a)].

2. A major deficiency in design, construction, control, or operation having significant safety implications that require immediate remedial action.

3. A serious safety-significant deficiency in management or procedural controls.

4. A series of events (in which the individual events are not of major importance), recurring incidents, or incidents with implications for similar facilities (generic incidents) that raise a major safety concern.

B. For Fuel Cycle Facilities

1. Absence or failure of all safety-related or security-related controls (engineered and

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

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

human) for a NRC-regulated lethal hazard (radiological or chemical) while the lethal hazard is present.

2. An NRC-ordered safety-related or security-related immediate remedial action.

C. For Medical Licensees

A medical event that:

1. Results in a dose that is
   a. equal to or greater than 1 Gy (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal or greater than 2.5 Gy (250 rad) to the gonads; or

   b. equal to or greater than 10 Gy (1,000 rad) to any other organ or tissue; and

2. Represents either
   a. a dose or dosage that is at least 50 percent greater than that prescribed, or
   b. a prescribed dose or dosage that
      (i) Uses the wrong radiopharmaceutical or unsealed byproduct material; or
      (ii) Is delivered by the wrong route of administration; or
      (iii) Is delivered to the wrong treatment site; or
      (iv) Is delivered by the wrong treatment mode; or
      (v) Is from a leaking source or sources; or
      (vi) Is delivered to the wrong individual or human research subject.

IV. Other Events of Interest

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

~~*Appendix I*~~

~~*Sample AO Write-Ups*~~

Example 1: Radiopharmaceutical Overexposure Write-up

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

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

Exposure

Nature and Probable Consequences A pharmacist trainee received an extremity exposure resulting in a shallow dose equivalent to the hand of 7,402 mSv (742 rem); a deep dose equivalent of 70 mSv (7.02 rem) to the hand; and a dose of 0.9 mSv (0.09 rem) to the thyroid, based on 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, who conducted a second survey of the area that revealed no remaining contamination. Upon return from a one week vacation, the pharmacist informed the Radiation Safety Officer that skin on the forearm had been contaminated as a result of an earlier I-131 spill received prior to vacation. Immediate action was taken to determine if any contamination still remained on his arm. Elevated levels were discovered on his right forearm and left fingertips. The appropriate hospital/nuclear medicine personnel were notified. The contaminated individual was suspended from any and all duties involving radioactive material during the investigation.

Source/Quantity

Cause or Causes The event occurred due to human error and failure to follow established procedures. An initial crimp failure on the vial 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**).

Example 2: Diagnostic Medical Event AO Write-up

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

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

Procedure/dose (actual vs. intended) **Nature and Probable Consequences** - A patient was prescribed a dose of 0.93 megabecquerel (MBq) (25 microcurie [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 (3,000 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 (3,000 µCi) of I-131 without requesting clarification or approval from the authorized users. As a result the patients thyroid received a dose of about 43 Gy (4,300 rads) instead of the prescribe

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

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

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

Actions taken To Prevent Recurrence

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

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

This event is closed for the purpose of this report.

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

Criteria	In accordance with the AO criteria IV, "For Medical Licensees," administering a dose that is (1) equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than the bone marrow, lens of the eye or the gonads) and (2) represents a prescribed dose or dosage that is delivered to the wrong treatment site.
	Date and Place – **[Date]; [Facility/Licensee], [City, State]**
Procedure/dose	**Nature and Probable Consequences** – A patient undergoing Gamma (intended vs. actual) Stereotactic Radiosurgery (Gamma Knife) was prescribed treatment of 20 Gy (2,000 rads) to a portion of the brain. However, the patient received a dose of 12.8 Gy (1,280 rads) to an unintended portion of the brain, (i.e. wrong treatment site).
What occurred?	During the treatment, the licensee completed three and one-half fractions of eight treatments before the medical physicist and radiation therapist realized that the administered treatment utilized the treatment parameters for another patient. The licensee's medical physics staff had prepared treatment plan for two patients, to be treated on the same day. The treatment plan for Patient A consisted of a prescribed dose of 18 Gy (1,800 rads). Prior to initiating treatment of Patient A, a licensee staff member handed the plan of treatment for Patient B to the licensee's radiation therapist; later, the therapist could not recall from whom the plan had been received. Using Patient B's treatment plan, the treatment team set up and delivered the first three fractions to Patient A and began delivery of the fourth fraction when the error was discovered by the medical physicist. Once notified of the error, the radiation oncologist terminated treatment. The medical physicist determined that the treatment delivered a dose of 12.8 Gy (1,280 rads) to an unintended region of the patient's brain. The radiation oncologist determined that the location of the unintended site was far enough away from the intended site to proceed with the intended treatment. The licensees subsequently administered the intended treatment without incident.
Notifications	The licensee notified the patient's referring physician and the radiation oncologist notified the patient of the event.
Health effect to patient	The radiation oncologist did not anticipate any immediate adverse effect to the patient, and was not certain of the potential for any long-term effects as a result of the administration.

Consultant report, where applicable	The licensee consultant agreed with the assessment. With regard to long-report term affects, the consultant concluded that this administration may be at the threshold of late central nervous system injury and may produce symptoms. The consultant further stated that long-term follow-up was indicated for the patient and that the patient was eligible for inclusion in the Department of Energy's Office of Epidemiology and Health Surveillance voluntary life-time morbidity study. The licensee conducted medical follow-up of the patient to identify and respond to potential adverse medical consequences resulting from this administration. However during further attempted follow-ups on the patient the licensee lost contact with the patient.
	Cause or causes The misadministration was caused by human error, as a result of the 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 licensee's corrective actions, which were found adequate by the State.
	This event is closed for the purposes of this report.

Appendix H

Field Code Changed

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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 ~~Abnormal Occurrence. As published in the Federal Register on October 12, 2006 (71 FR 60198).~~ 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.

~~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).~~

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 the Office of ~~State and Tribal Programs~~Federal and State Materials and Environmental Management Programs (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~~s~~ or 0.01 joule/kilogram (0.01 gray)

Rem Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert).

Sievert Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rem.).

References

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

NRC Policy

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

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

NRC Report

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

NMSS Licensee Newsletter, NUREG/BR-0017

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 Procedures

8.10 NRC Assessment Program for an Event Occurring at a Medical FacilityNRC Medical Event Assessment Program

8.14 Agency Action Review Meeting, AARM

NRC Inspection Manual Chapters

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

~~1301~~ Response to ~~Non-Emergency Incidents Involving~~ Radioactive Material Incidents That Do Not Require Activation of the NRC Incident Response Plan ~~(96-022)~~

~~1302~~ Follow-up Actions and Action Levels for Radiation Exposures ~~and Contamination~~ Associated with Material ~~Events~~ Incidents 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)~~

2800 Materials Inspection Program

~~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*~~ *FSME Correspondences*

~~STP~~ All Agreement State Letter (SP-98-018), dated ~~-~~March 17, 1998, "Use of the Nuclear Material Events Database (NMED) ~~A~~as a Central Listing o~~O~~f 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."

~~*STP*~~ *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.

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

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, 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.~~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 ~~external W~~website ~~under References~~ at ~~:~~ ~~http://www.nrc.gov/NRC/reference.html.~~ http://www.nrc.gov/reading-rm/doc-collections/. The Office of ~~State and Tribal Programs (STP)~~Federal and State Materials and Environmental Management Programs (FSME) documents are available at the ~~STP~~ FSME external ~~W~~website at~~:~~ ~~http~~://~~www.hsrd.ornl.gov/nrc/.~~ http://nrc-stp.ornl.gov/.

(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[4]
4 HOURS	**Significant** reportable events requiring **4 hours or less**[2] notification by Agreement State licensees.	Agreement States should report to NRC within 4 hours of notification by an Agreement State licensee.	Report initial information to the **NRC Operations Center**[5] **(301) 816-5100** or **(301) 951-0550** FAX #: (301) 816-5151
24 HOURS	**Significant** reportable events requiring **24 hours or less** notification 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 **FBI.**[3]	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.[6]	Email: NMED@INL.GOV Telephone: 208-526-6004 208-526-0990 fax Disk/CD: INL, P.O. Box 1625, Idaho Falls, ID 83415 Attn: Thomas W. Smith or Written: Director of STP US NRC, Washington, DC 20555
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.[7]	Email: NMED@INL.GOV

Rev. 3, December 2005

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

[2] 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 Table 1 of STP 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 Section 3 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 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.