

(SP-98-040, May 1998, Incident/Event, Report Material Events, SA-300)

DATED: MAY 7, 1998

SIGNED BY: PAUL H. LOHAUS

ALL AGREEMENT STATES
OHIO, OKLAHOMA, PENNSYLVANIA

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION (SP-98-040)

Your attention is invited to the enclosed correspondence which contains:

INCIDENT AND EVENT INFORMATION..... **XX GUIDANCE FOR
REPORTING MATERIAL
EVENTS**

PROGRAM MANAGEMENT INFORMATION....

TRAINING COURSE INFORMATION.....

TECHNICAL INFORMATION.....

OTHER INFORMATION.....

Supplementary information: Enclosed is Office of State Programs (OSP) Procedure SA-300, Reporting Material Events, and it's Appendix, a revised "Handbook on Nuclear Material Reporting in the Agreement States." The "Handbook" is a final version of the handbook previously provided to you for use and comment by OSP in March 1995 (SP-95-036). The procedure and handbook provide guidance for Agreement State reporting of material events to the NRC. SA-300 and the "Handbook" contain procedures for providing NRC:

- (1) Initial notification of the occurrence of a significant or routine event involving nuclear material (Section 1.0, of the "Handbook," pp.1-3).
- (2) Pertinent follow-up information (results of any evaluations or investigations, dose assessments, leak tests, equipment assessments, inspection reports, corrective actions, etc.); and any additional information on technical or regulatory action through resolution and close out of the event (Sections 1.3 and 1.4, pp. 4-6).
- (3) Guidance on electronic reporting of event information to the "Nuclear Materials Events Database" (NMED) and on written (hard copy) reporting through submission of Agreement State licensee event reports to the Director, OSP (Sections 1.3 and 1.4, pp. 4-6).

Guidance covering recent revisions to Title 18 of the Criminal Code, that expands the role of the Federal Bureau of Investigations (FBI) in the criminal use of radioactive material, and guidance on Agreement State notification to the FBI regarding specific categories of material events is contained in All Agreement States Letter SP-98-038. An Errata Sheet is also enclosed which adds the FBI guidance to the Reference Manual Section of the "Handbook."

For purposes of compatibility, the reporting of incidents and events involving the use of nuclear material by an Agreement State to NRC is now mandatory under the Policy Statement on Adequacy and Compatibility of Agreement State Programs approved by the Commission on June 30, 1997. The quality, thoroughness, and timeliness of material event reporting by the Agreement States to NRC, including Agreement State event information contained in NMED, will be reviewed during the annual meetings with Agreement States between the Integrated Materials Performance Evaluation Program (IMPEP) reviews, and will be evaluated during IMPEP reviews under the Common Performance Indicator, Response to Incidents and Allegations. We hope the enclosed procedure and handbook will be of assistance to you and your staff in the reporting of event information and will help in maintaining a national database of NRC and Agreement State information.

Information requested in the Handbook has been approved by OMB 3130-0178, expiration date June 30, 2000. If an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

If you have any questions regarding this correspondence, please contact me or the individual named below.

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Enclosures:
As stated



**SA-300 Reporting Material Events
Appendix**

Handbook on Nuclear Material Event Reporting in the Agreement States

Final Report

February 20, 1998

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

Contact: Patricia M. Larkins

ERRATA SHEET
April 30, 1998
for
Handbook on Nuclear Material
Event Reporting in
the Agreement States
(Issued: February 20, 1998)

Subsequent to publication of the “Handbook” the following corrections and additions apply:

Reference Manual insert:

FBI A recent revision to Section 831 of Chapter 39 of Title 18 of the U.S. Code regarding criminal activity, includes a significant expansion of Federal Bureau of Investigation (FBI) 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.

Please make the following pen and ink corrections to Table 1.2 Event Reporting Requirements, p. 10-11.

10 CFR Part

- | | |
|------------------|---|
| 20.2201(a)(1)(I) | Change to read as follows: 20.2201(a)(1)(i) |
| (a)(1)(ii) | Change the \geq symbol to read greater than $>$. |
| 34.25(d) | Change to read as follows: 34.27(d) |
| 34.30(a) | Change to read as follows: 34.101(a) |

Please add the following additional reporting requirement to Table 1.2.

- | | | |
|--------------|--|--------------------|
| 39.35 (d)(2) | reports of leaking sealed sources found during periodic leak testing requirement | 5 day notification |
|--------------|--|--------------------|

ABSTRACT

The review and evaluation of operational event information identifies safety-significant events and concerns, and their causes. This handbook has been developed to provide information to the staff of the Agreement States that are responsible for the preparation of event reports for incidents and events involving the use of nuclear materials that have occurred in their State. Reporting of Agreement State material events to NRC is mandatory for purposes of compatibility. The handbook describes the procedure to be followed in reporting significant and routine material events to NRC. Guidance is provided on what information should be reported, the level of detail, and where to report. Procedures for identifying and reporting Abnormal Occurrences (AOs) are also included. The objective of the handbook is to:

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

It has been divided into two sections and one appendix.

Section I - Event Reporting Process, describes the process for reporting significant and routine incidents and events involving the use of nuclear materials that have occurred in the Agreement States. Information is provided on reporting material events to the Nuclear Materials Events Database (NMED).

Section II - Abnormal Occurrence Guidelines and Criteria, describes the process for identifying and reporting material events that reach the level of an abnormal occurrence (AO) that have occurred in the Agreement States.

Appendix - contains a glossary of terms and listing of reference manuals and information.

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PREFACE

The regulatory authority and policies governing the Agreement State program are presented below.

Regulatory Authority

Section 274 of the Atomic Energy Act provides a statutory basis under which the Federal government may relinquish portions of its regulatory authority to the States and authorizes and 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. Pursuant to the "Act" and the Energy Reorganization Act of 1974, as amended, the NRC evaluates material events and abnormal occurrences in licensed facilities. In addition, the Energy Reorganization Act requires NRC to provide to Congress on an annual basis, information on significant events that meet the abnormal occurrence criteria.

Regulations have been established that require material licensees to monitor and control activities that can lead to the exposure of employees or the general public to radiation. For purposes of compatibility the reporting of incidents and events involving the use of nuclear materials by the Agreement States to NRC is now mandatory. The information from reports of medical misadministrations, overexposures, equipment failures, and other events that have occurred involving the use of nuclear materials licensed by both the NRC and the Agreement States is invaluable in assessing trends or patterns and inadequacies or unreliability of specific equipment or procedures. The reported information will significantly aid in understanding why the events occurred and identifying any actions necessary to improve the effectiveness of NRC and Agreement State regulatory programs.

SECTION I

Event Reporting Process

1.0 EVENT REPORTING PROCESS

1.1 Introduction

Procedures for the Agreement States to report to NRC information on material events that have occurred in their State are presented below. Guidance is provided on electronic reporting of event information to the "Nuclear Materials Events Database (NMED)." Guidance is also provided on hard copy reporting (written reports) of Agreement State licensee event reports to the Director, OSP. When submitting an event report, enough information about an event should be provided so that NRC and Agreement States can evaluate the event in terms of safety significance, long-term generic implications, and as a possible candidate for the "Abnormal Occurrence Report to Congress."

- **Reportability Determination**

Agreement States should receive event information from Agreement State licensees that is compatible with the information provided by NRC licensees under applicable, compatible Agreement State regulatory reporting requirements. Table 1.1 of this guide contains a listing of NRC regulatory reporting requirements that are the basis for equivalent reporting requirements in Agreement State regulations. Table 1.2 provides further clarification by including a brief description of the specific reporting requirement. These tables begin on page 7 of the "handbook."

- **How often are material events reported to NRC?**

Significant events (requiring 24 hour or less notification by an Agreement State licensee) should be reported promptly to NRC by an Agreement State, within 24 hours or less of notification by an Agreement State licensee. Routine events (requiring 5, 15, 30 or 60 day notification by an Agreement State licensee) should be reported within one month of notification of the occurrence of an event by an Agreement State licensee, member of the public, or other agency. Follow-up reports through closeout of the event should be provided within 30 days of receipt from an Agreement State licensee. Information on State action, e.g., investigation results or enforcement actions may be requested by NRC on an ad hoc basis.

- **Voluntary Reporting**

The Commission encourages voluntary reporting of an occurrence that actually happened (event) or something that may happen (condition) that does not meet the regulatory reporting criteria that the State believes might be of safety significance or of generic interest or concern, or involves media interest.

- **Event Report Number**

All event reports (significant and routine) should have a report identification number. For each agency in your State, Agreement States should assign an event report number to the preliminary or initial notification report and any follow-up reports, with the "Agreement State Identification No.," consisting of the State agency ID, year, and a sequentially assigned ID number, e.g., (NY-98-001), (NYC-98-001), (NYL-98-001), (NYE-98-001), (TX-97-001), (TXNR-98-001), (GA-98-001), (NE-98-001), (CA-98-001). NOTE: The Agreement State ID# field in NMED can accommodate up to four characters for the State or agency identifier. The "Agreement State ID No." should be specified by the State for all telephone, electronic or written notification involving each specific event. This will ensure proper coding in NRC's internal Document Control System (DCS) and that all information on a given event is contained in one record in NMED. It will also aid in simplifying the search for all of a State's information in the NMED database.

- **The Nuclear Materials Events Database (NMED)**

All material event information is maintained in the Nuclear Materials Events Database (NMED) by the NRC Office for Analysis and Evaluation of Operational Data (AEOD). NMED contains NRC's historical collection of information on the occurrence, description, and resolution of events involving the use of byproduct nuclear material in the United States. The database is maintained by NRC through a contractor, Idaho National Engineering and Environmental Laboratory (INEEL). NMED accommodates the sharing of material event data submitted by Agreement States and NRC licensees. INEEL enters material event information received from the Agreement States via PC diskette, e-mail file, or in writing into NMED. Agreement States will receive monthly updates of data directly from INEEL in a format previously designated by the State. The monthly update should be reviewed to ensure that each State's event information has been properly included. A copy of the NMED software, and the accompanying NMED Coding Manual, have been provided to all Agreement States.

1.2 Reporting Significant Events (requiring immediate or 4-24 hour notification by an Agreement State licensee)

- a. Report Significant Events to the NRC Operations Center.
- b. Agreement States should report to the NRC, within 24 hours or less of notification by an Agreement State licensee, significant events requiring prompt notification as determined under applicable Agreement State regulations. (For reference, NRC reporting requirements for significant events are presented in Table 1.1 and 1.2 on pages 7 and 9)

- c. Agreement States should report the events by telephone or FAX to the NRC Operations Center, telephone No. (301) 816-5100, (301) 951-0550, and FAX (301) 816-5151.

The following information should be provided, if known:

1. Event Report Identification No.
2. License No.
3. Licensee
4. Event time, date, location
5. Event type (e.g., misadministration, lost source, overexposure, etc.)
6. Any notifications, i.e., other agencies, patient, press release, etc.
7. Event description: release, isotope, activity, exposure(s), dose, contamination level(s), equipment malfunction, model, serial #, etc.
8. Transport vehicle description, if applicable
9. Media attention

NOTE: Personal or sensitive information, i.e., names, personal address, social security #, etc. should not be included in event descriptions.

- d. NRC Operations Center

The NRC Operations Center staff will promptly notify the appropriate Region Duty Officer (RDO) of Agreement State events. No separate notification of the appropriate NRC Region by an Agreement State is necessary.

- e. Event Notification System

All events reported to the NRC Operations Center will be entered into the Event Notification (EN) database. The EN will be publicly available through Internet on NRC's external home page at (<http://www.nrc.gov/opa>) under "Event Reports," within one day or less of notification. As a result of public access to this information, Agreement States may receive contacts from the public or media requesting additional information.

- f. Preliminary Notifications (PN)

Agreement States should be aware that the NRC regional staff may prepare Preliminary Notifications (PN), which are brief summary reports of significant events, as appropriate, based on information provided by the Agreement State. Region staff may contact the State for additional information on the event. PNs

are usually issued within approximately two hours of notification of the occurrence of a significant event. The PN will be publicly available through Internet on NRC's external home page under PN Reports at (<http://www.nrc.gov/opa>). Updates to PNs occur when significant additional information about an event is provided to NRC.

- g. NMED Initial Data Entry Record and NMED Follow-up Reports for "Significant" Events

Information about "significant" events initially reported to the NRC Operations Center will be entered into NMED by the NRC. The Agreement State initially reporting the event is responsible for updating the initial NMED report with revised or new information. In most cases this can be accomplished by reviewing the licensee's written event report and updating the initial event information incorporated into NMED by one of the reporting methods described in Section 1.3 or 1.4. The NMED event report update should be submitted within 30 days of receipt of the licensee's written report by the Agreement State. If the licensee submits multiple written reports, more than one NMED event report update may be required for all new or revised information.

- h. NRC Review of Significant Material Events

Both NRC and Agreement State events identified as having a "significant" potential risk to public health and safety will receive appropriate NRC management review. This review may be related to the reporting of additional information to the NMED database or may become part of a separate NRC initiative. Based on the "significance" of the event and/or the possibility of generic issues, the NRC may request that the State provide a final report. Additionally, based on the "significance" and/or generic implications, NRC staff may review and follow-up through closure (complete and final information has been received from the licensee; and the NRC or Agreement State evaluation is complete). The State may be requested to participate in NRC management briefings by telephone to keep NRC informed of actions taken by the State and others to protect public health and safety.

1.3 Electronic Reporting to NMED via PC Diskette or E-mail: Routine Event Reports and Follow-up Information on Routine and Significant Events (routine = 5-day Event Report, 15-day Medical Misadministration Report; 30 and 60 day Event Reports)

- a. Routine NMED Event Reports
 - 1. The Agreement State should provide an electronic NMED report via E-mail or PC diskette to NRC based on the information provided by the Agreement State licensee in the 5, 15, 30 or 60 day report. (for reference,

NRC routine reporting requirements are presented in Tables 1.1 and 1.2 on pages 7 through 10.)

2. The Agreement States assigned event report identification number (State\Yr.\No., e.g., GA-97-001) should be included in the NMED record. This will ensure that all information on a given event is contained in one record, eliminate duplicates, and aid in searching for information on events that have occurred in a specific State. The NMED record should be updated as new or clarifying information is developed. Follow procedures for data entry contained in the NMED Coding Manual provided by INEEL.
- b. NMED Event Report Updates (follow-up information on both significant and routine events)
1. The initial event report identification number (State\Yr.\No.) should be included whenever additional follow-up event information is provided to NRC. Indicate that it is a follow-up report.
 2. Any follow-up information that revises earlier information or provides additional information on a given event should be provided to NRC to ensure a complete historical NMED record. Follow-up information necessitating an NMED event update may be found in licensee event reports, results of any evaluations or investigations, dose assessments, leak tests, inspection reports, corrective actions, etc. Information on sealed sources and devices should include the manufacturer, model No. and serial No., and identify whether or not the lost or stolen gauge or material has been found. The follow-up event information may be provided in writing or extracted, summarized, and entered into NMED. Follow the procedures for filing NMED event update reports in the NMED Coding Manual provided by INEEL. Follow guidance below in item 1.4 for non-electronic (written) event reports.
 3. Additionally, when providing follow-up NMED event information, provide clear reference to documents on file that the State used to generate the NMED event reports, e.g., licensee inspection report dated mm/dd/yr., if applicable and appropriate.

1.4 **Non-Electronic Reporting of Material Events (Written Reports): Routine Event Reports and Follow-up Information on Routine and Significant Events** (Routine: 5-day Event Report, 15-day Medical Misadministration Report, 30 and 60 day Event Reports)

The following guidance is provided for Agreement States that report event information through submission of written reports. NOTE: Initial reporting of “significant” events should always be reported via telephone or FAX to the NRC Operations Center within 24 hours of notification by an Agreement State licensee (see Section 1.2).

- a. **Event Report Cover Page:** An Event Report Cover is included on page 18 of this Handbook. The Event Report Cover page should be included as the cover page for all written Agreement State licensee event information provided to NRC. The cover page will ensure proper identification and coding as an Agreement State Event Report.
- b. **Event Report Number:** Include the assigned event report number [Agreement State Identification No., (e.g.CO-98-001)] where indicated, on the cover page to avoid duplication of effort.
- c. Written event reports should be sent to the Director, OSP.
- d. Written report information should be comparable with the level of detail on an event that is specified in the "NMED" database and applicable regulatory requirements. A State may print out the NMED screens or provide a copy of the licensee's event report to NRC. A listing of the minimum basic information to be provided on a given event that is necessary for the NMED database is provided in item 1.14, page 19. A listing of the basic information for preparing a medical event report is also provided (see item 1.15, page 20).
- e. All follow-up information that revises the initial event information or provides additional information should be provided through close-out of the case. Send written event report information, along with a cover page (see p. 18 of the Handbook) to the Director, OSP.

1.5 **Public Availability of Event Information**

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

TABLES:

The following four tables are provided. NRC 10 CFR reporting requirements are contained throughout the 10 CFR rather than contained in one Part or Section. Therefore, the following tables provide a complete listing of the current 10 CFR material reporting requirements in one place. Additionally, the tables further differentiate significant and routine reporting requirements. The tables are listed as follows: 1.1 Event notification by category and NRC reporting requirement, 1.2 Event Reporting Requirements, 1.3 Examples of reportable events, and 1.4 Sample NMED data entry screens.

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TABLE 1.1 EVENT NOTIFICATION BY CATEGORY AND NRC REPORTING REQUIREMENT				
SIGNIFICANT EVENTS (POSSIBLE AO)			ROUTINE EVENTS (POSSIBLE AO)	
REGULATORY REPORTING REQUIREMENT	IMMEDIATE NOTIFICATION BY LICENSEE TO APPROPRIATE REGULATORY AGENCY WITHIN 1 HR.	PROMPT NOTIFICATION BY LICENSEE TO APPROPRIATE REGULATORY AGENCY WITHIN 24 HRS.	LICENSEE NOTIFICATION TO APPROPRIATE REGULATORY AGENCY VIA 30 DAY LICENSEE EVENT REPORT (LER)	LICENSEE NOTIFICATION TO APPROPRIATE REGULATORY AGENCY VIA 60 DAY LER REPORT
10 CFR Part 20, Standards for Protection Against Radiation	§20.1906(d)(1) and (d) 2)			
	§20.2201(a)(1)(I)		§20.2201(a)(1)(I) and (ii)	
	§20.2202(a)	§20.2202(2)(b)		
			§20.2203(a)	
10 CFR Part 21, Reporting of Defects and Noncompliance ¹				§21.21(a)(1) and (2)
10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material	§30.50(a)	§30.50(b)	§30.50(a) and (b)	
10 CFR Part 31, General Domestic Licenses for Byproduct Material			§31.5(c)(5)	
10 CFR Part 34, Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations		§34.25(d) NOTE: 5 day report	§34.30(a)	

¹ Not a compatibility requirement for Agreement State, but States voluntarily provide information on equipment failure and defects.

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Table 1.1 Event Notification cont.				
SIGNIFICANT EVENTS (POSSIBLE AO)			ROUTINE EVENTS (POSSIBLE AO)	
REGULATORY REPORTING REQUIREMENT	IMMEDIATE NOTIFICATION BY LICENSEE TO APPROPRIATE REGULATORY AGENCY WITHIN 1 HR.	PROMPT NOTIFICATION BY LICENSEE TO APPROPRIATE REGULATORY AGENCY WITHIN 24 HRS.	LICENSEE NOTIFICATION TO APPROPRIATE REGULATORY AGENCY VIA 30 DAY LICENSEE EVENT REPORT (LER)	LICENSEE NOTIFICATION TO APPROPRIATE REGULATORY AGENCY VIA 60 DAY LER REPORT
10 CFR Part 35, Medical Use of Byproduct Material ²		§35.33(a),(1),(2),(3) and (4)		
10 CFR Part 36, Licenses and Radiation Safety Requirements for Irradiators		§36.83(a) and (b)	§36.83(a) and (b)	
10 CFR Part 39, Licenses and Radiation Safety Requirements for Well Logging		§39.77(a),(b) and (c)	§39.77(b)	§39.77(a),(b),(c) and (d)
10 CFR Part 40, Domestic Licensing of Source Material		§40.60(a)	§40.60(b)	§40.60(c)(2)
10 CFR Part 70, Domestic Licensing of Special Nuclear Material		§70.50(a)	§70.50(b)	§70.50(c)
10 CFR Part 71, Packing and Transportation of Radioactive Material			§71.47,71.87 and 71.95	

² Misadministration event requires 15 day LER report and 24 hour notification to referring physician and patient.

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Table 1.2 EVENT REPORTING REQUIREMENTS

Typical items covered under reporting requirements include the following:

10 CFR Part	Reporting Requirement	Notification
20.1906(d) (1)	reports of removable contamination on package >limits in 10 CFR 71.87.	Immediate
(d)(2)	radiation levels on package > limits in 10 CFR 71.47	Immediate
20.2201(a)(1)(I)	reports of theft or loss of licensed material ≥ 1000 X App C value	(I) Immediate.
(a)(1)(ii)	reports of theft or loss of licensed material ≥ 10 X App. C value	(ii) 30 day
20.2202(a)(1)	exposure (real or threatened) \geq TEDE of 25 rem (.25 Sv), or eye or lens dose equiv. of 75 rem (.75 Sv) or shallow dose equiv. (skin\extremities) of 250 rads (2.5 Gy).	(a)(1) Immediate
(b)(1)	exposure (real or threatened) \geq TEDE of 5 rem (.05 Sv), or eye or lens dose equiv. of 15 rem (.15 Sv), or shallow dose equiv. (skin\extremities) of 50 rads (.5 Gy).	(b)(1) 24 hours
20.2202(a)(2)	release where individual could have intake > 5 X ALI over 24 hours.	(a)(1) Immediate
(b)(2)	release where individual could have intake > 1 X ALI over 24 hours	(b)(2) 24 hours
20.2203(a),(b)	radiation exposures, releases or concentrations of radioactive material that exceed the limits.	30 day
21.21(a)(1-2)	reporting of defect in basic component, structure or system. ³	60 day
30.50	reporting of events involving:	
(a)	prevention of immediate protective action, involving exposures or releases that could exceed regulatory limits	4 hour
(b)(1)	unplanned contamination restricting access >24 hours (no isotopes with half-lives <24 hrs)	24 hour
(b)(2)	equipment failure or disability to function as designed when equipment is required to be available and operable and no redundant equipment is available and operable.	24 hour

³ Not a compatibility requirement for Agreement States, but States voluntarily provide information on equipment failure and defects.

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Table 1.2 Event Reporting Requirements cont.

10 CFR Part	Reporting Requirement	Notification
30.50 cont.		
(b)(3)	unplanned medical treatment of contaminated person,	24 hour
(b)(4)	Fire, explosion affecting integrity of material, device or container.	24 hour
31.5(C)(5)	failure or damage to shielding, on-off mechanism or indicator, or ≥ 0.005 microcuries (185 Bq) removable radioactive material for generally licensed device.	30 day
34.25(d)	reporting of leaking sources, leak test results $\geq 0.005 \mu\text{Cu}$ (185 Bq)	5 day
34.30(a)	radiography source disconnect, inability to retract source, or component failure (critical to safe operation of device)	30 day.
35.33(a)	notifications and reports of misadministrations. ⁴	Next day(24 hr)
36.83	irradiator events, release of material, defective components, systems or structures; (if not reported under other 10 CFR reporting requirements)	24 hour
39.77(a,c)	well logging source rupture, irretrievable source, abandonment	(a)Immediate (c) When apparent recovery impossible
40.60	requirements for domestic licensing of source material to receive, possess, use transfer, or deliver source and byproduct material. (NOTE: Same as 30.50 above)	
70.50	events involving special nuclear material (SNM)	
(a)		(a) 24 hour
(b)		(b) 30 day
(c)		(c) 60 day
71.47, 71.87	transportation events involving defective packaging of material, contamination	30 day

⁴ Misadministration events require 15 day LER report and 24 hour notification to referring physician and patient.

TABLE 1.3 EXAMPLES OF REPORTABLE EVENTS

This Table provides examples of reportable material events or occurrences that are required to be reported by both NRC and Agreement State material licensees. The Table addresses specific reporting requirements for either immediate notification (within 24 hours or less) or 30 day written reports. The Agreement States should provide detailed event information that is comparable with the NMED database system.

<p>Immediately reportable under 10 CFR 20.2201</p>	<p>Stolen Portable Gauge</p> <p>Licensee reported that a [Manufacturer] [Model #] [serial #] portable gauge containing 9 millicuries of cesium-137 and 40 millicuries of americium-241:beryllium was stolen from the licensee’s vehicle parked at the licensee’s facility. The gauge was padlocked in its original carrying case. The State is following the incident and working with local authorities to develop a press release. Follow-up information will be provided to NRC on the recovery of the stolen gauge and entered into NMED.</p>
<p>Reportable within 24 hours under 10 CFR 30.50</p>	<p>Possible Damage to Portable Gauge</p> <p>Licensee reported that a [Manuf.] [Model #] [serial #] portable gauge was run over by a bulldozer at a field construction site. The gauge housing appeared to have been damaged, but the source appeared to be intact. The licensee is investigating why the radiographer failed to maintain constant surveillance. The gauge will be sent to the manufacturer for leak testing. A follow-up report will be provided to the State by the licensee, and the State will share information on the results of the licensee’s investigation into the occurrence and the results of the leak test with NRC through entry into NMED.</p>
<p>Reportable within 30 days under 10 CFR 71.47 and 20.1906</p>	<p>Shipment of Brachytherapy Sources Received with Radiation Levels Exceeding Regulatory Limits</p> <p>A medical licensee reported receiving a shipment of two packages containing cesium-137 brachytherapy sources. Radiation surveys of the packages with an ion chamber detector found radiation levels of 250 millirem per hour on one package, which exceeds the state and federal limit at the external surface of a package of 200 millirem per hour. The third and final package was received two days later with radiation levels of 400 millirem per hour at the surface of the package. The shipper has retained a consultant to determine the cause of the elevated radiation levels. The State will keep NRC informed of the results of the consultant’s review of the event, and the information will be entered into NMED.</p>
<p>Reportable within 24 hours under 10 CFR 20.1301, 20.2203</p>	<p>Exposure to Nonradiation Worker at a Licensed Facility</p> <p>A licensee reported to the State that a nonradiation worker had received an exposure as a result of picking up a 5 curie Americium-241:Beryllium neutron source used for well logging and placed it in his pocket. The worker, a temporary contractor employee, was cleaning a well logging tool at the licensee facility. (The licensee was under the assumption that all of the source material had been removed from the equipment.) While cleaning the tool, the source fell out, and the worker picked it up and placed it his pocket. The worker was not a radiation worker and had no knowledge of what the object was. Preliminary calculations performed by [identify Consultant/Contractor] indicate that the individual may have received a dose of 4-6 Rem. The licensee’s RSO is investigating the incident. The State plans to keep NRC informed of the ongoing results of the investigation, and the information will be entered into NMED.</p>

<p>Reportable within 24 hours under 10 CFR Part 35 and 30.50(b)(2)</p>	<p>Possible Misadministration involving a Teletherapy Unit Malfunction</p> <p>A patient undergoing a Cobalt-60 teletherapy treatment with a [Manufacturer][Model #] received an unintended exposure. The RSO estimated that the patient received an exposure of 138 centigray (Rads) to a depth of 0.5 centimeters to the wrong treatment site, based on a possible total treatment time of 1.5 minutes. The exposure occurred as a result of two power disruptions during a thunderstorm. The loss of electrical power caused the unit table to move which resulted in treatment to the wrong site. The patient received 0.35 minutes of the intended fractionated treatment time of 1.5 minutes. The patient was prescribed a total dose of 5040cGy to be given in 28 fractions of 180 cGy per day at the rate of 5 fractions per week. The prescribing physician elected not to make up the missed dose. The prescribing physician indicated that the patient is not expected to have any adverse effects from the misadministration. The patient and referring physician were notified of the event. The licensee was able to recreate the event to demonstrate how the event occurred. The licensee has contacted the manufacturer. The State will keep NRC informed of the results of the review for any generic implications.</p>
<p>Reportable within 24 hours under 10 CFR 36.83(9)</p>	<p>Possible Loss of Water or Leakage from Source Water Pool at Irradiator Facility</p> <p>Licensee notified the State that the controls at a Co-60 irradiator facility were indicating that the water level was low, circulating pump off, and fill valves were open. The pool water level gauge indicated a pool water level of 93 inches, well below the normal level of 137 inches. Previous incidents indicated that a loss of compressed air pressure to the water level gauge could result in an erroneously low water level gauge reading, causing the automatic pool fill valves to open, and the pool water circulating pump to turn off. The compressed air system pressure was found to be in the normal range, but the operator found water and congealed oil in the air line supplying the pool water level gauge, and the air line supplying the elevator control valve. Further investigation found that the compressed air line water traps were full of water. A past similar incident resulted in a failure to raise the elevator. The operator then verified that the pool water level was in fact normal. The licensee requested the building maintenance personnel to diagnose and repair the compressed air supply immediately, to prevent the conductivity in the pool water from reaching abnormal levels as a result of the resin filter circulating pump being automatically turned off by the false low pool water level meter reading. Maintenance personnel responded and replaced a failed compressed air dryer, and monitored the open air lines to clear the lines of water. A float activated automatic water drain was installed in the air line to prevent a possible reoccurrence by allowing any water to automatically drain from the air line.</p>

1.6 Nuclear Material Events Database (NMED) Sample Data Entry Screens

The following pages contain sample data entry screens from the NMED database which shows the level of detail the States need to provide for a given event. Detailed NMED user information is contained in the NMED Coding Manual provided by INEEL along with the software to the Agreement States.

“This information request has been approved by **OMB 3130-0178**, expiration date 06/30/2000. The estimated burden per response to comply with this collection request is 1.25 hours. Forward any comments regarding the burden estimate to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0052), Office of Management and Budget, Washington, DC 20503. 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, a collection of information unless it displays a currently valid OMB clearance number.”

Table 1.4 Sample NMED Data Entry Screens (OMB 3130-0178)

Basic Information

Event Classes










ABSTRACT

Item Number:

EVENT DATE/TIME

Date:

Time:

Time Zone:

DISCOVERY DATE/TIME

Date:

Time:

Time Zone:

REPORT DATE/TIME

Date:

Time:

Time Zone:

LICENSEE INFORMATION

Agreement State: <input style="width: 100%;" type="text"/>	Reciprocity: <input style="width: 100%;" type="text"/>
License No: <input style="width: 100%;" type="text"/>	Name: <input style="width: 100%;" type="text"/>
City: <input style="width: 100%;" type="text"/>	State: <input style="width: 100%;" type="text"/>
Program Code: <input style="width: 100%;" type="text"/>	Docket: <input style="width: 100%;" type="text"/>
Other License #: <input style="width: 100%;" type="text"/>	

SCREEN 2

Item Number:

SITE OF EVENT

License No: <input style="width: 100%;" type="text"/>	Site Name: <input style="width: 100%;" type="text"/>
NRC Reg. Office: <input style="width: 100%;" type="text"/>	State: <input style="width: 100%;" type="text"/>

ADDITIONAL INVOLVED PARTY

Name: <input style="width: 100%;" type="text"/>	City: <input style="width: 100%;" type="text"/>
License No: <input style="width: 100%;" type="text"/>	State: <input style="width: 100%;" type="text"/>

OTHER INFORMATION

Reportable Event: <input style="width: 100%;" type="text"/>	Abnormal Occurrence: <input style="width: 100%;" type="text"/>
Agreement State Reportability: <input style="width: 100%;" type="text"/>	Investigation: <input style="width: 100%;" type="text"/>
Atomic Energy Act Material: <input style="width: 100%;" type="text"/>	NRC Report: <input style="width: 100%;" type="text"/>
Consultant Hired: <input style="width: 100%;" type="text"/>	

Table 1.4 NMED cont.

Event Documents List

Item Number:

Report ID Number:

Coder Initials:

Report Source:

Entry Initials:

Reporting Requirements

Item Number: Class Event:

Report Required:

Requirement:

RADIATION LEVELS IN EXCESS OF 200 MREM/H AT THE SURFACE OF A PACKAGE OR
 GREATER THAN 10 MREM/H AT 3 FT FROM THE SURFACE OF A PACKAGE.

Report Mode:

Contributing Factors/Corrective Actions Information

Item Number: Class Event:

Factor Number:

Contributing Factors:

Precipitators:

Corrective Actions:

Table 1.4 NMED cont.

Equipment Information - System Level









Item Number: Class Event:

System ID Number:

System Name:

Manufacturer:

Model Number:

Serial Number:

Manufacture Date:

Consequence:

Equipment Information (Component Level)









Item Number: Class Event:

Compon. ID #: <input style="width: 50px;" type="text"/>	Manufacture Date: <input style="width: 100px;" type="text"/>
Compon. Name: <input style="width: 250px;" type="text"/>	Radionuclide: <input style="width: 150px;" type="text"/>
System Name: <input style="width: 250px;" type="text"/>	Activity: <input style="width: 100px;" type="text"/> Curies
Manufacturer: <input style="width: 200px;" type="text"/>	Assay Date: <input style="width: 100px;" type="text"/>
Model Number: <input style="width: 180px;" type="text"/>	Source Change Date: <input style="width: 100px;" type="text"/>
Serial Number: <input style="width: 140px;" type="text"/>	Leak Test Results: <input style="width: 100px;" type="text"/> microcuries
Consequence: <input style="width: 200px;" type="text"/>	

Table 1.4 NMED cont.

Release of Material Information

Add Undo Save Print

Item Number: Class Event:

Release Type:
 Activity: Curies

Consequence:

Radionuclide:

Over-exposure Information

Add Undo Save Print

Item Number: Class Event: Exposure Number:

Person ID Number:
 Radiation Exposure Source:
 Exposure Dose: (In REM)
 Body Part Receiving Dose:
 Consequence:

Consultant Information

Add Undo Save Print

Item Number: Class Event:

Consultant's Name:
 Consultant's Company:
 Who Hired Consultant:
 Consultant's Specialty:

Table 1.4 NMED cont.

Misadministration Information		
<input type="button" value="Add"/> <input type="button" value="Undo"/> <input type="button" value="Save"/> <input type="button" value="Print"/>		
Item Number: <input type="text"/>	Class Event: <input type="text"/>	Number of Patients: <input type="text"/>
Patient Number: <input type="text"/>	% Overexposed: <input type="text"/>	
Patient Informed: <input type="text"/>	% Underexposed: <input type="text"/>	
Date Informed: <input type="text"/>	Consequences: <input type="text"/>	
<p style="text-align: center;">INTENDED</p>		<p style="text-align: center;">GIVEN</p>
Procedure: <input type="text"/>	Procedure: <input type="text"/>	
Dose in RAD: <input type="text"/>	Dose in RAD: <input type="text"/>	
Organ: <input type="text"/>	Organ: <input type="text"/>	
Study: <input type="text"/>	Study: <input type="text"/>	
Radiopharm.: <input type="text"/>	Radiopharm.: <input type="text"/>	
Radionuclide: <input type="text"/>	Radionuclide: <input type="text"/>	
Millicuries: <input type="text"/>	Millicuries: <input type="text"/>	
Assay Time: <input type="text"/>	Family Dose: <input type="text"/> (In REM)	
Administered By: <input type="text"/>	Newborn Dose: <input type="text"/> (In REM)	
	Fetal Dose: <input type="text"/> (In REM)	

Demographic Information		
<input type="button" value="Add"/> <input type="button" value="Undo"/> <input type="button" value="Save"/> <input type="button" value="Print"/>		
Item Number: <input type="text"/>	Class Event: <input type="text"/>	
Individual ID Number: <input type="text"/>		
Individual's Group Code: <input type="text"/>		

The following pages contain items 1.7 Sample Event Report Cover Page (for event reports provided in writing), 1.8 a listing of the basic information to be included in a written event report, and item 1.9 a listing of the basic information to be included in a written medical misadministration event report.

EVENT REPORT COVER PAGE

AGREEMENT STATE

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

DATE:

TO:
Director
Office of State Programs

SUBJECT:

STATE:

Signature and Title: _____

1.8 EVENT REPORT (Basic Information)

This list is an option for those Agreement States who choose not to enter event data electronically into the Nuclear Material Events Database (NMED). The information provided must be compatible to the information needed for the NMED system and presented clearly in readable form.

- | | |
|--|---|
| <ul style="list-style-type: none"> (a) Licensee (Name, city and State) (b) Agreement State ID No. (NY-97-001) (MS-97-001), State ID, year, sequentially assigned ID number. (c) Type of License (d) License No. (e) This Item No. (Follow-up Report No. 01, 02, etc.) (f) Abnormal Occurrence (Y\N). See AO Criteria contained in NUREG-0090 (g) Isotope (i.e., Cs-137; Ir-192, Co-60, Am-241, Po-210 etc. <ul style="list-style-type: none"> - Activity - Need to clearly show radiopharmaceuticals, as well as isotopes. (h) Type of Isotope and activity (AEA material, accelerator produced, NORM) (I) Date of Event (j) Date of this Report (k) Amount of Radioactive Material (l) Events Involving Overexposure <ul style="list-style-type: none"> - No. of Individuals Overexposed - Source of Radiation - Type of Individual (occupational worker, member of the public) - Event Location - Dose Estimated to Individuals Involved in the Event (In REM) - Body Part Receiving Dose - Consequence | <ul style="list-style-type: none"> (m) Leaking Source <ul style="list-style-type: none"> - Leak test information (n) Lost or Stolen Material <ul style="list-style-type: none"> 1. Nuclear Material <ul style="list-style-type: none"> - Event - Event Location - Probable Disposition 2. Sealed Sources and Devices <ul style="list-style-type: none"> - Type - Manufacturer, Model No. - Serial No. - Disposition/Recovery (o) Release of Material <ul style="list-style-type: none"> - Form - Event - Location - Activity (Curies) (p) Events Involving Radiography <ul style="list-style-type: none"> - Location - Equipment description
Manufacturer, Model No. - Event (q) Event Involving an Irradiator (r) Events Involving Teletherapy (s) Transportation Event <ul style="list-style-type: none"> - Location - Shippers name and address - Package type - Package Identification No. (t) Regulatory reporting requirement (Indicate applicable licensee reporting requirement) (u) Demographic information (v) ABSTRACT: Include where, when, how, and why. (Describe the cause of the event(s), contributing factors, persons involved, consequences, and licensee corrective actions taken or planned.) Attach a copy of the licensee's 30 day report, where applicable. |
|--|---|

1.9 MEDICAL MISADMINISTRATION

(Basic Information)

This list is an option for Agreement States that choose not to enter event data electronically into the Nuclear Material Events Database (NMED). The information provided must be compatible with information needed for the NMED system and presented clearly in readable form.

- (a) Licensee (Name, City and State)
(b) Agreement State ID No. (NYC-97-001) (MS-97-001), State ID, year, sequentially assigned ID number.
(c) Type of License (Broad scope, private practice medical, etc.)
(d) License No.
(e) This Item No. (Follow-up Report No. 01, 02, 03, etc.)
(f) Abnormal Occurrence (Y/N). See AO Criteria contained in NUREG-0090.
(g) Patient\Responsible Relative Notified (Y\N)
(h) 15 day Written Report Provided (Y\N)
(i) Date of Event
(j) Date of this Report
(k) Regulatory reporting requirement (Indicate applicable licensee reporting requirement)
(l) ABSTRACT:
Initial report: Include where, when, how, cause, provide as much information as is known at the time of the initial report.

Procedure/Study: Actual and intended

NOTE: Need to clearly show radiopharmaceuticals, as well as isotopes.

Isotope and dose involved: (i.e., 200 µCi of Iodine Hippurate I-131; 5 mCi of Iodine-125; 10 mCi of Iodine-131; 40 mCi of Cs-137; 2 mCi of Tc-99m; 5 mCi of P-32, etc. (clearly identify chemical and physical form).

Exposure: Intended and actual

Treatment plan: fractionations, if any.

Device (Equipment) involved: High Dose Rate Afterloader, Make and Model No. ____ (where applicable).

Systems: Computer program and developer, where applicable.

Referring Physician notified: (Y\N)

Patient notified: (Y/N)

Include information on all person(s) that may have been involved including employees, i.e. assistants, technicians, nurses, etc. Where applicable, describe the prescribed treatment plan and the actual treatments administered, including fractionations, include consequences. Provide an assessment of any expected effects on all those who were exposed, for unusual cases it may be necessary to include a medical consultant. Consultant used, identify. Describe licensees corrective actions.

Updated Information: provide any updated information in future reports, use the Original Item ID# (MS-97-001) and indicate on the cover page that it is updated information.

Demographic information (Description)

SECTION II

Abnormal Occurrence Guidelines and Criteria

2.0 ABNORMAL OCCURRENCE GUIDELINES AND CRITERIA

2.1 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. Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438, 42 USC 5848) identified an abnormal occurrence (AO) as an unscheduled incident or event that the Commission determines to be significant from the standpoint of public health and safety. Section 208 of the Act also requires that the Commission inform Congress of any abnormal occurrences. The Agreement States support the NRC in their effort to keep Congress apprised of any significant events that may directly affect public health and safety by providing information on proposed abnormal occurrences that have occurred in their State.

2.2 Abnormal Occurrence Policy Information

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

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

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

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

An incident or event will be considered an AO if it involves a major reduction in the degree of protection of the public health or safety. This type of incident or event would have a moderate

or severe impact on the public health or safety and could include, but need not be limited to the following:

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

2.3 Agreement State Proposed AOs

Agreement State staff should screen events against the AO criteria and identify potential AO events as part their routine program to inform NRC of all events reported by Agreement licensees. In addition to routine reporting of significant and routine events to NRC, Agreement States are requested to prepare a special written report for potential abnormal occurrences. Agreement State staff should follow the guidelines for preparing AO write-ups contained in Section 2.5 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.

2.4 Abnormal Occurrence Criteria (Appendix A, 62 FR 18822)

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 exposure⁵ to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more; or an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ or tissue other than the lens of the eye, bone marrow and the gonads, of 2500 mSv (250 rem) or more; or an annual dose equivalent to the lens of the eye, of 1 Sv (100 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow, and the gonads, of 1 Sv (100 rem) or more; or an annual shallow-dose equivalent to the skin or extremities of 2500 mSv (250 rem) or more.
2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.
3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

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

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

An “unintended radiation exposure” includes any occupational exposure, exposure to the general public, or exposure as a result of a medical misadministration (as defined in §35.2) involving the wrong individual that exceeds the reporting values established in the regulations.

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

- 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.*⁶
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.*

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.

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

1. *An accidental criticality [10 CFR 70.52(a)].*
2. *A major deficiency in design, construction, control, or operation having significant safety implications requiring immediate remedial action.*
3. *A serious deficiency in management or procedural controls in major areas.*
4. *Series of events (where individual events are not of major importance), recurring incidents, and incidents with implications for similar facilities (generic incidents) that create a major safety concern.*

II. *For Commercial Nuclear Power Plant Licensees.*

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

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

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

1. *Discovery of a major condition not specifically considered in the safety analysis report (SAR) or TS that requires immediate remedial action.*
2. *Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, GDC 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).*

III. For Fuel Cycle Facilities.

1. A shutdown of the plant or portion of the plant resulting from a significant event and/or violation of a law, regulation, or a license/certificate condition.
2. A major condition or significant event not considered in the license/certificate that requires immediate remedial action.
3. A major condition or significant event that seriously compromises the ability of a safety system to perform its designated function that requires immediate remedial action to prevent a criticality, radiological or chemical process hazard.

IV. For Medical Licensees.

A medical misadministration that:

- (a) Results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1000 rad) to any other organ; and
- (b) Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive or (2) a prescribed dose or dosage that (I) is the wrong radiopharmaceutical,⁷ or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source(s).

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 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 are items that may possibly be perceived by the public to be of health or safety significance. Such items would not involve a major reduction in the level of protection provided for public health or safety; therefore, they would not be reported as abnormal occurrences. An example is an event where upon final evaluation by an NRC Incident Investigation Team, or an Agreement State equivalent response, a determination is made that the event does not meet the criteria for an abnormal occurrence.

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

2.5 GUIDELINES FOR ABNORMAL OCCURRENCE 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 Technical Publications Specialist using the Kodak Ektaprint Electronic Publishing System.

NOTE: Those Agreement States that already have INTERNET E-Mail capability may electronically send their AO information to OSP via Internet using WordPerfect or an ASCII text file. NRC is currently using WordPerfect 6.1. The file may be attached to an e-mail transmission. The OSP AO coordinator, Patricia Larkins, may be reached at (PML@NRC.GOV).

Margin notation - Indicate the Original ID No., State ID-YR.-ITEM NO. (XX-94-01).

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

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

Nature and Probable Consequences - Briefly explain what happened and what were the circumstances. Provide the specific details of the event, i.e., exposure (where applicable), source, indicate the specific isotope(s), quantity, dose (where applicable), treatment plan (where applicable), equipment, manufacturer and Model No. Describe any immediate actions taken by the licensee or the State (confirmatory action letter, special inspection, enforcement conference, enforcement action(s), etc.). The write-up should answer where, when, how, why, and efforts to prevent recurrence.

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

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

Cause or Causes - Self explanatory

Action(s) taken to prevent recurrence - Briefly explain what actions were taken to prevent recurrence by the licensee, and indicate whether or not the State directed the licensee to take the specific action(s), i.e., was State satisfied with the licensee's corrective actions, if so, please indicate that the "state was satisfied with the following corrective actions taken by the licensee" or "the licensee has complied with the corrective actions recommended by the State as follows . . ." Were there any enforcement actions, penalties, etc.?

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

The following pages contain two sample AO write-ups.

Fig. 2.1 SAMPLE INDUSTRIAL RADIOGRAPHY AO REPORT

State ID-Yr.-No.
(XX-97-01)

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

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

Date and Place: The Agency was notified on **(notification date)**, by **(Licensee)**, that a radiography overexposure had occurred on **(event date)**, at **(facility, location (Catastate))**.

Source\Quantity
Exposure

Nature and Probable Consequences: On **(event date)**, at approximately 7:00 PM, a radiography trainer working for **(Licensee)** in **(facility, location, (City, State))**, experienced a source disconnect of a 96 curie iridium-192 radiography source, that resulted in an extremity exposure of at least 500 rem to the thumb and index finger of a radiographer's left hand. The radiography trainer was radiographing welds on a 12 inch pipe line in a five foot deep ditch at **(Licensee)**, and began experiencing difficulty with the source exiting from and retracting into the camera earlier in the day. After completing a radiograph, while trying to retract the source to the shielded position, survey meter readings indicated a source disconnect. The radiographer got a one inch thick lead sheet from the radiography truck and covered the source in the guide tube. By this time it was dark. The radiographer helper rope off a larger area and stayed a distance from the source. He then asked the **(Licensee)** inspector to notify the radiography company RSO, but to tell him that everything was under control, and that the radiographer could handle the situation. As the trainer disconnected the guide tube, the source assembly fell into the mud at the bottom of a ditch. While picking up the source assembly from the mud with channel lock pliers, the source slipped. He instinctively reached for and straightened the source assembly (pigtail) with his hand, apparently touching the source in the process. He placed the pigtail into the camera, intending to place the source capsule in first. He noticed the survey meter reading high, indicating the source was outside of the camera. The radiographer then removed the source from the camera and placed it under the lead sheet. He then removed the lockbox from the camera, inserted the

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

sheet. He then removed the lockbox from the camera, inserted the source end of the pigtail, replaced the lockbox and locked it. The source was now secured in the shielded position. The barricades were taken down, the equipment was loaded on the truck, and the crew returned to the office. The company did not notify the Agency of the disconnect.

*Equipment\Device
(Manuf.\Model No.)*

About 10 days later, the radiographer started experiencing discomfort in his left thumb and index finger and visited a doctor for treatment on March 9, 1994, March 14, and April 1, 1994. On April 11, 1994, the RSO and the radiographer visited the Agency office and reported the incident. The Agency investigated the incident at this time. The radiographer's film badge reading was 1.06 rem whole body. An inspection of the camera was performed by the company RSO the day after the incident. The Licensee and the State Agency determined that the company had ordered two model #22 pigtails and sources from (**Manufacturer, City, State**), for the company's Gamma Century radiography cameras. (**Manufacturer**) inadvertently sent a model #22 and a Model #23 pigtail instead of the two model #22's ordered. The two models appear similar, but close examination reveal two differences. The model #22 is manufactured with 1/8 inch aircraft cable and a 3/4 inch connector, the model #23 is manufactured with teleflex cable, the same as the drive cable material, and a one inch connector. The model #23 is not made to be used in the Gamma century camera. The radiography company assumed the two pigtails sent to them were model #22's. The #23 was mistakenly placed in the Gamma century camera and is apparently the cause of the disconnect. The Agency investigation determined that the trainer had received at least a 1500 rem exposure to the thumb and index finger of the left hand. The (**State**) Radiation Control Program, in which the manufacturer was licensed, was informed of the incident and investigated the manufacturer's (**Licensee**) error in sending the two different pigtails to the radiography company.

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

Actions Taken to Prevent Recurrence

Licensee - Actions will be given at the enforcement conference.

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

Status

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

Fig. 2.2 SAMPLE MEDICAL AO REPORT

State ID-YR.-NO.
(XX-9702)

Medical Brachytherapy Misadministration at
(Name of facility, City, State) location.

Criteria

In accordance with the AO criteria, administering a therapeutic dose that is at least 50 percent greater than the prescribed dose should be considered an abnormal occurrence.

Date and Place - The Agency was notified on (**Date**), that a brachytherapy overexposure had occurred on (**Event date(s)**); at **Facility; City and State** location).

Procedure
Source(s)
Treatment plan
Device\Equipment

Nature and Probable Consequences - A 68-year-old woman with Stage II vaginal cancer was referred to the hospital's radiation therapy department for a gynecological brachytherapy procedure involving the afterloading of cesium-137 and iridium-192 sources. A plan was developed to deliver a total dose of 6000 centiGray (cGy) (6000 rad) by a combination of 4000 cGy (4000 rad) from an external beam (linear accelerator) and 2000 cGy (2000 rad) from vaginal implant therapy. The external beam therapy was completed on September 9, 1993. The patient was then evaluated and plans were made to complete the implantation portion of the treatment. The treatment plan for the implant therapy included calculations for the time required to deliver 6000 cGy (6000 rad). The dose already delivered by the external beam was not considered in the plan.

Actual vs. intended administration

The attending physician reviewed the dose calculations on October 9, the fourth day of the implant, and determined that the duration of the implant treatment was likely to have been too long. He immediately removed the implants. Calculations revealed that the patient received 4000 to 4500 cGy (4000 to 4500 rad) from the brachytherapy treatment. Two days later, on Monday October 11, the attending physician verified with the physics staff that his dose calculations were correct. The patient received a total dose of 8000-8500 cGy (8000-8500 rad), (4000 from external beam and (4000-4500 from the implant) rather than the 6000 cGy intended (4000 from external beam and 2000 from the implant). On October 11, the attending physician in radiation oncology reviewed the radiation therapy calculations and verified with staff the actual administered dose. A telephone report was made to the [**Identify State Health Department**] on October 12, 1993, and an on-site investigation by State staff was conducted on

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

**Health effect
to patient**

October 14, written report from the licensee was submitted to the State agency on October 26. A committee of professionals convened to perform a quality review. As a result of a literature and standard practice review the committee concluded that the recommended treatment for Stage II vaginal carcinoma is generally in a range of 7000-7500 cGy (7000-7500 rad) total dose with an external dose of 4000-5000 cGy (4000-5000 rad) and delivery of the remaining dose by implant. Others have recommended up to a total dose of 8500 cGy (8500 rad). This patient while receiving more than her physician initially intended, did not receive a dose markedly beyond

**Patient
notification**

recommended treatment for her disease. The dose was within an acceptable range, therefore, it is not anticipated that any complications beyond those normally seen with treatment for this therapy will occur. However, the patient will be closely monitored for any complications and appropriate treatment will be provided. The patient had been notified of the event by the physician on October 20. A letter confirming the discussion of the event was also sent to the patient.

Cause or Causes - The reportable event was caused by a failure to account for the previously administered external beam therapy. The incident occurred due to lack of communication of the prior therapy during the planning of the brachytherapy treatment.

Actions Taken to Prevent Recurrence

Licensee - As soon as the licensee's management determined that a reportable event had occurred, they formed a committee of professionals not involved in the patient's care to conduct a quality assurance review. The committee concluded that the incident occurred due to lack of communication of the prior therapy during the planning of the brachytherapy treatment. They recommended that no brachytherapy be given without a signed, written prescription by the attending physician. The written prescription must contain information about all radiation therapy given to the patient. The medical center has adopted the committee's recommendations and has initiated training to the affected staff. This action should prevent a recurrence of a similar event.

State agency - The results of the on-site investigation by the State staff agrees with the findings of the licensee's quality assurance review. The licensee's proposal appears to be adequate to prevent recurrence.

Status

The State considers this item (**open, closed**).

Appendix

Glossary

- DCS** The Document Control System (DCS) is an internal NRC automated document search and retrieval system, indexed by a unique identification (assessment) No. for use by the staff of the NRC.
- EN** The Event Notification (EN) system is an internal NRC automated event tracking system used by the NRC Operations Center to track information on incoming notifications of the occurrence of significant material events that have or may affect public health and safety. Significant material events are reported to the NRC Operations Center by NRC licensees, staff of the Agreement States, other Federal agencies, and the public. The EN's are published daily through Internet.
- Gray** Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule/kilogram (100 rads).
- Metric Sys.** The metric system is now included in all Federal documents. All event reports should include the dual system of Units (SI) in the following order. First use the International System of Units (SI) with the English System unit equivalent following in parentheses. Spell out the first time it appears, continue with an abbreviation, (see examples below).
1000 centigray (cGy) (1000 rad) the first time, and continue with 1000 cGy (1000 rad).
50 millisieverts (mSv) (5 rem)
730 megabecquerel (MBq) (20.4 mCi)
- NMED** The Nuclear Materials Events Database (NMED), maintained by NRC, is a historical collection of incidents and events that have occurred throughout the United States involving the use of radioactive material covered under the Atomic Energy Act. This excludes events occurring at nuclear power plants.
- NRC Ops Center** The NRC Operations Center in Rockville, MD, 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** Events reports that appear to have health and safety significance or major public or media interest are summarized and presented in Preliminary Notification (PN) reports. These reports are available to the public through Internet.

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

Reference Manual

The following is a list of NRC manuals and procedures that contain additional information on event response and abnormal occurrences. Additionally information is provided on the NRC Region contact for Agreement State issues, the Federal Radiological Emergency Response Plan (FRERP), and the Radiation Emergency Assistance Center (REACTS) along with a telephone number.

NRC Management Directives

- 8.1 Abnormal Occurrence Reporting Procedures
- 8.10 NRC Medical Event Assessment Program

NRC Inspection Manual (Series 1300, Incident Response)

- 1300 Incident Response Actions - Responsibility and Authority (84-080)
- 1301 Response to Non-Emergency Incidents Involving Radioactive Material (96-022)
- 1302 Action Levels for Radiation Exposures and Contamination Associated with Material Events Involving Members of the Public (94-004)
- 1303 Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE) (95-009)
- 1330 Response to Transportation Accidents Involving Radioactive Materials (84-22)
- 1360 Use of Physician and Scientific Consultants in the Medical Consultant Program (94-013)

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

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

- FRERP** The Commission is the lead federal agency for response to any event involving NRC-licensed Atomic Energy Act material under the Federal Radiological Emergency Response Plan (FRERP), which includes other federal agencies, i.e. Department of Energy (DOE), Environmental Protection Agency (EPA), Federal Emergency Response Administration (FEMA). FRERP covers any peacetime radiological emergency that has actual, potential or perceived radiological consequences within the United States.
- REACTS** The Radiation Emergency Assistance Center/Training Site (REACTS), is a Department of Energy (DOE) resource headquartered in Oak Ridge, Tennessee. 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.
- 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 Programs regarding Agreement State radiation control programs, and who participates in technical reviews of Agreement State radiation control programs.