

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

January 10, 1996

NRC INFORMATION NOTICE 96-04: INCIDENT REPORTING REQUIREMENTS FOR
RADIOGRAPHY LICENSEES

Addressees

All U.S. Nuclear Regulatory Commission radiography licensees and manufacturers of radiography equipment.

Purpose

NRC is issuing this information notice to addressees to alert them to, and inform them of, the reporting requirements under 10 CFR 34.30. It is expected that recipients will review the information for applicability to their facilities and activities and consider actions, as appropriate. This includes manufacturers of radiography equipment who advise radiography licensees or potential licensees on the requirements of 10 CFR Part 34. However, suggestions contained in this information notice are not NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances

On January 10, 1990, Part 34 was amended to add a reporting requirement, under 10 CFR 34.30, that made it necessary for radiography licensees to report to NRC, occurrences of source disconnects, source hangups, or the failure of any safety related radiography equipment component to properly perform its intended function. NRC is concerned that incidents are not being reported either because licensees have not understood the requirements of this section or because they do not know that such requirements exist.

As of January 1995, NRC has received only about 65 reports under this section. Based on other sources of information -- including audits of radiography equipment manufacturers' records, reports filed in accordance with 10 CFR Part 21 requirements, and unofficial reports from radiography licensees and equipment suppliers -- NRC believes that many more reports of incidents should have been received. Specifically, an audit of a radiography equipment manufacturer's customer complaint file showed that there had been a substantial number of complaints from radiographers about the failure of a locking mechanism. However, NRC has received only a few reports of this type of failure. In addition, a substantial number of the reports that NRC has received have been submitted by only a small percentage of NRC radiography licensees. Such incidences of reportable events would likely be more evenly distributed.

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This information notice is intended to alert radiography licensees to the requirement to report incidents under 10 CFR 34.30, to describe and provide examples of the types of incidents that must be reported, and to clarify the information that must be included in a report to satisfy the requirements of this section. Attachment 1 to this notice lists frequently asked questions and answers that provide additional guidance on the types of incidents that must be reported under 10 CFR 34.30, and how and where the reports are to be made. Licensees may use the attachment and this notice as a guide when preparing reports in accordance with 10 CFR 34.30. This notice (and attachment) will also serve to inform manufacturers of radiography equipment (who advise and assist radiography licensees) of this requirement. This notice describes only the minimum information that must be reported. However, licensees may include additional information in a report, as necessary, or appropriate.

NRC uses information from these reports to detect trends or identify generic issues associated with the construction or use of radiography equipment, and to take appropriate actions to reduce or eliminate similar incidents in the future. Licensee failure to make the required reports hampers this effort and violates NRC regulations.

Discussion

There are about 169 NRC specific licensees authorized to perform radiographic operations under NRC jurisdiction. The majority of the reports received during a 5-year period concerned source disconnects or source hangups. In addition, several reports were received, early in the period, about manual-locking-mechanism failures that were determined to be caused by a manufacturing defect. The following paragraphs illustrate examples of reports received, in accordance with 10 CFR 34.30, on these types of incidents. A number of other reports, on a variety of other failures, were also received.

A disconnect occurs when the source capsule or source assembly becomes separated from the drive cable and cannot be normally retracted to the fully shielded position. Approximately half of all the reports received involved disconnects. The primary causes of the disconnects were reported to have resulted from wear in the connector, human error, design flaws, or equipment malfunction or defect caused during manufacture. For example, disconnects have occurred when the end of the male connector broke off, when the crimp holding the female connector on the drive cable failed, and when the pigtail frayed and broke.

A hangup occurs when the entire source assembly remains connected to the drive cable, but the source cannot be retracted to the fully shielded position because of resistance in the equipment or an obstruction. All the reported hangups have occurred either in the guide tube, the S-tube, or at the exposure

device outlet fitting. The majority of the hangups reported were indicated to be caused by human error or wear in the equipment. Reports indicating human error have included incidents where the radiographer did not set up the exposure jigs properly, which then toppled onto and crushed the guide tube sufficiently to prevent source retraction, and where the radiographer bent the guide tube around too sharp an angle, crimping the tube and preventing proper source movement. Reports indicating wear in the equipment have included causes such as extensive wear in the S-tube and surrounding depleted uranium, sufficient to cause the source capsule to become stuck in the resulting indentation.

In the cases where manual-locking-mechanism failures were reported, the manufacturer determined that the reported failures were caused by an inherent design flaw that allowed the key to be removed when in the unlocked position, or caused the lock to partially malfunction. The manufacturer corrected the design flaw, and no additional reports of these types of failures have been received.

The failures discussed above are intended to provide general guidance on, and familiarize radiography licensees with, the typical types of incidents that have been reported. Radiography licensees should consider this guidance, and the additional guidance contained in Attachment 1, when determining if an incident should be reported. It is extremely important that radiography licensees make the required reports to the Commission in a timely manner, since the reports are used to detect trends or generic issues that have the potential to cause a significant safety hazard. In addition, NRC uses the information gleaned from the reports to determine the appropriate course of action to reduce or eliminate similar incidents in the future, and to protect the health and safety of both the radiography licensees and the public.

In addition to the information specified in 10 CFR 34.30 (see Question 3 of Attachment 1), we strongly suggest that submitted reports contain a contact's name and phone number, so that NRC personnel may follow up on the report, if necessary. Information on other means of communication, such as facsimile phone numbers and Internet E-mail addresses, is also helpful.

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact the technical contact listed below or the appropriate regional office.



Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contact: Douglas Broaddus, NMSS
301-415-5847
Internet:dab@nrc.gov

Attachments:

1. Questions and Answers for Reporting Requirements in 10 CFR 34.30
2. List of Recently issued NMSS Information Notices
3. List of Recently issued NRC Information Notices

FREQUENTLY ASKED
QUESTIONS AND ANSWERS FOR REPORTING
REQUIREMENTS IN 10 CFR 34.30

1. WHAT INCIDENTS MUST BE REPORTED?

Section 34.30(a), paragraphs (1) to (3), describe the types of events that must be reported. These include: (a) source disconnects involving a separation of the source capsule or source assembly from the drive cable; (b) hangups that prevent the source assembly from being retracted to the fully shielded position, and to be secured in this position, as designed and intended; and (c) the failure of any other component of the radiography equipment that could cause the equipment to operate in an unsafe manner. Disconnects would include not only separation of the source assembly from the drive cable, but also loss of radioactive material from the source capsule, separation of the source capsule from the source assembly, and separation of the drive cable along its length. Hangups may occur at any point along the intended travel of the source, including the S-tube, the outlet fittings, the guide tube, and any fittings connected to the end of the guide tube (e.g., collimator, end stops, etc.). Examples of the failure of other components to operate properly, causing the device to operate in an unsafe manner, include: (a) failure of the lock or securing mechanism to adequately secure the source assembly in the fully shielded position, thereby allowing unintended movement of the source assembly; (b) failure of the guide tube or controls to connect to the exposure device as intended, or operate properly; and (c) failure of source position indicators to show actual source position. The licensee is responsible for evaluating events that may be reportable under 10 CFR 34.30 and use appropriate judgment as to whether the event is reportable. If, after evaluation, the licensee is not sure whether to report the event, we recommended that the licensee make the report to the Commission, according to 10 CFR 34.30, and include the reasons why the licensee is unsure whether the event is reportable.

2. WHEN AND WHERE SHOULD THE REPORTS BE SENT?

Within 30 days of an event that is determined to be reportable under 10 CFR 34.30, two copies of the report must be submitted to NRC, to the addressees listed in 10 CFR 34.30, paragraph (a). The addressees are:

Branch Chief
Medical, Academic, and
Commercial Use Safety Branch
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Director
Office for Analysis and Evaluation
of Operational Data
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

3. WHAT MUST THE REPORTS INCLUDE?

The requirements for what must be included in a report are contained in 10 CFR 34.30, paragraph (b), and are detailed below:

Section 34.30(b)(1) requires that the report contain "A description of the equipment problem." The description should include the type of incident (disconnect, hangup, lock failure, etc.) along with an explanation of how the event occurred. This explanation could include the number of exposures taken before the incident happened, the arrangement of the equipment at the time of the incident, and the environment in which the incident occurred (a roadside trench, an exposure cell, excessively hot, cold, or humid conditions, etc.). The report should always include how the incident was noticed. For example, a disconnect may be noticed by a sudden release in tension on the cable or a high survey meter reading approaching the exposure device.

Section 34.30(b)(2) requires that the report contain the "Cause of each incident, if known." The licensee should attempt to determine the root cause of the incident to the best of its ability and describe it in the report. We are especially interested in why a licensee believes a part has failed, whether caused by a manufacturing problem, a design flaw, improper use, or insufficient maintenance.

Section 34.30(b)(3) requires that the report contain the "Manufacturer and model number of equipment involved in the incident." This would include the source assembly, exposure device, guide tube, control assembly, and any fittings, placed on the end of the guide tube, that were involved in the incident. In all cases, information on the camera and source assembly involved in the incident should be provided. This section does not require serial numbers of equipment, although a licensee may include serial number(s) in the report, and in some cases, this information is helpful.

Section 34.30(b)(4) requires that the report contain the "Place, time, and date of the incident." The place should be a complete street address, if possible. If the site has no address, the licensee should describe the site to the best of its ability, including the name of the site, the nearest road to the site, the nearest town or city, and any other descriptive information that would be useful in identifying the location of the incident. The time (including a.m. or p.m.) the incident occurred and the date(s) it occurred on must also be included in the report. If the description of the incident includes events that occurred over several days, the date each event occurred should be clear.

Section 34.30(b)(5) requires that the report contain a description of the "Actions taken to establish normal operations." This includes any

action taken by the licensee or other persons following the incident to return to a normal and safe situation. It would include actions like attempting to get the equipment to operate properly, posting barriers and maintaining surveillance of the area while a source is exposed, and source-retrieval procedures. It does not include investigation into the cause of the incident or corrective actions following the investigation (see next section).

Section 34.30(b)(6) requires that the report contain a description of the "Corrective actions taken or planned to prevent recurrence." This includes training given to personnel to better detect and respond during an incident. It also includes investigation into the cause of the equipment failure, any repairs made on the equipment, whether the equipment was removed from service, and whether the equipment was sent for testing. If testing was performed, the results from such testing should be provided.

Section 34.30(b)(7) requires that the report contain a description of the "Qualifications of personnel involved in the incident." This section does not need to be extensive. All that is needed is a description of the types of personnel involved. For instance, was the radiographer or the radiographer's assistant operating the equipment when the incident was noticed? Who was operating the equipment before that time? Was the radiation safety officer involved at any time? Specific names are not required, only the positions of the people involved. However, the field experience of the personnel involved may be useful information to include.

4. WHAT IF DETAILS OF THE INCIDENT ARE REPORTABLE UNDER ANOTHER REGULATION?

Unless a specific exclusion is contained in the regulations, all reports required in the regulations must be submitted, regardless of whether the information has been provided in accordance with the regulations in another separate report. However, in some situations, one report can be submitted to multiple addressees to satisfy several requirements. For example, section 34.30, paragraph (c) requires "Reports of overexposure submitted under section 20.405 [new Part 20, section 20.2203] which involve failure of safety components of radiography equipment must also include the information specified in paragraph (b) of [10 CFR 34.30]." Therefore, the report submitted under section 34.30 may also be submitted to meet part or all of the requirements contained in section 20.2203. Reports submitted under regulations other than 10 CFR 34.30 should contain a statement that the incident is also reportable under 10 CFR 34.30 so that the reports can be properly cataloged by the Commission.

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
95-58	10 CFR 34.20; Final Effective Date	12/18/95	Industrial Radiography Licensees.
95-55	Handling Uncontained Yellowcake Outside of a Facility Processing Circuit	12/6/95	All Uranium Recovery Licensees.
95-51	Recent Incidents Involving Potential Loss of Control of Licensed Material	10/27/95	All material and fuel cycle licensees.
95-50	Safety Defect in Gammamed 12i Bronchial Catheter Clamping Adapters	10/30/95	All High Dose Rate Afterloader (HDR) Licensees.
95-44	Ensuring Compatible Use of Drive Cables Incorporating Industrial Nuclear Company Ball-type Male Connectors	09/26/95	All Radiography Licensees.
95-39	Brachytherapy Incidents Involving Treatment Planning Errors	09/19/95	All U.S. Nuclear Regulatory Commission Medical Licensees.
95-29	Oversight of Design and Fabrication Activities for Metal Components Used in Spent Fuel Dry Storage Systems	06/07/95	All holders of OLs or CPs for nuclear power reactors. Independent spent fuel storage installation designers and fabricators.
95-28	Emplacement of Support Pads for Spent Fuel Dry Storage Installations at Reactor Sites	06/05/95	All holders of OLs or CPs for nuclear power reactors

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Information Notice No.	Subject	Date of Issuance	Issued to
96-03	Main Steam Safety Valve Setpoint Variation as a Result of Thermal Effects	01/05/96	All holders of OLs or CPs for nuclear power reactors
96-02	Inoperability of Power-Operated Relief Valves Masked by Downstream Indications During Testing	01/05/96	All holders of OLs or CPs for PWRs
96-01	Potential for High Post-Accident Closed-Cycle Cooling Water Temperatures to Disable Equipment Important to Safety	01/03/96	All holders of OLs or CPs for PWRs
95-58	10 CFR 34.20; Final Effective Date	12/18/95	Industrial Radiography Licensees
95-57	Risk Impact Study Regarding Maintenance During Low-Power Operation and Shutdown	12/18/95	All holders of OLs or CPs for nuclear power reactors.
95-56	Shielding Deficiency in Spent Fuel Transfer Canal at a Boiling-Water Reactor	12/11/95	All holders of OLs or CPs for nuclear power reactors.
95-55	Handling Uncontained Yellowcake Outside of a Facility Processing Circuit	12/06/95	All Uranium Recovery Licensees.

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Attachments filed in Jacket

Coordinated with IMAB (Pat Santiago) and AEOD (Sam Pettijohn)

* See previous concurrence

OFC	SCDB*	E	SCDB*	E	NMSS*	N	IMOB*	E	D:IMNS
NAME	DBroaddus/tk/11		RBaer		EKraus		KRamsey		<i>DCool</i>
DATE	12/21/95		12/22/95		12/20/95		10/10/95		1/5/96

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DOCUMENT NAME: 96-04.IN

In the cases where manual-locking-mechanism failures were reported, the manufacturer determined that the reported failures were caused by an inherent design flaw that allowed the key to be removed when in the unlocked position, or caused the lock to partially malfunction. The manufacturer corrected the design flaw, and no additional reports of these types of failures have been received.

The failures discussed above are intended to provide general guidance on, and familiarize radiography licensees with, the typical types of incidents that have been reported. Radiography licensees should consider this guidance, and the additional guidance contained in Attachment 1, when determining if an incident should be reported. It is extremely important that radiography licensees make the required reports to the Commission in a timely manner, since the reports are used to detect trends or generic issues that have the potential to cause a significant safety hazard. In addition, NRC uses the information gleaned from the reports to determine the appropriate course of action to reduce or eliminate similar incidents in the future, and to protect the health and safety of both the radiography licensees and the public.

In addition to the information specified in 10 CFR 34.30 (see question 3 of Attachment 1), we strongly suggest that submitted reports contain a contact's name and phone number, so that NRC personnel may follow up on the report, if necessary. Information on other means of communication, such as facsimile phone numbers and Internet E-mail addresses, is also helpful.

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Coordinated with IMAB (Pat Santiago) and AEOD (Sam Pettijohn)

* See previous concurrence

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OFC	SCDB*	E	SCDB*	E	PMDA*	N	IMOB*	E	D: IMNS		
NAME	DBroaddus		RBaer		EKraus		KRamsey		DCool		
DATE	12/21/95		12/22/95		12/20/95		10/10/95		1/3 /96		

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DATE	12/21/95		12/22/95		12/20/95		10/10/95		12/ /95		

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The number of reports received to date may not be all inclusive, in part, because radiography licensees are not familiar with the types of incidents required to be reported under 10 CFR 34.30, or are completely unaware of the requirement to report. The above descriptions are intended to provide guidance to ensure radiography licensees are familiar with the typical types of incidents reported. In addition, the attached list of questions and answers provides additional guidance on the types of incidents that must be reported under 10 CFR 34.30, and how the reports are to be made. It is extremely important that radiography licensees make the required reports to the Commission in a timely manner as the reports are used to detect trends or generic issues that have the potential to cause a significant safety hazard. NRC uses the information gained in the reports to determine the appropriate action to take to reduce or eliminate similar incidents in the future, and to protect the health and safety of the radiography licensees and the public.

In addition to the requirements outlined above and in the attachment, it is strongly suggested that each report contain a contact's name and phone number, so that NRC personnel may follow-up on the report, if necessary. Information concerning other means of communication, such as facsimile phone numbers and Internet E-mail addresses, are also helpful.

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NAME	DBroaddus		RBaer		PSantiago		LCampbell		SPettijohn		KRamsey		CJones
DATE	9/26/95		9/26/95		9/26/95		9/26/95		10/13/95		10/10/95		10/10/95
OFC	IMOB	E	DD:YMNS		D:IMNS								
NAME	GRandburn		FCombs		DCool								
DATE	10/10/95		10/11/95		9/ /95								

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