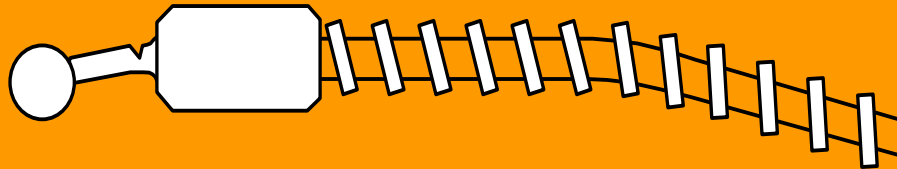


Equipment Malfunction Reporting: (A Manufacturer's Perspective)



Human Nature



PDE Publications
1st ed.: 1994; 2nd ed.: 2001

Target Risk

Dealing with the danger of death,
disease & damage in everyday decisions

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There are two types of overexposure:
chronic and acute.

Which type of overexposure are most
radiography equipment regulations
designed to prevent?

There are two types of overexposure:
chronic and acute.

Which type of overexposure are most
radiography equipment regulations
designed to prevent?

Answer: Acute overexposures

What are the likely consequences of an acute overexposure incident to the following parties?

A. Public

B. Regulators

C. Licensee

D. Worker

E. Manufacturer

What are the likely consequences of an acute overexposure incident?

- | | |
|-----------------|--|
| A. Public | Usually None |
| B. Regulators | Administrative labor |
| C. Licensee | Potential violation and
civil penalty |
| D. Worker | Pain, partial disability |
| F. Manufacturer | Product liability litigation |

Conclusion:

Manufacturers have a very high financial interest to improve safety, especially to reduce acute overexposures.

Subpart F--Notifications

Sec. 34.101 Notifications.

- (a) In addition to the reporting requirements specified in Sec. 30.50 and under other sections of this chapter, such as Sec. 21.21, each licensee shall provide a written report to the U.S. Nuclear Regulatory Commission, Division of Industrial and Medical Nuclear Safety, Washington, DC 20555-0001, with a copy to the Director, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, within 30 days of the occurrence of any of the following incidents involving radiographic equipment:
- (1) Unintentional disconnection of the source assembly from the control cable;**
 - (2) Inability to retract the source assembly to its fully shielded position and secure it in this position; or**
 - (3) Failure of any component (critical to safe operation of the device) to properly perform its intended function;**

Sec. 34.101 Notifications (cont).

(b) The licensee shall include the following information in each report submitted under paragraph (a) of this section, and in each report of overexposure submitted under 10 CFR 20.2203 which involves failure of safety components of radiography equipment:

- (1) A description of the equipment problem;
- (2) **Cause of each incident, if known;**
- (3) Name of the manufacturer and model number of equipment involved in the incident;
- (4) Place, date, and time of the incident;
- (5) Actions taken to establish normal operations;
- (6) Corrective actions taken or planned to prevent recurrence; and
- (7) Qualifications of personnel involved in the incident.

Are most equipment malfunctions reported
by radiography licensees?

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 manufacturer's 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.

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

April 6, 2001

NRC INFORMATION NOTICE 2001-03: INCIDENT REPORTING REQUIREMENTS FOR RADIOGRAPHY LICENSEES

Addressees:

All industrial radiography licensees.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this Information Notice (IN) to provide updated guidance on reporting requirements for radiographers. Licensees should review this information for applicability to their own procedures and consider actions, as appropriate. This includes manufacturers of radiography equipment who advise radiography licensees or potential licensees on the requirements of 10 CFR 34.30. However, information contained in this notice are not new NRC requirements; therefore, no specific action nor written response is required.

Background:

NRC issued IN 1996-04 on January 10, 1996, to alert licensees to, and inform them of, the reporting requirements under 10 CFR 34.30. This IN supersedes IN 1996-04. The guidance provided in Attachment 1 of IN 1996-04 has been revised to reflect the amended requirements in 10 CFR 34.30 and has been incorporated into this IN as Attachment 1. As with IN 1996-04, it is expected that licensees use this notice as a guide when preparing reports in accordance with (b)(2) and 10 CFR 34.101.

Description of Circumstances:

Since the issuance of IN 1996-04, NRC has identified several instances where licensees have failed to notify NRC, within 24 hours, in accordance with requirements in 10 CFR 30.50(b)(2), after the occurrence of an unintentional disconnection of the source assembly from the control cable, and an inability to retract the source assembly to its fully shielded and secured position.

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- Financial burden
- Licensee's fear of regulatory consequences
- Licensee's confidence of not getting caught

Should equipment manufacturers be required to report users' equipment malfunctions?

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Why?

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Absolutely not!

Why?

- Conflicts with manufacturers' need to maintain customer relations.
- Customers will purchase from other vendors.

Since many malfunctions are not reported, what could be done to influence more accurate reporting?

Actively enforce the malfunction reporting requirement.

- Inspectors can ask workers if any malfunctions have occurred lately.
- If “yes” inspectors can ask the RSO for a copy of the malfunction report.

If enough reports are issued, hazardous trends can be observed and corrective action taken for the highest risk equipment problems.

Equipment Malfunction Reporting



Questions?