PHILIPPINE NUCLEAR RESEARCH INSTITUTE

REGULATORY BULLETIN

NUCLEAR REGULATIONS, LICENSING AND SAFEGUARDS DIVISION

BULLETIN No. 04-03 **April 15, 2004**

INCIDENT REPORTING REQUIREMENTS FOR RADIOGRAPHY LICENSEES

A. ADDRESSEES

All PNRI radiography licensees and licensed suppliers of radiography equipment.

B. PURPOSE

PNRI is issuing this bulletin to remind radiography licensees and suppliers of the reporting requirements in CPR Part 11 about incidents arising from radiographic operations. It is expected that recipients will review the information for applicability to their facilities and activities and consider actions, as appropriate. This bulletin also addresses suppliers of radiography equipment who advise radiography licensees or potential licensees on the performance and safety features of the device. Suggestions contained in this bulletin are not new requirements, however, it suggests appropriate guidelines for complying with the reporting requirements

C. DESCRIPTION OF CIRCUMSTANCE

Section 31 of CPR Part 11 requires radiography licensees to report to PNRI occurrences of ***source disconnect***, ***source hangups***, or failure of any safety related radiography equipment component to properly perform its intended function. PNRI is concerned that incidents of this nature are not being reported either because licensees may not understand the safety implications of Section 31 or because they do not know that such requirements exist.

Based on available information filed with PNRI, that includes regulatory inspection and audit reports of radiography facilities, reports from radiography licensees and equipment suppliers, and reports of possible significant exposure of radiography personnel, PNRI believes that there could have been more reports of incidents received. Unofficial reports indicate that there had been a number of complaints from radiographers about the failure of cranking and locking mechanisms. However, only a few reports of this type of failure were received by PNRI. In addition, the reports that PNRI received have been submitted by only a small number of PNRI radiography licensees.

This bulletin is intended to remind radiography licensees to report incidents described in the preceding paragraphs as required by Section 31 of CPR Part 11, to describe and

provide examples of the types of incidents that must be reported, and to clarify the information that must be included in the report to satisfy the requirements of this Part.

The Attachment to this bulletin provides additional guidance on the types of incidents that must be reported under Section 31 of CPR Part 11, and how and where the reports are to be made. Licensees may use the Attachment to this bulletin as a guide when preparing reports in accordance with this Section. This bulletin describes only the minimum information that must be reported. However, licensees may include additional information in a report, as necessary, or appropriate.

If all licensees render such reports diligently and objectively, PNRI will use the information from these reports to analyze trends and/or identify relevant and 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. Inadvertent failure to make the required reports impedes any progress along this effort and licensees would be liable of violation of PNRI regulations if found to have willfully ignored this reporting requirement.

D. DISCUSSIONS

The following paragraphs illustrate examples of reportable incidents in accordance with Section 31 of CPR Part 11.

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. The primary causes of the **disconnects** may be the result of the usual wear and tear in the connector, human error, design flaws, 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 reported hangups have occurred either in the guide tube, the S-tube, or at the exposure device outlet fitting. The hangups could be caused by human error or wear and tear in the equipment. When human error is indicated as the cause of the incident, the radiographer may not have set up the exposure jigs properly, which then toppled onto and crushed the guide tube seriously to prevent source retraction, and where the radiographer had 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 indention.

In cases where manual-locking-mechanism failures occur, the reported failures could be 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. This design flaw should be corrected by the manufacturer.

The failures discussed above are intended to provide general guidance on, and familiarize radiography licensees with, the typical types of incidents that are usually

reported. Radiography licensees should consider this guidance, and the additional guidance contained in the Attachment, when determining if an incident should be reported. It is extremely important that radiography licensees make the required reports to PNRI promptly, since the reports are used to analyze trends or generic issues that have the potential to cause a significant safety hazard. In addition, PNRI would use the information gathered 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 workers and the public.

PNRI strongly suggests that submitted reports contain a contact name and phone number, so that PNRI staff may follow up on the report, if necessary. Likewise, suppliers of radiography equipment should constantly advise its clients on any operating experience gathered from its manufacturers. Information on other means of communication, such as facsimile phone numbers and Internet E-mail addresses, is also helpful.

E. REQUIRED LICENSEE ACTION

This bulletin does not require specific action or written response.

F. CONTACT PERSON

If you have any questions about this bulletin, please contact the technical contact listed below.

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Attachment: Q&A for Radiography Reporting Requirements

ATTACHMENT

QUESTIONS AND ANSWERS FOR RADIOGRAPHY REPORTING REQUIREMENTS

1. WHAT INCIDENTS MUST BE REPORTED?

Section 31 of CPR Part 11, paragraphs (1)-(3), describes the types of events that must be reported to PNRI within 24 hours followed by a written report within 30 days of the occurrence. These events include: (1) unintentional source disconnects involving a separation of the source capsule or source assembly from the drive cable; (2) hang-ups 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 (3) the failure of any other component (critical to safe operation of the device) 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.

Hang-ups 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:

1. 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;
2. failure of the guide tube or controls to connect to the exposure device as intended, or operate properly;
3. failure of the coupling between the source assembly and the control cable; and
4. failure of source position indicators to show actual source position.

The licensee is responsible for evaluating events that may be reportable under this Section and using appropriate judgment as to whether the event is reportable. If, after evaluation, the licensee is not sure whether to report the event, we recommend that the licensee make the report to PNRI, in accordance with this Section, and include the reasons why the licensee is unsure whether the event is reportable. In addition the licensee should consider whether the failure constitutes an equipment defect that could create a substantial safety hazard.

2. WHEN AND WHERE SHOULD THE REPORTS BE SENT?

Within 30 days of an event that is determined to be reportable under Section 31 of CPR Part 11, two copies of the report must be submitted to PNRI.

3. WHAT MUST THE REPORTS INCLUDE?

The requirements for what must be included in a report are detailed below:

- ***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.

- ***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. PNRI is 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.

- ***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, including serial numbers, involved in the incident should be provided.

- ***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.

- ***Actions taken to establish normal operations***; This includes any action, taken by the licensee or other persons, after 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 nor corrective actions after the investigation.

- ***Corrective actions taken or planned to prevent recurrence***; This includes training personnel to better detect incidents and better respond during incidents. It also includes investigations into the causes of the equipment failure, any repairs made on the equipment, whether such equipment were removed from service, and whether such equipment were sent for testing. If testing took place, the results from such testing should be provided.

- ***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.

- ***The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name***. This information can include personnel dosimetry results, self-reading dosimeter readings, and estimates based on calculations. The information provided, however, should not contain the individuals' names or any personal privacy information (e.g., social security numbers, phone numbers, dates of birth, etc.).