

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

May 11, 1995

NRC INFORMATION NOTICE 95-25: VALVE FAILURE DURING PATIENT TREATMENT WITH
GAMMA STEREOTACTIC RADIOSURGERY UNIT

Addressees

All U.S. Nuclear Regulatory Commission Medical Licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to alert addressees to an incident in which the patient couch of a Leksell Gamma System Model 23016 ("gamma knife") unit failed to retract from the treatment position because of a failure of a two-position, solenoid-operated valve on the hydraulic system of the unit. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances

NRC was notified of an incident that occurred at an Agreement State licensee in which a patient undergoing gamma stereotactic radiosurgery received a dose, for a single fraction, that was 127 percent greater than the dose prescribed for that fraction. On October 25, 1994, a patient was prescribed to receive a series of 10 exposures in a Leksell Gamma System Model 23016 ("gamma knife") unit. At the end of the sixth exposure, the patient couch failed to retract from the treatment position because of a failure of a two-position, solenoid-operated valve on the hydraulic system of the unit.

The licensee's staff attempted to: (1) manually pump the hydraulic system; and (2) shut the unit off. The latter action would normally turn the pump on and direct the pressure to allow the bed to retract. However, in this case, the valve was stuck in the 'bed-in' position and the internal spring could not reset the valve to allow the bed to move. The valve failure disabled both the normal and primary emergency patient retraction systems on the unit, resulting in the patient being irradiated for 3.8 minutes longer than the intended 3-minute treatment time. Medical personnel entered the room, pulled a pressure equalization latch on the bed, and were able to move the bed approximately 50 centimeters (20 inches). Subsequently, they manually disconnected the helmet from the unit to remove the patient from the treatment room. The U.S. distributor, Elekta Radiosurgery, Inc., was notified of the event and subsequently replaced the valve. The distributor also notified all its customers of the event and attributed it to a valve failure, with no specific information on the cause of the failure.

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updated on 5/16/95

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At the request of the State of Georgia (Elekta Radiosurgery, Inc., is located in Georgia), NRC, through a contract with the Idaho National Engineering Laboratory (INEL), conducted a root-cause analysis of the incident. The INEL team was comprised of a mechanical engineer, risk analyst, medical physicist, and radiation oncologist.

Discussion

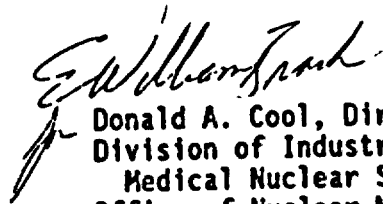
The findings of the INEL report indicate that the cause of the valve failure was the existence of metal contaminants in the hydraulic fluid system, which either became caught between the valve spool and valve body or scored the spool, thereby locking the valve in the 'bed-in' position. It appears that during installation, several months before, pieces of dirt, metal, and rubber that are typically found in new hydraulic hoses were not properly cleaned from one of the hoses. The report concluded that other machines that were installed before and have been cycled repeatedly are less likely to have a similar failure; however, this type of failure remains a concern for the installation of new machines.

When the patient couch failed to retract, the facility staff released the latch at the foot of the couch, thereby dropping the helmet to the lowest position corresponding to the low point of the couch track. When the helmet is at the low point, the maximum dose rate at the focus of the primary collimator through the helmet is approximately 10 percent of the dose rate at the treatment position because of the lack of alignment with the helmet openings. Although the one exposure delivered a 127 percent overdose, it was delivered to a partial volume of the complete target volume with the result that there was a slight increase in the percentage of the target within the 45 percent isodose. However, changes in the isodose contour were minor at the 20 percent isodose contour. The maximum total dose delivered to the patient was approximately 33.5 Gray (Gy) (3350 rads) for all 10 exposures (fractions), compared with a planned dose of 33.33 Gy (3333 rads), therefore the medical consequences of this incident are minimal. Furthermore, it appears that the medical staff who responded to the emergency all received less than 0.03 mSv (3 mrem) each.

The report provides several recommendations: 1) to further reduce the possibility of a repeat failure of the kind experienced at the facility, any proposed design change should include installation of a 20-micron filter; 2) a one-time laboratory analysis of hydraulic fluid after each new unit installation in addition to such analysis of, at least five other gamma knife units currently in operation; 3) all gamma knife users should obtain a second emergency tool to disengage the head frame from the unit; 4) all gamma knife users should review their emergency procedures to ensure they include provisions in the event the bed fails to retract; and 5) review and retraining of all emergency procedures with operating staff.

As part of the licensing process, license applicants are requested to submit procedures for emergencies which could result in radiation exposure of patients, workers, and the general public. Emergency procedures for the gamma knife unit should address situations in which the hydraulic pressure is within normal operating range, but the bed fails to retract when the timer reaches 0.0. In addition, the emergency procedures should include procedures for releasing the helmet from the trunnions in the housing, using the long-handled emergency tools provided by the manufacturer. Licensees who may be installing a gamma knife unit should be aware of the potential for contamination of the hydraulic fluid.

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 NRC regional office.


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

Technical contact: Patricia K. Holahan, NMSS
(301) 415-7847

Attachments:

1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

| Information Notice No. | Subject | Date of Issuance | Issued to |
|------------------------|--|------------------|--|
| 94-64, Supp. 1 | Reactivity Insertion Transient and Accident Limits for High Burnup Fuel | 04/06/95 | All holders of OLs or CPs for nuclear power reactors. |
| 95-07 | Radiopharmaceutical Vial Breakage during Preparation | 01/27/95 | All U.S. Nuclear Regulatory Commission medical licensees authorized to use byproduct material for diagnostic procedures. |
| 95-01 | DOT Safety Advisory: High Pressure Aluminum Seamless and Aluminum Composite Hoop-Wrapped Cylinders | 01/04/95 | All U.S. Nuclear Regulatory Commission licensees. |
| 94-89 | Equipment Failures at Irradiator Facilities | 12/28/94 | All U.S. Nuclear Regulatory Commission irradiator licensees. |
| 89-25, Rev. 1 | Unauthorized Transfer of Ownership or Control of Licensed Activities | 12/07/94 | All fuel cycle and material licensees. |
| 94-81 | Accuracy of Bioassay and Environmental Sampling Results | 11/25/94 | All U.S. Nuclear Regulatory Commission licensees. |
| 93-60, Supp. 1 | Reporting Fuel Cycle and Materials Events to the NRC Operations Center | 10/20/94 | All 10 CFR Part 70 fuel cycle licensees. |
| 94-74 | Facility Management Responsibilities for Purchased or Contracted Services for Radiation Therapy Programs | 10/13/94 | All U.S. Nuclear Regulatory Commission Medical Licensees. |

LIST OF RECENTLY ISSUED
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| Information Notice No. | Subject | Date of Issuance | Issued to |
|------------------------|--|------------------|---|
| 95-24 | Summary of Licensed Operator Requalification Inspection Program Findings | 04/25/95 | All holders of OLs or CPs for nuclear power reactors. |
| 95-23 | Control Room Staffing Below Minimum Regulatory Requirements | 04/24/95 | All holders of OLs or CPs for nuclear power reactors and all licensed operators and senior operators at those reactors. |
| 95-22 | Hardened or Contaminated Lubricants Cause Metal Clad Circuit Breaker Failures | 04/21/95 | All holders of OLs or CPs for nuclear power reactors. |
| 95-21 | Unexpected Degradation of Lead Storage Batteries | 04/20/95 | All holders of OLs or CPs for nuclear power reactors. |
| 94-64, Supp. 1 | Reactivity Insertion Transient and Accident Limits for High Burnup Fuel | 04/06/95 | All holders of OLs or CPs for nuclear power reactors |
| 95-18, Supp. 1 | Potential Pressure-Locking of Safety-Related Power-Operated Gate Valves | 03/31/95 | All holders of OLs or CPs for nuclear power reactors. |
| 95-20 | Failures in Rosemount Pressure Transmitters due to Hydrogen Permeation into the Sensor Cell | 03/22/95 | All holders of OLs or CPs for nuclear power reactors. |
| 95-19 | Failure of Reactor Trip Breaker to Open Because of Cutoff Switch Material Lodged in the Trip Latch Mechanism | 03/22/95 | All holders of OLs or CPs for nuclear power reactors. |

OL = Operating License
CP = Construction Permit

As part of the licensing process, license applicants are requested to submit procedures for emergencies which could result in radiation exposure of patients, workers, and the general public. Emergency procedures for the gamma knife unit should address situations in which the hydraulic pressure is within normal operating range, but the bed fails to retract when the timer reaches 0.0. In addition, the emergency procedures should include procedures for releasing the helmet from the trunnions in the housing, using the long-handled emergency tools provided by the manufacturer. Licensees who may be installing a gamma knife unit should be aware of the potential for contamination of the hydraulic fluid.

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DOC NAME: 95-25.IN

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| OFFICE | IMAB* | | IMAB* | | IMAB* | | Tech Ed* | |
| NAME | PKHolahan | | JMPiccone | | LWCamper | | EKraus | |
| DATE | 03/01/95 | | 03/27/95 | | 03/30/95 | | 03/10/95 | |

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|--------|----------|--|-----------|--|----------|--|----------|--|
| OFFICE | IMOB* | | OSP* | | OGC* | | DD/IMNS* | |
| NAME | FCCombs | | RLBangart | | STreby | | EWBrach | |
| DATE | 04/12/95 | | 04/20/95 | | 04/27/95 | | 05/03/95 | |

| | | |
|--------|----------|--|
| OFFICE | D/IMNS* | |
| NAME | DACool | |
| DATE | 05/03/95 | |

As part of the licensing process, license applicants are requested to submit procedures for emergencies which could result in radiation exposure of patients, workers, and the general public. Emergency procedures for the gamma knife unit should address situations in which the hydraulic pressure is within normal operating range, but the bed fails to retract when the timer reaches 0.0. In addition, the emergency procedures should include procedures for releasing the helmet from the trunnions in the housing, using the long-handled emergency tools provided by the manufacturer. Licensees who may be installing a gamma knife unit should be aware of the potential for contamination of the hydraulic fluid.

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Technical contact: Patricia K. Holahan, NMSS
 (301) 415-7347

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| OFC | IMAB | E | IMAB* | E | IMAB* | E | Tech Ed* | N |
| NAME | PKHolahan | | JMPiccone | | LWCamper | | EKraus | |
| DATE | 05/1/95 | | 03/27/95 | | 03/30/95 | | 03/10/95 | |
| OFC | IMOB* | E | OSP* | E | OGC* | E | DD/IMNS | D/IMNS |
| NAME | FCCombs | | RLBangart | | STreby | | EBrach | DACool |
| DATE | 04/12/95 | | 04/20/95 | | 04/27/95 | | 04/2/95 | 04/3/95 |

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Emergency procedures, for the gamma knife unit, should address situations in which the hydraulic pressure is within normal operating range, but the bed fails to retract when the timer reaches 0.0. In addition, the emergency procedures should include procedures for releasing the helmet from the trunnions in the housing, using the long-handled emergency tools provided by the manufacturer. Licensees who may be installing a gamma knife unit should be aware of the potential for contamination of the hydraulic fluid.

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| NAME | PKHolahan | | JMPiccone | | LWCamper | | EKraus |
| DATE | 03/12/95 | | 03/27/95 | | 03/30/95 | | 03/10/95 |
| OFC | IMOB | C | OSR | E | DD/IMNS | | D/IMNS |
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Licenses who possess a gamma knife unit should review their emergency procedures to ensure that they address situations in which the hydraulic pressure is within normal operating range, but the bed fails to retract when the timer reaches 0.0. In addition, operating staff should review emergency procedures to include releasing the helmet from the trunnions in the housing, using the long-handled emergency tools provided by the manufacturer. Licenses who may be installing a gamma knife unit should be aware of the potential for contamination of the hydraulic fluid.

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| NAME | PKH/Holahan | | JMPiccone | | JNCamper | | EKraus |
| DATE | 03/26/95 | | 03/27/95 | | 03/30/95 | | 03/10/95 |

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|------|---------|-----------|---------|---------|---------|
| OFC | IMOB | OSP | OGC | DD/IMNS | D/IMNS |
| NAME | FCCombs | RLBangart | STreby | EWBrach | DACool |
| DATE | 03/ /95 | 03/ /95 | 03/ /95 | 03/ /95 | 03/ /95 |

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