

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555-0001

September 2, 1999

**NRC INFORMATION NOTICE 99-27: MALFUNCTION OF SOURCE RETRACTION
MECHANISM IN COBALT-60 TELE THERAPY
TREATMENT UNITS**

Addressees:

All medical licensees authorized to conduct teletherapy treatments.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to alert addressees to potential failures in the source retraction mechanisms of cobalt-60 teletherapy units, involving the Picker Model C-9 Teletherapy Unit (hereafter Unit) and the Advanced Medical System (AMS) Model C-9 Unit. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to address these issues. 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 has become aware of a repeated pattern of source mechanism failures in Model C-9 Units, according to six reported events that have occurred within the last 7 years. Five of these events happened on Picker Model C-9 Units and one on an AMS Model C-9 Unit. In some events, the personnel were unaware that the sources had not retracted into their fully shielded positions because treatment door lights and console lights failed to perform properly and/or were ignored. In another event, the safety mechanisms (treatment door interlock and emergency stop) failed to return the source into the shielded position. Although none of these reported events led to serious health effects, they nevertheless resulted in unnecessary radiation exposure to employees not consistent with the as low as is reasonably achievable philosophy. Licensees should be aware of the potential for similar failures, with both Model C-9 Units, during the course of patient treatments, and the possible risks of misadministrations.

A brief summary of some of the unintended exposures follows:

1. A patient received an unplanned absorbed dose of 410 centigray (cGy) [410 rad] instead of the prescribed 300 cGy (300 rad). A radiation worker received an estimated 0.7 milliSievert (mSv) [70 mrem] deep-dose equivalent (DDE) in emergency actions to terminate the patient's treatment;

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2. Another patient received an unintended dose in excess of about 35 cGy (35 rad); and,
3. An authorized user, unaware that the source was exposed, received 10.7 mSv (1070 mrem) DDE and 29.9 mSv (2990 mrem) shallow dose equivalent (SDE, extremity). An individual under his supervision received 11.8 mSv (1180 mrem) DDE and an estimated 33 mSv (3300 mrem) SDE, extremity.

Discussion:

Before 1982, Picker Corporation manufactured and provided service for Model C-9 Units. In 1982, AMS purchased the manufacturing and servicing rights for the Model C-9 Unit from Picker Corporation. AMS' application for registration of its Model C-9 Unit included design and prototype test data that demonstrated that the unit is the same basic design as the Picker Corporation Model C-9 Unit. It is possible that, over time, some of the Picker Model C-9 Units may have been refurbished by other vendors and may no longer be carrying the Picker identification. Therefore, NRC is alerting the licensees using Picker and AMS Cobalt-60 teletherapy units of the potential failure of the source retraction mechanisms in Model C-9 Units.

The root cause of these failures has yet to be determined. Information gathered from licensees that provide service to teletherapy units indicates that the jamming of the source drive mechanism may be attributable to one of the following:

1. When a new source is placed in these units, the heat generated by a high-activity source tends to cause some deformation of the source housing, which causes the source wheel to rub against the internal surface of the unit's head, causing restriction of the source assembly movement; or
2. The radiation-induced breakdown of lubricant causes it to harden and impede proper movement of the bearings in the shutter wheel mechanism.

To avoid recurrence of these events, licensees are reminded that 10 CFR 35.634(a)(2) requires licensees to perform monthly checks on their teletherapy units to determine "on-off errors." One service company recommends that when the licensee monitors the on-off time of its Model C-9 Unit during the monthly spot check, the monitoring should be performed with the head at 90 and 270 degrees. This should provide the licensee with an indication of some friction in the source drive system, before it becomes sufficient to block the source from returning fully to the shielded position at the end of a treatment. Also, 10 CFR 35.634(d)(1) requires licensees to perform monthly checks of electrical interlocks at each teletherapy room entrance.

Under 10 CFR 35.647(a), licensees are required to have their teletherapy units fully inspected and serviced during teletherapy source replacements, or at intervals not to exceed 5 years, whichever comes first. The purpose of the inspection is to assure safe operation of the units, including proper functioning of the source exposure mechanism.

Licensees should pay close attention to the results of their monthly checks and 5 year inspections, to assure that the recommended maintenance is performed promptly and in an

adequate manner, consistent with NRC regulations. Failure to maintain teletherapy units in safe operating condition could result in unnecessary radiation exposures that could lead to NRC enforcement action.

Licensees should also be aware that medical device user facilities are now subject to mandatory adverse event reporting requirements for medical devices. Information concerning Food and Drug Administration (FDA) mandatory reporting requirements can be obtained by contacting the Center for Devices and Radiological Health, Office of Surveillance and Biometrics, Division of Surveillance Systems, at 301-594-2735. Since the FDA mandatory reporting requirements may not be applicable to all medical device events, FDA also depends on information voluntarily provided by device users, because they are often the first to recognize medical device-related hazards. Any concerns that licensees may have about the safety or quality problems associated with medical devices can be voluntarily reported to the FDA by calling MedWatch at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; over the Internet at <http://www.fda.gov/medwatch/>; or by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane (HF-2), Rockville, MD 20857. Voluntary reports can be submitted anonymously.

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

Attachments:

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

Technical Contact: Roberto J. Torres, NMSS
301- 415-8112
E-mail: rjt@nrc.gov

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
99-26	Safety and Economic Consequences of Misleading Marketing Information	8/24/99	All Distributors and/or Manufacturers of Generally Licensed Products
99-24	Broad-Scope Licensees' Responsibilities for Reviewing and Approving Unregistered Sealed Sources and Devices	7/12/99	All medical licensees' of broad-scope and master materials licensees
99-23	Safety Concerns Related To Repeated Control Unit Failures of the Nucletron Classic Model High-Dose-Rate Remote Afterloading Brachytherapy Devices	7/6/99	All U.S. NRC medical licensees authorized to use brachytherapy sources in Nucletron Classic Model high-dose-rate (HDR) remote afterloaders
99-22	10 CFR 34.43(a)(1): Effective Date for Radiographer Certification and Plans for Enforcement Discretion	6/25/99	Industrial Radiography Licensees
99-20	Contingency Planning for the Year 2000 Computer Problem	6/25/99	All material and fuel cycle licensees and certificate holders
99-18	Update on NRC's Year 2000 Activities for Materials Licensees and Fuel Cycle Licensees and Certificate Holders	6/14/99	All material and fuel cycle licensees and certificate holders
99-16	Federal Bureau of Investigation's Nuclear Site Security Program	5/28	All U.S. Nuclear Regulatory Commission fuel cycle, power reactor, and non-power reactor licensees
99-11	Incident Involving the Use of Radioactive Iodine-131	4/16/99	All medical use licensees
99-09	Problems Encountered When Manually Editing treatment Data on the Nucletron Microselectron-HDR (New) Model 105-999	3/24/99	All medical licensees authorized to conduct high-dose-rate (HDR) remote after loading brachytherapy treatments

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99-21	Recent Plant Events Caused By Human Performance Errors	6/25/99	All holders of licenses for nuclear power, test, and research reactors
99-20	Contingency Planning for the Year 200 Computer Problem	6/25/99	All material and fuel cycle licensees and certificate holders
99-19	Rupture of the Shell Side of a Feedwater Heater at the Point Beach Nuclear Plant	6/23/99	All holders of operating licenses or construction permits for nuclear power reactors

OL = Operating License
 CP = Construction Permit

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