

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

July 6, 1999

NRC INFORMATION NOTICE 99-23: SAFETY CONCERNS RELATED TO REPEATED CONTROL UNIT FAILURES OF THE NUCLETRON CLASSIC MODEL HIGH-DOSE-RATE REMOTE AFTERLOADING BRACHYTHERAPY DEVICES

Addressees:

All U.S. Nuclear Regulatory Commission (NRC) medical licensees authorized to use brachytherapy sources in Nucletron Classic Model high-dose-rate (HDR) remote afterloaders.

Purpose:

NRC is issuing this information notice to alert you to ongoing control unit failures with Nucletron Classic Model HDR devices. You should review this information for applicability to your facilities and consider actions, as appropriate, to minimize the impact of such failures on patient treatments and personnel exposures. However, suggestions contained in this information notice are not NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

By January 1996, NRC was aware of three incidents where the Nucletron Classic Model HDR control units failed (locked up) for unexplained reasons. These control unit failures exposed a deficiency in the design of the door interlock circuitry for the Nucletron Classic Model HDR. Nucletron issued a Safety Alert on March 4, 1996, describing this problem and providing information on the proper operator response to such failures. This safety alert was also issued as an attachment to NRC Information Notice 96-21, issued on April 10, 1996, that discussed both the door interlock problem and the control unit failures. Following these three reported failures of the control unit, Nucletron Corporation made field modifications to these devices to correct the door interlock failure mechanism and to eliminate the unexplained control unit failures.

Following these modifications, two similar failures were reported in 1997, four in 1998, and three to date in 1999. These additional nine control unit failures, reported since the 1996 corrective action, indicate an ongoing problem with unexplained control unit failures. However, no further problems have been reported with the operation of the door interlocks. Nucletron has continued to investigate the ongoing control unit failures and now believes it has found the root cause of the failures and subsequently developed appropriate corrective measures. We understand that the newly developed corrective measures are presently undergoing testing before implementation.

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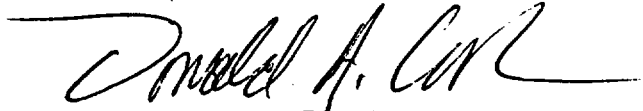
Discussion:

In all 12 reported control unit failures no patient or personnel overexposures were reported. In each case the treatment unit continued to operate, as designed, when communications with the control unit was lost. In this event, the microprocessor in the treatment unit continues the preprogrammed treatment to the catheter being treated when the failure occurs, halting upon completion. If the failure occurs during a single catheter treatment or during the last catheter in a multi-catheter operation, then the treatment will proceed to completion. Otherwise, it will terminate with completion of the catheter being treated, leaving any remaining catheters untreated. Most users, however, when faced with a blank or frozen display on an inoperative control unit, immediately abort the treatment, using the "Emergency Stop" button on the control unit. The "Treatment Interrupt" button (called for in the 1st step on the Safety Alert procedures) on the control unit is rendered inoperative by the control unit failure. Irrespective of the method of terminating the patient's treatment, the actual treatment data can subsequently be read from the treatment unit, using a handheld terminal device.

Most patients receive less than the prescribed dose in the event of a control unit failure and, at the discretion of the Authorized User, either the Written Directive must be revised to reflect the actual dose given or the remaining portion of the treatment given after repair or replacement of the defective control unit. To date, none of the reported control unit failures has resulted in overexposures or misadministrations. However, the failure of the control unit removes the first layer of radiation safety protection. At this point, the avoidance of excessive radiation exposures depends upon either the continued proper operation of the treatment unit or operator intervention.

NRC previously issued Information Notice 96-21 on April 10, 1996, and included a copy of the Nucletron issued Safety Alert, addressing the control unit failures, as an attachment. This Safety Alert sets forth a series of four steps to be taken if, for any reason, the Control Unit stops updating the status of the treatment in progress. These steps should ensure that the treatment is interrupted and the source retracted before licensee personnel enter the treatment room. You are encouraged to follow these recommendations from the device vendor, as contained in its Safety Alert of March 4, 1996. Any questions you may have related to these control unit failures and related corrective actions, or to get a copy of the Safety Alert, should be addressed to your Nucletron Corporation representative.

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

Contact: Robert L. Ayres, NMSS
(301) 415-5746
E-mail: rxa1@nrc.gov

Attachments:

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

Attachments Filed in Jacket.

LIST OF RECENTLY ISSUED
 NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
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
99-06	1998 Enforcement Sanctions as a Result of Deliberate Violations of NRC Employee Protection Requirements	3/19/99	All U. S. Nuclear Regulatory Commission licensees
99-05	Inadvertent Discharge of Carbon Dioxide Fire Protection System and Gas Migration	3/8/99	All holders of licenses for nuclear power, research, and test reactor, and fuel cycle facilities
99-04	Unplanned Radiation Exposures to Radiographers, Resulting From Failures to Follow Proper Radiation Safety Procedures	3/8/99	All radiography licensees
99-03	Exothermic Reactions Involving Dried Uranium Oxide Powder (Yellowcake)	1/29/99	All operating uranium recovery facilities that produce oxide powder (U ₃ O ₈) (yellowcake)

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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
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
99-17	Problems Associated with Post-Fire Safe-Shutdown Circuit Analyses	6/3/99	All holders of OL for nuclear power reactors, except those who have permanently ceased operations and have certified that the fuel has been permanently removed from the reactor
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
99-15	Misapplication of 10 CFR Part 71 Transportation Shipping Cask Licensing Basis to 10 CFR Part 50 Design Basis	5/27/99	All holders of operating licenses or construction permits for nuclear power reactors

OL = Operating License
 CP = Construction Permit

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(ORIG. SIGNED BY)
 Donald A. Cool, Director
 Division of Industrial and
 Medical Nuclear Safety
 Office of Nuclear Material Safety
 and Safeguards

Contact: Robert L. Ayres, NMSS
 (301) 415-5746
 E-mail: rxa1@nrc.gov

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1. List of Recently Issued NMSS Information Notices
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DOCUMENT NAME: A & G:AYRES\IN99C-XX.WPD

* See previous concurrence

OFFICE	MSIB	C	Editor*		MSIB*		MSIB*	N	MSIB*	N
	RAYres/lucy		EKraus		FSturz		LCamper		DCool	
DATE	6/ 09 /99		6/ 09 /99		6/15/99		6/15/99		6/28/99	

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