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

April 10, 1996

NRC INFORMATION NOTICE 96-21: SAFETY CONCERNS RELATED TO THE DESIGN OF THE DOOR INTERLOCK CIRCUIT ON NUCLETRON HIGH-DOSE RATE AND PULSED DOSE RATE REMOTE AFTERLOADING BRACHYTHERAPY DEVICES

Addressees

All U.S. Nuclear Regulatory Commission Medical Licensees authorized to use brachytherapy sources in high- and pulsed-dose-rate remote (HDR/PDR) afterloaders.

Purpose

The NRC is issuing this information notice to alert addressees to the recent discovery that the treatment room door interlocks used with the Nucletron HDR and PDR devices are rendered inoperative by the failure of either the control unit or by a loss of communications between the control and treatment units. 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 NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances

During the administration of the third of a three-fraction vaginal treatment of a patient on January 9, 1996, the treatment console of the Nucletron HDR unit locked up and the console alarm sounded when the afterloader was nearly finished treating the seventh dwell position of an 11-position treatment. At the sound of the alarm, the physicist directed the device operator to terminate the treatment. The operator pushed the console-mounted "Treatment Interrupt" button, but the treatment unit did not respond by withdrawing the source. The physicist then instructed the device operator to open the treatment room door slightly so that the door interlock would cause the source to withdraw. This was done but the source did not retract into the storage safe as expected. At this point, the physicist entered the treatment room, opened the top of the treatment unit, and started to turn the manual source retraction mechanism. The treatment unit sensed this movement/resistance and automatically executed an emergency retraction of the source.

The original treatment plan was to deliver three fractions of 7 gray (Gy) (700 rads) each at a distance of 0.5 centimeters (cm) from the surface of a 3 cm diameter vaginal cylinder, using 11 dwell positions of 0.5 cm spacing. Thus, the full course of therapy would have delivered 21 Gy (2100 rads) to the

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prescription point according to the plan. As a result of the interrupted treatment during the third fraction, the full course of therapy actually delivered 18.88 Gy (1888 rads) to the prescription point, a deviation from the planned dose of 10.1 percent.

Discussion

Before this incident on January 9, 1996, there had been at least two other reported failures of the Nucletron HDR console resulting in aborted patient treatments. Unlike the present failure, these treatments were properly aborted by use of the device's "Emergency Stop" button, which activates the emergency source retract mode via a direct-wire connection to the treatment unit's emergency source retraction circuit. After these earlier failures, Nucletron revised the oscillator circuit on the console processor circuit board to correct the failures. Since then, NRC has received no further reports of console failures caused by this console oscillator failure. The most recently reported failure is believed to be caused by a loss of the communications link, for unknown reasons, between the control unit and the treatment unit.

In the latest console failure incident, the licensee's attempt to use the door interlock in lieu of the "Emergency Stop" button, to abort the treatment, alerted the NRC to the fact that the door interlock was not functioning in a manner that provided adequate protection for attempted entries into the treatment room with the source exposed. NRC believes that the door interlock protection system should be independent of the proper functioning of other circuitry in the performance of its essential safety function. This can be achieved by designing the circuitry in such a manner that the emergency source retraction cycle is immediately implemented on opening the treatment room door.

After this incident, Nucletron-Oldelft Corporation issued a "Safety Alert" (Attachment 1) to all of its HDR/PDR device customers, on March 4, 1996, which sets forth a series of four steps to be taken if the Control Unit stops updating the status of the treatment in progress, for any reason. These steps should ensure that the treatment is interrupted and the source retracted before licensee personnel enter the treatment room. Discussions between Nucletron-Oldelft (a State licensee) and the State of Maryland are ongoing, at this time, on the development of an appropriate corrective action by Nucletron for this door interlock design deficiency.

It should be noted that NRC is uncertain whether similar defects in the design of the door interlock circuitry of other makes and models of HDR devices may exist. Unless established by test or vendor documentation, all users of these devices should consider that the door interlock protection circuit could be rendered inoperative by various device component failures. NRC is concerned about the possibility of either patients or licensee staff receiving excessive exposures to radiation if an HDR/PDR source fails to retract as expected when the treatment room door is opened. Because this failure mode is documented

for the Nucletron devices, all affected licensees are encouraged to follow the recommendations of the device vendor, as contained in its "Safety Alert" of March 4, 1996.

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 contacts listed below or the appropriate regional office.

Donald A. Cool

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

Technical contacts: Robert L Ayres, NMSS
(301) 415-5746
Internet:rxal@nrc.gov

James A. Smith, NMSS
(301) 415-7904
Internet:jas4@nrc.gov

Attachments:
1. Nucletron Safety Alert dated March 4, 1996
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices

Attachments filed in Jacket

Nucletron - Oldelft Corporation
7080 Columbia Gateway Drive
Columbia, Maryland 21046-2133
Telephone: 410-312-4100
Fax: 410-312-4199

March 4, 1996

Dear Nucletron microSelectron HDR & PDR Users:

Your attention is directed to the attached Safety Alert describing a situation that may occur in routine operation of the device. This alert is based on an event that occurred recently at a facility using this device. Please follow the instructions contained in this Alert to prevent loss of treatment data and potential radiation exposure to operators.

If you have any questions regarding this Safety Alert or the procedure to be followed, please call the 1-800 number listed that the bottom of the Safety Alert.

Sincerely,
NUCLETRON CORPORATION

Stephen P. Teague
Director of Regulatory Affairs

Attachment: Safety Alert # 300.074

nucletron - Oldelft

Safety Alert

Validity: mHDR/mPDR

Situation

During normal treatment operation, the micro-Selectron HDR and PDR control unit may freeze up. The door switch and interrupt buttons may be inoperative during these situations The printer will stop printing the record of dwell positions and treatment times delivered..

Cause

The exact cause is uncertain at this time, but is believed to be a momentary loss of communications between the Treatment Unit, and the Control Unit. The Treatment Unit, which has control of the treatment parameters, continues to function properly.

Solution

If the display on the Control Unit stops updating the status of the treatment, the operator is required to perform the following steps in sequence:

1. Depress the Interrupt button, and then
2. Depress the Master Emergency Stop button.
3. Note the exact time that the display stopped and the condition of all lamps, keyswitches, and information shown on display.
4. Call Nucletron at the number listed on the Emergency Procedures sheet posted on the console. DO NOT attempt to reset the system and continue the treatment.

You will be given instructions in the proper method of resetting the Control Unit and continuing with the treatment. There is no danger of overexposure to the patient or operator if the procedure is followed.

FOR MORE INFORMATION, CONTACT:
Nucletron-Oldelft Corporation
Columbia, Maryland, 21046
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Tel: 1-800-445-9295
Fax: (410)-312-4196
Issue Date: Mar. 4, 1996
Part 300.074

LIST OF RECENTLY ISSUED NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
96-20	Demonstration of Associated Equipment Compliance with 10 CFR 34.20	04/04/96	All industrial radiography licensees and radiography equipment manufacturers
96-18	Compliance With 10 CFR Part 20 for Airborne Thorium	03/25/96	All material licensees authorized to possess and use thorium in unsealed form
96-04	Incident Reporting Requirements for Radiography Licensees	01/10/96	All Radiography Licensees and Manufacturers of Radiography Equipment
95-58	10 CFR 34.20; Final Effective Date	12/18/95	Industrial Radiography Licensees.
95-55	Handling Uncontained Yellowcake Outside of a Facility Processing Circuit	12/6/95	All Uranium Recovery Licensees.
95-51	Recent Incidents Involving Potential Loss of Control of Licensed Material	10/27/95	All material and fuel cycle licensees.
95-50	Safety Defect in Gammamed 12i Bronchial Catheter Clamping Adapters	10/30/95	All High Dose Rate Afterloader (HDR) Licensees.
95-44	Ensuring Combatible Use of Drive Cables Incorporating Industrial Nuclear Company Ball-type Male Connectors	09/26/95	All Radiography Licensees.
95-39	Brachytherapy Incidents Involving Treatment Planning Errors	09/19/95	All U.S. Nuclear Regulatory Commission Medical Licensees.
95-29	Oversight of Design and and Fabrication Activities for Metal Components Used in Spent Fuel Dry Storage Systems	06/07/95	All holders of OLs or CPs for nuclear power reactors. Independent spent fuel storage installation designers and fabricators.

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
96-20	Demonstration of Associated Equipment Compliance with 10 CFR 34.20	04/04/96	All industrial radiography licensees and radiography equipment manufacturers
96-19	Failure of Tone Alert Radios to Activate When Receiving a Shortened Activation Signal	04/02/96	All holders of OLs or CPs for nuclear power reactors
96-18	Compliance with 10 CFR Part 20 for Airborne Thorium	03/25/96	All material licensees authorized to possess and use thorium in unsealed form
95-03 Supp. 1	Loss of Reactor Coolant Inventory and Potential Loss of Emergency Mitigation Functions While in a Shutdown Condition	03/25/96	All holders of OLs or CPs for PWR power plants
96-17	Reactor Operation Inconsistent with the Updated Final Safety Analysis Report	03/18/96	All holders of OLs or CPs for nuclear power reactors
96-16	BWR Operation with Indicated Flow Less Than Natural Circulation	03/14/96	All holders of OLs or CPs for boiling-water reactors
96-15	Unexpected Plant Performance During Performance of New Surveillance Tests	03/08/96	All holders of OLs or CPs for nuclear power reactors
96-14	Degradation of Radwaste Facility Equipment at Millstone Nuclear Power Station, Unit 1	03/01/96	All holders of OLs or CPs for nuclear power reactors
96-13	Potential Containment Leak Paths Through Hydrogen Analyzers	02/26/96	All holders of OLs or CPs for nuclear power reactors

OL = Operating License
CP = Construction Permit

for the Nucletron devices, all affected licensees are encouraged to follow the recommendations of the device vendor, as contained in its "Safety Alert" of March 4, 1996.

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/s/

Donald A. Cool, Director
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Official Record Copy 96-21.IN

OFC	IMAB	E	IMAB		IMAB		OGC		Tech Ed	
NAME	JASmith		PKHolohan		LWCamper		SATreby@		EKraus@	
DATE	4/5/96		/ /96		/ /96		3/21/96		03/22/96	

OFC	DD/IMNS		D/IMNS					
NAME	FCCombs		DACool					
DATE	/ /96		4/9/96					

C = COVER E = COVER & Attachment N = NO COPY @- See Previous Concurrence

about the possibility of either patients or licensee staff receiving excessive exposures to radiation if an HDR/PDR source fails to retract as expected when the treatment room door is opened. Because this failure mode is documented for the Nucletron devices, all affected licensees are encouraged to follow the recommendations of the device vendor, as contained in its "Safety Alert" of March 14, 1996.

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OFC	IMAB	E	IMAB	E	IMAB	E	OGC		Tech Ed	
NAME	JASmith		PKholohan		LWCamper		SATreby©		EKraus©	
DATE	3/25/96		3/26/96		3/29/96		3/21/96		03/22/96	

OFC	DD/IMNS		D/IMNS	4/4/96				
NAME	FCCombs		DACool					
DATE	/ /96		4/3/96					

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