RI - DNMS Licensee Event Report Disposition

Licensee: Lankenau Hospital

Event Description: Report of HDR Source Failing to Retract During Spot Check

License No: 37 07905-04 Docket No: 03 0-03098 MLER-RI: 2005 - 021

Event Date: 4-7-05 Report Date: 4-7-05 HQ Ops Event #:

1. REPORTING REQUIREMENT

- [ ] 10 CFR 20.1906 Package Contamination
- [ ] 10 CFR 20.2201 Theft or Loss
- [ ] 10 CFR 20.2203 30 Day Report
- [ ] Other
- [X] 10 CFR 30.50 Report or Part 21.21(d) ?
- [ ] 10 CFR 35.3045 Medical Event
- [ ] License Condition

2. REGION I RESPONSE

- [ ] Immediate Site Inspection — Inspector/Date
- [ ] Special Inspection — Inspector/Date
- [ ] Telephone Inquiry — Inspector/Date
- [ ] Preliminary Notification/Report
- [X] Information Entered in RI Log
- [ ] Report Referred To:
- [ ] Daily Report
- [X] Review at Next Inspection

3. REPORT EVALUATION

- [✓] Description of Event
- [✓] Levels of RAM Involved
- [✓] Cause of Event
- [ ] Corrective Actions
- [ ] Calculations Adequate
- [✓] Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION N/A

- [ ] Release w/Exposure > Limits
- [ ] Repeated Inadequate Control
- [ ] Exposure 5x Limits
- [ ] Potential Fatality
- [ ] Deliberate Misuse w/Exposure > Limits
- [ ] Pkging Failure>10 rads/hr or Contamination>1000x Limits
- [ ] Large# Indivs w/Exp>Limits or Medical Deterministic Effects
- [ ] Unique Circumstances or Safeguards Concerns

If any of the above are involved:

- [ ] Considered Need for IIT
- [ ] Considered Need for AIT

Decision/Made By/Date:

5. MANAGEMENT DIRECTIVE 8.10 EVALUATION (additional evaluation for medical events only) NA -- no medical event

- [ ] Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
- [ ] Medical Consultant Used-Name of Consultant/Date of Report:
- [ ] Medical Consultant Determined Event Directly Contributed to Fatality
- [X] Device Failure with Possible Adverse Generic Implications (NA)
- [ ] HQ or Contractor Support Required to Evaluate Consequences

6. SPECIAL INSTRUCTIONS OR COMMENTS

[X] Public Inspector Signauture: [signature] Date: 5-24-05

[ ] Non-Public Branch Chief Initials: RKellar for PHenderson Date: 6-23-06

Location of File: G:\Reference\Blank Forms\2004 LER FORM.wpd

U.S. NUCLEAR REGULATORY COMMISSION **TELEPHONE CONVERSATION RECORD**	Conversation Date: 4/7/05 Time:	
Mail Control No.:	License No.: 37-07905-04	Docket No.: 030-03098
Licensee/Applicant Participant(s): Nate Anderson	Organization: Lankenau Hospital	Telephone No.: 610-645-3581
Person(s) Calling: T. Weidner		
Subject: Report of HDR source failing to retract during Spot Check		
Summary: A call from Nate Anderson (AMP) was received on 4/7/05. Mr. Anderson stated that while performing the morning QA/QC on the Nucletron HDR (Model 105.999) unit the source was sent out of the unit but failed to retract. An error message stated that there was a lag on the stepper motor. The licensee hit the emergency stop button and the source still did not retract. The licensee secured the room and contacted Nucletron for emergency service. A Nucletron service tech entered the HDR room and retracted the source with the hand crank. A full calibration of the HDR was performed after the service call and all systems operated as planned. The licensee will review Part 21 to determine if this incident should be reported.		
Action Required/Taken: Enter as an LER		
Prepared By: T. Weidner	Date: 4/7/05	

Document Name:P:\Lankenuatelconform.wpd
Blank Form: G:\Reference\Blank Forms\telcon1.wpd

Lankenau Hospital
100 Lancaster Ave
Wynnewood PA, 19096

April 8, 2005

NRC Operations Center
NRC Region One Office
NRC Document Control Center

Dear Sir or Madam:

I am writing to notify the NRC of an incident involving the performance of our Nucletron V2 microselectron High Dose Rate Afterloading device. We are filing this report according to the requirements of 10 CFR 21.21(d). While it is our belief that we are not required to do so, we are following the suggestion of Michelle Beardsley of NRC Region 1, Medical Branch in filing this report. The information that we are supplying here has all been provided to Nucletron Corporation of Columbia, MD for their analysis. It is our belief that they, if anyone at all, should be the party responsible for the management of these issues under these regulations and those of the FDA. That viewpoint aside, we are following this Region 1 interpretation. Additionally, I am attaching a copy of the Nucletron Service Report from this incident.

Required Information under reporting in 10 CFR 21.21(d)(4):

i) Informing Individual – Nathan Anderson, Authorized Medical Physicist, Lankenau Hospital, Department of Radiation Oncology, 100 Lancaster Ave., Wynnewood, PA 19096

ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity with in the United Stated which fails to comply or contains a defect – The supplier of the treatment device and the transfer tube is Nucletron Corporation, of Columbia MD. The item which had the initial breakdown in performance was a Nucletron microSelectron GYN transfer tube for channel 1. This item developed an internal constriction that caused the source's inability to retract. We are contending that the classification of the component performance as failing to comply or containing a defect is not something that we as end users are able to determine. This may or may not be true. Nucletron Corporation would be the determinate of that.

iii) Same as above

iv) The situation described here created the situation whereby we were required to initiate our emergency procedures. During routine daily quality assurance testing, the HDR treatment device was set up with two GYN transfer tubes connected between the treatment device and the autoradiograph device. All pieces are manufactured and supplied by Nucletron Corporation and their use here is within the intended uses. After transfer tubes were attached and locked in place, the morning QA treatment delivery to the autoradiograph device was initiated. During initial runs through the tube, a number of daily checks were performed to verify the functionality of the emergency stops and interruption buttons. Finally, on the last iteration, the check cable went out through transfer tube one and returned. This indicated that the tube was clear. Then the source went out into transfer tube one. It dwelled in the tube for 101.2 seconds. When the cable was being driven back into the safe, it encountered a lag in the stepper motor, indicating that there was either a partial or total constriction of the path. The unit correctly initiated an emergency stop. The source position indicator correctly displayed that the source was stuck in the exposed position. The interrupt button and emergency stop buttons were activated but the source remained in the transfer tube. The room was secured until Nucletron service arrived. When they arrived, they decided to enter the room, and use the emergency source retraction handles to try to drive the source into the safe. The engineer entered the room alone. The manual crank for the source cable functioned correctly and the source was returned to the safe within 17 seconds of entry into the room. The engineer's personal dosimeter indicated an exposure of 5 mR whole body dose. Upon inspection of the transfer tube after removal from the machine, there was no external sign of any wear on the transfer tube. However, when a check wire was run through, it was discovered that there was a constriction or edge that had developed just inside the end that connects to the treatment unit. This constriction is what caused the source drive in to fail. These transfer tubes are measured and inspected on a monthly basis as required. The same transfer tube is used on a daily basis and had in fact been used twice the day before successfully. The nature of the defect in the tube therefore can only be described in my opinion as wear and tear. This transfer tube was approximately two years old. This same opinion was expressed by the on site engineer.

v) This incident occurred on Wednesday April 6, 2005

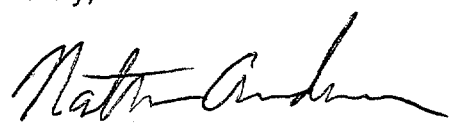
vi) There are transfer tubes for all of our applicators. We possess a total of 22 transfer tubes. Each of them is measured and inspected on a monthly basis for condition according to 10 CFR 35.

vii) The corrective action taken was that the transfer tube was replaced with a new one. The source and cable were inspected on camera and no

problems were identified. This action has corrected the root problem. Additionally, it should be noted that the procedures for source recovery as described in the Nucletron manuals and the on site emergency procedures were followed and were successful. The final manner of source retraction was the one that was successful, but successful it was.

viii) Related advice - As I explained to Nucletron, I agree the source retraction failed to retract due to a constriction in the transfer tube. This condition was easily detectable with a test cable once it was removed. Currently we inspect the tubes for length and condition thoroughly on a monthly basis as required by part 35. The tubes are also visually inspected before each use. However, it seems reasonable to expect that the check cable should have identified this constriction; it did not detect this. Additionally, it seems that the emergency stop button should have had enough pull to negotiate this constriction; again, it did not. Without significant testing from Nucletron, we can not know the specifics of the internal circumstances which caused the source cable to encounter a constriction that the check cable did not.

Sincerely,



Nathan Anderson
Medical Physicist
Department of Radiation Oncology
Lankenau Hospital

Cc: Lankenau Hospital Rad Onc Incident File
Nancy Sherwin, MD, RSO
Gary Antonelli, Manager/Radiation Oncology
NRC Document Control Desk
Region 1 Office, Medical Division

Nucletron®

Field Service Report

Nucletron Corporation, Service Department, 8671 Robert Fulton Drive, Columbia, MD 21046 PH: 410-872-4400 Fax: 410-312-4196

Customer	Call Type			Call No.	US3007_155966_R		
Lankenau Hospital	☐ Phone	☐ Recall	☑ Repair	SPC	Equip.	Failure	Action
Address	☐ Install	☐ Training	☐ PM	Codes	023	D1	A2
100 Lancaster Avenue	☐ CA	☐ Other	☐	Serial No.	31412		
Wynnewood, PA 19016	Charge Type			FW version	1.50A		
Phone No. 610 645.2433	☑ Contract	☐ No Charge	☐ Bill	Date in	6-Apr-05	Out	6-Apr-05
PO No.	☐ Install	☐ Warranty	☐	Time in	9:45	Out	11:45
Dosimeter Reading: 5 mR							

Symptom

System displays EC 4, EC 16, source will not retract via normal means or emergency stop action.

Resolution

Entered room under Nucletron RSO supervision via telephone, confirmed source not retracted. Turned crank to manually retract source. Experienced moderate resistance at the start of action, restriction immediately released, after which crank turned normally with almost no resistance to end stop. All alarms ceased, confirmed source in safe with Ludlum meter.

Channel 1 GYN transfer tube was connected to appropriate port on Nucletron autoradiograph device, and was the channel involved with the incident. Upon inspection, no external indication was present of any defect. Manual insertion of dummy cable was met with mild resistance when transfer tube was held straight, but with mild deflection at proximal end (indexer connector), dummy cable will not enter beyond the approximate point where the aluminum connector body joins yellow transfer tube material.

Returned defective transfer tube to Nucletron office for RMA, requested a replacement be sent via Fedex next day.

For Office Use Only - This Is Not An Invoice

Qty used	Description	Part Number	Qty ret	Return Status	RX Call (if different)	Description of problem / failure
	Transfer tube, V2, GYN Channel 1	111002	1	DEF		Source sticks @ indexer end

Travel Charged	3.00 Hrs	Airline		Travel Expenses (Meals, Tolls, etc)	
Regular Charged	2.00 Hrs	Rental Car			
Overtime Charged	Hrs	Hotel			
O/T (Sundays & Holidays)	Hrs	No of Miles			

Wed Apr 2005 04/06/05 08:27:23
Engineer

Wed Apr 2005 04/06/05 08:28:09
Customer