RI - DNMS Licensee Event Report
Disposition

Licensee:	Nucletron
Event Description:	Defect identified that could create a substantial safety hazard if left undetected and uncorrected.

License No:	19-28772-01	Docket No:	03032842	MLER-RI:	2011-012
Event Date:	04/06/11		04/08/11	HQ Ops Event #:	

1. REPORTING REQUIREMENT

	10 CFR 20.1906 Package Contamination		10 CFR 30.50 Report
	10 CFR 20.2201 Theft or Loss		10 CFR 35.3045 Medical Event
	10 CFR 20.2203 30 Day Report		License Condition
x	Other		10 CFR 21.21

2. REGION I RESPONSE

	Immediate Site Inspection	Inspector/Date	
	Special Inspection	Inspector/Date	
	Telephone Inquiry	Inspector/Date	
	Preliminary Notification/Report	✓	Daily Report
x	Information Entered in RI Log	✓	Review at Next Inspection
	Report Referred To:		

3. REPORT EVALUATION

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

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

	Release w/Exposure > Limits		Deliberate Misuse w/Exposure > Limits
	Repeated Inadequate Control		Pkging Failure>10 rads/hr or Contamination>1000x Limits
	Exposure 5x Limits		Large# Indivs w/Exp>Limits or Medical Deterministic Effects
	Potential Fatality		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)

	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
	Device Failure with Possible Adverse Generic Implications
	HQ or Contractor Support Required to Evaluate Consequences

6. SPECIAL INSTRUCTIONS OR COMMENTS

□ Non-Public — Inspector Signature: [signature] Date: 6-7-2011

X Public-SUNSI REVIEW COMPLETE — Branch Chief Initials: [signature] Date: 6/28/11

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

Nucletron Corporation
7021 Columbia Gateway Drive
Suite 200
Columbia, MD 21046-2133
Phone 410-312-4100
Fax 443-769-1570
http://www.nucletron.com

Kathy Modes
Senior Health Physicist
USNRC Region 1
Division of Nuclear Materials Safety
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Docket No. 030-32842

Our reference:	Your reference:	Date:
Cor.052311	19-28772-01	May 23, 2011

Dear Ms. Modes:

Please find enclosed a product problem follow-up report for the Laser Weld issue discovered at QSA Global which serves as written notification under 10 CRF §21.21. This problem is being reported because the identification of the defect could create a substantial safety hazard were it to remain undetected and uncorrected. The problem did not result in unnecessary exposure to staff, patient mistreatment, or an unshielded/unsecure source situation. The non-conformity assessment, root cause investigation, and corrective and preventive actions have been provided in the enclosed report. If you have any questions concerning the enclosed, please contact the undersigned at 443-545-2220 or via e-mail Debbie.bensen@us.nucletron.com.

Sincerely,

Debra L. Bensen
RSO

Product Problem Follow-up Report

1. Data

Source Manufacturer:	**QSA Global** **40 North Avenue** **Burlington, MA 01803** **Contact: Jake Bourn, QSA Sales Director** **Phone: 781-272-2000**
Cable Manufacturer:	**Covidien** **Postbus 3** **1755 ZG Petten** **The Netherlands**
Customers Involved:	**Please see attached list**
Device/Source description:	**HDR source model 105.002 for Nucletron microSelectron HDR models 105.999 or 106.990**
Date and Time of Event:	**April 6, 2011 @ 2:03 PM**
Date of Initial Notification	**April 8, 2011**
Date of Follow-up Report	**May 23, 2011**
Docket No.	**030-32842**
Reporter:	**Debra Bensen** **Nucletron Corporation** **7021 Columbia Gateway Drive** **Suite 200** **Columbia, MD 21046**

2. Description of Event

On April 6, 2011, Covidien received a complaint from QSA Global concerning a defective sleeve of a source cable (Lot #1105901607). The problem involved the sleeve that protects the welding at the transition of the rigid part of the cable to the very flexible part. The defective sleeve was discovered while wiping the source cable before shipment. At the time of the discovery, 13 sources from this batch had been shipped to customer sites but were not installed.

3. Investigation and Analysis

The 13 sources that had been released from this batch were returned to QSA Global for inspection. Additionally, QSA Global had 46 assembled sources in storage from Lot #1105901607 (Covidien Lot #304449). All sources were visually inspected for evidence of the collar (or sleeve) under 5X magnification and included a complete circumferential inspection to look for a clear dark rim identifying evidence of welding combined with verifying no collar movement during manipulation/wipe testing. All of the sources had shown evidence of welding and there was no discernable movement of the collar. Nucletron B.V. provided documentation for the release of the 13 returned sources and the remaining 46 assemble sources.

Covidien reviewed the batch documentation of Lot #304449 (corresponding to QSA Lot #1105901607) and no exceptions or non-conformities were found for the 98 cable assemblies of this lot. Maintenance records of the laser used for welding show that no changes in the settings of the laser were introduced since January 2011. No exceptions occurred during the welding process. Hence, it is not likely that the laser performance failed.

Based upon the root-cause investigation done by Covidien and supplemented by memoranda from QSA, this complaint was determined to be an isolated occurrence issue.

4. Discussion and Conclusion

At Covidien, no exception occurred during the laser process and no changes were made to the settings of the laser since January 2011. A double check of the laser process was performed and there was no indication that the reported defect was caused by a bad welding. QSA confirmed that the sleeve was not welded to the cable at all.

After confirmation from QSA, the operator at Covidien who performed the end control of the cables was interviewed. Given the operator's performance history and experience with the end control, it was determined that the root cause of this complaint was an isolated occurrence caused by an operator failure.

5. Corrective/Preventive Actions

As a corrective action, QSA investigated all cable assemblies, including the completed sources from this batch (QSA Lot #1105901607, Covidien Lot #304449, 98 cable assemblies). For this purpose, Covidien had sent 2 pictures to QSA for comparison, one showing a sleeve that is properly welded and one that is not welded to the cable. The deviation was clearly visible and not prone to misinterpretation.

As a preventive action, the Covidien production flow chart will be updated with more instructions about the end control of the cables. In addition, more pictures of incorrect welding will be added in the flow chart.

Customers Involved

Facility	City	State	Contact	Phone
Providence Hospital	Mobile	AL	Paul Hi	251 639 2719
Good Samaritan	Phoenix	AZ	Steve Sapareto	602 239 4500
M.D. Anderson	Orlando	FL	Thomas Wagner	407 648 3800
GammaWest	Salt Lake City	UT	Jim Sweet	801 350 8400
Montgomery Cancer Ctr	Montgomery	AL	Mike Skowronski	334 260 5000
Mobile Infirmary	Mobile	AL	Mike Williams	251 435 3549
Trinitas Hospital	Elizabeth	NJ	Linda Veldkamp	908 994 8751
21st Century MIRO	Pontiac	MI	Adib Shamaoun	248 338 0300
Memorial Hospital West	Pembroke Pines	FL	Vidia Nathasingh	954 430 6808
St. Joesph Mercy	Ann Arbor	MI	Mathew McMullen	734 712 3597
McGill University	Montreal	QC	Michael Evans	514 934 8052
Arizona Cancer Specialists	Gilbert	AZ	Amir Sadeghi	210 317 2320
Georgetown Cancer Center	Georgetown	SC	Ingrid Marshall	843 545 5600