

Facilities Management

June 25, 2008

U.S. Nuclear Regulatory Commission
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RE: NRC Byproduct Materials License 45-00048-17
Document No. 03003297

Notice of Violation

Virginia Commonwealth University is submitting this written statement regarding the Severity Level IV violation noted in the Notice of Violation dated June 9, 2008, pursuant to 10 CFR 2.201.

- (1) The reason for the violation: The incident occurred at 12:40 PM, 2/20/2008, when Daniel J. Komorowski, M.D (Interventional Radiology) was trying to deliver Y-90 MicroSpheres (prescribed activity: 1.42 GBq, TheraSphere, MDS Nordion) to the patient for cancer treatment (HCC). The clinical protocol for the Therasphere radiation therapy procedure was based on MDS Nordion's guideline. The first flush was successful but the second flush was not. The procedure normally requires three flushes. To prevent a spill of the radioactive glass microspheres, the remaining activity was re-directed to a waste container, and the procedure was terminated. There was no personnel injury, no room contamination or equipment damage. The patient was informed of the under dose and the referring physician was notified of the incident.

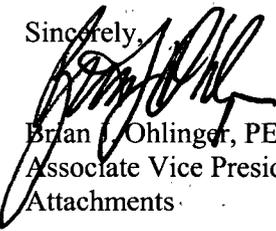
The incident occurred when inlet/outlet tubing was crimped by the insertable beta shield during the attempted second flush. This appears to have occurred because the supporting arm for the blue three-way stopcock that controls the flow of radioactivity to the patient was installed in the opposite direction. This caused the tubing to be crimped when the insertable beta shield was installed. While this did not affect the first flush, the additional pressure applied during the second flush was enough to crimp the line.

- (2) The corrective steps: The incident was reviewed with the staff involved and considerations were given to altering the device to eliminate assembly errors. The patient was later treated with an additional dose to complete the prescribed therapy.
- (3) The corrective steps to avoid further violations: To ensure this does not occur again the device was modified in the machine shop by locking the stopcock (blue three way) holder in place. Additionally, the lower and upper sections of the assembly were etched with arrows to delineate proper orientation. Nuclear Medicine and Interventional Radiology reviewed the protocol, and will check the set up before each injection procedure.

- (4) Date of full compliance: Full compliance was achieved on March 3, 2008.

Should you have any questions or require any additional information, please contact Dr. Dean Broga in our Radiation Safety Section at (804) 828-5877.

Sincerely,


Brian J. Ohlinger, PE
Associate Vice President for Facilities Management

Attachments

IED 7
RGN I

p.c.: U. S. Nuclear Regulatory Commission, Region I
Division of Nuclear Materials Safety
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