12/3/99 EVENT RPS - DIST.
DCD (SP04)
cc: PLarkins, OSP
DSollenberger, ASPO

RUSH-PRESBYTERIAN-ST. LUKE'S MEDICAL CENTER 1653 WEST CONGRESS PARKWAY, CHICAGO, ILLINOIS 60612

Received NOV 1999 IL Dept. of Nuclear Safety Office of Radioactive Materials

October 11, 1999

Bruce Sanza, Head
Inspection and Enforcement
Illinois Department of Nuclear Safety
1035 Outer Park Drive
Springfield, Illinois 62704

Re: RAM License # Il-01766-01

Dear Mr. Sanza:

This letter is to inform you of a malfunction that occurred with the Betacath® by Novoste. The incident occurred on Tuesday, during a routine procedure. The procedure had been completed and the sources were verified to be in the instrument. The Radiation Oncologist checked the instrument again and could not verify that the sources were present.

The catheter was removed immediately and both the patient and catheter were surveyed and radiation levels were not above background. The instrument and all items were transferred into the emergency plexiglass container for transport to another work area. The patient and room were surveyed again to ensure no sources were present.

The radiation oncologist and the medical physicist were able to confirm 10 sources (9 sources and 1 marker) in the instrument. There are a total of 18 sources (16 active 2 marker) in the instrument. The catheter was disconnected and it was noted that 7 sources (6 sources and 1 marker) were jammed in the end of the catheter. The sources were immediately placed in a shielded container.

The catheter was reattached to the instrument and the sources were transported to the end of the catheter in a shielded container. Again only 10 sources were visually verified. The instrument was then surveyed. Radiation levels indicated that a source was lodged somewhere inside the instrument.

The Radiation Safety Officer and the manufacturer was notified immediately. The manufacturer came to the facility the following morning.

Novoste representatives arrived and inspected the instrument. Again 17 sources were visually

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SP-E-9

Followup Rpt.
NMED ITEM # 990696

PDR STPRG

verified. All of the sources were placed in a shielded container. and the device was visually inspected for any abnormalities. None were found. A radiation detector confirmed that a source was still in the device.

The instrument was flooded with saline to push the source out. The source did not come out. The device was systematically dismantled. Each piece was surveyed to ensure no sources were present. Ultimately the source was located adhered to an internal magnet. The source was removed and placed within a shielded container. All of the sources were present.

All of the sources were inspected and one source was noted to have damage. The sources were placed into a shielded container for future transport to the manufacturer. All of the sources were leak tested and no significant contamination above background was noted. The Novoste representatives took the device to further evaluate the malfunction.

Manufacturer of Source Train	Bebig
Model Number	Sr0.S03
Serial Number	139/99
Radionuclide	Sr-90
Activity	2.07 Gbq (56 mCi)
Activity Assay Date	April 8, 1999
Transfer Device	7Z519

Source train contains 16 active seeds for a total length of 40 mm. The source train also has two 2.54 mm gold marker seeds used for radio-opaque end markers.

Individuals Involved

James Chu, Ph.D.	Medical Physicist
Cam Nguyen, M.D.	Radiation Oncologist
Glenn Sullivan	Radiation Safety Officer
Manjeet Hansra	Radiation Safety Technician
Tony Hursey	Cardiology

Chris Can, R.N., BSN	Clinical Technical Specialist, Novoste Corporation
Roel Trip	Director Product Development, Novoste Corporation
John Lobdell, Ph.D.	CHP Director, Radiation Management, Novoste Corporation

If you have any questions, please do not hesitate to contact me at 312-942-5763.

Sincerely,

Glenn Sullivan
Radiation Safety Officer

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