VCU
MCV CAMPUS
Virginia Commonwealth University

OFFICE OF THE VICE
PRESIDENT FOR RESEARCH
AND GRADUATE STUDIES

SANGER HALL
1101 EAST MARSHALL STREET
P.O. BOX 980568
RICHMOND, VIRGINIA 23298-0568

804 828-0732
FAX: 804 828-2051
TDD: 1-800 828-1120

August 16, 1999

U. S. Nuclear Regulatory Commission, Region II
Material Licensing/Inspection Branch I
Division of Nuclear Materials Safety
61 Forsyth St., N.W., Suite 23T85
Atlanta, Georgia 30303

Dear Sir or Madam:

RE: License Number 45-00048-17
Report of Possible Misadministration

In the following narrative paragraphs, Virginia Commonwealth University would like to report a possible misadministration that occurred on July 23, 1999:

A cardiology patient who had undergone previous stent placement underwent a cardiac catheterization study and was deemed eligible for participation in the Beta-Cath START 40/20 trial in which the stent region is irradiated to examine the effects of radiation on restenosis. Radiation Oncology personnel were notified and proceeded immediately to the Cath Lab with the radioactive Sr-90 applicator to prepare for the brachytherapy procedure. The patient's vessel diameter was measured by the cardiologist (the patient's referring physician), on the basis of which a written directive was prepared by the radiation oncologist, Brian Kavanagh, M.D., to deliver 16 Gy to the prescription point at 2 mm from the source center line. Prior to placement of the irradiation catheter in the patient, the catheter was connected to the transfer device which was tested by sending the source train and markers out to the designated section of the catheter and returning them. The source train consists of a line of 16 Sr-90 seeds bounded by a radiopaque marker seed at each end. The source train is moved into position hydraulically, by injecting saline or water into the applicator. The two radiopaque markers show the end positions of the source train when it is properly positioned in the patient. The tests carried out prior to the procedure showed that the transfer device and catheter were functioning properly as all seeds and both markers were seen to move into position correctly. The applicator in question, Novoste™ Beta-Cath SN 68359, was a new device which had not been used previously for patient procedures at VCU/MCVH.

During the patient irradiation procedure the catheter was positioned as desired in the patient, and fluid was injected into the transfer device to move the source train into position. Under fluoroscopy, it was noted that the distal radiopaque marker had

IE72
M624

moved into position within a few seconds, but the proximal marker had not. The radioactive seeds cannot be readily distinguished under fluoroscopy. A period of less than 30 seconds was spent trying to move the proximal marker into view on the fluoro screen, but without success. At this point, the physicians involved decided that the most appropriate action would be to discontinue the brachytherapy procedure. The catheter was removed from the patient within a few seconds, during which time the radioactive seeds were hydraulically returned to the applicator. The procedure was then terminated.

The applicator with the same catheter attached was again tested outside the patient immediately after the procedure on July 23, 1999, and in this test all seeds and markers moved correctly into position. A later test carried out on Aug 6, 1999, confirmed that both marker seeds in the source train were radiopaque.

A close examination of the high resolution cinefluoroscopic images at a later date showed that during the patient procedure all the radioactive seeds were in position in the treatment area and only the non-radioactive proximal marker seed was missing. With this information the maximum possible dose to the patient was determined to be no greater than 2.6 Gy at the prescription point.

The patient was informed immediately after the procedure that only part of the intended dose had been given. The highly localized dose delivered to the patient is not be expected to cause any complications or other negative effects. With regard to the prevention of restenosis, the effectiveness of the irradiation is not known and is currently the subject of this and other studies. Therefore, any negative effects resulting from failure to deliver the full prescribed dose cannot be demonstrated at this time. The source applicator involved in this incident has been returned to the manufacturer for testing and analysis. The cause of this incident appears to be equipment failure of presently unknown origin, and speculative answers would not be appropriate until the device is examined. To prevent recurrence, a new applicator has been received from the manufacturer and will be carefully tested as directed in the current safety protocol before treating patients.

The NRC was approached for advice on this occurrence by telephone on July 28, 1999, and visited the facility on Aug. 9 and 10, 1999, at which time the determination was made that the incident was a possible misadministration. The date of our discovery of a potential misadministration is therefore August 10, 1999.

If after reviewing this report you have any questions or need any additional information, please contact Dean W. Broga, Ph.D., at (804) 828-6347.

Sincerely,

William L. Dewey, Ph.D.
Vice President for Research