Bryn Mawr Hospital
130 S. Bryn Mawr Ave
Bryn Mawr. PA, 19010

NRC License Number:37-07722-04

May 19, 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 Novoste Intravascular Brachytherapy Beta-Cath system Transfer Device. We are filing this report according to the requirements of 10 CFR 21.21(d). The information that we are supplying here has all been provided to Novoste Corporation of Norcross, GA 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.

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

i) Informing Individual – Mike Bieda, Authorized Medical Physicist, 130 S. Bryn Mawr Ave, Bryn Mawr, PA, 19010

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 is Novoste Corp, Norcross, GA. The item which had the breakdown in performance was an Active Transfer Device SN 90556. This item failed to provide adequate hydraulic pressure to return the Sr-90 source train from the catheter back into the device. 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. Novoste 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 a patient case in

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which two individual coronary artery locations where being irradiated, the device failed to return the source train from the catheter into the afterloading device. In the first location, the site was successfully irradiated. Upon returning the source train, it was noticed that the sources where not in the Active Transfer Device. We saw this both visibly and by a light indicator on the device which indicated the source was "out". At this point we pulled the entire catheter out of the patient. Within 1 minute we were able to get the sources safely into the device. We assumed that there was a problem with the catheter and the connection of the catheter to the Transfer Device, so we continued to the next location. Again the site was successfully irradiated. Upon attempting to return the source, we noticed on the fluoroscopic image that the sources were not moving from the patient. Within 5-10 seconds we pulled the entire catheter from the patient. We then placed the entire system (catheter and Active Transfer Device0 into the "bailout" out. This box provides shielding for the beta radiation and allows one to visualize the contents to identify the location of the sources. The catheter and Active Transfer Device remained connected. The case was over and the bailout box and its contents were removed from the cath-lab. I was able to get the source eventually back into the Transfer Device by applying a great deal of pressure and reconnecting the syringe and pouch. The next day I called the company (Novoste) and explained the events. They determined it was a faulty transfer device and sent me a replacement. On May 19, 2005 the replacement arrived and the faulty device was sent back to the company. This was not deemed to fit the definition of a Medical Event under 10 CFR 35.3045 because the source was only in the patient an extra 10 s. This amounted to an excess dose of 5% greater than the prescribed dose and the limit for reporting is 20%.

v) This incident occurred on Tues. April 17, 2005

vi) There is one such device at our facility.

vii) The corrective action taken was that the problem Active Transfer Device was returned to the company and replaced by a new one. This action has corrected the root problem. Additionally, it should be noted that the procedures for source recovery as described in the Novoste manuals and the on site emergency procedures were followed and were successful.

viii) Related advice - None given.

May 19, 2005

Sincerely,

Mike Bieda
Medical Physicist
Department of Radiation Oncology
Bryn Mawr Hospital

Cc: Bryn MawrHospital Rad Onc Incident File
Marchello Barbarisi, MD, RSO
Lynne Quinn, Manager/Radiation Oncology
NRC Document Control Desk
Region 1 Office, Medical Division

Hospital Event # 41720

Rep Org: BRYN MAWR HOSPITAL	**Notification Date / Time:** 05/19/2005 15:57 (EDT)
Licensee: BRYAN MAWR HOSPITAL	**Event Date / Time:** 04/17/2005 15:30 (EDT)
	Last Modification: 05/19/2005
Region: 1	**Docket #:**
City: BRYN MAWR	**Agreement State:** No
County:	**License #:** 37-07722-04
State: PA	
NRC Notified by: MICHAEL BIEDA	**Notifications:** RONALD BELLAMY R1
HQ Ops Officer: JOHN KNOKE	
Emergency Class: NON EMERGENCY	
10 CFR Section:	
21.21 UNSPECIFIED PARAGRAPH	

PART 21 REPORT - MALFUNCTION OF NOVOSTE INTRAVASCULAR BRACHYTHERAPY BETA-CATH SYSTEM TRANSFER DEVICE

During a medical procedure on a patient, two individual coronary artery locations were being irradiated with Sr-90 (2.05 GBq, serial # ZA-494. The device being used, Novoste Intravascular Brachytherapy Beta-Cath System Transfer (S/N# 90556], hereinafter called "Device", failed to work properly.

The licensee noticed the source did not retract into the Device. At this point the licensee pulled the entire catheter out of the patient, and within one minute was able to return the sources safely into the Device. It was assumed the problem was with the catheter and it's connection to the Device.

The licensee continued to the next location on the patient. Upon attempting to return the source, the licensee noticed the sources were not moving from the patient. Within 5-10 seconds, the licensee pulled the entire catheter from the patient, and then placed the entire system into the "bailout" box for proper shielding from beta radiation. The next day the licensee called Novoste and explained the events. Novoste determined it was a faulty Device and sent the licensee a replacement.

On May 19, 2005 the replacement arrived and the faulty device was sent back to the company.

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