DCS No.: 99999999030325
Date: April 2, 2003

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PNO-I-03-009

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the Region I staff on this date.

Facility
New York State Department of Health Licensee

Licensee Emergency Classification
___ Notification of Unusual Event
___ Alert
___ Site Area Emergency
___ General Emergency
_X_ Not Applicable

Docket No.: NA
License No.: Agreement State Licensee

SUBJECT: MEDICAL EVENT INVOLVING NOVOSTE BETA-CATH INTRAVASCULAR BRACHYTHERAPY SYSTEM

On March 27, 2003, at 5:40 p.m., the New York State Department of Health notified the NRC Operations Center that a medical misadministration involving a Novoste Beta-Cath Model A1767 Intravascular Brachytherapy (IVB) system with Model SIC W.2 source train (approximately 80 millicuries of Sr-90) occurred at a State licensee on March 25, 2003. New York State law prohibits the release of any identifying information of the patient or the facility involved in a medical misadministration.

During an IVB procedure on a 76-year old woman, two attempts to advance the source train into the delivery catheter were unsuccessful. The third attempt resulted in the source train becoming stuck in the patient's femoral artery, somewhere in the lower groin area. Since the sources could not be returned to the base unit, the treatment team removed the catheter, with the sources extended, and placed these items into the emergency bailout box.

The licensee estimated that the patient received a dose of 250 rads to an area of the femoral artery in the lower groin area. The oncologist and cardiologist decided not to proceed with the IVB treatment of this patient. The licensee concluded that the radiation dose to the wrong treatment site would not have a significant health effect on the patient. The facility will investigate the circumstances, procedures, training, and history of use and will submit a written report to the State by April 4, 2003. The device, including catheter and hydraulic attachment (syringe) have been sent to the vendor for evaluation. Upon receipt and review of the licensee's report, the State plans an on-site investigation.

The New York Department of Health concurs with the contents of this notification. Region I is prepared to respond to media inquiries.

This information is current as of 2:00 p.m. on April 2, 2003

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