DCS No.: 7D05101020128
Date: February 27, 2002

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PNO-I-02-006

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
Rhode Island Hospital
Providence, Rhode Island
(Agreement State Licensee)

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

Agreement State License No.: 7D-051-01

SUBJECT: INTRA VASCULAR BRACHYTHERAPY MISADMINISTRATION

The State of Rhode Island notified Region I and the Office of State and Tribal Programs on February 27, 2002, of a misadministration at Rhode Island Hospital involving a Cordis Checkmate IVBT system device during the intra vascular brachytherapy (IVB) treatment of a patient. On January 28, 2002, the patient's coronary artery was treated with the Cordis device which contained approximately 243 millicuries of iridium 192. During a review of dosimetry and physician records on January 31, 2002, the licensee discovered that the diameter of the artery was used in the calculation instead of the radius. The licensee informed the State the next day by telephone of a possible misadministration and provided a written report on February 14, 2002. The licensee estimated that the dose to the patient's outer portion of the coronary artery was 14.6 Grays (Gy) rather then the intended 8 Gy. The licensee indicated that there are probably no adverse effects to the patient as a result of the overdose.

This error resulted when a second IVB device (Novoste) was used for calculating the dose and the Cordis device was used for treatment of the patient. The Novoste device uses the diameter of the artery in the dosimetry calculations whereas the Cordis device uses the radius. The authorized user provided the wrong dimension (diameter instead of the radius) which led to an overdose being calculated.

To prevent recurrence, the licensee has modified its prescription form to indicate whether radius or diameter is being used for the treatment plan. Additional in-house training is being provided to all involved in IVB procedures. The State plans to confirm the licensee's proposed corrective and preventive actions at an upcoming inspection.

The content of this notification was confirmed with the State of Rhode Island. The Region I Office of Public Affairs is prepared to respond to media inquiries.

This notification is current as of 11:00 a.m. on February 27, 2002.

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Region I Form 83
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