

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
☒ 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 than 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.

Contact: Duncan White
610-337-5042

DISTRIBUTIONS:

BY E-MAIL:

OWFN
Chairman Meserve

TWFN
IRO

LST
PDR

Comm. Diaz	ACRS
Comm. McGaffigan Jr.	NMSS
Comm. Merrifield	OIG
Comm. Dicus	RES
OIP	
OCA	
OGC	
EDO	
OE	
NRR	
SECY	
Regional Offices	

BY FAX:

DOT:Trans

INPO

NSAC

RI Resident Office

Licensee: _____
(Reactor Licensees)

DOCUMENT NAME: S:\PN\PN1000

OFFICE	RI/DNMS	RI/DNMS	RI/ORA	RI/	RI/
NAME	Dwhite ADW	Gpangburn GCP	Dscrenci DPS		
DATE	2/27/02	2/27/02	2/2702		

Region I Form 83
(Rev. August 17, 2000)