DCS No: 03001287940621
Date: June 23, 1994

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PN1-9438A

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:
William W. Backus Hospital
326 Washington Street
Norwich, Connecticut 06360

Licensee Emergency Classification:
____ Notification of Unusual Event
____ Alert
____ Site Area Emergency
____ General Emergency
__X__ Not Applicable

Docket No.: 030-01287
License No.: 06-11734-02
Event No.: 27423
Event Location Code: HOS

SUBJECT: MEDICAL MISADMINISTRATION REQUIRING MEDICAL INTERVENTION UPDATE

Region I inspection team arrived at the hospital at approximately 2:00 p.m. on June 22, 1994 and started the investigation into the circumstances surrounding the therapeutic misadministration reported by the licensee on June 21, 1994. At 7:30 p.m., Dr. Ronald Bellamy, team leader, briefed the Commissioner's assistants, representatives of NMSS and Region I as to the status of the patient and the incident. The team had interviewed the majority of the individuals involved and confirmed that a written directive was prepared that specified 112, iodine-125 seeds of an activity of 0.43 to 0.46 millicurie per seed for the treatment of prostrate cancer in a 73 year old male patient.

The seeds were ordered from MediPhysics, a licensed supplier, on June 16, 1994 by the Chief Nuclear Medicine Technologist and the seeds were received on June 17, 1994. The seeds supplied by MediPhysics were logged in as 112 seeds with activity of 4.49 millicuries per seed with total activity of 502.88 millicuries by a nuclear medicine technologist.

On June 21, 1994 at 7:15 a.m. the iodine-125 seeds were taken from the storage area to the operating room where at approximately 10:30 a.m. the authorized user and a surgeon implanted the seeds into the patient. All 112 seeds were implanted. In documenting the implant, the dosimetrist noted that the seeds were logged in at 4.49 millicuries per seed, and thinking this was an error corrected the logbook to read 0.449 millicuries per seed. Later, when checking the MediPhysics Certifications of activity sent in the shipment, the dosimetrist discovered that the activity of the seeds was indeed, 4.49 millicuries per seed.

The surgeon, the authorized user and the patient were informed of the misadministration and the patient, who had not been discharged from the hospital, was returned to the operating room, where the surgeon removed the prostrate. Through removal of the prostrate and suctioning the tissues in the area, 69 seeds were removed. In removing the seeds, the individuals involved noted that one seed ruptured as it was removed from the patient. The remaining 42 seeds are believed to still remain in the patient. The licensee collected all contaminated blood and materials. The NRC team has verified that there is no contamination in the operating room. Measurements indicated that only background radiation levels are present. In addition, initial thyroid monitoring performed by the licensee of the operating room personnel were negative. The licensee will perform follow-up thyroid monitoring of both the patient and staff. As a precaution the patient's thyroid has been blocked with 300 milligrams of potassium iodide.

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NRC measurements in the patient room area indicated only background radiation levels in the unrestricted areas.

The licensee plans to transfer the patient this morning to the Yale-New Haven Hospital, where state-of-the-art x-ray equipment can precisely locate the remaining 42 seeds, in order that as many seeds as possible can be surgically removed from the patient. It is expected that this surgical intervention will occur on Friday, June 24, 1994. The licensee has also voluntarily agreed to suspend all further brachytherapy procedures at its facility until authorized by the NRC to resume. A Confirmatory Action Letter (CAL) will be executed later today outlining the licensee's actions.

Region I, in consultation with NMSS and AEOD, will be upgrading its inspection effort to an Augmented Inspection Team (AIT). NMSS has contacted INEL, who will send a team to support the Region I AIT.

Region I has engaged an NRC medical consultant who has reviewed the events and the licensee actions with regard to the patient and has advised the NRC that the licensee's actions with regard to the patient appear appropriate.

The State of Connecticut has been notified. The Region I Office of Public Affairs is prepared to respond to media inquiries. This information is current as of 11:00 a.m. June 23, 1994.

Contact: Jenny Johansen
(610) 337-5304

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