September 15, 2003

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-IV-03-040A

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 IV staff on this date.

Facility	**Licensee Emergency Classification**
Northridge Hospital	___ Notification of Unusual Event
Van Nuys, CA	___ Alert
License No.: 0041	___ Site Area Emergency
California Agreement State Licensee	___ General Emergency
	_X_ Not Applicable

SUBJECT: UPDATE - HIGH DOSE RATE AFTERLOADER EQUIPMENT FAILURE

DESCRIPTION:

On September 8, 2003, the California Radiologic Health Branch (the Branch) notified NRC's Operations Center that a Nucletron MicroSelectron High Dose Rate (HDR) afterloader device, Model Number 31324 (Serial Number D36A4476), had failed to retract upon completion of patient treatment.

The event, as originally reported, is as follows:

> Northridge Hospital, a California licensee, reported to the Branch on the morning of September 8, 2003, that a 4.6 curie (170.2 GBq) iridium-192 sealed source had failed to retract upon completion of patient treatment. After noting that the sealed source was stuck in the transfer tube, the physicist started his stopwatch, entered the room, and attempted to manually retract the source. Manual retraction of the sealed source failed. The physicist then called the physician, who was waiting outside the room. The physician then entered the room and disconnected the apparatus from the patient and dropped the transfer tube into a lead pig. Both the physicist and physician then moved the patient out of the room. The physicist stopped the stop watch and observed that 2 minutes had elapsed. The physicist then carefully surveyed the patient and obtained no measurement above background. The physicist re-entered the room, performed a radiation survey, and found a hot spot along the transfer tube that was shielded in the pig. The shielded pig measured 10 millirem/hr at 3 feet (0.1 mSv/hr at 0.91 m). The room was locked and posted until the manufacturer's representative arrived.
> The manufacturer's representative also was unable to make the source retract. He then placed the transfer tube into a shipping container and returned it to the manufacturer for further investigation.

Initially, the cause of the event was reported to be that the transfer tube used by the licensee, which was reportedly not of the same make as the afterloader, was not designed for use with the Nucletron device. However, Nucletron has now clarified that, although the transfer tube was also manufactured by Nucletron, the rigid gynecological-type transfer tube used by the licensee was not designed for use with the Proxima Therapeutics Mammosite applicator for the procedure being performed. As a result of the incorrect use, the sealed source was inadvertently positioned inside the transfer tube at a distance of 3.9-5.5 inches (10-14 cm) from the patient's breast, not in the breast as planned. That is, the source of the radiation never arrived at the treatment site within the patient's body. The use of the incorrect tube with the Mammosite applicator apparently caused the subsequent failure to retract.

Discussion with Nucletron indicated that the licensee should have used Nucletron's flexible transfer tube, approved for use for non-gynecological type treatments, which is designed to accommodate the Mammosite applicator.

Doses to the patient, physicist, and physician (as originally reported) were estimated as follows: patient's skin dose at 3.9 inches (10 cm) from the sealed source for 2 minutes was 61 rem (0.61 Sv); physicist's whole body dose for 2 minutes was 45 millirem (0.45 mSv); and physician's whole body dose was 125 millirem (1.25 mSv) and an extremity dose of 15 rem (0.15 Sv).

The Branch is continuing to investigate the event.

Region IV received the updated information on September 12, 2003 at 10:30 a.m.

This information has been discussed with the State and is current as of 11:30 a.m. (CDT) on September 12, 2003.

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