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Radiation Safety Office

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United States Nuclear Regulatory
Commission Region III
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Attn: Roy Caniano

January 27, 1994

34-06903-05
030-02764

Mr. Caniano:

This report is being submitted by the University of Cincinnati in accordance with 10 CFR 35.33. As required the report includes: the licensees' name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent reoccurrence; actions taken to prevent reoccurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian, and if not, why not, and if the patient was notified, what information was provided to the patient.

Licensee Name:

University of Cincinnati

Prescribing Physician's Name:

John Breneman, M.D.

A brief description of the event:

On January 7, 1994, a brachytherapy procedure was performed on a patient with a recurrent malignant glioma (brain tumor). The patient is a 33 year old male.

The procedure comprised of placing sixteen iodine-125 seeds (ranging in activity from 10 to 30 millicuries) within eight catheters (1 to 3 seeds each) and surgically implanting the catheters into a tumor in the patient's brain. On January 14, 1994, the seeds were removed. Upon removal of the seeds it was determined that one of the seeds had leaked.

In addition to the brachytherapy procedure the patient also underwent two diagnostic brain scans. On January 7, 1994, prior to implant of the brachytherapy seeds a brain scan was

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performed on the patient. To perform the brain scan the patient was administered 9.8 millicuries of technetium-99m and 4.15 millicuries of thallium-201. In addition, on January 14, 1994, prior to explant of the brachytherapy seeds another brain scan was performed on the patient. To perform the second scan the patient was administered 5.0 millicuries of technetium-99m and 4.9 millicuries of thallium-201.

After the leaking seed was discovered, areas most likely to be contaminated were surveyed. The areas surveyed, included the operating room where the seeds were removed, the patient's private room, areas outside the operating room, areas outside the patient's room, nurse's stations, patient visitation areas, operating room staff locker room and the brachytherapy room. The only areas where contamination was detected were the operating room, the patient's private bathroom and an L-block shield used to count the seeds after removal. All patient care areas (i.e. the operating room and the patient's private bathroom) were designated radioactive material restricted areas until contamination was reduced to levels less than those listed in 10 CFR 35.315.

Thyroid uptake bioassays were performed on personnel and visitors who may have come in contact with the patient. All results indicated I-125 levels at less than the minimum detectable activity of 1 nanocurie.

Why the event occurred:

While securing the seeds during implant a surgical clip used to secure the catheters in place inadvertently crushed one of the seeds.

The effect on the patient:

On the morning of the implant, after installation of a sterotatic instrument and prior to implant, the patient had a CT scan which included intravenous administration of iodinated contrast (iotholamate meguline injection). Ionic iodinated contrast media typically blocks radioiodine uptake to subnormal levels for a period of 4-6 weeks. Analysis of the leaking seed, indicates approximately 2.0 - 2.1 millicuries was released. On January 26, 1994 a uptake bioassay was performed on the patient's thyroid and the bioassay measurement indicated 77 microcuries were present in the patient's thyroid. Using MIRD dose report #5 and NCRP 80 as references, a conservatively high estimation of the dose would be 300 rads to the thyroid and 0.231 rads to the whole body. The whole body dose is less than that received from standard diagnostic nuclear medicine procedures or a CT scan. In regards to the thyroid dose, a dose of 30,000 rads (Maxon et al, Journal of Nuclear Medicine, Vol 33, 1992, pages 132-136)

is usually administered to ablate normal thyroid tissue in patients who have thyroid cancer.

What improvements are needed to prevent recurrence and actions taken to prevent reoccurrence:

In the future, seed implants will be planned so seeds are placed further from the sites where the catheters are secured. Whenever possible catheters will be secured by means other than surgical clips. If in the future Nuclear Medicine scans are performed on brachytherapy patients, contamination detected will be isotopically analyzed.

Whether the licensee notified the patient or the patient's responsible relative or guardian and if not, why not, and if the patient was notified, what information was provided to the patient.

The patient and members of the patient's family have been notified.

The patient and the members of the patient's immediate family were notified that one of the iodine seeds placed into the patient's brain had leaked and because a seed had leaked, the patient still contained radioactive material (in addition to the radioactive material from diagnostic nuclear medicine studies). The patient and the member's of the patient's family were also informed that analysis for radiation dose, including thyroid uptake scans and/or urine bioassay, would be performed.

If the NRC needs additional information in regards to this misadministration, do not hesitate to call.

Sincerely,

Victoria Morris, M.S., CHP
Radiation Safety Officer
University of Cincinnati

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