NMED 090368

union HOSPITAL

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January 15, 2010

U. S. Nuclear Regulatory Commission, Region III
Material Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: NRC Material License
No. 13-16457-01

Ref: (a) Phone conversation between Mr. Darrel G. Wiedeman of USNRC Region III and Dean A. Taylor, Radiation Safety Consultant for Union Hospital on January 15, 2010.

Encl: (1) Memo dated May 22, 2009, ***Update on Radiological Incident Involving a Hux Cancer Center Patient***

On the recommendation of Mr. Wiedeman in reference (a), we are submitting this leaking source report. Enclosure (1) is a copy of the summary of findings for an incident originally reported to the NRC in February 2009. It involved the implantation of I-125 sources for treatment of prostate cancer. We had only indirect evidence that this involved a leaking source (i.e.: an empty source cartridge was found to be contaminated after all sources were implanted). Enclosure (1) documents all actions taken in response to this incident.

The following information pertains to the suspected leaking source:

(1) Manufacturer: Oncura
(2) Model # 6711
(3) Calibrated activity: 0.538 mCi of Iodine-125 (as of February 26, 2009)
(4) Leak testing of empty source cartridge exhibited contamination > 0.005 μCi (February 26, 2009).
(5) Contaminated cartridge components held in storage for decay and eventual disposal

We regret that this report was overlooked at the time of the incident. Our focus at the time was on patient safety and communicating his status to NRC Region III. If you have any questions regarding this report please contact our Radiation Safety Officer, Rasiklal Ganatra, MD at (812) 238-7581 or Dean Taylor our Radiation Safety Consultant at (812) 238-7275.

Sincerely,

David R. Doerr
President/Chief Executive Officer

Copy to:
Director, Office of Federal and State Materials and Environmental Management Programs

MEMORANDUM

To: Radiation Safety Committee, Union Hospital
From: R. B. Ganatra, MD, Radiation Safety Officer

Date: May 22, 2009

Subj: UPDATE ON RADIOLOGICAL INCIDENT INVOLVING A HUX CC PATIENT

union

1. Name of the Patient: [redacted]
2. Date of the Incident: February 26, 2009
3. Referring Physician: P. Patel, M.D.
4. Authorized User: R. Haerr, M.D.
5. Allied Health Pers.: D. Diethrich, CMD
   T. Nascimbene, RT(T)(R)

6. Radiopharmaceutical present: I-125 Seals Sources (prostate implantation)

   Estimation of activity present: Each source contained 0.538 mCi of I-125 as of the implantation date. The sources were pre-loaded in a Mick Cartridge designed to hold 15 sources. The case involved 115 such sources which were supplied as 7 pre-loaded cartridges and 10 loose sources. All 115 sources were implanted in the patient's prostate.

7. Description of the sources: OncoSeed Model 6711 consisting of a welded titanium capsule containing silver iodide-125 absorbed onto a silver rod. Source length is 4.5 mm with a diameter of 0.8 mm.

8. Description of the incident: The implant case was scheduled for February 26, 2009 and the source shipment was received on February 19, 2009. The sources came with a certificate attesting to successful leak testing (removable activity was less than 0.005 μCi) on February 03, 2009 and signed by the manufacturer's representative on February 17, 2009. Prior to sterilization for use in the case, the sources were assayed to confirm their activity. This was carried out on February 19, 2009. For the pre-loaded cartridges this involved removing the cartridges from their sterile packs. All packing materials were surveyed once the cartridges were removed and found be at background (a Ludlum Model #3 survey meter with a Model 44-3 NaI Low Energy Gamma probe was used). For the loose sources this involved removing them from their shipping vials and loading them in a cartridge to be assayed. Again, all packing materials were surveyed once the sources were removed and found be at background. The cartridges were the screwed into a shield block (stainless steel) which was then

place in a stainless steel carrier ready for sterilization. The carrier was transferred from the source store room to SPD on February 24, 2009, was sterilized, and returned to the source store room without incident. The morning of the case the source carrier was brought to OR #1 and the case commenced. The pre-loaded cartridges were used first. The implantation of sources proceeded without incident until the fifth cartridge was emptied. Our procedure calls for each cartridge to be surveyed after use to ensure that no sources remain. The fifth cartridge in this case was still showing significant activity so it was suspected that one or more sources remained in the cartridge. Ms. Diethrich and Mr. Nascimbene separated the two major components of the cartridge but did not find any sources. The cartridge was set aside for investigation after the case. The Mick Applicator was surveyed and was found to be free of contamination so the case was completed without further incident. After the case, the patient was examined under X-ray and all 115 seeds were visualized in the area of the prostate.

Follow on actions included a complete survey of OR#1, surgical instrument, drapes, trash, etc. No items other that the two white plastic portions of the cartridge that came in direct contact with the sources were found to be contaminated. The cartridge shield block and carrier was also found to be free of contamination. On February 27, 2009 wipe testing was conducted on the packing materials in which the shipment was received and were found to be free of contamination. Oncura was also contacted but they were able to provide limited help in the form of journal articles on related source breaches.

9. Suspected source of the contamination. Based on the limited number of items contaminated it is suspected that the source of the free Iodine was a breached weld on a seed in cartridge #5 as a result of the sterilization process. Since hundreds of cases of this type have been completed without incident it is assumed that the weld on one of the seeds was defective, leading to the breach during steam sterilization.

10. Patient management following surgery:

a. Administration of Lugol's solution on February 26, 2009.
b. Prescribed KI 30 mg twice a day for up to 420 days. Shorter terms of treatment will be considered once the bioassay protocol is completed and results are known.
c. Bioassay of the thyroid on: February 26, February 27, March 5, March 12, March 20, March 26, 2009 and April 27, 2009. (This initially included scans of patient's neck for iodine uptake and counting of blood and urine samples in a well counter).

11. Results of bioassays through April 27, 2009 are summarized below:

Bioassay	Neck Survey	Blood Survey	Urine Survey	Thyroid Imaging
February 26, 2009	Not tested	Background	Background	Not tested
February 27, 2009	Not tested	Background	124 ± 16 dpm	Negative
March 05, 2009	<Background	<Background	48.7 ±16.4 dpm	Not tested
March 12, 2009	6.3 nCi	Not tested	425 ± 32.4 dpm	Not tested
March 20, 2009	<Background	25.3 ± 13 dpm	323.6 ± 27 dpm	Not tested
March 26, 2009	<Background	<Background	181.3 ± 24 dpm	Not tested
April 27, 2009	<Background	27.3 ± 13.8 dpm	117.0 ± 19.1 dpm	Not tested

12. NRC Medical Event Criteria: For this incident to be considered a Medical Event under 10 CFR 35.3045(a)(2)(v), the effective thyroid dose equivalent will need to exceed 50 rem. A thyroid burden of about 60 µCi of I-125 would be sufficient to provide this dose equivalent given the long half-life of I-125 (60 days). As of March 05, 2009, there has been no measurable uptake. The NRC was called on February 27, 2009 and we reported a "possible" medical event. Ongoing discussions with the NRC Region III staff has lead us to the following plan:

    Should the bioassay results continue to indicate no measurable uptake in the patient's thyroid, we will report this by phone to Region III and request that our "possible" event report be withdrawn. If we do detect uptake in the patient then we will need to follow him for a longer period of time in an effort to quantify the thyroid burden.

    Update: As of March 26, 2009 the Possible Medical Event Report was withdrawn. The patient is being followed by an endocrinologist to determine health of his thyroid and whether the KI treatment can be terminated earlier than the 420 days originally planned.

//signature on file//

R. B. Ganatra, MD
Radiation Safety Officer