INDIANA UNIVERSITY
PURDUE UNIVERSITY
INDIANAPOLIS

October 13, 2004

U.S. Nuclear Regulatory Commission
Region III Office
2443 Warrenville Rd., Ste. 210
Lisle, IL 60532-4351

Re: Report of lost material – NRC license No. 13-02752-03

Dear Sir/Madam:

RADIATION
SAFETY OFFICE

Attached please find a report of lost byproduct material that is being submitted in accordance with the requirements of 10 CFR 20.2201(b). Should you have any additional questions, please do not hesitate to contact me at the telephone number or address at the left or via electronic mail at mrichar@iupui.edu.

Sincerely,

Mack L. Richard, M.S., C.H.P.
Radiation Safety Officer

Attachment

Cc: M. Brenner, Ph.D.
M. Yoder, Jr., M.D.
O. Pescovitz, M.D.
M. Randall, M.D.
T. Gannon, J.D.

Clinical Building 159
541 Clinical Drive
Indianapolis, Indiana
46202-5111

317-274-4797
Fax: 317-274-2332

IU School of Medicine
IU Medical Center &
Associated Facilities

B/27

18 2004

Report of Missing ^{125}I Seeds

A patient was implanted on September 15, 2004 in University Hospital OR #2 with 20 seeds of ^{125}I with an activity 0.33 mCi/seed. The site of the implant was the base of tongue. During the procedure, a total of 3 seeds had been dislodged from the intended site and were removed from the patient's mouth and re-implanted. Surveys were continually being performed to assure that seeds were not being suctioned out and any instruments which had been in the patient's mouth were immediately surveyed. The implant procedure started at approximately 10:00 am and was completed by 10:45 am.

At the completion of the implant and before personnel involved in the implant procedure left the room, a general area survey was performed by the medical physicist trainee under the supervision of a staff medical physicist, Colleen DesRosiers with a Ludlum Model 3 Geiger survey instrument, set at the lowest setting. The areas surveyed again focused on the suctioning device, the seed preparation table and the table containing instruments used in the procedure. No areas above background were detected, indicating that all seeds had been implanted into the patient. This survey was performed in compliance with 10 CFR 35.404(a).

A survey of the patient was also performed with a Victoreen 450B ion chamber survey instrument. The measured radiation level at 1 meter from the patient was 0.06 mR/h. Based upon this survey meter reading, the patient was eligible to be released from the hospital in accordance with NRC regulations (10 CFR 35.75). However, since the patient was scheduled for simulation films in the radiation oncology department at 2:00 pm, nursing instructions were placed in the patient chart and the patient was transported to the recovery room, later to be transported to his private hospital room until the simulation films were performed.

At approximately 12:00 noon, Christy, the patient's nurse on the floor, contacted the radiation oncology department asking for specific radiation safety instructions for the patient, saying there were none in the chart. Colleen DesRosiers obtained instructions, provided by Alisha Mahin from Radiation Safety, for patients with permanent implants being hospitalized for reasons other than the implant and provided them to the 3 North nursing staff. The instructions that had been placed in the chart while the patient was in the OR were still in the chart and a copy of the same instructions was posted on the patient room door. At this time, Colleen DesRosiers had some discussion with the patient's wife, and provided her with home instructions.

The patient was transported to the radiation oncology department for simulation films at 2:30 pm. Orthogonal radiographs confirmed proper placement of 14 of the 20 seeds that were originally implanted. Additional radiographs indicated the presence of 2 additional seeds, one in the patient's throat and another in his abdomen, implicating a migration of the seeds from the implant site. The remaining 4 seeds could not be accounted for at that time.

At this point another medical physicist, Phil Dittmer returned to the operating room and performed another GM survey; however, the operating room had been thoroughly cleaned since the procedure had been performed. Dr. Dittmer performed additional surveys in the corridor leading to the area of the recovery room where the patient was located immediately following the surgery. Dr. Dittmer then proceeded to the patient's room (3 South – Rm 3725) and performed

additional GM surveys there (the patient was still in the Radiation Oncology Department). The survey results for all of the aforementioned locations indicated nothing above background levels. At this point, Dr. Dittmer notified the Radiation Safety Office (RSO) of the missing seeds.

RSO health physicist, Mike Smith and Dr. Dittmer initiated another survey for the seeds, utilizing a Ludlum Model 3 Survey Meter equipped with a thin crystal, NaI detector. The following areas were surveyed and/or resurveyed with the NaI detector: the simulator room and adjacent hallway in radiation oncology, the isolation room in surgery recovery, the patient room, dirty linens, and trash in the 3 South wing. No seeds were located during the surveys.

In addition to the surveys, Mr. Smith and Dr. Dittmer discussed the patient's condition while in the recovery room with the nurse that attended him there. She indicated that the patient was not coughing or doing anything else that might cause the seeds to be expelled or dispersed. The recovery room nurse verified that the bed linens being utilized by the patient in the recovery room went with him to his room on 3 South. As indicated above, a careful survey of the dirty linen area on 3 South indicated that no seeds were present.

In the opinion of the medical physicist assisting in the implant procedure (Colleen DesRosiers), there are two possibilities which would explain what most likely happened to these seeds:

1) Either during or after the procedure, the sources were dislodged and swallowed by the patient, digested fully by the time the patient was brought to the radiation oncology department, ending up in the sewage system, or
2) After the procedure, a source was dislodged and expelled (coughing, sneezing, etc.) from the patient either in the OR, recovery room or patient's room.

Although either scenario is possible, the consensus of the individuals involved in the implant and follow-up procedures was that the missing seeds had been digested by the patient for the following reasons:

1) The initial simulation radiographs confirmed that this happened with two of the seeds.
2) The patient was lying flat on his back during the procedure and the seeds were implanted in a downward fashion into the patient's mouth. Thus, if a seed had become loose during the procedure, it would have been likely to go down his throat, rather than outside of his body.
3) Careful GM surveys performed throughout the procedure of each hollow needle utilized for seed insertion and other related equipment verified that the seeds were being properly inserted and not inadvertently lost or misplaced.
4) Radiographs performed later in the day and also the day following the implant procedure (a seed was visualized in the patient rectum the following day) indicated that seeds were migrating from the treatment site.
5) There is no indication that the patient had been coughing or sneezing, per the recovery room nurses, following the implant.
6) If all four seeds had otherwise been expelled from the patient, it is highly unlikely that not a single seed would have been found during any of the initial or follow-up surveys.

The Radiation Safety Officer, Mack Richard reviewed the pertinent section of the regulations (10 CFR 20.2201) that apply to loss of material. 10 CFR 20.2201(a)(i) requires immediate reporting

of lost material if the activity of same exceeds 1000 times the 10 CFR 20, Appendix C quantity under such circumstances that an exposure could result to persons in unrestricted areas. For ^{125}I, the immediately reportable quantity would be 1000 times 1 microcurie or 1000 microcuries. Since each of the seeds contained 0.33 millicuries and 4 seeds were originally unaccounted for, the 4 lost seeds met the quantity condition for immediate reporting. However, due to the conclusion that the seeds were swallowed and excreted into the sanitary sewer, no exposures to persons in unrestricted areas occurred.

10 CFR 20.2201(a)(ii) requires a written report within 30 days if 10 times the 10 CFR 20, Appendix C quantity (for ^{125}I, this quantity corresponds to 10 times 1 microcurie or 10 microcuries) is still missing at that time. Although it appears that the seeds were swallowed and excreted, since the seeds were not recovered, they were considered lost and subject to the reporting requirements of this section of the regulations.

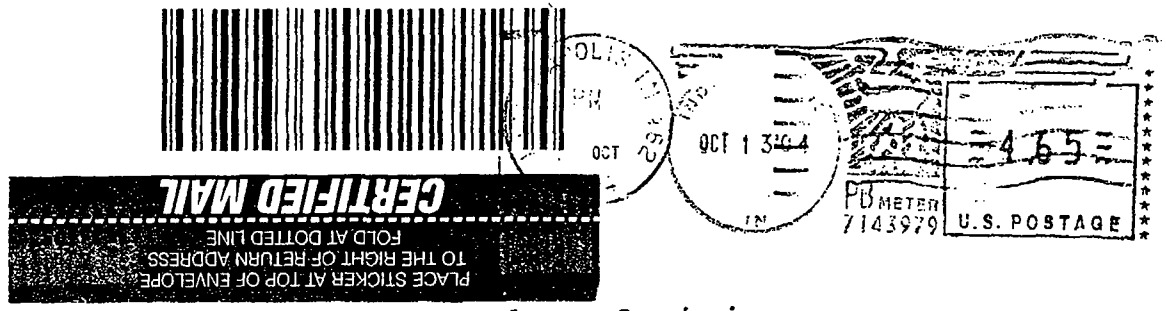
The Radiation Safety Officer also reviewed the pertinent section of the NRC regulations with respect to reporting medical events. 10 CFR 35.3045(a)(3) addresses the requirement to report as a "medical event" variations in doses to other organs and tissues; however, it specifically excludes permanent implants (seeds) that were implanted in the correct site but migrated outside the treatment site. Since all indications are that the seeds were initially implanted as intended, but later migrated (in this case, were swallowed) outside the treatment site, this incident does not qualify as a medical event.

Both the implant and survey procedures are jointly being reviewed by the Department of Radiation Oncology and the Radiation Safety Office to determine if any changes in either procedure is warranted. The circumstances surrounding this incident will be discussed at the December 14, 2004 meeting of the Radionuclide Radiation Safety Committee.

INDIANA UNIVERSITY
PURDUE UNIVERSITY
INDIANAPOLIS

Clinical Building 159
541 Clinical Drive
Indianapolis, Indiana
46202-5111

RADIATION
SAFETY OFFICE



U.S. Nuclear Regulatory Commission
Region III Office
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4351