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December 11, 1986

 MEMORANDUM FOR:
 C. J. Heltemes, Jr., Director, Office of Analysis and Evaluation of Operational Data

 FROM:
 James G. Keppler, Regional Administrator, Region III

 SUBJECT:
 PROPOSED ABNORMAL OCCURRENCE REPORT - UNIVERSITY OF CINCINNATI

As requested by Paul Bobe of your staff, we have prepared the enclosed draft Abnormal Occurrence Report on a misadministration which occurred in 1984 at the University of Cincinnati. If you have any questions, please feel free to contact Mr. Jan Strasma at FTS 388-5674.

Original signed by

James G. Keppler Regional Administrator

Enclosure: As stated

cc w/enclosure: J. G. Davis, NMSS H. R. Denton, NRR J. J. Fouchard, PA G. W. Kerr, SP R. B. Minogue, RES J. M. Taylor, IE G. H. Cunningham, ELD Regional Administrators

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PROPOSED ABNORMAL OCCURRENCE REPORT -- UNIVERSITY OF CINCINNATI

Date and place -- On September 4, 1984, NRC Region III (Chicago) was notified by the University of Cincinnati that an iodine-125 radiation source, which had been implanted in a patient, had leaked, causing an unintended radiation exposure to the patient's thyroid. The leaking radioactive source was one of eight implanted in a patient August 27, 1984, for treatment of a brain tumor. The eight sources were removed on September 1, 1984.

At the time of the incident, it was not classified as a misadministration. However, a reevaluation by the NRC staff in 1986 determined that it was a misadministration because the treatment was intended to irradiate the brain tumor, but because of the leaking source, also irradiated the thyroid. (In the body, iodine is deposited in the thyroid, and therefore, the radiation from the leaking iodine would be concentrated there.)

On August 27 a total of eight seeds were placed in thin plastic catheter . tubes and were temporarily implanted in a termally ill patient. The next day, iodine-125 contamination was detected in the brachytherapy source storage room. Bioassay results showed that the technicians who had worked with the iodine-125 seeds had measurable uptakes of iodine. When the seeds were removed from the patient on September 1, a radiation survey of the patient's neck revealed a radiation level of 1.5 millirem per hour at two inches from the thyroid, which confirmed the seeds were leaking inside the patient. The patient was then discharged from the hospital with instruction to return for further bioassay analyses.

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Subsequent bioassay testing of the patient's thyroid determined that there had been a deposition of 557 microcuries of iodine-125 in the thyroid. This level of deposition would result in a radiation dose to the thyroid of 2,087 rad. (A rad is a standard measure of radiation exposure.) Such an exposure would be expected to result in some diminished thyroid function. Drugs are available to compensate for the reduced thyroid function.

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Urine bioassay testing of the two technicians involved in preparing the iodine-125 seeds showed a thyroid deposition of 29 nanocuries for one and 57.6 nanocuries for the other. The results of thyroid function testing of both individuals were normal.

Contamination surveys of the storage room used for the handling of the iodine-125 seeds showed evidence of surface contamination. The room was decontaminated and then painted to fix any remaining contamination in place. Subsequent air samples in the room and in adjoining areas showed no detectable radioactivity. Some equipment -- a sink, shelving, and storage safe -- were found to have some residual contamination, and they were covered in plastic to allow for radioactive decay prior to use.

The licensee's investigation of the contamination incident determined that one of the iodine-125 seeds as cut, apparently when it was being removed from a catheter tube from a previous patient implanted on August 13-17, 1984. Two technicians were involved in removing the seeds, and reported that after the tubes were removed from the previous patient, they were discolored and the seeds were difficult to see. One technician stated that he believed the damage most likely occurred when the ends of the catheter tubes were cut off with scissors.

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Cause or causes -- The cause of the misadministration was found to be an inadequate procedure used in removing the iodine-125 seeds from the catheter tubes for reuse. Further, there were inadequate radiation surveys performed in the work area where the source preparation was performed. Had adequate surveys occurred, the leaking seed might have been discovered prior to its being implanted in the patient.

Steps taken to prevent recurrence ---

Licensee -- The licensee's Radioisotope Committee recommended that the use of the high-intensity iodine-125 seeds be discontinued for this type of radiation therapy, pending a thorough review of the health physics aspects of their use. The hospital also constructed a new radiation source storage room with a greater distance between the storage area and the source preparation area. A fume hood was also installed in the room.

NRC -- Region III (Chicago) conducted a special inspection at the hospital on October 10-12, 1984, to evaluate the circumstances of the source leakage and patient use. A Notice of Violation was issued for two violations -- opening a sealed source and failure to make an adequate survey for the source storage area following the preparation of the iodine-125 seeds for patient use.

Followup inspections have been conducted to determine the adequacy of the licensee's corrective actions.

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MEMORANDUM FOR:

C. J. Heltemes, Jr., Director, Office for Analysis and Evaluation of Operational Data

FROM:

J. B. Martin, Regional Administrator

SUBJECT:

ABNORMAL OCCURRENCE REPORT TO CONGRESS FOR THIRD QUARTER CY 1986

Your memorandum of January 14, 1987 forwarded a draft Commission Paper, subject as above, for our review, comment and concurrence.

This is to confirm our concurrence in the issuance of the subject Commission Paper as proposed.

Comments of an editorial nature were provided to your office (J. Crews to P. Bobe) by telephone on January 21, 1987.

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