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MAY 28 1993

MEMORANDUM FOR: John E. Glenn, Chief, Medical, Academic, and Commercial Use Safety Branch, NMSS

FROM: Roy J. Caniano, Chief, Nuclear Materials Safety Branch, Region III

SUBJECT: TECHNICAL ASSISTANCE REQUEST CONCERNING A QUALITY MANAGEMENT PROGRAM AND A BRACHYTHERAPY INCIDENT AT ST. JOSEPH HOSPITAL

I. Quality Management Program

The enclosed copy of St. Joseph Hospital's Quality Management Program (QMP) is for your review. It is Region III's opinion that the QMP is deficient, especially regarding brachytherapy since it contains few, if any, details about how the requirements presented are to be met.

We request a prompt review of the QMP so that, if necessary, the licensee can begin revising the QMP as soon as possible. We wish to point out that St. Joseph Hospital does not have an afterloader or a teletherapy unit, as implied in the QMP. It does, however, have a fairly active brachytherapy program and a less active I-131 therapy (thyroid cancer) program.

II. Brachytherapy Incident

The following description of a brachytherapy incident is for your review. On April 20, 1993, the patient, a female in her early eighties who had been diagnosed with vaginal cancer, was admitted to St. Joseph Hospital for a temporary implant (brachytherapy) treatment. The written directive called for a spacer and three 23.3 mCi Cs-137 sources to be placed in a hollow tandem in a vaginal cylinder which would then be inserted into the patient's vagina. The spacer was to be used to shield the bladder. The dose prescription was 2000-2500 cGy to be delivered over 48 hours. This treatment plan was done by the dosimetrist and checked by the medical physicist. At the time of the implant (2:30 p.m.), the radiation oncologist noted that approximately 0.5 cm of the third source could be seen extending past the opening of the vagina. The oncologist felt uneasy about this, but decided to consult with the medical physicist before taking any action. Approximately 2.5 hours later, at 4:10 p.m., the oncologist removed the tandem and took out the spacer. The treatment plan was revised by the medical physicist, and a

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new directive was written by the oncologist. At 5:30 p.m., the sources (without the spacer) were reloaded and the treatment was resumed. At 9:30 p.m., the patient and the implant were checked by a nurse and everything appeared to be fine. At midnight, the patient was checked by another nurse. At this time, the patient, who was awake when the nurse entered the room, moved her hand from under a sheet and gave the nurse the tandem containing the three Cs-137 sources. The nurse didn't recognize the tandem as anything containing radioactive material, so she simply placed it on the window sill. During the remainder of the morning, the same nurse entered the room for short amounts of time, always standing behind the lead shield. At 8:30 a.m. the next day, the oncologist entered the patient's room and immediately saw the tandem on the window sill. The oncologist then used forceps to place the tandem into the nearby lead container and then called the RSO. According to the nurse who was handed the sources, no one else entered the patient's room between midnight and 8:30 a.m.

The inspectors were not able to determine definitely from the interviews how the tandem was removed from the patient. However, the nurses who cared for the patient indicated that they did not remove the tandem. Thus, it seems likely that the patient either directly removed the device, or it became loose due to the patient's excessive movement.

This incident was reenacted for the inspectors by the persons involved (without the patient). It is estimated that the nurse held the tandem in her hand for approximately four seconds. The estimated distance of closest approach from the nurse's hand to the sources is 5 cm. The estimated distance of closest approach from the patient's bed to the window sill is 1.8 meters.

The licensee estimates that the dose to the attending nurse was 0.7 millirem (mrem) to the whole body and 13 mrem to the fingers. Furthermore. the licensee estimates that the patient received 333 cGy of the 2000 cGy intended dose.

A medical consultant has been contacted to provide an opinion on the biological effects expected for the patient and nurse, and to provide an opinion on the total dose received to the target area and the dose from the dislodged source to the nontarget area during the initial 8 hours of treatment.

As of April 30, 1993, the oncologist has found no evidence of erythema on the nurse who was handed the tandem, or the brachytherapy patient.

Based on the information gathered at the on-site inspection and a review of the license's Quality Management Program, it appears that the licensee failed to instruct nurses in the size and appearance of the brachytherapy sources used by the licensee as required by 10 CFR 35.410. However, it does appear that the QMP was followed throughout the treatment.

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The licensee's corrective actions include holding a mandatory training session for all brachytherapy nurses where instructions on the size and appearance of the brachytherapy sources used by the licensee, among other topics, were given. Furthermore, the licensee is developing a procedure whereby the nursing manager and medical physicist review the training received by the oncology nurses <u>before</u> the nurses are assigned to brachytherapy patients, to ensure that untrained nurses are not given these assignments.

We request that OGC and NMSS review this incident as it relates to the definition of a misadministration as found in 10 CFR 35.2.

Enclosed is a copy of our inspection report, the licensee's QMP, the licensee's written directives, and the licensee's written report. The licensee's inspection history may be found in the inspection report.

Please review this information and advise the Region III staff of your conclusions.

If you have any questions, please feel free to contact me at 708-790-5621 or Gary Shear at 708-790-5620.

Roy J. Caniano, Chief
Nuclear Materials Safety Branch

Enclosures:
1. Inspection Report 03002003/93001(DRSS)
2. Quality Management Program
3. Licensee's Written Directives
4. Licensee's Written Report

cc w/enclosures:
J. Lieberman, OE
S. Treby, OGC

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