Mercy
Health System

PEGGY LANZISERA
GEORGE PANEBAKER
JOHN WRAY

April 30, 2005

US Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, D.C. 20555

Subject: Reply to Notice of Violation
Docket No. 03008702

Dear Sir or Madam:

In response to your letter dated April 6, 2005 enclosed is the "Reply to Notice of Violation" for Mercy Fitzgerald Hospital. If you have any questions concerning this, please call me at (610) 237-4065 or our Radiation Safety Officer, John C. Babu at (610) 237-4296.

Sincerely,

Marsha Rowe
Chief Operating Officer

Cc: Regional Administrator
US NRC, Region 1
475 Allendale Rd.
King of Prussia, PA 19406-1415

Reply to a Notice of Violation

Mercy Fitzgerald Hospital
Darby, PA

Docket No. 03008702
License No. 37-00993-05

VIOLATION A:

10 CFR 20.1501(a) requires, in part, that a licensee make or cause to be made, surveys that - (1) may be necessary for the licensee to comply with the regulations in this part; and (2) are reasonable under the circumstances to evaluate - (I) the magnitude and extent of radiation levels; (ii) concentrations or quantities of radioactive material; and (iii) the potential radiological hazards.

Contrary to the above, on January 23 and 26, 2004, the licensee did not make surveys make or cause to be made, surveys that - (1) may be necessary for the licensee to comply with the regulations in this part; and (2) are reasonable under the circumstances to evaluate - (I) the magnitude and extent of radiation levels; (ii) concentration or quantities of radioactive material; and (iii) the potential radiological hazards. Specifically, after the completion of a brachytherapy implant conducted on January 23, 2004, surveys conducted of equipment, facilities, and patients were inadequate in that the licensee failed to adequately assess the extent of the contamination, including possible public exposure and patient thyroid and whole body dose from suspected contaminated or leading seeds.

Discussion:

Mercy Fitzgerald Hospital has a policy to survey all incoming and outgoing packages containing brachytherapy sources for radiation levels. Packages are surveyed at 3 feet and surface. On January 23, 2005, after implantation, the authorized medical physicist performed a survey with a Na I probe for dislodged seeds at all areas where the I-125 seeds were used, including OR room, patient couch, mick applicator, floor, etc. There were no loose seeds, but the sterilized water used during implant showed a high reading. The authorized medical physicist called the pharmacy and reported this issue, but forgot to alert the radiation safety officer. On January 27, 2004, the authorized medical physicist shipped the unused sources and sample of the sterilized water in a special package supplied by the manufacturer.

On January 28, 2004, the authorized medical physicist reported this incident to the RSO. The RSO immediately contacted NRC, and instructed the Authorized Physician to contact the patient for a bioassay. The authorized physician, resident and authorized medical physicist were called back to the Nuclear Medicine Department by the RSO and conducted the bioassay tests.

1. Reason for violation:

On January 23, 2004, the authorized medical physicist could not confirm that contaminated seeds were implanted to the patient's prostate, and failed to report the issue immediately to the radiation safety officer.

2. Corrective Action:

Authorized medical physicist has been instructed to report any unusual reading above the background to the RSO for further evaluations.

3. Corrective action to avoid further violation:

Any unusual occurrences in brachytherapy will be reported to the RSO immediately, whether it is significant or not, to assure safety of public and compliance to the NRC and DOT regulations. We have instructed our new authorized medical physicist to report all unusual incidents related to brachytherapy to the RSO by telephone or through paging system. The previous authorized medical physicist has left Mercy Fitzgerald Hospital as of September, 2004.

4. Compliance date:

The compliance date was February 5, 2004.

VIOLATION B.

10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers license material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.475 requires, in part, that before each shipment of any Class 7 (radioactive) material package, the offeror must insure by examination or appropriate tests, that the external radiation and contamination levels are within the allowable limits in 49 CFR Parts 171-178. 49 CFR 173.443(a) requires, in part, with exceptions not applicable here, that for beta and gamma emitting contaminants, the level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for transport, at the beginning of transport, not exceed 4 Becquerel per square centimeter on any single wiping material, divided by the surface area wiped and divided by the efficiency of wipe procedure. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the non-fixed contamination levels.

Contrary to the above, on January 27, 2004, the licensee delivered to a carrier for transport a package which contained iodine-125 brachytherapy sources suspected to be leaking and/or contaminated, and the licensee did not determine the non-fixed contamination level prior to offering the package for transport.

Discussion:

Same as violation A.

1. Reason for violation:

The authorized medical physicist shipped the sources speedly as requested by the manufacturer, and, failed to report the issue to RSO.

2. Corrective Action:

Authorized medical physicist has instructed to seek help from the RSO before any brachytherapy sources were shipped back to the pharmacy. The newly hired authorized medical physicist has also been instructed to contact RSO before shipments are made to an outside agency.

3. **Corrective action to avoid further violation:**

The authorized medical physicist will contact RSO and inform the exact nature and date of shipments that needed to be made. RSO will direct the AMP on the requirement of DOT regulations.

4. Compliance date:

The compliance date was February 5, 2004.

VIOLATION C.

10 CFR 35.40(a) requires, in part, that each written directive for brachytherapy must be dated and signed by an authorized user before the administration of any therapeutic dose of radiation from byproduct material.

Contrary, to the above, on February 5, 2004, the brachytherapy written directive was not signed by the authorized user before the administration of the therapeutic dose. Specifically, the written directive was not signed by the authorized user prior to completion of the brachytherapy procedure and release of the patient from the operating room.

Discussion:

Mercy Fitzgerald Hospital has a Quality Management Program that covers all diagnostic or therapeutic administration of I-131 or I-125 greater than 30 uCi, and other therapies such as Sr-89, P-32, Sm-153 etc. The Radiation Oncology QM program covers all LDR and HDR Brachytherapy. The QM policy requires that written directive must be prepared and signed by the authorized physician before treatment. The authorized physician has stated that the actual details of the implant are verified, but failed to sign the written directive before treatment.

1. Reason for violation:

Authorized Medical Physicist did not pursue the physician to sign the written directive before treatment, but was able to get his signature immediately after implantation.

2. Corrective Action:

Authorized Medical Physicist will ensure that the written directive is signed before treatment. The new AMP was instructed to assure that the written directive is complete before the implantation starts.

3. Corrective action to avoid further violation:

AMP will check the details of all brachytherapy implantation prior to treatment, including the prescribed dosage, site, total activity, activity per seed and physician's signature.

4. Compliance date:

The compliance date was February 5, 2004.