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April 6, 1994

U.S. Nuclear Regulatory Commission
Region III
John A. Grobe, Chief
Nuclear Materials Inspection
Section 2
801 Warrenville Road
Lisle, Illinois 60532-4351

Dear Mr. Grobe:

This letter is in response to your inquiry regarding information given to the patient following the misadministration at Marquette General Hospital.

As documented in the medical record, the patient was contacted by phone on 11/20/93, at about 10:45 a.m. on the morning after the discovery of the misadministration, to check on her clinically and to inform her of the occurrence. She was informed that the sources were not positioned deep enough in the pelvis to achieve the desired dose to the cancer and that the difference would be made up with the 2nd planned implant. She appeared to have a good understanding and gave me a progress report, stating that she was feeling fairly well aside from 2 loose BM's, a yellowish vaginal discharge, and mild irritation around the introitus, not unanticipated. The referring physician Dr. Addison, was contacted on the same morning about 10:30 a.m. informed of the misadministration and my intention to contact the patient by telephone.

On 11/24/93, I discussed the case with Dr. Stitt of the University of Wisconsin, primarily to inform her of my plan to compensate for the difference in the planned dose with the second implant. She agreed with this approach. She also noted that as long as the patient had already been notified, of the misadministration, she would not need a copy of the letter to the NRC. We agreed that a letter would be unduly distressing for the patient and this topic had been "addressed at the last NRC meeting" which she attended.

On 12/2/93, I discussed with Dr. Addison, referring physician, the possibility of written notification of the misadministration for the patient. He and I agreed that a letter to the patient would not be in her best interest, causing anxiety out of proportion to the actual risk to her from the misadministration. 10CFR 35.33(a) states that "The licensee shall also notify ... the patient ... unless the referring physician ... believes, based on medical judgement, that telling the patient ... would be harmful ...".

The referring physician and I felt an ethical responsibility to notify the patient of what had happened. We also believed, based on medical judgement, that a copy of the written report would be "harmful" to the patient, causing emotional distress out of proportion to the actual risk to her from the misadministration.

Sincerely,

Cheryl Davison MD

Cheryl Davison, M.D.
Medical Director
Radiation Oncology

Richard F. Moreland

Richard F. Moreland, Ph.D.
Radiation Safety Officer

cc: Robert Neldberg
Linda Olsen
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CD/RFM:mmo