

AC01/008

APR 09 1993

Docket No. 030-02049
License No. 21-04177-01
CAL No. RIII-93-006

Mercy Memorial Medical Center
ATTN: Robert P. Harrison
Chief Operating Officer
1234 Napier Avenue
St. Joseph, MI 49085

Dear Mr. Harrison:

SUBJECT: CONFIRMATORY ACTION LETTER

This refers to the telephone conversation of April 8, 1993, between you and Mr. Roy Caniano of my staff regarding the inspection conducted of your facility from March 26 through April 8, 1993. This routine safety inspection identified a brachytherapy source event, which occurred on February 16, 1993, that resulted in radiation exposure to a site that was different from the intended treatment site.

During the telephone conversation, Mr. Caniano explained that we have evaluated the information obtained during the inspection and concluded that the February 16, 1993 event constituted a misadministration as defined in 10 CFR 35.2. This conclusion was based on the fact that the dislodged brachytherapy source delivered a radiation dose to the wrong treatment site.

Based on that conversation, it is our understanding that you will:

1. Calculate the total radiation dose to the patient's skin and tissues in the immediate area (e.g., within 5 centimeters) of the dislodged brachytherapy source. The calculation should indicate the radiation dose to the unintended area during the first 15 1/2 hours when the source was dislodged. A copy of the report documenting the calculations will be provided to Region III within the next 7 days.
2. Notify the patient, the patient's referring physician, and the Nuclear Regulatory Commission of the misadministration as required by 10 CFR 35.33.

Pursuant to Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, and 10 CFR 2.204, you are required to:

1. Notify me immediately if your understanding differs from that set forth above;
2. Notify me if for any reason you cannot complete the actions within the specified schedule and advise me in writing of your modified schedule in advance of the change; and

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3. Notify me in writing when you have completed the actions addressed in the Confirmatory Action Letter.

Issuance of this Confirmatory Action Letter does not preclude issuance of an order formalizing the above commitments or requiring other actions on the part of Mercy Memorial Medical Center, nor does it preclude NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter. In addition, failure to take the actions addressed in this Confirmatory Action Letter may result in enforcement action.

The responses directed by this letter are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter will be placed in the NRC Public Document Room.

Sincerely,

Original Signed by C.E. Norelius

Charles E. Norelius, Director
Division of Radiation Safety
and Safeguards

bcc: H. Thompson, DEDS
J. Lieberman, OE
J. Goldberg, OGC
R. Bernero, NMSS
A. Davis, RIII
R. DeFayette, RIII

PUBLIC

RIII *(YES)*
CLS for
Young/dg
04/9/93

RIII *(YES)*
CLS for
Shear
4/9/93

RIII *(YES)*
CLS for
Caniano
4/9/93

RIII *(YES)*
CLS for
Berson
4/9/93

(YES) NAL FILE
RIII *(YES)*
CLS for
DeFayette
4/9/93

(YES)
RIII *(YES)*
CLS for
Norelius
4/9/93