

September 21, 1994

West Virginia University
Hospitals, Inc.
ATTN: Mr. Bernard G. Westfall
President
Medical Center Box 6401
Arlington, WV 22506-8030

Dear Mr. Westfall:

This refers to a letter from Mr. Eric Raudenbush of your staff dated June 8, 1993, which was in response to our letter dated June, 1993. Our letter requested that you review a May 28, 1991 misadministration to determine whether required notifications had been made pursuant to 10 CFR 35.33. This issue was also discussed in a telephone conversation between Dr. Mathis Frick of your staff and me on September 21, 1994.

Mr. Raudenbush's letter stated, in part, that the patient had not been notified because such notification might reduce the palliative effects of the treatment. It is not clear from Mr. Raudenbush's letter who made the decision not to notify the patient, or if the patient's responsible relative or guardian was notified. NRC has reviewed the issue of patient notifications required by 10 CFR 35.33. The NRC's evaluation of these matters is as follows:

1. If the referring physician personally informs a licensee that based on medical judgement, notifying the patient would be harmful, the licensee is required to inform the patient's responsible relative or guardian, even if the patient is a competent adult.
2. Regardless of whether the licensee or the referring physician notified the patient, the licensee is still responsible for providing the written report to the patient or the patient's responsible relative or guardian.
3. The licensee is not required to notify the patient or the responsible relative or guardian if the referring physician has personally informed the licensee that, based on medical judgement, telling the patient or the responsible relative or guardian would be harmful to one or the other or both.

NRC staff have concluded, based on the information provided, that you are required to provide written notification of the misadministration to the patient's responsible relative or guardian. Therefore, you must provide a response to the NRC, within 30 days of the date of this letter that includes a copy of the written report provided to the patient's responsible relative (or guardian) and the date on which the written report was provided or documentation of the referring physician's decision that the responsible relative or guardian should not be told.

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Failure to either respond to this letter or make the required notifications within 30 days of the date of this letter may result in escalated enforcement action being taken against you including assessment of a civil penalty. If you are unable to respond to this letter for any reason, contact me at (404) 331-5586 as soon as possible prior to expiration of the 30 day period.

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

The response directed by this letter and the accompanying Notice 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.

Sincerely,

Original Signed By
D. M. Collins

Douglas M. Collins, Chief
Nuclear Materials Safety and
Safeguards Branch
Division of Radiation Safety
and Safeguards

Docket No.: 030-20233
License No.: 47-23006-02

cc: Mathis Frick, M.D.
West Virginia University Hospital, Inc.

State of West Virginia

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