



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

JUL 13 1994

Docket: 030-00503
License: 42-00220-08

Department of Veterans Affairs
Veterans Administration Medical Center (VAMC)
ATTN: Alan G. Harper
Medical Center Director
4500 South Lancaster Road
Dallas, Texas 75216

SUBJECT: PHYSICIAN/PATIENT NOTIFICATION OF MISADMINISTRATION

This refers to your letter of January 26, 1994, regarding a misadministration that occurred at your facility in February 1992. The misadministration was identified by NRC during an inspection conducted in July and August 1993, and was discussed with you, among other items, during an enforcement conference held on September 22, 1993. During that conference, VAMC explained that no action had been taken subsequent to the inspection to notify either the referring physician or the patient's relatives. (The patient was deceased at the time of the inspection.) In response to NRC's request during the enforcement conference, VAMC subsequently evaluated NRC's requirements for physician and patient notification, took actions as it believed appropriate, and submitted the above noted letter documenting the actions taken by VAMC in regard to this issue.

Regional and headquarters NRC staff and NRC's Office of General Counsel have reviewed your letter of January 26 and have determined that based upon information provided in your letter and through discussions with NRC personnel, VAMC has met the intent of the provisions of 10 CFR 35.33 regarding notification of the "referring physician." However, based upon our review of the information provided to date, we have determined that further information is necessary in order for NRC to evaluate VAMC's compliance with the requirement to notify the patient's responsible relative or guardian of the misadministration. The specific information to be considered by VAMC and the NRC regarding this issue is described below.

VAMC noted in its correspondence that because the referring physician and authorized user in this case were no longer employed by VAMC and could not be located, VAMC convened a panel of physicians to act in lieu of the referring physician in determining whether the patient's family should be notified of the misadministration. The panel concluded that, due to the family's distress over the death of the patient, notifying the patient's relatives would be psychologically detrimental, and therefore, based on medical judgment, would be harmful. However, it is unclear as to whether the panel reached this conclusion on a generic basis for any family distressed over the death of a family member, or if the decision was based on potential harm to specific members of the family of the patient in this case.

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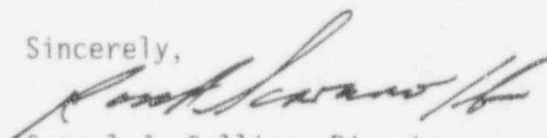
The purpose of the requirement for notifying the patient or his/her relative is to ensure full disclosure to either the affected individual or a relative or guardian with the patient's interest in mind who can make decisions regarding any action that needs to be taken. In the event that notification cannot be provided to the patient, as in this case, the decision to withhold notification from the patient's relatives or guardian must be based upon the referring physician's knowledge (from whatever source) and medical judgement that telling the patient's responsible relative would be harmful to that individual. In such cases, a decision to withhold notification must be based on information relative to the specific individuals involved.

Therefore, VAMC is requested to respond to this letter and provide further information regarding the basis for its decision not to notify the patient's relatives. Specifically, your response should describe whether the physicians' decision that telling the patient's relatives in this case was based on generic information or whether specific knowledge that telling the patient's relatives would be harmful served as the basis for their decision. In your response, you should describe the specific information used by the physicians to make their decision regarding notification of the patient's relatives. If VAMC determines that the physicians' decision was not based upon a specific medical judgement of harm, then VAMC must either seek further information regarding this issue or notify the patient's relatives or guardian. If VAMC determines that a specific medical judgement cannot be made in this case and provides notification to the patient's relatives or guardian, your response to this letter should verify that notification was provided pursuant to 10 CFR 35.33. Your response to this letter should be provided to the NRC Region IV office within 30 days of the date of this letter.

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

Should you have any questions concerning this letter, please contact Ms. Linda Kasner at (817) 860-8213.

Sincerely,



Samuel J. Collins, Director
Division of Radiation Safety
and Safeguards

cc:
Texas Radiation Control Program Director

Department of Veterans Affairs
Office of the Program Director
Nuclear Medicine Service
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24 Frank Loyd Wright Drive
P.O. Box 505 Lobby M
Ann Arbor, Michigan 48106

bcc:
 DMB - Original (IE-07)
 LJCallan
 SJCcollins
 RAScarano
 WLFisher
 CLCain
 FAWenslawski
 LLKasner
 DSerig, IMAB/NMSS (8-F-8)
 NMIB
 MIS System
 RIV Files (2)

RIV:NMIB <i>JK</i>	AC:NMIB <i>W</i>	DD:DRSS <i>W</i>	D:DRSS <i>W</i>	
LLKasner <i>JK</i>	CLCain	RAScarano	SJCcollins <i>W</i>	
07/7/94	07/7/94	07/12/94	07/12/94	

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