

JUN 03 1993

Docket No. 030-02976

License No. 37-01072-01

St. Francis Medical Center  
ATTN: Sister M. Rosita Wellinger  
Chief Executive Officer  
45 Street (Off Penn Avenue)  
Pittsburgh, Pennsylvania 15201

Dear Sister Wellinger:

According to our records, a misadministration occurred at your facility on April 17, 1990. Based on a review of NRC inspection reports and followup with appropriate licensee representatives, we have determined that you may not have met all notification requirements in accordance with 10 CFR 35.33(a).

By way of background, during a recent survey of data on therapeutic misadministrations occurring at NRC licensed facilities over calendar years 1990 through 1992, it was discovered that the patient had not been notified verbally of the misadministration in 20 of 72 of the cases. In 7 of 20 cases in which the patient was not notified, the referring physician made a decision, based on medical judgement, that telling the patient would be harmful. This reason is the only exception to the patient notification requirement described in 10 CFR 35.33(a)(3). It should be noted that, for the purposes of NRC misadministration reporting requirements, the "patient" also includes the patient's responsible relative or guardian. As a result, in instances where, based on medical judgement, the patient is not notified or the patient has died prior to notification, the licensee must assure that the patient's responsible relative or guardian is notified, unless, based upon medical judgement, telling them would also be harmful to them. In another 7 of 20 cases in which the patient was not notified, licensees provided reasons that are not an exception to the notification requirement, such as that "no adverse effects were expected" or that the dose was "within acceptable clinical limits." Licensees relying on such reasons are in violation of 10 CFR 35.33(a)(3). In those instances in which the patient was notified verbally, a written report was not provided to the patient in 23 of 52 misadministrations. Failure to provide the patient with written notification, in the form of either a copy of the report to NRC or a summary of the misadministration, if the patient was informed of the misadministration, is a violation of 10 CFR 35.33(a)(4). If a summary report is provided to the patient it must include a statement indicating that a copy of the report submitted to the NRC can be obtained from the licensee. NRC considers the failure to make the required notifications of a misadministration to be a significant regulatory concern. Enclosed is Information Notice 93-36, "Notifications, Reports, and Records of Misadministrations," issued May 7, 1993, to alert medical licensees of these failures to comply with the regulations and remind them of the notification and reporting requirements.

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In addition, IN 93-36 also emphasizes that the misadministration notification and reporting requirements do not cease to apply upon the death of the patient.

If you **have made** the required notifications and provided the patient a written report, please provide a response to the NRC as described below within 30 days of the date of this letter that includes the following:

- 1) when the referring physician was notified;
- 2) when the patient, or patient's responsible relative or guardian, was notified and by whom;
- 3) a copy of the written report provided to the patient; and
- 4) the date on which the written report was provided to the patient.

If you **have not** made the required notifications, to include providing the patient with a written report, you must promptly notify the referring physician and patient, unless the referring physician makes a decision based on medical judgement that telling the patient would be harmful. In addition, you must provide a response to the NRC, within 30 days of the date of this letter than includes:

- 1) when the referring physician and patient, or patient's responsible relative or guardian, was notified;
- 2) if the patient was not notified, an explanation of why not;
- 3) a copy of any documentation of the referring physician's decision not to inform the patient, if it exists;
- 4) a copy of the written report provided to the patient; and
- 5) the date on which the written report was provided to the patient.

Label your response, "RESPONSE TO PATIENT NOTIFICATION INQUIRY," and send your response to the appropriate NRC Regional Office, attention Regional Administrator, with a copy to NRC Headquarters at the address below:

U.S. Nuclear Regulatory Commission  
Medical, Academic, and Commercial  
Use Safety Branch  
MS OWFN 6 H 3  
Washington, D.C. 20555

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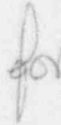
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Failure to either respond to this letter or make the required notifications within 30 days of the date of this letter may result in escalated enforcement action being taken against you including assessment of a civil penalty. If you are unable to respond to this letter for any reason, contact the appropriate NRC Regional Office as soon as possible prior to expiration of the 30 day period.

The information collections directed by this letter were approved by the Office of Management and Budget (OMB) as required by the Paperwork Reduction Act of 1980, (44 U.S.C., 3501 et seq.), OMB approval number 3150-0017, which expires March 31, 1996.

Sincerely,

Original Signed By:  
Richard W. Cooper



Thomas T. Martin  
Regional Administrator

Enclosure: Information Notice 93-36

bcc:  
Region I Docket Room