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Lic # 34-01055-01

ERIE CHAPMAN, JD
Chief Executive Officer
Vice Chairman of the Board

3535 Olentangy River Rd.
Columbus, Ohio 43214

Telephone
(614) 566-5000

February 4, 1994

W. L. Axelson, Director
Division of Radiation Safety and Safeguards
Nuclear Regulatory Commission Region III
801 Warrenville Road
Lisle, IL 60532-4351

RE: Reply to a Notice of Violation

Dear Mr. Axelson:

This letter is in response to your letter dated January 7, 1994 and received on January 12, 1994. Your letter states that having reviewed our letter of July 29, 1993, NRC has concluded that the violations set out in the Notice of Violation Dated July 1, 1993 ("NOTICE") are valid. You requested that we respond to the Notice.

1. **10 CFR 35.33(a)(3): Notification of patient and referring physician of a misadministration within 24 hours of its discovery.**

We respectfully refer the NRC to our response set out in our letter of July 29, 1993. Please be aware that prior to submitting our July 29 response all involved individuals, including Drs. Crnkovich and Reid met to go over the event. We were careful to represent the events surrounding the decision regarding notifying the patient as accurately as possible.

Mark Crnkovich, M.D. and John Niemkiewicz, M.S. Chief Medical Physicist reviewed the patient notification requirements on the day the misadministration was discovered,

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February 25, 1993. Drs. Crnkovich and Reid discussed the misadministration on February 26, 1993. During the conversation the referring physician decided not to notify the patient at that time as it was his medical judgment that doing so might be harmful.

Attached are affidavits by Drs. Reid and Crnkovich.

2. **10 CFR 35.33 (a)(4): Providing patient with written report within 15 days of discovery of misadministration, if patient was notified and the reporting requirements of 10 CFR 35.33(a)(2).**

Again, we refer you to our letter of July 29, 1993.

Dr. Reid's subsequent actions and conversation with an NRC representative seems to contradict the conversation Drs. Crnkovich and Reid had. According to Dr. Reid he did not recollect the incident or the decision-making process he and Dr. Crnkovich talked through when he spoke to the NRC on June 10, 1993, more than 3 months later. We recognize that Dr. Reid's actions indicate a less than thorough understanding of the patient notification requirements.

To reiterate, as soon as we learned that Dr. Reid had notified the patient, we followed up with a letter to the patient. A copy of which was sent to you on June 10, 1993.

The NRC also expressed concern regarding proper managerial oversight and lack of involvement by the Radiation Safety Officer. To address these concerns we have sent an educational memorandum to all appropriate administrators, radiation oncologists, the radiation safety officer and attending physicians discussing the NRC's notification requirements in the event a misadministration should occur. Further, the Radiation Safety Officer will be involved in the notification process in the event a future misadministration should occur. (Please be aware that the Radiation Safety Officer was involved in the event under review, although it was the Chief Medical Physicist who reviewed the requirements with the radiation oncologist).

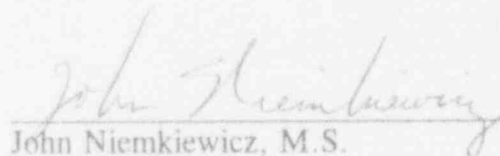
This information is being provided in response to the NRC's request of January 7, 1994 to address the Notice of Violation dated July 1, 1993.

Please let us know if you need further information or answer any questions.

Sincerely,

Marian Hamm
Senior Vice President

Ralph C. Kennaugh, M.D.
Director
Radiation Oncology



John Niemkiewicz, M.S.
Chief Medical Physicist

Enclosures: Affidavit from Dr. Mark Crnkovich
Affidavit from Dr. Gary Reid

AFFIDAVIT OF GARY REID, M.D.

STATE OF OHIO)
)SS
COUNTY OF FRANKLIN)

Gary Reid, M.D., having first been duly cautioned and sworn, does hereby state the following:

1. I was the referring physician of the patient that received the misadministration at Riverside Methodist Hospitals in February, 1992.

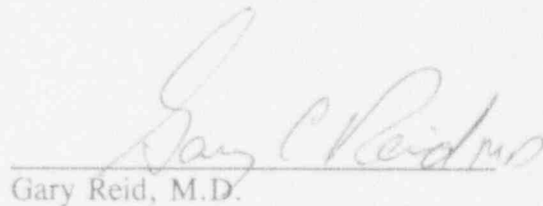
2. Dr. Mark Crnkovich called me on February 26, 1993, and we discussed the event and whether or not we should notify the patient.

3. During our conversation we concluded that due to the patient's personality and elderly age it was our medical judgement that calling her at that time would be potentially harmful and confusing to her.

4. It was my intent at the time of our phone conversation to tell her of the misadministration at her next scheduled appointment when I could explain it to her in person and assess her reaction and treat accordingly.

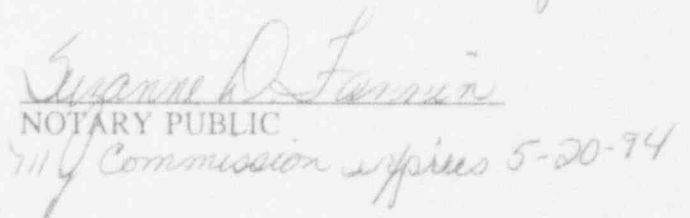
5. After reconsideration several days later, I decided to call the patient's daughter and patient to inform them of the radiation misadministration.

6. Further affiant sayeth naught.



Gary Reid, M.D.

Sworn to before me and subscribed in my presence on this the 3rd day of February, 1994.



NOTARY PUBLIC

My Commission expires 5-20-94

AFFIDAVIT OF MARK CRNKOVICH, M.D.

STATE OF OHIO)
)SS
COUNTY OF FRANKLIN)

Mark Crnkovich, M.D., having first been duly cautioned and sworn, does hereby state the following:

1. I am a Radiation Oncologist at Riverside Methodist Hospitals.

2. I was the treating physician of the patient who received the misadministration in February, 1992.

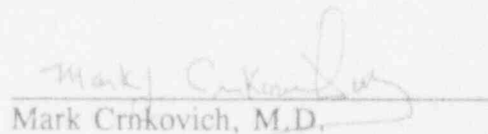
3. I was made aware of the misadministration on the day it was discovered, February 25, 1993.

4. John Niemkiewicz, M.D., Chief Medical Physicist, discussed the incident and and reviewed with me the regulations regarding patient notification requirements.

5. I called the referring physician, Dr. Gary Reid, on February 26. We discussed the event and whether or not based on our medical judgment notifying the patient immediately would be harmful.

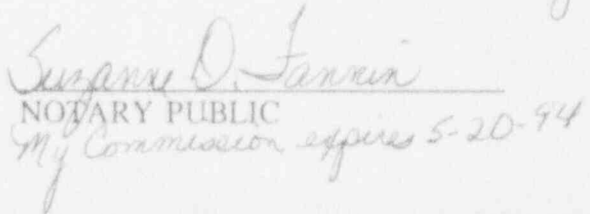
6. Dr. Reid and I both agreed that in light of the patient's fragile physical and mental status that telling the patient by phone could be harmful. Dr. Reid decided that he would not tell the patient by phone but that he would evaluate the patient's physical and mental health at her next follow-up visit, and discuss it with her personally.

7. Further affiant sayeth naught.



Mark Crnkovich, M.D.

Sworn to before me and subscribed in my presence on this the 3rd day of February, 1994.



NOTARY PUBLIC
My Commission expires 5-20-94

RIVERSIDE METHODIST HOSPITALS
Columbus, Ohio

M E M O R A N D U M

DATE : January 18, 1994

TO : Hospital Management, Radiation Oncologists, Radiation Safety Officer, and Attending Physicians

FROM : Paul Lundahl, M.S.
Medical Physicist, Radiation Oncology

SUBJECT : Patient Notification requirements of the Nuclear Regulatory Commission

The U.S. Nuclear Regulatory Commission has asked us to review patient notification procedures in the event that a radiation misadministration should occur.

The rule that has been in place since 1980 states that "patients have a <u>right</u> to know when they have been involved in a serious misadministration, unless this information would be harmful to them." This appears in Part 35 of the Code of Federal Regulations.

On January 27, 1992, the "Quality Management Program and Misadministrations" (QM) rule became effective and required the Department of Radiation Oncology to establish and maintain a Quality Management Program. This rule also modified the definition of misadministration and the requirements for notifications, reports, and records of misadministrations.

Following is a summary of the specific guidelines contained in Chapter 10, Part 35.33 of the Code of Federal Regulations:

- The NRC licensee (Radiation Oncology) is required to notify the NRC no later than the next calendar day after discovery of the misadministration.

- The licensee must submit a written report to the NRC within 15 days after discovery of the misadministration. This would include, among other things, "whether the licensee notified the patient, or the patient's relative or guardian and if not, why not; and if the patient was notified, what information was provided to the patient." The report would not include the patient's name or other information that could lead to identification of the patient.

- The licensee will "notify the referring physician and the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the patient or that, based on medical judgement, telling the patient would be harmful."

  If the referring physician decides that, based on medical judgement, informing the patient would be harmful, then the responsible relative or guardian should be notified. If the physician decides that informing this person would also be harmful, then the physician would not need to inform him/her. In this case, then, the licensee is not required to notify the patient or responsible relative (or guardian) because the referring physician has personally informed the licensee that, based on medical judgement, telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, or both.

  It should be noted, however, that this does not include other reasons for not informing the patient, such as: "no adverse effects were expected"; "the dose was within acceptable clinical limits"; "it was not in the patient's best interest"; or "the patient has died."

  The reporting requirements still apply if the patient is deceased. Therefore, if the patient has died, the family, in the person of the responsible relative (or guardian), is still entitled to receive the information contained in the misadministration report.

- If the patient was notified, the licensee must furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either a copy of the report submitted to the NRC or a brief description of both the event and the consequences as they may affect the patient. This description must state that the report submitted to the NRC can be obtained from the licensee. If the referring physician notifies the patient, the licensee is still required to inform the NRC as to what information was provided to the patient.

- The licensee will retain a record of each misadministration for five years. It includes the names of all individuals involved (including the patient's), the patient's social security or identification number, a brief description of and reason for the misadministration, the effect on the patient, and actions and improvements taken to prevent recurrence.

If you have questions about any of this information, please feel free to contact John Niemkiewicz or Paul Lundahl in Radiation Oncology.