matson

St. John's Mercy Medical Center

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A Member of the Sisters of Mercy Health System—St. Louis

February 9, 1994

Evelyn Matson
Division of Radiation Safety & Safeguards
Region III
Nuclear Regulatory Commission
801 Warrenville Rd.
Lisle, IL 60532-4351

Re: Reply to a Notice of Violation

License No. 24-00794-03
Docket No. 030-02283

Dear Ms. Matson;

This is in response to Notice of Violations dated Dec 3, 1993 and phone conversation between Shan Quint, R.S.O. and Evelyn Matson of your office on January 28, 1994. Previous communication of Dec. 21, 1993 addressed violations 1, 2, 4 and 5 sufficiently. This will further address violation number 3.

This reply will include: (a) the reason for the violation (b) corrective actions taken and results achieved, (c) corrective steps that will be taken to avoid further violations, and (d) date when full compliance will be achieved.

3. Failure of licensee to survey contiguous restricted and unrestricted areas during I-131 therapy requiring hospitalization as required in 10 CFR 35.315(a)(4).

(a): Reason for the violation:

It has always been the practice of Nuclear Medicine physicians to monitor radiation exposure levels following the administration of I-131 for therapy of hospitalized patients. Points of measurement include at one meter from the patient, at the doorway to the patient's room, in the hallway where non-radiation workers may be present and adjacent rooms if accessible. This violation (as well as all others) was discussed at the meeting of the Radiation Safety Committee on November 11, 1993. Many members including Administration and Legal Counsel agree with the Nuclear Medicine physician that it is an unreasonable intrusion on the privacy of the patient in the next room to come into their room to survey for radiation. Concern over radiation exposure can lead to unnecessary stress on these already troubled patients on the Oncology wing.

Rooms used for radiopharmaceutical therapy (subsequently to be referred to as the therapy rooms) are 334 and 336. Room 332 (see attached map) is considered the adjacent room when the therapy patient is in 334, and rooms 334 and 336 can be either the therapy room or the adjacent room depending on use. Lead shielding in the walls is shown on the map by hash marks.

Lead shielding used to provide compliance with 10 CFR Part 20 is not mobile; it is firmly mounted in the wall between patient rooms. There is no reason to suspect a shift or change in its ability to modify the radiation intensity passing through the wall.

The shielding requirements were originally calculated for Cs-137 since these rooms also are used for brachytherapy implant patients. Thicker shielding is required for Cs-137 than for I-131. In December 1992, additional shielding was placed in the walls of therapy room 334 to extend the coverage beyond the area of the bed to include the entire living space over an area approximately 6 feet by 8 feet. Prior to this time, maximum radiation exposure rates were found in the foyer of the adjacent room 332 at 1.5 mrem/hr. With the increased lead coverage, rates are generally in the 0.1 mrem/hr range just inside the door. This rate is the maximum that will be found in the room, because the entire living area is shielded with lead. Typical readings in the bed area are 0.02 to 0.06 mrem/hr.

Testing was conducted in August 1991 and again in December 1993, after additional shielding was added, which demonstrated both the improvement in reduced rates in adjacent rooms and the adequacy of shielding to maintain rates at such a level as to ensure compliance with new 10 CFR Part 20 regulations. A pure source (not including patient absorption) of 150 mCi of I-131 located on the bed of therapy room 334 has been demonstrated to yield 0.142 mrem/hr at the foot of the bed in adjacent room 332 and 0.533 mrem/hr at the bed in adjacent room 336. (There is greater distance to the bed in room 332 than room 336.)

TLD monitors were placed in various locations during recent treatments of two patients, one each in room 334 and 336 and each receiving approximately 150 mCis of I-131 to monitor actual exposure received at various points. The results of this testing are not available at this time. The film badge vendor is experiencing delays due to new reporting regulations. Results are anticipated to confirm our dose-rate evaluations in showing compliance with Part 20.

We recognize our responsibility to protect the public from excessive radiation exposure as limited by 10 CFR 20 and in the spirit of ALARA. It was through these concerns that we shielded these rooms and tested the adequacy of that shielding. The taking of daily measurements of radiation exposure in adjacent rooms can cause undue anxiety to patients who are already under the stress of having cancer while adding nothing to their safety.

(b) Corrective actions taken: An amendment request will be sent to Licensing Division to revise procedures to be followed in monitoring radiation exposure levels in unrestricted areas. (The vendor of film badges and TLD monitors is experiencing a delay in reports due to changes in reporting requirements. They anticipate December results to be available in the next two weeks. Once the supporting data has been received and analyzed, the amendment request will be sent; estimated data of submittal will be Feb. 25, 1994.) As previously noted, measurements will be taken in adjacent rooms if there is no occupant. However, in the event that the patient is in the room, we are requesting to make estimated dose rate assessments based on experimental data, the measured exposure rate at the wall inside the therapy room and the calculated shielding reduction factor. The estimated dose rates will be documented as such.

(c) Corrective steps to avoid further violations: Until such time as a decision is made on our amendment request, proper monitoring (in all contiguous areas) will be conducted by trained personnel and documented to show compliance with 10 CFR 20.1301 exposures to the public. The Radiation Safety Officer currently audits patient charts during the therapy with regard to the accurate dose administration relative to the written directive as required by the Quality Management Program. She will add to the routine a check of the appropriate exposure levels as listed in the patient chart.

(d) Date of full compliance: Compliance with the requirement has been in force since December 2, 1993. Changes described in amendment request and in (c) above will be instituted as approved.

If you have any further questions, please contact the Radiation Safety Office at 314-569-6657.

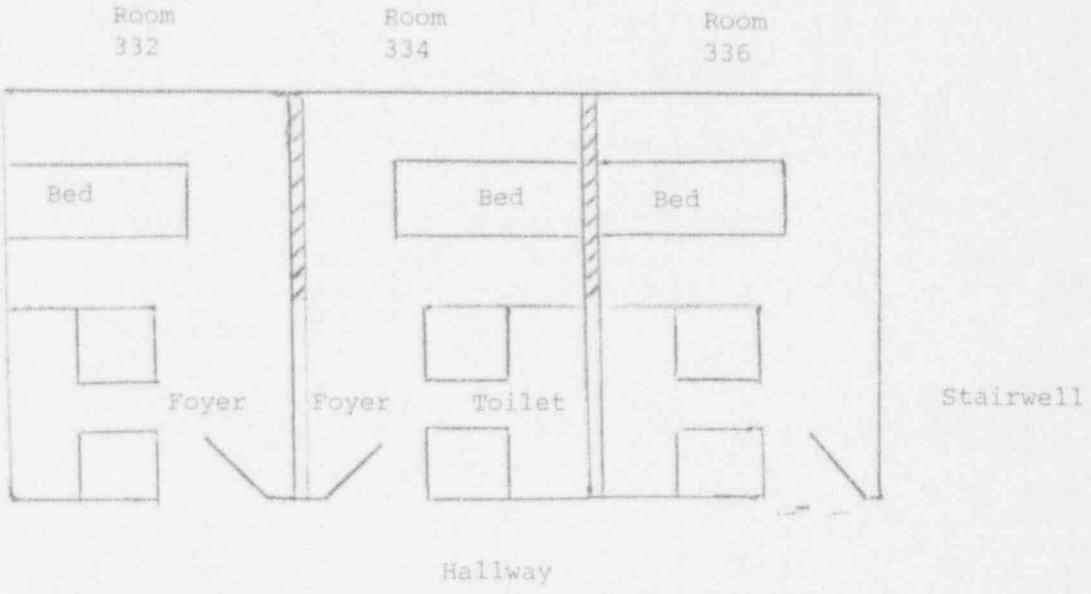
Sincerely,

Sister Mary Angelique Foto, R.S.M.

Sr. Mary Angelique Foto, R.S.M.
Vice President

SMAF/SQ/jak
enc.

Floor Plan of 3B Oncology - End Wing



Room dimensions: 11.5' x 17.5'

Bed size: 7.5' x 2.8'

Thickness of wall: 7.5"

Distance center of bed to center of bed

Room 332 - 334 $\tilde{=}$ 16'

Room 334 - 336 $\tilde{=}$ 8'