Weber



May 2, 1994

John D. Jones, Acting Chief Nuclear Materials Inspection Section 2 United States Nuclear Regulatory Commission 801 Warrenville Road Lisle, IL 60532-4351

RE: Reply to a Notice of Violation License No. 21-04177-01

Dear Mr. Jones:

This response is to comply with the provisions of 10 CFR 2.201 regarding the violations, under license number 21-04177-01 docket number 030-02049, found of the inspection conducted April 4, 1994.

Violation 1:

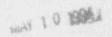
Failure to comply with 10 CFR 35.32(a), ITEM 3, stating that the licensee's (MP requires a written directive be prepared for any administration of a therapeutic radiopharmaceutical.

Two Sr-89 Metastron therapies were administered by an authorized user without a written directive. This was a complete oversight on the technologist and was not intentional.

The Nuclear Medicine Staff was advised at the time of the inspection and instructed to obtain written directives for any radiopharmaceutical therapy.

The QM Program has been revised (see attached revision effective April 27, 1994). A standard written directive, similar to those utilized for I-131 Therapies, has been developed for Sr-89 Therapy.

Full compliance was achieved April 27, 1994.



VIOLATION 2:

Failure to comply with 10CFR 35.205(e), requiring that the operation of reusable collection systems for radioactive gases be checked monthly.

The operation of the reusable collection system for radioactive xenon-133 gas was not checked during the months of September and October of 1993 and for the months of January and February 1994.

There was a turn over of staff in the months of September/October and it was believed that this task had been shown to the new staff. The staff was advised of the importance of this procedure and a demonstration was given at the time the department noticed that we were not in compliance and again at the time of the violation.

The operation check of the reusable collection system for radioactive xenon-133 has been incorporated into the new employee orientation check list.

Full compliance will be achieved by May 13, 1994.

VIOLATION 3:

Item 10.4 in regards to condition 20 of the License stating that no food shall be stored in areas where radioactive material is used or stored.

A refrigerator for staff use was located in the injection room. This violation occurred due to a pure oversight.

The refrigerator was removed to an area where no radioactive materials are stored or used the day of the NRC inspection.

Full compliance was achieved April 4, 1994.

I believe that the institution is in full compliance with all applicable parts of 10 CFR. The RSO and Radiation Safety Committee are working on all of the concerns mentioned at the time of the exit meeting.

If you need any further information or have any questions, please contact Cheryl Weise at (616) 983-8868.

Sincerely,

Robert P. Harrison

Progen

Chief Operating Officer

Alex Bogda, RSO