302 Kensington
Flint, Michigan 48503-2000
Phone 313-762-8000

St. Joseph Hospital

January 29, 1991

Roy J. Caniano, Chief
Nuclear Materials Safety
United States Nuclear
Regulatory Commission
Region III, Materials
Licensing Section
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Re: License No. 21-01103-04
Docket No. 030-02003

Dear Mr. Caniano:

This letter is in response to the Notice of Violation dated January 2, 1991 in the above referenced matter in which you requested for each violation corrective steps and results achieved, corrective steps that will be taken to avoid further violations and, the date when full compliance will be achieved.

1. 10 CFR 35.50(b) requires, in part, that the licensee test each dose calibrator for accuracy, linearity, and geometry dependence upon installation.

   Contrary to the above, on November 5, 1990, the licensee installed a dose calibrator and did not test it for accuracy and geometry dependence until November 13, 1990, or for linearity until November 19, 1990.

   Corrective Action: The staff technologists are now fully aware that the required tests must begin immediately upon installation.

   Action taken to prevent recurrence: Staff technologists have been instructed to perform required tests on dose calibrator when it returns and to ascertain that tests are complete and satisfactory prior to its use.

   Date of compliance: December 20, 1990

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2. 10 CFR 35.205(d) requires, in part, that the licensee post the calculated time and safety measures to be instituted in case of a spill of a radioactive gas at the area of use.

   Contrary to the above, on the date of inspection, the licensee had not posted the calculated time and safety measures in case of a spill of xenon-133 gas at the area of use.

   Corrective Action: At the time of the inspection the necessary measurements had been made and the time was in the process of being calculated. Emergency Procedures for Accidental Release of Xenon-133 are now posted in the area of use. A calculated evacuation time is included in this posting.

   Action taken to prevent reoccurence: The required procedures and time are now posted. The time will be recalculated when a substantial decrease in the exhaust rate is observed. If a new area of use of Xenon-133 gas is employed, the safety measures and evacuation time will be posted before Xenon-133 gas is used in the area.

   Date of Compliance: January 8, 1991

3. 10 CFR 35.315(a)(6) requires that a licensee measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, within three days after the administration.

   Contrary to the above, as of the date of inspection, the licensee did not measure the thyroid burden of the physicians or technologists who helped prepare and administer dosages of iodine-131 for patients receiving radiopharmaceutical therapy on June 22, 1990 and July 24, 1990 and hospitalized for compliance with 10 CFR 35.75, within three days of the dosages.

   Corrective Action: A compliance inspection by a newly contracted physics group on November 13, 1990 identified this lapse. This was a new requirement for our facility since we had recently renewed our license which resulted in a change of license conditions with respect to the bioassay requirement for doses in capsule form. On June 22 and July 24, 1990 (the date of the therapies performed under the new license conditions), the Nuclear Medicine staff was not aware that

bioassay was now required for capsule doses.

On November 13, 1990, the efficiency factor necessary to evaluate the bioassay results was determined, the requirement for performing bioassay on any dose 30 mCi or greater was reviewed, and the procedure for performing bioassay was explained to the Nuclear Medicine staff by the new consulting physicist.

Action taken to prevent recurrence: The staff has been instructed regarding this requirement and now have the efficiency factor necessary to evaluate the bioassay results.

Date of Compliance: November 13, 1990

If you have any further questions concerning this matter, please feel free to contact me at (313) 762-8599.

Sincerely,

St. Joseph Hospital

Homer W. Read
Vice President

HWR/cmn
Enclosures

Medical Physics Consultants, Inc.

Date: 12/20/90
Type: NUC

CNO: 1778MI
INSPECTNO: 35100

DOSE CALIBRATOR GEOMETRICAL VARIATION TEST

Calibrator Manufacturer: CAPINTEC

Model No: CRC-30 BC Serial No.: 30786 VIAL

Test Date: 12/20/90

Volume (ml)	Activity (mCi)	Correction Factor
.50	13.40	1.018
1.00	13.37	1.020
5.00	13.40	1.010
10.00	13.64	1.000
15.00	13.68	.997

Note: Correction factors are derived from the quotient of the activity (13.64 mCi) of the reference volume divided by the sample (variable volume) activities.

RSO: _____

Ver 1.2 (c) MPC 10/88

Date: 12/20/90
Type: NUC

CNO: 1778MI
INSPECTNO: 35100

DOSE CALIBRATOR GEOMETRICAL VARIATION TEST

Calibrator Manufacturer: CAPINTEC

Model No: CRC-30 BC Serial No.: 30786 SYRINGE

Test Date: 12/20/90

Volume (ml)	Activity (mCi)	Correction Factor
.50	7.34	.982
1.00	7.21	1.000
1.50	7.34	1.013
2.00	7.01	1.029
2.50	6.91	1.043
3.00	6.78	1.063

Note: Correction factors are derived from the quotient of the activity (7.21 mCi) of the reference volume divided by the sample (variable volume) activities.

RSO: _____

Ver 1.2 (c) MPC 10/88

Medical Physics Consultants, Inc.

Date: 12/20/90
Type: NUC

CNO: 1778MI
INSPECTNO: 35100

DOSE CALIBRATOR ACCURACY TEST

Calibrator Manufacturer: CAPINTEC

Model No.: CRC-30 BC Serial No.: 30786

Cs-137 M/N: 77325 S/N: _____

Calibrated activity = 560.00 uCi on 08/04/78

Measured activity = 456.00 uCi
Calculated activity = 420.66 uCi

Percent error = 8.400 %

Co-57 M/N: CTC.VI S/N: 9305MA

Calibrated activity = 5500.00 uCi on 08/01/89

Measured activity = 1552.00 uCi
Calculated activity = 1508.03 uCi

Percent error = 2.920 %

Ba-133 M/N: _____ S/N: _____

Calibrated activity = _____ uCi on / /

Measured activity = _____ uCi
Calculated activity = _____ uCi

Percent error = _____ %

RSO: _____

Ver 1.2 (c) MPC 10/88

EMERGENCY PROCEDURES FOR ACCIDENTAL RELEASE OF XENON-133

Item 10.13.4

1. Notify persons in the room that a spill (release) has occured.
2. All persons should vacate the room at once.
3. Notify the RSO immediately.
4. Prevent entry into the room until the calculated evacuation time has occurred.

EVACUATION TIME: T = 37 MINUTES

Evacuation time (t) = $(-V/Q)\ \ln(CV/A)$ where:

A = the highest activity of gas in a single container (20,000 uCi).

S = measured airflow supply from each vent in the room (2.62 x 10E7, 925 cfm).

Q = the total room air exhaust determined by measuring in the airflow to each exhaust vent in the room (3.33 x 10E7, 1175 cfm).

C = the maximum permissible air concentration in restricted and unrestricted areas. For Xe-133, MPC = 1 x 10E-5 uCi/ml (restricted) and 3 x 10E-7 uCi/ml (unrestricted).

V = the volume of the room (2.16 x 10E8).

St. Joseph Hospital - Flint
revised 01/03/91