DCD

April 10, 1997

John Betjemann
Chief Executive Officer
Methodist Hospital of Gary, Inc.
600 Grant Street
Gary, IN 46402

SUBJECT: NOTICE OF VIOLATION DATED FEBRUARY 21, 1997

Dear Mr. Betjemann:

This acknowledges receipt of your letter dated March 18, 1997, in response to our letter dated February 21, 1997, transmitting a Notice of Violation (Notice). Based on a teleconference between John Chang, Ph.D. of your staff and Robert Gattone of my staff on April 3, 1997, it is our understanding that the reasons for the Violations cited in the Notice are as follows:

- Violation 1 occurred because your ventilation system malfunctioned and you tried to get the ventilation system installer to pay for the repair, which resulted in a delay in achieving compliance;

- Violation 2 occurred because the person doing the dose calibrator linearity test didn't administer iodine-131, so he didn't realize that the linearity test activity range didn't include the highest dosage administered to patients; and

- Violation 3 occurred because the person doing the dose calibrator geometry dependence test didn't know that the syringe configuration was required to be tested.

If our understanding is incorrect, please contact this office immediately.

We have reviewed your corrective actions, which appear to be adequate, and have no further questions at this time. These corrective actions will be examined during a future inspection.

Sincerely,

Original Signed by Roy J. Caniano.

Roy J. Caniano, Acting Director
Division of Nuclear Materials Safety

License No. 13-16558-01
Docket No. 030-11234

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bcc w/ltr dtd 03/18/97: PUBLIC

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OFFICE	DNMS/RIII	C	DNMS/RIII	C	DNMS/RIII					
NAME	RGattone/brt		JRMadera		RJCaniano					
DATE	04/8 /97		04/ 8 /97		04/ 9 /97					

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THE METHODIST HOSPITALS

Northlake Campus
Corporate Office
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8701 Broadway
Merrillville, IN 46410
(219) 738-5500

March 18, 1997

U. S. Nuclear Regulatory Commission
Document Control Desk
Washington, D.C. 20555-0001

RE: Reply to a Notice of Violation
License No. 13-16558-01
Docket No. 030-11234

Gentlemen:

This is in response to your recent letter concerning the inspection of our nuclear medicine facilities of January 17, 1997. We have taken the following action to correct the deficiencies noted during the inspection:

1. 10CFR35.205(b) requires that a licensee administer radioactive gases only in rooms that are at negative pressure compared to surrounding rooms.

   RESPONSE: All self-identified problems or weaknesses will be promptly reported to the Radiation Safety Officer and the Radiation Safety Committee. Under no circumstances will the Radiation Safety Committee or management allow any self-identified, non-compliance to go uncorrected beyond a reasonable response period of 30 days. All corrective actions will be reviewed, discussed and documented in the Radiation Safety Committee meeting minutes. See attached policy R.S.#44.

   Compliance with this item has been achieved.

2. 10CFR35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 30 micro curies.

   RESPONSE: We confirm that a dose calibrator linearity check was performed over the highest dosage (>150 millicuries and 30 micro curies) on January 20, 1997 (the next working day). This dosage range will be checked and documented on all subsequent linearity tests. See attached policy Q.C.#1.

   Compliance with this item has been achieved.

3. 10CFR35.50(b)(4) requires, in part, that a licensee test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used.

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RESPONSE: We confirm that geometry dependence and volume configuration (using both vial and syringe) were performed on January 20, 1997 and our policy has been revised to reflect continuation of this practice. See attached policy Q.C. #1. All results were within limits.

Compliance with this item has been achieved.

We hope the action taken shows our willingness to comply with the NRC regulations applicable to our program and the conditions of our materials license. If additional information is needed concerning our follow-up action, please contact Conrad Brown, Service Unit Manager, Nuclear Medicine at (219) 886-4270 or 4211.

Thank you.

Sincerely,

John Betjemann, CEO

cc: Regional Administrator, NRC Region III

THE METHODIST HOSPITALS, INC.	PREPARED BY CONRAD BROWN, CNMT SERVICE UNIT MANAGER	POLICY NO. Q.C.#1
POLICY AND PROCEDURE		EFFECTIVE DATE May'88
SUBJECT: LINEARITY TEST FOR DOSE CALIBRATOR	ISSUED BY NUCLEAR MEDICINE DEPT. APPROVED BY	REVISION Rev#1 6/95 Rev#2 1/97 Rev#3 3/97 PAGE 1 OF

TECHNICAL AND INFORMATIONAL NOTES

Linearity tests must be performed quarterly. It is the primary responsibility of the Service Unit Manager to see that the test is done at the specified times. All technologists, however, are to participate in the actual testing and calculations.

Linearity tests must be done at the prescribed time (quarterly) in order to ensure that the instrument is functioning properly and to be in compliance with Nuclear Regulatory Commission regulations.

Variance of more than 10% must be reported to the Service Unit Manager immediately.

The dose calibrator must be zeroed and the background at zero prior to assaying the sample.

PROCEDURE:

Using the CALICHECK Linearity test system and provided worksheet, place a 3cc syringe into the black only tube and assay the activity and record on the worksheet.

Place the red tube over the black tube and record the activity on the worksheet.

Continue to do this with the Orange, Yellow, Green, Blue, and Purple tubes and record the activity in mCi on the worksheet.

Take the Displayed Activity figures and multiply by the Calibration Factor that are provided. **

The seven products are then totaled and the man is determined. The mean is then multiplied by 1.10 and 0.90 to establish the upper and lower limits.

The linearity test should be done using two Tc99m check sources. One measuring >150 mCi and one measuring between 3 - 4 mCi. This will allow the system to be checked over the full range of activity.

** Calibration factors are determined once and these figures are used during each linearity test. The Kit Calibration figures and worksheets, which are specific for each campus, can be found inside the folder containing the quarterly linearity test results in the file cabinet in the Service Unit Manager's office.

In the event that a new dose calibrator is installed or requires servicing, new calibration factors will be determined and geometric variation for volume and volume configurations will also be performed.

THE METHODIST HOSPITALS, INC.	PREPARED BY: CONRAD BROWN, CNMT SERVICE UNIT MANAGER	POLICY NO.: R.S.#44
POLICY AND PROCEDURE		EFFECTIVE DATE: 3'97
SUBJECT:	ISSUED BY: NUCLEAR MEDICINE and RADIATION SAFETY COMMITTEE	REVISION:
IDENTIFYING AND REPORTING DEFICIENCIES	APPROVED BY:	PAGE OF

PURPOSE: To provide guidelines for identifying and reporting deficiencies identified within the Nuclear Medicine Department or our Radiation Safety Program.

1) All self-identified problems or weakness within our Radiation Safety Program will be promptly reported to the Service Unit Manager of Nuclear Medicine and the Radiation Safety Officer. The RSO will identify radiation safety problems, will initiate, recommend or provide corrective action as necessary and verify that the corrective action is in compliance with NRC regulations.

2) Under no circumstances will the Radiation Safety Officer, the Radiation Safety Committee, or Management allow any self-identified non-compliance to go uncorrected beyond a reasonable response period of 30 days.

3) All self-identified problems or weaknesses, and corrections will be reviewed, discussed and documented in the Radiation Safety Committee meeting minutes.