MetroHealth Medical Center
2500 MetroHealth Drive, Cleveland, Ohio 44109-1998

216 398-6000

Radiology

Reichold

January 4, 1994

B.J. Holt, Chief
Nuclear Materials Inspection, Sec 1
U. S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Ill 60532-4351

Re: Reply to a Notice of Violation
License Nos. 34-03749-10 34-03749-07
Dockets 030-0410 030-13873

Dear Ms. Holt:

This letter is in response to your letter of December 17, 1993, Docket Nos. 030-00410 and 030-13873. The following paragraph numbers refer to the paragraph numbers of "Notice of Violation" enclosure.

Reported Violations:

1(a) & (b) were failures to properly document aspects of the Quality Management Program (QMP) at MetroHealth Medical Center. With approval of the Radiation Safety Committee, the QMP program is changed to insure that the proper documentation is completed. A checklist is provided to the Nuclear Medicine Technologist to insure that all forms are completed properly as they must check off all items before they may administer the radiopharmaceutical. A copy of the QMP and checklist is enclosed. To further insure future compliance, a one hour in-service training session was held for the Nuclear Medicine and Radiation Safety Technologists on January 2, 1994. Compliance was achieved on January 2, 1994.

1 (c) The written directives in teletherapy were initialed and not signed. All written directives for teletherapy treatments will be signed by the authorized user. The forms were changed after the recent inspection to reflect this change and we are in compliance on January 2, 1994.

2 (a) & (b) were reported violations in which the authorized user verbally changed the written directive, but the written directive was not changed. Previous QMP did not have provisions to either allow changes in the written directive or to document such changes. The QMP program is changed to allow for changes in the written directive. A copy of the new QMP program is enclosed with the forms used. Compliance was achieved on January 2, 1994. The working record used by the technologist now has a line

that allows the authorized user to change the dosage. If the administered dose differs from the written directive dose, the authorized user must initial the change on the working record.

3. Radioactive waste was found in one general waste paper basket in the Nuclear Medicine laboratory. Over a period of ten days, the RSO surveyed the waste basket daily and no activity was found. It is our belief that the detection of waste during NRC inspections was the exception and not the norm. However, a program has been put into effect on January 10th that labels the waste basket with a "Radioactive Materials" sign. This will prevent pickup of the material by our environmental services personnel. The basket will be included in the daily survey. If no activity is found in the basket during the daily survey, the waste will be released. If activity is found, the waste material will be held for "Decay-in-Storage" until no activity can be detected. As part of the above in-service session, the technologists were again reminded to place any waste that might be radioactive in the proper container.

4. There was failure to do a radiation survey in the Cardiology Exercise Laboratory each day a patient was injected. A map of the area was drawn with the area to be surveyed marked. Detailed instructions on conducting a survey for radioactive materials were written and presented to the Cardiology Technologist. In-service training was given the Cardiology Technologist on conducting radiation safety surveys, including hands-on-use of a survey meter. A copy of the documents is appended. The Radiation Safety Technologist will audit the surveys during her weekly wipe test of the area.

Concerns from Inspections on September 29 and December 2:

Concern One: Concern one was of the small sample of Brachytherapy cases reviewed. The QMP Committee of the Oncology Section meets monthly. Concern one is addressed by having the QMP Committee review <u>all</u> Brachytherapy cases monthly as part of the monthly meeting.

Concern Two: The yearly audit of radiopharmaceutical therapy cases was not of sufficient depth and quality. Concern two is addressed as part of the change in radiopharmaceutical QMP. New forms have been developed including a check list that covers all aspects of the program. Before the radiopharmaceutical can be administered, the check list must be completed. A new method of filing the forms is in place that allows easy access to the data, making more frequent audits easier. These changes and additions make the review easier with better information available during the audit and review. Both the RSO and an Authorized user in Nuclear Medicine will review all cases using the check list.

If more information is necessary, we will be most happy to supply it.

Sincerely,

John M. Stelma

John Stelma, Vice President
Clinical/Management Support

Ernest J. Wiesen

Ernest J. Wiesen
Radiation Safety Officer

MetroHealth Medical Center
Department of Radiology
Nuclear Medicine Section

QUALITY MANAGEMENT PROGRAM (QMP)

A. Introduction:

MetroHealth Medical Center is committed to provide the highest quality, safest care to its patients. A quality management program, outlined in this section, is a specific set of provisions designed to assure this safe, high quality of care as well as to meet the requirements of the state of Ohio, JCAHO, and federal (NRC) regulations. The specific mechanisms and detailed procedures for the Quality Management Program are properly part of all policies and procedures of Nuclear Medicine. As such, the various procedures for implementing the goals and provisions of the QMP are spread throughout the Policy and Procedure Manuals. The procedures may not use the exact terminology and phraseology required by regulating agencies. Therefore, to avoid any misunderstanding, the following policies and procedures are in effect and supersede any existing policies and procedures if any conflict in interpretation exists.

B. Policies and Procedures for Radiopharmaceutical Uses

1. The Nuclear Medicine Authorized User will sign and date the prescription (written directive) prior to the administration of any therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 microcurie of either sodium iodide I-125 or I-131.

2. Before administering a radiopharmaceutical dosage, the patient will be identified by at least two methods. The first method may be by asking the patient his name and then confirming the name. Some other method of verification must be used: birth date, address, social security number, name on patient ID bracelet.. etc..

3. Before administering the byproduct material, the specific details of the administration will be in accordance with the written directive (prescription). The dosage, the radiopharmaceutical and the route of administration will be verified.

4. Authorized persons participating in the administration will seek further guidance if they do not understand how to carry out the instructions on the written directive.

5. The authorized user or technologist under his direction will make, date, sign or initial a written record that documents the administered dosage and the records will be added to the patient chart or other appropriate record. The written record will show the dosage ordered and dosage given, the person administering the dosage and any change in written directive dosage. Any change must be written on the form and signed or initialed by the authorized user.

6. If the dose received from the radiopharmacy differs by more than 10 % from the written directive, the technologist will confer with the Authorized User. The Authorized User may change the dose on the written record, writing in the new value and writing their initials approving the new value.

7. The Nuclear Medicine Radiopharmaceutical QMP will be reviewed at least annually and will be documented at the next scheduled meeting of the Radiation Safety Committee. All cases will be reviewed by the Nuclear Medicine Physician and the Radiation Safety Officer

MetroHealth Medical Center
Department of Radiology
Radiation Safety Office

Checklist Before Administration of Radiopharmaceuticals (Before one is made, all items must be completed and checked.):

☐ Authorized User signed and dated written directive with isotope, activity with units, chemical form and route of administration.

☐ Patient was identified by at least two methods.

☐ Change in Written Directive may be made if authorized user authorizes change. If change is made, the new dose must be written on the work sheet and the authorized user must initial the change on the work sheet.

☐ Before Administration, the following should be verified:

1. Radiopharmaceutical with complete name.
2. Dosage with proper units listed.
3. Route of administration.
4. Authorized user signed and/or initialed form.

☐ Every line on form is completed before dose is administered.

METROHEALTH MEDICAL CENTER
DEPARTMENT OF RADIOLOGY

NUCLEAR MEDICINE SECTION

I^{131} DIAGNOSTIC/THERAPY CAPSULE

PATIENT'S NAME: _____

PATIENT'S NUMBER: _____

REFERRING M.D.: _____

SUGGESTED DOSE ORDERED: _____ REC'D: _____

I^{123} UPTAKE & DATE: _____

NUCLEAR MEDICINE DR.: _____

_____ _____

M.D. SIGNATURE DATE

DOSE GIVEN: _____ P.O. TECH: _____ OK'D: _____

I131CAP.NM
REV.10/93

METROHEALTH MEDICAL CENTER
DEPARTMENT OF RADIOLOGY

NUCLEAR MEDICINE SECTION

SR^{89} CHLORIDE THERAPY INJECTION

PATIENT'S NAME: _____

PATIENT'S NUMBER: _____

REFERRING M.D.: _____

OPTIMAL DOSE ORDERED: _____ REC'D: _____

DOSE DRAWN UP: _____ TECH: _____

NUCLEAR MEDICINE DR.: _____

_____ _____

M.D. SIGNATURE DATE

DOSE GIVEN: _____ I.V.

SR89INJ.MM
REV.12/93

METROHEALTH MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
RADIATION SAFETY OFFICE

GEIGER COUNTER PROCEDURE FOR CARDIOLOGY

1. Turn main knob to **bat.**. Turn **response** knob to **med.**.

2. Needle should deflect to the lined **bat check** area on the meter face. If it does not, replace the two "D" batteries.

3. Turn main knob to **10**.

4. Extend inner probe. Lay alongside (parallel to) the **OPERATIONAL CHECK SOURCE**. The reading should be at the **.1** mark on the dial. (Actually it is **1.0** since you are on the **x10** scale.) See the calibration tag taped on the side of the instrument.

5. Retract the inner probe.

6. Turn main knob to **1**.

7. Point at and around the areas designated on the map. All areas except #4 should read at or under .1 on the meter face.

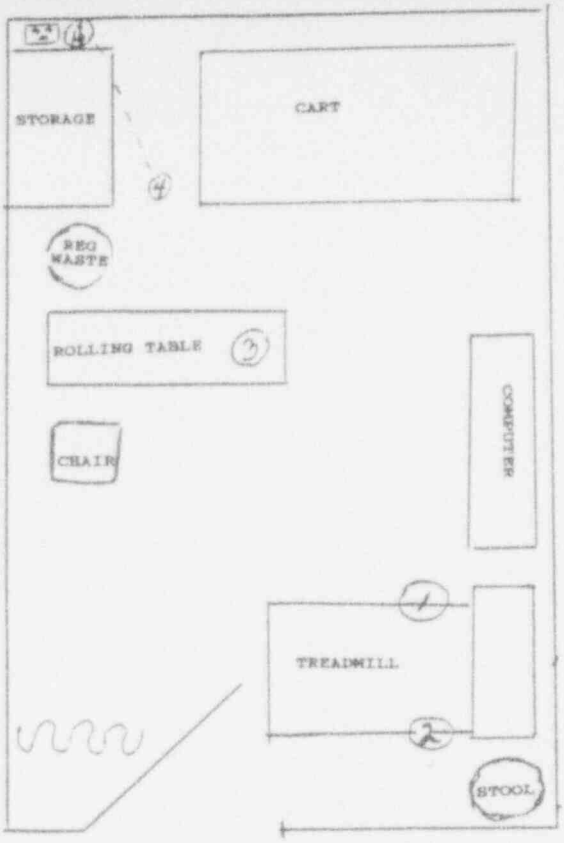
8. Area #4 should be checked at approximately 1 meter from the waste box. See diagram.

9. Monitor at 1 meter on 1 setting. If needle "pins" at the far right side of the dial, back away and switch the knob to **10** and try the same area monitoring again. This means that any reading you get must be multiplied by ten.

10. Record the readings in the appropiate box, date and sign your initials.

11. This must be done every day that there are injections in that room. If there is a weekday that there are no patients, put down the date and x out the rest of the row.

12. Turn main knob to **off**.



HEART AND VASCULAR CENTER

LAB C

EXERCISE LABORATORY

H 310

Date	1	2	3	4										limit
trigger	.1	.1	.1	2.0										