MATSON

St. John's Mercy Medical Center

615 South New Ballas Road
St. Louis, MO 63141-8277
314/569-6000

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

December 21, 1993

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 Sirs:

This is in response to Notice of Violations dated Dec 3, 1993 regarding routine safety inspection of November 4-5, 1993 identifying five violations of regulations or license conditions. Promptly following the inspection, the Radiation Safety Officer discussed each issue with the concerned department or area. Inspection findings were also presented at the Radiation Safety Committee meetings on November 11 and 19, 1993 at the Medical Center and Hospital, respectively. The Notice of Violations was received on December 9, 1993. Copies were distributed and posted in all areas under discussion. The first violation concerns practices at St. John's Mercy Hospital and the remaining four were cited at St. John's Mercy Medical Center.

This reply will include for each violation: (a) the reason for the violation or basis for disputing, (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.

1. Failure of licensee to routinely check survey meter with a dedicated check source each day of use as required by 10 CFR 35.51(c).

(a) Reason for the violation:
The technologist questioned by the inspector was a new technologist. She had not been instructed in her initial orientation to perform the daily check. The technologist who normally performed this duty was the person she replaced. It is not required that this check be documented.

(b) Corrective actions taken:
The Chief technologist re-instructed the two Nuclear Medicine technologists in the proper use of the dedicated check source to test proper function of the survey instrument prior to use. The location of the source is known to all personnel. The Chief Technologist has questioned both technologists and they have indicated that they are routinely using the check source.

(c) Corrective steps to avoid further violations:
A line item will be added to the detailed SJMH Hea_th Physics audit conducted quarterly by the Radiation Safety Officer to include a verbal verification by all technologists that the procedure is being performed properly. All future new technologists will receive these instructions by the Chief Technologist in initial orientation.

(d) Date of full compliance:
Full compliance was achieved on November 5, 1993 when the issue was discussed with all personnel.

2. Failure of the licensee to survey with a radiation detection instrument at least once each week the storage area on Floor 1L where radiopharmaceutical waste is stored as required by 10 CFR 35.70(b).

(a) Reason for the violation:
Item 10.12 of our NRC license specifies that surveys of the RAM (radioactive materials) waste storage area will be taken with a low range survey meter only if the integrity of a storage container appears compromised. This condition has been in our license since 1986 through numerous inspections, amendments and a renewal in 1991. We recognize condition 19 of our license which reminds licensees that NRC regulations govern unless license conditions are more restrictive. However, it was the lack of specific rejection of our statement that lead us to believe that our procedure was acceptable.

(b) Corrective actions taken:
Weekly ambient exposure surveys have been made in and around the waste storage room. A new form has been generated for use in documenting these surveys. The maximum exposure rate found to date in the waste storage room has been 1.7 mR/hr. The maximum rate outside this locked facility has been 0.3 mR/hr. The area surrounding this locked room is storage for Receiving. No individual regularly works in the vicinity of this room.

(c) Corrective steps to avoid further violations:
Procedures for required surveys given in license attachment 10.12 have been modified to reflect proper steps to be taken. This amended ATT 10.12 is enclosed.

(d) Date of full compliance:
Date of full compliance was December 1, 1993.

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

(a) Basis for disputing the violation (request for exemption):
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 <u>if accessible</u>. 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. Lead shielding used to provide compliance with 10 CFR Part 20 is not mobile; it is firmly mounted in the walls. 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 as these rooms are also 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 the two therapy rooms, 334 and 336, to extend the coverage beyond the area of the bed to include the entire living space. Prior to this time, maximum radiation exposure rates were found in the foyer at 1.5 mrem/hr. With the increased lead coverage, rates are generally in the 100 urem/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 1 inch lead. Typical readings in the bed area are 20-60 urem/hr.

Testing was conducted in August 1991 and again in December 1993, after additional shielding, 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 in the bed of room 334 has been demonstrated to yield 0.142 mrem/hr at the foot of the bed in room 332 and 0.533 mrem/hr at the bed in room 336. (There is greater distance to the bed in room 332 than room 336, see enclosed map.)

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 will not be available until late January. 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.

We believe it should be sufficient, therefore, to survey as previously stated including the doorway to the adjacent patient's room. The level at the doorway will be used to demonstrate compliance with regulations. The physical laws will predict that the levels inside the patient's living space will be below the level at the door.

4A. Disposal of Xenon-133 waste (masks) in a trash can which was not designated, labeled or properly shielded for radioactive waste as specified in our license attachment 10.4, Item 9.

(a) Reason for the violation:
Technologists did not fully appreciate the ability of the masks and ventilation tubing used for Xenon-133 studies to retain significant Xenon-133 gas. While many technologists were disposing of the masks in radioactive trash in the hot lab, this procedure was not uniformly followed throughout the laboratory.

(b) Corrective actions taken:
All violations were reported to the Nuclear Medicine staff at bi-weekly staff meeting on November 16, 1993. A large lead container was transferred from waste storage to Imaging Room 1 (the only room approved for Xenon-133 use) and lined with a plastic liner. The container is labeled for disposal of radioactive material, specifically Xenon-133.

(c) Corrective steps to avoid further violations:
A procedure will be written for the proper use of this container for Xenon-133 masks and tubing disposal, including transfer of the waste to long-lived storage for decay according to standard policy. All imaging and radiopharmacy personnel will be required to sign the procedure statement to attest to reading, understanding and agreeing to follow the procedure. Any person disposing of radioactive waste in improper (non-radioactive) trash containers will be subject to Disciplinary Actions according to SJMMC policy.

(d) Date of full compliance:
Due to Holiday vacations, all signatures may not be obtained until Jan. 3, 1994. That will be the date of full compliance.

4B. Emergency procedures were not displayed by the Cs-137 Blood Irradiator as stipulated in Item 9.6 of the application dated February 26, 1991.

(a) Reason for the violation:
Supervisor of the Blood Bank had interpreted the license condition requiring that "emergency procedures for the Blood Irradiator be displayed" referred to the enclosed page from the Administrative Policy/Procedure Manual (also included in our NRC license) entitled Disaster Preparedness and Emergency Procedures: Emergency in Blood Bank. The inspector requested more detailed emergency procedures as listed in the Operating Manual for the apparatus.

(b) Corrective actions taken:
Two page Emergency Procedures from the Operating Manual have been covered in plastic for protection and posted beside the aforementioned Emergency Procedures (copy enclosed).

(c) Corrective steps to avoid further violations:
Emergency Procedures have been posted and shall remain so posted.

(d) Date of full compliance:
Full compliance was completed on November 8, 1993.

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

Sincerely,

Sister Mary Angelique Foto, RSM

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

SMAF/SQ/jak
enc.

ATT 10.12 Area Surveys

Ambient Exposure Rate Survey

1. Survey Areas

   a. In all areas where radiopharmaceuticals are routinely preparaed for use and administered, **survey at the end of each day** of use with a low range survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed, (less than 200 microcuries at a time), routine **surveys are not necessary**, (see section on removable contamination surveys).

   c. All radiopharmaceutical waste will be packaged in a plastic bag, a rigid plastic container or left in its original container (i.e. generator) before transfer to the radioactive material (RAM) waste storage area. Surveys of the RAM waste storage area will be taken with a low range survey meter once a week.

   d. In the brachytherapy storage area, **survey quarterly** with an ionization chamber survey meter.

   e. In laboratory areas where iodine is handled in a non routine manner (i.e. iodination reactions, dilutions), **routine surveys are not necessary** (see section on removable contamination surveys).

   f. In blood irradiator area, **survey the irradiator and immediate area at installation and thereafter at least annually** with an ionization chamber survey meter.

   g. In laboratory areas where only small quantities of beta-emitting radioactive material are processed, (less than 200 microcuries at a time), routine **surveys are not necessary,** (see section of removable contamination surveys).

   h. In patient's rooms following radiopharmaceutical therapy, **survey after the patient has been discharged.**

2. Immediately notify a member of the Radiation Safety Office if you find unexpected high or low levels.

   a. **Action level for all areas except the blood irradiator is > 0.1 mR/hr.**

   b. **The action level for the blood irradiator is > 0.2 mR/hr at one meter and/or > 2.0 mR/hr at the surface.**

3. All surveys are to be performed by the area's respective laboratory technologist, except in paragraph (d) and (f) above which will be performed by the Radiation Safety Officer.

Removable Contamination Surveys

1. Survey of Restricted Areas

   a. In all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored, **survey weekly** for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of gamma emitting radioactive material are processed (less than 200 microcuries at a time), **survey monthly** for removable contamination.

   c. All radiopharmaceutical waste will be packaged in a plastic bag, a rigid plastic container or left in its original container (i.e. generators), before transfer to the radiopharmaceutical waste storage area. Removable contamination surveys of the RAM waste storage area will be taken only if the integrity of a storage container appears compromised.

   d. In laboratory areas where iodine is handled in a non routine manner (i.e. iodination reactions, dilutions), **survey after the procedure is completed**.

   e. In laboratory areas where only small quantities of beta emitting radioactive material are processed (less than 200 microcuries at a time), **survey monthly** for removable contamination.

   f. In patient's rooms following radiopharmaceutical therapy, **survey after the patient has been discharged**.

2. Action level for removable contamination surveys in Nuclear Medicine Imaging, Nuclear Pharmacy and RAM waste storage area:

   a. Use a sodium iodide detector to measure all removable contamination survey wipes.

   b. **The action level is 22,000 dpm/100cm^2.**

   c. If the sample measures above the action level, decontaminate the area and re-wipe.

3. Action level for removable contamination surveys in Nuclear Medicine RIA Laboratory, Molecular Laboratory and Pediatric Laboratory (I-125 or P-32).

   a. Use a sodium iodide detector to measure removable contamination wipe samples.

   b. **The action level is 2,000 dpm/100cm^2.**

   c. If the sample measures above the action level, decontaminate the area and re-wipe.

4. Action level for removable contamination surveys in Pediatric Laboratory (H-3).

   a. Use a liquid scintillation detector to measure removable contamination wipe samples.

   b. **The action level is 2,000 dpm/100cm^2.**

   c. If the sample measures above the action level, decontaminate the area and re-wipe.

5. Action level for removable contamination surveys in patient's rooms following radiopharmaceutical therapy.

   a. Use a sodium iodide detector to measure removable contamination wipe samples.

   b. **The action level is 200 dpm/100cm^2.**

   c. If the sample measures above the action level, decontaminate the area and re-wipe.

6. All surveys are to be performed by the area's respective laboratory technologist.

Records

1. Keep a record of exposure rate and contamination survey results. It must include the following information:

   a. The date, area surveyed, and equipment used.

   b. The name or initials of the person who made the survey.

   c. A drawing of the areas surveyed and contamination and exposure rate action levels as established by the RSO.

   d. Record exposure rates and removable contamination levels as above or below their respective action levels.

   e. Notify a member of the Radiation Safety Office if you find unexpectedly high levels.

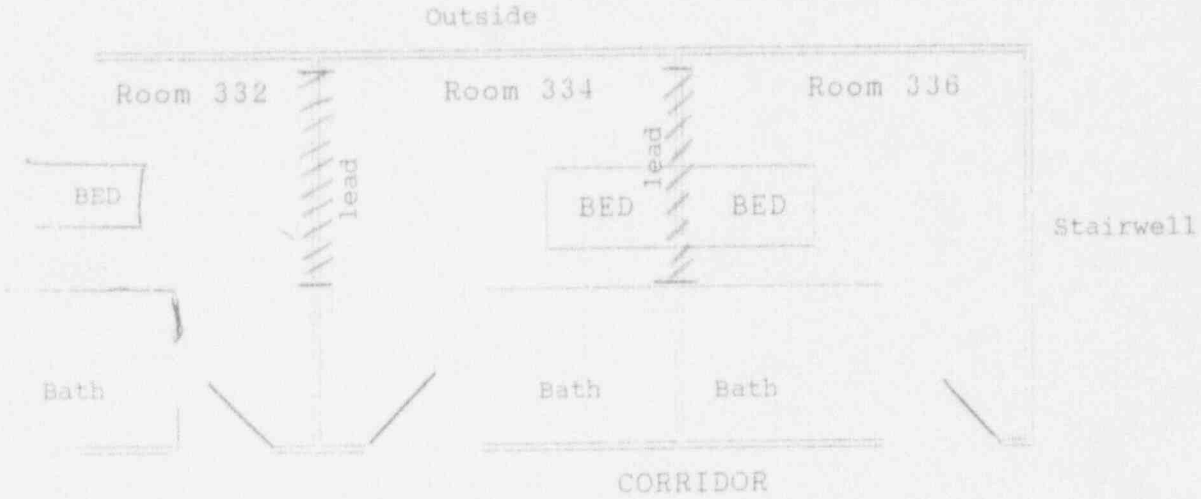
   f. Actions taken in the case of excessive exposure rates or contamination and follow up survey information.

2. A member of the Radiation Safety Office will review and initial the record at least quarterly and also promptly in those cases in which action levels were exceeded.

   See Forms 10.12/1-9 and 10.14/3

License # 24-00794-03

Map of 3B Oncology
Radiotherapy Rooms



ST. JOHN MERCY MEDICAL CENTER
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ADMINISTRATIVE POLICY/PROCEDURE
NUMBER 800.24

CATEGORY: DISASTER PREPAREDNESS AND EMERGENCY PROCEDURES

TITLE: EMERGENCY IN BLOOD BANK

PROCEDURE ONLY

An emergency in this area would probably occur in the Blood Bank Laboratory area. In an emergency, notify one of the following in order:

1. Shan Quint, R.S.O.*
   Station Number: 6657
   Home Nubmer: 940-0158
   Beeper Number: 740-1108 (digital)

2. Jim Riggio, B.S., Associate R.S.O.
   Station Number: 3175
   Home Number: 239-3659

3. Dr. Antonio Salvador, Medical Director
   Station Number: 3177
   Home Number: 567-4487
   Beeper Number: 740-0478 (digital)

4. Dr. George Oliver
   Station Number: 6844
   Home Number: 537-2958
   Beeper Number: 740-0225

* Shan Quint is the Radiation Safety Officer and has the ultimate responsibility.

EFFECTIVE DATE: 2/90 REVISED: 5/92 REVIEWED: 1/91

AREAS AFFECTED: All Areas ORIGINATED BY: Radiation Safety

APPROVED BY: _____

4:57:05:92

this case, leave the yellow copy of the shipping form for the manager/supervisor. A total of six times the charge code #6714 will be assessed for each cannister of product irradiated over the weekend and ten times the charge code #6714 will be assessed for each cannister irradiated during the work week (Mon. - Fri.).

EMERGENCY PROCEDURE

Interruption of Irradiation Cycle

1. Press the "Cycle Break" switch (red-6). The red light will come on and the drum will return to the loading/unloading position.

2. Press the "Cycle Break" switch to continue the irradiation cycle. "Cycle Break" light goes off and "Cycle Start" light comes on.

Electrical Defects

1. Push in "Emergency Stop" switch on front face of unit in cases of electrical shock or insulation defects. The unit and battery are electrically disconnected. The drum remains in place.

   NOTE: This may result in overexposure to the products in the canister. Note the total time the product(s) are exposed to the source.

2. When the problem is corrected, insert and turn the key. The drum will return to the loading/unloading position.

3. Remove product(s) and quarantine. Consult Medical Director as to whether product(s) should be discarded.

POWER FAILURE

When the main power fails, all lights except "Battery" (blue-10) go off, the drum returns to the loading/unloading position, and the timer stores in memory the value of the irradiation time remaining.

1. Remove the product from the canister and store on the "quarantine" shelf of refrigerator or platelet rotator until power is restored.

2. Reload the product in the canister and repeat STEPS 5-9 of the "Irradiation Procedure".

3. Press the "Cycle Start" switch and the irradiation cycle will resume beginning with the preserved value.

CANISTER FAILS TO ROTATE OR DRUM REMAINS IN "IRRADIATION" POSITION

1. The "Canister Rotation" light will stop flashing and remain illuminated or go off.

2. The drum should return to the loading/unloading position. If this fails to happen, press the "Cycle Break" switch.

3. Push the "Emergency Stop" switch.

4. See "Manual Rotation of Drum" procedure.

MANUAL ROTATION OF THE DRUM

Refer to the diagram of the IBL 437 C Irradiator. (See page 7)

1. Push the "Emergency Stop" switch to disconnect the unit from the power source.

2. Remove the front lower panel.
3. Remove the "Safety Return Lever" (4).

4. Insert the lever into the holes of the can bearer disk.

5. Manually rotate the drum clockwise to the loading/unloading position.

POSSIBLE RADIATION LEAK

1. If, for any reason, a possible radiation leak is suspected, survey the irradiator and area with an Ionization Chamber Survey Meter.

2. Contact the Radiation Safety Officer if the level of radiation is 0.2mR/hr at 1 meter and/or 2.0mR/hr at the surface. Call ext. 6657 or beeper # 740-1108 and ask for the RSO.

3. See "Use of the Geiger-Mueller Survey Meter" procedure.

INTERPRETATION: Any change in the pre-set 2500 RADS needs to be approved by the Medical Director and the irradiator should be changed back to the pre-set 2500 RADS after any changes are made.