UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
631 PARK AVENUE
KING OF PRUSSIA, PENNSYLVANIA 19406

03 DEC 1987

License No. 37-11438-02
Docket No. 030-13111
Control No. 107892

Franklin Regional Medical Center
ATTN: James P. Reber
President
One Spruce Street
Franklin, PA 16323

Gentlemen:

This is in reference to your application dated September 29, 1987, to renew License No. 37-11438-02. In order to continue our review, we need the following questions answered:

1. Your request to authorize John W. Shonnard, M.D. for uptake, dilution and excretion studies, as described in Section 35.100 of 10 CFR 35 (enclosed), cannot be granted until we have received an outline of his training and experience in this area. As a minimum, his training and experience must cover the requirements specified in 10 CFR 35.910. Please submit this information.

2. We are concerned that Charles Mason, M.D., acting as RSO, may not have sufficient authority to halt procedures that may involve unsafe or hazardous conditions or practices. Consequently, please submit a written statement, signed by management, stating that the RSO will have sufficient authority to act on these problem areas. Refer to page F-3 of Appendix F to Regulatory Guide 10.8, Rev.2 (August 1987) for a sample memo.

3. Regarding the calibration of your survey meters, confirm you will check your survey instrument(s) for proper operation with the dedicated check source each day of use.

4. Regarding your area surveys, you mention following the area wipe survey procedures outline in Appendix N, but failed to specify the surface contamination trigger levels for each isotope. Please specify these levels. Refer to Table N-1 of the Guide.

5. Confirm that individuals who were present during the handling and preparation of I-131 therapeutic dosages from multi-dose vials will be given a bioassay.

6. Regarding your sealed sources, brachytherapy and implant protocol:

   (a) Confirm you will survey all linen for loose seeds prior to removal from the implant patient's room.

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(b) Submit copies of the forms you will use to record the results of your quarterly sealed source and brachytherapy source inventory and of the dose rate surveys performed in all areas where such sources are stored.

(c) Submit an outline of the precautions you will follow for handling these sources. Include a description of the procedures and equipment used to transport them.

7. Confirm that all waste, with a half-life of 65 days or less, will be held for decay a minimum of 10 half-lives prior to surveying and disposal (if background).

We will continue our review of your application upon receipt of the above information. Please reply in duplicate, referencing Control No. 107892. If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

for John E. Glenn, Ph.D., Chief
Nuclear Materials Safety Section B
Division of Radiation Safety and
Safeguards

Enclosures:
1. 10 CFR 35
2. Regulatory Guide 10.8, Rev.2 (August 1987)

Krishnadas Banerjee, Ph.D., FACR

CONSULTING RADIOLOGICAL PHYSICIST

641 Ravencrest Road • Pittsburgh, PA 15215

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DIRECTOR, RADIOLOGICAL PHYSICS
ST. FRANCIS MEDICAL CENTER
PITTSBURGH, PA 15201

December 16, 1987

Margaret Heffernan, RT, CNMT
Chief Nuclear Medicine Technologist
Franklin Regional Medical Center
Franklin, PA 16323

Dear Margaret,

While I was going through Regulatory Guide 10.8, Revision 2, August 1987, I noticed on Page P-2, Item #10, that even if you treat patients with an I-131 gelatin capsule with more than 30.0 millicuries, the NRC wants the thyroid burden to be measured. Therefore, I believe you might have to revise your answer to that question stating that: If we treat a patient with more than 30 millicuries, then we will measure the thyroid burden. Otherwise it will not be applicable to us.

If you have any other questions, please do not hesitate to contact me.

Very truly yours,

Krishnadas Banerjee

Krishnadas Banerjee, Ph.D.

KB:cf

FRANKLIN REGIONAL MEDICAL CENTER

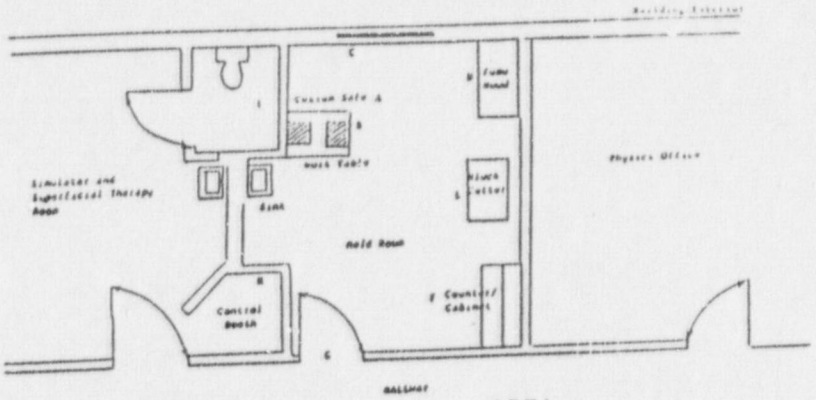
DEPARTMENT OF RADIATION ONCOLOGY

QUARTERLY SEALED SOURCE INVENTORY AND AREA SURVEY

PERSON PERFORMING SURVEY _____ DATE _____

SURVEY INSTRUMENT USED _____

SURVEY



AREA	READING	AREA	READING
- background	_____	E. block cutter	_____
A. max around safe	_____	F. counter	_____
B. max around cabinet	_____	G. door	_____
C. outside wall	_____	H. control booth	_____
D. fume hood	_____	I. toilet	_____

INVENTORY

ISOTOPE	A. # SOURCES SAFE / CABINET	B. # SOURCES ON LOG	A = B ?
I-125			
Au-198			
Ir-192			
Cesium 137 5 mg			
10 mg			
15 mg			
20 mg			
25 mg			
30 mg			

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107892

franklin regional medical center

December 17, 1987

Thomas Thompson
United States
Nuclear Regulatory Commission
Region I
631 Park Avenue
King of Prussia, Pa. 19406

RE: Amendment to License No. 37-11438-02

Mail Control No. 108073

Dear Dr. Thompson,

Enclosed is the information you requested during our phone conversation on December 15, 1987. The specific items you asked about have been highlighted for your convenience. As far as the storage of our sources from outside vendors, we have decided to enclose the bottom of the table on which the safe is located. This will have a door which can be locked, thereby securing the sources even if the mold room door were to be accidentally left unlocked. We still do plan to keep the mold room locked.

Thank you for the prompt attention you have given this matter. If you have further questions, please give me another call (814-437-4581).

Sincerely,

Robert J. Surgent, B.A.
Chief Physicist
Department of Radiation Oncology

RJS/h

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FRANKLIN REGIONAL MEDICAL CENTER

RADIATION SAFETY POLICIES

DEPARTMENT OF RADIATION ONCOLOGY

CESIUM AND OTHER SEALED SOURCES

1. Purpose

   A. To provide maximum protection for all individuals from exposure radiation.

   B. To prevent accidental loss of sealed sources.

2. General Information

   A. Supply of Sealed Radionuclides

      (1) All brachytherapy sources are stored in the mold room. The cesium sources are stored in the locked safe. Other sealed radionuclides are ordered from outside authorized vendors according to necessity. These are stored in the locked cabinet under the safe. A running inventory is maintained.

      (2) The physicist is responsible for checking all sealed radionuclides in the department.

         a. Wipe tests of the cesium tube sources are done every six months and records are maintained.

         b. A quarterly inventory of all sources is performed and records are maintained.

         c. A quarterly survey of the area around the safe is performed and records are maintained.

      (3) A mobile lead cart is used to transport the sealed radionuclides to and from various parts of the hospital.

      (4) Cesium 137 is generally used for intracavitary applications.

         a. The applicator or after-loading tube is loaded and unloaded under direction of the physicist. The amount of cesium leaving the department is noted in the log book by the technician or physicist loading it.

         b. After each application, the cesium sources are accounted for prior to their return to the storage unit.

      (5) When sealed radionuclides are ordered from outside vendors, the physicist surveys the container as soon as it arrives in the department and records kept. The pig containing the sources is stored in the locked cabinet underneath the table on which the safe is located.

ESIUM AND OTHER SEALED SOURCES (continued)
RADIATION SAFETY POLICIES, DEPARTMENT OF RADIATION ONCOLOGY

(6) When sources must be transported between the main hospital and West Unit, Dr. Lines accompanies the sources so as to fall under the regulations of 10 CFR Part 71.9.

(7) The physicist carries the radionuclides to the OR using the lead carts and keeps it in the hallway until the patient is ready. (all personnel in the OR wear film badges, or use pocket dosimeters, for personal monitoring). Lead aprons are provided for additional protection.

(8) Only those who have been properly in-services are permitted to handle sources. Precautions include but are not limited to:

a) Never touch sources with fingers. Always use tongs or forceps.

b) Work behind lead blocks and wear lead aprons.

c) Use time, distance and shielding to keep exposure as low as practical.

3. Procedures to Follow After the Application of Radionuclides

A. The chart is labeled with a notation that the patient is undergoing treatment with cesium or with other radionuclides as the case may be. An arm band labeled "Caution Radioactive Material" is attached to the patient's wrist.

B. The time of insertion is also noted on the label.

C. If the patient is sent to the Recovery Room, the patient's bed is placed at the far end of the room and the bed tagged with a "Radioactive Material" sign.

D. After the patient leaves the Operating Room, the area including the linens used, the suction pump (if used), the waste containers, are surveyed with a G. M. counter to make sure that no radioactive material is left in the OR.

E. The remaining unused sealed sources are returned to the Radiation Oncology Department. The amount is noted in the log book. Unused seeds are either returned to the safe and allowed to decay or they are sent back to the company.

F. (1) All patients containing sealed radionuclides occupy a private room.

(2) These rooms are surveyed after the patient is inside and the actual exposure at one meter from the patient is noted on the "Radioactive Label" sign. Additional measurements inside the room are made and recorded in a book as a permanent record.

(3) The room adjacent to the patient's room is surveyed to comply with recommendations in NCRP Report #37. These readings are also maintained as a permanent record.

(4) Proper signs and instructions are posted on the door of the patient's room; visitors are asked to check with the nurse at the desk prior to entering the room.

(5) Proper precautions are taken for the visitors and the nurses so that they are not over-exposed.

(6) Pregnant women and children are not allowed in the room with patients containing sealed sources.

(7) When the patient is discharged, the physicist is responsible for removing the signs from the room.

(8) Procedures for taking care of the patients containing radioactive sealed sources are given to the unit nurses to minimize the exposure of their personnel

4. Special Precautions

A. The linen should be kept in a hamper in the patient's room until it has been surveyed for sources by the Radiation Oncology Department. The patients containing intracavitary cesium are not allowed to use the toilets. Personnel must be alerted to the possibility of the cesium slipping out of the cervix into the bedpan.

B. Patients containing radioactive seeds may be discharged by the physician with proper instructions according to NCRP Report #37.

C. Removal of cesium interstitial sources.

(1) Notify Radiation Oncology Department.

(2) Obtain the mobile lead cart from the Radiation Oncology Department. The cesium sources are usually removed in the patient's room.

(3) The sources will be removed by the physician and placed in the mobile lead cart. The nursing supervisor is responsible for returning the lead cart containing the cesium to the Radiation Oncology Department during off hours. The technician unloading the cesium will enter the amount of cesium received in the log book kept in the department and check that it tallies with the amount which left the department.

(4) In case of implants, the sealed sources are removed from the patient by the physician either in the OR or in the Radiation Oncology Department. An inventory is taken at this time.

(5) If the sealed sources are removed during the night, holidays, or weekends, the supervisor returns the sources in the lead cart to the Radiation Oncology Department and this is checked by the personnel in the Radiation Oncology Department the next working morning.

CESIUM AND OTHER SEALED SOURCES (cont ed)
RADIATION SAFETY POLICIES, DEPARTMENT O. RADIATION ONCOLOGY

(6) The following should be noted on the patient's chart:

a. Date and time sources were removed
b. Physician removing sources
c. Patient tolerance
d. Any other pertinent observations.

D. After Removal of Sources from the Patient.

(1) No patients are discharged until the physicist surveys the patient and the room to make sure no radioactive sealed sources are remaining. This data is maintained in a log book.

(2) After the source is removed, the patient is no longer a source of radiation.

(3) After the sealed sources have been accounted for, the linens may be disposed of in the usual manner.

(4) The patient may be transferred to a semi-private room if necessary.

E. Personal monitoring of nurses taking care of radioactive patients.

(1) Nurses taking care of patients containing therapeutic amounts of radioactive sources are monitored using a pocket dosimeter or film badge.

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Sincerely,
Original Signed By:
Jenny M. Johansen

John E. Glenn, Ph.D., Chief
Nuclear Materials Safety Section B
Division of Radiation Safety and
Safeguards

Enclosures:
1. 10 CFR 35
2. Regulatory Guide 10.8, Rev.2 (August 1987)

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