

January 13, 1988

U.S. Nuclear Regulatory Committee ATTN: John E. Glenn, Ph.D., Chief Region I Nuclear Material Licensing - Section B 631 Park Avenue King of Prussia, Pennsylvania 19406

License # 07-14850-01 Docket # 030-07565 Control # 107845

Dear Mr. Glenn:

This is in reference to your letter dated January 6, 1988, requesting additional information in support of our application for license renewal.

We respectfully submit revised copies of Items #7, #15, and #17 in order to confirm or clarify the information you requested.

- 1. In response to your question regarding the policies and and responsibilities of the Radiation Safety Committee;
 - a) Item #7, Step 8 ensures the amendment of the hospital's license before changes in facilities, equipment, policies, procedures, and personnel.
 - b) Item #7, Step 10 confirms the establishment of a quorum.
- 2. Regarding our general rules for Radiation Safety, Item #15, Step 10 confirms the application of cosmetics is prohibited in restricted areas and Step 11 prohibits the storage of food and drinks in any area where radioactive material is stored or used.
- 3. Regarding our Area Survey Procedures
 - a) The results of all wipe counts will be recorded in dpm/cm2.
 - b) The trigger levels defined for decontamination are those recommended by the N.R.C. Table N-1 in Regulatory Guide 10.8, Revision 2, August 1987. See Item #7, Step 2,b. 1000 TWI 55 EN 1: 58

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- 4. We have decided to discontinue our Xe-133 program.
- The correct date for Regulatory Guide 10.8, Revision 2 is August, 1987.

Thank you for your efforts on our behalf.

Sincerely,

Victor Ribaudo, Senior Assistant Administrator

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Responsibility

The committee is responsible for:

- 1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with N.R.C. regulations and the conditions of the license.
- 2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with N.R.C. regulations and the conditions of the license.

Duties

The committee shall:

- Be familiar with all pertinent N.R.C. regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.
- 2. Review the training and experience of any individuals who uses radioactive material (including physicians, technologists, physicists, and pharmacists) and determine that the qualifications are sufficient to enable them to perform their duties safely and in accordance with N.R.C. regulations and the conditions of the license.
- 3. Review and approve all requests for use of radioactive material within the institution.
- Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examination of users, and special monitoring procedures.
- 5. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with N.R.C. regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of the N.R.C. inspections, written safety procedures, and the adequacy of the management control system.
- 6. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
- 7. Maintain written records of all Committee meetings, actions, decisions, and recommendations.
- 8. Ensure the byproduct material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.
- 9. Meet once each calender guarter.

10. Establish a guorum, one-half of the Committee's membership, including the RSO and the management representative, must be present at each quarterly meeting.

Membership

- To include:
- 1. Radiation Safety Officer
- 2. Representative of Hospital Administration
- 3. Representative of Nursing Administration
- 4. Representative of Pathology/Special Chemistry Department
- Supervisor--Radiology/Nuclear Medicine
 Representative of Nuclear Medicine Technical Staff

CNERAL RULES FOR RADIATION SAFE NUCLEAR MEDICINE

- 1. Laboratory coats or other protective clothing are to be worn at all times in areas where radioactive materials are stored or used.
- 2. Wear disposable gloves whenever handling radioactive materials.
- 3. Film badges and ring badges are to be worn at all times while in areas where radioactive materials are stored or used.
- Use syringe shields for preparation and administration of patient doses, except in circumstances when their use would compromise the patients wellbeing.
- 5. Confine radioactive solutions to covered lead containers. Plainly label to identify the compound, radionuclide, date, time, activity, and volume.
- 6. Always transport radioactive material in shielded containers.
- 7. Prior to administration, assay each patient dose in the dose calibrator to assure no variance greater than 10% from prescribed dose.
- 8. Hands, feet, and clothing are to be monitored regularly. Document the absence of contamination before leaving for the day.
- 9. Never pipette by mouth.
- 10. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
- 11. Storage of food, drink, or personal effects is prohibited in areas where radioactive material is stored or used.
- 12. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- 13. Survey all areas of the department, including generator storage, kit preparation, and injection areas at the end of the day. Decontaminate if necessary. See Item #17 for survey definition and procedure.

Personnel to be notified in the event of an emergency:

Radiation Safety Officer (Robert O. France, M.D.)

Nuclear Medicine Technologist On-Call

Emergency phone numbers are available from the PBX operator.

Item #15 Revised 1/88

PERSONNEL SURVEY

DATE	TIME	NAME	mR/Hr	INST.	DECONTAMINATION
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AREA SURVEY PROCEDURES

- 1. All elution, kit preparation, and injection areas will be surveyed as appropriate with a low-range, thin-window GM survey meter. If necessary, decontaminate or secure the area for decay.
- 2. All other laboratory areas will be surveyed weekly. This weekly survey will consist of:
 - a. Use of survey meter sufficiently sensitive to detect 0.1 mR/hr.
 - b. A series of wipe tests utilizing the department spectrometer to detect contamination. The trigger limits are as listed below:

Recommended Action Levels in dpm/100 cm2 for Surface Contamination

I-123, I-131, In-111 CO-57, TC-99m, Ga-67, T1-201

I. Unrestricted areas, personal clothing

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2,000

- II. Restricted areas, protective clothing used only in restricted 20 000 areas, skin 2,000
 - 3. A permanent record will be kept of all survey results in include:
 - a Location, date, and equipment used.
 - b. Name of person conducting the survey.
 - c. Coded drawing of the areas surveyed.
 - d. Measure exposure rates, keyed to location on the drawing.
 - e. Correcctive action taken in the event of contamination and their effects.

Item #17 Revised 1/88

NUCLEAR MEDICINE DAILY SURVEY

-		SURVEY	SWIPE	DECONTAMINATION
Α.	Radioactive Storage			
в.	Generator Elution Area			1
С.	Shielded Dose Prep Area			
D.	Counter Top			
E.	Hot Lab Floor			
F.	Hot Trash (lead-lined)			
G.	Refrigerator			
н.	Desk			
Ι.	Floor Near Injection Chair			
J.	Spectrometer Work Area/Sink			
К.	Restroom			
L.	Entrance Door			
м.	Floor Near Entrance	1		
N.	Closet Door Knob			
0.	Exam Table (Area #2)			
P.	Floor (Area #2)			
Q.	Control Panel-MDS/Picker			
R.	Collimator Carts			
s.	Control Panel-Siemens			
т.	Exam Table (Area #1)			
U.	Floor (Area #1)			
v.	SPECT Table			
W.	Regular Trash (3 locations)			

DATE:

INSTRUMENT USED:

ACCOMPLISHED BY:

All surveys will be performed with Beta window open.

All surveys will be recorded in mR/hr.

All swipes will be recorded in dpm/cm2

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9/87 Nuclear Medicine