Medical Center
Brockton, MA
West Roxbury, MA 02132

MS-16
P-7

Veterans Administration

March 1, 1988

U.S. Nuclear Regulatory Commission
Region I
ATTN: Thomas K. Thompson
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards
631 Park Avenue
King of Prussia, PA 19406

License No. 20-08551-01
Docket No. 030-01902
Control No. 107993

Gentlemen:

This is our response to your letter dated January 20, 1988 in regard to the renewal application of our NRC license.

1. A copy of the revised duties and responsibilities of the Radiation Safety Committee is attached (Attachment A).

2. The criteria for the proposed use of any radioactive materials will be based upon the ALARA program of our medical center in sustaining the exposure levels to a minimum. Any exposures exceeding 10% of the permissible level will be investigated to determine the cause and recommendations made to eliminate any future exposures. The review of any procedures will include an evaluation of the radionuclides involved as to their emissions, energies, and potential hazard to any users. Regulations will be formulated to require shielding (lead for gammas and lucite for betas) the necessity of any ventilation for volatile materials such as approved hoods, occupational and environmental monitoring, the adequacy of both the counting and monitoring instrumentation. Personnel will be instructed regarding these requirements to include the use of proper dosimetric devices including finger rings as well as whole body badges, bioassays, and personal surveys after handling the materials. Emergency and spill procedures will be posted to include immediate action, persons to be notified, decontamination procedures, and subsequent action to include surveys, bioassays, isolation of the affected area (if necessary), and evacuation of the area.

3. New users must meet the criteria established to comply with the regulations including the completion of an approved course with a

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final examination. This course must cover at least the Principles and Practices of Radiation Protection, Instrumentation (monitoring and measurement of radioactivity), Internal and External dose calculations, Waste disposal, Biological effects of radiation, Statistics, definitions, emergency Procedures, Regulations, Posting of areas and equipment, and the hazards associated with each radionuclide. The user must also have had experience using the particular radionuclides and to have demonstrated the capability to use these material safely. The formal training and experience must be at least forty (40) hours and meet the approval of the Radiation Safety Committee.

4. The Chairman of the Radiation Safety Committee, Dr. Donald E. Tow, is a representative of management as he is also a member of the Clinical Executive Board. He has the authority to speak for management in matters of equipment purchases and allocation of funds so that the Radiation Safety Committee can function in accordance with the terms and conditions of the NRC license. Mr. Guy Innocente is the Safety Manager of the medical center and has the authority of the overall safety program of the medical center. As such, Mr. Innocente also represents management.

5. Calibration of survey instruments is done by Harvard University Health Services Radiation Protection Team annually for West Roxbury Division, and by Neil A. Gaeta, Radiation Protection Specialist, certified by the American Board of Health Physics (NRC License #20-20743-01) for Brockton Division semiannually. Each survey instrument is checked with a dedicated source each day of use.

6. We will establish and implement a model procedure for calibrating our dose calibrator which is published in Appendix C to Regulatory Guide 10.8, Revision 2. The following items will be given special attention.

    a. A dose calibrator linearity test will be performed over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

    b. A dose calibrator constancy check will be performed on a frequently used setting.

    c. The dose calibrator will be repaired or replaced if the accuracy or constancy error exceeds 10 percent.

    d. The dose calibrator will be tested for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. Records of this test shall be kept for the duration of the use of the dose calibrator.

7. Our "Laboratory Rules for the Use of Radioactive Materials" will be revised according to the model safety rules published in Appendix I

to Regulatory Guide 10.8, Revision 2. A record of the measurement of radiopharmaceutical dosages will contain the:

a. Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

b. Patient's name and identified number, if one has been assigned;

c. Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 10 microcuries;

d. Date and time of the measurement; and

e. Initials of the individual who made the record.

8. We will establish and implement a model procedure for area surveys that is published in Appendix N to Regulatory Guide 10.8, Revision 2.

9. We wish to continue to use Xenon-133 gas.

a. We will collect spent noble gas in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the instructions of the manufacturer (RADX).

b. Performance of the collection and trapping devices will be checked according to the specifications of the manufacturer. The survey meter will be place at the exhaust outlet of the trapping system and the activity will be measured. Records will be kept for these checks. If there is any leakage from the outlet, the filter will be replaced.

c. We will calculate spilled gas clearance time according to the procedure that was published in Appendix 0.4 to Regulatory Guide 10.8, Revision 2.

d. The ventilation rates (air supply and air exhaust) will be measured every six months in areas of Xenon-133 or aerosol use, and those collection systems will be checked monthly.

10. No patient will be released until either the exposure rate from the patient is less than 5 millirem per hour at 1 meter or the retained radioactivity is less than 30 millicuries.

11. All personnel caring for patients receiving radiopharmaceutical therapy and hospitalized for compliance with 35.75 will be instructed in accordance with 35.310.

12. All of the required safety precautions described in 10 CFR 35.315 will be a part of our procedure when patients are hospitalized for radiopharmaceutical therapy.

13. We will maintain records of waste disposed of by decay in storage as required in 10 CFR 35.92 (4) (b).

14. The bioassay program may be divided into two categories; thyroid scans for radioiodine, and urinalyses for tritium. These are as follows:

    a. Any individual performing an iodination with 0.1 mCi or more will have a baseline thyroid scan prior to such use. Additional scans will be performed within 14 days (two weeks) of any iodination with the efficiency of the counting system determined by using a commercial standard in a "phantom" to simulate the absorption through tissue. Action levels are set at 20% of the permissible level or 10 nCi in the thyroid. Any individual exceeding the weekly uptake of 52 nCi will be suspended from any further iodinations until future thyroid scans indicate that the level has dropped below 10 nCi. Any individual exceeding the 20% level (10 nCi) will warrant an investigation, an evaluation of the probable cause, and recommendations made to prevent any further uptakes.

    b. Any individual using 10 mCi of any tritiated organic compound or 25 mCi of an inorganic compound will require urinalyses with samples to be submitted within 48 hours of such use. A baseline on all individuals will be made prior to such use with the body burden expressed in µCi/l of urine. Any body burden exceeding 10% of the permissible level of 28 µCi/l will require an investigation to determine the probable cause of the uptake and recommendations made to prevent a recurrence. In addition, any spill, emergency, or other incident as determined by the radiation safety officer will result in the submission of a urine sample for bioassay.

15. All iodinations will be carried out in an approved hood meeting the criteria for air flow through the hood. A continuous air sampler with a charcoal cartridge will be installed in the duct just prior to exhaust to the environment to evaluate the release. The sampling cartridges will be evaluated semimonthly at the beginning, and if the release is minimal, the cartridges will be changed monthly at the discretion of the radiation safety officer. Charcoal filters or a minihood with an iodine trapping system will be installed if the release data indicates a release exceeding 2×10^{-11} µCi/cc averaged over the counting period. The RSO will maintain reports of all releases. The RSO will be responsible for changing the cartridge and determining the release levels. Any iodination exceeding 2 mCi of radioiodine will require a personal air sample to evaluate the concentration of radioiodine in the breathing zone. If any thyroid scan indicates an uptake exceeding 10 nCi, breathing zone samplers will be worn for all further iodinations by the iodinators. The cartridges will be counted on a thin crystal scintillation detector attached to a multichannel analyzer which has been calibrated for

125I or 131I.

Tritium surveys will be made in two ways. Any individual using 50 mCi per experiment or more will conduct a materials balance by counting the final product and the waste, and the release will be determined by adding these two together and substracting from the initial quantity. In addition, these syntheses will be carried out in an approved hood where the effluent is pumped through a liquid collection system and counted by taking an aliquot in a liquid scintillation counter.

Prior to such use of either tritium or radioiodine, the user will submit a detailed description to the RSO for approval. A dry run will be made to minimize the chance of any error with the radioactive materials. The procedures will be modified to minimize the release by means of the use of syringe injections through a septum on the vials and subsequent sealing of all containers. Users will wear double gloves and subsequently double-bag all waste material. Safety glasses and laboratory coats will also be worn in addition to the gloves.

16. All bedding and animal waste which has been injected with any amount of radioactive material will be treated as radioactive waste.

ERNEST M. BARSAMIAN, M.D.
Acting Medical Center Director

Enclosure

ATTACHMENT A

VETERANS ADMINISTRATION MEDICAL CENTER
BROCKTON/W. ROXBURY, MASSACHUSETTS

MEDICAL CENTER MEMORANDUM
NO. 115-88-3

FEBRUARY 8, 1988

RADIATION SAFETY COMMITTEE

I. PURPOSE: To establish policy and procedures to supervise the institution's radiation safety program.

II. POLICY: The committee is established to supervise the safe practices of radiation protection and ALARA (As Low As Reasonably Achievable) program.

The committee shall:

1. Ensure that licensed material will be used safely. This includes review, as necessary, of training programs, equipment, facilities, supplies and procedures.

2. Ensure that licensed material is used in compliance with NRC regulations and the institutional license.

3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program.

4. Establish a table of investigational levels for individual occupational radiation exposures.

5. Identify program problems and solutions.

III. RESPONSIBILITY: The committee shall:

1. Be familiar with all pertinent NRC regulations, the license application, the license, and amendments.

2. Review the training and experience of the proposed authorized users, the Radiation Safety Officer (RSO), and the teletherapy physicist to determine that their qualifications are sufficient to enable the individuals to perform their duties safely, and are in accordance with the regulations and the license.

3. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the institution.

4. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures.

5. Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive.

6. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., nursing, security, housekeeping, physical plant) are appropriately instructed as required in § 19.12 of 10 CFR Part 19.

7. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with NRC regulations and the conditions of the license and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of NRC inspections, written safety procedures, and the adequacy of the management control system.

8. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

9. Maintain written minutes of all committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken.

10. Ensure that the byproduct material license is amended, if required, prior to any changes in facilities, equipment, policies, procedures and personnel.

11. The committee will report to the Clinical Executive Board semiannually, and at the direction of the chairman of the Clinical Executive Board.

IV. REFERENCES: VA Manual M-2, Part XX, Chapter 2. Appendix F to Regulatory Guide 10.8, Revision 2 NRC.

V. RESCISSION: Medical Center Memorandum No. 115-87-3, dated September 21, 1987.

VI. AUTOMATIC RESCISSION DATE: February 8, 1991.

VII. FOLLOW-UP RESPONSIBILITY: Chief, Nuclear Medicine Service.

SMITH JENKINS, JR.
Medical Center Director

Attachment

DIST: A,D
Committee members

MEDICAL CENTER MEMORANDUM
NO. 115-88-3

ATTACHMENT A

PROCEDURES:

1. The committee shall meet as often as necessary to conduct its business, but not less than once in each calendar quarter.

2. Membership:

Donald E. Tow, M.D., Chief, Nuclear Medicine Service	CHAIRMAN
Charles C.S. Ahn, M.D., Assoc. Chief, Nuclear Medicine	Radiation Safety Officer
Paul W. Doherty, M.D., Staff, Nuclear Medicine Service	Member
Michael Jay, M.D., Staff, Radiology Service	Member
Gifford Lum, M.D., Staff, Laboratory Service	Member
Daniel Garcia, D.D.S., Staff, Dental Service	Member
Guy Innocente, Medical Center Safety Officer	Member
Lisa Coveney, R.N., Staff, Nursing Service	Member

ExOfficio:

Frances Achee, Ph.D., Administrative Officer, Research
Neil Gaeta, Radiation Consultant
Chih-Chou Yu, Ph.D., Radiochemist
Frederick Murray, Assistant RSO, Brockton

3. To establish a quorum, one-half of the committee's membership, including the RSO and the management representative, must be present.

4. To the extent that they do not interfere with the mission of the committee, managment may assign other responsibilities such as X-ray radiation safety, quality assurance oversight, and research project review and approval.

5. The Radiation Safety Officer (RSO) is responsible for managing the radiation safety program, identifying radiation safety problems, initiating, recommending or providing corrective actions, verifying implementation of corrective actions, and ensuring compliance with regulations. The RSO is delegated the authority necessary to meet those responsibilities.

The RSO is also responsible for assisting the Radiation Safety Committee in performance of its duties and serving as its secretary.