



Springfield Hospital Wesson Memorial Hospital Wesson Women's Hospital

1879

August 22, 1980

Michael A. Lamastra
Materials Licensing Branch
Division of Fuel Cycle and Material Safety
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Your Control No. 99661; FCMLB; MAL; 030-09946
Reference: Your letter dated August 5, 1980
Subject: Renewal of NRC Broad License 20-01412-05

AUG 22 PM 11 29

Dear Mr. Lamastra:

This is in reply to your request for additional information related to our renewal of NRC Broad License at Baystate Medical Center. We would like to draw your attention to the fact that the additional information you have requested is already contained in the documents submitted with our letters April 26, 1979 and March 4, 1980. However, we will try to answer your questions with proper reference to our previous documents in your file and provide you with necessary information on other items.

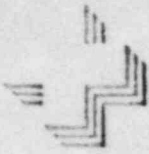
Our itemized answers relate to your questions in your letter dated August 5, 1980.

1. a) The criteria of Appendix A, Regulatory Guide 10.8 have been used in the past for approval of physicians for use of isotopes under our broad license 20-01412-05 at BMC. We re-confirm that these procedures will be followed by Radiation Safety Committee for approval of physicians at BMC.
- b) We do not have projects involving non-human use of isotopes (animal or pure scientific research) at BMC. As and when we introduce such projects, we intend to develop the necessary criteria for approval of users. A copy of such procedures will be sent to NRC.
- c) Our Medical Isotope Committee has been re-named as Radiation Safety Committee and the list of committee members for 1980 is enclosed. The committee members include a member of administration (Vicki Thoma) and a member of nursing staff (Miss Betsy Beck).
2. Under our broad license we do not have any active Radioactive Drug Research projects and therefore we do not have a Drug Research Committee with FDA.

Our broad license undertakes Phase III clinical trials in co-operation with Radiopharmaceutical Companies who have established all essential procedures with FDA for compliance. A 1573 form is filed with Radiopharmaceutical Company interested in gathering clinical data on their new investigational drugs. Our compliance with FDA regulations is provided by our strict adherence to procedures for preparation and use. Such step-by-step procedures are provided by the Radiopharmaceutical Companies as inserts to the kit. All radioactive drugs are obtained in precalibrated and final kit form for use at BMC.

XA Copy Has Been Sent to PDR

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3. a) This administrative procedure has been established. Refer to our letter dated March 4, 1980 to Patricia Vacca. Attachment #3, Item 7d, Responsibility 14. To clarify the channels of communications, a letter of appointment from President of BMC is enclosed.
- b) Answer to this question is included in our documents sent to you with our letter dated March 4, 1980 to Patricia Vacca. Refer to Attachment #8. Refer to RSO forms 3, 3A, 3B included in this attachment #8. These inspections are equivalent to NRC inspections.

The RSO inspections will be at least on a Quarterly basis. These inspections are supplemented by Radiation Safety Technologist Inspections conducted on a Monthly basis.

In addition, there will be an Annual audit by the Administration of BMC and Radiation Safety Committee.

4. a) Again, this has been answered in our documents submitted (April 26, 1979) in support of item #12. Refer to documents for item #12, page 3 and attached announcement of hospital-wide Radiation Safety Instruction Program for all employees.

We confirm that these instructions will be given initially and annually thereafter on a refresher basis.

- b) Same as 4 a) above.
The Radiation Safety Instruction Program is divided into two parts:

Part I: For all Hospital Employees
"Radiation: Risks and Safety"

The Lecture-Slide-Video presentation will include the following topics.

- Sources of Radiation at BMC.
- Basics of Radiation Safety and Standards.
- Handling of Radioactive Patients.
- Handling of Radioactive Materials.
- Federal, State and Local Regulations.
- Receiving of Radioactive Packages.
- Radiation Incidents and Emergencies.
- Risks associated with Radiation.
- Related Questions and Answers.

Part II: For Special Groups of Employees
"Operational Radiation Safety Update"

These are given at any time at the request of area supervisors or scheduled by Radiation Safety Office at least once a year. The special groups are:

- Nursing Staff handling Brachytherapy Patients.
- Nursing Staff of areas where portable diagnostic x-rays are used.
- Emergency Room Personnel.
- Security, Housekeeping and Building Services.



- Technologists from Laboratories.
- Technologists from Nuclear Medicine, Diagnostic X-ray and Radiation Therapy.
- Residents, Interns and members of medical staff.
- etc.

5. There is no non-human research undertaken at present time at BMC. Before any non-human research projects are started. We intend to develop the safety procedures and send to NRC for approval.
6. A copy of Nursing Instructions for use of P-32 is enclosed. In addition, the following procedures will be followed.
 - a) To keep Bremsstrahlung radiation at minimum, a plexiglass shield will be used.
 - b) A radiation survey and wipe-test will be done after each use.
 - c) The finger monitors are already in use.
 - d) A simulated dry run will be undertaken before any special or non-routine therapy involving P-32. A radiation safety technician will be present and radiation safety officer will provide all necessary assistance during a new special procedure.
 - d) Eye protection glasses will be obtained for use during P-32 therapy.

I hope these details are sufficient to continue your review of our renewal application for a broad NRC license at BMC.

Thank you.

Sincerely,

Suresh M. Brahmavar, Ph.D.
 Director,
 Medical Physics & Radiation Safety
 Radiation Safety Officer

Said M. Zu'bi, M.D.
 Chairman,
 Radiation Safety Committee

Harry C. F. Gifford, President
 Baystate Medical Center

Robert A. Grugan, M.D.
 Chairman, Dept. of Radiology

cc: Gerald A. Kerrigan, M.D.
 Signatories

USNRC, Region I



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MEDICAL STAFF COMMITTEE 1980

RADIATION SAFETY COMMITTEE:

Chairman Said M. Zu'bi, M.D., CHAIRMAN

Other Members Won C. Park, M.D.
John P. Sullivan, M.D.
John Rousou, M.D.
Michael Ross, M.D.
George H. Holsten, III, M.D.
Thomas Parker, M.D.
James Polga, M.D.
Robert Stein, M.D.
John W. Turner, M.D.
Suresh Brahmavar, Ph.D.
Burritt L. Haag, M.D.

ADMINISTRATION

Vicki Thoma

NURSING

Betsy Beck