UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

April 21, 2006

Docket No. 03002452 License No. 29-02641-03
Control No. 138022

Barbara A. Hopkins
Vice President, Operations
Hackensack Medical Center
30 Prospect Avenue
Hackensack, NJ 07601

SUBJECT: HACKENSACK MEDICAL CENTER, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 138022

Dear Ms. Hopkins:

This is in reference to your application dated November 8, 2005 requesting to renew Nuclear Regulatory Commission License No. 29-02641-03. In order to continue our review, we need the following additional information:

1. Your current license lists “Hackensack Medical Center” as the licensee name. Section 2 of your renewal application lists “Hackensack University Medical Center” as the licensee name. Do you wish to change the name listed on your license? Please indicate whether this is solely a name change or if a change has occurred in ownership, management, or control of your facility.

   If a change in ownership, management, or control has occurred, please provide the "Information Needed for Change of Control" listed in Appendix F of NUREG-1556, Vol. 15. This document can be found at:
   http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v15/

2. Your license will be written in a format which requires modification of some possession limits and forms. In your response to this letter, please provide limits commensurate with your program and sealed source identification in the format shown below. For sealed sources, please list all manufacturers and model numbers that you currently possess or may use in the future. When setting the limits for the materials below, please consider the maximum activity you will have on site at any one time including waste. For sealed sources in devices, you may wish to request a possession limit adequate to allow for the possession of a spare source during replacement of the source in the device.

Materials permitted by:	Form or Manufacturer/Model No.	Possession limit:
10 CFR 35.300	Any	___ curies (e.g., 2 curies)
10 CFR 35.400	Sealed Sources (Manufacturer ____, Model No. _____; Manufacturer ____, Model No. _____)	___ curies

Please note that 10 CFR 35.300 material includes I-131 unsealed material and 10 CFR 35.400 material includes I-125, Cs-137 and Cs-131 sealed sources.

3. With regard to your request to add 10 CFR 35.300 use for Drs. Budin, DeMeritt and Miller, we noted that Drs. Budin and DeMeritt are not currently authorized for 35.300 material use and Dr. Miller is only authorized for iodine-131. Please provide a preceptor statement documenting their work experience with a minimum of three cases in each category described in 10 CFR 35.390(b)(ii)(G). In addition, regarding the addition of high dose-rate remote afterloader use for Dr. Ingenito requested in this application and in your previous letter dated July 21, 1997, please provide documentation to support receipt of vendor training. Finally, please confirm that John Napoli is the same person as John Joseph Napoli currently listed on your license and indicate your preference for listing Mr. Napoli's name on the license.

4. With regard to your facility and equipment descriptions, please provide the following:

   a. For all brachytherapy sealed sources, please describe the storage location(s) and shielding for the sources. Show that adequate steps have been taken to assure that radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301. In addition, please indicate whether you have moved your brachytherapy storage room since your last description in your 1994 renewal application.

   b. For your HDR treatment room, please provide shielding calculations, with information about the type, thickness and density of all shielding materials, including walls, floor, ceiling, and voids in the shielding to enable independent verification of shielding calculations. Include information on the maximum "on time" per hour and per week and occupancy factors used for all adjacent areas. Shielding calculations must demonstrate compliance with the limits specified in 10 CFR 20.1301. In addition, please indicate whether you have moved your HDR treatment room since your last description in your 1994 renewal application.

   c. Describe the radioactive material use and storage in your basement hot lab.

   d. Describe the emergency response equipment available for manual brachytherapy treatments.

e. It appears that several labs in your 3rd flood research area that were previously used for P-33 research are no longer used. Please confirm that either these labs were never used (i.e., research use on the 3rd floor only included areas currently requested in your license application) or provide the close out surveys for these labs.

f. It appears that you no longer use your general chemistry area previously described in your 1994 renewal application. Please confirm that either this area was never used or provide the close out surveys for these labs.

g. Provide a description of your radioactive material receiving area(s).

h. Describe your radioactive material use in the patient surgery and recovery rooms (e.g., I-125 only). In addition, please specify the survey instrument used to locate stray seeds (e.g., thin sodium iodide crystal detector probe in order to detect iodine-125).

I. A description, including the dimensions, of any portable shields used for manual brachytherapy and radiopharmaceutical therapy treatments. In addition, describe your procedures used to confirm that moveable shields remain in place during the treatment.

j. Indicate the instrument/probe used for conducting leak tests of sealed sources and wipe tests of facilities.

k. If performing in-house calibrations for research and irradiator instruments, describe the source(s) used. Also, provide the names and training of personnel calibrating instruments and describe calibration facilities, including shielding.

5. Please provide the training method, frequency, and assessment method for your research training program.

6. With regard to your HDR program, please provide the following:

a. Confirm that Authorized Users (AU's) and Authorized Medical Physicist (AMP's) will receive HDR vendor training, including a drill of emergency response procedures, prior to first clinical use.

b. Confirm that daily spot-checks of the HDR includes ensuring that the source retracts when the door interlock is triggered. Additionally, confirm that the prime alert on the bunker wall is checked with a check source after completion of the dwell position.

c. Confirm that the HDR emergency equipment includes wire cutters and a suture removal kit.

d. Confirm that the calculated decayed source activity is confirmed to be within +/- 1-2% of that in the unit's computer.

e. It appears that a simulator may be located in the same treatment room as the HDR. Describe your procedural mechanism or engineering control in place to ensure that the two units are not used at the same time.

f. Attachment 10.6 provides names of personnel licensed by Nucletron performing installation, maintenance, repair, etc. of the HDR. This document was not required to be submitted and was not reviewed. If you require HUMC personnel to perform these types of services on your HDR, please describe the use requested and provide the names and training documentation for all personnel requested.

g. Please confirm that the HDR source will only be used for medical treatment when it is less than 10 curies in accordance with FDA requirements.

h. Indicate whether you would like to limit the total possession of the Ir-192 sources to below those referenced in security orders (e.g., 21 curies: two sources, one source not to exceed 13 curies and one source not to exceed 8 curies).

I. Please confirm your Emergency Procedures for the HDR system will include the names and telephone numbers of AU's, AMP's, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally. In addition, please note that 10 CFR 35.610 requires, in part, that all device operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

7. With regard to your low dose-rate manual brachytherapy and radiopharmaceutical therapies performed in-house, please confirm that the 4th Floor patient rooms are surveyed to ensure compliance with 10 CFR Part 20 limits when therapeutic patients are housed on the 3rd Floor.

8. If licensed materials are to be used in animals, please submit:

a. a description of the animal housing facilities,

b. a description of the training that will be provided to individuals caring for animals containing licensed materials, and

c. a copy of the instructions provided to animal caretakers for handling of animals, animal waste carcasses, and cleaning and decontamination of animal cages.

Appendix H of NUREG-1556, Volume 7 addresses considerations for laboratory animal uses and may be helpful to you in developing a response.

9. With regard to your self-shielded irradiator:

   a. Describe non-routine maintenance performed by HUMC staff and provide supporting documentation in accordance with Appendix I of NUREG - 1556, Vol. 5. This document can be found at: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v5/

   b. Confirm that irradiator AU's will receive training in accordance with Appendix G of NUREG-1556, Vol. 5.

10. For your intravascular brachytherapy (IVB) system, please confirm that you will follow all of the requirements in 10 CFR Part 35 for brachytherapy and manual brachytherapy use. Also confirm that you will follow items a-k listed below (you may repeat or paraphrase each of them):

   a. The authorized user, interventional cardiologist/physician, and authorized medical physicist will receive the vendor training for use of the device.

   b. Procedures will be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and authorized medical physicist before initiating treatment. The procedures will be conducted in the physical presence of the authorized user or the authorized medical physicist.

   c. The written directive will, before treatment, specify treatment site, the radionuclide, and dose.

   d. The authorized medical physicist will perform independent measurement of source output, before the first patient treatment, using a dosimetry system that meets the requirements of 10 CFR 35.630(a).

   e. You will develop, implement, and maintain written emergency procedures for both stuck and detached sources, including the provision of appropriate emergency response equipment and any appropriate surgical procedures.

   f. You will survey the patient and IVB treatment catheter immediately following source retraction or removal to confirm complete retraction of the source(s) as specified in 10 CFR 35.404.

   g. In order to protect the radiation safety of patients and to reduce the risk of a medical event, an introducer sheath will be used unless such use is contraindicated for an individual patient.

   h. In order to protect the radiation safety of patients and to reduce the risk of a medical event, a dual syringe system will be used.

   I. "Source stepping" is permitted, if you establish appropriate procedures in writing. Source stepping procedures are not covered by the manufacturers' instructions.

j. You will provide locked storage of the storage container in a secure location.

k. The device will be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair will be performed only by the manufacturer or persons specifically licensed by NRC or an Agreement State to perform such services.

Please note that Novoste strontium-90 source is now produced by Best Medical International, Inc.

11. For your GliaSite brachytherapy system, please confirm that you will follow all of the requirements in 10 CFR Part 35 for brachytherapy and manual brachytherapy use, except where the items a-h listed below provide regulatory relief. Provide your procedures that specify how to confirm that the balloon does not leak prior to injection of the Iotrex or while Iotrex is implanted in the patient. Also confirm items a-g listed below (you may repeat or paraphrase each of them):

a. "Prescribed dose" means the total dose documented in the written directive.

b. The written directive will include two sections:

(1) prior to implantation: the treatment site, the radionuclide (including the chemical/physical form [Iotrex]), and dose; and

(2) after implantation but before completion of the procedure: the treatment site, the radionuclide (including the chemical/physical form [Iotrex]), and the total dose.

c. An authorized user with experience in radiopharmaceutical therapy procedures will be on call to provide guidance in case of leakage of the implanted device.

d. Source leakage for Iotrex implanted in the GliaSite RTS means leakage of I-125 that results in a dose that exceeds 50 rem dose equivalent to any organ other than the treatment site (based on the definition of a medical event).

e. You will retain a record of each leak test for three years (the period that 10 CFR 35.2067 requires for brachytherapy sources).

f. You will report a leaking source to the NRC within five days of the leakage test to the locations specified and provide the information identified in 10 CFR 35.3067.

g. You will provide instructions on how to safely handle contamination of unsealed materials, in addition to the instructions required by 10 CFR 35.410, "Safety instructions."

h. You will label syringes and syringe radiation shields with the radioisotope, form, and therapeutic procedure (i.e., I-125 Iotrex™ for brain brachytherapy), and you

will label vials and vial radiation shields with the radioisotope and form (i.e., I-125 Iotrex™).

12. With regard to your IVB Ir-192 intravascular brachytherapy sealed sources, please provide the transfer records and confirmation of receipt from the vender.

Please note that the following documents were not required to be submitted and they were not reviewed as part of your renewal: 1) in-service education documents for medical uses; 2) Appendices J, M, R, T, N and W (referred to as Attachments 10.2, 10.3, 10.4, 10.5, and 11.1) of NUREG1556 Vol.9.; 3) Appendix O of NUREG 1556 Vol.7; and 4) Quarterly quality assurance tests of the high dose rate remote afterloader.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Industrial, and Academic Uses of Nuclear Material;** then **Toolkit Index Page.** Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 138022. If you have any technical questions regarding this deficiency letter, please call Shirley Xu at (610) 337-5006.

In order to continue prompt review of your application, we request that you submit your response to this letter within 15 calendar days from the date of this letter.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
Eric Weiss, Radiation Safety Officer

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