

Essex Heart Group, LLC
62 South Fullerton Street
Montclair, New Jersey 07042

October 25, 2007

NMSB

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License Assistance Section
Nuclear Medicine Safety Branch
Division of Radiation Safety & Safeguards
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

03036303

RE: Essex Heart Group - Amendment Request
License Number: 29-30829-01

Dear License Reviewer:

Please amend our byproduct material license to name Harold Jason Kim, M.D. as an authorized user for all procedures and materials approved on our current license. In addition, we request that Dr. Kim be named as the radiation safety officer. Dr. Kim will replace Dr. Blood in this capacity.

Dr. Kim is currently listed as the radiation safety officer and authorized user for North Shore Medical Specialists, P.C. (New York State License Number: 5226). A copy of this license is provided within Attachment A. Please refer to this section for training and experience confirmation.

All remaining items referenced on our byproduct material license are to remain unchanged.

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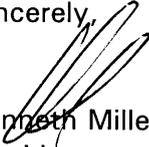
NMSS/RGN1 MATERIALS-002

If you have additional questions regarding this licensing request, please contact Michael W. Lairmore or myself. Mr. Lairmore may be reached at (201) 693-2277.

We thank you in advance for your assistance with this pending licensing action.

Any assistance you may provide in expediting this amendment request is greatly appreciated.

Sincerely,



Kenneth Miller, M.D.
President

Attachment A

**NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE**

Pursuant to the Public Health Law and Part 16 of the New York State Sanitary Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing radioactive material(s) for the purpose(s), and at the place(s) designated below. The license is subject to all applicable rules, regulations, and orders now or hereafter in effect of all appropriate regulatory agencies and to any conditions specified below.

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- | | |
|---------------------------------------------------------------|---------------------------------------|
| 1. Name | 3. License Number |
| North Shore Medical Specialties, P.C. | 5226 |
| 2. Address | 4. a. Effective Date |
| 1 Hollow Lane, Suite 312
Lake Success, New York 11042 | November 2, 2005 |
| Attention: Harold Jason Kim, M.D.
Radiation Safety Officer | b. Expiration Date |
| | November 2, 2015 |
| | 5. Reference Number
DII No. 05-310 |
-
- | | | |
|--------------------------------------------------|-------------------------------------|------------------------------------------------------------|
| 6. Radioactive Materials
(element & mass no.) | 7. Chemical and/or
Physical Form | 8. Maximum quantity
licensee may possess
at one time |
| A. Technetium 99m | A. Any | A. 1,000 millicuries
(all forms combined) |
| B. Thallium 201 | B. Thallous Chloride | B. 50 millicuries |
9. Authorized use (unless otherwise specified, the authorized place of use is the licensee's address stated in Item 2, above).
- A. and B. Determination of cardiac function and muscle viability.

**NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE**

CONDITIONS

License No. 5226

10. A. Radioactive material listed in Item 6 shall only be used by:
Harold Jason Kim, M.D.
- B. Radioactive materials listed in Item 6 shall be used by Harold Jason Kim, M.D., as appropriate to fulfill the responsibilities of the Radiation Safety Officer.
11. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license, in accordance with statements, representations, and procedures contained in the documents (including any enclosures) listed below:
- A. Application for New York State Department of Health Radioactive Materials License dated July 5, 2005, signed by Barton Cohen, M.D.
- B. Letter dated September 9, 2005, signed by Barton E. Cohen, M.D.
- The New York State Department of Health's regulations shall govern the licensee's statements in applications or letters unless the statements are more restrictive than the regulations.
12. A. Radioactive material shall be stored in a locked facility in the original shipping container, or a container providing equivalent radiation protection. Such a facility may be a cabinet, a safe, or a room, providing the facility is locked at all times when no activities are in progress relating to the use of the radioactive material. This includes periods of brief absence of personnel from a nuclear medicine department, laboratory, etc., where radioactive materials are used or stored.
- B. Radioactive materials shall not be stored in the same facilities with materials which might substantially increase the fire or explosion hazard of the storage space and its radioactive contents.
13. A. Transportation of licensed radioactive material shall be subject to all regulations of the U.S. Department of Transportation and other agencies of the United States having jurisdiction insofar as such regulations relate to the packaging of radioactive material, marking and labeling of the packages, loading and storage of packages, monitoring requirements, accident reporting, and shipping papers.

**NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE**

CONDITIONS

License No. 5226

13. B. Transportation of low level radioactive waste shall be in accordance with the regulations of the New York State Department of Environmental Conservation as contained in 6 NYCRR Part 381.
14. The licensee shall have available an appropriate survey meter which shall be maintained operational and shall be calibrated before initial use and at subsequent intervals not exceeding twelve months by person(s) specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. Records of all calibrations shall be kept a minimum of five years.
15. Leak tests of sealed sources shall be performed in accordance with Section 16.10 (a)(4), New York State Sanitary Code (10 NYCRR 16). Off-site analysis of leak test samples shall be performed by persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. On-site analysis of leak test samples shall be in accordance with procedures approved by the Department.
16. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash, provided:
 - A. Affected radioactive waste shall be held for decay a minimum of ten half-lives.
 - B. Prior to disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels will be removed or obliterated.
17. The licensee shall not administer technetium-99m to patients if the technetium-99m contains more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.
18. A. The licensee shall not release any licensed radioactive materials into the environment except as allowed by the New York State Department of Environmental Conservation.
 - B. Before use or disposal of any licensed radioactive material in a manner that could result in discharge or release to the environment, the licensee shall obtain from the New York State Department of Environmental Conservation either:

**NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE**

CONDITIONS

License No. 5226

18. B. i) A valid permit, or
ii) A letter stating that no permit is required.
C. The licensee shall maintain the letter or valid permit required in paragraph B of this condition on file for the duration of the license and make such letter or permit available for inspection by the Department upon request.
19. The licensee shall submit complete decontamination procedures to the Department for approval ninety (90) days prior to the termination of operations involving radioactive materials in any restricted area.
20. Plans of facilities which the licensee intends to dedicate to operations involving the use of radioactive material shall be submitted to the Department for review and approval prior to any such use.
21. The licensee shall maintain records of information important to safe and effective decommissioning at the location listed in License Condition No. 2, and at other locations as the licensee chooses. The records shall be maintained until this license is terminated by the Department and shall include:
- A. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site;
- B. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination, such as buried pipes which may be subject to contamination;
- C. Records of the cost estimate performed for the decommissioning funding plan or the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.
22. The licensee may receive, possess and use calibration and reference standards in accordance with section 16.123(e) of 10 NYCRR Part 16.

**NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE**

CONDITIONS

License No. 5226

23. Nuclear Medicine Technologists who meet the criteria of 10 NYCRR 16.123(a)(3)(i) may perform parenteral injections of radioactive materials for diagnostic purposes under the supervision of a physician on the premises. Prior to allowing parenteral administration by a nuclear medicine technologist, the Radiation Safety Officer shall insure that the technologist is competent in the performance of parenteral administration. Records of this approval must be retained as long as the Nuclear Medicine Technologist is working under the license.

FOR THE NEW YORK STATE DEPARTMENT OF HEALTH

Date: **NOV - 2 2005**
RD/JC:jmf/ks

By Robert E. Dansereau
Robert E. Dansereau, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

This is to acknowledge the receipt of your letter/application dated

10/25/2007, and to inform you that the initial processing which includes an administrative review has been performed.

AMCWA. 29-30829-01
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 141276.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.