

SCHOOL OF
OSTEOPATHIC
MEDICINE

University of Medicine & Dentistry of New Jersey

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November 1, 2006

Penny Henderson
U.S. Nuclear Regulatory Commission
Medical Branch
Division of Nuclear Safety
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

Br. 1

03013606
RE: License No. 29-17895-01 Contact # 610-337-5269

Dear Ms Henderson:

We respectfully submit this correspondence to request that Dr. Valery Kalika, MD be added to our NRC License for the materials use described:
10 CFR 35.100; 10CFR 35.200

Dr. Kalika is included on our New Jersey State Radioactive Materials License and is approved for materials in the following groups:

Group I, Section 4.7 of NJAC 7:28-4

Group II, Section 4.7 of NJAC 7:28-4

Group III Section 4.7 of NJAC 7:28-4

CO-57 Sealed Source

Ralph Cavallone BSRT
Director of Imaging Services

Joseph S. Orlando
President & Chief Executive Officer

139649
NMSS/RGNI MATERIALS-C02

State of New Jersey

Department of Environmental Protection

Bureau of Environmental Radiation

Radioactive Materials Section

PO Box 415, Trenton, NJ 08625-0415

Phone (609) 984-5462

License No.: NJSL-70119/01/032

Amendment No.: 032

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New Jersey Radioactive Materials License

Pursuant to the New Jersey Radiation Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, use the naturally occurring and/or accelerator produced material(s) (NARM) designated below; and to such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the State Department of Environmental Protection, now or hereafter in effect, and to any conditions specified below.

1. License No. NJSL-70119/01/032	2. Expiration Date 03/31/2007
3. Licensee: BARNERT MEMORIAL HOSPITAL	4. Address: 680 Dr. Martin Luther King Jr Way
Radiation Safety Officer: Valery Kalika, M.D.	Paterson NJ 07614-0000
Administrator: Joseph Orlando	County: Passaic Telephone: (973) 977-6662
	SP Reference No.: 2500

RADIOACTIVE MATERIALS DATA (A)

6. Material	7. Limit (mCi)	8. Form
A. Any NARM included under Group I, Section 4.7 of NJAC 7:28-4.	5,000	Any radiopharmaceutical included under Group I, Section 4.7 of NJAC 7:28-4.
B. Any NARM included under Group II, Section 4.7 of NJAC 7:28-4.	300,000	Any radiopharmaceutical included under Group II, Section 4.7 of NJAC 7:28-4.
C. Any NARM included under Group III, Section 4.7 of NJAC 7:28-4.	300,000	Any radiopharmaceutical included under Group III, Section 4.7 of NJAC 7:28-4.
D. CO-57	25,000	Sealed Source

RADIOACTIVE MATERIALS DATA (B)

9. Authorized Use
A. Any diagnostic procedure under Group I of NJAC 7:28-4, Section 4.7
B. Any diagnostic procedure under Group II of NJAC 7:28-4, Section 4.7
C. Preparation and use of radiopharmaceuticals for any diagnostic procedure under Group III of NJAC 7:28-4, Section 4.7
D. Reference and/or calibration source.

Conditions begin on the following page.

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10. Radioactive material shall only be used at 680 Broadway, Paterson, New Jersey.

11. Radioactive material listed in items 6A - 6D shall be used by or under the supervision of the following:

Joel S. Cooperman, M.D.
Stuart C. Moses, M.D.
Daniel Levy, M.D.

Patrick J. Hines, M.D.
Orestes Sanchez, M.D.
Corey Weiner, M.D.

Valery Kalika, M.D.

12. Compliance with other U.S. Agencies having jurisdiction and regulations for radiopharmaceuticals must be maintained.

13. The licensee shall retain records of misadministrations in the use of the licensed radioactive materials. Misadministrations being defined as a radiopharmaceutical or radiation from a sealed source which is improperly used as follows:

- A. Administration of the wrong radiopharmaceutical or sealed source.
- B. Administration to the wrong patient.
- C. Administration by a route other than that intended by the prescribing physician.
- D. Administered diagnostic dose differing by more than 50 percent of the prescribed dose.
- E. Administered therapeutic dose differing by more than 10 percent of the prescribed dose.

Records of misadministrations shall include the following information: name of the referring physician, description of the event, the effect on the patient and the action taken to prevent recurrence.

14. The licensee shall not open sealed sources containing radioactive material.

15. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months.

- A. The test shall be capable of detecting the presence of 0.005 microcuries of removable radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surface of the device in which the sealed source is permanently mounted or stored.
- B. If the test reveals the presence of 0.005 microcuries of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with the Department regulations. Within five days after obtaining results of the test, a report shall be filed with the Department describing the circumstances, the test results and the corrective action taken.
- C. The sealed sources shall be tested for leakage and/or contamination by appropriately trained personnel.

16. Repair, initial leak tests and disposal of sealed sources containing radioactive material shall be performed only by the manufacturer or by other persons specifically licensed by New Jersey or the Federal Government to perform this service.

17. Radioactive material with a physical half live of less than 300 days may be disposed of as non-radioactive waste provided that (a) the radioactive waste is stored behind adequate shielding to meet the requirements of New Jersey Radiation Code 28-6, (b) the radioactive waste is held for ten half-lives of the longest lived radioisotope to be disposed of, (c) the radioactive waste is monitored with a GM meter prior to disposal to insure background levels, (d) all radiation labels are removed or obliterated and (e) a log shall be maintained to include the results of the radiation survey and date of disposal.

18. A survey of the administration area used for stress thallium studies shall be performed and documented on the day the test is done.

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19. In laboratory areas where small quantities of radioactive materials are used (i.e. less than 200 microcuries):
- Monthly surveys of areas are to be performed and the results documented.
 - Monthly wipe test of areas are to be performed and the results documented.
 - Protective gloves are to be worn by individuals handling radioactive material.
 - Decayed radioactive waste will be surveyed prior to disposal to ensure background levels.
 - Radioactive material symbols shall be removed and/or obliterated from all containers no longer containing material prior to disposal.
20. The licensee shall make the following items available to their staff:
- Copy of the New Jersey Radiation Protection Code.
 - Copy of the New Jersey State Radioactive Material License.
21. The licensee shall post the following items in an area frequented by employees engaged in the use of licensed materials:
- Notice to employees - RPP-14.
 - Emergency procedures involving major, minor spills including the names and phone numbers of people to contact.
 - Appropriate signs and labels in areas and/or containers and equipment in which radiation and/or radioactive material are contained. These postings are to conform to Subchapter 10 of the Code.
22. The following tests shall be performed as a minimum:
- Surveys of:
 - All radioactive materials received.
 - All radioactive waste decayed to background levels prior to release.
 - Uncontrolled areas where sealed and unsealed sources are routinely used to be surveyed on days they are used.
 - Controlled area, where sealed and unsealed sources are used on days they are used.
 - Personnel at the end of the day.
 - Wipe tests of:
 - Controlled and uncontrolled area where unsealed sources of radioactive material are routinely used, weekly.
23. The following records shall be maintained:
- Radioactive materials received including but not necessarily limited to date of receipt, radionuclide, activity, mass or volume of material, results of package survey, instrument used for surveys and surveyor's initials.
 - Radioactive materials administered to patients including but not necessarily limited to date of administration, radionuclide, calibrated activity administered, quantity, patient name, administrator's signature.
 - Radioactive material disposals including but not necessarily limited to:
 - Disposals to Vendor: nuclide, activity, vendor name, quantity, date of disposal.

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2. Disposal by Decay: Results of survey of the waste, date of survey, date of waste disposal, instrument used, and surveyor's initials.
3. Disposal to Sanitary Sewer: nuclide, activity, volume of dilution waste per day, date of disposal.
- D. Survey instrument calibration performed annually and after instrument repair.
- E. Sealed source leak tests at intervals not to exceed six months. Results are to be reported in microcuries.
- F. Surveys performed in controlled and uncontrolled areas including but not necessarily limited to: test results in mR/hr, date performed, instrument used and surveyor's initials.
- G. Wipe tests performed in controlled and uncontrolled areas including but not necessarily limited to: test results in dpm, date performed, instrument used and surveyor's initials.
- H. Personnel dosimetry records including but not necessarily limited to: name, social security number, and prior employment exposure history.
- I. Daily personnel monitoring results including but not necessarily limited to: instrument used, date performed and initials.
24. Protective equipment and clothing including but not necessarily limited to syringe shields, remote handling equipment, adequate shielding, laboratory coats, and disposable gloves shall be used by personnel while utilizing radioactive material.
25. Eating, drinking, smoking and applying cosmetics shall not be permitted in controlled areas.
26. Except as specifically provided by this license, the licensee may possess and use radioactive material described in this license in accordance with statements, representations and procedures contained in the New Jersey Radioactive Materials License Application dated March 26, 2002 by Stephen M. Patz.
 - A. Letter dated February 28, 2002
 - B. Letter dated February 28, 2003
 - C. Letter dated April 1, 2004
 - D. Letter dated January 11, 2006
 - E. Letter dated February 1, 2006

New Jersey Department of Environmental Protection Signature

Date:

2/6/06

By:

William P. Cooney
For the NJ Department of Environmental Protection

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

11/1/2006, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment 29-17895-01 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 139649.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.