

Suketu Nanavati, MD, F.A.C.C.
Cardiology - Internal Medicine
Cape Heart Clinic
#2 Village Drive

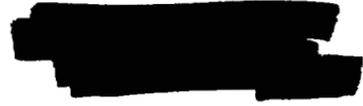
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Cape May Court House, NJ 08210
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29-28684-02
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FAX

DATE: 4-13-05



TO : Dennis Lawyer

FROM: Dr. Pean

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NMSS/RONI MATERIALS-002



State of New Jersey
Department of Environmental Protection

Richard J. Codey
Acting Governor

Bradley M. Campbell
Commissioner

Bureau of Environmental Radiation
Radioactive Materials Section
Phone (609) 984-5462
PO Box 415, Trenton, NJ 08625-0415

March 14, 2005

Suketu Nanavati, M.D.
CAPE HEART CLINIC
2 Village Drive,
Cape May Court House, NJ 08210

SUBJECT: New Jersey State License for Radioactive Material

Dear Dr. Nanavati:

Enclosed is Amendment No.004 amending New Jersey Radioactive Materials License No. NJSL-20685/01 in its entirety.

This license contains conditions affecting the use of radioactive materials. Please review each condition carefully.

Although the Bureau has made a determination that your use of radioactive materials will not constitute a hazard to health and safety, it is the Licensee's responsibility to maintain compliance with the New Jersey Radiation Protection Code.

Should you have any questions regarding your license, please contact me at (609) 984-5462. Thank you for your cooperation.

Sincerely,

A handwritten signature in cursive script that reads "William P. Csaszar".

William P. Csaszar, License Administrator
Radioactive Materials Section

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 Amendment No.: 004
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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

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 or 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-20685/01/004	2. Expiration Date: 09/30/2009
3. Licensee: CAPE HEART CLINIC	4. Address: 2 Village Drive Cape May Court House NJ 08210
Radiation Safety Officer: Suketu Nanavati, M.D.	County: Cape May Telephone: (609) 465-7517
Administrator: Suketu Nanavati, M.D.	5. Reference No.: 400

RADIOACTIVE MATERIALS DATA (A)

6. Material	7. Limit (mCi)	8. Form
A. Any naturally occurring and/or accelerator produced material included under Group II, Section 4.7 of NJAC	100.0000	Any radiopharmaceutical included under Group II, Section 4.7 of NJAC 7:28-4.
B. CO-57	30.0000	Sealed Source

RADIOACTIVE MATERIALS DATA (B)

9. Authorized Use
A. Any diagnostic procedure under Group II of NJAC 7:28-4, Section 4.7
B. For calibrating and checking of instruments.

Conditions begin on the following page.

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New Jersey Radioactive Materials License

10. Radioactive material shall only be used at Cape Heart Clinic, 2 Village Drive, Cape May Court House, Cape May, New Jersey.
11. Radioactive material listed in Conditions 6, 7, and 8 shall be used by or under the supervision of the following: Suketu Nanavati, M.D. and Jules Pean, 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 are to 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 life 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.
19. The licensee shall make the following items available to their staff:
 - A. Copy of the New Jersey Radiation Protection Code.

New Jersey Radioactive Materials License

B. Copy of the New Jersey State Radioactive Material License.

20. The licensee shall post the following items in an area frequented by employees engaged in the use of licensed materials:

- A. Notice to Employees -- RPP-14.
- B. Emergency procedures involving major/minor spills including the names and phone numbers of people to contact.
- C. 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.

21. The following tests shall be performed as a minimum:

A. Surveys of:

1. All radioactive materials received.
2. All radioactive waste decayed to background levels prior to release.
3. Controlled areas, where licensed materials are used on days they are used.
4. Uncontrolled areas, where licensed materials are used on days they are used.
5. Personnel who handle radioactive materials when radioactive materials are used.

B. Wipe tests of:

1. Controlled areas, weekly, where unsealed sources of licensed materials are used during weeks the material is used.

22. The following records shall be maintained:

- A. 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.
- B. Radioactive materials administered to patients including but not necessarily limited to date of administration, radionuclide, calibrated activity administered, quantity, patient name, administrator's signature.
- C. Radioactive material disposals including but not necessarily limited to:
 1. Disposals to Vendor: nuclide, activity, vendor name, quantity, date of disposal.
 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 areas including but not necessarily limited to: test results in dpm, date performed, instrument used and surveyor's initials.

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- 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.
- 23. While utilizing radioactive material, personnel shall use protective equipment and clothing including but not necessarily limited to: syringe shields, remote handling equipment, adequate shielding, laboratory coats and disposable gloves.
- 24. Eating, drinking, smoking, and applying cosmetics shall not be permitted in controlled areas.
- 25. This license is based on the licensee's statements and representations listed in:
 - A. New Jersey Radioactive Materials License Renewal Certification dated June 10, 2004 signed by Suketu Nanavati, M.D.
 - B. Letter dated January 21, 2005

New Jersey Department of Environmental Protection Signature

Date: 3/24/05 By: William P. George
For the NJ Department of Environmental Protection

