



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

April 21, 2005

Docket No. 03035478
Control No. 136538

License No. 29-28684-02

Suketu Nanavati, M.D.
Cape Heart Clinic
2 Village Drive
Cape May Court House, NJ 08210

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION
FOR AMENDMENT TO LICENSE, CONTROL NO. 136538

Dear Dr. Nanavati:

This is in reference to your letter dated February 17, 2005 requesting to amend Nuclear Regulatory Commission License No. 29-28684-02. In order to continue our review, we need the following additional information:

In support of your request to authorize Dr. Jules Pean for materials permitted under 10 CFR 35.200, please provide one of the following, as applicable:

- a. Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an authorized user for the uses requested; **(On the request letter, dated February 17, 2005, it stated that Dr. Jules Pean was an authorized user under Kentucky license #202-257-24. However, upon obtaining a copy of the Kentucky license, Dr. Pean was not an authorized user. The New Jersey State license NJSL-20685/01/004 faxed to us is insufficient as New Jersey is not an Agreement State and uses different types of radionuclides.)** or
- b. Copy of the certification(s) for the board(s) recognized by NRC under 10 CFR Part 35, Subparts D, E, F, G, or H, and as applicable to the use requested; or
- c. Description of the training and experience identified in 10 CFR Part 35 Subpart J demonstrating that the proposed authorized user is qualified by training and experience for the use requested; or
- d. Description of the training and experience identified in 10 CFR Part 35 Subparts D, E, F, G, or H demonstrating that the proposed authorized user is qualified by training and experience for the use requested; and

- e. Written certification, signed by a preceptor physician authorized user, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an authorized user for the medical uses authorized has been achieved; **(The preceptor physician statement, enclosed with the letter dated, February 17, 2005, was insufficient in that it did not discuss classroom training)** and
- f. If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

It is **highly recommended** that NRC Form 313A (enclosed) is used to submit Dr. Pean's training and experience along with all supporting documentation to facilitate a quicker review process. Please note that if the board certification, or training and experience, was received more than 7 years ago, evidence of recentness of training in accordance with 10 CFR 35.59 must also be submitted.

Current NRC regulations and guidance are available at the NRC Web sites listed below or 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. 136538. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5303.

If we do not receive a reply from you **within 10 calendar days** from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original signed by Thomas K. Thompson

Thomas K. Thompson
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
NRC Form 313A

NRC Web site addresses
NRC regulations

<http://www.nrc.gov/reading-rm/doc-collections/cfr/>

Licensing guidance

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>

General Policy and Procedure for NRC Enforcement Actions

[Http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf](http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf)

206 of the Energy Reorganization Act of 1974

<http://www.nrc.gov/who-we-are/governing-laws.html>

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