J-6

CARDIAC DIAGNOSTIC SERVICES OF VIRGINIA

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45-25533-01
03035466

TELECOPY COVER SHEET

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Date: 10/8/08 Time: 1:18 pm

To: Dennis Lawyer

From: N. Christian Smarte control # 142632

Fax Number: 610-377-5269

Total number of pages, including cover sheet: 11

[redacted]

REMARKS:

Dennis,
Here is the
corrected 313A
control # 142632
My numbers are
301-580-5328 or 703-641-0500
Chris Smarte

443-247-0582
142632

NRC FORM 313A (AUD) (3-2007) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User	State or Territory Where Licensed
Michael Notarianni, M.D.	Virginia

Requested Authorization(s) *(check all that apply)*

- ☐ 35.100 Uptake, dilution, and excretion studies
- ☑ 35.200 Imaging and localization studies
- ☐ 35.500 Sealed sources for diagnosis (specify device _____)

PART I – TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ 1. **Board Certification**

a. Provide a copy of the board certification.

b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

☐ 2. **Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.

b. Supervised Work Experience.
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			

Total Hours of Experience:

Supervising Individual	License/Permit Number listing supervising individual as an authorized user

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check all that apply)*.

☐ 35.290 ☐ 35.390 + generator experience in 32.290(c)(1)(ii)(G)

NRC FORM 313A (AUD) (9-2007) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. **Training and Experience for Proposed Authorized User (continued)**

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages	Beth Israel Deaconess Medical Center Boston, Mass Mass. Radiation Control Program #600432	☑ Yes ☐ No	July 1996-1997
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Beth Israel Deaconess Medical Center Boston, Mass Mass. Radiation Control Program #600432	☑ Yes ☐ No	July 1996-1997
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Beth Israel Deaconess Medical Center Boston, Mass Mass. Radiation Control Program #600432	☑ Yes ☐ No	July 1996-1997
Administering dosages of radioactive drugs to patients or human research subjects	Beth Israel Deaconess Medical Center Boston, Mass Mass. Radiation Control Program #600432	☑ Yes ☐ No	July 1996-1997
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs	Beth Israel Deaconess Medical Center Boston, Mass Mass. Radiation Control Program #600432 per Dr. Thomas Hauser + Rosemary Kennedy, RSO BIDMC	☑ Yes ☐ No RSO	July 1996-1997

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Mylan C. Cohen, MD T. Hauser	Mass. Radiation Control Program #600432

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check one)*.

☐ 35.190 ☑ 35.290 ☐ 35.390 ☐ 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

NRC FORM 313A (AUD)
(5-2007)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☑ 3. **Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	St. Elizabeth's Medical Center of Boston 736 Cambridge Street, Boston, Mass. 02135	40 hours	January to March 1997
Radiation protection	St. Elizabeth's Medical Center of Boston 736 Cambridge Street, Boston, Mass. 02135	40 hours	January to March 1997
Mathematics pertaining to the use and measurement of radioactivity	St. Elizabeth's Medical Center of Boston 736 Cambridge Street, Boston, Mass. 02135	40 hours	January to March 1997
Chemistry of byproduct material for medical use *(not required for 35.590)*	St. Elizabeth's Medical Center of Boston 736 Cambridge Street, Boston, Mass. 02135	40 hours	January to March 1997
Radiation biology	St. Elizabeth's Medical Center of Boston 736 Cambridge Street, Boston, Mass. 02135	40 hours	January to March 1997
Total Hours of Training: 200 hours			

b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervised Work Experience | **Total Hours of Experience:**

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	Beth Israel Deaconess Medical Center Boston, Mass Mass. Radiation Control Program #600432	☑ Yes ☐ No	July 1996-1997
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Beth Israel Deaconess Medical Center Boston, Mass Mass. Radiation Control Program #600432	☑ Yes ☐ No	July 1996-1997

NRC FORM 313A (AUD) (3-2007) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

First Section
Check one of the following for each use requested:

For 35.190

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

☑ I attest that Michael Notariani,M.D has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section
Complete the following for preceptor attestation and signature:

☑ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☐ 35.190 ☑ 35.290 ☐ 35.390 ☐ 35.390 + generator experience

Name of Preceptor	Signature	Telephone Number	Date
Thomas Hauser, MD		(617) 667-8800	25 Aug 2008

License/Permit Number/Facility Name
Commonwealth of Massachusetts Radiation Control Program # 800432

FAX

To	Chris Sharpe	**Fax Number**	1 703 204 9056
From	Rosemary Kennedy	**Date**	October 8, 2008
Department	Radiation Safety	**Total pages C +**	5

Comments [click here and begin typing message]

This document may contain information that is privileged, CONFIDENTIAL and exempt from disclosure under applicable law. If you are not the intended recipient, please notify me immediately, as the use of this information is strictly prohibited.

Radiation Safety Office, KSB-324
Beth Israel Deaconess Medical Center, Boston, MA 02215

617 667-2038 (office)
617 667-4320 (fax)

DEACONESS HOSPITAL RADIATION SAFETY OFFICE

RADIOISOTOPE PERMIT

DATE OF PERMIT 06/02/93

INVESTIGATOR: HILL
THOMAS

PERMIT NUMBER: 6
INCEPTION DATE: 09/01/70
Expiration Date: 01/31/95

Department: NUCLEAR MEDICINE

Location: BAKER 2

Users: LONGMAID,CONNOLLY,EMOND,CARROLL
HOLMES,BERTUCCI,RINALDI,STUDENTS
COHEN-NUC.CARD.06/16/93

INSTRUMENTS

Instrument: LUD 3 #58716; #22453 Probe: GM #47046;SCIN#96628
Ion Chamber: KEITHLEY #33525

SPECIAL AUTHORIZED USES

1. DIAGNOSTIC CLINICAL NUCLEAR MEDICINE-PROCEDURES IN 10CFR35 HUMAN USE
2. HUMAN-DR.RAND AT JDC-I-125 IOTHALAMATE 0.035 MICROCURIE/PATIENT-06/10/87

SPECIAL CONDITONS

[***]TRAINING [***]INSTRUMENTS [***]BADGE [***]RING [ ]ANIMALS [***]THYROID
[ ]BIOASSAY [***]SHIELDS [***]OTHER-CHECK SOURCE(2)

RADIOISOTOPE	FORM	MAXIMUM AMOUNT	DATE
CS-137	CALIBRATION - NUCLEAR CHIC	0.01 mCi	03/01/64
CS-137	CALIBRATION - CAPINTEC	0.10 mCi	03/01/72
CS-137	CALIBRATION - PICKER	0.01 mCi	01/01/74
BA-133	CALIBRATION - NEN-294	0.26 mCi	02/01/77
CO-60	CALIBRATION - NEN-294	0.05 mCi	02/01/77

DEACONESS HOSPITAL RADIATION SAFETY OFFICE

RADIOISOTOPE PERMIT

DATE OF PERMIT 06/02/93

BA-133	CALIBRATION - NEN-358	0.27 mCi	05/01/81
CO-60	CALIBRATION - NEN-354	0.05 mCi	11/01/83
C-14	NITRENDIPINE	2.00 mCi	10/09/85
CS-137	CALIBRATION - NEN - ROD	0.01 mCi	11/01/85
CO-60	CALIBRATION - NEN-1425	0.01 mCi	02/01/86
BA-133	CALIBRATION - NEN-358	0.01 mCi	09/01/86
BA-133	CALIBRATION - NEN-1385	0.01 mCi	10/01/86
I-131	CAPSULE	20.00 mCi	01/01/87
MO-99	GENERATOR	3000.00 mCi	01/01/87
TC-99M	GENERATOR	2000.00 mCi	01/01/87
CO-57	CALIBRATION - S206045-003	5.40 mCi	03/01/90
GA-67	ANY	75.00 mCi	03/19/91
I-123	ANY	80.00 mCi	03/19/91
IN-111	ANY	10.00 mCi	03/19/91

DEACONESS HOSPITAL RADIATION SAFETY OFFICE

RADIOISOTOPE PERMIT

DATE OF PERMIT 06/02/93

SE-75	ANY	10.00 mCi	03/19/91
XE-133	GAS	30.00 mCi	03/19/91
CO-57	CALIBRATION - CIS-789	10.00 mCi	10/01/91
CO-57	CALIBRATION - NUCLEAR MED	0.12 mCi	11/18/91
CO-57	CALIBRATION NUC.ASS.#624	0.15 mCi	11/06/92
CO-57	CALIBRATION NENS8121011-003	4.00 mCi	03/08/93
CO-57	CALIBRATION NEN S8120011	0.50 mCi	03/08/93

MAXIMUM TOTAL ACTIVITY 5247.96 mCi

New England Deaconess Hospital

185 Pilgrim Road
Boston, Massachusetts 02215
(617) 732-8460
Fax (617) 738-4942

DEPARTMENT OF RADIOLOGY

Affiliated with
Harvard Medical School

Thomas C. Hill, M.D.
Director, Nuclear Medicine
Associate Professor of Radiology
Harvard Medical School

To Whom it May Concern:

This letter is to affirm that Mylan C. Cohen, M.D. gained clinical experience at our institution in nuclear cardiology. The preceptorship began July 1, 1990 and continued through May 12, 1993. During this period, Dr. Cohen actively participated in the following number of procedures:

50 Thallium stress imaging/function procedures
50 Thallium rest imaging/function procedures
50 Technetium rest imaging/function procedures
50 Technetium stress imaging/function procedures
10 PYP/RBC multi-gated acquisition rest procedures
10 Ejection fraction calculation procedures
10 Wall motion evaluation studies
5 Shunt evaluation calculations
15 Myocardial Gallium scintigram

Dr. Cohen has also interpreted 1000 stress myocardial scintigrams and 100 radionuclide ventriculograms. He has also gained experience in the preparation of radiopharmaceutical kits during this period, and eluted the 99m Tc/99Mo generator.

During this time, the doctor also acquired experience in health physics, radiopharmaceutical preparation, and administrative procedures of our facility, as well as general operations as stipulated by our license conditions.

The hours of nuclear cardiology clinical experience accrued during this period total 600 hours. Dr. Cohen has fulfilled all requirements as stipulated by the Code of Federal Regulations (CFR 35.920).

Sincerely

May 25 '93

Thomas C. Hill, M.D.
NRC# 20-00289-07

May 25, 1993

Phil,

Attached is the copy of Tom Hills letter verifying that I have completed all requirements as stipulated by CFR 35.920 to become an authorized user under the Deaconess licence. I would like to be placed under Tom's permit. Please forward confirmation to Cardiology on Baker 3.

Thank you.

Myfam Cohen

3-2746