

Cardiology Consultants of Philadelphia
Cardiac Imaging Center
1703 South Broad Street, Suite 400
Philadelphia, PA 19148
(215) 339-0409

NMSB2

November 20, 2007

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

2007 DEC 20 PM 1:07

RECEIVED
REGION 1

03032361

RE: License Number: 37-28653-01
Amendment Application
Cardiac Imaging Center

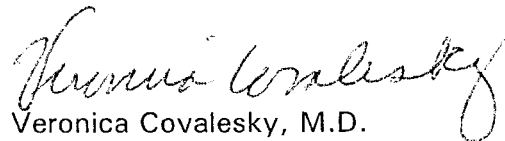
Dear License Reviewer:

Please amend our byproduct material license to add Christopher M. Schulze, D.D. as an authorized user for all material and procedures authorized on our current license. Documentation attesting to his clinical and academic training are enclosed in Attachment A. Please refer to this section to reference specific training details.

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

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

Sincerely,


Veronica Covalesky, M.D.
Administrative Representative

enclosures

141468

NMSS/RGN1 MATERIALS-002

Attachment A



Drexel University College of Medicine

In the tradition of Woman's Medical College of Pennsylvania and Hahnemann Medical College

Department of Medicine

Diwakar Jain, M.D., F.R.C.P. (UK), FACC

Professor of Medicine

Director Nuclear Cardiology and Cardiology Consult Service

May 17, 2006

Certification Board of Nuclear Cardiology
19562 Club House Road
Montgomery Village, MD 20886 USA

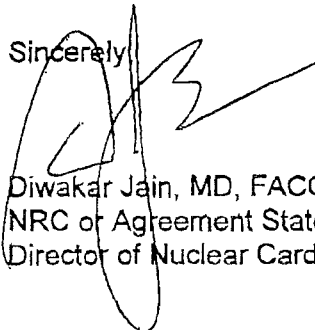
RE: Christopher M. Schulze, DO

To Whom It May Concern:

Dr. Christopher Schulze, DO has completed a training program in nuclear cardiology that meets the requirements for Level 2 training as outlined in the ACC/ASNC COCATS Guidelines [revised 2006].

Dr. Christopher Schulze, DO is competent to independently function as an authorized user under NRC 10 CFR 35.290 uses.

Sincerely,



Diwakar Jain, MD, FACC, FRCP, FASNC
NRC of Agreement State Authorized User Number: 37-00467-36
Director of Nuclear Cardiology Laboratory

| | | |
|---------------------------|---|---|
| NRC FORM 313A (4-2005) | U.S. NUCLEAR REGULATORY COMMISSION MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION | APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2005 |
|---------------------------|---|---|

PART I -- TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35)

1. Name of Individual, Proposed Authorization (e.g. Radiation Safety Officer), and Applicable Training Requirements (e.g. 10 CFR 35.50)

AUTHORIZED USER

CHRISTOPHER M. SCHULZE, D.O.

10 CFR 35.290

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

PENNSYLVANIA

3. CERTIFICATION

a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a), continue if applying under other subparts.)

b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).

c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.

Stop here after completing items 3a, 3b and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS

a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)

b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c)

c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

| Description of Training | Location | Clock Hours | Dates of Training |
|--|--|------------------|----------------------------------|
| Radiation Physics and Instrumentation | <i>DREXEL UNIVERSITY COLLEGE OF MEDICINE</i> | <i>100 HOURS</i> | <i>SEPTEMBER 2004</i> |
| Radiation Protection | <i>PHILADELPHIA, PA</i> | <i>30 HOURS</i> | <i>THROUGH JUNE 2005</i> |
| Mathematics Pertaining to the Use and Measurement of Radioactivity | <i>↓</i> | <i>20 HOURS</i> | <i>↓</i> |
| Radiation Biology | | <i>20 HOURS</i> | |
| Chemistry of Byproduct Material for Medical Use | | <i>30 HOURS</i> | |
| OTHER | | | |

NRC FORM 313A
(4-2006)

U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

| Description of Experience | Name of Supervising individual(s) | Location and Corresponding Materials License Number | Dates and/or Clock Hours of Experience |
|--|-----------------------------------|--|--|
| Work Experience in Nuclear Lab with Radiopharmaceuticals As outlined in 35.290 (c)(ii) | DIWAKER Jain, MD | Hahnemann University Hospital; Drexel Univ. College of Medicine Philadelphia, PA | 7/2003 through 6/2006 > 1000 Hours |
| | | # 37-0046736 | |

6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

| Radionuclide | Type of Use | No. of Cases Involving Personal Participation | Name of Supervising Individual | Location and Corresponding Materials License Number | Dates and/or Clock Hours of Experience |
|--------------|---------------------|---|--------------------------------|--|--|
| Tl-201 | Cardiac Imaging | 100 | DIWAKER Jain, MD | Hahnemann University Hospital; | 7/2003 through |
| Tc-99m | Localization | > 500 | | Drexel University College of Medicine Philadelphia, PA | 6/2006 > 1000 Hours |
| Gd-153 | Cardiac Attenuation | > 500 | | | |
| Co-57 | Flood | | | | |
| | | | | # 37-0046736 | |

NRC FORM 313A (4-2005) **U.S. NUCLEAR REGULATORY COMMISSION**
MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)

| Training Element | Type of Training * | Location and Dates |
|------------------|--------------------|--------------------|
| | | |
| | | |
| | | |
| | | |

* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists

| Degree, Area of Study or Residency Program | Name of Program and Location with Corresponding Materials License Number | Dates | Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490) |
|--|--|-------|---|
| | | | |

8. RADIATION SAFETY OFFICER (RSO) – ONE-YEAR FULL-TIME EXPERIENCE

- YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.
- N/A of _____ the RSO for License No. _____

9. MEDICAL PHYSICIST -- ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

- YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of _____
- N/A who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

and

- YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) _____
- N/A under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) _____

NRC FORM 313A
(4-2005)

U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR Part 35, provide the following information for each):

A. Name of Supervisor

B. Supervisor is:

D WAXER JAIN, MD

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35. Section(s)

10 CFR 35.290

for medical uses in Part 35. Section(s)

10 CFR 35.200

D. Address D WAXER JAIN, MD

E. Materials License Number

DREXEL UNIV. COLLEGE OF MEDICINE

HANNEEMANN UNIV. HOSPITAL

BROAD & VINE ST. PHILADELPHIA, PA 19102

37-00467-36

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet training requirements in 35.590 or Part 35, Subpart J (except 35.980).

I attest the individual named in Item 1:

11a.

has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 10 CFR 35.290 as documented in section(s) _____ of this form

11b. Select one

meets the requirements in 35.50(e) 35.51(c) 35.390(b)(1)(ii)(G) 35.690(c) for _____

N/A

types of use, as documented in section(s) _____ of this form

11c.

has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **OR**

has achieved a level of competency sufficient to function independently as an authorized USER for 10 CFR 35.200 uses (or units); **OR**

has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; **OR**

N/A

11d

I am an Authorized Nuclear Pharmacist; **OR** I am a Radiation Safety Officer; **OR**

I meet the requirements of 10 CFR 35.290 section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor

AUC

AMP

for the following byproduct material uses (or units): _____

A. Address

HANNEEMANN UNIVERSITY HOSPITAL

B. Materials License Number

BROAD & VINE STREETS

PHILADELPHIA, PA 19102

37-00467-36

C. NAME OF PRECEPTOR (print clearly)

D. SIGNATURE & PRECEPTOR

F. DATE

DREXEL UNIVERSITY COLLEGE OF MEDICINE

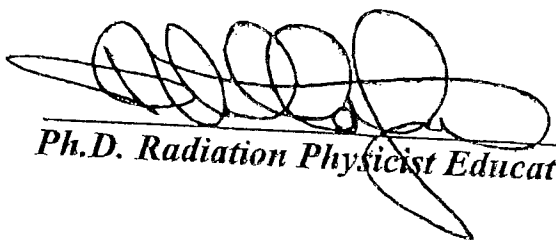
This is to certify that

Christopher M. Schulze, D.O.

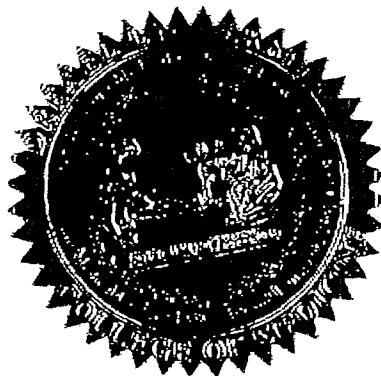
has successfully completed a 200-hour course of study and laboratory sessions on the principles and practices of nuclear technology including radiation physics and instrumentation (100 hours), radiation protection (30 hours), mathematics pertaining to use and measurement of radioactivity (20 hours), radiation biology (20 hours), and radiopharmaceutical chemistry (30 hours).

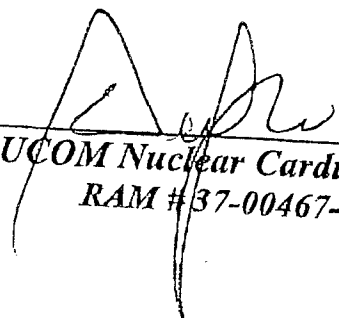
This course of study was conducted at Drexel University College of Medicine.

September 2004 to June 2005



Ph.D. Radiation Physicist Educator





DUCOM Nuclear Cardiology Staff
RAM #37-00467-36

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

11/20/2007 ^{RECEIVED} (12/20/2007), and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 37-28653-01
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** 141468.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (R1)
(6-96)

Sincerely,
Licensing Assistance Team Leader