

26th April, 2007

J-6

Nuclear Regulatory Commission, Region 1
Materials Licensing Section
475 Allendale Road
King of Prussia, PA 19406-1415
610-337-5309

03030030

RE: Radioactive materials license number 29-28041-01

Request for amendment

Dear Sir or Madam:

Please amend the above referenced license in the following sections:

Section 12.B :

ADD: Authorized User

Material and Use

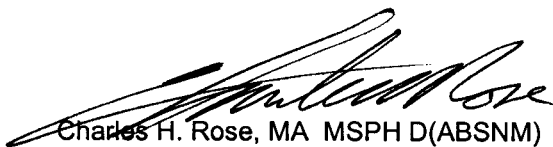
George S. Abela, M.D.

35.200

I am enclosing a preceptorship letter and certificates of didactic coursework completion to document the Training and Experience of George Abela, M.D.

Should you have any question regarding this amendment, please contact me or Callie Pratt at 800-548-4024.

Sincerely,



Charles H. Rose, MA MSPH D(ABSNM)
CEO/Administrator
PO Box 778
Red Bank, NJ 07701-0000

RECEIVED
REGION 1

2007 MAY -2 AM 10: 29

140317

NMSS/RGN1 MATERIALS-002

**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 <p style="text-align:center">George Abela, M.D.</p>	State or Territory Where Licensed <p style="text-align:center">MI</p>
---	--

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	See attached statement of training		02/02/07

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)

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	See attached certificates		
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>			
Radiation biology			
Total Hours of Training:			200

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.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	29-28041-01		June 20-23 2005
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	29-28041-01		June 20-23 2005
Calculating, measuring, and safely preparing patient or human research subject dosages	29-28041-01		June 20-23 2005

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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	29-28041-01		June 20-23 2005
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	29-28041-01 and - See Attached		1995 - 03/07
Administering dosages of radioactive drugs to patients or human research subjects	29-28041-01 and - See Attached		1995 - 03/07
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	See attached generator experience		

Total Hours of Experience: 500+

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

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.

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, with regards to these areas, 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, with regards to these areas, as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

I attest that George Abela has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

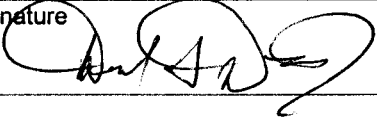
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently, with regards to these areas, as an authorized user for the medical uses authorized under 10 CFR 35.100 and 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 <i>DAVID I DROUT, M.D.</i>	Signature 	Telephone Number <i>732-380-9090</i>	Date <i>4-25-07</i>
License/Permit Number/Facility Name <i>29-28041-01 / PHYSICIANS IMAGING CENTER</i>			

FAX RECEIVED

FEB 03 2007

@ _____ by _____

Statement of training and experience.


RE: Generator

To Whom It May Concern:

GEORGE S. ABELA M.D has gained work experience at (Name of facility),
(address),(State) (Zip) on (Date)
CAPITAL PHARMACY, 3960 Patient Care Dr. Suite 105
The training/experience involved the following: Lansing, MI 48911 - 2/2/07

Eluting generator systems appropriate for 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.

Name(Print): Benjamin F. Blomcke

Signed: 

Date: 2/2/07

Title: R.Ph.

Radioactive materials license number: ZT-26597-01 MO

Experience Summary

George Abela, MD, FACC

**Sparrow Hospital
Lansing, Michigan**

1995 – 1999

SPECT Nuclear Cardiology Procedures

Ordered 60 – 90 / year
Total 300 – 450

Performed 120 – 180 / year
Total 600 – 900

2000 – 2005

SPECT Nuclear Cardiology Procedures

Ordered 15 – 23 / year
Total 90 – 138

Performed 60 – 90 / year
Total 360 – 540

Total procedures at Sparrow Hospital

Ordered 390 – 588
Performed 960 – 1,440

Assume Ordered 300
Performed 800

Experience Summary

**Michigan State University
East Lansing, Michigan**

PET Cardiac Imaging
01/17/06 – 03/27/07

Ordered 95 Procedures
Performed 145 Procedures

Assume as above

Summary 1995 – 03/07

Ordered	395
Performed	945

For purposes of documentation of experience form:

1 – 3	Use 395 Cases
4 – 6	Use 945 Cases

CALCULATION OF EXPERIENCE

PRIOR EXPERIENCE DOCUMENTATION

ORDERED PROCEDURES

Evaluated the medical considerations including but not limited to the indications, contra indications, contra considerations and other cardio pharmaceutical biological and safety issues including the selection of the radio pharmaceutical. (See 1-3 of the Experience Document)

PERFORMED PROCEDURES

Evaluated the clinical and radiological considerations of the procedure for this patient. Supervised the stressing of the patient and authorized the injection of the radiopharmaceutical. Responsible for the radiological consequences of the handling of the radiopharmaceutical prior to injection, during administration and after administration. Responsibility included but was not limited to the supervision that would be required in the event of a spill, misadministration of other radiological occurrence. (See 4-6 of the Experience Document)

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion & Competency

This document is to attest that

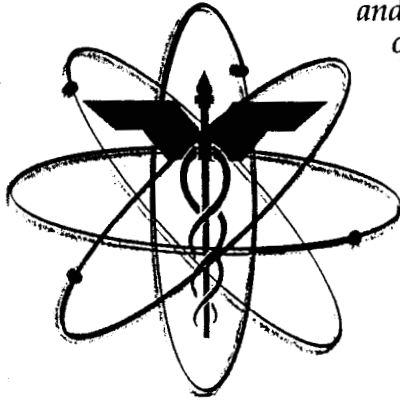
George S. Abela, MD

has successfully completed the didactic program

MEDICAL RADIATION PROTECTION

and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.

This program provides the following levels of accomplishment:



- 5.0 Continuing Education Units (CEU)
- 50 Didactic Instructional Hours (DIH)
In compliance with 10CFR35 / AEA 73-689
- 50 Board Accepted Hours NUSPEX, NMTCB III b,
ABMRSO, CBNC, MRLB
- 3.0 Semester Hours American Council on
Education (ACE), American Association for
Collegiate Registrars



Charles H. Rose
Certifying Official

5 December 2001
Date Completed

199704
Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.
INME1132-Class III-Comp&Comp 1/00

NUCLEAR MEDICAL EDUCATION PROGRAM

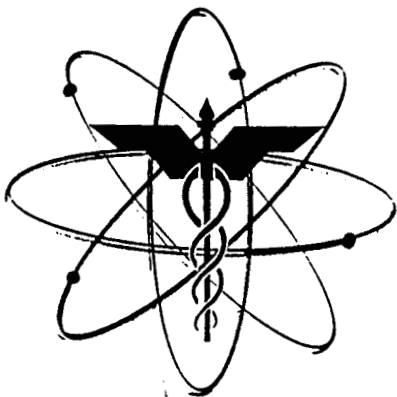
Affidavit of Academic Completion & Competency

*This document is to attest that
George S. Abela, MD.*

has successfully completed the didactic program

MEDICAL RADIATION INSTRUMENTATION

*and has provided evidence of attendance in this program
and evidence of achieving the objectives of program hours.
This program provides the following levels of accomplishment:*



- 5.0 Continuing Education Units (CEU)
- 50 Didactic Instructional Hours (DIH)
In compliance with 10CFR35/AEA 73-689
- 50 Board Accepted Hours NUSPEX, NMTCB III b,
ABMRSO, CBNC, MRLB
- 3.0 Semester Hours American Council on
Education (ACE), American Association for
Collegiate Registrars



Charles H. Rose
Certifying Official

17 June 2001

Date Completed

199363

Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.
INME1132-Class I-Complete 1/00

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion & Competency

This document is to attest that

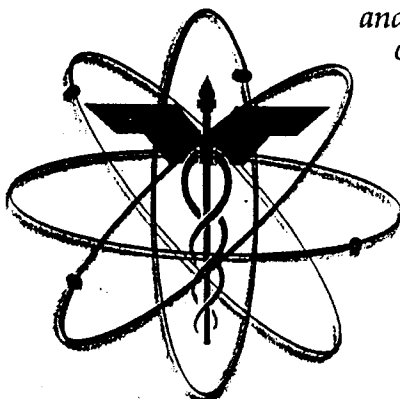
George S. Abela, MD

has successfully completed the didactic program

RADIOPHARMACEUTICALS AND CHEMISTRY

and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.

This program provides the following levels of accomplishment:



- 5.0 Continuing Education Units (CEU)
- 50 Didactic Instructional Hours (DIH)
In compliance with 10CFR35/AEA 73-689
- 50 Board Accepted Hours NUSPEX, NMTCB III b,
ABMRSO, CBNC, MRLB
- 3.0 Semester Hours American Council on
Education (ACE), American Association for
Collegiate Registrars



Charles H. Rose
Certifying Official

9 December 2001
Date Completed

199738
Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.
INME1132-Class IV-CompI&Comp 1/00

NUCLEAR MEDICAL EDUCATION PROGRAM

Affidavit of Academic Completion & Competency

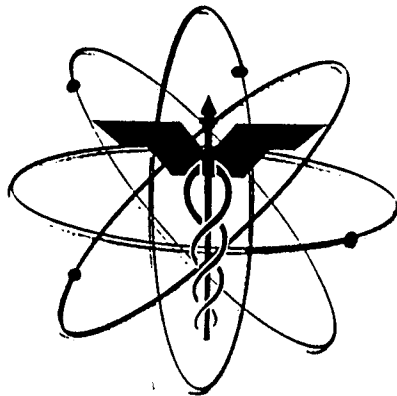
This document is to attest that

George S. Abela, MD.

has successfully completed the didactic program

PRINCIPLES OF RADIATION PHYSICS

*and has provided evidence of attendance in this program
and evidence of achieving the objectives of program hours.
This program provides the following levels of accomplishment:*



- 5.0 Continuing Education Units (CEU)
- 50 Didactic Instructional Hours (DIH)
In compliance with 10CFR35/AEA 73-689
- 50 Board Accepted Hours NUSPEX, NMTCB III b,
ABMRSO, CBNC, MRLB
- 3.0 Semester Hours American Council on
Education (ACE), American Association for
Collegiate Registrars



Charles H. Rose
Certifying Official

13 June 2001
Date Completed

199302
Certification

Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.
INME1132-Class I-Complete 1/00