

Nemours

Alfred I. duPont
Hospital for Children

Nemours
Children's Clinic

May 21, 2007
Region I, Materials Licensing Assistance Branch
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415
(610) 337-6942

NMSBI

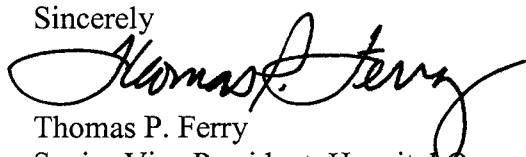
RE: Control No. 139850
Docket No 03019939
Resubmission of License Amendment Request
NRC License No. 07-16199-02

Please amend our Nuclear Medicine License (No. 07-16199-02) to include Gungel Acikgoz, M.D. as an Authorized User for Uptake, Dilution and Excretion studies permitted by 10CFR35.100 and for any Imaging and Localization study permitted by 10 CFR35.200. This amendment request was approved by our Radiation Safety Committee.

Copies of Dr. Acikgoaz's American Board of Nuclear Medicine certification and NRC Form 313A completed by her preceptor, Charles Intenzo, M.D. from Thomas Jefferson University Hospital are enclosed.

If additional information, or clarification, is needed, please contact our consultant medical health physicist, Mary E. Moore, at (856) 235-1674.

Sincerely



Thomas P. Ferry
Senior Vice President, Hospital Operations

cc M. Keller, M.D., Chair, RSC
L. States, M.D., RSO
A. Baker
K. Maas
M. Moore

2007 JUN -6 AM 10:31
RECEIVED
REGION I

140619
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 GUNSEL AKKOOZ	State or Territory Where Licensed Delaware
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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)

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	Thomas Jefferson University and Thomas Jefferson University Hospital	300	7/1/2003 to 6/30/2005
Radiation protection	Thomas Jefferson University and TJU Hospital	100	7/1/03 to 6/30/05
Mathematics pertaining to the use and measurement of radioactivity	Thomas Jefferson University and TJU Hospital	150	7/1/03 to 6/30/05
Chemistry of byproduct material for medical use (not required for 35.590)	Thomas Jefferson University and TJU Hospital	150	7/1/03 to 6/30/05
Radiation biology	Thomas Jefferson University and TJU Hospital	100	7/1/03 to 6/30/05
Total Hours of Training:		800	

**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	Thomas Jefferson University Hospital (37-00148-06)	20	7/1/03 to 6/30/05
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Thomas Jefferson University Hospital (37-00148-06)	50	7/1/03 to 6/30/05
Calculating, measuring, and safely preparing patient or human research subject dosages	Thomas Jefferson University Hospital (37-00148-06)	100	7/1/03 to 6/30/05

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	Thomas Jefferson University Hospital (37-00148-06)	500	7/1/2003 to 6/30/2005
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Thomas Jefferson University Hospital (37-00148-06)	20	7/1/03 to 6/30/05
Administering dosages of radioactive drugs to patients or human research subjects	Thomas Jefferson University Hospital (37-00148-06)	200	7/1/03 to 6/30/05
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	Thomas Jefferson University Hospital (37-00148-06)	200	7/1/03 to 6/30/05

Total Hours of Experience: 920

Supervising Individual

Charles Intenzo MD

License/Permit Number listing supervising individual as an authorized user

37-00148-06

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 GUNSEL AKIBOL 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 GUNSEL AKIBOL 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 _____ 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
CHARLES INTENZO	<i>Charles Intenzo MD</i>	215 955 1911	3/21/07
License/Permit Number/Facility Name	THOMAS JEFFERSON HOSPITAL		
37-00148-06			

The American Board of Nuclear Medicine

Incorporated 1971

Certifies that

Gunsel Acikgoz

*has met the requirements of this Board and is qualified
during the period of 2005 through 2015 to practice as a Specialist
in all aspects of Clinical and Laboratory*

Nuclear Medicine

*including but not limited to Radiobioassay, Nuclear Imaging,
In Vivo Measurements & Therapy with Unsealed Radionuclides*

Tom R. Miller

Chairman



07536

*Number
United States*

J. Anthony Parker

Secretary-Treasurer

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

5/21/2007, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 07-16199-02
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 140619.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.