

RECEIVED
REGION I
2007 FEB -9 PM 12: 14

MSL6
J-1

2/8/07

USNRC, Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415
ATTN: Michelle Beardsley
610-337-6942

03036502

RE: License No 45-30881-01, Control number 139945

Dear Michelle Beardsley:

In response to your letter dated January 12, 2007, Please find enclosed a completed NRC 313A(AUD) form.

Should you require any other information, Please contact me at 949-266-3750.
Sincerely,



Daniel G. Amen, M.D. / Owner
Amen Clinics, Inc., D.C.
1875 Campus Commons Drive, Suite 101
Reston, VA 20191

139945

NMSS/ROSI MATERIALS-001

**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 Barton A. Branscum, M.D.	State or Territory Where Licensed 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)

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	Atlanta, GA	50	11/11/06 to 11/19/06
Radiation protection	SAME	15	SAME
Mathematics pertaining to the use and measurement of radioactivity	SAME	10	SAME
Chemistry of byproduct material for medical use (not required for 35.590)	SAME	15	SAME
Radiation biology	SAME	10	SAME
Total Hours of Training:		100	

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	Amen Clinics, Reston, VA NRC 45-30881-01		Oct. 04 to Dec. 06
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters			SAME
Calculating, measuring, and safely preparing patient or human research subject dosages			SAME

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	Amen Clinics, Inc Reston, VA		OCT. 04 to DEC. 06
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures			SAME
Administering dosages of radioactive drugs to patients or human research subjects			SAME
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		

Total Hours of Experience: Total for all elements 600

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Daniel G. Amen, M.D.	45-30881-01
Supervisor meets the requirements below, or equivalent Agreement State requirements (check one).	
<input type="checkbox"/> 35.190 <input checked="" type="checkbox"/> 35.290 <input type="checkbox"/> 35.390 <input type="checkbox"/> 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 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 Barton A. Branscum has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

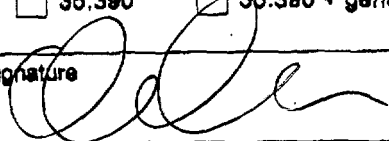
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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 Daniel Amen, M.D.	Signature 	Telephone Number 949-266-3700	Date 2/8/07
--	---	----------------------------------	----------------

License/Permit Number/Facility Name

Statement of training and experience.

RE: Generator

To Whom It May Concern:

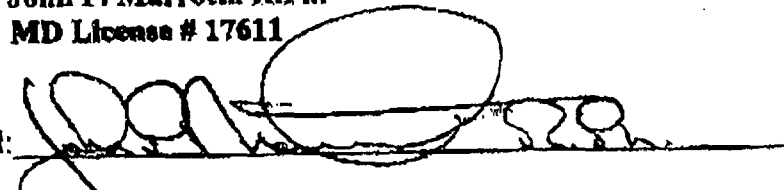
 M.D has gained work experience at

GE Healthcare
12120 Plum Orchard Dr
Suite G
Silver Spring, MD 20904 on 2/7/2007

The training/experience involved the following:

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: John P. Marrotta R.Ph.
MD License # 17611

Signed: 

Date: February 7, 2007
Title: Facility Manager
Radioactive materials license number: MD-31-222-01
Telephone number: 301-572-7022

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 of 2 PAGES

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 80, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee

1. Amen Clinics, Inc. D.C.

3. License No. 45-30661-01

2. 1875 Campus Commons Drive
Suite 101
Reston, Virginia 20191

4. Expiration Date: April 30, 2014

5. Docket No. 090-36502

6. Byproduct, source, and/or special nuclear material

7. Chemical and/or physical form

8. Maximum amount that licensee may possess at any one time under this license

A. Any byproduct material permitted by 10 CFR 35.100

A. As needed

B. Any byproduct material permitted by 10 CFR 35.200

B. As needed

9. Authorized Use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.

B. Any imaging and localization study permitted by 10 CFR 35.200.

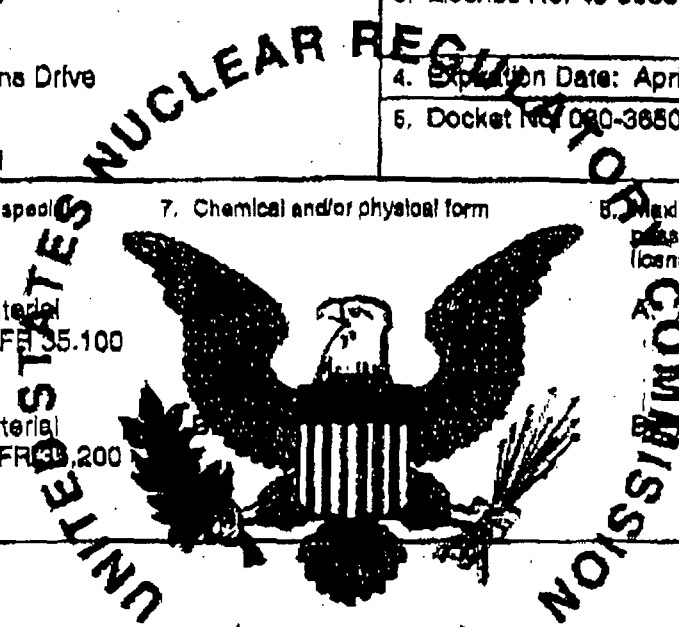
CONDITIONS

10. Licensed material shall be used or stored only at the licensee's facilities located at 1875 Campus Commons Drive, Suite 101, Reston, Virginia.

11. The Radiation Safety Officer (RSO) for this license is Charles Parker, D.O.

12. Licensed material is only authorized for use by, or under the supervision of:

A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.



NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 2 of 2 PAGES

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License No.
45-30881-01

Docket No.
030-36502

12. B. The following individuals are authorized users for the materials and uses indicated:

<u>Authorized User</u>	<u>Material and Use</u>
Charles Parker, D.O.	35.100; 35.200
Daniel G. Amen, M.D.	35.100; 35.200

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the maximum limit specified in 10 CFR 35.35(e) for establishing decommissioning financial assurance.

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation."

15. Except as specifically provided otherwise in the license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies to the procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U. S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated February 6, 2004

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

Date April 14, 2004

BY /RA/
Bryan A. Parker
Nuclear Materials Safety Branch 3
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406-1415