



45-30881-01

Amen Clinics, Inc.
A Medical Corporation

03036502

www.amenclinics.com

"Change Your Brain. Change Your Life"

Betsy -

MS-16

7/2/08

As per our conversation, I have included a copy of the California license showing that Dr. Amen is already an R.S.O. on another R.A.M. license.

Thank you for your assistance with this matter. Please feel free to contact me at 949-266-3749 should you have any questions.

Sincerely,

Catherine Hannon

142423

NMSS/RGNI MATER. ALS-002

Southern California
4019 Westerly Pl. #100
Newport Beach, CA 92660
(949) 266-3700
Fax (949) 266-3750

Northern California
350 Chadbourne Road
Fairfield, CA 94534
(707) 429-7181
Fax (707) 429-8210

Pacific Northwest
3315 S. 23rd Street #102
Tacoma, WA 98405
(253) 779-4673
Fax (253) 779-8969

Washington D.C. Area
1875 Campus Commons Dr. #101
Reston, VA 20191
(703) 860-5600
Fax (703) 860-5760



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 3, 2008

Docket No. 030-361502

License No. 45-30881-01

Control No. 142423

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

**SUBJECT: AMEN CLINICS, INC., REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL
NO. 142423**

Dear Dr. Amen:

This is in reference to your letter dated May 27, 2008 requesting to amend Nuclear Regulatory Commission License No. 45-30881-01. In order to continue our review, we need the following additional information:

- In support of your request to authorize Dr. Amen as the Radiation Safety Officer, in addition to the information provided (the copy of the license on which the physician was specifically named as an authorized user for the uses requested, and the description of the experience in radiation safety procedures), you must also provide:
- a. a brief description of the training in radiation safety, regulatory issues and emergency procedures for the medical uses authorized on your license, using the table in Part I, Item 3.c. of Form 313A (RSO) that is enclosed with this letter. This table also requires that you list the name of the supervising individual, who must be a radiation safety officer, authorized user, authorized nuclear pharmacist, or authorized medical physicist for those medical uses and list the license/permit number of the supervising individual.
 - b. a preceptor attestation, using one of the options in Part II of Form 313A(RSO) enclosed with this letter. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an authorized user for the medical uses authorized has been achieved.
 - f. If applicable, description of recent (within the past 7 years) related continuing education and experience as required by 10 CFR 35.59 if the board certification, or training and experience, was received more than 7 years ago.

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RECEIVED
REGISTRATION

D. Amen
Amen Clinics, Inc.

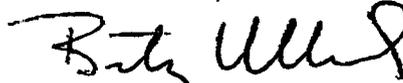
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Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material; Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 142423. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5040.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,



Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

enclosure:
Form 313A(RSO)

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the places(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereafter in effect and to any standard or specific condition specified in this license.

1. Licensee: The Amen Clinic for Behavioral Medicine, Inc.	3. License Number: 6785-30 Amendment Number: 5
2. Address: 4019 Westerly Place, Suite 100 Newport Beach, CA 92660	4. Expiration date: June 16, 2010 (3)
Attention: Daniel G. Amen, M.D. Radiation Safety Officer	5. Inspection agency: Radiologic Health Branch South

In response to the letter, dated January 17, 2007, signed by Daniel G. Amen, M.D., Owner and Radiation Safety Officer, License Number 6785-30 is hereby amended as follows:

6. Nuclide	7. Form	8. Possession Limit
A. Group 2 as specified in Item 9. Any radionuclide with atomic number 3-83	A. Any Excluding Xenon Excluding generators	A. Combined possession limit for Group 2 not to exceed 800 mCi.
B. Group 9 as specified in Item 9. Any radionuclide with atomic number 383 inclusive, except: Strontium-90 and Lead-210	B. Sealed or solid sources manufactured in accordance with a specific license issued by the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State.	B. Total not to exceed 30 mCi. Each source not to exceed 15 mCi.

9. Authorized Use

To be used for nuclear medicine procedures as specified in groups below:

- A. Group 2 Diagnostic studies involving imaging excluding the use of Xenon-127 and/or Xenon-133 gas.
- B. Group 9 Marker and calibration sources.

LICENSE CONDITIONS

10. Radioactive material shall be used only at the following location:

- (a) 4019 Westerly Place, Suite 100, Newport Beach, CA.

11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in Items 6, 7, 8 and 9 of this license. The annual fee for this license is required by and computed in accordance with Title 17, California Code of Regulations, Sections 30230-30232 and is also subject to an annual cost-of-living adjustment pursuant to Section 100425 of the California Health and Safety Code.

12. The individuals named below are authorized the specific uses of radioactive material described in Items 6, 7, 8, and 9 of this license as follows:

- (a) Daniel G. Amen, M.D. Group 2 (restricted to brain imaging only) and 9
- (b) Todd Clements, M.D. Group 2 (restricted to brain imaging only) and 9

RADIOACTIVE MATERIAL LICENSELicense Number: 6785-30Amendment Number: 5

13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, 8 and 9 of this license in accordance with the statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - (a) The License Application, with attachments, dated May 4, 2000, the letter, with attachment, dated April 29, 2000; the letters, both with attachments, dated May 26, 2000, and June 11, 2000, and the letter dated June 14, 2000, all signed by Daniel G. Amen, M.D., Radiation Safety Officer.
 - (b) The letter dated August 25, 2000, and the letter, with attachments, dated September 14, 2000, both signed by Daniel G. Amen, M.D., Radiation Safety Officer, regarding dose calibrator and survey instrument information.
14.
 - (a) The Radiation Safety Officer in this program shall be Daniel G. Amen, M.D.
 - (b) The Custodian of sealed sources shall be Daniel G. Amen, M.D.
15. Sealed sources possessed under this license shall be tested for leakage and/or contamination as required by Title 17, California Code of Regulations, Section 30275 (c).
16. The following individuals are authorized to collect wipe test samples of sealed sources possessed under this license using leak test kits acceptable to the California Department of Health Services:
 - (a) The Radiation Safety Officer
 - (b) Qualified individuals designated in writing by the Radiation Safety Officer
17. The licensee is authorized to hold radioactive materials with a physical half-life of less than 65 days for decay in storage before disposal in ordinary trash provided:
 - (a) Radioactive waste to be disposed of in this manner shall be held for decay in storage for at least 10 half-lives.
 - (b) Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
18. The licensee may use one constancy source for the dose calibrator constancy test provided that the dose calibrator manual indicates that only one constancy source is needed for proper Quality Control.
19. The licensee may use any commercially available device, acceptable to the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, for doing linearity tests of its dose calibrator provided the procedures described by the manufacturer of the linearity device are followed.
20. Nuclear medicine technology procedures shall be performed by nuclear medicine technologists pursuant to Title 17, California Code of Regulations, Subchapter 4.6. Such procedures shall be performed under the supervision of authorized user physicians on this license who meet the criteria specified in Section 30510. Certificates or special permits issued pursuant to Subchapter 4.6 shall be prominently displayed at the facility(ies) authorized on this license.
21. Notwithstanding the definition of "Misadministration" in title 17, 30100(j), and the requirements listed in title 17, section 30322, the Licensee shall notify and submit reports regarding "Medical Events," as defined in title 10, Code of Federal Regulations, Part 35, section 35.2, to the Department in accordance with title 10, Code of Federal Regulations, Part 35, section 35.3045.

RADIOACTIVE MATERIAL LICENSE

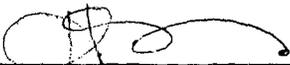
License Number: 6785-30

Amendment Number: 5

- 22. Production or processing of radiopharmaceuticals for the purpose of commercial distribution to other licensees is not authorized by this license.
- 23. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material so that at no time will the total quantity of radioactive material possessed require financial surety for decommissioning in accordance with the California Code of Regulations, Title 17, Section 30195.1. The Code of Federal Regulations, Title 10, Part 30, Appendix B, is hereby supplemented by assigning a value of 100 microcuries to Cobalt-57.
- 24. At least 30 days prior to vacating any address of use listed in Condition 10 of this license, the licensee shall provide written notification thereof to the Department of Health Services, in accordance with Title 17, California Code of Regulations, Section 30256 (b).
- 25. A copy of this license and a copy of all records and documents pertaining to this license shall be maintained available for inspection at 4019 Westerly Place, Suite 100, Newport Beach, CA 92660.

Issued for the State Department of Health Services

Date: February 27, 2007

By: 

Radiologic Health Branch
MS 7610, P.O. Box 997414
Sacramento, CA 95899-7414