

BALA MEDICAL CENTER
Wayne V. Arnold, D.O., F.A.C.O.I.

CARDIOLOGY - PERIPHERAL VASCULAR DISEASES

15 NORTH PRESIDENTIAL BLVD.
SUITE 100
BALA CYNWYD, PA 19004

(610) 667-2746
(610) 667-2749
Fax# (610) 667-9420

Dennis Lawyer
U.S Nuclear Regulatory Commission, Region 1
Licensing Assistance Team
475 Allendale Road
King of Prussia, PA 19409-1415

J-6

9 March 2006

Re: Docket No. 03030949
Control No. 138143

37-28333-01

RECEIVED
REGION 1
2006 MAR 13 PM 1:05

Dear Mr. Lawyer:

As per your request, please accept the following in support to our amendment request to our Medical Use Materials License, No. 37-28333-01:

1. Leak test results on sealed sources that are used at our facility in Galloway Twp., NJ.
2. Please find attached an updated NRC Form 313a for Dr. David Kann as Authorizer Users to our license. Dr. Kann recently completed training and experience in generator elution, QC and kit preparation at the GE Healthcare radiopharmacy in Harrisburg, PA, as specified in 10 CFR 35.290 (c)(1)(ii)(G).

If you have any questions or concerns regarding this amendment, please do not hesitate to contact me at 610-667-2746, or our Nuclear Operations Manager, Terry Day, RT, at 856-786-4700.

Sincerely,

Wayne Arnold, DO
Wayne Arnold, D.O.
Radiation Safety Officer

Enclosures

138143

NMSS/RGNI MATERIALS-002

DATE 8/14/05

BIO-MED ASSOCIATES, INC.
 4 MAIN STREET FLEMINGTON, NEW JERSEY 08822

201-788-9440

SEALED RADIOACTIVE SOURCE WIPE TEST

Hospital: Omni Absecon

Test Procedure:

Accessible areas of the source(s) were wiped with a cotton swab. The wipes were counted in a well-type scintillation detector with pulse height analyzer. The results are listed below:

Isotope	Model No. Serial No.	Activity Date	Background (cpm)	Wipe (cpm)	Removable Activity (uCi)
CS137 DC	NES 356 S356040-015	214 uCi 6/8/99	180	191	1.8×10^{-5}
Co57 DC	RV0575M 10472524	5.429 mCi 4/1/04	180	219	1.8×10^{-5}
Co57 FLOOD	NES8496-10M 1059-126	10 mCi 6/1/04	180	219	1.8×10^{-5}

Instrumentation: Manufacturer Carpenter
 Model No. CPC15W, S/N 170028
CS137 965 361 Standard counted 267300 cpm. Co57 9670
 Therefore 0.005 uCi equals CS137 3041 cpm. CS137 27.7%

Comments: No leakage. Results are acceptable.

Clara Bachma
 Health Physicist

Reviewed by: [Signature]
 Radiation Safety Officer
 8-30-05

**MEDICAL USE TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**

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)

DAVID KANN, M.D. 10CFR 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	Consultants in Nuclear Medicine 2910 W. Estes Ave. Chicago, IL		Completed: 03 Nov. 05
Radiation Protection	"		"
Mathematics Pertaining to the Use and Measurement of Radioactivity	"		"
Radiation Biology	"		"
Chemistry of Byproduct Material for Medical Use	"		"
OTHER		Total hours: 85	

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
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	Wayne Arnold, D.O.	See item 9	9/03 to Present 100
Performing quality control procedures on instruments used to determine the activity of dosages ; performing checks for proper operation of survey meters	"	"	100
Calculating, measuring, and safely preparing patient or human research subject dosages	"	"	200
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	"	"	100
Using procedures to safely contain spilled radioactive material and using proper decontamination procedures	"	"	50
Administering dosages of radioactive drugs to patients or human research subjects	"	"	200
Eluting generator systems for preparation of radioactive drugs ; testing the eluate for radionuclidic purity; processing the eluate with syringes to prepare labeled radioactive drugs	Cliff Webber, RPh, BCMP	GE Radiopharmacy Harrisburg, PA	March 2006 4
			Total hours: >700

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
Tc-99m	Cardiac Imaging	50	Wayne Arnold, D.O.	See Item 10	9/03 to Present

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
n/a		

* 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)
n/a			

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) _____

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

Wayne Arnold, D.O.

B. Supervisor is:

Authorized User

Radiation Safety Officer

Authorized Medical Physicist

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 290

for medical uses in Part 35, Section(s) 200

D. Address

850 Walnut Bottom Rd.
Carlisle, PA

E. Materials License Number

37-28333-01

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) 35.290 (c), as documented in section(s) 5,6a 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 types of use, as documented in section(s) of this form.

N/A

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 290 section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor AU or AMP

for the following byproduct material uses (or units):

A. Address

15 N. Presidential Blvd., Suite 100
Bala Cynwyd, PA 19004

B. Materials License Number

37-28333-01

C. NAME OF PRECEPTOR (print clearly)

Wayne Arnold, D.O.

D. SIGNATURE -- PRECEPTOR

E. DATE