625 West Berry Street Fort Wayne, IN 46802 Ph: 260-439-0074 Fax: 260-439-0075

Baltes Cardiology

To:	**James Mullauer**	Fax:	**630.829.9873**
From:	**Matthew Hall**	Date:	**11/10/2008**
Re:	**NRC FORM 313A (AUD)**	Pages:	**5**
Cc:			

☐ Urgent ☑ For review ☐ Please comment ☐ Please reply ☐ Please recycle

Jim:

This is the signed authorized user training and experience and preceptor attestation form (NRC FORM 313A (AUD)). If you need further information or forms please do not hesitate to contact us.

Matthew Hall
Baltes Cardiology
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Signed:

NRC FORM 313A (AUD) (10-2007) U.S. NUCLEAR REGULATORY COMMISSION

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	State or Territory Where Licensed
Thomas Patrick Ryan, D.O.	Indiana

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)

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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	Orlando, FL	40	6/14/08 - 6/22/08
Radiation protection	Orlando, FL & San Francisco, CA	40	6/14/08 - 6/22/08 & 9/6/08 - 9/14/08
Mathematics pertaining to the use and measurement of radioactivity	Orlando, FL & San Francisco, CA	40	6/14/08 - 6/22/08 & 9/6/08 - 9/14/08
Chemistry of byproduct material for medical use *(not required for 35.590)*	San Francisco, CA	40	9/6/08 - 9/14/08
Radiation biology	Orlando, FL & San Francisco, CA	40	6/14/08 - 6/22/08 & 9/6/08 - 9/14/08
	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.)

Supervised Work Experience	**Total Hours of Experience:** 720		
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	Fort Wayne, IN/13-32694-01	☑ Yes ☐ No	7/12/08 - 11/6/08
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Fort Wayne, IN/13-32694-01	☑ Yes ☐ No	7/12/08 - 11/6/08

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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 Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages	Fort Wayne, IN/13-32694-01	☑ Yes ☐ No	7/12/08 - 11/6/08
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Fort Wayne, IN/13-32694-01	☑ Yes ☐ No	7/12/08 - 11/6/08
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Fort Wayne, IN/13-32694-01	☑ Yes ☐ No	7/12/08 - 11/6/08
Administering dosages of radioactive drugs to patients or human research subjects	Fort Wayne, IN/13-32694-01	☑ Yes ☐ No	7/12/08 - 11/6/08
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	Fort Wayne, IN/13-32694-01	☑ Yes ☐ No	7/12/08 - 11/6/08

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
B. A. [illegible]	13-32694-01

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.

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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)

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section
Check one of the following for each use requested:

For 35.190

Board Certification

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the requirements in 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 _____ (Name of Proposed Authorized User) has satisfactorily completed the 60 hours of training and 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 _____ (Name of Proposed Authorized User) has satisfactorily completed the requirements in 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 **Thomas P. Ryan, D.O.** (Name of Proposed Authorized User) has satisfactorily completed the 700 hours of training 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
Bhaktavatsala R. Apuri, M.D.	B. Apuri	**(260) 425-3701**	11/7/08

License/Permit Number/Facility Name

13-32694-01