

Fax cover sheet

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To: Name: Attn: Medical Licensing Amendment
Company: NRC
Destination fax #: 1-817-860-8263
Destination phone#: _____

Note:

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OCT - 5 2009

DNMS



Saint Alphonsus

St. Alphonsus RMC
1055 N Curtis Rd
Boise, ID 83706
208-367-3124

05OCT09

St. Alphonsus Regional Medical Center
1055 N. Curtis Rd.
Boise, ID 83706

NRC Region IV
611 Ryan Plaza Dr., Suite 400
Arlington, TX 76011
Fax: 817-860-8263

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RE: Amendment to License Number # 11-27306-01

Item 1.B Amendment to License number 11-27306-01

Item 2 St. Alphonsus Regional Medical Center
1055 N. Curtis Rd.
Boise, ID 83706

Item 3 Same as Item 2

Item 4 Timothy B. Stack, MS, DABR, Medical Physicist
208-367-3124

Item 5, 6, 8 Authorized Users Materials and Use

Add Michael A. Codina, MD 35.200
(see Form 313A attached)

Sincerely,

Timothy B. Stack, MS
RSO, SARMC, 208-367-3124

NRC FORM 313A (AUD)
(3-2009)

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: 3/31/2012

Name of Proposed Authorized User

Michael A. Codina, M.D.

State or Territory Where Licensed

Idaho

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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 _____)

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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)

NRC FORM 313A (AUD) U.S. NUCLEAR REGULATORY COMMISSION
 (3-2009) **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	University of Cincinnati	40	2002-04
Radiation protection	University of Cincinnati	10	2002-04
Mathematics pertaining to the use and measurement of radioactivity	University of Cincinnati	20	2002-04
Chemistry of byproduct material for medical use (not required for 35.590)	University of Cincinnati	10	2002-04
Radiation biology	University of Cincinnati	10	2002-04
Total Hours of Training: 90			

**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:	
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	University of Cincinnati	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2002-04
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	University of Cincinnati	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2002-04

NRC FORM 313A (AUD)
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

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	University of Cincinnati	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2002-04
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University of Cincinnati	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2002-04
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University of Cincinnati	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2002-04
Administering dosages of radioactive drugs to patients or human research subjects	University of Cincinnati	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2002-04
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	University of Cincinnati	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2002-04

Supervising Individual: **Myron C. Gerson, M.D.**
License/Permit Number listing supervising individual as an authorized user: **0410 02110310001**

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.

NRC FORM 513A (AUD)
(2-2009)

U.S. NUCLEAR REGULATORY COMMISSION

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 _____ 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 Michael A. Codina, M.D. 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

MYRON E. GEORSON MD

Signature

[Signature]

Telephone Number

513 558 3074

Date

8/21/09

License/Permit Number/Facility Name

OHIO 02110310001

UNIVERSITY HOSPITAL ; CINCINNATI, OHIO

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: St. Alphonsus Regional Med Ctr. **License:** 11-27306-01
Docket: 030-32263 **Mail Control:** 472433
Type of Action: Amend **Date of Requested Action** 10-05-09
Reviewer Assigned: **ARM reviewer(s):** Torres

Response	Deficiencies Noted During Acceptance Review
	<input type="checkbox"/> Open ended possession limits. Submit inventory. Limit possession. <input type="checkbox"/> Submit copies of latest leak test results. <input type="checkbox"/> Add IC L.C./Fingerprint LC, add SUNSI markings to license. <input type="checkbox"/> Confirm with licensee if they have NARM material. <input type="checkbox"/> Change of contact information (RSO), send request to update IC database.

Reviewer's Initials: _____ **Date:** _____

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Request for unrestricted release Group 2 or >. Consult with Bravo Branch.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Termination request < 90 days from date of expiration
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)
<input type="checkbox"/> Yes	<input type="checkbox"/> No	TAR needed to complete action.

Branch Chief's and/or HP's Initials: _____ **Date:** _____

SUNSI Screening according to RIS 2005-31

Yes No **Sensitive and Non-Publicly Available** if any item below is checked

General guidance:

- _____ RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule
- _____ Exact location of RAM [suite #, bldg. #, location different from mailing address] (whether = or > than Category 3 or not)
- _____ Design of structure and/or equipment (site specific)
- _____ Information on nearby facilities
- _____ Detailed design drawings and/or performance information
- _____ Emergency planning and/or fire protection systems

Specific guidance for medical, industrial and academic (above Category 3):

- _____ RAM quantities and inventory
- _____ Manufacturer's name and model number of sealed sources & devices
- _____ Site drawings with exact location of RAM, description of facility
- _____ RAM security program information (locks, alarms, etc.)
- _____ Emergency Plan specifics (routes to/from RAM, response to security events)
- _____ Vulnerability/security assessment/accident-safety analysis/risk assess
- _____ Mailing lists related to security response

Branch Chief's and/or HP's Initials:  **Date:** 10/23/09

OCT 30

DATE

This is to acknowledge the receipt of your letter/application dated 10-05-09, and to inform you that the initial processing, which includes an administrative review, has been performed.

There were no administrative omissions. Your application will be assigned to a technical reviewer. Please note that the technical review may identify other omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card:

The action you requested is normally processed within 90 days.

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** 472433.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,

Celien Murnahan
Licensing Assistant

: (FOR LFMS USE)
 : INFORMATION FROM LTS
 : -----
 :
 : Program Code: 02240
 : Status Code: 0
 : Fee Category: 7C
 : Exp. Date: 20130228
 : Fee Comments:
 : Decom Fin Assur Reqd: N
 :

BETWEEN:
 License Fee Management Branch, ARM
 and
 Regional Licensing Sections

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: ST. ALPHONSUS REG. MEDICAL CENTER
 Received Date: 20091005
 Docket No: 3032263
 Control No.: 472433
 License No.: 11-27306-01
 Action Type: Amendment

2. FEE ATTACHED

Amount: _____
 Check No.: /

3. COMMENTS

Signed Colleen Murnahan
 Date 10-26-09

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /_/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment _____
 Renewal _____
 License _____

3. OTHER _____

Signed _____
 Date _____