



Sisters of Charity of Leavenworth Health System

December 11, 2007

Re: License # 25-07553-01

Roberto J. Torres, Senior Health Physicist
Nuclear Materials Licensing Branch
United States Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064

Dear Mr. Torres,

This letter is an amendment request for license number 25-07553-01.

We wish to amend our license to include Joseph C. Apostol, M.D. as an authorized user for 10 CFR 200 uses. Please find attached a copy of Dr. Apostol's NRC form 313A to support this amendment. Please note we have added an additional preceptor attestation since Dr. Apostol's initial training was completed in 1999. The addition training includes attending a 100 hour radioisotope handling class in 2005 and 500 hours of supervised experience from an authorized user.

Please contact Chris Fitz at 406-672-6756 if you have questions regarding this amendment.

Best regards,

Steve Shandera
Vice President, Clinical Support Services
St. Vincent Healthcare

Christopher Fitz, JD, MS
Radiation Safety Officer
St. Vincent Healthcare

cc: Karen Costello

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DEC 17 2007
DNMS

**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

Joseph C. Apostol, MD

State or Territory Where Licensed

Montana

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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 _____)

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	ACGME Accredited Cardiology Residency Program, Georgetown University Medical Center/VA Medical Center Washington D.C.	20	7/1/97 to 6/30/99
	Consultants in Nuclear Medicine, Chicago, IL	20	June 5, 2005
Radiation protection	ACGME Accredited Cardiology Residency Program, Georgetown University Medical Center/VA Medical Center Washington D.C.	20	7/1/97 to 6/30/99
	Consultants in Nuclear Medicine, Chicago, IL	20	June 5, 2005
Mathematics pertaining to the use and measurement of radioactivity	ACGME Accredited Cardiology Residency Program, Georgetown University Medical Center/VA Medical Center Washington D.C.	20	7/1/97 to 6/30/99
	Consultants in Nuclear Medicine, Chicago, IL	20	June 5, 2005
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>	ACGME Accredited Cardiology Residency Program, Georgetown University Medical Center/VA Medical Center Washington D.C.	20	7/1/97 to 6/30/99
	Consultants in Nuclear Medicine, Chicago, IL	20	June 5, 2005
Radiation biology	ACGME Accredited Cardiology Residency Program, Georgetown University Medical Center/VA Medical Center Washington D.C.	20	7/1/97 to 6/30/99
	Consultants in Nuclear Medicine, Chicago, IL	20	June 5, 2005
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 1020 + 500 (St Vincent Healthcare) 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	ACGME Accredited Cardiology Residency Program, Georgetown University Medical Center/VA Medical Center Washington D.C.	<input checked="" type="checkbox"/> Yes	7/1/97 to 6/30/99
	St Vincent Healthcare, Billings MT	<input type="checkbox"/> No	8//06 to Present
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	ACGME Accredited Cardiology Residency Program, Georgetown University Medical Center/VA Medical Center Washington D.C.	<input checked="" type="checkbox"/> Yes	7/1/97 to 6/30/99
	St Vincent Healthcare, Billings MT	<input type="checkbox"/> No	8//06 to Present

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	Cardiology Residency Program, Georgetown University Medical Center/VA Medical Center Washington D.C. St Vincent, Billings MT	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11-12/98 01-02/99 05-06/99 8/06-Present
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Cardiology Residency Program, Georgetown University Medical Center/VA Medical Center Washington D.C. St Vincent, Billings MT	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11-12/98 01-02/99 05-06/99 08/06-Present
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Cardiology Residency Program, Georgetown University Medical Center/VA Medical Center Washington D.C. St Vincent, Billings MT	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11-12/98 01-02/99 05-06/99 08/06-Present
Administering dosages of radioactive drugs to patients or human research subjects	Cardiology Residency Program, Georgetown University Medical Center/VA Medical Center Washington D.C. St Vincent, Billings MT	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11-12/98 01-02/99 05-06/99 08/06-Present
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	ACGME Accredited Cardiology Residency Program, Georgetown University Medical Center/VA Medical Center Washington D.C. St Vincent Healthcare, Billings MT	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	11-12/98 01-02/99 05-06/99 08/06 - Present

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Daniel J. Fernicola, MD	0800942-5
Paul LaVeau, MD	25-07553-01

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.

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 Joseph C. Apostol, MD has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

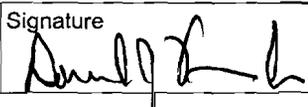
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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 J. Fernicola, MD	Signature 	Telephone Number 301-990-0040	Date 8/2/07
License/Permit Number/Facility Name 08-00942-05 Veterans Administration Med. Ctr			

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 Joseph C. Apostol, MD has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

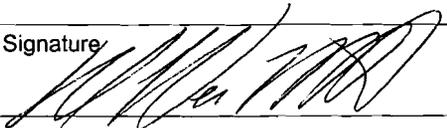
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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 Paul LaVeau, MD	Signature 	Telephone Number 406-237-5555	Date 12/10/07
License/Permit Number/Facility Name USNRC 25-07553-01 St Vincent Healthcare, Billings, Montana			

: (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
:
:
: Program Code: 02240
: Status Code: 0
: Fee Category: 7C
: Exp. Date: 20150430
: Fee Comments: CODE 21
: 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. VINCENT HEALTHCARE
Received Date: 20071217
Docket No: 3002396
Control No.: 471594
License No.: 25-07553-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____
Check No.: /

3. COMMENTS

Signed Colleen Murnahan
Date 12-19-07

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 _____

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: St. Vincent Healthcare **License No.:** 25-07553-01
Docket No.: 030-02396 **Mail Control No.:** 471594
Type of Action: Amendment **Date of Requested Action:** 12-11-07
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., split cover letter from license, add SUNSI markings to license. <input type="checkbox"/> Confirm with licensee if they have NARM material.

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 (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: RTC **Date:** 12-28-07

Checklist to Ensure That Radioactive Material Will Be Used as Intended

Applicant Information:

Control No. 471594

Name: St. Vincent Healthcare	Type of Request: Amendment Program Code(s): 02240	
Location: MT	License No.: 25-07553-01	Docket No.: 030-02396

STEP 1, ITEM A - INITIAL SCREENING

<p>Instructions for Step 1: Complete Step 1 for all applications. If Step 1, Items A and B, are "YES" then do not complete Step 2. Sign and date the completed form and add it to ADAMS as Non-Sensitive and Non-Publicly Available. If a "NO" response is indicated for Item A or Item B, add the completed form to ADAMS as Sensitive and Non-Publicly Available, and complete Step 2 (Additional Screening). If the type of use is subject to a Security Order, complete Step 3, Item A, without delay. If the additional requirements for increased controls will be applied or voided, complete Step 3, Item B, without delay.</p>	YES or NO
A. The applicant is a known entity or a licensee transferring control to a known entity. This determination has been made using the screening criteria in Worksheet A below.	Yes

Worksheet A

<p>Instructions for Worksheet A: Answer each of the 6 questions below by placing a "Yes", "No", or "NA" response in the column on the right. Best practices for a reviewer are provided after each of the questions. If the answer to any of the 6 questions is "Yes" then indicate "Yes" in Step 1, Item A, above. If the answers to all of the 6 questions is "No" then indicate "No" in Step 1, Item A, above. NOTE - If the reviewer has personal knowledge of the applicant's veracity, this can be taken into account in responding to any questions. For example, if the applicant's management and/or RSO have been associated with a current or previous NRC or Agreement State license, then the applicant may be considered as a known entity.</p>	YES, NO, or NA
1. Does the applicant have a current Agreement State or NRC license? The reviewer should 1) confirm that a valid license/registration/authorization exists for the applicant; and 2) compare the current license to the application to verify that the application represents a reasonable expansion of the licensee's operation (i.e., medical facility adding a gamma knife or an Agreement State licensee obtaining an NRC license in order to work in NRC jurisdiction without filing reciprocity).	yes
2. Does the applicant have a current Agreement State or NRC license at another location and the new application represents the addition of a new facility within the scope of the licensee's core business? The reviewer should contact the appropriate licensing authority to confirm that a valid license/registration/authorization exists for the applicant and the corporate office of the licensee to verify that it has knowledge of and approves of the new application.	
3. Does the applicant have a current State or Federal government license, registration, authorization, etc., for other operations within the scope of its proposed license activities? (e.g., a company authorized by a State for mining that is now requesting authorization to use fixed gauges). The reviewer should contact the appropriate government office to confirm that the license, registration, authorization, etc., is valid; and the applicant's corporate office to confirm that it has knowledge of and approves of the new application to possess radioactive materials.	
4. Is the applicant a local, State or Federal government agency? The reviewer should contact the local, State or Federal government office to confirm that the applicant is a government entity.	
5. Does the application only involve the relocation of an existing licensee, or its mailing address, to another State? This includes new licenses created from existing licenses listing locations in multiple States, in preparation for transfer of licenses to States that will shortly sign an Agreement with the NRC.	
6. Is the application only the result of a licensee failing to submit a renewal application in a timely manner?	

STEP 1, ITEM B - INITIAL SCREENING CONTINUED

<p>B. The applicant is requesting certain radionuclides and quantities that are less than the Risk Significant Quantity (TBq) values in Worksheet B, below, as "highlighted" by the reviewer, or is currently subject to a security order or additional requirements for increased controls. If "Yes", there is no need to proceed further.</p>	<p>N/A</p>
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Worksheet B - Risk Significant Quantities

(Category 2 Quantities, IAEA Safety Guide No. RS-G-1.9, Categorization of Radioactive Sources, August 2005)

Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)	Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)
Am-241	0.6	16	Pm-147	400	11,000
Am-241/Be	0.6	16	Pu-238	0.6	16
Cf-252	0.2	5.4	Pu-239/Be	0.6	16
Cm-244	0.5	14	Ra-226 ²	0.4	11
Co-60	0.3	8.1	Se-75	2	54
Cs-137	1	27	Sr-90 (Y-90)	10	270
Gd-153	10	270	Tm-170	200	5,400
Ir-192	0.8	22	Yb-169	3	81

¹ The primary values are TBq. The curie (Ci) values are for informational purposes only.
² The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

<p>Calculations of the Total Activity or the Unity Rule were completed. NOTE—If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).</p>	<p>Yes, No, or Not Applicable (NA)</p>
<p>Total Activity—multiple activities are requested for a single radionuclide and the sum of the activities is less than the Risk Significant Quantity (TBq) for the radionuclide.</p>	<p>—</p>
<p>Unity Rule—multiple radionuclides are requested and the sum of the ratios is less than 1.0, e.g., [(total activity for radionuclide A) ÷ (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) ÷ (risk significant quantity for radionuclide B)] < 1.0.</p>	<p>—</p>

Signature and Date for Step 1:

 12-28-07
 License Reviewer and Date