

# ACCEPTANCE REVIEW MEMO (ARM)

Licensee: St. Vincent Healthcare

License No.: 25-07553-01

Docket No.: 030-02396

Mail Control No.: 471043

Type of Action: Amend

Date of Requested Action: 07-14-06

Reviewer Assigned: Roberto

ARM reviewer(s): Cook

Response	Deficiencies Noted During Acceptance Review
	<ul style="list-style-type: none"><li>[ ] Open ended possession limits. Limit possession. Submit inventory.</li><li>[ ] Submit copies of most recent leak test results.</li><li>[ ] Add - delete IC license condition. Add IC paragraph in cover letter.</li><li>[ ] Split license from cover letter. Add SUNSI marking to license.</li><li>[ ] Ask the licensee if they have any type-amount of EPAct Material.</li></ul>
	<b>REVIEWER:</b> Confirm T & E is adequate for both doctors. (NRC Form 313a) Confirm if board certification for Dr. Brandon is NRC recognized.

Reviewer's Initials: \_\_\_\_\_

Date: \_\_\_\_\_

- ☐ Yes ☐ No      Unrestricted release Group 2 or >: Transfer memo to FCDB within 10 days.
- ☐ Yes ☐ No      Decommissioning notification should be completed within 30 days.
- ☐ Yes ☐ No      Termination request < 90 days from date of expiration
- ☐ Yes ☐ No      Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)
- ☐ Yes ☐ No      TAR needed to complete action.

Branch Chief's and/or Sr. HP's Initials: \_\_\_\_\_

Date: \_\_\_\_\_

## SUNSI Screening according to RIS 2005-31

☐ Yes ☒ No      **Non-Publicly Available, Sensitive** 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 Sr. HP's Initials: \_\_\_\_\_

Date: 7/21/06

# Pre-Licensing Screening

## Applicant Information:

Control No. 471043

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

## STEP 1—Radioactive Materials and Quantities Requested:

<b>Instructions for Step 1: Complete Step 1 for all applications.</b> If all your responses in Step 1 are "No" then do not complete Step 2 (Screening Criteria). Sign and date the completed step-sheet and add it as the sensitive and non-publicly available OAR in ADAMS. If a "yes" response is indicated for any item in Step 1, also complete Step 2. If the type of use is subject to a Security Order or the requirements for increased controls, complete Step 3 (Item A or Item B) without delay.		Yes or No
A.	The request is from a new applicant.	No
B.	NUREG-1556, Volume 20, Section 4.9 indicates a licensing site visit is needed for the requested type of use, e.g., (1) Type A broad scope license, (2) panoramic irradiator containing > 10000 curies, (3) manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material, (4) radioactive waste brokers, (5) radioactive waste incinerators, (6) commercial nuclear laundries, and (7) any other application that in the judgement of the reviewer and cognizant supervisor involves complex technical issues, complex safety questions, or unprecedented issues that warrant a site visit.	NO
C.	The applicant requested certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, that have been "highlighted" by the reviewer	NO

## Table of 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 <sup>1</sup> )	Risk Significant Quantity (Ci <sup>1</sup> )	Radionuclide	Risk Significant Quantity (TBq <sup>1</sup> )	Risk Significant Quantity (Ci <sup>1</sup> )
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 <sup>2</sup>	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

<sup>1</sup> The primary values are TBq. The curie (Ci) values are for informational purposes only.

<sup>2</sup> 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.

Calculations of the Total Activity or the Unity Rule are attached to document whether or not the screening criteria in Step 2 were also completed to evaluate the application. <b>NOTE—If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).</b>	Yes, No, or Not Applicable (NA)
Total Activity—multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the quantity of concern for the radionuclide	
Unity Rule—multiple radionuclides are requested and the sum of the ratios equals or exceeds unity, 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.	

## Signature and Date for Step 1:

*RITC* 7/27/06  
License Reviewer and Date

**From:** Roberto Torres  
**To:** rodwimmer@lycos.com  
**Date:** 09/12/2006 3:27:34 PM  
**Subject:** Amendment request

Dr. Wimmer:

On 7/27 I sent you the email below requesting additional information on Dr. Brandon and Dr. Apostol. These physicians can work under the supervision of an authorized user until they can meet the training and experience requirements to be named on an NRC license. Please let me know if you are going to submit Forms 313A for Dr. Brandon and Dr. Apostol or if you prefer to void this amendment request and resubmit at a later date. Thank you.

XXXXXXXXXXXXXXXXXXXXXXXXXXXX

Dr. Wimmer:

Our revised medical training and experience regulations no longer differentiate between diagnostic or therapeutic procedures, or cardiovascular versus non cardiovascular procedures. The new regulations require an individual who wants to become an authorized user to have:

- 1) a board certification recognized by NRC AND a preceptor attestation, or
- 2) have required training and experience AND a preceptor attestation, or
- 2) be listed as an authorized user in an NRC or Agreement State license for the same type of uses for which the individual is seeking recognition.

The new regs are dose based. Therefore, training and experience requirements for a physician who wants to administer only I-131 (no other unsealed radionuclide) in quantities less than or equal to 33 millicuries are described in 10 CFR 35.392. See next link.

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0392.html>

Training and experience requirements for a physician who wants to administer only I-131 (no other unsealed radionuclide) in quantities greater than 33 millicuries are described in 10 CFR 35.394. See next link.

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0394.html>

Training and experience requirements for a physician who wants to administer all unsealed radionuclides (including I-131) are described in 10 CFR 35.390. See next link.

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0390.html>

Training and experience requirements for a physician who wants to administer radionuclides for imaging and localization studies are described in 10 CFR 35.290. See next link.

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0290.html>

Current boards recognized by NRC are in this link.

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

Use the attached NRC Form 313A to resubmit your amendment since Dr. Brandon and Dr. Apostol cannot be name as authorized users with the documentation that you originally sent. Also please clarify if Dr. Brandon is pursuing using I-131 only. Please call me so I can help you with the process of filling out forms 313A.

Roberto J. Torres  
Senior Health Physicist  
U.S. Nuclear Regulatory Commission, Region IV  
Division of Nuclear Materials Safety  
Nuclear Materials Licensing Branch  
611 Ryan Plaza Drive, Suite 400  
Arlington, Texas 76011  
Telephone 817-860-8189  
Facsimile 817-860-8188  
[rjt@nrc.gov](mailto:rjt@nrc.gov)

**Mail Envelope Properties** (45071836.B2E : 18 : 64234)

**Subject:** Amendment request  
**Creation Date** 09/12/2006 3:27:34 PM  
**From:** Roberto Torres

**Created By:** RJT@nrc.gov

<b>Recipients</b>	<b>Action</b>	<b>Date &amp; Time</b>
lycos.com	Transferred	09/12/2006 3:28:18
PM		
rodwimmer (rodwimmer@lycos.com)		

nrc.gov		
ARL_PO.ARL_DO	Delivered	09/12/2006 3:27:34
PM		
RJT BC (Roberto Torres)	Opened	09/12/2006 3:28:51
PM		

<b>Post Office</b>	<b>Delivered</b>	<b>Route</b>
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<b>Files</b>	<b>Size</b>	<b>Date &amp; Time</b>
MESSAGE	4776	09/12/2006 3:27:34 PM
nrc313a.pdf	161321	07/25/2006 7:24:45 AM

**Options**

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<b>Notify Recipients:</b>	No
<b>Priority:</b>	Standard
<b>ReplyRequested:</b>	No
<b>Return Notification:</b>	None

<b>Concealed Subject:</b>	No
<b>Security:</b>	Standard

<b>To Be Delivered:</b>	Immediate
<b>Status Tracking:</b>	Delivered & Opened

**From:** Roberto Torres  
**To:** rodwimmer@lycos.com  
**Date:** 07/27/2006 5:04:41 PM  
**Subject:** Amendment request

Dr. Wimmer:

Our revised medical training and experience regulations no longer differentiate between diagnostic or therapeutic procedures, or cardiovascular versus non cardiovascular procedures. The new regulations require an individual who wants to become an authorized user to have:

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Roberto J. Torres  
Senior Health Physicist  
U.S. Nuclear Regulatory Commission, Region IV  
Division of Nuclear Materials Safety  
Nuclear Materials Licensing Branch  
611 Ryan Plaza Drive, Suite 400  
Arlington, Texas 76011  
Telephone 817-860-8189  
Facsimile 817-860-8188

**Mail Envelope Properties** (44C93879.B2E : 18 : 64234)

**Subject:** Amendment request  
**Creation Date** 07/27/2006 5:04:41 PM  
**From:** Roberto Torres

**Created By:** RJT@nrc.gov

<b>Recipients</b>	<b>Action</b>	<b>Date &amp; Time</b>
lycos.com rodwimmer (rodwimmer@lycos.com)		
nrc.gov		
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PM		
RJT BC (Roberto Torres)	Opened	07/27/2006 5:04:52
PM		

<b>Post Office</b>	<b>Delivered</b>	<b>Route</b>
	Pending	lycos.com
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<b>Files</b>	<b>Size</b>	<b>Date &amp; Time</b>
MESSAGE	4107	07/27/2006 5:04:41 PM
nrc313a.pdf	161321	07/25/2006 7:24:45 AM

**Options**

<b>Auto Delete:</b>	No
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<b>Priority:</b>	Standard
<b>ReplyRequested:</b>	No
<b>Return Notification:</b>	None

<b>Concealed Subject:</b>	No
<b>Security:</b>	Standard

<b>To Be Delivered:</b>	Immediate
<b>Status Tracking:</b>	Delivered & Opened

United States Nuclear Regulatory Commission  
611 Ryan Plaza Suite 400  
Arlington, TX 76011-4005

RE NRC License Number: 25-07553-01

Gentlemen:

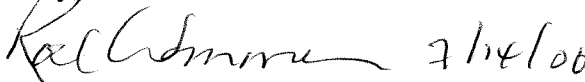
St. Vincents Healthcare would like to add to its Byproduct Materials License Dr. John Brandon M.D. and Dr. Joseph Apostol M.D.

Dr. Jack. Brandon is a ABR certified Radiologist (Board certificate enclosed) and requests Authorized User status for material permitted by 10 CFR 35.100, 200 and 300.

Dr. Joseph Apostol is a Cardiologist requesting Authorized User status for materials permitted by 10 CFR 35.200 for cardiovascular clinical procedures. Please see attached letter for training documentation.

If there are any additional questions please contact me at St. Vincent Healthcare 1233 North 30<sup>th</sup> St. Billings, MT 59101, e-mail [rodwimmer@lycos.com](mailto:rodwimmer@lycos.com) or by phone (406) 788-0477.

Sincerely,

Handwritten signature of Rod Wimmer in cursive script, followed by the date 7/14/06.

Rod Wimmer Ph.D.  
RSO St. Vincents Healthcare

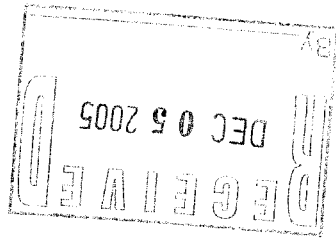
RECEIVED

JUL 20 2006

DNMS

471043





# The American Board of Radiology

*Organized through the cooperation of the  
American College of Radiology, the American Roentgen Ray Society,  
the American Radium Society, the Radiological Society of North America,  
the Section on Radiology of the American Medical Association,  
the American Society for Therapeutic Radiology and Oncology, the Association of  
University Radiologists, and American Association of Physicians in Medicine*

*Hereby certifies that*

**John Scott Brandon, MD**

*Has pursued an accepted course of graduate study  
and clinical work, has met certain standards and qualifications and  
has passed the examinations conducted under the authority of*

*The American Board of Radiology*

*On this eighth day of June, 2005*

*Thereby demonstrating to the satisfaction of the Board  
that he is qualified to practice the specialty of*

**Diagnostic Radiology**

*Allen A. Licht, M.D.*  
President

*Michael P. Soppa, MD*  
Secretary-Treasurer

*R. R. Harte, MD*  
Executive Director

THE CLEVELAND CLINIC  
FOUNDATION

May 20, 2005

**Manuel D. Cerqueira, M.D.**

Chairman

Dept. of Molecular and Functional Imaging - Gb3

Office: 216-444-2665

Fax: 216-444-3943

E-mail: cerquem@ccf.org; cerqm@concentric.net

Certification Board of Nuclear Cardiology  
19562 Club House Road  
Montgomery Village, MD 20886

To the Certification Board of Nuclear Cardiology:

✓ Joseph C. Apostol, M.D. has completed a training program in nuclear cardiology that meets the requirements as outlined in the ACC/ASNC COCATS Guidelines (revised 2000). As an authorized medical user I provided training as part of a cardiology fellowship training program from 1997 to 1999. During this time he had greater than 500 hours of clinical patient selection, stress testing and interpreting of perfusion and equilibrium gated blood pool images. Over 100 of these patients had cath correlation. He had an additional 500 hours in radiation safety handling.

✓ Joseph C. Apostol, M.D. is competent to independently function as an authorized user under NRC 10 CFR 35.290 uses.

Sincerely,

Manuel D. Cerqueira, MD

ODH - 02110180013

Ohio NRC # - 083057701

(FOR LEMS USE)  
INFORMATION FROM LTS  
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.....
Program Code: 02240
Status Code: 0
Fee Category: 7C
Exp. Date: 20150430
Fee Comments: CODE 21
Decom Fln Assur Regd: N
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:      Decom Fin Assur Req'd: N
:.....

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:      Decom Fin Assur Req'd: N
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:      Decom Fin Assur Req'd: N
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