

## ACCEPTANCE REVIEW MEMO (ARM)

Licensee: St. Patrick Hospital

License No.: 25-16773-02

Docket No.: 030-14734

Mail Control No.: 471470

Type of Action: Notify

Date of Requested Action: 08-15-07

Reviewer  
Assigned:

ARM reviewer(s): Torres

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>

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: RTZ

Date: AUG 28 2007

## Pre-Licensing Screening

### Applicant Information:

Control No. 471470

Name: St. Patrick Hospital	Type of Request: Notify Program Code(s):	
Location: MT	License No.: 25-16773-02	Docket No.: 030-14734

### 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:

AUG 28 2007  
 License Reviewer and Date

500 West Broadway, P.O. Box 4587  
Missoula, Montana 59806  
406/543-7271  
www.saintpatrick.org



ST. PATRICK HOSPITAL AND HEALTH SCIENCES CENTER  
Sponsored by the Sisters of Providence

RECEIVED

AUG 15 2007

DNMS

Licensing Division  
U.S. NRC Region IV  
Texas Health Resources Tower  
611 Ryan Plaza, Suite 400  
Arlington, TX 76011-4005

Re: Additional AU for NRC License # 25-16773-02

Dear Sir/Madam;

We respectfully provide notification, pursuant to 10CFR35.14(a) of the addition of a new authorized user, Dr. Mark Sanz, M.D. Dr. Sanz will use Tc-99m for cardiac studies. 35.200

Action was taken by our Radiation Safety Committee on August 8, 2007 to grant Dr. Sanz AU status in light of the enclosed supporting documents.

Dr. Sanz received the required didactic training from the Consultants in Nuclear Medicine (Certificate enclosed) and has been working under the supervision of Dr. Bradley Berry for performing cardiac imaging/function studies. A preceptor attestation is enclosed.

Respectfully,

James H. Brewer, Ph.D., RSO

471470

**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

MARK SANZ, M.D.

MONTANA

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	SAINT PATRICIA HOSPITAL MISSOULA, MONTANA  25-16773-02		

**Total Hours of Experience:**

Supervising Individual

License/Permit Number listing supervising individual as an authorized user

DR. BRADLEY BERRY

NRC # 25-16773-02

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	Marriott Suites Downers Grove, IL	15	5/12 - 5/20 2007
Radiation protection	Marriott Suites Downers Grove, IL	25	5/12 - 5/20 2007
Mathematics pertaining to the use and measurement of radioactivity	Marriott Suites Downers Grove, IL	10	5/12 - 5/20 2007
Chemistry of byproduct material for medical use (not required for 35.590)	Marriott Suites Downers Grove, IL	20	5/12 - 5/20 2007
Radiation biology	Marriott Suites Downers Grove, IL	18	5/12 - 5/20 2007

Total Hours of Training:

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	SAINT PATRICK HOSPITAL	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2003 - 2007
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	SAINT PATRICK HOSPITAL	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2003 - 2007

## 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 MARK SANZ, M.D. 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 MARK SANZ, 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

Signature

Telephone Number

Date

BRUCE T. BURRY[Signature]406-543-72718/8/2007

License/Permit Number/Facility Name

**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	SAINT PATRICK HOSPITAL	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2003 - 2007
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	SAINT PATRICK HOSPITAL	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2003 - 2007
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	SAINT PATRICK HOSPITAL	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2003 - 2007
Administering dosages of radioactive drugs to patients or human research subjects	SAINT PATRICK HOSPITAL	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2003 - 2007
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	SAINT PATRICK HOSPITAL	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2003 - 2007

Supervising Individual

DR BRADLEY BERRY  
BERRY

License/Permit Number listing supervising individual as an authorized user

NRC # 25-16773-02

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.**

*Consultants in Nuclear Medicine*

*2910 W. Estes Avenue*

*Chicago, IL 60645*

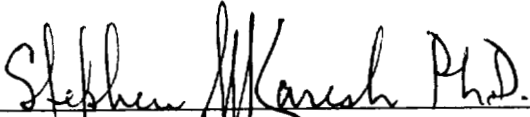
*This certificate verifies that on May 20, 2007*

***Dr. Mark Sanz***

*Completed 88 hours of the  
Basic Radioisotope Handling Course  
Covering the Topics of*

***Radiopharmacy, Radiation Biology,  
Radiation Protection, Instrumentation and Physics,  
and the Mathematics Associated with Radioactivity***

*And received a passing grade. This course is designed to qualify a  
physician as an authorized user of radiopharmaceuticals, generators,  
and reagent kits and meets all requirements set forth by the US  
Nuclear Regulatory Commission and all agreement states as outlined  
in the Code of Federal Regulations.*

  
*Stephen M. Karesh, PhD, Course Director*



08-19-07  
*rec'd*  
This is to acknowledge the receipt of your letter/application ~~dated~~  
8-15-07, and to inform you that the initial processing,  
which includes an administrative review, has been performed.

DATE

☒ There were no administrative omissions. Your application will be assigned to a technical reviewer. Please note that the technical review may identify additional 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      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** 471470.  
When calling to inquire about this action, please refer to this mail control number.  
You may call me at 817-860-8103.

Sincerely,

*Cathleen M. Mulvaney*

Licensing Assistant

BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

: (FOR LFMS USE)  
: INFORMATION FROM LTS  
: -----  
:  
: Program Code: 02120  
: Status Code: 0  
: Fee Category: 7C 3E  
: Exp. Date: 20150731  
: Fee Comments: CODE 21  
: Decom Fin Assur Req'd: N  
: .....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: ST. PATRICK HOSPITAL  
Received Date: 20070815  
Docket No: 3014734  
Control No.: 471470  
License No.: 25-16773-02  
Action Type: Notifications

2. FEE ATTACHED

Amount: \_\_\_\_\_  
Check No.:       /      

3. COMMENTS

Signed  
Date

Colleen Murahan  
8-23-07

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

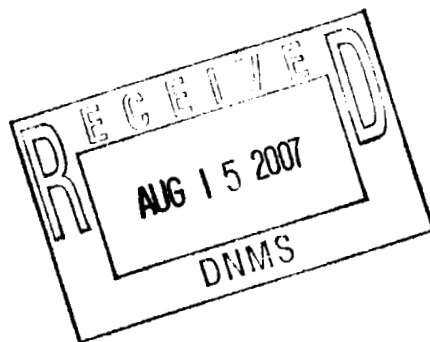
\_\_\_\_\_  
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Montana Cancer  
Center



500 W. Broadway  
P.O. Box 4587  
Missoula, MT 59807-4587

25-16773-02  
030-14734  
471470



20 00

Licensing Division  
U.S. NRC Region IV  
Texas Health Resources Tower  
611 Ryan Plaza Ste 400  
Arlington, TX 76011-4005

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