MARQUETTE GENERAL HEALTH SYSTEM
580 W. College Avenue • Marquette, Michigan 49855 • 906-228-9440 • Toll free 1-800-562-9753 • Website: www.mgh.org

November 8, 2007

Nuclear Materials Licensing Branch
Nuclear Regulatory Commission Region III
2443 Warrenville Rd., Suite 210
Lisle, IL 60532-4352

RE: MATERIALS LICENSE NO. 21-05432-04

This letter is to request the addition of Y-90 SirSpheres to the approved uses for Dr. Christopher Mehall. He is already authorized for 35.300 uses of I-131 sodium iodide including therapeutic uses. Enclosed are copies of his vendor training documentation and preceptor statement. He was the original Interventional Radiologist trained to perform these procedures and has been working with the Radiation Oncologist (AU), Dr. Paul Thieme, for the past two years. This action was approved by management and the Radiation Safety Officer.

If you have further questions, please contact Shan Marlette, R.S.O. at (906) 225-3102 or fax number (906) 225-3772.

Sincerely,

A. Gary Muller, FACHE
Chief Executive Officer

AGM/jmr

Enclosure

NRC FORM 313A (AUT) (3-2007) | U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User	State or Territory Where Licensed
Dr. Christopher Mehall	Michigan

Requested Authorization(s) *(check all that apply)*:

☐ 35.300 Use of unsealed byproduct material for which a written directive is required

OR

☒ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ 35.300 Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☒ 35.300 Parenteral administration of any other radionuclide for which a written directive is required

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 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. For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.

c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.

d. Skip to and complete Part II Preceptor Attestation.

☒ **2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**

a. Authorized User on Materials License 21-05432-04 *under the requirements below or equivalent Agreement State requirements (check all that apply)*:

☐ 35.390 ☒ 35.392 ☒ 35.394 ☐ 35.490 ☐ 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☐ **3. Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training ☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience ☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

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		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	
Calculating, measuring, and safely preparing patient or human research subject dosages		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. **Training and Experience for Proposed Authorized User** *(continued)*

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user

Supervising individual meets the requirements *below, or equivalent Agreement State requirements (check all that apply)***:

☐ 35.390
☐ 35.392
☐ 35.394
☐ 35.396

With experience administering dosages of:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
☐ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience
If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral adminstration of any other radionuclide for which a written directive is required Y-90 (List radionuclides)	26 cases SirSpheres	Marquette General Hosp. NRC # 21-05432-04 Marquette Michigan	05/04/06 to 10/18/07

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. *Training and Experience for Proposed Authorized User* (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Paul Thieme, D.O.	24-05432-04

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☒ 35.390
☐ 35.392
☐ 35.394
☐ 35.396

With experience *administering* dosages of:

- ☒ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☒ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☒ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☒ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

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.

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

For 35.390:

Board Certification

☐ I attest that _____ has satisfactorily completed the training and experience
Name of Proposed Authorized User

requirements in 35.390(a)(1).

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

NRC FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION
(3-2007)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

For 35.394 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

Second Section

☒ I attest that Dr. Christopher Mehall has satisfactorily completed the required clinical case
Name of Proposed Authorized User

experience required in 35.390(b)(1)(ii)G listed below:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☒ Parenteral administration of any other radionuclide requiring a written directive

Third Section

☐ I attest that Dr. Christopher Mehall has satisfactorily achieved a level of competency to
Name of Proposed Authorized User

function independently as an authorized user for:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☒ Parenteral administration of any other radionuclide requiring a written directive

NRC FORM 313A (AUT) (3-2007) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☐ I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral adminstration of any other radionuclide for which a written directive is required

OR

Board Certification:

☐ I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral adminstration of any other radionuclide for which a written directive is required

---

Fifth Section
Complete the following for preceptor attestation and signature:

☒ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☒ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

☒ I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☒ Parenteral administration of any other radionuclide requiring a written directive

RST

Name of Preceptor	Signature	Telephone Number	Date
Paul Thieme, D.O.	Paul O Thieme DO	906 225.3102	11-7-7

License/Permit Number/Facility Name
24.05432.04 Marquette General Health System

SIRTeX

SITE SET-UP CHECKLIST

Name of Institution: *Marquette General Marquette, Michigan*

PART 1 APPROVAL REQUIREMENTS

Facility

Is the facility appropriately approved to receive SIR-Spheres®? ☒ yes ☐ no

If yes, please fax a copy of license together with this form to *Operations Manager*

License checked and treatment centre approved to receive training dose of SIR-Spheres by:

Signature: (Operations Manager) Date: (dd/mm/yy)

Physician Name(s): Drs Chris Mehall and Paul Theime

Is the physician approved to treat the patient with SIR-Spheres®? ☒ yes ☐ no

NB: It is the responsibility of the authorised person in the facility, and of any and every personal licence holder to maintain currency of any relevant radiation licences and inform Sirtex of changes.

PART 2 EQUIPMENT & PROCEDURE

Does the site have the required equipment to receive, handle, dispense and administer SIR-Spheres®? ☒ yes ☐ no

Does the site have procedure to *decontaminate* SIR-Spheres® in the event of a spill? ☒ yes ☐ no

PART 3 TRAINING

Nuclear Medicine Technicians/Physicians trained / to be trained *on dose preparation:*

Name/s: Shan Marlette, RSO and Physisist Date: 4-Nov-05 (dd/mm/yy)

Nuclear Medicine Technicians/Physicians trained /to be trained on delivery apparatus assembly:

Name/s: Dr. Chris Mehall and Nathan Aho, Tech Date: 4-Nov-05 (dd/mm/yy)

Sirtex Rep. conducted the training: Joni Payne

PART 4 FIRST IMPLANT

Date of First Implant: 6-Apr-06 (dd/mm/yy) x 2 5-4-06 x 2 total 4 + proctor + Vendor

Name/s of physician/s trained on first implant: Drs Chris Mehall and Paul Thieme

Dose correctly dispensed ☒ yes ☐ no

Delivery apparatus correctly assembled ☒ yes ☐ no

Medical Director (or delegate) present to supervise ☒ yes ☐ no

Name of Medical Director/Delegate: David Cade Signature:

Approved for dispatch of ongoing doses by Regulatory: Date: 05/11/07 (dd/mm/yy)

Comments (if any): This form also is to document that all of the above - Drs, RSO , Nurses and Techs were in-serviced on the new v-vial and delivery set. The new supplies were used.

MARQUETTE GENERAL
HEALTH SYSTEM
420 W. Magnetic Street Marquette, MI 49855
REGIONAL MEDICAL CENTER

Nuclear Materials Licensing Branch
Nuclear Regulatory Commission Region III
2443 Warrenville Road Suite 210
Lisle, IL 60532-4352