

Hill, Carol

From: Traci Hollingshead <Traci.Hollingshead@avera.org>
Sent: Wednesday, March 30, 2016 11:24 AM
To: Hill, Carol
Subject: [External_Sender] Amendment request 40-16571-01
Attachments: PATEL ABR w CAQ IR certificate effective 10-28-2013.pdf; Request letter.pdf; Jay Patel_TEC_Completion_Letter.pdf; NRC Form 313.pdf

Ms. Hill,

Attached is documentation for an amendment request to Avera McKennan's radioactive material license.

I would like to add Dr. Jay Patel as an Authorized User.

Sincerely,
Traci

Traci Hollingshead
Radiation Safety Officer
Avera Radiation Oncology
1000 E. 23rd Street, Suite 100
Sioux Falls, SD 57105
(605) 310-0916
traci.hollingshead@avera.org

PUBLIC

- ☐ Immediate Release
☒ Normal Release

NON-PUBLIC

- ☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other: _____

Reviewer: NRK Date: 4/6/16

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 Radiation Oncology, the Association of University Radiologists,
the American Association of Physicians in Medicine, and the Society of Interventional Radiology,
the American Board of Radiology hereby certifies that*

Jay H. Patel, MD

*Has pursued an accepted course of graduate study and clinical work; has met certain standards
and qualifications, including passing the examinations conducted under the authority of
the American Board of Radiology, demonstrating to the satisfaction of the Board qualification
to practice; and is therefore awarded the Board's certification in*

Harshar and Interventional Radiology

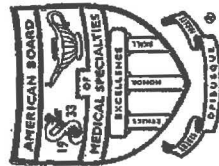
a Subspecialty of

Diagnostic Radiology

*Ongoing validity of this certificate is contingent upon
meeting the requirements of Maintenance of Certification.*

*This diplomate of the American Board of Radiology
is permitted to use the ABR mark to signify this certification.*

ABR



James P. Bryant, MD
President

C. P. Evans
Secretary-Treasurer

Harold Schultz
Executive Director

Certificate No. 60066

Effective: October 28, 2013



1325 S. Cliff Ave.
P.O. Box 5045
Sioux Falls, SD 57117-5045
605-322-8000

AveraMcKenna.org

March 30, 2016

U.S. Nuclear Regulatory Commission
Nuclear Materials Safety Branch B
Region IV
1600 East Lamar Boulevard
Arlington Texas 76011

RE: NRC license #40-16571-01

To Whom it May Concern:

The intent of this amendment request is to add Jay Patel, M.D. as an authorized user for 10 CFR 35.1000 Y-90 micorspheres. Dr. Patel's board certification and training documentation is enclosed for your review.

Please contact me at (605) 310-0916 if you have any questions regarding this amendment request.

Sincerely,

A handwritten signature in cursive script that reads "Traci Hollingshead".

Traci Hollingshead
Radiation Safety Officer
Avera McKennan

*Sponsored by the Benedictine
and Presentation Sisters*

No 590519



SIRTEX MEDICAL INC.

300 Unicorn Park Drive

Woburn, MA 01801

Tel: +1 (781) 721 3800

Fax: +1 (781) 721 3880

Ref: 105US03

March 22, 2016

Jay Patel
Avera McKennan Hospital
1325 S Cliff Ave
Sioux Falls SD 57117

Dear Dr Patel,

Re: SIR-Spheres® Microspheres Training, Evaluation, Certification (TEC) Program

I am writing to confirm that on, February 10th, 2016 Dr. Randall Smith presented and discussed in detail the preparation and procedures associated with the treatment of patients with SIR-Spheres yttrium-90 microspheres that are injected via the hepatic artery to treat patients with unresectable liver tumors. The patients were treated with SIR-Spheres microspheres.

Dr. Smith proctored the treatments and I am pleased to inform you that he considers that you and your staff are now trained in the preparation and the clinical aspects of treating patients with SIR-Spheres microspheres.

This letter also certifies that you were proctored for at least 3 cases by a Sirtex certified proctor in the use of SIR-Spheres® microspheres.

I would like to thank you and your team for your support and commitment to the Sirtex **Training, Evaluation, Certification (TEC) Program**.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Eric First".

Eric First, M.D.

Medical Director – Americas



Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submission of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollections.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (315)0-1120, Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

3-28-1C

FOR INFORMATION

| FILE NUMBER | FEB TOGN | FILE CATEGORY | AMOUNT RECEIVED | SETTLEMENT NUMBER | COMMENTS |
|-------------|----------|---------------|-----------------|-------------------|----------|
|-------------|----------|---------------|-----------------|-------------------|----------|

APPROVED



DATE

03/31/2016

| | |
|---|---|
| NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE Tracy Hollingshead, Radiation Safety Officer Nuclear Medicine Department Avera McKennan 1325 South Cliff Avenue Sioux Falls, SD 57117-5045 | LICENSE NUMBER 40-16571-01 |
| | MAIL CONTROL NUMBER 590519 |
| | LICENSING AND/OR TECHNICAL REVIEWER CH |

This is to acknowledge the receipt of your:

☒ LETTER and/or ☐ APPLICATION DATED: 03/30/2016

The initial processing, which included an administrative review, has been performed.

☒ AMENDMENT ☐ TERMINATION ☐ NEW LICENSE ☐ RENEWAL

- ☐ There were no administrative omissions identified during our initial review.
- ☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.
- ☐ Your application for a new NRC license did not include your taxpayer identification number. Please fill out NRC Form 531, located at the following link:

<http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>

Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387

A copy of your action has been emailed to our License Fee and Accounts Receivable Branch, in our Headquarters office in Rockville, MD. You will be contacted separately if there is a fee issue involved.

Your application has been assigned the above listed **MAIL CONTROL NUMBER**. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV
U. S. Nuclear Regulatory Commission
DNMS/NMSB - B
1600 E. Lamar Boulevard
Arlington, TX 76011-4511
(817) 200-1140

V3/31/16

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 02310
Status Code: Pending Amendment
Fee Category: 2B 7A 7C
Exp. Date:
Fee Comments: CODE 21
Decom Fin Assur Req: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: Avera McKennan
Received Date: 03/30/2016
Docket Number: 3011252
Mail Control Number: 590519
License Number: 40-16571-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: _____

Date: _____

Carl R. Heine

3/31/16

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: _____