NRC FORM 313
(03-2013)
10 CFR 30, 32 33, 34, 35, 36, 39 and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 05/31/2015

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal 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 Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), 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.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

RECEIVED
OCT - 1 2015
DNMS

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE
- [x] B. AMENDMENT TO LICENSE NUMBER 40-16571-01
- [ ] C. RENEWAL OF LICENSE NUMBER

PUBLIC
☐ Immediate Release
☒ Normal Release

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Avera McKennan
1325 South Cliff Avenue
Sioux Falls South Dakota 57117-5045

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

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

Reviewer: [illegible] Date: 10-14-15

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
John Wood, Associates in Medical Physics, LLC

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
(216) 663-7000	(216) 496-7829

BUSINESS EMAIL ADDRESS
j.wood@ampmedicalphysics.com

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL.
a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE. (See Attached)

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*)
(See 10 CFR 170 and Section 170.31)

FEE CATEGORY: 7C

AMOUNT ENCLOSED $:

13. CERTIFICATION. *(Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.*

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER--TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
David L. Kapaska, DO Regional President	[signature]	9/28/15

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

589044

SIRTEX MEDICAL INC.
300 Unicorn Park Drive
Woburn, MA 01801
Tel: +1 (781) 721 3800
Fax: +1 (781) 721 3880

Ref: 105US03

February 26, 2015

Jennifer Williams
Avera McKennan Hospital
1325 S Cliff Ave
Nuclear Medicine
Sioux Falls, SD 57117

Dear Dr Williams

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

I am writing to confirm that on February 13 2015, 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 Dr Smith 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,

Eric First, M.D.
Medical Director – Americas

cc: <Account Manager>
TEC@sirtex.com

® SIR-Spheres is a Registered Trademark of Sirtex SIR-Spheres Pty Ltd

589044

Avera
McKennan Hospital
& University Health Center

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

AveraMcKennan.org

September 28, 2015

NRC
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 Jennifer M. Williams, D.O. as an authorized user for 10 CFR 35.1000 Y-90 micorspheres. Dr. Williams' form 313A (AUS) and board certification is enclosed for your review.

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

Sincerely,

David Kapaska, D.O.
President & CEO

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 Physicists in Medicine, and the Society of Interventional Radiology,
the American Board of Radiology hereby certifies that

Jennifer M. Williams, DO

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

Vascular 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

THE AMERICAN BOARD OF RADIOLOGY INCORPORATED IN THE DISTRICT OF COLUMBIA 1934

President

Secretary-Treasurer

Executive Director

AMERICAN BOARD OF MEDICAL SPECIALTIES 1933 EXCELLENCE

Certificate No. 61508

Effective: November 10, 2014

The American Board of Radiology

Organized through the corporation 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, and the American Association of Physicists in Medicine,
Hereby certifies that

Jennifer M. Williams, DO

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

Diagnostic Radiology

AH Eligible

DABR

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 **DABR** *mark to signify this certification.*

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED
IN THE
DISTRICT
OF
COLUMBIA
1934

Bruce J. Hillman
President

Richard L. Morin
Secretary-Treasurer

Hayt Pickens
Executive Director

Certificate No. 61503

Effective: July 01, 2012

5 8 0 0 4 4

PLACE STICKER AT TOP OF ENVELOPE TO THE RIGHT OF THE RETURN ADDRESS, FOLD AT DOTTED LINE

CERTIFIED MAIL®

7015 1520 0003 3883 8846

UNITED STATES POSTAGE

$ 07.67⁰

22 1R 0006559593 SEP 29 2015

MAILED FROM ZIP CODE 57105

RECEIVED
OCT - 1 2015
DNMS

Nuclear Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region IV
1600 E. Lamar Boulevard
Arlington, TX 76011-4511

1659260

589044

Torres, RobertoJ

From: Traci Hollingshead <Traci.Hollingshead@avera.org>
Sent: Wednesday, October 14, 2015 11:24 AM
To: Torres, RobertoJ
Subject: [External_Sender] RE: 9-28-15 amendment to add authorized user (Jennifer Williams)
Attachments: 20151014111040555.pdf

Mr. Torres,

Please see attached letter.

Thank you,
Traci

From: Torres, RobertoJ [mailto:RobertoJ.Torres@nrc.gov]
Sent: Wednesday, October 14, 2015 7:55 AM
To: Traci Hollingshead
Subject: 9-28-15 amendment to add authorized user (Jennifer Williams)

Ms. Hollingshead:

The attached amendment request letter to add an authorized user states that Form 313A(AUS) is enclosed; however it was not included. Please provide 313A by reply email as a pdf file. Thank you.

Avera
McKennan Hospital
& University Health Center

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

AveraMcKennan.org

October 14, 2015

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

RE: NRC license #40-16571-01

Mr. Torres:

The amendment request letter dated September 28, 2015 stated that there is a form 313A (AUS) attached for Jennifer M. Williams, D.O.

This was stated in error. There is no form 313A (AUS) documenting her training. The SIRTeX letter dated February 26, 2015 is the document that should have been referenced for Ms. Williams training, evaluation and participation in the certification program.

I apologize for this error.

Sincerely,

Traci Hollingshead

Traci Hollingshead
Radiation Safety Officer
Avera McKenann