

NRC FORM 313 (01-2020) 10 CFR 30, 32, 33, 34, 35, 36, 37, 39, and 40	U.S. NUCLEAR REGULATORY COMMISSION  APPLICATION FOR MATERIALS LICENSE	APPROVED BY OMB: NO. 3150-0120 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-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by 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 CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.										
APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: MATERIALS SAFETY LICENSING BRANCH DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001 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 IF YOU ARE LOCATED IN: 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) <input type="checkbox"/> A. NEW LICENSE <input checked="" type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER <u>40 16571 02</u> <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____	2. NAME AND MAILING ADDRESS OF APPLICANT (Include zip code) Avera McKennan Hospital/Nuclear Medicine 1325 S. Cliff Avenue Sioux Falls, SD 57117-5045									
3. ADDRESS WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED Avera McKennan Hospital/Nuclear Medicine 1325 S. Cliff Avenue Sioux Falls, SD 57117-5045	4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION Michelle White <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%;">BUSINESS TELEPHONE NUMBER</td> <td style="width:50%;">BUSINESS CELLULAR TELEPHONE NUMBER</td> </tr> <tr> <td></td> <td style="text-align: center;">605-929-9056</td> </tr> <tr> <td colspan="2">BUSINESS E-MAIL ADDRESS</td> </tr> <tr> <td colspan="2" style="text-align: center;">michelle.white@avera.org</td> </tr> </table>		BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER		605-929-9056	BUSINESS E-MAIL ADDRESS		michelle.white@avera.org	
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michelle.white@avera.org										
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 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.									
8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.	7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.									
10. RADIATION SAFETY PROGRAM.	9. FACILITIES AND EQUIPMENT.									
12. LICENSE FEES (Fees required only for new applications, with few exceptions*) (See 10 CFR 170 and Section 170.31) *Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.	FEE CATEGORY <input type="text"/>	AMOUNT ENCLOSED \$ <input type="text"/>								
PER THE DEBT COLLECTION IMPROVEMENT ACT OF 1996 (PUBLIC LAW 104-134), YOU ARE REQUIRED TO PROVIDE YOUR TAXPAYER IDENTIFICATION NUMBER. PROVIDE THIS INFORMATION BY COMPLETING NRC FORM 531: https://www.nrc.gov/reading-rm/doc-collections/forms/nrc531info.html .										
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, 37, 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 Michelle White, RSO	SIGNATURE 	DATE 10-25-21								
FOR NRC USE ONLY										
TYPE OF FEE	FEE LOG	FEE CATEGORY								
AMOUNT RECEIVED \$	CHECK NUMBER	DATE								
APPROVED BY		DATE								

@gTW (S" ++
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 >[UW@g TW, &'Z#') #Z S
 >[UW@S_ W3hMS? U-W S' !@gUWd? WU W



**McKenna Hospital
& University Health Center**

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

Avera.org

October 25, 2021

U.S. Nuclear Regulatory Commission
Region IV
1600 E. Lamar Blvd.
Arlington, Texas 76011-4511

Dear Sir or Madam:

Re: NRC Radioactive Material License #40-16571-02

At this time, Avera McKennan wishes to add one Authorized User for Material and Use of 35.1000 Y-90 TheraSphere use under Item 12. B. The proposed Authorized user is Marek Siorek. Attached you will find the Certificate from the American Board of Radiology which states he is AU eligible and his proof of Y-90 TheraSphere training.

Avera McKennan would also like to remove from the license Sub item D under item 6, any byproduct material permitted by 10 CFR 35.400. This removal will also require removal of Kyle Arneson, MD. who is listed under 12.B.

If you have any questions or need additional information regarding this request, please contact me at (605) 929-9056.

Sincerely:

A handwritten signature in cursive script that reads "Michelle White".

Michelle White, RSO
Radiation Safety Officer
Avera McKennan

*Sponsored by the Benedictine
and Presentation Sisters*

TheraSphere™ Training Record
Marek Siorek, MD
Marshfield Medical Center, Marshfield, WI

- April 17, 2020- Completed Safe Handling Practices training, including 3 in-vitro administrations
- April 17, 2020 – Proctoring Supervision of Patient Treatment #1 Completed
- April 21, 2020 – Proctoring Supervision of Patient Treatment #2 Completed
- July 10, 2020 – Proctoring Supervision of Patient Treatment #3 Completed

This is to confirm that Boston Scientific provided training on the recommended use of TheraSphere in accordance with the TheraSphere Instructions for Use at Marshfield Medical Center. Dr. Siorek has successfully completed the Authorized User training program. The full scope of training included:

1. Safe Handling Practices training:

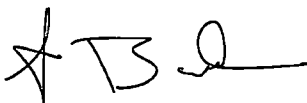
- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters;
- Evaluation of each patient or human research subject for the dose/activity of Y-90 microspheres to be administered to each treatment site;
- Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject;
- Using administrative controls to prevent a medical event involving the use of byproduct material;
- Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures; and
- Follow up and review of each patient's or human research subject's case history for Y-90 microspheres

2. Three in-vitro administrations with focus on:

- Safe handling practices
- TheraSphere Administration Set and TheraSphere Administration Accessory Kit overview
- Dose Calibrator verification using Calibration Data Sheet for Y-90
- Preparation of TheraSphere dose vial
- Assembly of the Administration Set
- System priming
- TheraSphere administration
- Disassembly

3. Three in vivo, hands-on patient cases with focus on:

- Dosimetry
- Written Directive
- Therasphere Administration



Aaron Bartoo, PhD
Regional Medical Director
Boston Scientific

September 30, 2021

The American Board of Radiology

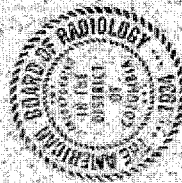
Organized through the cooperation of the
 American College of Radiology, the American Roentgen Ray Society,
 the American Roentgen Society, the Radiological Society of North America,
 the Section on Radiology of the American Medical Association,
 the American Society for Radiation Therapy, the Association of University Radiologists,
 the American Association of Physicists in Medicine and the Society of Interventional Radiology.
 The American Board of Radiology hereby certifies that

Starek J. Siorek, MD

Has passed an accepted course of graduate study and clinical work, has met certain standards
 and qualifications, including passing the examination conducted under the authority of
 the American Board of Radiology, demonstrating to the satisfaction of the Board qualification
 to practice and to supervise in the field of radiology.

Diagnostic Radiology

All Eligible



By the majority of the members constituting a
 meeting the requirements of Maintenance of Certification.

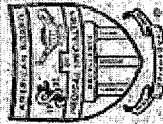
This diploma of the American Board of Radiology
 is presented to the DARR member to signify the certification.

James H. Gray, MD
 President

S. J. ...
 Secretary

Henry ...
 Executive Director

DARR



Effective: June 12, 2013

Certificate No. 60714

From: [Michelle White](#)
To: [Hill, Carol](#)
Cc: [Trisha Laake](#)
Subject: [External_Sender] License 40-16571-02
Date: Monday, November 1, 2021 2:15:41 PM
Attachments: [Amendment request add Dr. Siorek remove Arneson.pdf](#)

Greetings,

Please accept the attached amendment for the above license. If you have any questions, please contact me at the numbers below or Trisha Laake at 712-212-0040.

Thank you,

*Michelle White, RSO, BA | Radiation Safety Officer, Nuclear Medicine/PET/CT
Avera McKennan | Mobile NRC
1325 S. Cliff Avenue | Sioux Falls, SD 57105
Phone 605-322-7155 | Cell 605-929-9056/Fax 605-322-7181*



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Michelle White, BA, CNMT
Radiation Safety Officer
Avera McKennan/Nuclear Medicine
1325 S. Cliff Ave
Sioux Falls, SD 57117-5045

Date

11/01/2021

License Number(s)

40-16571-02

Mail Control Number(s)

629091

Licensing and/or Technical Reviewer or Branch

C. Hill

This is to acknowledge receipt of your: Letter and/or Application Dated: 10/25/2021

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 complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

The following administrative omissions have been identified:

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) 200-1103 or (817) 200-1140**

Agency: NRC

WBL WORKSHEET

DOCKET NUMBER: 3039216 LICENSE NUMBER: 40-16571-02 STATUS: Pending Amendment

MAIL CONTROL NUMBER: 629091 RECEIPT DATE: 11/01/2021 ACTION TYPE: Amendment

DUE DATE: 01/30/2022 INST. CODE: 16571 LICENSE REGION: Region 4

LICENSE TYPE: 30 ENTITY TYPE: C LICENSE GROUP: Medical

ISSUE DATE: ORIGINAL DATE: 03/10/2020 EXPIRATION DATE: 03/31/2035

DECOMMISSIONING CATEGORY: LAST ISSUE DATE:

LICENSEE NAME: Avera McKennan/Nuclear Medicine DECOM FIN ASSUR REQD: N SUBM: N

MAILING ADDRESS LINE1: 1325 South Cliff Avenue CONT PLAN REQD: N APPRV: N

MAILING ADDRESS LINE 2:

CITY: Sioux Falls STATE: SD ZIP: 57117-5045

CONTACT PERSON: PREFIX: FIRST NAME: Michelle MIDDLE INITIAL:

LAST NAME: White SUFFIX:

JOB TITLE: PHONE: 605-322-7155 FAX: EMAIL: michelle.white@avera.c

BILLING ADDRESS LINE 1:

BILLING ADDRESS LINE 2:

CITY: STATE: South Dakota ZIP:

BILLING CONTACT PERSON: FIRST NAME: MIDDLE INITIAL: LAST NAME:

PHONE: EMAIL: FAX:

PRIMARY PGM CODE: 04826 SECONDARY PGM CODE: 04810,04820

INSPECTION REGION: Region 4 PRIORITY: 2

RSO: PREFIX: FIRST NAME: Michelle MIDDLE INITIAL: LAST NAME White

SUFFIX: BA, CNMT RSO JOB TITLE: Radiation Safety Officer

RSO PHONE: 605-322-7155 RSO FAX: RSO EMAIL: michelle.white@avera.org

STATES WHERE USE IS AUTHORIZED: 0- ALL LISTED STATES 1- SAME AS STATE IN ADDRESS 2- ALL STATES 3- NON-AGREEMENT-STATES

AUTHORIZED STATES (USE ONLY IF ABOVE IS ZERO):