Avera
McKennan Hospital
& University Health Center

RECEIVED
08/24/2022

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

AveraMcKennan.org

August 24, 2022

Nuclear Regulatory Commission
Region IV
1600 E. Lamar Blvd.
Arlington, TX 76011

Mail Control Number: 632272
Docket Number : 3039216
License Number : 40-16571-02
Licensee Name : Avera McKennan/Nuclear Medicine

Re: Adding New Authorized User under Condition 12. B. RML# 40-16571-02.

Dear Sir or Madam:

We, Avera McKennan Hospital, would like to amend our Radioactive Materials License number 40-16571-02 to conduct the following:

- **Add** under condition 12.B. "The following individuals are authorized users for the material and medical uses as indicated";
  - **Shandon D. Hatch M.D.** for Material and Use, 35.100, 35.200, 35.300, and 31.11. Supporting documents are enclosed.

If you have further questions, or need additional information, please feel free to contact me.

Thank you for your time,

Mary Hennings-Frank

Mary Hennings-Frank, B.S., CNMT
Radiation Safety Officer
Avera McKennan Hospital
Mary.henningsfrank@avera.org
Office: 605-322-7155
Cell: 605-368-4609

Enclosed: Saint Louis University, Doctor of Medicine 2008
American Board of Radiology, 2013
American Board of Nuclear Medicine, 2014 – 2024

NRC FORM 313 (06-30-2022) 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 **EXPIRES: 01/31/2023**

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 FOIA, Library, and Information Collections Branch (T-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and the OMB Reviewer at: OMB Office of Information and Regulatory Affairs, (3150-0120), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; e-mail: oira_submission@omb.eop.gov. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

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 AND TRIBAL LIAISON BRANCH
DIVISION OF MATERIALS SAFETY, SECURITY, STATE AND TRIBAL 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 RADIOLOGICAL SAFETY AND SECURITY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD, SUITE 102
KING OF PRUSSIA, PA 19406-1415
R1DRSSMail.Resource@nrc.gov
*Note: The preferred method to submit NRC Form 313 is e-mail. Any other document (e.g., financial assurance documents) should be sent via mail.

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
R3DNMSMAIL.Resource@nrc.gov
*Note: The preferred method to submit NRC Form 313 is e-mail. Any other documents (e.g., financial assurance documents) should be sent via mail.

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:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511
r4licensingactionsubmittals@nrc.gov
*Note: The preferred method to submit NRC Form 313 is e-mail. Any other document (e.g., financial assurance documents) should be sent via mail.

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 40-16571-02
- [ ] C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include zip code)*

Avera McKennan Hospital/Nuclear Medicine
1325 S Cliff Ave.
Sioux Falls, SD 57117-5045

3. ADDRESS WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED

Avera McKennan Hospital/Nuclear Medicine
1325 S Cliff Ave.
Sioux Falls, SD 57117-5045

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Mary Hennings-Frank, B.S., CNMT, RSO

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
605-322-7155	605-368-4609

BUSINESS E-MAIL ADDRESS
mary.henningsfrank@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. 7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.
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)
***Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.**

FEE CATEGORY [ ] AMOUNT ENCLOSED $ [ ]

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	SIGNATURE	DATE
Mary Hennings-Frank, Radiation Safety Officer	Mary Hennings-Frank	8/24/22

FOR NRC USE ONLY

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

NRC FORM 313A (AUT)
(01-2020)

U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 01/31/2023

AUTHORIZED USER TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION
(for uses defined under 35.300)
[10 CFR 35.57, 35.390, 35.392, 35.394, and 35.396]

Name of Proposed Authorized User	State or Territory Where Licensed
Shandon D. Hatch, M.D.	South Dadota RML# 40-16571-02

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 radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, 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. <u>Board Certification</u>**

a. Provide a copy of the board certification.

b. For 35.**390**, provide documentation on supervised 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. Skip to and complete Part II Preceptor Attestation.

d. For a board certification issued on or before October 24, 2005 that is listed in 10 CFR 35.57(b)(2)(ii), provide the following:

(i) Documentation that the individual performed each use checked above on or before October 24, 2005.

(ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.

e. Stop here.

☐ **2. <u>Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization</u>**

a. Authorized User on Materials License _____ 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. If board certified, provide a copy of the certificate and stop here. If not board certified then provide completed Part II Preceptor Attestation.

Saint Louis University

To all to whom these presents may come, greetings in the Lord
We, the President and Board of Trustees,
certify that on the recommendation of the Dean and Faculty of the

School of Medicine

have conferred on

Shandon Dale Hatch

the degree of

Doctor of Medicine

With all the rights and privileges pertaining to that degree.
In witness whereof we have signed our names and affixed the Seal
of the University to this diploma at Saint Louis, Missouri, on this
seventeenth day of May, two thousand and eight.

L. Pisoni S.J.
President

Philip O Ansell
Dean

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

Shandon Dale Hatch, 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

Diagnostic Radiology

AM Eligible

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

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.*

DABR

AMERICAN BOARD OF MEDICAL SPECIALTIES 1933
EXCELLENCE
SCIENTIA PRUDENTIA VIRTUS
SOCIIS ORBISQUE

James P. Bonatelli, M.D.
President

Secretary-Treasurer

Executive Director

Certificate No. 63301

Effective: June 12, 2013

The American Board of Nuclear Medicine

Incorporated 1971

Certifies that

Shandon Hatch, M.D.

has met the requirements of this Board and is qualified during the period of 2014 through 2024 to practice as a Specialist in all aspects of Clinical and Laboratory

Nuclear Medicine

Maintenance of this certificate requires full participation in the ABNM's Maintenance of Certification program.

Janis P. O'Malley, M.D.
Chair

Munir V. Ghesani, M.D., FACNM
Secretary-Treasurer

08788
Number

United States

ABMS MOC™
American Board of Nuclear Medicine
Certification Matters

The American Board of Nuclear Medicine

A Member Board of the American Board of Medical Specialties

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Boston, Massachusetts

Administrator
Maria J. Watts, MBA
St. Louis, Missouri

December 5, 2014

To: ABNM Diplomates passing 2014 Certification and MOC Exams

RE: AMA Credit for Certification Activities

Effective September 1, 2010, the American Medical Association enacted a policy whereby the AMA will award 60 *AMA PRA Category 1 CME*™ credits for both the successful initial certification and the subsequent re-certification of ABMS Member Board diplomates. The cost of awarding the 60 credits is $30.00 for an AMA member and $75.00 for a non-AMA member.

A diplomate must submit proof of the successful completion of certification or re-certification with a photocopy of the Board certificate or other direct proof from the certifying Board. In addition, the diplomate must complete an on-line application for CME credit on the AMA website.

Diplomates who successfully passed the certification and re-certification examinations *before* September 1, 2010, can apply for 25 credits. Diplomates who passed examinations *after* September 1, 2010, can apply for 60 credits.

Diplomates may apply for CME credits for up to six years from the effective date on their certificate.

Information about the credit and how to apply for the CME credit can be found at:

www.ama-assn.org/go/directcredit

4555 Forest Park Boulevard, Suite 119 • St. Louis, Missouri 63108-2173 • Telephone: (314) 367-2225 • E-mail: abnm@abnm.org • Website: www.abnm.org

From: Mary Hennings Frank
To: R4 Licensing Action Submittals
Subject: [External_Sender] Amendment Request to add AU under RML 40-16571-02
Date: Wednesday, August 24, 2022 4:16:00 PM
Attachments: Amendment request to add Dr. Hatch as AU.pdf

Good Afternoon,

I would like to amend our RML to add a new Authorized User.

Let me know if you require additional information,

Have a nice evening,

Mary Hennings-Frank | Radiation Safety Officer
Avera McKennan Hospital & University Health Center
1325 S. Cliff Ave. | Sioux Falls, SD 57105
Direct: 605-322-7155 | Cell: 605-368-4609 | Fax: 605-322-7181

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee	Date
Michelle White, BA, CNMT Radiation Safety Officer Avera McKennan/Nuclear Medicine 1325 S Cliff Ave Sioux Falls, SD 57117-5045	08/29/2022
	License Number(s) 40-16571-02
	Mail Control Number(s) 632272
	Licensing and/or Technical Reviewer or Branch C. Hill

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** 08/24/2022

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

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 04826
Status Code: Pending Amendment
Fee Category:7C(1)
Exp. Date: 03/31/2035
Fee Comments:
Decom Fin Assur Reqd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee:	Avera McKennan/Nuclear Medicine
Received Date:	08/24/2022
Docket Number:	3039216
Mail Control Number:	632272
License Number:	40-16571-02
Action Type:	Amendment

2. FEE ATTACHED

Amount: N/A

Check No.: N/A

3. COMMENTS

Signed: Carol L. Hill

Date: 08/29/2022

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: _____

Web-Based Licensing System
WBL WORKSHEET

DATE: 08/29/2022

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

MAIL CONTROL NUMBER: 632272 RECEIPT DATE: 08/24/2022 ACTION TYPE: Amendment

DUE DATE: 11/22/2022 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: Mary MIDDLE INITIAL:

LAST NAME: Hennings-Frank SUFFIX:

JOB TITLE: Radiation Safety Officer PHONE: 605-368-4609 (FAX: EMAIL: mary.henningsfrank@a

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: Mary MIDDLE INITIAL: LAST NAME Hennings-Frank

SUFFIX: RSO JOB TITLE: Radiation Safety Officer

RSO PHONE: 605-368-4609 (cell) RSO FAX: RSO EMAIL: mary.henningsfrank@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):