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
APR 18 2016
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 40-15633-01

C. RENEWAL OF LICENSE NUMBER _____

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

Avera Queen of Peace Hospital
525 North Foster
Mitchell, South Dakota 57301

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

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
CAREY BUTLER MD RSO		4/15/16

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS

APPROVED BY | DATE

PUBLIC
[X] Immediate Release
[ ] Normal Release

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

Reviewer: MKV Date: 4/22/16

590703

NRC FORM 313 (03-2013)

ITEM #7

INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

AUTHORIZED USERS FOR MEDICAL USE

AUTHORIZED USER	AUTHORIZATION
Casey T. Swenson , M.D.	35.100, 35.200, 35.300 (I-131 only)

For the above physician, please see form NRC 313 (AU) and NRC 313 (AUT) and board certification for evidence of training and experience.

AUTHORIZED USER	AUTHORIZATION
Kathleen Lynne Schneekloth, M.D.	35.400, 35.600 (only I-192 for uses in a High Dose Rate Remote Afterloading Unit)

For the above physician, please see NRC byproduct license 40-16571-01 for evidence of training and experience.

Please remove Alric Beach MSc, DABR from our NRC license for 35.600 use.

NRC FORM 313A (AUD) (05-2012) | U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]

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

Name of Proposed Authorized User	State or Territory Where Licensed
Casey T. Swenson, M.D.	South Dakota

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

- [x] 35.100 Uptake, dilution, and excretion studies
- [x] 35.200 Imaging and localization studies
- [ ] 35.500 Sealed sources for diagnosis (specify device)

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 obtained 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.

- [x] 1. **Board Certification**

  a. Provide a copy of the board certification.

  b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

- [ ] 2. **Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

  a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.

  b. Supervised Work Experience.
  (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			
Total Hours of Experience:			

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

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check all that apply).*

- [ ] 35.290
- [ ] 35.390 + generator experience in 32.290(c)(1)(ii)(G)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

a. Classroom and Laboratory Training.

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 *(not required for 35.590)*			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

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	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
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	
Administering dosages of radioactive drugs to patients or human research subjects		☐ Yes ☐ No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		☐ Yes ☐ No	

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

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check one)*.

☐ 35.190 ☐ 35.290 ☐ 35.390 ☐ 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses **only**, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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. (Not required to meet training requirements in 35.590)

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

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

For 35.190

Board Certification

☑ I attest that Casey T. Swenson, M.D. has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

☑ I attest that Casey T. Swenson, M.D. has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section
Complete the following for preceptor attestation and signature:

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

☑ 35.190 ☑ 35.290 ☑ 35.390 ☑ 35.390 + generator experience

Name of Preceptor	Signature	Telephone Number	Date
Michael M. Graham, PhD, MD	Michael M. Graham	(319) 356-3380	07/23/2015

License/Permit Number/Facility Name

0037-1-5-AAB University of Iowa, Iowa City, Iowa

NRC FORM 313A (AUT) (05-2012) | 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: (05/31/2015)

Name of Proposed Authorized User	State or Territory Where Licensed
Casey T. Swenson, M.D.	South Dakota

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 _____ 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 administration of any other radionuclide for which a written directive is required (List radionuclides)			

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

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.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

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).

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 Casey T. Swenson, M.D. (Name of Proposed Authorized User) has satisfactorily completed the 80 hours of classroom 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 Casey T. Swenson, M.D. (Name of Proposed Authorized User) has satisfactorily completed the 80 hours of classroom 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 _____ (Name of Proposed Authorized User) has satisfactorily completed the required clinical case 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 Casey T. Swenson, M.D. (Name of Proposed Authorized User) has satisfactorily achieved a level of competency to 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

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 administration 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 administration 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

Name of Preceptor	Signature	Telephone Number	Date
Michael M. Graham, PhD, MD	Michael M. Graham	(319) 356-3380	07/23/2015

License/Permit Number/Facility Name
0037-1-5-AAB University of Iowa, Iowa City, Iowa

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 E. LAMAR BLVD.
ARLINGTON, TX 76011-4511

April 14, 2014

Avera McKennan
ATTN: Nuclear Medicine Department
Tracy Hollingshead
Radiation Safety Officer
1325 South Cliff Avenue
Sioux Falls, SD 57117-5045

SUBJECT: LICENSE RENEWAL – CORRECTED COPY

Please find enclosed the corrected copy of Amendment Number 58 to NRC License Number 40-16571-01 updating the license expiration date. An environmental assessment for this licensing action is not required since this action is categorically excluded under 10 CFR 51.22(c)(14)(iv). You should review the enclosed document carefully and be sure that you understand all conditions. You can contact me at 817-200-1590 if you have any questions about this license.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's expectations for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. **We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.**

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through the NRC's Agencywide Documents Access and Management System (ADAMS). The RIS may be located on the NRC Web site at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/. Pursuant to NRC's RIS 2005-31, the enclosed materials license will not be made publicly available.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant. Since the NRC also accepts a letter requesting amendment of an NRC license, the signatory for such a request should also be the licensee or certifying official rather than a consultant.

NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available on the following internet address: http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

An electronic version of the NRC's regulations is available on the NRC Web site at www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web site at: http://www.nrc.gov/materials/miau/med-use-toolkit.html. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

The NRC medical list server has been set up. The list server will send automatic e-mail notifications of medical-related generic communications, Federal Register Notices, and NMSS/FSME newsletters as they are published. Anyone may subscribe/unsubscribe to the new medical list server by sending an e-mail to medical-gc@nrc.gov with "Subscribe" or "Unsubscribe" in the subject line.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Thank you for your cooperation.

Sincerely,

Michelle Simmons, Health Physicist
Nuclear Materials Safety Branch B

Docket: 030-11252
License: 40-16571-01
Control: 582292

Enclosure: As stated

NRC FORM 374 PAGE 1 OF 7 PAGES

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 58

CORRECTED COPY

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70 and 71, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Avera McKennan	In accordance with application received October 17, 2013 3. License number 40-13571-01 is amended in its entirety to read as follows:
2. 1325 South Cliff Avenue Sioux Falls, South Dakota 57117-5045	4. Expiration date March 31, 2024
	5. Docket No. 030-11252 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As needed
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 900 millicuries
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed sources (3M Model 6500 series; AEA Technology Model 6500 Series; Bard Brachytherapy, Inc. Model STM-1251; Theragenics Corp Model TheraSeed Model 200)	D. 2 curies
E. Iridium-192 permitted by 10 CFR 35.600	E. Sealed sources (Nucletron Model 105.002 manufactured by Nucletron B.V., Mallinckrodt Medical BV or QSA Global [formerly AEA Technology])	E. 12 curies per source and 21 curies total
F. Any byproduct materials identified in 10 CFR 31.11	F. Prepackage Kits	F. 50 millicuries

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MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 40-16571-01
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6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
G. Yttrium-90 permitted by 10 CFR 35.1000	G. Sealed sources Sirtex Medical SIR-Spheres® microspheres	G. 800 millicuries total
H. Depleted Uranium	H. Metal	H. 200 kilograms

9. Authorized use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.

B. Any imaging and localization study permitted by 10 CFR 35.200.

C. Any use permitted by 10 CFR 35.300.

D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.

E. One source for medical use as described in 10 CFR 35.600, in a Nucletron microSelectron-HDR Model 105.999 V2 or Nucletron microSelectron Model 106.990 remote afterloading brachytherapy device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.

F. In vitro studies.

G. For permanent manual brachytherapy using Sirtex Medical SIR-Spheres® microspheres and delivery system permitted by 10 CFR 35.1000.

H. For use as shielding contained inside generators used to elute material permitted under 10 CFR 35.200.

CONDITIONS

10. Licensed material may be used or stored only at the following licensee=s facilities:

A. Byproduct material identified in Items 6.A. through 6.D. and 6.F. through 6.H. at Avera McKennan Hospital, 1325 South Cliff Avenue, Sioux Falls, South Dakota.

B. Byproduct material identified in Items 6.A. through 6.D. and 6.F. at Avera St. Benedict Hospital, 401 West Glynn Drive, Parkston, South Dakota.

C. Byproduct material identified in Items 6.A. and 6.B. at 901 East 17th Street, Sioux Falls, South Dakota, and Avera Breast Center, 1000 East 23rd Street, Suite 330, Sioux Falls, South Dakota.

D. Byproduct material identified in Item 6.B. at Heart Hospital of South Dakota, 4500 West 69th Street, Sioux Falls, South Dakota; North Central Heart a Division of Avera Heart Hospital, 4520 West 69th Street, Sioux Falls, South Dakota; and the Mitchell Clinic, Ltd., 818 W. Havens Street, Mitchell, South Dakota.

E. Byproduct material identified in Item 6.E. at Avera Radiation Oncology, Avera Cancer Institute, Prairie Center, 1000 E. 23rd Street, Suite 100, Rooms 1321-1324 and 1326, Sioux Falls, South Dakota.

F. Byproduct material identified in Items 6.A. through 6.C.; 6.F. at Avera PET-CT Center, 6001 South Sharon Avenue, Suite #2, Sioux Falls, South Dakota.

G. Byproduct material identified in Items 6.A. and 6.B. (except generators) at any hospital located in the states of South Dakota, provided:

i. The hospital does not have a byproduct material license under Section 35.18 of 10 CFR Part 35, and

ii. The licensee addresses all use and record keeping requirements outlined in Section 35.80 of 10 CFR Part 35, and

iii. The licensee has the prior written permission from the hospital's Administrator, and

iv. The licensee maintains a list of all hospitals serviced.

The licensee shall maintain for inspection by the Commission, copies of written permission specified in Subitem 3 and the list specified in Subitem 4.

11. The Radiation Safety Officer for this license is Traci Hollingshead.

12. Licensed material is only authorized for use by, or under the supervision of:

A. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

B. Physicians permitted to work as authorized users for 35.1000 SIR-Spheres® Y-90 microsphere use in accordance with commitments for notification to NRC in e-mail dated May 5, 2011.

C. The following individuals are authorized users for the material and medical uses indicated:

Authorized Users	Material and Use
Terry S. Bloom, M.D.	35.600 only Iridium-192 for uses in a High Dose Rate Remote Afterloading Unit; *In vitro* studies
Christopher Gregory, M.D.	35.100; 35.200; 35.300; *In vitro* studies
Matthew Helgeson, M.D.	35.100; 35.200; Oral administration of sodium iodide I-131 ; *In vitro* studies
Brad Alan Paulson, M.D.	35.100; 35.200; Oral administration of sodium iodide I-131; *In vitro* studies
Barbara Schlager, M.D.	35.600 only Iridium-192 for uses in a High Dose Rate Remote Afterloading Unit
Kathleen L. Schneekloth, M.D.	35.400; 35.600 only Iridium-192 for uses in a High Dose Rate Remote Afterloading Unit
Andrew I. Soye, M.D.	35.100; 35.200; 35.300; *In vitro* studies
Henry P. Travers, M.D.	35.100; 35.200; *In vitro* studies
Matthew R. Casey, M.D.	35.1000 Y-90 SIR-Spheres® use
Kathleen A. Nordstrom, M.D.	35.600 only Iridium-192 for uses in a High Dose Rate Remote Afterloading Unit
Josie R. Alpers, M.D.	35.100; 35.200; 35.300; *In vitro* studies
Joseph J. Baka, M.D.	35.100; 35.200; *In vitro* studies
Sabina Choudhry, M.D.	35.100; 35.200; 35.300; *In vitro* studies
Ryan D. Jepperson, M.D.	35.100; 35.200; *In vitro* studies
Michael J. Kihne, M.D.	35.100; 35.200; 35.300; *In vitro* studies
Patrick A. Nelson, M.D.	35.100; 35.200; *In vitro* studies

Authorized Users	Material and Use
Matthew T. Pardy, M.D.	35.100; 35.200; *In vitro* studies
Daryl C. Rife, M.D.	35.100; 35.200; 35.300; *In vitro* studies
Randal L. Welter, M.D.	35.100; 35.200; Oral administration of sodium iodide I-131; *In vitro* studies
Suzanne Woodward, M.D.	35.100; 35.200; *In vitro* studies
Joseph T. Jordahl, M.D.	35.100; 35.200; *In vitro* studies
James H. Simon, M.D.	35.400; 35.600 only iridium-192 for uses in a High Dose Rate Remote Afterloading Unit

D. The following individual is an authorized medical physicist:

Authorized Medical Physicists	Material and Use
Jamie Marie Harris, M.S.	Iridium-192 in a High Dose Rate Remote Afterloader unit for calibrations, spot checks, and training
Laura O'Neill	Iridium-192 in a High Dose Rate Remote Afterloader unit for calibrations, spot checks, and training
Xiang Kong, M.S.	iridium-192 in a High Dose Rate Remote Afterloader unit for calibrations, spot checks, and training

13. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:

A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

E. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region IV, 1600 East Lamar Boulevard, Arlington, Texas 76011-4511, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.

G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

H. Records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.

14. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.

15. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 3 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

16. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing financial assurance for decommissioning.

17. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee=s ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Email dated May 5, 2011 [ML11132A076]
B. Application received October 17, 2013 [ML13301A813]

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date April 14, 2014

By

Michelle Simmons, Health Physicist
Nuclear Materials Safety Branch B
Region IV
Arlington, Texas 76011-4511

NRC FORM 532
(1-2012)

U. S. NUCLEAR REGULATORY COMMISSION

DATE

04/20/2016

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE	LICENSE NUMBER
Mr. Dennis Wilaby Radiation Safety Officer City of Rapid City Engineering Division 300 Sixth Street Rapid City, SD 57701-2724	40-15633-01
	MAIL CONTROL NUMBER 590703
	LICENSING AND/OR TECHNICAL REVIEWER JAB

This is to acknowledge the receipt of your:

☑ LETTER and/or ☐ APPLICATION DATED: 04/19/2016

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

NRC FORM 532
(1-2012)

√ 4-21-16

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 02230
Status Code: Pending Amendment
Fee Category: 7C
Exp. Date:
Fee Comments:
Decom Fin Assur Reqd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee:	Queen of Peace Health Services
Received Date:	04/18/2016
Docket Number:	3009486
Mail Control Number:	590703
License Number:	40-15633-01
Action Type:	Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: Jennifer Budge

Date: 4-21-16

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: _____