

Roldan, Lizette

From: Roldan, Lizette
Sent: Thursday, June 14, 2012 12:52 PM
To: 'Matthews, Robert J.'
Subject: REQUEST FOR ADDITIONAL INFORMATION REGARDING RENEWAL CONTROL 576628

License No.: 11-27307-01
Docket No.: 030-32264
Control No.: 576628

Dear Dr. Matthews:

This is in reference to application dated December 30, 2011 regarding the renewal of Nuclear Regulatory Commission License No. 11-27307-01. In order to continue our review, we need the following additional information:

1. You have requested to add Arne Michalson, M.D. as an authorized user for 35.300 and Y-90 applications. In the NRC form 313A (AUT) you selected pathway 1 "Board Certification" and submitted the information following pathway 3 "Training and Experience for Proposed Authorized User".
 - a. If you would like to follow pathway 1, please provide a copy of the board certification.
 - b. If you are going to follow pathway 3, on each table there is a section designated to document the hours of training and experience including classroom and laboratory training. In accordance with 10 CFR 35.390 an individual must complete 700 hours of training in order to be qualified for 35.300 procedures, where a minimum of 200 hours must be classroom and laboratory training. Please include the total hours of classroom and laboratory training, and supervised work experience the individual has completed. In addition, please check the appropriate box for the supervised experience in 3.b "Supervised Work Experience".
2. You have requested to add Casey John Fatz, M.D. as an authorized user for 35.300 and Y-90 applications. The NRC does not recognize the board certification you provided because the dates are out of the acceptable range. In the NRC form 313A (AUT) you also submitted the information following pathway 3 "Training and Experience for Proposed Authorized User", which is the correct pathway for the proposed individual. However, in this section you have documented 650 hours of training and experience including classroom and laboratory training. In accordance with 10 CFR 35.390 an individual must complete 700 hours of training in order to be qualified for 35.300 procedures, where a minimum of 200 hours must be classroom and laboratory training. If the amount of hours was a typo, please resubmit the entire form with the correct hours. Otherwise, please resubmit the entire form when the individual has completed at least 200 hours of supervised work experience.
3. For your convenience, you may view the specialty board certifications recognized by NRC Under 10 CFR Part 35 modalities using the following link: <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

Please reply to my attention and refer to Mail Control No. 576628. If you reply via email, please attach a signed letter in PDF format or you may fax your response to (817) 200-1263. Please reply by **Friday, June 22, 2012**. If I do not receive a response by the due date, I will assume you do not wish to continue with those changes to the license and will void that part of the renewal application without prejudice to the resubmission of a license amendment requesting the individuals be added to the license for the modalities requested.

If you have any technical questions regarding this deficiency letter, please call me at (817) 200-1596.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Industrial, and Academic Uses of Nuclear Material**; then **Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

Sincerely,

Lizette Roldán-Otero, Ph.D.

Health Physicist

U.S. Nuclear Regulatory Commission

1600 E. Lamar Blvd.

Arlington, TX 76011-4511

Office: 817-200-1596

Fax: 817-200-1188

Roldan, Lizette

From: Matthews, Robert J. [rmatthews@kmc.org]
Sent: Friday, June 22, 2012 11:54 AM
To: Roldan, Lizette
Cc: Mike 'Blee'; Melissa 'Filipkowski-Pelton; Jennifer L.--KMC Neely; Jeremy S. Evans (jevans@kmc.org)
Subject: RE: REQUEST FOR ADDITIONAL INFORMATION REGARDING RENEWAL CONTROL 576628
Attachments: ArneMichalson313(aut).pdf; CaseyFatz313(aut).pdf

2nd response corrected subject. Re: License no: 11-27307-01, Docket no: 030-32264, Control no: 576628

Dr. Roldan-Otero,

We have reviewed your request for additional information regarding the NRC form 313A(AUT) regarding Arne Michalson, M.D. and Casey Fatz, M.D. submitted for our license renewal. Corrected forms are attached. The information we submit for correction of these forms was garnered from a more thorough review of our records, a parsing of the didactic lecture programs and the practicum schedules for residents at the University of Iowa and University of Texas for each of these physicians, respectively. Credit for the additional year of residency in the joint radiology and nuclear medicine program was not determined for Dr. Michalson. The license number for the Gulf Coast Medicine Center where Dr Michalson served as Director of Nuclear Medicine could not be determined. Nor were additional hours included for Dr. Michalson's additional year as fellow in interventional radiology.

Note that because Dr. Michalson has proctored cases of Bexxar administrations we are requesting his additional privilege of parenteral administration of any other radionuclide requiring a written directive. However, Dr. Fatz has had no proctored cases in this category and his request for privileges has been modified to reflect this fact.

We trust these corrections and additions answer your request for additional information. If you have additional concerns please contact Dr. Robert J. Matthews at 208-666-2529 or email: rmatthews@kmc.org. Thank you for your considerations in this matter.

Robert J. Matthews, Ph.D., DABR
Medical Physicist
Kootenai Medical Center

**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: 3/31/2012

Name of Proposed Authorized User

Casey John Fatz, M.D.

State or Territory Where Licensed

Idaho

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

- Provide a copy of the board certification.
- For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.
- 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.

2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization

- 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

- 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.
- 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	University of Texas, Houston (Radiology Residency) MD Anderson, Houston (Fellow Interventional Rad)	258	Jul '99 - Jun '03 Jul '03 - Jun '04 Jan '04 - Dec '11
Radiation protection	University of Texas, Houston (Radiology Residency) MD Anderson, Houston (Fellow Interventional Rad)	137	Jul '99 - Jun '03 Jan '04 - Dec '11
Mathematics pertaining to the use and measurement of radioactivity	University of Texas, Houston (Radiology Residency) MD Anderson, Houston (Fellow Interventional Rad)	34	Jul '99 - Jun '03 Jan '04 - Dec '11
Chemistry of byproduct material for medical use	University of Texas, Houston (Radiology Residency) MD Anderson, Houston (Fellow Interventional Rad)	79	Jul '99 - Jun '03 Jan '04 - Dec '11
Radiation biology	University of Texas, Houston (Radiology Residency) MD Anderson, Houston (Fellow Interventional Rad)	226	Jul '99 - Jun '03 Jan '04 - Dec '11

Total Hours of Training: 734

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

David E. Davenport, M.D.

Total Hours of Experience:

326

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	University of Texas, Houston (Radiology Residency) MD Anderson, Houston (Fellow Interventional Rad) Sirtex Medical, Phoenix, AZ Kootenai Medical Center - 11-27307-01	✓ Yes No	Jul '99 - Jun '03 Jul '03 - Jun '04 Jun '05 Jan '04 - Dec '11
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	University of Texas, Houston (Radiology Residency) MD Anderson, Houston (Fellow Interventional Rad) Sirtex Medical, Phoenix, AZ Kootenai Medical Center - 11-27307-01	✓ Yes No	Jul '99 - Jun '03 Jul '03 - Jun '04 Jun '05 Jan '04 - Dec '11
Calculating, measuring, and safely preparing patient or human research subject dosages	University of Texas, Houston (Radiology Residency) MD Anderson, Houston (Fellow Interventional Rad) Sirtex Medical, Phoenix, AZ Kootenai Medical Center - 11-27307-01	✓ Yes No	Jul '99 - Jun '03 Jul '03 - Jun '04 Jun '05 Jan '04 - Dec '11
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University of Texas, Houston (Radiology Residency) MD Anderson, Houston (Fellow Interventional Rad) Sirtex Medical, Phoenix, AZ Kootenai Medical Center - 11-27307-01	✓ Yes No	Jul '99 - Jun '03 Jul '03 - Jun '04 Jun '05 Jan '04 - Dec '11
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University of Texas, Houston (Radiology Residency) MD Anderson, Houston (Fellow Interventional Rad) Sirtex Medical, Phoenix, AZ Kootenai Medical Center - 11-27307-01	✓ Yes No	Jul '99 - Jun '03 Jul '03 - Jun '04 Jun '05 Jan '04 - Dec '11

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

David E. Davenport, M.D.

11-27301-01

Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:

- ✓ 35.390 With experience administering dosages of:
- ✓ 35.392 ✓ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ✓ 35.394 ✓ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ✓ 35.396 ✓ 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 Casey John Fatz, M.D.

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)

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

b. Supervised Work Experience (continued)

Supervising Individual

David E. Davenport, M.D.

License/Permit Number listing supervising individual as an authorized user

11-27301-01

Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:

- ✓ 35.390 With experience administering dosages of:
- ✓ 35.392 ✓ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ✓ 35.394 ✓ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ✓ 35.396 ✓ 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)	100	Kootenai Medical Center - 11-27307-01	Jan '04 - Dec '11
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	100	Kootenai Medical Center - 11-27307-01	Jan '04 - Dec '11
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	3 Y-90 microsphere 30 Y-90 microsphere	Sirtex Medical, Phoenix, AZ Kootenai Medical Center - 11-27307-01	Jun '05 Jan '04 - Dec '11
Parenteral administration of any other radionuclide for which a written directive is required			
(List radionuclides)			

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 John Fatz, M.D. has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User
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 John Fatz, M.D. has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User
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 Casey John Fatz, M.D. has satisfactorily completed the required clinical case
Name of Proposed Authorized User

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 John Fatz, M.D. has satisfactorily achieved a level of competency to
Name of Proposed Authorized User

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 Casey John Fatz, M.D. 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

David E. Davenport, M.D.

Signature



Telephone Number

208-666-3800

Date

6/21/12

License/Permit Number/Facility Name

Kootenai Medical Center / 11-27307-01

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 Therapeutic Radiology and Oncology, the Association of
University Radiologists, and American Association of Physicians in Medicine

Hereby certifies that

Casey John Katz, MD

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of

The American Board of Radiology

On this tenth day of November, 2003
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology

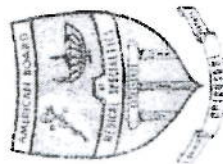


Certificate No. 48736

William H. ...
President

Ray D. Nelson, MD
Secretary-Treasurer

R.P. Hooten, MD
Executive Director



Valid through 2013



SIRTEX MEDICAL, INC.
16 Upton Drive, #2-4
Wilmington, MA 01887
Tel: 978 642 3000

December 27, 2011

Dr. Casey Fatz, MD
Interventional Radiology
Kootenai Medical Center
2003 Kootenai Health Way
Coeur d'Alene, ID 83814

Dear Dr. Fatz:

Re: SIR-Spheres® Microspheres Authorized User Training and Certification

This letter certifies that you successfully completed training in the operation of the delivery system, safety procedures and clinical use of SIR-Spheres yttrium-90 microspheres that are to be injected via the hepatic artery to treat patients with unresectable liver tumors in accordance with the September 2008 NRC guidance. This training included three (3) supervised hands-on *in-vitro* simulated set-up and delivery procedures that demonstrate possible issues encountered during the yttrium-90 microsphere administration.

Following the license amendment that names you as an AU for SIR-Spheres yttrium-90 microspheres use, Sirtex will provide documentation that the first three (3) *in-vivo* patient cases were performed in the physical presence of a Sirtex proctor.

Sirtex would like to thank you for your support in this process.

Yours sincerely,

Knute J. Lund
Regional Sales Manager

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

00072 Renewal Application 11/27/2011 11:00 AM 00

**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: 3/31/2012

Name of Proposed Authorized User

Arne Michelson, M.D.

State or Territory Where Licensed

Idaho

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

- Provide a copy of the board certification.
- For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.
- 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.

2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization

- 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
- 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.
- 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	University of Iowa (Resident in Radiology & Nuclear Med) Gulf Coast Med Cntr, Biloxi, MS /	260	Jun '91- Jun '95
Radiation protection	University of Iowa (Resident in Radiology & Nuclear Med) Gulf Coast Med Cntr, Biloxi, MS /	73	Jun '91- Jun '95
Mathematics pertaining to the use and measurement of radioactivity	University of Iowa (Resident in Radiology & Nuclear Med) Gulf Coast Med Cntr, Biloxi, MS /	34	Jun '91- Jun '95
Chemistry of byproduct material for medical use	University of Iowa (Resident in Radiology & Nuclear Med) Gulf Coast Med Cntr, Biloxi, MS /	143	Jun '91- Jun '95
Radiation biology	University of Iowa (Resident in Radiology & Nuclear Med) Gulf Coast Med Cntr, Biloxi, MS /	226	Jun '91- Jun '95

Total Hours of Training:

736

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

Arne Michelson, M.D.

Total Hours of Experience:

313

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	University of Iowa (Resident in Radiology & Nuclear Med) Gulf Coast Med Cntr, Biloxi, MS / Kootenai Medical Center /11-27307-01	✓ Yes No	Jun '91- Jun '95 Jul '95 - Jun '97 Jul '97 - Dec '11
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	University of Iowa (Resident in Radiology & Nuclear Med) Gulf Coast Med Cntr, Biloxi, MS / Kootenai Medical Center /11-27307-01	✓ Yes No	Jul '97 - Dec '11 Jul '95 - Jun '97 Jul '97 - Dec '11
Calculating, measuring, and safely preparing patient or human research subject dosages	University of Iowa (Resident in Radiology & Nuclear Med) Gulf Coast Med Cntr, Biloxi, MS / Kootenai Medical Center /11-27307-01	✓ Yes No	Jul '97 - Dec '11 Jul '95 - Jun '97 Jul '97 - Dec '11
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University of Iowa (Resident in Radiology & Nuclear Med) Gulf Coast Med Cntr, Biloxi, MS / Kootenai Medical Center /11-27307-01	✓ Yes No	Jul '97 - Dec '11 Jul '95 - Jun '97 Jul '97 - Dec '11
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University of Iowa (Resident in Radiology & Nuclear Med) Gulf Coast Med Cntr, Biloxi, MS / Kootenai Medical Center /11-27307-01	✓ Yes No	Jul '97 - Dec '11 Jul '95 - Jun '97 Jul '97 - Dec '11

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

David Devenport, M.D.

11-27307-01

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

- ☒ 35.390 With experience administering dosages of:
- ☒ 35.392 ☒ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☒ 35.394 ☒ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☒ 35.396 ☒ 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 requirements in 35.390(a)(1).
Name of Proposed Authorized User

OR

Training and Experience

☒ I attest that Arne Michalson, M.D. has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).
Name of Proposed Authorized User

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

David E. Davenport, M.D.

Kootenai Medical Center / 11-27307-01

Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:

- ✓ 35.390 With experience administering dosages of:
- ✓ 35.392 ✓ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ✓ 35.394 ✓ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ✓ 35.396 ✓ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive
- ✓ 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)	150	Kootenai Medical Center / 11-27307-01	Jul '97 - Dec '11
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	100	Kootenai Medical Center / 11-27307-01	Jul '97 - Dec '11
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	20 Zevalin Y-90	Kootenai Medical Center / 11-27307-01	Jul '97 - Dec '11
Parenteral administration of any other radionuclide for which a written directive is required	10 Benxar	Kootenai Medical Center / 11-27307-01	Jul '97 - Dec '11
I-131 (List radionuclides)			

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 Arne Michalson, M.D. has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User
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 Arne Michalson, M.D. has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User
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 Arne Michalson, M.D. has satisfactorily completed the required clinical case
Name of Proposed Authorized User
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 Arne Michalson, M.D. has satisfactorily achieved a level of competency to
Name of Proposed Authorized User
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 Arne Michelson, M.D. 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)

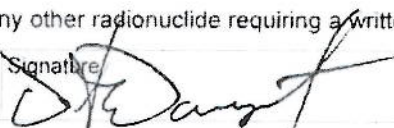
✓ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

✓ 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
David E. Davenport, M.D.

Signature



Telephone Number
208-666-3800

Date

5/21/12

License/Permit Number/Facility Name
11-27307-01 / Kootenai Medical Center

The American Board of Radiology

Organized through the cooperation of the American College of Radiology, the American Roentgen Ray Society, the American Radiology Society, the Radiological Society of North America, the Section on Radiology of the American Medical Association, the American Society for Therapeutic Radiology and Oncology, the Association of University Radiologists, and American Association of Physicians in Medicine

Thereby certifies that

Arne Edward Michelson, M.D.

Has passed an accepted course of graduate study and clinical work, has met certain standards and qualifications and has passed the examinations conducted under the authority of

The American Board of Radiology

On this seventh day of June, 1935
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology



Chicago, May 1935 *Willis J. Small, M.D., President* *1935*