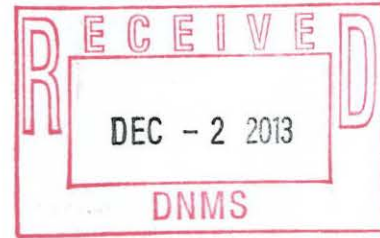




November 27, 2013

Jacqueline "Jackie" D. Cook
 Senior Health Physicist
 Division of Nuclear Materials Safety
 Nuclear Materials Safety Branch B
 1600 E. Lamar Blvd., Arlington, TX 76011



Subject: Amendment to Radioactive Materials License 50-17838-01
 Addition of Dr. Eric J. Maurer as Authorized User for 35.1000 for Yttrium-90 microspheres

Dear Ms. Cook,

We wish to amend our Radioactive Materials License 50-17838-01 to add Eric J. Maurer, M.D. as Authorized User for 35.1000 Other medical uses of byproduct material or radiation from byproduct material for Yttrium-90 microspheres. Please note that Dr. Maurer is an authorized user for 35.100 and 35.200 currently listed in our NRC Materials License.

Dr. Eric J. Maurer meets the training and experience requirements of 10 CFR 35.390 and 35.490. He has successfully completed training for Sir-spheres, including dose calculation and prescription, source order, dose administration through interventional radiology, and safety and protection procedures. The proctoring was provided by SirTex Medical Inc. in Providence Alaska Medical Center on 10/30/2013. Dr. Eric J. Maurer has also been actively involved in the procedure and accumulated work experiences in six cases for Sir-spheres for which he is seeking AU status. The six cases were implemented in the Providence Alaska Medical Center in the following dates separately:

Date	MR#
5/2/2012	1039485
5/16/2012	640923
10/9/2012	345452
10/24/2012	223584
11/6/2012	76525
10/30/2013	761327

PUBLIC

- Immediate Release
- Normal Release

NON-PUBLIC

- A.3 Sensitive-Security Related
- A.7 Sensitive Internal
- Other: _____

Reviewer: ACE Date: 12-10-13

The training and experience requirements were satisfactorily completed under supervision of the preceptor, Chakri S. Inampudi, M.D. who is AU of 35.1000 for



microspheres. Dr. Maurer also attended the training course for TheraSphere provided by the vendor, BTG International (or Nordion as previously posted).

Please see the attached documents as follows:

1. NRC Form 313A (AUS), signed by Dr. Chakri S. Inampudi, AU and Preceptor.
2. Board certificate of Dr. Eric J. Maurer.
3. Certificate for Angiography, Interventional Radiology.
4. Letter to certify the proctoring of Sir-spheres by SirTex.

If you have any questions, please do not hesitate to call me at (907) 212-5691.

Sincerely,

A handwritten signature in black ink, appearing to read "Yongli Ning".

Yongli Ning, M.S.
Chief Medical Physicist - Radiation Oncology
Radiation Safety Officer
Providence Alaska Medical Center
3200 Providence Drive
Anchorage, AK 99516-6604

Tel: (907)212-5691
Email: yning@provak.org

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.400 and 35.600)
[10 CFR 35.490, 35.491, and 35.690]

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

Name of Proposed Authorized User

Eric J. Maurer, M.D.

State or Territory Where Licensed

Alaska

- Requested Authorization(s)** (check all that apply)
- 35.400 Manual brachytherapy sources
 - 35.400 Ophthalmic use of strontium-90
 - 35.600 Teletherapy unit(s)
 - 35.600 Gamma stereotactic radiosurgery unit(s)
 - 35.600 Remote afterloader unit(s)
 - 35.1000 Y-90 microspheres

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.

1. Board Certification

- a. Provide a copy of the board certification.
- b. For 35.600, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.
- c. Skip to and complete Part II Preceptor Attestation.

2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above

- a. Go to the table in section 3.e. to document training for new device.
- b. Skip to and complete Part II Preceptor Attestation.

3. Training and Experience for Proposed Authorized User

- a. Classroom and Laboratory Training 35.490 35.491 35.690

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			
Radiation biology			

Total Hours of Training:

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work and Clinical Experience for 10 CFR 35.490 (If more than one supervising individual is necessary to document supervised work experience, 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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking survey meters for proper operation		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing, implanting, and safely removing brachytherapy sources		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Maintaining running inventories of material on hand		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using emergency procedures to control byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

c. Supervised Clinical Experience for 10 CFR 35.491

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			
Supervising Individual		License/Permit Number listing supervising individual as an Authorized User	

d. Supervised Work and Clinical Experience for 10 CFR 35.690

- Remote afterloader unit(s)
 Teletherapy unit(s)
 Gamma stereotactic radiosurgery unit(s)

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*
Reviewing full calibration measurements and periodic spot-checks		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual		License/Permit Number listing supervising individual as an Authorized User

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation			
Safety procedures for the device use			
Clinical use of the device			
Supervising Individual. (If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)		License/Permit Number listing supervising individual as an Authorized User	
Authorized for the following types of use: <input type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

f. Provide completed 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.

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 35.490: ~~and 35.390:~~

Board Certification

I attest that Eric J. Maurer, M.D. has satisfactorily completed the requirements in
Name of Proposed Authorized User

35.490(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 200 hours of
Name of Proposed Authorized User

classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

For 35.491:

I attest that _____ has satisfactorily completed the 24 hours of
Name of Proposed Authorized User

classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Second Section

For 35.690:

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

35.690(a)(1).

OR

Training and Experience

I attest that _____ has satisfactorily completed 200 hours of classroom
Name of Proposed Authorized User

and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

AND

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

Third Section

For 35.690: (continued)

I attest that _____ has received training required in 35.690(c) for device
Name of Proposed Authorized User
operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

- Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section

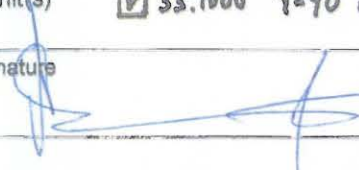
I attest that Eric J. Maurer, M.D. has achieved a level of competency sufficient to
Name of Proposed Authorized User
achieve a level of competency sufficient to function independently as an authorized user for:

- Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)
 microspheres unit(s)

Fifth Section

Complete the following for preceptor attestation and signature:

- I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:
- 35.400 Manual brachytherapy sources 35.600 Teletherapy unit(s)
 35.400 Ophthalmic use of strontium-90 35.600 Gamma stereotactic radiosurgery unit(s)
 35.600 Remote afterloader unit(s) 35.1000 Y-90 microspheres

Name of Preceptor	Signature	Telephone Number	Date
Chakri S. Inampudi, M.D.		(907) 212-3641	11-26-2013
License/Permit Number/Facility Name NRC Materials License 50-17838-01, Amendment No. 62, Providence Alaska Medical Center			



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

Ref: 105US03

November 18, 2013

Dr Erik Maurer
Providence Alaska
3200 Providence Drive
Anchorage AK 99508

Dear Dr. Maurer,

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

I am writing to confirm that on October 30, 2013, Dr Jayson Brower presented and discussed in detail the preparation and procedures associated with the treatment of patients with SIR-Spheres yttrium-90 microspheres that are injected via the hepatic artery to treat patients with unresectable liver tumors. The patients were treated with SIR-Spheres microspheres.

Dr Brower proctored the treatments and I am pleased to inform you that Dr Brower considers that you and your staff are now trained in the preparation and the clinical aspects of treating patients with SIR-Spheres microspheres.

This letter also certifies that you were proctored for at least 3 cases by a Sirtex certified proctor in the use of SIR-Spheres® microspheres.

I would like to thank you and your team for your support and commitment to the Sirtex **Training, Evaluation, Certification (TEC)** Program.

Yours sincerely,

A handwritten signature in blue ink that reads "Jim Liu".

cc: <Account Manager>
TEC@sirtex.com

Murnahan, Colleen

From: Cook, Jackie
Sent: Monday, December 02, 2013 8:40 AM
To: Murnahan, Colleen
Cc: Hill, Carol
Subject: FW: License amendment for AU of 35.1000 Y-90 microspheres
Attachments: 131127 NRC license Maurer.pdf; Form 313A (AUS) Maurer.pdf; Maurer ABR certificate.jpg; Certificate of Angio & Intervention.jpg; 2013 SirTex training Maurer.pdf

Colleen:

Please set up this request.

Thanks,

Jackie

From: Ning, Yongli [<mailto:Yongli.Ning@providence.org>]
Sent: Wednesday, November 27, 2013 1:42 PM
To: Cook, Jackie
Subject: License amendment for AU of 35.1000 Y-90 microspheres

Jackie,

Please see the attached for an amendment to our license 50-17838-01 to add Dr. Maurer as AU for 35.1000 Y-90 microspheres.

If you need the hard copy I will do that upon your request.

Thank you.

Yongli Ning, MS
Chief Medical Physicist - Radiation Oncology
Radiation Safety Officer
Providence Alaska Medical Center
Phone: 907 212-3186, 907 212-5691
Cell: 907-230-2072; Fax: 907 212-3665
Email: yning@provak.org

This message is intended for the sole use of the addressee, and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If you are not the addressee you are hereby notified that you may not use, copy, disclose, or distribute to anyone the message or any information contained in the message. If you have received this message in error, please immediately advise the sender by reply email and delete this message.

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: 03/31/2015
Fee Comments:
Decom Fin Assur Reqd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: PROVIDENCE ALASKA MEDICAL CENTER
Received Date: 12/02/2013
Docket Number: 3013426
Mail Control Number: 582585
License Number: 50-17838-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: _____

Colleen Murnahan

Date: _____

12-5-13

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: _____



DATE
12/05/2013

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE Providence Alaska Medical Center ATTN: Yongli Ning, M.S. Radiation Safety Officer 3200 Providence Drive Anchorage, AK 99519-6604	LICENSE NUMBER 50-17838-01
	MAIL CONTROL NUMBER 582585
	LICENSING AND/OR TECHNICAL REVIEWER cmurnahan <i>Cm</i>

This is to acknowledge the receipt of your:

LETTER and/or APPLICATION DATED: 11/27/2013

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 Blvd.
Arlington, TX 76011-4511
(817) 200-1103 or (817) 200-1140

*emailed to licensee
12-5-13
Cm*