

Hill, Carol

From: Ning, Yongli <Yongli.Ning@providence.org>
Sent: Tuesday, April 12, 2016 12:57 PM
To: Cook, Jackie
Cc: Hill, Carol
Subject: [External_Sender] License amendment for AU of 35.300 for parenteral administration of Ra-223 Xofigo
Attachments: 160411 NRC license-Xofigo Halligan.pdf; Form 313A (AUT) Xofigo Halligan.pdf

Jackie,

Please see the attached for an amendment to our license 50-17838-01 to add Dr. Halligan as AU for parenteral administration of Ra-223 Xofigo.

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 & Providence Imaging Center

Phone: 907 212-3186, 907 212-5691
Cell: 907-230-2072; Fax: 907 212-3665
Email: yning@provak.org

PUBLIC

- ☐ Immediate Release
☒ Normal Release

NON-PUBLIC

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

Reviewer: mtc Date: 4/13/16

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April 11, 2016

Jacqueline 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. John Halligan as Authorized User for 35.300 for parenteral
administration of Ra-223 Xofigo for which a written directive is required

Dear Ms. Cook,

We wish to amend our Radioactive Materials License to add John Halligan, M.D. as Authorized User for 35.300 for parenteral administration of Ra-223 Xofigo for which a written directive is required. Please note that Dr. Halligan, as a radiation oncologist, is an authorized user for 35.300 for Oral administration of sodium iodine I-131 requiring a written directive, 35.400, 35.600 and 35.1000 currently listed in the NRC Materials License number 50-17838-01, Amendment No. 67.

Dr. John Halligan meets the training and experience requirements of 10 CFR 35.390 and 35.396. He has successfully completed training for Ra-223 Xofigo therapeutic dose treatment in ordering the materials, performing QC, calculating dose, administering dose by IV injection, and safety and protection procedures. Specifically, Dr. John Halligan has successfully completed supervised work experience in three cases for parenteral administration of Ra-223 Xofigo for which he is seeking AU status. The three cases were implemented in the Radiation Oncology of Providence Alaska Medical Center, Anchorage, Alaska in the following dates separately:

Date	MR#	Preceptor
4/30/2015	01200520	Dr. Blom
5/28/2015	01200520	Dr. Blom
4/7/2016	00334188	Dr Bertucio



The training and experience requirements were satisfactorily completed under the supervision of the preceptors, James G. Blom, M.D and Clare S. Bertucio, M.D., who is AU for Xofigo.

Please see the documents as attached:

NRC Form 313A (AUT), signed by Dr. James G. Blom, AU and Preceptor.

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

Sincerely,

A handwritten signature in cursive script, 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 35.300)
[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

John Halligan, M.D.

State or Territory Where Licensed

ALASKA

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

☒ 35.300 Use of unsealed byproduct material for which a written directive is required *(Ra-223 Xofigo)*

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 #50-17838-01, Amendment No. 67 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 Usera. 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: <input type="text"/>			

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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<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)

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
James G. Blom, M.D.	NRC Material license #50-17838-01, Amendment No. 67

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

- | | |
|--|--|
| <input type="checkbox"/> 35.390 | With experience administering dosages of: |
| <input type="checkbox"/> 35.392 | <input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) |
| <input type="checkbox"/> 35.394 | <input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) |
| <input checked="" type="checkbox"/> 35.396 | <input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required |
| Ra-223
Xofigo | <input checked="" type="checkbox"/> 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 <div>Ra-223 Xofigo</div> <div>(List radionuclides)</div>	Three clinical cases with personal participation	Providence Alaska Medical Center NRC Material license #50-17838-01, Amendment No. 65	6/24/2015 6/26/2015 7/22/2015

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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 James G. Blom, M.D.	License/Permit Number listing supervising individual as an authorized user NRC Material license #50-17838-01, Amendment No. 67
Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:	
<input type="checkbox"/> 35.390 <input type="checkbox"/> 35.392 <input type="checkbox"/> 35.394 <input checked="" type="checkbox"/> 35.396 <i>Rq223</i> <i>Xof:go</i>	With experience administering dosages of: <input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required <input checked="" type="checkbox"/> 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 John Halligan, M.D. 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 _____ 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)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ I attest that _____ 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 _____ 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 John Halligan, 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

*Ra 223
Xofigo*

Third Section

☒ I attest that John Halligan, 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

*Ra 223
Xofigo*

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 James G. Blom, M.D.	Signature 	Telephone Number (907) 212-3186	Date 4/11/2016
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License/Permit Number/Facility Name

NRC Material license #50-17838-01, Amendment No. 67, Providence Alaska Medical Center

590622



DATE

04/12/2016

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE

Mr. Yongli Ning, M.S., Radiation Safety Officer
Providence Alaska Medical Center
3200 Providence Drive
P.O. Box 196604
Anchorage, Alaska 99519-6604

LICENSE NUMBER

50-17838-01

MAIL CONTROL NUMBER

590622

LICENSING AND/OR TECHNICAL REVIEWER

CH

This is to acknowledge the receipt of your:

☒ LETTER and/or ☐ APPLICATION DATED: 04/11/2016

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

✓ 4/12

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 Req'd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: Providence Alaska Medical Center
Received Date: 04/12/2016
Docket Number: 3013426
Mail Control Number: 590622
License Number: 50-17838-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: _____

Date: _____

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: _____