

Cook, Jackie

From: Ning, Yongli [Yongli.Ning@providence.org]
Sent: Tuesday, June 18, 2013 5:13 PM
To: Cook, Jackie
Subject: RE: YT-90 THERA SPHERE AMENDMENT REQUEST

Jackie,

Nice talking to you. The following are the required information:

1) Manufacturer: Nordion

2) Product:

TheraSphere®. Y-90 glass microsphere

3) Therasphere comes in vials ranging from 3 Gbq to 20 Gbq.

4) Maximum possession limit: 6.5 Ci (240 GBq).

Again, PAMC will commit to following the license commitments – written directives, inventory, patient release, labeling, and Medical Event Reporting as specified in the Microsphere Brachytherapy Sources and Devices Guidance, Revised June 2012.

Thank you very much for your help.

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

PUBLIC

- Immediate Release
 Normal Release

NON-PUBLIC

- Sensitive-Security Related
 Sensitive Internal
 Other

Reviewer: JAC Date: 6/18/13

From: Cook, Jackie [<mailto:Jackie.Cook@nrc.gov>]
Sent: Tuesday, June 18, 2013 11:54 AM
To: Ning, Yongli
Subject: YT-90 THERA SPHERE AMENDMENT REQUEST

Mr. Ning:

Please disregard my voice mail message from earlier. I see on your current license that you are authorized for SIRSpheres; however, please submit the following in order to add authorization for Theraspheres to your license. Please submit the manufacturer, model, and quantity of Theraspheres per vial and maximum possession limit. In addition, commit to following the license commitments – written directives, inventory, patient release, labeling, and Medical Event Reporting as specified in the Microsphere Brachytherapy Sources and Devices Guidance, Revised June 2012 (go to <http://www.nrc.gov/materials/miau/med-use->

[toolkit.html#other](#) to Licensing Guidance for 35.1000 sealed sources & devices and click on "TheraSphere and SIRspheres Yttrium-90 Microspheres June 2012" link to download a copy of this guidance). Please submit your response to this requested information no later than COB Friday, July 5th. Please do not hesitate to contact me if additional time is needed to submit your response.

In addition, please contact me at your convenience if you have any questions regarding this email.

Warmest Regards,

Jacqueline "Jackie" D. Cook

Senior Health Physicist

Division of Nuclear Materials Safety

Nuclear Materials Safety Branch B

1600 E. Lamar Blvd., Arlington, TX 76011

817-200-1132 (office)/817-200-1263 (fax)

e-mail address: Jackie.Cook@nrc.gov

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June 5, 2013

Colleen Murnahan, Licensing Assistant
US Nuclear Regulatory Commission
1600 E. Lamar Blvd.
Arlington, TX 76011-4511

Subject: Amendment to Radioactive Materials License 50-17838-01
Adding TheraSphere by Nordion for medical use

Dear Ms. Murnaha,

This is to request an amendment to Radioactive Materials License #50-17838-01 for Providence Alaska Medical Center (PAMC) to use TheraSphere (Yttrium-90 Microspheres) by Nordion for patient care.

Please notice that under the License #50-17838-01, PAMC is a licensee for Yttrium-90 Microspheres permitted by 10 CFR 35.1000, specified in G for ANSTO radiopharmaceuticals and industrial Model Microspheres, and has Dr. John Halligan and Dr. Chakri Inampudi as Authorized User for 35.1000 for Yttrium-90 Microspheres.

Following the guidance on Microsphere Brachytherapy Sources and Devices Revised June 2012, The Authorized User for Y-90 microspheres under PAMC will attend and complete the supervised hands-on cases training provided at the designated location by the vendor, Nordion-Therasphere. Besides, Nordion-Therasphere will provide proctoring for the first three cases that will be conducted in PAMC. The schedule of the training is attached with this letter.

PAMC will keep all the commitments to be in compliance with the NRC guidelines and requirements for radiation safety.

Sincerely,

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

PUBLIC
 Immediate Release
 Normal
NON-PUBLIC
 A.3 Sensitive Information
 A.7 Sensitive Information
 Other:

Reviewer: JOC Date: 6/19/13

Centre of Excellence (CoE) Invitation

June 26, 2013

Airline Reservations

Arrival: Tuesday, June 25th, in Chicago, Illinois
Departure: Wednesday, June 26th, after 5:00 PM CST

Please book your airline reservations and keep receipts

Transportation

Arrival: Taxis to the hotel are available outside the Baggage Claim area.
Departure: Taxis to the airport are available at the Hyatt Chicago Hotel.
Please allow at least 45 minutes for travel to and from the airport

Please obtain receipts

Hotel: Your hotel accommodation will be made for you. The room rate and taxes will be paid by Nordion.

Hyatt Chicago Magnificent Mile (formerly Wyndham Hotel)
633 North St. Clair
Chicago, IL 60611
312-787-1234

Tuesday: You are invited to join us for dinner at 7:00 PM CST at the Capital Grille.

Wednesday: Hotel meeting room will be posted by Hyatt.
6:45 AM Light continental breakfast will be available in the meeting room.
7:00 AM Session begins:

- Didactic Sessions with Dr. Salem and staff, to include radiation safety and patient management;
- Observation of TheraSphere Treatments;

Lunch Served during meeting.

- Dosimetry and treatment planning;
- Angiographic Considerations in TARE;
- Niche Applications/treatment considerations;
- Case Studies (please prepare one or two potential TheraSphere cases for review).

3:15 PM Session ends.

Depart for Airport: Approximately 3:20 PM CST.

Contact Mark Busch for any questions; 952-221-3614, mark.busch@nordion.com



May 15, 2013

Roberto J. Torres
Senior Health Physicist
U.S. Nuclear Regulatory Commission - Region IV
Nuclear Materials Safety Branch B
612 East Lamar Boulevard, Suite 400
Arlington, Texas 76011-4125

Subject: Amendment to Radioactive Materials License 50-17838-01
Adding TheraSphere by Nordion for medical use

Dear Mr. Torres,

After my notification of 4/30/2013 to NRC for Use of TheraSphere by Nordion I reviewed the license again and realized that this might need an amendment to the license. Hence is the following:

This is to request an amendment to Radioactive Materials License #50-17838-01 for Providence Alaska Medical Center (PAMC) to use TheraSphere (Yttrium-90 Microspheres) by Nordion for patient care.

Please notice that under the License #50-17838-01, PAMC is a licensee for Yttrium-90 Microspheres permitted by 10 CFR 35.1000, specified in G for ANSTO radiopharmaceuticals and industrial Model Microspheres, and has Dr. John Halligan and Dr. Chakri Inampudi as Authorized User for 35.1000 for Yttrium-90 Microspheres.

PAMC will keep all the commitments to be in compliance with the NRC guidelines and requirements for radiation safety.

Should you have any questions regarding this notice, please contact me at (907)212-5691.

Sincerely,

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

PUBLIC

- General Release
- Not for Release

NON-PUBLIC

- A-39 Security Related
- A-7 Sensitive Internal
- Other: _____

Reviewer: JOC Date: 6/19/13

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





RECEIVED

MAY - 1 2013

DNMS

April 30, 2013

Roberto J. Torres
Senior Health Physicist
U.S. Nuclear Regulatory Commission - Region IV
Division of Nuclear Materials Safety
Nuclear Materials Safety Branch B
612 East Lamar Boulevard, Suite 400
Arlington, Texas 76011-4125

Subject: Notification to US NRC for
Use of TheraSphere by Nordion

Dear Mr. Torres,

This is to notify that Providence Alaska Medical Center (PAMC), under the Radioactive Materials License #50-17838-01, will adopt TheraSphere (Yttrium-90 Microspheres) regimen for patient care.

Please notice that under the License #50-17838-01, PAMC is a licensee for Yttrium-90 Microspheres permitted by 10 CFR 35.1000 and has Dr. John Halligan and Dr. Chakri Inampudi as Authorized User for 35.1000 for Yttrium-90 Microspheres.

This notification is to inform the NRC that PAMC is adding another brand of microspheres to its patient service, besides the current use of Sir-spheres by SirTex, upon NRC approval.

PAMC will keep all the commitments to be in compliance with the NRC guidelines and requirements for radiation safety.

It is the understanding that this brand adding does not need a license amendment.

Should you have any questions regarding this notice, please contact me at (907)212-5691.

Sincerely,

Handwritten signature of Yongli Ning

Yongli Ning, M.S.
Chief Medical Physicist - Radiation Oncology
Radiation Safety Officer

PUBLIC

- Immediate Release
Normal Release

NON-PUBLIC

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

Reviewer: JOC Date: 6/19/13

Handwritten note at bottom right

Providence Alaska Medical Center
3200 Providence Drive
Anchorage, AK 99516-6604

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

Hill, Carol

From: Ning, Yongli [Yongli.Ning@providence.org]
Sent: Tuesday, April 30, 2013 6:40 PM
To: Torres, RobertoJ; Hill, Carol; Murnahan, Colleen
Cc: Hazelbaker, Scott
Subject: Notification for use of TheraSphere by Nordion
Attachments: 130430 NRC PAMC TheraSphere.pdf

Dear Roberto,

Please see the attached, a notification for use of TheraSphere by Nordion under our current Radioactive Materials License No. 50-29357-01.

I assume this email is sufficient and there is no need to send a hard copy.

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

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Secure Message Center

From: yongli.ning@providence.org
To: colleen.murnahan@nrc.gov; carol.hill@nrc.gov; RobertoJ.Torres@nrc.gov
Cc: Scott Hazelbaker <scott.hazelbaker@providence.org>
Subject: Provsecure: License amendment for use of TheraSphere by Nordion
Attachments: 130515 NRC PAMC TheraSphere.pdf [475 KB] Download View

Sent: 5/15/2013 1:07:27 PM

Dear Roberto,

Please see the attached, an amendment request for the use of TheraSphere by Nordion under our current Radioactive Materials License No. 50-29357-01.

I assume this email is sufficient and there is no need to send a hard copy.

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

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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: 05/15/2013
Docket Number: 3013426
Mail Control Number: 580869
License Number: 50-17838-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____
Check No.: _____

3. COMMENTS

Signed: Colleen Murnahan
Date: 5-21-13

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: _____