St Luke's
Mountain States
Tumor Institute

100 E. Idaho Street
Boise, Idaho 83712
P (208) 381-2711 F (208) 381-4675
(800) 845-4624

1118 NW 16th Street, Suite D
Fruitland, Idaho 83619 P (208) 452-7677 F (208) 452-8681
(800) 473-9618

520 S. Eagle Road
Meridian, Idaho 83642
P (208) 706-5651 F (208) 706-5344
(800) 473-0331

308 E. Hawaii Avenue
Nampa, Idaho 83686
P (208) 467-6700 F (208) 463-6001
(800) 553-6415

725 Pole Line Road W.
Twin Falls, Idaho 83301
P (208) 814-1600 F (208) 814-1910
(800) 947-4852

August 20, 2018

Carol L. Hill, Licensing Assistant
US Nuclear Regulatory Commission Region IV
Nuclear Materials Licensing Branch
1600 East Lamar Boulevard
Arlington, Texas 76011-4511

RE: Amendment of License #11-27312-01

Dear Carol Hill:

This letter is to inform you that we intend to begin using LUTATHERA (lutetium Lu-177 dotatate) injection, for intravenous use. These radiolabeled injections will fall under 10 CFR 35.300 material use section of our current license. As per the NRC letter "LICENSING OF LUTETIUM-177" (STC-18-042) our current AU's for unsealed source therapy requiring a written directive will already meet the education requirements for the NRC. These injections will be administered within the defined use areas that are currently on our license for the following addresses:

- 100 E. Idaho Street, Boise, Idaho
- 190 E. Bannock, Boise, Idaho.

The shipping and receiving will take place at the 190 E. Bannock, Boise, Idaho address which is the location of our Nuclear Medicine Hot Lab.

Should you need additional information regarding this request, please feel to call me at 208-706-4186, or by email at blackerj@slhs.org.

Sincerely,

James Blacker, MS
Radiation Safety Officer

PUBLIC
☐ Immediate Release
☒ Normal Release

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

Reviewer: Rvtt Date: 8/30/18

St. Luke's Boise
stlukesonline.org

Hill, Carol

From: Blacker, James <blackerj@slhs.org>
Sent: Tuesday, August 21, 2018 2:09 PM
To: Hill, Carol
Cc: Fuller, Scott
Subject: [External_Sender] RE: Amendment of License #11-27312-01
Attachments: sp18042.pdf; Lu-177 Draft location addition.pdf

RE: Amendment of License #11-27312-01

Dear Carol Hill:

This letter is to inform you that we intend to begin using LUTATHERA (lutetium Lu-177 dotatate) injection, for intravenous use.

Sincerely, James Blacker

RSO

St. Luke's Health System

208-706-4186

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 21, 2018

ALL AGREEMENT STATES, VERMONT, WYOMING

LICENSING OF LUTETIUM-177 (STC-18-042)

Purpose: To inform Agreement States of the U.S. Nuclear Regulatory Commission (NRC) Lutetium-177 (Lu-177) licensing decision.

Background: On January 26, 2018, the U.S. Food and Drug Administration (FDA) approved a radiopharmaceutical (LUTATHERA®) that uses lutetium-177 (Lu-177) to treat gastroenteropancreatic neuroendocrine tumors (GEP-NETs). Lu-177 has a half-life of 6.7 days and is delivered in a similar manner as other beta-emitting therapy parenteral administrations. Lu-177 has a short penetration radius, which makes it suitable for radioimmunotherapy for smaller tumors like GEP-NETs. Lu-177 has both gamma and beta emissions, allowing for the acquisition of images incidental to the intended therapeutic treatment.

Discussion: The NRC staff reviewed the radiation safety and regulatory aspects (e.g., radionuclide and progeny emissions, radiation detection, monitoring and measurements, authorized user training and experience needs, patient administration and release considerations, dose delivery, and handling and waste disposal) of the medical use of Lu-177 and has determined that the applicable licensing provisions are in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, Subpart E, "Unsealed Byproduct Material – Written Directive Required." The medical use of Lu-177 is similar to other commonly used beta- and photon-emitting therapeutic radiopharmaceuticals.

The NRC staff concluded that physicians approved for the use of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV under 10 CFR 35.390, "Training for use of unsealed byproduct material for which a written directive is required" may also be authorized for the medical use of Lu-177. Physicians authorized under 10 CFR 35.396, "Training for the parenteral administration of unsealed byproduct material requiring a written directive," may also be authorized for the medical use of Lu-177.

The NRC staff evaluated waste storage issues when handling Lu-177. Lu-177 waste may be decayed in storage under the performance-based rule in 10 CFR 35.92, "Decay-in-storage." Small quantities of metastable Lu-177 (Lu-177m), with a half-life of 161 days, may be present as a contaminant generated from the production of Lu-177. If present, Lu-177m may contribute approximately 0.02 percent of the total amount of Lu-177. Lu-177m emits low-energy photons and beta emissions that, even in low quantities, are detectable using standard scintillator detectors and Geiger counters. If Lu-177m is detected by appropriate survey methods, then licensees must dispose of the waste material as low-level radioactive waste in accordance with the requirements in 10 CFR Part 20 Subpart K, "Waste Disposal." Further, the licensee would need to develop safe handling and disposal procedures for detectable quantities of Lu-177m.

Additional radiation safety considerations for Lu-177 can be found using NRC's Agencywide Documents Access and Management System Accession No. ML18136A824. If the NRC becomes aware of future developments related to the production, distribution, or medical use of Lu-177 that may negatively impact radiation safety, the NRC staff will consider revisiting this licensing decision for any additional actions.

POINT OF CONTACT: Dr. Said Daibes
TELEPHONE: (301) 415-6863
INTERNET: Said.Daibes@nrc.gov

/RA/

Andrea L. Kock, Acting Director
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Hill, Carol

From: Torres, RobertoJ
Sent: Tuesday, August 21, 2018 1:11 PM
To: Hill, Carol
Subject: FW: Notification Question
Attachments: sp18042.pdf

Carol:

Please set up as an initial amendment and place a note for the reviewer to change it to a notification if there is no amendment involved (a review will still be needed). Thank you.

From: Blacker, James [mailto:blackerj@slhs.org]
Sent: Tuesday, August 21, 2018 12:59 PM
To: Torres, RobertoJ <RobertoJ.Torres@nrc.gov>
Subject: [External_Sender] Notification Question

RE: Amendment of License #11-27312-01

Mr. Torres,

This letter is to inform you that we intend to begin using LUTATHERA (lutetium Lu-177 dotatate) injection, for intravenous use. These radiolabeled injections will fall under 10 CFR 35.300 material use section of our current license. As per the NRC letter "LICENSING OF LUTETIUM-177" (STC-18-042) our current AU's for unsealed source therapy requiring a written directive will already meet the education requirements for the NRC. These injections will be administered within the defined use areas that are currently on our license for the following addresses:

- 100 E. Idaho Street, Boise, Idaho
- 190 E. Bannock, Boise, Idaho.

The shipping and receiving will take place at the 190 E. Bannock, Boise, Idaho address which is the location of our Nuclear Medicine Hot Lab.

Beyond this notification is there anything else required from us to satisfy the NRC? Since we already have 35.300 on our license with AU is this notification necessary? Please let me know what future notifications are required with respect to adding a new radiopharmaceutical under 10 CFR 35.300

Sincerely, James Blacker
RSO
St. Luke's Health System
208-706-4186

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 21, 2018

ALL AGREEMENT STATES, VERMONT, WYOMING

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Discussion: The NRC staff reviewed the radiation safety and regulatory aspects (e.g., radionuclide and progeny emissions, radiation detection, monitoring and measurements, authorized user training and experience needs, patient administration and release considerations, dose delivery, and handling and waste disposal) of the medical use of Lu-177 and has determined that the applicable licensing provisions are in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, Subpart E, "Unsealed Byproduct Material – Written Directive Required." The medical use of Lu-177 is similar to other commonly used beta- and photon-emitting therapeutic radiopharmaceuticals.

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POINT OF CONTACT: Dr. Said Daibes
TELEPHONE: (301) 415-6863
INTERNET: Said.Daibes@nrc.gov

/RA/

Andrea L. Kock, Acting Director
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee	Date
James D. Blacker, M.S. Radiation Safety Officer St. Luke's Regional Medical Center 190 E. Bannock Boise, ID 83712	08/28/2018
	License Number(s) 11-27312-01
	Mail Control Number(s) 609748
	Licensing and/or Technical Reviewer or Branch C. Hill

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** 08/20/2018

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 complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link:** http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf

Follow the instructions on the form for submission.

☐ **The following administrative omissions have been identified:**

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) 200-1103 or (817) 200-1140

✓ 8/29/18

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 02230
Status Code: Pending Amendment
Fee Category: 3E 7C
Exp. Date: 03/31/2025
Fee Comments:
Decom Fin Assur Reqd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee:	St. Luke's Regional Medical Center
Received Date:	08/21/2018
Docket Number:	3032196
Mail Control Number:	609748
License Number:	11-27312-01
Action Type:	Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: Carol L Hicie

Date: 8/29/18

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: _____