



From day one.

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2827 Fort Missoula Road  
Missoula, MT 59804  
TEL (406) 728-4100  
www.communitymed.org

May 26, 2016

Roberto J. Torres, M.S. Senior Health Physicist

USNRC  
Region IV  
1600 E. Lamar Blvd.  
Arlington, TX 76011-4511

RE: **License No. 25-18361-01**  
RCHP-Billings-Missoula LLC  
DBA Community Medical Center  
  
2827 Fort Missoula Road  
  
Missoula, MT 59804

Dear Mr. Torres:

This letter is a request to amend NRC radioactive material license No. 25-18361-01 to permit radioactive seed localization (RSL) of non-palpable lesions.

I have enclosed a description of our proposed program, following the format and guidance of U.S. NRC Licensing Guidance Document, "Iodine-125 and Palladium-103 Low Dose Brachytherapy Seeds Used for Localization of Non-Palpable Lesions."

For questions, please contact Kim Ryan-O'Hara at 406-327-4333 or [kryanohara@communitymed.org](mailto:kryanohara@communitymed.org).

Thank you very much for your assistance.

Sincerely,

  
Dean French, MD,

CEO

**PUBLIC**

- ☐ Immediate Release  
☒ Normal Release

**NON-PUBLIC**

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

Reviewer: 

Date: 6/9/16

591050

## **General**

### **Radionuclides, Form, Possession Limits, and Purpose of Use**

Radionuclides	Iodine-125 and/or Palladium-103
Form	Sealed brachytherapy sources
Possession limit	1.5 milliCurie maximum per treatment and 500 milliCurie maximum amount in possession at any one time.

500 mCi is requested based on an estimated patient workload of 10 patients per week, 1.5 mCi maximum per patient and with allowance for future growth in patient workload.

### **Purpose of Use**

For use as temporary implants to localize non-palpable lesions 10 CFR 35.1000, "Other medical uses of radioactive material or radiation from radioactive material."

### **Facility Address and Description**

1. Seeds will be shipped to and received in the Nuclear Medicine Department at 2827 Fort Missoula Road, Missoula, MT 59804. Seeds will be unpacked in the Nuclear medicine Department. This room is already identified on our license as a location of use for radioactive material on our current license.
2. Seeds will be stored in the locked nuclear medicine hot lab.
3. Seeds will be implanted in the radiology ultrasound rooms located at the same address or at Advanced Imaging 2803 South Ave W. Missoula, MT 59804. Please note Advanced Imaging is on the Hospital Grounds and is located next to the Hospital Radiology and Emergency Departments.
4. Seed explanation will be done in the Operating Rooms at 2827 Fort Missoula Road.
5. Seeds will be removed from specimens in our Pathology Laboratory at 2827 Fort Missoula Road. The Pathology Laboratory is not a location of use on our license. Specimens will be stored in a locked cabinet in that Laboratory and returned to the nuclear medicine department or immediately returned to the nuclear medicine department. The seeds will then be placed in our long term storage locked cabinet.

## **Authorized Users**

We will initially have one Authorized User, Michael A. Stewart, M.D, who is an authorized user on our license for 10 CFR 35.300 uses. Dr. Stewart has completed the required training for RSL uses and his training and experience is included with this request. Dr. Stewart will supervise the breast radiologists in source implantation, the breast surgeons in seed explantation, and pathology staff in seed removal from specimens.

After the breast radiologists have acquired training and supervised work experience to satisfy Authorized User requirements specified in the U.S. NRC guidance document "Iodine-125 and Palladium-103 Low Dose Rate Brachytherapy Seeds Used for Localization of Non-Palpable Lesions," we will submit a license amendment request to add them as Authorized Users for RSL procedures.

All staff participating in RSL procedures will receive training commensurate with their duties. Training will be done under the direction of the Authorized User, Radiation Safety Officer, or Medical Physicist. Training methods may include in person training or online training.

General surgeons, working under the supervision of an Authorized User, will receive training that includes:

- Performing the related radiation surveys using appropriate instrumentation;
- Preparing, implanting, and safely removing brachytherapy sources;
- Performing routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source; and
- Emergency procedures, including how to respond to a leaking source.

Pathology personnel will receive training that includes:

- Minimizing time handling the specimen;
- Using an appropriate survey instrument to perform surveys of hands and works areas following handling of the specimen
- Performing routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source;
- Emergency procedures to be followed in the event contamination is identified;
- Accountability and security of the seeds post implantation; and
- Proper disposition of the seeds and/or specimens containing the seed(s).

## **Written Directives**

A written directive will be used for each RSL procedure. The written directive will meet the requirements of 10 CFR 35.

## **Safety Precautions and Instructions for Iodine-125 and Palladium-103 Seed Localization for Non-Palpable Lesions**

Our protocol for RSL procedures will follow the requirements of the most recent NRC license guidance for RSL. In addition, because the seeds are temporarily implanted, we will meet the requirements for temporary implants and develop, implement, and maintain the appropriate procedures in the following regulations: 10 CFR 35.40(a), (b)(6), (c), and (d), 35.41, 35.67, 35.75, 35.310, 35.404, 35.406, 35.410, 35.432, or the equivalent Agreement State regulations.

### **Survey Instrumentation**

Ludlum Model 3 Survey meters with a scale reading from 0 to 200 mR/hour and equipped with a Ludlum Model 44-3 sodium iodide (NaI) low energy scintillation probe or GM type probe will be used for the RSL procedures. A meter and probe will be used in each of the following locations:

- Advanced Imaging Center or Radiology Ultrasound rooms (seed implantation)
- Operating Room (seed explanation)
- Pathology Laboratory (seed removal from specimens)

A NeoProbe Portable Radioisotope Gamma Detection Device or equivalent will be used in the Operating Rooms to localize the seed/s in the breast.

### **Revisions to the RSL Program**

As recommended in U.S. NRC guidance document "Iodine-125 and Palladium-103 Low Dose Rate Brachytherapy Seeds Used for Localization of Non-Palpable Lesions," we request authorization to allow future changes to our radiation safety program as NRC RSL licensing guidance is revised and as we acquire experience in RSL procedures, provided the following conditions are met:

- The revision is in compliance with NRC or Agreement State regulations;
- The revision is based on the current guidance for RSL 35.1000 use posted on the NRC website;
- The revision has been reviewed and approved by the Radiation Safety Officer and management;
- The affected individuals are instructed on the revised program before the change is implemented;
- A record of each change will be retained for 5 years; and
- The record will include a copy of the appropriate web guidance, the old procedure, the new procedure, the effective date of the change, and the signature of management that reviewed and approved the change.

Extremely Urgent





## ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

## Name and Address of Applicant and/or Licensee

Mr. Christopher Fitz, Radiation Safety Officer  
RCHP Billings – Missoula LLC  
dba Community Medical Center  
2827 Fort Missoula Road  
Missoula, Montana 59804

## Date

06/07/2016

## License Number(s)

25-18361-01

## Mail Control Number(s)

591050

## Licensing and/or Technical Reviewer or Branch

CLH

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 05/26/2016

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 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) 200-1140

✓ 6/7/16

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: CODE 23  
Decom Fin Assur Req: N

## License Fee Worksheet - License Fee Transmittal

### A. REGION

#### 1. APPLICATION ATTACHED

Applicant/Licensee: RCHP Billings - Missoula LLC dba Community Medical Center  
Received Date: 06/07/2016  
Docket Number: 3014921  
Mail Control Number: 591050  
License Number: 25-18361-01  
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: \_\_\_\_\_