

## ACCEPTANCE REVIEW MEMO

Licensee: Community Medical Center

License No.: 25-18361-01

Docket No.: 030-14921

Mail Control No.: 470692

Type of Action: Amend. Date of Requested Action:

Reviewer Assigned: Torres Date Assigned to Reviewer:

Reviewer(s) Who  
Performed Review: Torres

| Response Received | Deficiencies Noted During Acceptance Review                    |
|-------------------|--|
| <u>10/14/05</u>   | 1. Dr. Brake does not qualify for 35.300 uses according to the |
|                   | 2. evidence submitted with the amendment request.              |
|                   | 3.   |
|                   | 4.   |

Reviewer's Initials: RSTC

Date: 10/18/05

Branch Chief's and/or SR. HP's Initials: RSTC

Date: 10/18/05

|  |   |
|--|---|
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Action - decommissioning notification should be issued within 30 days.  |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Termination request < 90 days from date of expiration   |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Action to be expedited  |
|  | <input type="checkbox"/> Medical emergency  |
|  | <input type="checkbox"/> Licensee in noncompliance (i.e. no RSO, location of use/storage not on license, radioactive material in possession not on license) |
|  | <input type="checkbox"/> National Security  |
|  | <input type="checkbox"/> Other ( )  |

Branch Chief's and/or Sr. HP's Initials: \_\_\_\_\_ Date: \_\_\_\_\_

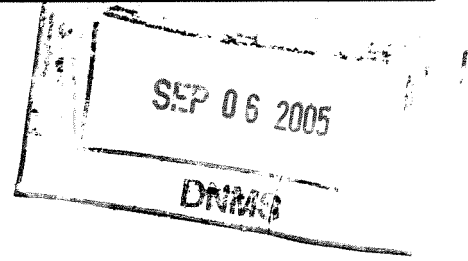
| SISP Review   |  |
|---|--|
| <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Non-Publicly Available, Sensitive if <u>any</u> item below is checked  |
|   | <input type="checkbox"/> Radionuclides, forms, and quantities  |
|   | <input type="checkbox"/> Location of RAM   |
|   | <input type="checkbox"/> Building drawings with locations of RAM   |
|   | <input type="checkbox"/> Security of RAM (locks, alarms, etc.)   |
|   | <input type="checkbox"/> SS&D Catalog information  |
|   | <input type="checkbox"/> Specifics of Emergency Plan (routes to and from RAM, response to security events, etc.) |
|   | <input type="checkbox"/> Safeguards Information  |

Branch Chief's and/or Sr. HP's Initials: RSTC Date: 10/18/05

2827 Fort Missoula Road  
Missoula, Montana 59804

## Community Medical Center

# Fax



**To:** NRC, Region IV

**From:** Kim Ryan-O'Hara

**Fax:** 817-860-8263

**Pages:** 9, including cover

**Phone:** 800-952-9677

**Date:** 8/30/2005

**Re:** Amendment request for RAM license #25- **CC:**

18361-01

☐ **Urgent**    ☐ **For Review**    ☐ **Please Comment**    ☐ **Please Reply**    ☐ **Please Recycle**

● **Comments:** I am faxing our request to add Dr. Brake as an Authorized User. I will also mail this request to you. If you have any questions, please e-mail me at [kryanohara@communitymed.org](mailto:kryanohara@communitymed.org) or call (406) 728-4100 ext 7673.

Thank you.

CNU

## TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT

## PART I - TRAINING AND EXPERIENCE

**Note:** Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

Joel Brake, MD

Diagnostic Radiologist

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

x Montana (see attached license copy)

## 3. CERTIFICATION

| Specialty Board             | Category             | Month and Year Certified |
|-----------------------------|----------------------|--------------------------|
| American Board of Radiology | Diagnostic Radiology | 6/04                     |

Stop here when using Board Certification to meet 10 CFR Part 35 training and experience requirements.

## 4. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

| Description of Training  | Location | Clock Hours | Dates of Training |
|--|----------|-------------|-------------------|
| Radiation Physics and Instrumentation                              |          |             |                   |
| Radiation Protection   |          |             |                   |
| Mathematics Pertaining to the Use and Measurement of Radioactivity |          |             |                   |
| Radiation Biology  |          |             |                   |
| Chemistry of Byproduct Material for Medical Use                    |          |             |                   |
| OTHER  |          |             |                   |

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

5a. WORK EXPERIENCE WITH RADIATION

| Description of Experience | Name of Supervising Individual(s) | Location and Corresponding Materials License Number | Dates and Clock Hours of Experience |
|---------------------------|-----------------------------------|---|-------------------------------------|
|                           |                                   |   |                                     |
|                           |                                   |   |                                     |
|                           |                                   |   |                                     |
|                           |                                   |   |                                     |
|                           |                                   |   |                                     |
|                           |                                   |   |                                     |
|                           |                                   |   |                                     |
|                           |                                   |   |                                     |

5b. SUPERVISED CLINICAL CASE EXPERIENCE

| Radionuclide | Type of Use | No. of Cases Involving Personal Participation | Name of Supervising Individual | Location and Corresponding Materials License Number | Dates and Clock Hours of Experience |
|--------------|-------------|---|--------------------------------|---|-------------------------------------|
|              |             |   |                                |   |                                     |
|              |             |   |                                |   |                                     |
|              |             |   |                                |   |                                     |
|              |             |   |                                |   |                                     |
|              |             |   |                                |   |                                     |
|              |             |   |                                |   |                                     |
|              |             |   |                                |   |                                     |
|              |             |   |                                |   |                                     |

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

6. FORMAL TRAINING (applies to Medical Physicists and Therapy Physicians)

| Degree, Area of Study<br>or<br>Residency Program | Name of Program and<br>Location with<br>Corresponding<br>Materials<br>License Number | Dates | Name of Organization that<br>Approved the Program<br>(e.g., Accreditation Council<br>for Graduate Medical Education)<br>and the Applicable Regulation<br>(e.g., 10 CFR 35.490) |
|--|--|-------|--|
|  |  |       |  |

7. RADIATION SAFETY OFFICER -- ONE-YEAR FULL-TIME WORK EXPERIENCE

- ☐ YES Completed 1-year of full-time radiation safety experience (in areas identified in item 5a) under supervision  
☐ N/A of \_\_\_\_\_ the RSO for License No. \_\_\_\_\_

8. MEDICAL PHYSICIST -- ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

- ☐ YES Completed 1-year of full-time training in therapeutic radiological physics under the supervision of  
☐ N/A \_\_\_\_\_ who meets requirements for Authorized Medical Physicists; and
- ☐ YES Completed 1-year of full-time work experience (for areas identified in item 5a) for \_\_\_\_\_  
☐ N/A modality(ies) under the supervision of \_\_\_\_\_ who meets  
requirements of Authorized Medical Physicists for \_\_\_\_\_ modality(ies).

9. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR 35, provide the following information for each):

A. Name of Supervisor

B. Supervisor is:

\_\_\_\_\_

- ☐ Authorized User  
☐ Radiation Safety Officer

- ☐ Authorized Medical Physicist  
☐ Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) \_\_\_\_\_

for medical uses in Part 35, Section(s) \_\_\_\_\_

D. Address

E. Materials License Number

\_\_\_\_\_

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

PART II – PRECEPTOR STATEMENT

**Note:** This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in 10 CFR 35.590.

Item 10 must be completed for Nuclear Pharmacists meeting the requirements of 10 CFR Part 35, Subpart J. Preceptors do not have to complete items 11a, 11b, or the certifying statements for other individuals meeting the requirements of 10 CFR Part 35, Subpart J.

☐ YES      10. The individual named in item 1 has satisfactorily completed the training requirements in  
☐ N/A      10 CFR 35.980 and is competent to independently operate a nuclear pharmacy.

☐ YES      11a. The individual named in Item 1 has satisfactorily completed the requirements in Part 35, Section(s)  
☐ N/A      and Paragraph(s) \_\_\_\_\_.

☐ YES      11b. The individual named in Item 1. is competent to independently function as an authorized  
☐ N/A      \_\_\_\_\_ for \_\_\_\_\_ uses (or units).

12. PRECEPTOR APPROVAL AND CERTIFICATION

☐ I certify the approval of item 10 and certify I am an Authorized Nuclear Pharmacist;

or

☐ I certify the approval of items 11a and 11b, and certify I am an Authorized Nuclear Pharmacist;

or

☐ I certify the approval of Items 11a and 11b, and I certify that I meet the requirements of \_\_\_\_\_  
or equivalent Agreement State requirements to be a preceptor authorized \_\_\_\_\_  
for the following uses (or units) of byproduct material: \_\_\_\_\_

A. Address

B. Materials License Number

C. NAME OF PRECEPTOR (print clearly)

D. SIGNATURE – PRECEPTOR

E. DATE

Board of Medical Examiners

It is your responsibility to notify this  
agency within 10 days of any changes.

STATE OF MONTANA  
DEPARTMENT OF LABOR AND INDUSTRY

Board of Medical Examiners

Active

This verifies that the below named is currently licensed  
as a Medical Doctor

10779

Expires: 03/31/2006

JOEL ABRAHAM BRAKE MD

STATE OF MONTANA - DEPARTMENT OF LABOR AND INDUSTRY

Board of Medical  
Examiners

JOEL ABRAHAM BRAKE MD  
Medical Doctor 10779

Active

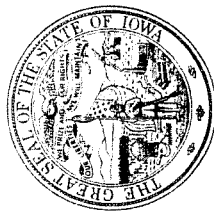
Exp: 03/31/06

SIGNATURE

SIGNATURE

YOU MUST NOTIFY THIS AGENCY OF ANY CHANGES WITHIN 10 DAYS

# State of Iowa



## Iowa Board of Medical Examiners

Hereby Authorizes And Licenses

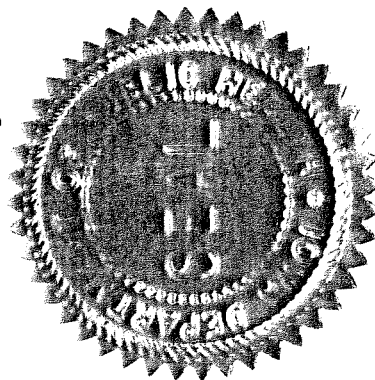
**Joel Abraham Brake, M.D.**

to practice Medicine and Surgery in the State of Iowa under and pursuant to the provisions of Chapter one hundred forty seven, Iowa Statutes Annotated and acts amendatory thereof and supplemental thereto.

Given under the hands and seal of the Iowa Department of Public Health

this 14th day of May, A.D. 2004

Ann E. Horney  
Executive Director



[Signature]  
Chairperson

License No. 35608



# The American Board of Radiology

Organized through the cooperation of the  
American College of Radiology, the American Roentgen Ray Society,  
the American Radium Society, the Radiological Society of North America,  
the Section on Radiology of the American Medical Association,  
the American Society for Therapeutic Radiology and Oncology, the Association of  
University Radiologists, and American Association of Physicians in Medicine

Hereby certifies that

**Joel Abraham Brake, M.D.**

Has pursued an accepted course of graduate study  
and clinical work, has met certain standards and qualifications and  
has passed the examinations conducted under the authority of

The American Board of Radiology

On this ninth day of June, 2014

Thereby demonstrating to the satisfaction of the Board  
that he is qualified to practice the specialty of

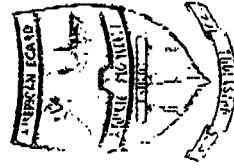
**Diagnostic Radiology**



*William H. ...*  
President

*Ray O. Nelson, M.D.*  
Secretary-Treasurer

*R.R. Haines, M.D.*  
Executive Director



Valid through 2014

Certificate No. 50350

**From:** "Ryan-O'Hara, Kimberly" <KRyanOhara@communitymed.org>  
**To:** "Roberto Torres" <RJT@nrc.gov>  
**Date:** 10/14/05 12:02PM  
**Subject:** RE: Request for additional information

Mr. Torres,

I spoke with Dr. Brake this morning. He feels he does not have enough time to get the documentation required by October 24th to be authorized to be a user for 35.300. He has contacted the facility where he did his training and cannot get a response from them. Therefore, we will just request that Dr. Brake be added to our license as an authorized user for parts 35.100 and 35.200.

Thank you for all your help on this matter. If you have any questions, please call or e-mail.

Kimberly R. Ryan-O'Hara, CNMT, RT(N), NCT  
Nuclear Medicine  
Community Medical Center  
2827 Fort Missoula Road  
Missoula, Montana 59804  
(406) 728-4100 ext 7673

-----Original Message-----

From: Roberto Torres [mailto:RJT@nrc.gov]  
Sent: Tuesday, September 27, 2005 1:29 PM  
To: Ryan-O'Hara, Kimberly  
Cc: joelbrake@mac.com  
Subject: RE: Request for additional information

Kimberly:

In your email you stated: "Meanwhile, we will try and have him [Dr. Brake]document supervised clinical experience as required under 35.930."

35.930 will no longer be valid after October 24, 2005. After that date, Dr. Brake will need to document his training and experience under 35.390. (I know it's a bit confusing, the expiring regulation is 35.930 and the new regulation is 35.390). Here's the link to 35.390.

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0390.html>

P.S.: The expiring regulation (35.930) requires only documentation of 80 hours of classroom and laboratory training whereas the new regulation requires 700 hours.

Roberto J. Torres  
Senior Health Physicist  
U.S. Nuclear Regulatory Commission, Region IV Division of Nuclear  
Materials Safety Nuclear Materials Licensing Branch  
611 Ryan Plaza Drive, Suite 400

Arlington, Texas 76011  
Telephone 817-860-8189  
Facsimile 817-860-8188  
rjt@nrc.gov

>>> "Ryan-O'Hara, Kimberly" <KRyanOhara@communitymed.org> 09/27/05 10:53

>>> AM >>>  
Mr. Torres,

I am still slightly confused by the terminology. Dr. Brake says that he had this training during his residency and fellowship, which he recently completed (his ABR certification is dated June 2004). Dr. Brake was trained in handling isotopes for PET imaging and did do therapies as part of his training.

However, he will be unable to get the documentation of that prior to the October 24, 2005 deadline. Therefore, we will just have him listed as authorized user for 35.100 and 35.200.

Meanwhile, we will try and have him document supervised clinical experience as required under 35.930.

Thank you.

Sincerely,

Kimberly R. Ryan-O'Hara, CNMT, RT(N), NCT Nuclear Medicine Community  
Medical Centr  
2827 Fort Missoula Road  
Missoula, Montana 59804  
(406) 728-4100 ext 7673

-----Original Message-----

From: Roberto Torres [mailto:RJT@nrc.gov]  
Sent: Wednesday, September 21, 2005 8:00 AM  
To: Ryan-O'Hara, Kimberly  
Subject: RE: Request for additional information

Dr. Brake's American Board of Radiology certification is in diagnostic radiology (which makes him eligible to become a 35.100 and 35.200 authorized user right away). His board certification is not in therapeutic radiology or radiation oncology, which is one of the requirements to become a 35.300 authorized user. ABR no longer gives certification on "radiology" only. The regulation that I provided below is 10 CFR 35.930 and will be in effect until October 24, 2005. After that, the training requirements for a physician to become a 35.300 user will be more stringent.

Roberto J. Torres  
Senior Health Physicist  
U.S. Nuclear Regulatory Commission, Region IV  
Division of Nuclear Materials Safety

Nuclear Materials Licensing Branch  
611 Ryan Plaza Drive, Suite 400  
Arlington, Texas 76011  
Telephone 817-860-8189  
Facsimile 817-860-8188  
rjt@nrc.gov

Roberto J. Torres  
Senior Health Physicist  
U.S. Nuclear Regulatory Commission, Region IV  
Division of Nuclear Materials Safety  
Nuclear Materials Licensing Branch  
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Arlington, Texas 76011  
Telephone 817-860-8189  
Facsimile 817-860-8188  
rjt@nrc.gov

>>> "Ryan-O'Hara, Kimberly" <KRyanOhara@communitymed.org> 09/20/05 12:16 PM >>>  
Mr. Torres,

We submitted documentation for Dr. Brake's certification by the American Board of Radiology in radiology. Is that not the same certification as listed under a) (2)?

Kimberly R. Ryan-O'Hara, CNMT, RT(N), NCT  
Nuclear Medicine  
Community Medical Center  
2827 Fort Missoula Road  
Missoula, Montana 59804  
(406) 728-4100 ext 7673

-----Original Message-----

From: Roberto Torres [mailto:RJT@nrc.gov]  
Sent: Friday, September 16, 2005 10:39 AM  
To: Ryan-O'Hara, Kimberly  
Subject: Request for additional information

Ms. Ryan-O'Hara:

In your telephone conversation with me held today (9/16/05), you requested that Joel Brake, M.D. be recognized as an authorized user for 35.100, 35.200, and 35.300 uses. The documentation submitted to us only supports the authorization of Dr. Brake for 35.100 and 35.200 uses because of his American Board of Radiology Certification in diagnostic radiology. The following documentation needs to be submitted in NRC Form 313A to recognize Dr. Brake as a 35.300 authorized user. Recognition under 35.300 can be achieved under one of two pathways until October 24, 2005: Either board certification as described under pathway (a), or classroom/laboratory training and clinical experience as described under pathway (b). See below.

(a) Certification by--

- (1) The American Board of Nuclear Medicine;
  - (2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;
  - (3) The Royal College of Physicians and Surgeons of Canada in nuclear medicine; or
  - (4) The American Osteopathic Board of Radiology after 1984; or
- (b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows--
- (1) 80 hours of classroom and laboratory training that includes--
    - (i) Radiation physics and instrumentation;
    - (ii) Radiation protection;
    - (iii) Mathematics pertaining to the use and measurement of radioactivity; and
    - (iv) Radiation biology; and
  - (2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes--
    - (i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and
    - (ii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.

Please respond to this fax within 5 days of receipt. My fax number is 817-860-8188. If you have any questions you can call me at 817-860-8189. Please include the license number (25-18361-01), docket number (030-14921), and mail control number (470692) if you respond by fax. If responding by email, please submit signed documentation in pdf format. Thank you.

Roberto J. Torres  
Senior Health Physicist  
U.S. Nuclear Regulatory Commission, Region IV Division of Nuclear  
Materials Safety Nuclear Materials Licensing Branch  
611 Ryan Plaza Drive, Suite 400  
Arlington, Texas 76011  
Telephone 817-860-8189  
Facsimile 817-860-8188  
rjt@nrc.gov

**Mail Envelope Properties** (434FE4A7.4E9 : 23 : 13545)

**Subject:** RE: Request for additional information  
**Creation Date:** 10/14/05 12:01PM  
**From:** "Ryan-O'Hara, Kimberly" <[KRyanOhara@communitymed.org](mailto:KRyanOhara@communitymed.org)>  
**Created By:** [KRyanOhara@communitymed.org](mailto:KRyanOhara@communitymed.org)

**Recipients**

nrc.gov

ARL\_PO.ARL\_DO

RJT (Roberto Torres)

**Post Office**

ARL\_PO.ARL\_DO

**Route**

nrc.gov

**Files**

MESSAGE

Mime.822

**Size**

7078

8454

**Date & Time**

10/14/05 12:01PM

**Options****Expiration Date:**

None

**Priority:**

Standard

**Reply Requested:**

No

**Return Notification:**

None

**Concealed Subject:**

No

**Security:**

Standard