

ACCEPTANCE REVIEW MEMO

Licensee: Community Medical Center, Inc

License No.: 25-¹⁸³⁶¹~~2824~~-01

Docket No.: 030-14921

Mail Control No.: 470692

Type of Action: Amend Date of Requested Action: 08-30-05

Reviewer Assigned: Roberto Date Assigned to Reviewer: 09-15-05

Reviewer(s) Who Performed Review: Torres

Response Received	Deficiencies Noted During Acceptance Review
9/27/05	1. Licensee needs to state authorization request for Dr. Brake (35.100, 35.200).
	2. Left voicemail message with Ms. Ryan-O'Hara requesting information. → 9/15/05
	3. 9/16/05 call from Ms. O'Hara - request is for 35.100, 35.200 and 35.300.
	4. → Ms. O'Hara retracted 35.300 request (separated email).

Reviewer's Initials: RSTC

Date: 10/4/05

Branch Chief's and/or SR. HP's Initials: [Signature]

Date: 10/4/05

<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 checked="" type="checkbox"/> Radionuclides, forms, and quantities
	<input checked="" type="checkbox"/> Location of RAM
	<input checked="" type="checkbox"/> Building drawings with locations of RAM
	<input checked="" type="checkbox"/> Security of RAM (locks, alarms, etc.)
	<input checked="" type="checkbox"/> SS&D Catalog information
	<input checked="" type="checkbox"/> Specifics of Emergency Plan (routes to and from RAM, response to security events, etc.)
	<input checked="" type="checkbox"/> Safeguards Information
Branch Chief's and/or Sr. HP's Initials: <u>RSTC</u> Date: <u>9/15/05</u>	

From: "Ryan-O'Hara, Kimberly" <KRyanOhara@communitymed.org>
To: "Roberto Torres" <RJT@nrc.gov>
Date: 9/27/05 10:55AM
Subject: RE: Request for additional information

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 Center
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
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> 09/20/05 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 (43396B51.B65 : 3 : 15205)

Subject: RE: Request for additional information
Creation Date: 9/27/05 10:53AM
From: "Ryan-O'Hara, Kimberly" <KRyanOhara@communitymed.org>

Created By: KRyanOhara@communitymed.org

Recipients

nrc.gov
ARL_PO.ARL_DO
RJT (Roberto Torres)

Post Office

ARL_PO.ARL_DO

Route

nrc.gov

Files	Size	Date & Time
MESSAGE	5182	09/27/05 10:53AM
Mime.822	6508	

Options

Expiration Date: None
Priority: Standard
Reply Requested: No
Return Notification: None

Concealed Subject: No
Security: Standard

From: Roberto Torres
To: kryanohara@communitymed.org
Date: 9/16/05 11:39AM
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--

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- (2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;
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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 (432AF530.BE8 : 16 : 64234)

Subject: Request for additional information
Creation Date: 9/16/05 11:39AM
From: Roberto Torres

Created By: RJT@nrc.gov

Recipients	Action	Date & Time
communitymed.org		
kryanohara (kryanohara@communitymed.org)		
nrc.gov		
ARL_PO.ARL_DO	Delivered	09/16/05 11:39 AM
RJT BC (rjt)	Opened	09/16/05 11:39 AM
Post Office	Delivered	Route
	Pending	communitymed.org
ARL_PO.ARL_DO	09/16/05 11:39 AM	nrc.gov
Files	Size	Date & Time
MESSAGE	4197	09/16/05 11:39AM

Options

Auto Delete: No
Expiration Date: None
Notify Recipients: Yes
Priority: Standard
Reply Requested: No
Return Notification: None

Concealed Subject: No
Security: Standard

To Be Delivered: Immediate
Status Tracking: Delivered & Opened

470692

2827 Fort Missoula Road
Missoula, Montana 59804

**Community Medical
Center**

Fax

406-728-4100 x 7673
KRYANOHARA@communitymed.
org

To: NRC, Region IV	From: Kim Ryan-O'Hara
Fax: 817-860-8283	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 krvanohara@communitymed.org or call (406) 728-4100 ext 7673.

Thank you.



2827 Fort Missoula Road • Missoula, MT 59804

(406) 728-4100 • www.communitymed.org

August 22, 2005

US Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Dr., Suite 400
Arlington, TX 76011-8064

To Whom It May Concern:

We are submitting an amendment for your consideration and approval. We appreciate your prompt action on this matter.

Please amend our license number 25-18361-01 to add Joel Brake, M.D. as an Authorized User.

*9/16/05 Call from Ms. Ryan
request is for → 35-100, 35-200 and 35-300*

Attached please find all necessary documentation to support this amendment request.

Please address all correspondence regarding this request to Kimberly Ryan-O'Hara, CNMT. Ms. Ryan-O'Hara may be reached at the above address and phone number or by e-mail, kryanohara@communitymed.org.

Thank you,

Roy Zimmer / krd

Roy W. Zimmer, III, M.D.
Medical Director
Diagnostic Imaging



2827 Fort Missoula Road ▪ Missoula, MT 59804

(406) 728-4100 ▪ www.communitymed.org

August 22, 2005

US Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Dr., Suite 400
Arlington, TX 76011-8064

To Whom It May Concern:

We are submitting an amendment for your consideration and approval. We appreciate your prompt action on this matter.

Please amend our license number 25-18361-01 to add Joel Brake, M.D. as an Authorized User.

Attached please find all necessary documentation to support this amendment request.

Please address all correspondence regarding this request to Kimberly Ryan-O'Hara, CNMT. Ms. Ryan-O'Hara may be reached at the above address and phone number or by e-mail, kryanohara@communitymed.org.

Thank you,

Roy Zimmer / kro (original signature)

Roy W. Zimmer, III, M.D.
Medical Director
Diagnostic Imaging

470392

CML

NRC FORM 313A (10-2002)		U.S. NUCLEAR REGULATORY COMMISSION		APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2005	
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					

NRC FORM 313A (10-2002)		U.S. NUCLEAR REGULATORY COMMISSION			
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

NRC FORM 313A (10-2002)		U.S. NUCLEAR REGULATORY COMMISSION	
TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)			
PART II -- PRECEPTOR STATEMENT			
<p>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.</p> <p>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.</p>			
<input type="checkbox"/> YES <input type="checkbox"/> N/A	10. The individual named in item 1 has satisfactorily completed the training requirements in 10 CFR 35.980 and is competent to independently operate a nuclear pharmacy.		
<input type="checkbox"/> YES <input type="checkbox"/> N/A	11a. The individual named in Item 1 has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) _____		
<input type="checkbox"/> YES <input type="checkbox"/> N/A	11b. The individual named in Item 1. is competent to independently function as an authorized _____ for _____ uses (or units).		
12. PRECEPTOR APPROVAL AND CERTIFICATION			
<input type="checkbox"/> I certify the approval of item 10 and certify I am an Authorized Nuclear Pharmacist;			
OR			
<input type="checkbox"/> I certify the approval of items 11a and 11b, and certify I am an Authorized Nuclear Pharmacist;			
OR			
<input type="checkbox"/> 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

JOEL ABRAHAM BRAKE MD 10779
Medical Doctor

Active Exp: 03/31/06

SIGNATURE: *Joel A. Brake*

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

Joel A. Brake

SIGNATURE

YOU MUST NOTIFY THIS AGENCY OF ANY CHANGES WITHIN 10 DAYS



Iowa Board of Medical Examiners

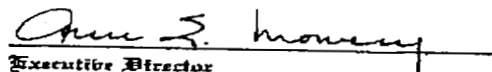
Hereby Authorizes And Licenses

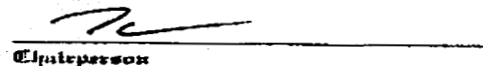
Joel Abraham Brake, M.D.

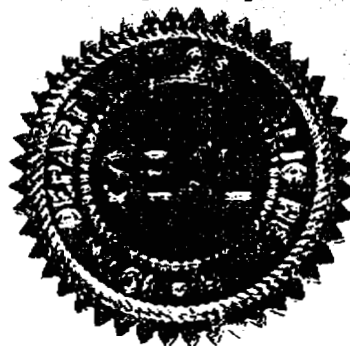
to practice Medicine and Surgery in the State of Iowa under and pursuant to the provisions of Chapter one hundred forty seven, Iowa Statutes Annotated and acts amendatory thereof and supplemental thereto.

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

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


Executive Director


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 Bruke, MD

*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, 2006

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

Diagnostic Radiology



Certificate No. 50350

W. H. H. H.
President

Philip O. Williams, MD
Secretary-Treasurer

P. R. H. H.
Executive Director



Valid through 2014

T-464 P.02/02 F-238

FROM-HISSOULA RADIOLOGY

AUG-22-05 15:38

08/30/2005 TUE 13:37 FAX

009/009

OCT 12 2005

DATE

This is to acknowledge the receipt of your letter/application dated 8/22/05, and to inform you that the initial processing, which includes an administrative review, has been performed.

☒ There were no administrative omissions. Your application will be assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card:

The action you requested is normally processed within 90 days.

☐ A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 470692.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,

Colleen Murnahan

Licensing Assistant

(FOR LIMS USE)
 INFORMATION FROM LTS

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Program Code: 02120
Status Code: 0
Fee Category: 7C
Exp. Date: 20130531
Fee Comments: CODE 23
Decom Flt Assur Req'd: N
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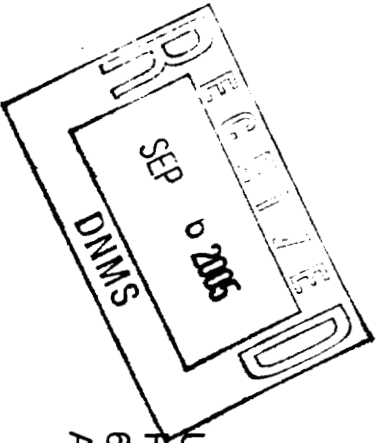
.....
Program Code: 02120
Status Code: 0
Fee Category: 7C
Exp. Date: 20130531
Fee Comments: CODE 23
Decom Flt Assur Req'd: N
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2827 Fort Missoula Road
Missoula, MT 59804

Nuclear Medicine



US Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Dr., Suite 400
Arlington, Texas 76011-8064

76011#8064

