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DICKINSON
COUNTY
HEALTHCARE
SYSTEM

May 28, 2010

Nuclear Materials Licensing Branch
Nuclear Regulatory Commission Region III
2443 Warrenville Road Suite 210
Lisle, IL 60532-4352

Re: Materials License No. 21-18889-01

This letter is to request the addition of Joann M. Leahy, M.D. as authorized user on our materials license for 35. Part 400 brachytherapy. Enclosed are copies of her ABR certification, Michigan medical license, form 313A including preceptor attestation and license from North Dakota listing her for remote after loading devices.

This request has been approved by our Radiation Safety Committee and Administration.

If you have further questions, please contact Shan Marlette, Consultant Physicist at (906) 225-6967.

Sincerely,

Jeff Gussert - Director of Operations

John Schon
Administrator/CEO

1721 S. Stephenson
Iron Mountain
Michigan
49801

Phone
906/774-1313

RECEIVED JUN 0 8 2010

May 28, 2010

Nuclear Materials Licensing Branch
Nuclear Regulatory Commission Region III
2443 Warrenville Road Suite 210
Lisle, IL 60532-4352

Re: Materials License No. 21-18889-01

I would like to point out an error in the numbering of our amendments. I believe there was a printer problem on amendment # 24 as the 4 was hand written on our copy. It appears the computer might have that listed as # 2 since the next amendment was numbered #3, but should have been 25. So this request should be 26, I think.

If you have further questions, please contact me at (906) 225-6967.

Sincerely,

Shan Marlette

Shan Marlette, Consultant Physicist

NRC FORM 313A (AUS)
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.400 and 35.600)
[10 CFR 35.490, 35.491, and 35.690]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized User	State or Territory Where Licensed
Joann M. Leahy, M.D.	Michigan

Requested Authorization(s) (check all that apply)

- [x] 35.400 Manual brachytherapy sources
- [ ] 35.400 Ophthalmic use of strontium-90
- [ ] 35.600 Remote afterloader unit(s)
- [ ] 35.600 Teletherapy unit(s)
- [ ] 35.600 Gamma stereotactic radiosurgery unit(s)

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

[ ] **1. Board Certification**

a. Provide a copy of the board certification.

b. For 35.600, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.

c. Skip to and complete Part II Preceptor Attestation.

[ ] **2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above**

a. Go to the table in section 3.e. to document training for new device.

b. Skip to and complete Part II Preceptor Attestation.

[x] **3. Training and Experience for Proposed Authorized User** + previous license

a. Classroom and Laboratory Training [ ] 35.490 [ ] 35.491 [ ] 35.690

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			
Total Hours of Training:			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work and Clinical Experience for 10 CFR 35.490 *(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)*

Supervised Work Experience		**Total Hours of Experience:**	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		☐ Yes ☐ No	
Checking survey meters for proper operation		☐ Yes ☐ No	
Preparing, implanting, and safely removing brachytherapy sources		☐ Yes ☐ No	
Maintaining running inventories of material on hand		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of byproduct material		☐ Yes ☐ No	
Using emergency procedures to control byproduct material		☐ Yes ☐ No	

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: ☐ Residency Review Committee for Radiation Oncology of the ACGME ☐ Royal College of Physicians and Surgeons of Canada ☐ Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. **Training and Experience for Proposed Authorized User (continued)**

c. Supervised Clinical Experience for 10 CFR 35.491

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			

Supervising Individual	License/Permit Number listing supervising individual as an Authorized User

d. Supervised Work and Clinical Experience for 10 CFR 35.690

☐ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

Supervised Work Experience		**Total Hours of Experience:**	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks		☐ Yes ☐ No	
Preparing treatment plans and calculating treatment doses and times		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of byproduct material		☐ Yes ☐ No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		☐ Yes ☐ No	
Checking and using survey meters		☐ Yes ☐ No	
Selecting the proper dose and how it is to be administered		☐ Yes ☐ No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: ☐ Residency Review Committee for Radiation Oncology of the ACGME ☐ Royal College of Physicians and Surgeons of Canada ☐ Committee on Postdoctoral Training of the American Osteopathic Association		

Supervising Individual	License/Permit Number listing supervising individual as an Authorized User

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation			
Safety procedures for the device use			
Clinical use of the device			

Supervising Individual. *If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)*	License/Permit Number listing supervising individual as an Authorized User

Authorized for the following types of use:

☐ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

f. Provide completed Part II Preceptor Attestation.

NRC FORM 313A (AUS)
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section
Check one of the following for each requested authorization:

For 35.490:

Board Certification

☒ I attest that Dr Joann M Leahy has satisfactorily completed the requirements in
Name of Proposed Authorized User

35.490(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

OR

Training and Experience

☑ I attest that Joann M. Leahy, M.D. has satisfactorily completed the 200 hours of
Name of Proposed Authorized User

classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

For 35.491:

☒ I attest that Dr Joann M Leahy has satisfactorily completed the 24 hours of
Name of Proposed Authorized User

classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 8 individuals, as required by 10 CFR 35.491(b), and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Second Section

For 35.690:

Board Certification

☒ I attest that Dr Joann M Leahy has satisfactorily completed the requirements in
Name of Proposed Authorized User

35.690(a)(1).

OR

Training and Experience

☑ I attest that Joann M. Leahy, M.D. has satisfactorily completed 200 hours of classroom
Name of Proposed Authorized User

and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

AND

NRC FORM 313A (AUS)
(9-2008)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

Third Section

For 35.690: (continued)

☒ I attest that Dr. Jon Leeb has received training required in 35.690(c) for device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

Name of Proposed Authorized User

☐ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section

☑ I attest that Dr Jon Leeb has achieved a level of competency sufficient to achieve a level of competency sufficient to function independently as an authorized user for:

Name of Proposed Authorized User

☐ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

Fifth Section

Complete the following for preceptor attestation and signature:

☑ I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:

☑ 35.400 Manual brachytherapy sources ☐ 35.600 Teletherapy unit(s)

☐ 35.400 Ophthalmic use of strontium-90 ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

☐ 35.600 Remote afterloader unit(s)

Name of Preceptor	Signature	Telephone Number	Date
Luther W. Brady, M.D.	Luther W. Brady MD	(215) 762-1998	05/28/2010

License/Permit Number/Facility Name

Dept. Rad Onc/Nuc. Med Hahnemann Univ Hospital Philadelphia Pa 19102

1874

Commonwealth of Pennsylvania Department of State
Bureau of Professional and Occupational Affairs
Medical Physician and Surgeon

License Number
MD004879E

Expiration Date
12/31/2010

Registration Code
G21 91 641

License Status
Active

LUTHER WELDON BRADY
226 W WASHINGTON SQUARE
PHILADELPHIA PA 19106

COPY COPY COPY

OFFICIAL DOCUMENT

READ THE FOLLOWING INFORMATION CAREFULLY CONCERNING YOUR LICENSE:

1. SIGN THE WALLET CARD AND CERTIFICATE WHERE INDICATED.
2. DETACH THE WALLET CARD AND CERTIFICATE AT PERFORATION.

LUTHER WELDON BRADY
226 W WASHINGTON SQUARE
PHILADELPHIA PA 19106

Registration Code

Your **registration code** is found on the attached wallet card.

Use this **registration code** online to: renew your license, change your personal or license address, or order duplicate licenses.

Visit our website at: www.mylicense.state.pa.us

First **time users** will be required to use this **registration code** to create a user ID and password.

DISPLAY THIS CERTIFICATE PROMINENTLY • NOTIFY AGENCY WITHIN 10 DAYS OF ANY CHANGE

08 0893868

Commonwealth of Pennsylvania
Department of State
Bureau of Professional and Occupational Affairs
PO Box 2649, Harrisburg PA 17105-2649

License Type
Medical Physician and Surgeon

License Status
Active

Initial License Date
06/21/1956

LUTHER WELDON BRADY
226 W WASHINGTON SQUARE
PHILADELPHIA PA 19106

License Number
MD004879E

Expiration Date
12/31/2010

Commissioner of Professional and Occupational Affairs

Signature

ALTERATION OF THIS DOCUMENT IS A CRIMINAL OFFENSE UNDER 18 PA.C.S.§ 4911

NORTH DAKOTA
DEPARTMENT of HEALTH

ENVIRONMENTAL HEALTH SECTION
Gold Seal Center, 918 E. Divide Ave.
Bismarck, ND 58501-1947
701.328.5200 (fax)
www.ndhealth.gov

NORTH DAKOTA DEPARTMENT OF HEALTH

RADIOACTIVE MATERIAL LICENSE

Pursuant to Section 23-20.1-01 through Section 23-20.1-11 of Chapter 23-20.1 of the North Dakota Century Code, and Article 33-10 of the North Dakota Administrative Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, possess, and use the radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders now or hereafter in effect of the North Dakota Department of Health and to any conditions specified below:

Licensee	
1. Name Bismarck Cancer Center	3. License Number 33-41919-01 is amended in its entirety Amendment No. 08
2. Address 500 North 8th Street Bismarck, ND 58506	4. Expiration Date January 31, 2014
	5. Reference Number 307

6. Radioactive Materials (element and mass number)	7. Chemical and/or physical form	8. Maximum quantity which licensee may possess at any one time
A. Iridium-192	A. Medical gamma Afterloading source (Nucletron Corporation Model 105.002)	A. One source not to exceed 444 gigabecquerels (12 curies) & one replacement source not to exceed 481 gigabecquerels (13 curies) stored for

decay to 444 gigabecquerels (12 curies) at facility. The replacement source may not be acquired until the original source has decayed sufficiently so that at no time may the aggregate of the two sources equal or exceed 800 giga-becquerels (21.6 curies).

---

9. Authorized Use:

A. For use in Nucletron Corporation Model 105.999 microSelectron-HDR remote afterloading brachytherapy unit for interstitial, intracavitary, interluminal and gynecological radiotherapy, and quality assurance measurements. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.

CONDITIONS

10. Licensed material may be used only at the licensee's facility stated in Item 2 above.

11. The licensee shall comply with the following chapters of the North Dakota Radiological Health Rules:

Chapter 33-10-01	General Provisions
Chapter 33-10-03	Licensing of Radioactive Material
Chapter 33-10-04.1	Standards for Protection Against Radiation
Chapter 33-10-07.1	Medical Use of Radioactive Material
Chapter 33-10-10	Notices, Instructions, and Reports to Workers - Inspections
Chapter 33-10-11	Fees for Issuance of License and Registration Certificates and Inspections

12. Radioactive material is only authorized for use by, or under the supervision of:

A. Individuals permitted to work as an authorized user or authorized medical physicist in accordance with North Dakota Radiological Health Rules Sections 33-10-07.1-09 ("License Amendments") or 33-10-07.1-10 ("Notifications").

B. The following individuals are authorized users for the following radioactive materials identified in Items 6-9:

Physician	Authorized For
Kathleen A. Nordstrom, M.D.	A
Shrikant S. Kubsad, Ph.D.	A
Joann M. Leahy, M.D.	A

C. The Authorized Medical Physicist and Radiation Safety Officer for this license is Shrikant S. Kubsad, Ph.D. The alternate Radiation Safety Officers are Kathleen A. Nordstrom, M.D and Joann M. Leahy, M.D.

13. Sealed sources or detector cells containing radioactive material shall not be opened or sources removed from source holders by the licensee.

14. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in North Dakota Radiological Health Rules Section 33-10-03-05, subsection 14, subdivision d for establishing financial assurance for decommissioning.

15. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission Pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

16. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in North Dakota Radiological Health Rules Section 33-10-07.1-15 ("Radiation Protection Program Changes"). The North Dakota Radiological Health Rules shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the North Dakota Radiological Health Rules.

A. Application dated November 11, 2003, as amended by

B. Letter dated June 2, 2004.

C. Letter dated October 4, 2004.

D. Letter dated November 29, 2005.

E. Amendment request dated April 24, 2007.

F. Amendment request dated June 15, 2007.

G. Amendment request dated June 6, 2008.

H. Application renewal date of April 14, 2009.

FOR THE NORTH DAKOTA DEAPRTMENT OF HEALTH

Date: 6/11/09

By: Terry O'Clair

Terry L. O'Clair, P.E., Director
Division of Air Quality

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,
and the Association of University Radiologists
Hereby certifies that

Joann M. Leahy, 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 seventh day of June, 1990
Thereby demonstrating to the satisfaction of the Board
that she is qualified to practice the specialty of

Radiation Oncology

THE AMERICAN BOARD OF RADIOLOGY INCORPORATED IN THE DISTRICT OF COLUMBIA 1934

AMERICAN BOARD OF MEDICAL SPECIALTIES EXCELLENCE 1970 SPIRITUS

Robert G. Parker
President

Secretary

M431230 001 R -001

CUT OUT FOR WALLET CARD

STATE OF MICHIGAN - DEPARTMENT OF COMMUNITY HEALTH

BOARD OF MEDICINE
PHYSICIAN
LICENSE

JOANN MARIE LEAHY MD
3367 GALLATIN DRIVE
BISMARCK ND 58504

PERMANENT I.D. NO.	EXPIRATION DATE	
4301064363	01/31/2011	2516499

COMPLAINT INFORMATION:

The issuance of this license should not be construed as a waiver, dismissal or acquiescense to any complaints or violations pending against the licensee, its agents or employees.

WALL CERTIFICATE INFORMATION:

If the box is checked, you may purchase a State of Michigan Official Wall Certificate. Please visit http://tbsddp.com/certificates or call 1-800-875-3676

X

FUTURE CONTACTS:

You should direct all inquires regarding this license or address changes to the:

DEPARTMENT OF COMMUNITY HEALTH

BOARD OF MEDICINE

P.O. BOX 30670
LANSING MI 48909-8170

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

REVERSE SIDE OF LICENSE CONTAINS IMPORTANT INFORMATION.

JENNIFER M. GRANHOLM
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH

L1662092

BOARD OF MEDICINE

PHYSICIAN
LICENSE

JOANN MARIE LEAHY MD

PERMANENT I.D. NO.	EXPIRATION DATE	
4301064363	01/31/2011	2516499

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN.

M531230 001 CS-001

CUT OUT FOR WALLET CARD

STATE OF MICHIGAN - DEPARTMENT OF COMMUNITY HEALTH

BOARD OF PHARMACY
CONTROLLED SUBSTANCE LICENSE

JOANN MARIE LEAHY
3367 GALLATIN DRIVE
BISMARCK ND 58504

PERMANENT I.D. NO.	EXPIRATION DATE	
5315043802	01/31/2011	2515825

COMPLAINT INFORMATION:

The issuance of this license should not be construed as a waiver, dismissal or acquiescense to any complaints or violations pending against the licensee, its agents or employees.

WALL CERTIFICATE INFORMATION:

If the box is checked, you may purchase a State of Michigan Official Wall Certificate. Please visit http://tbsddp.com/certificates or call

(NOT ELIGIBLE)

FUTURE CONTACTS:

You should direct all inquires regarding this license or address changes to the:

DEPARTMENT OF COMMUNITY HEALTH

BOARD OF
PHARMACY

P.O. BOX 30670
LANSING MI 48909-8170

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

REVERSE SIDE OF LICENSE CONTAINS IMPORTANT INFORMATION.

JENNIFER M. GRANHOLM
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH

L1662093

BOARD OF PHARMACY
CONTROLLED SUBSTANCE LICENSE

*THIS LICENSE VALID ONLY IF PROFESSIONAL LICENSE IS ACTIVE

JOANN MARIE LEAHY

PERMANENT I.D. NO.	EXPIRATION DATE	
5315043802	01/31/2011	2515825

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN.

Smarlette, K Se
Radiology
MGH
420 W Magnetic
Marquette MI 49855

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06/04/2010
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011D11607527

Nuclear Materials Licensing Branch
Nuclear Regulatory Commission Region III
2443 Warrenville Road Suite 210
Lisle IL 60543-4352