

February 8, 2010

U.S. Nuclear Regulatory Commission
Region III
Attn: Materials Licensing
2443 Warrenville Rd., Suite 210
Lisle, IL 60532-4352

RE: NRC License #21-00943-03 – New Authorized User

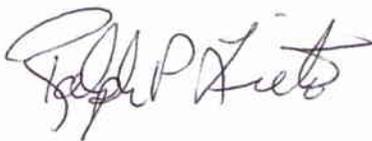
To Whom It May Concern:

We request to amend our NRC License No. 21-00943-03 to add Sirisha Nandalur, MD as an authorized user (AU) in accordance with 10 CFR 35.940 and 35.960. We request that this evaluation be completed as soon as possible.

Based on her training and experience, we seek authorization for Dr. Nandalur to perform all duties of an AU for 10 CFR Parts 35.400 and 35.600 (except for gamma stereotactic radiosurgery units, i.e., "gamma knife"). Dr. Nandalur has successfully completed her Radiation Oncology residency and is seeking approval in accordance with the "alternate pathway" of 10 CFR 35.940 and 35.960. NRC Form 313A documenting the relevant training and experience and preceptor affirmation is enclosed. Her credentials have been reviewed and approved by Management and the Radiation Safety Committee of the St. Joseph Mercy Health System in January 2010.

If you should have any questions or require further information, please contact the Radiation Safety Office.

Sincerely,



Ralph P. Lieto, MSE
Radiation Safety Officer



Kathy Kasperek-Korelis
Program Director, Radiation Oncology
Management Representative,
Radiation Safety Committee

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**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

Sirisha Nandalur, MD

Michigan

Requested

35.400 Manual brachytherapy sources 35.600 Teletherapy unit(s)

Authorization(s)

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

(check all that apply)

35.600 Remote afterloader 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**

- Provide a copy of the board certification.
- 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.
- Skip to and complete Part II Preceptor Attestation.

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

- Go to the table in section 3.e. to document training for new device.
- Skip to and complete Part II Preceptor Attestation.

3. **Training and Experience for Proposed Authorized User**

- 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	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	80	9/2005-5/2008
Radiation protection	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	20	9/2005-5/2008
Mathematics pertaining to the use and measurement of radioactivity	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	20	9/2005-5/2008
Radiation biology	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	384	9/2005-5/2008

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: 540 hours	
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	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/2005-5/2008
Checking survey meters for proper operation	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/2005-5/2008
Preparing, implanting, and safely removing brachytherapy sources	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2005-6/2009
Maintaining running inventories of material on hand	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/2005-5/2008
Using administrative controls to prevent a medical event involving the use of byproduct material	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2005-6/2009
Using emergency procedures to control byproduct material	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2005-6/2009

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: <input checked="" type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	7/2005-6/2009

Supervising Individual Inga Grills, MD	License/Permit Number listing supervising individual as an Authorized User 21-01333-01
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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)

Not approved
[Signature]

Supervised Work Experience

Total Hours of Experience: **540 hours**

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	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/2005-5/2008
Preparing treatment plans and calculating treatment doses and times	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2005-6/2009
Using administrative controls to prevent a medical event involving the use of byproduct material	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2005-6/2009
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2005-6/2009
Checking and using survey meters	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2005-6/2009
Selecting the proper dose and how it is to be administered	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2005-6/2009

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: <input checked="" type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association	William Beaumont Hospital 3601 W. 13 Mile Royal Oak, MI 48073	7/2005-6/2009
Supervising Individual Inga Grills, MD		License/Permit Number listing supervising individual as an Authorized User 21-01333-01

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	7/05-6/2009		1/2008-6/2009
Safety procedures for the device use	7/05-6/2009		1/2008-6/2009
Clinical use of the device	7/05-6/2009		1/2008-6/2009
Supervising Individual. <i>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.)</i> Inga Grills, MD		License/Permit Number listing supervising individual as an Authorized User 21-01333-01	
Authorized for the following types of use: <input checked="" type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input checked="" type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

Not approved

f. Provide completed Part II Preceptor Attestation.

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 _____ 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 Sirisha Nandalur, MD 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 _____ 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 5 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 _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

35.690(a)(1).

OR

Training and Experience

I attest that Sirisha Nandalur, MD 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

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

Third Section

For 35.690; (continued)

I attest that Sirisha Nandalur, MD has received training required in 35.690(c) for device
Name of Proposed Authorized User
operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

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

Not approved

AND

Fourth Section

I attest that Sirisha Nandalur, MD has achieved a level of competency sufficient to
Name of Proposed Authorized User
achieve a level of competency sufficient to function independently as an authorized user for:

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

Not approved

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)

Not approved

Inga Grills is an authorized Gamma Knife user

Name of Preceptor

Inga Grills, MD

Signature

Telephone Number

(248) 551-7032

Date

12/9/09

License/Permit Number/Facility Name

21-01333-01 / William Beaumont Hospital

Dr. Nandalur is not approved for Gamma knife radiosurgery.

William Beaumont Hospital

Royal Oak, Michigan

This certifies that

Sirisha Reddy Nandalur, M.D.

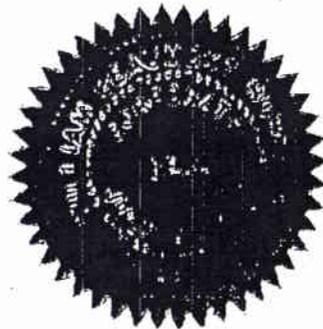
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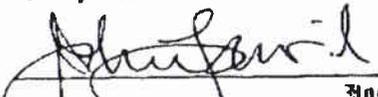
Resident in Radiation Oncology

from July 1, 2005 thru June 30, 2009


Chairman, Board of Directors

Program Director




Hospital Director

Chief Medical Officer

CERTIFIED MAIL™

St. Joseph Mercy Hospital
Radiation Safety Office
5301 E. Huron River Dr.
Ann Arbor, MI 48106-0995
CC#16090



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