BRIDGEPORT HOSPITAL
YALE NEW HAVEN HEALTH

Br. 1

NRC License No.: 06-01060-01
Docket No.: 030-01247

May 30, 2013

U.S. Nuclear Regulatory Commission, Region 1
United States Nuclear Regulatory Commission Region 1
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406

RE: Bridgeport Hospital Amendment Request to Add a New Authorized User to License No.: 06-01060-01.

03001247

Gentlemen & Women of the NRC:

Bridgeport Hospital would like to amend its license to add Terence W. Hughes, M.D. as an Authorized User for Y-90 SirSpheres, under the NRC June 2012 training and experience guidance (A.3. & B.) on Microsphere Brachytherapy Sources and Devices (ML12179A353).

Attached to this letter you will find a completed preceptor statement signed by Dr. Scott Williams, who is an Authorized User for Y-90 SirSpheres under the Bridgeport Hospital license and copies of Dr. Hughes ABR Certifications in Vascular and Interventional Radiology (2012) and in Diagnostic Radiology (2000).

If you have any further questions, please feel free to contact Mr. Bohan at (203) 688-2950, or mike.bohan@yale.edu.

Regards,

Michael R. Tatta

Michael R. Tatta
Director, Imaging, Laboratory & Radiation Oncology

267 Grant Street
P.O. Box 5000
Bridgeport, CT 06610-0120
203.384.3000

REC'D IN LAT 6/7/13

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NMSS/RGN1 MATERIALS-002

Attachments: Preceptor Statement for Dr. Hughes
Dr. Hughes ABR Certificate VIR (2012)
Dr. Hughes ABR Certificate DR (2000)

NRC FORM 313A (AUT) (05-2012) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (05/31/2015)

Name of Proposed Authorized User	State or Territory Where Licensed
Terence W. Hughes, M.D.	Connecticut

Requested Authorization(s) *(check all that apply)*:

☐ 35.300 Use of unsealed byproduct material for which a written directive is required

OR

☐ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ 35.300 Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ 35.300 Parenteral administration of any other radionuclide for which a written directive is required

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 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 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.

c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.

d. Skip to and complete Part II Preceptor Attestation.

☐ 2. **Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**

a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements *(check all that apply)*:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.490 ☐ 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

a. Classroom and Laboratory Training ☐ 35.390 ☐ 35.392 ☐ 35.394 ☑ 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Bridgeport Hospital, 267 Grant Street, Bridgeport, CT 06610, NRC Lic.: 06-01060-01	20	May 2011 - May 2013
Radiation protection	Same as above	20	May 2011 - May 2013
Mathematics pertaining to the use and measurement of radioactivity	Same as above	20	May 2011 - May 2013
Chemistry of byproduct material for medical use	Same as above	20	May 2011 - May 2013
Radiation biology	Same as above	20	May 2011 - May 2013
	Total Hours of Training: 100		

b. Supervised Work Experience ☐ 35.390 ☐ 35.392 ☐ 35.394 ☑ 35.396

If more than one supervising individual is necessary to document supervised training, 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	Bridgeport Hospital, 267 Grant Street, Bridgeport, CT 06610, NRC Lic.: 06-01060-01	☑ Yes ☐ No	May 2011 - May 2013
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Same as above	☑ Yes ☐ No	May 2011 - May 2013
Calculating, measuring, and safely preparing patient or human research subject dosages	Same as above	☑ Yes ☐ No	May 2011 - May 2013
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Same as above	☑ Yes ☐ No	May 2011 - May 2013
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Same as above	☑ Yes ☐ No	May 2011 - May 2013

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Scott Williams, M.D.	06-01060-01

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☑ 35.390
☑ 35.392
☑ 35.394
☑ 35.396

With experience administering dosages of:

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
☐ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience
If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required	> 15 Cases Y-90 SirSpheres	Bridgeport Hospital, 267 Grant Street, Bridgeport, CT 06610, NRC Lic.: 06-01060-01	May 2011 - May 2013
Parenteral administration of any other radionuclide for which a written directive is required (List radionuclides)			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Scott Williams, M.D.	06-01060-01

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☑ 35.390	With experience administering dosages of:
☑ 35.392	☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
☑ 35.394	☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
☑ 35.396	☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
	☐ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

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 35.390:

Board Certification

☑ I attest that Terence W. Hughes, M.D. (Name of Proposed Authorized User) has satisfactorily completed the training and experience requirements in 35.390(a)(1).

OR

Training and Experience

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

For 35.394 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

Second Section

☑ I attest that Terence W. Hughes, M.D. has satisfactorily completed the required clinical case
Name of Proposed Authorized User

experience required in 35.390(b)(1)(ii)G listed below:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Third Section

☑ I attest that Terence W. Hughes, M.D. has satisfactorily achieved a level of competency to
Name of Proposed Authorized User

function independently as an authorized user for:

☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

NRC FORM 313A (AUT)
(05-2012)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☐ I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

☑ I attest that Terence W. Hughes, M.D. has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☑ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

Fifth Section

Complete the following for preceptor attestation and signature:

☑ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☑ 35.390 ☑ 35.392 ☑ 35.394 ☑ 35.396

☑ I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☐ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date
Scott Williams, M.D.	[signature] MD	203-384-3739	5/25/13

License/Permit Number/Facility Name

Bridgeport Hospital, 267 Grant Street, Bridgeport, CT 06610, NRC Lic.: 06-01060-01

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 Radiation Oncology, the Association of
University Radiologists, and the American Association of Physicists in Medicine,
the American Board of Radiology declares that

Terence William Hughes, MD

has fulfilled the requirements of this Board's Maintenance of Certification
Program and is certified as a diplomate of the American Board of Radiology in

Vascular and Interventional Radiology

a Subspecialty of

Diagnostic Radiology

Ongoing validity of this certificate is contingent upon
meeting the requirements of Maintenance of Certification.

This diplomate of the American Board of Radiology
is permitted to use the **DABR** *mark to signify this certification.*

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

President

Secretary-Treasurer

Executive Director

DABR

AMERICAN BOARD 1933 OF MEDICAL SPECIALTIES EXCELLENCE

Certificate No. 46321

Effective December 28, 2012

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 Physicists in Medicine
Hereby certifies that

Terence William Hughes, 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 seventeenth day of May, 2000
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology

R.P. Hattery, MD
President

Steven A. Kirkel, M.D.
Secretary-Treasurer

Executive Director

Certificate No. 46321

This is to acknowledge the receipt of your letter/application dated 3/30/13, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (06-01060-01)

[X] There were no administrative omissions. Your application was 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

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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** 581063.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader