



January 10, 2018

Dr. l

Ms. Penny Lanzisera
Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

REC RG 10119 18 AM 0709

Licensee: Danbury Hospital, #06-085440-1 /03001274

Dear Ms. Lanzisera,

Enclosed please find a letter from Sirtex confirming the completion of three proctored cases using Yttrium-90 SIR-Spheres by Dr. Joseph Santoro.

Please add Drs. Folashade Ajegba, M.D. and Kim Clarkin, M.D. as Authorized Users for Iodine-125 Sealed Sources for Localization of Non-Palpable Lesions. Enclosed are letters attesting that they have completed three proctored cases under the guidance of Drs. Anna Mah and Donald Hulnick, both of whom are Authorized Users for Iodine-125 Sealed Sources for Localization of Non-Palpable Lesions. Drs. Ajegba and Clarkin are listed as Authorized Users for 35.100 and 35.200 on our current NRC license.

Please add Dr. Allison Rubin as an Authorized User for 35.100 and 35.200. Enclosed is her Board Certificate and Form 313A (AUD).

Please add Dr. Joseph Bargellini as an Authorized User for uses permitted by 35.300, 35.400, and Iridium-192 for uses in a High Dose Rate Remote Afterloader Unit. Dr. Bargellini is listed on the NRC license for New Milford Hospital as an Authorized User for the above.

Please remove Dr. Barbara Blanco from our license as she is no longer with the institution.
Thank you,

Sharon Adams, RN, BSN, MA, MSHCA
Chief Operating Officer and Chief Nursing Officer
Western Connecticut Health Network

Vladimir Monastyrenko
Vladimir Monastyrenko, Ph.D.
Radiation Safety Officer
Danbury Hospital
203-739-7904

Ruth Shanley
Ruth Shanley, MS, RT (R), RDMS
Radiation Safety Coordinator
Western Connecticut Health Network
203-739-7182 or 475-289-1277



SIRTEX MEDICAL INC.
300 Unicorn Park Drive
Woburn, MA 01801
Tel: +1 (781) 721 3800
Fax: +1 (781) 721 3880

Ref: 105US03

December 27, 2017

Joseph Santoro, M.D.
Danbury Hospital
24 Hospital Ave
Danbury, CT 06810

Dear Dr. Santoro,

Re: SIR-Spheres® Yttrium-90 Resin Microspheres Training, Evaluation, Certification (TEC) Program

I am writing to confirm that on November 9, 2017, Dr. Joshua Weintraub presented and discussed the preparation of and procedures associated with SIR-Spheres yttrium-90 (Y-90) resin microspheres that are injected via the hepatic artery to treat patients with unresectable liver tumors. I am pleased to inform you that Dr. Weintraub considers that you and your staff are trained in the preparation and clinical aspects of treating patients with SIR-Spheres Y-90 resin microspheres.

This letter also certifies that you were proctored by a Sirtex certified proctor in the use of SIR-Spheres Y-90 resin microspheres on the following dates: May 2, 2017 (administration); May 19, 2017 (mapping); June 7, 2017 (Administration) and November 9th, 2017 (Administration).

I would like to thank you and your team for your support and commitment to the Sirtex **Training, Evaluation, Certification (TEC)** Program.

Yours sincerely,

David N. Cade, M.D.
Chief Medical Officer
Sirtex Medical, Inc.

cc: George Cross
Ashley Cockerham
TEC@sirtex.com

DANBURY HOSPITAL

24 Hospital Ave
Danbury, CT 06810
203.739.7000
DanburyHospital.org

December 22, 2017

Licensee: Danbury Hospital

License Number: 06-08544-01

Requested Authorization: Folashade Ajegba, M.D., currently Authorized User for 35.100 and 35.200, seeking to add Iodine-125 Sealed Sources for Localization of Non-Palpable Lesions

State where licensed: Connecticut

Preceptor Attestation:

This is to attest that I have precepted Dr. Folashade Ajegba in the use of radioactive breast seed localization. I directly supervised her on three cases between October 26 and November 13, 2017, and attest that she has received the training required for safety procedures and clinical use for Iodine-125 Sealed Sources for Localization of Non-Palpable Lesions.

Work experience and training included:

- Work experience including 3 cases where the authorized user ordered, received and unpacked radioactive material safely;
- Work experience that included performing the related radiation surveys using appropriate instrumentation;
- Work experience that included implanting preloaded RSL sources safely, to include the use of appropriate remote handling tools to manipulate seeds and the proper use of shielding devices on the localization needle;
- Work experience that included routine monitoring before, during and after all uses of seeds to ensure rapid identification and remediation of a broken or leaking source;

- Work experience that included instruction in emergency procedures, such as procedures regarding broken or leaking seeds;
- Work experience that included reviewing and understanding the administrative controls in place to prevent a medical event; and
- Work experience in maintaining running inventories of radioactive material on hand.

Radiologists do not remove RSL devices at Danbury Hospital.

Policies and procedures for the use of I-125 for localization of non-palpable lesions have not changed since the time of her proctored cases.


I also attest that Dr. Folashade Ajegba has achieved a level of competency sufficient to function independently as an Authorized User for Iodine-125 Sealed Sources for Localization of Non-Palpable Lesions.

I meet the NRC requirements as an Authorized User for Iodine-125 Sealed Sources for Localization of Non-Palpable Lesions.

Name of Preceptor: Dr. Donald Hulnick

Phone: 203-739-7938

Signature:



Date: 12/26/17

Licensee: 06-98544-01, Danbury Hospital

December 18, 2017

Licensee: Danbury Hospital
License Number: 06-08544-01

Requested Authorization: Kim Clarkin, M.D., currently Authorized User for 35.100 and 35.200, seeking to add Iodine-125 Sealed Sources for Localization of Non-Palpable Lesions

State where licensed: Connecticut

Preceptor Attestation:

This is to attest that I have precepted Dr. Kim Clarkin in the use of radioactive breast seed localization. I directly supervised her on three cases between October 5 and October 23, 2017, and attest that she has received the training required for safety procedures and clinical use for Iodine-125 Sealed Sources for Localization of Non-Palpable Lesions.

Work experience and training included:

- Work experience including 3 cases where the authorized user ordered, received and unpacked radioactive material safely;
- Work experience that included performing the related radiation surveys using appropriate instrumentation;
- Work experience that included implanting preloaded RSL sources safely, to include the use of appropriate remote handling tools to manipulate seeds and the proper use of shielding devices on the localization needle;
- Work experience that included routine monitoring before, during and after all uses of seeds to ensure rapid identification and remediation of a broken or leaking source;
- Work experience that included instruction in emergency procedures, such as procedures regarding broken or leaking seeds;



**Danbury
Hospital**

Western Connecticut
Health Network

- Work experience that included reviewing and understanding the administrative controls in place to prevent a medical event; and
- Work experience in maintaining running inventories of radioactive material on hand.

Radiologists do not remove RSL devices at Danbury Hospital.

Policies and procedures for the use of I-125 for localization of non-palpable lesions have not changed since the time of her proctored cases.

I also attest that Dr. Kim Clarkin has achieved a level of competency sufficient to function independently as an Authorized User for Iodine-125 Sealed Sources for Localization of Non-Palpable Lesions.

I meet the NRC requirements as an Authorized User for Iodine-125 Sealed Sources for Localization of Non-Palpable Lesions.

Name of Preceptor: Dr. Anna Mah
7938

Phone: 203-739-

Signature:

A handwritten signature in black ink, appearing to be 'AMC'.

Date:

12/20/17

Licensee: 06-98544-01, Danbury Hospital



**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.190, 35.290, and 35.590]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 06/30/2019

Name of Proposed Authorized User <i>Allison Rabin, M.D.</i>	State or Territory Where Licensed <i>CT</i>
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Requested Authorization(s) (check all that apply)

35.100 Uptake, dilution, and excretion studies

35.200 Imaging and localization studies

35.500 Sealed sources for diagnosis (specify device) _____

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. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.
- 2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**
- a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.
 - b. Supervised Work Experience.
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			

Total Hours of Experience:

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
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Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

- 35.290 35.390 + generator experience in 32.290(c)(1)(ii)(G)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

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			
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Supervising Individual	License/Permit Number listing supervising individual as an authorized user		
Supervisor meets the requirements below, or equivalent Agreement State requirements (<i>check one</i>).			
<input type="checkbox"/> 35.190 <input type="checkbox"/> 35.290 <input type="checkbox"/> 35.390 <input type="checkbox"/> 35.390 + generator experience in 35.290(c)(1)(ii)(G)			

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete 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. (Not required to meet training requirements in 35.590)

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 use requested:

For 35.190

Board Certification

I attest that Allison Rubin, M.D. has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

I attest that Allison Rubin, M.D. has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section

Complete the following for preceptor attestation and signature:

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

- 35.190 35.290 35.390 35.390 + generator experience

Name of Preceptor Todd Everett, M.D.	Signature 	Telephone Number (203) 739-7532	Date 01/10/2018
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License/Permit Number/Facility Name
Danbury Hospital #06-08544-01

ABR

AMERICAN
BOARD OF
RADIOLOGY

Diagnostic Radiology
ABR ID: [REDACTED]

November 17, 2017

Allison Nicole Rubin, MD
[REDACTED]

Dear Dr. Rubin:

I am pleased to inform you that you passed the Diagnostic Radiology Certifying Examination held on October 20 - 21, 2017. The American Board of Radiology hereby grants you certification in Diagnostic Radiology.

In addition, because you completed the appropriate training for Authorized User eligibility and passed the NRC-related portions of the Core and Certifying examinations, you will receive the Authorized User-Eligible (AU-E) designation on your certificate. You may apply to the NRC for Authorized User (AU) status; information and forms are available on the NRC website.

All new diplomates are enrolled in Continuous Certification, a process that links the ongoing validity of certificates to meeting the requirements of Maintenance of Certification (MOC). Certificates no longer have "valid-through" dates, but instead have the date of initial certification accompanied by the statement that "ongoing validity of this certificate is contingent upon meeting the requirements of Maintenance of Certification." Further information regarding the MOC process will be provided to you in a separate communication.

You may now use the ABR's registered certification mark, DABR® (Diplomate, American Board of Radiology), following your name and degree. More information can be found on the policies page of the ABR website www.theabr.org.

Our printer will send your certificate to the above address in approximately three months. If you have an address change, you must update your address using the myABR portal by December 1, 2017. Your name will appear on the certificate as it is shown above. If you wish to have your name displayed differently on your certificate, please email information@theabr.org with your requested change and supporting documentation by December 1, 2017. Please be sure to title the email "Certificate Name Change."

Your name and demographic information also will be included in a directory published by the American Board of Medical Specialties. It is your responsibility to notify other local, state, or national organizations of your certification.

Personally, and on behalf of the Boards of Governors and Trustees of the American Board of Radiology, I wish to congratulate you for this distinguished achievement.

Sincerely,

Valerie P. Jackson, MD
Executive Director



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee Danbury Hospital ATTN: Sharon Adams, RN, BSN, MA, MSHCA, Chief Operating Officer & Chief Nursing Officer 24 Hospital Avenue Danbury, CT 06810	Date January 25, 2018
	License Number(s) 06-31293-01
	Mail Control Number(s) 602243
	Licensing and/or Technical Reviewer or Branch Medical Branch

This is to acknowledge receipt of your: Letter and/or Application Dated: 01/10/2018

The initial processing, which included an administrative review, has been performed.
 Amendment Termination New License Renewal

There were no administrative omissions identified during our initial review.

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
 Follow the instructions on the form for submission.

The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
 U. S. Nuclear Regulatory Commission
 Division of Nuclear Materials Safety
 2100 Renaissance Boulevard, Suite 100
 King of Prussia, PA 19406-2713
 (610) 337-5260, (610) 337-5313,
 (610) 337-5398, or (610) 337-5239