BRONSON Methodist Hospital

May 31, 2016

US NRC Region III
2443 Warrenville Rd, Suite 210
Lisle, Il 60532-4352
Attn: Materials Licensing

RE: Add AU for 10 CFR 35.1000, limited to Yttrium-90 as Sir-Spheres.

We request **an expedited review** to add Dr. Kevin K Hannawa, MD to our Radioactive Material license #21-13125-01 for 10 CFR 35.1000, limited to Yttrium-90 as Sir-Spheres. Dr. Hannawa meets the training and experience guidelines of:

- Three years supervised clinical experience in diagnostic radiology and one additional year of supervised clinical experience in interventional radiology, and;
- Has over 80 hours of classroom and laboratory training for byproduct material, including Y-90 microspheres, which may be concurrent with training received in accordance with
    - Radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity; radiation biology, and;
- Has work experience under the supervision of AU for Y-90 microspheres or training provided by a Y-90 microsphere manufacturer representative involving:
    - Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys; performing qc procedures on instruments used to determine the activity of Y90 microspheres and performing checks for proper operation of survey meters; Evaluation of each patient or human research subject for the dose and activity of Y90 microspheres to be admin to each treatment site; calculating and measuring the activity and safely preparing the Y90 microspheres to be delivered to the patient or human research subject; using administrative controls to prevent a medical event involving the use of byproduct material; using procedures to control and contain spilled byproduct material; including Y-90microspheres, safely and using proper decontamination procedures. These procedures address any special circumstance that may be encountered, such as electrostatic charge of microspheres and proper survey instruments and survey techniques for Y90 microspheres, and;
- Has successfully completed training in the operation of the delivery system, safety procedures, and clinical use for Sir-Spheres, Y-90 by the Y-90 Sir-Sphere manufacturer, with at least three supervised hands-on in-vitro simulated cases for Sir-Sphere.

We have attached all paperwork & documentation. Following the license amendment we agree this individual will have Y-90 Sir-sphere hands on supervised in the physical presence of the Sir-Sphere manufacturer for the first three cases. We will submit documentation from the manufacturer within 30 days of when these three patient cases have been satisfactorily completed. Please email me with any concerns to help expedite the amendment approval. Please note form 313Aaud used in addition to required .

Thank you,

Laura T. Smith, MS, DABR
lsphysics@att.net
Radiation Safety Officer
Bronson Methodist Hospital

601 John Street
Kalamazoo, MI 49007
269.341.7654
bronsonhealth.com

DEPARTMENT OF RADIOLOGY
UNIVERSITY OF MICHIGAN HEALTH SYSTEM

Department of Radiology
University Hospital BID502C
1500 East Medical Center Drive
Ann Arbor, Michigan 48109-0030
(734) 936-8869 phone (734) 763-9523 fax
E-mail: jbailey@umich.edu
Janet E. Bailey, M.D.
Program Director, Radiology Residency
Professor of Radiology

May 10, 2016

RE: KEVIN HANNAWA, M.D.

To Whom It May Concern:

I am writing this letter on behalf of Kevin Hannawa, M.D. to confirm nuclear medicine training during his residency at the University of Michigan Health System.

Dr. Hannawa was a resident in Diagnostic Radiology at the University of Michigan from July 1, 2009 through September 30, 2014. During his training, Dr. Hannawa completed six months of training in nuclear radiology. His training included 16 weeks of clinical rotations in adult nuclear medicine, nuclear cardiology, pediatric nuclear medicine, and a camera-pharmacy rotation, in all over 800 hours of clinical experience.

During his time on the nuclear medicine service, Dr. Hannawa was responsible for interpreting over a wide variety of studies with attending physician supervision, including bone scans, ventilation perfusion scans, HIDA scans, thyroid scans, liver/spleen scans, peptide and antibody scans for cancer diagnosis, FDG PET scans, and myocardial perfusion studies (using Tc-99mMIBI or thallium), and a minimum of three cases of I-131 thyroid therapies. Direct participation in cardiac stress testing related to the myocardial perfusion studies and participation in the thyroid disease/therapy clinic was also included in the training. In addition, he had extensive exposure to radiopharmacy and related radiopharmaceutical quality control, as a specific clinical assignment

Dr. Hannawa's training in nuclear medicine also included night and weekend on-call assignments (a total of five weeks) the last part of the first year of training and the first part of the second year of his residency. Training was also supplemented by over 76 hours of didactic lectures given by nuclear medicine faculty and 35 hours of lectures in nuclear radiology physics and radiation biology given by physicists.

If you have any further questions regarding Dr. Hannawa's qualifications with respect to his nuclear medicine training, please do not hesitate to contact me.

Sincerely,

Janet E. Bailey, M.D.
Program Director, Radiology Residency Training Program

DEPARTMENT OF RADIOLOGY

Department of Radiology
University Hospital/B1D502
1500 East Medical Center Drive
Ann Arbor, Michigan 48109
(734) 647-4144 phone
(734) 763-9523 fax

April 26, 2016

RE: Kevin Hannawa, MD

To Whom It May Concern:

This letter will serve as verification that Kevin Hannawa completed one year of supervised clinical experience in the Vascular Interventional Radiology Fellowship Program at the University of Michigan Health System.

Please feel free to contact me with any questions or for further information.

Sincerely,

Bill Majdalany, MD
VIR Fellowship Director

DEPARTMENT OF RADIOLOGY

Department of Radiology
University Hospital/B1D502
1500 East Medical Center Drive
Ann Arbor, Michigan 48109
(734) 647-4144 phone
(734) 763-9523 fax

April 26, 2016

RE: Kevin Hannawa, MD

To Whom It May Concern:

This letter will serve as verification that Kevin Hannawa completed four years of supervised clinical experience in the Diagnostic Radiology Residency Program at the University of Michigan Health System.

Please feel free to contact me with any questions or for further information.

Sincerely,

Janet Bailey, MD
Residency Program Director

SIRTeX

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

Ref: 1040S07

April 27, 2016

Kevin Hannawa, M.D.
Interventional Radiology
Bronson Methodist Hospital
601 John Street.
Kalamazoo, MI 49007

Dear Dr. Hannawa,

Re: SIR-Spheres® Microspheres Authorized User Training and Certification

This letter certifies that on April 27, 2016, you successfully completed training in the operation of the delivery system, safety procedures and clinical use of SIR-Spheres yttrium-90 microspheres that are to be injected via the hepatic artery to treat patients with unresectable liver tumors in accordance with the June 2012 NRC guidance. This training included three (3) supervised hands-on *in-vitro* simulated set-up and delivery procedures as well as encompassing the following:

a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
b) Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters;
c) Evaluation of each patient for the dose/activity of Y-90 microspheres to be administered to each treatment site;
d) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient;
e) Using administrative controls to prevent a medical event involving the use of by-product material;
f) Using procedures to control and to contain spilled by-product material, including Y-90 microspheres, safely and using proper decontamination procedures; and
g) Follow up and review of each patient's case history for Y-90 microspheres

Once your license has been appropriately amended, Sirtex will arrange with you to have a proctor oversee your first three (3) patient treatments at a minimum, including being on site for each case.

® SIR-Spheres is a Registered Trademark of Sirtex SIR-Spheres Pty Ltd

Sirtex would like to thank you for your support in this process.

Yours sincerely.

Joe Dugan
Regional Sales Manager

cc: Derek Webster
Area Sales Manager

NRC FORM 313A (AUD) (06-2016) U.S. NUCLEAR REGULATORY COMMISSION

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: 06/30/2016

Name of Proposed Authorized User	State or Territory Where Licensed
Kevin Hannawa, MD	Michigan

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

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)

NRC FORM 313A (AUD) (08-2016) U.S. NUCLEAR REGULATORY COMMISSION

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	University of Michigan	20[illegible]	July 1, 2009 thru Sept 30, 2014
Radiation protection	University of Michigan	20	July 1, 2009 thru Sept 30, 2014
Mathematics pertaining to the use and measurement of radioactivity	University of Michigan	15	July 1, 2009 thru Sept 30, 2014
Chemistry of byproduct material for medical use *(not required for 35.590)*	University of Michigan	10	July 1, 2009 thru Sept 30, 2014
Radiation biology	University of Michigan	11	July 1, 2009 thru Sept 30, 2014
Total Hours of Training: 80			

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 YES **Total Hours of Experience:** 31

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	University of Michigan	☑ Yes ☐ No	July 1, 2009 thru Sept 30, 2014
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	University of Michigan	☑ Yes ☐ No	July 1, 2009 thru Sept 30, 2014

NRC FORM 313A (AUD) (06-2016) U.S. NUCLEAR REGULATORY COMMISSION

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	University of Michigan	☑ Yes ☐ No	July 1, 2009 thru Sept 30, 2014
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University of Michigan	☑ Yes ☐ No	July 1, 2009 - Sept 30, 2014
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University of Michigan	☑ Yes ☐ No	July 1, 2009 - Sept 30, 2014
Administering dosages of radioactive drugs to patients or human research subjects	University of Michigan	☑ Yes ☐ No	July 1, 2009 - Sept 30, 2014
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	University of Michigan	☑ Yes ☐ No	July 1, 2009 - Sept 30, 2014

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Peter Miller	21-13125-01

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check one)*.

☐ 35.190 ☑ 35.290 ☐ 35.390 ☐ 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.

NRC FORM 313A (AUD)
(05-2016)

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. (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 Kevin Hannawa, MD 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 Kevin Hannawa, MD 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	Signature	Telephone Number	Date
Peter Miller, MD			5/12/16

License/Permit Number/Facility Name
Bronson Methodist Hospital - #21-13125-01

SIR-Spheres® Authorized User Checklist

Follow instructions
Insert text
Attach document

This checklist is provided for use by the Radiation Safety Officer and/or a physician to document training and experience for a physician seeking Authorized User status on a limited scope license for the medical use of SIR-Spheres® in accordance with the February 2016 U.S. Nuclear Regulatory Commission (NRC) licensing guidance. The checklist should be used as a guide and does not guarantee Authorized User approval for the medical use of SIR-Spheres®. Regulations may vary by state. Verify additional requirements with the local regulatory authority.

Date: 05/18/16 Name of physician: Kevin Hannawa, MD

Part A

Section A.1. Radiation Oncologist

For radiation oncologists, CHECK **one** of the following three options.

☐ Physician is an Authorized User for medical uses under 10 CFR 35.400, "Use of sources for manual brachytherapy," ATTACH COPY OF RADIOACTIVE MATERIAL LICENSE.

☐ Physician is certified* by the American Board of Radiology for Radiation Oncology speciality or the American Osteopathic Board of Radiation Oncology for Radiation Oncology speciality. ATTACH COPY OF BOARD CERTIFICATE.
*Verify 10 CFR 35.490 specialty board and certification dates recognized by NRC online.

☐ Physician meets requirements in 10 CFR 35.490(b)(1)-(3): 500 hours of training and experience with a minimum of 200 hours of classroom and laboratory experience in specific radiation safety areas; three years supervised clinical experience in radiation oncology; and written attestation from a preceptor. ATTACH COMPLETED NRC FORM 313A(AUS) for 10 CFR 35.400.

PROCEED to Part B on Page 3.

Section A.2. Nuclear Medicine Physician

For nuclear medicine physicians, CHECK **one** of the following three options.

☐ Physician is an Authorized User for medical uses under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required (with no restrictions, e.g. I-131 less than 30 mCi.) ATTACH COPY OF RADIOACTIVE MATERIAL LICENSE.

☐ Physician is certified* by the American Board of Nuclear Medicine, the American Board of Radiology for Radiation Oncology speciality, or the American Osteopathic Board of Radiation Oncology for Radiation Oncology speciality. ATTACH COPY OF BOARD CERTIFICATE.
*Verify 10 CFR 35.390 specialty board and certification dates recognized by NRC online.

☐ Physician meets requirements in 10 CFR 35.390(b)(1)-(2): 700 hours of training and experience with a minimum of 200 hours of classroom and laboratory experience in specific radiation safety areas; experience (minimum 3 cases) administering dosages of radioactive drugs to patients; and written attestation from a preceptor. ATTACH COMPLETED NRC FORM 313A(AUT) for 10 CFR 35.300.

PROCEED to Part B on Page 3.

SIR-Spheres® Authorized User Checklist

Section A.3.i. **Interventional Radiologist**

For interventional radiologists, CHECK **one** of the following two options.

☐ Physician is certified by the American Board of Radiology in diagnostic radiology, and the physician has subspecialty certification in interventional radiology. ATTACH COPY OF BOARD CERTIFICATE AND SUBSPECIALITY CERTIFICATION.

☑ Physician has three years supervised clinical experience in diagnostic radiology and one additional year of supervised clinical experience in interventional radiology. ATTACH LETTER FROM RESIDENCY DIRECTOR AND LETTER FROM FELLOWSHIP DIRECTOR

PROCEED to Section A.3.ii.

Section A.3.ii. **Interventional Radiologist**

For interventional radiologists, CHECK **one** of the following three options.

☑ Physician has successfully completed 80 hours of classroom and laboratory training for byproduct material, including Y-90 microspheres, during residency (e.g., nuclear medicine rotation). ATTACH LETTER FROM RESIDENCY DIRECTOR.

☐ Physician has successfully completed 80 hours of classroom and laboratory training for byproduct material, including Y-90 microspheres, under the supervision of an existing Authoorized User for SIR-Spheres®. ATTACH LETTER FROM EXISTING AU.

☑ Physician has successfully completed 80 hours of classroom and laboratory training for byproduct material, including Y-90 microspheres, during various training sessions as described below/attached. COMPLETE TABLE AND ATTACH SUPPORTING DOCUMENTATION (e.g., receipts, completion certficates, etc.).

Description of Training	Location of Training	Hours	Dates
Radiation physics & instrumentation	U of Michigan	20	July 1, 2009 thru Sept 30, 2014
Radiation protection	" "	20	" "
Mathematics pertaining to the use and measurement of radioactivity	" "	15	" "
Radiation biology + Chemistry	" " " "	" 10 = 21	" "

PROCEED to Section A.3.iii.

SIR-Spheres® Authorized User Checklist

Section A.3.iii. **Interventional Radiologist**

For interventional radiologists, CHECK one of the following two options.

☐ Physician has received training on the topics in (a)-(g) listed below from an existing Authorized User for SIR-Spheres®. ATTACH LETTER FROM EXISTING AU.

☑ Physician has received training on the topics in (a)-(g) listed below from a Sirtex representative. ATTACH SIGNED SIRTEX LETTER 104US.

Training Topics

a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
b) Performing quality control procedures on instruments used to determine the activity of SIR-Spheres® and performing checks for proper operation of survey meters;
c) Evaluation of each patient or human research subject for the dose/activity of SIR-Spheres® and performing checks for proper operation of survey meters;
d) Calculating and measuring the activity and safely preparing SIR-Spheres® to be delivered to the patient or human research subject;
e) Using administrative controls to prevent a medical event involving the use of byproduct material
f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures, and
g) Follow-up and review of each patient's or human research subject's case history for SIR-Spheres®.

PROCEED to Part B.

Part B

For radiation oncologists, nuclear medicine physicians, and interventional radiologists, CHECK one of the following two options.

☐ **Pathway 1** - Physician has successfully completed training in the operation of the delivery system, safety procedures, and clinical use for SIR-Spheres® under the supervision of an existing SIR-Spheres® Authorized User. The clinical use experience includes at least three supervised hands-on cases using SIR-Spheres®. ATTACH LETTER FROM EXISTING AU AND SUPPORTING CASEWORK DOCUMENTATION

☑ **Pathway 2** - Physician has successfully completed training in the operation of the delivery system, safety procedures, and clinical use for SIR-Spheres® provided by a Sirtex representative. The clinical use experience includes at least three supervised hands-on *in-vitro* simulated cases using SIR-Spheres®. ATTACH SIGNED SIRTEX LETTER 104

jdd
RSO Initials

Pathway 2 commitment for future documentation - After the physician is named as an AU on the license for SIR-Spheres®, at least the first three patient cases will be supervised in the physical presence of a Sirtex representative, and documentation will be forwarded to the appropriate regulatory authority within 30 days of the final case. SUBMIT SIGNED SIRTEX LETTER 105 WITHIN 30 DAYS OF FINAL PATIENT CASE.

Fax

From:	Smith, Laura T. – BMH RSO
Phone:	586 808 3058
Fax:	586 716 0577
Company Name:	Bronson Methodist Hospital
To:	NRC -
Phone:	
Fax:	1630 515 1078
Company Name:	

Comments:

13 pages plus this cover sheet

We Request expedited due to our main 4-90 staff is leaving & we have patients needing treatment

LTS

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle