

 **BRONSON**
Methodist Hospital

June 22, 2016

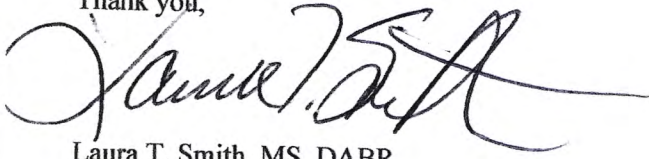
US NRC Region III
2443 Warrenville Rd, Suite 210
Lisle, IL 60532-4352
Attn: Materials Licensing

RE: Additional information for Dr. Hannawa AU license amendment

I have corrected the Sir-Spheres Authorized user checklist, and apologize for the incorrect math in adding up the 80 hours. The form is now corrected and attached.

If you have any question, feel free to email me at the email below.

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

SIR-Spheres® Authorized User Checklist

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: 5/18/2016

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 _____ 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 _____ 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 SUBSPECIALTY 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 certificates, etc.).

Description of Training	Location of Training	Hours	Dates
Radiation physics & instrumentation	U of Michigan	25	July 1, 2009 thru Sept 30, 2014
Radiation protection	U of Michigan	20	July 1, 2009 thru Sept 30, 2014
Mathematics pertaining to the use and measurement of radioactivity	U of Michigan	15	July 1, 2009 thru Sept 30, 2014
Radiation biology + Chemistry	U of Michigan	21	July 1, 2009 thru Sept 30, 2014

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

Its

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.

Parker, Bryan

From: Laura T. Smith- Physics <lsphysics@att.net>
Sent: Monday, June 27, 2016 8:01 AM
To: PARKER, BRYAN A
Subject: [External_Sender] whoops
Attachments: SCAN0306.PDF

I was reviewing my email to you, and you specifically said no jpegs and that is what I sent you....
wow, so I fixed that. These are the same exact attachments, but in pdf format.

Thanks,

Sorry.

Laura Smith I prefer email communications