



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

March 9, 2016

Docket No. 03001246
Control No. 589611

License No. 06-00854-03

Robert Falaguerra
Vice President, Facilities, Support Services,
and Construction
St. Francis Hospital and Medical Center
114 Woodland Street
Hartford, CT 06105

SUBJECT: ST. FRANCIS HOSPITAL AND MEDICAL CENTER, VOIDANCE OF
APPLICATION FOR LICENSE AMENDMENT, CONTROL NO. 589611

Dear Mr. Falaguerra:

This concerns the subject application for an amendment to your material license. Because Greg Hisel informed us that he was not able to supply the additional information required to complete the requested action for some time, we have voided your application. This action is taken without prejudice to the resubmission of your request. If you wish to resubmit your request to add yttrium-90 TheraSpheres, you may resubmit reference Control No. 589611 and provide the following additional information:

1. Based on our telephone conversation on March 8, 2016, you indicated that both Dr. Feld and Dr. Bee were authorized users on medical licenses for the use of TheraSpheres. If that is the case, all I will need is a copy of the Commission or Agreement State license, a permit issued by a Commission master materials license, a permit issued by a Commission or Agreement State licensee of broad scope, or a permit issued by a Commission master materials license broad scope permittee.
2. Otherwise, I will need the following for Dr. Feld:
 - a. Documentation of one of the following to support his Interventional Radiology training: (a) American Board of Radiology certification in diagnostic radiology **and** subspecialty certification in interventional radiology; or (b) One year of supervised clinical experience in interventional radiology.
 - b. Documentation of 80 hours of classroom and laboratory training for byproduct material, including Y-90 microspheres, in: (a) radiation physics and instrumentation, (b) radiation protection, (c) mathematics pertaining to the use and measurement of radioactivity, and (d) radiation biology.
3. For Dr. Bee, I will need the following additional information if you are not able to

obtain the permit from Johns Hopkins. Documentation that Dr. Bee has completed three years of clinical experience in diagnostic radiology and one additional year of supervised clinical experience in interventional radiology plus 80 hours of classroom and laboratory training for byproduct material, including Y-90 microspheres, in: (a) radiation physics and instrumentation, (b) radiation protection, (c) mathematics pertaining to the use and measurement of radioactivity, and (d) radiation biology.

4. For both Dr. Feld and Dr. Bee, confirm that each will complete at least the first three hands-on patient cases supervised in the physical presence of a Nordion representative. In addition, please confirm that you will submit documentation from Nordion to the NRC Region I within 30 days of when these three patient cases have been satisfactorily completed.
5. Please confirm if you wish to be authorized to notify the NRC in the future that you have permitted an authorized user to work at your facility without requesting an additional license amendment, providing the following are met:
 - a. The authorized user (AU) satisfies the training and experience listed in NRC's licensing guidance for Y-90 microspheres; and
 - b. The AU is currently listed for the same type of Y-90 microsphere use on a Commission or Agreement State license, a permit issued by a Commission master materials license, a permit issued by a Commission or Agreement State licensee of broad scope, or a permit issued by a Commission master materials license broad scope permittee; and
 - c. The licensee provides to the NRC a copy of the license or permit on which the AU is listed for a specific microsphere use; and
 - d. The licensee provides documentation of the above listed conditions to NRC for each AU no later than 30 days after the date that the licensee allows the AU to work as an AU for the specific microsphere.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

R. Falaguerra

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We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office. If you have any technical questions regarding the additional information requested, please call me at (610) 337-5272 or by e-mail at tara.weidner@nrc.gov.

Sincerely,

Original signed by Tara L. Weidner

Tara L. Weidner
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
Greg Hisel, Radiation Safety Officer

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SUNSI Review Complete: TWeidner

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