Sara A.B. Forster
MATERIALS LICENSING BRANCH
U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

NUCLEAR REGULATORY COMMISSION
REGION III
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LISLE, ILLINOIS 60532-4351

(630) 829-9892 FAX: (630) 515-1078 email:Berry.Stewart@franciscanalliance.org

TELECON & FAX TRANSMITTAL

TO: file

COMPANY: N/A

PAGES: 5 TEL.: N/A

FAX #: N/A

CONVERSATION RECORD

TIME	DATE
10:00 am	August 30, 2012

NAME OF PERSON(S) CONTACTED	TELEPHONE NO.	ORGANIZATION
Berry L. Stewart, M.S., RSO Radiation Safety Officer (RSO)	(317) 528-5649	Franciscan St. Francis Health

REPRESENTED PERSON or PERSONS	ORGANIZATION
Berry L. Stewart, Radiation Safety Officer (RSO)	Franciscan St. Francis Health

SUBJECT
License No.: 13-02128-03 Control No.: 577926

SUMMARY

We have reviewed your requesting license amendment requests and find that we are unable to continue this action until we have received information regarding the following requirements for the use of microspheres, as outlined at the NRC public website:

http://pbadupws.nrc.gov/docs/ML1217/ML12179A353.pdf.

1. The letter dated July 10, 2012, indicates that, "due to a consolidation of services," the primary address for the license is 8111 South Emerson Avenue. **Please indicate whether the "consolidation" is a Transfer of Control, and whether the change is a new mailing address only. If there has been a "Transfer of Control" please submit additional information needed for a Transfer of Control, included in NUREG 1556 Volume 9, Revision 2, page G-1.**

2. The letter dated July 9, 2012, requests to add yttrium-90 SIR-spheres authorizations for two physicians – Franklin W. Sequeria, M.D., and Rajat Gupta, M.D., but lacks sufficient training and experience documentation to qualify either as an Authorized User (AU) for Y-90 microspheres. Training and experience requirements are outlined on pages 1-3 of the guidance.

   Please submit 1 of the 2 items listed regarding Dr. Sequeria's SIR-spheres training:

   (a) Documentation showing Dr. Sequeria's completion of SIR-spheres training under the supervision of an Authorized User, including at least 3 hands-on cases; OR

   (b) Documentation showing Dr. Sequeria's completion of hands-on SIR-spheres training, including at least 3 hands-on in-vitro simulated cases completed with the manufacturer. If in-vitro cases are submitted in support of the training requirement, include a commitment to that Dr. Sequeria will complete at least his first 3 hands-on patient cases supervised in the physical presence of the SIR spheres manufacturer, and that documentation of the same will be submitted to the NRC within 30 days of completion.

Please submit all of the following regarding Dr. Gupta's training and experience:

(a) A copy of Dr. Gupta's ABR Board Certification, including both the diagnostic radiology specialty and the subspecialty of interventional radiology OR documentation confirming Dr. Adler's completion of one year of supervised clinical experience in interventional radiology;
(b) A statement confirming Dr. Gupta's completion of classroom & lab training applicable to the use of Y-90 microspheres;
(c) Documentation showing Dr. Gupta's work experience under the supervision of an Authorized User or a microsphere representative; AND
(d) Documentation showing that Dr. Gupta has completed the hands-on SIR-spheres training, including both the in-vitro simulated cases completed with the manufacturer and a commitment to submit documentation of the final requirements to the NRC, as indicated in the microsphere guidance.

We have requested that you submit the referenced items

- Clarification regarding consolidation & mailing address change, as noted;
- SIR-spheres training documentation for Dr. Sequeria; and
- SIR-spheres qualifications for Dr. Gupta

– via facsimile, to (630) 515-1078. Please reference the Control No. 577926, as listed at the top of this memo. We expect to hear from you on or before September 13, 2012.

For future reference, please always include the name, phone number and fax number of at least one person whom we may contact for additional information when reviewing your licensing correspondence and requests.

Please submit the requested information within **14** days of this record. **Include reference control number 577926, Please FAX your response to my attention at (630) 515-1078.** You may also scan your response and send to me via email, as a pdf file.

Please direct any questions you have to me at **(630) 829-9892** or **sara.forster@nrc.gov.**

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Sara A.B. Forster	Sara A.B. Forster	08/30/2012

Re: Dr Sequeira - Microsphere Guidance, June 2012

pathway 1) an AU who is authorized for the type of microsphere for which the individual is seeking authorization. The clinical use experience should include at least three supervised hands-on cases for each type of Y-90 microsphere for which the individual is seeking AU status; or N/A

pathway 2) a Y-90 microsphere manufacturer. The clinical use experience should include at least three supervised hands-on *in-vitro* simulated cases for each type of Y-90 microsphere for which the individual is seeking AU status. *In-vitro* simulated cases should demonstrate issues that are encountered during Y-90 microsphere administration procedures. Following the license amendment that names the individual as an AU for Y-90 microsphere use, the first three patient cases completed by the individual should be hands-on and supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which the individual is authorized.

The applicant must submit documentation for the above training and experience. For individuals obtaining clinical use experience under pathway 1 above, this documentation includes the clinical use cases. For individuals obtaining clinical use experience under pathway 2 above, this documentation includes the *in-vitro* simulated cases and a commitment that each individual will complete at least the first three hands-on patient cases supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which authorization is sought. (Additionally for pathway 2, the licensee's commitment will include submitting documentation from the manufacturer to the appropriate NRC Regional Office within 30 days of when these three patient cases have been satisfactorily completed.)

In addition, the applicant shall commit to provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

If the NRC staff revises the training and experience criteria, physicians who were authorized for the medical use of a specific type of Y-90 microsphere under these criteria or previous criteria, do not have to meet the revised criteria for that type of microsphere.

Leak Tests

Leak tests are not required for Y-90 microspheres based on the criteria in 10 CFR 35.67(f).

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Re: Dr. Gupta - from Microsphere Guidance, June 2012

3) Is an interventional radiologist who meets the training and experience guidelines as follows:

i)

a) American Board of Radiology certification in diagnostic radiology and subspecialty certification in interventional radiology; or

b) Three years supervised clinical experience in diagnostic radiology and one additional year of supervised clinical experience in interventional radiology; and

ii) has 80 hours of classroom and laboratory training for byproduct material, including Y-90 microspheres, which may be concurrent with training received in accordance with Item A.3.i. in:

a) Radiation physics and instrumentation;

b) Radiation protection;

c) Mathematics pertaining to the use and measurement of radioactivity;

d) Radiation biology; and

iii) has work experience under the supervision of an AU for Y-90 microspheres or training provided by a Y-90 microsphere manufacturer representative involving:

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 or human research subject 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 or human research subject;

e) Using administrative controls to prevent a medical event involving the use of byproduct material (Appendix S to NUREG-1556, Volume 9 provides additional guidance on this subject);

f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures (Appendix N to NUREG-1556, Volume 9 provides additional guidance on this subject. The procedures should address any special circumstances that may be encountered, such as electrostatic charge of microspheres and proper survey instrument and survey technique for beta emitters); and

g) Follow up and review of each patient's or human research subject's case history for Y-90 microspheres; and

B) has successfully completed training in the operation of the delivery system, safety procedures, and clinical use for each type of Y-90 microspheres for which authorization is sought. The additional Y-90 microsphere specific training and experience requirements may be satisfied by satisfactory completion of a training program provided by either:

Re Dr. Gupta's trng, cont'd

pathway 1) an AU who is authorized for the type of microsphere for which the individual is seeking authorization. The clinical use experience should include at least three supervised hands-on cases for each type of Y-90 microsphere for which the individual is seeking AU status; or

pathway 2) a Y-90 microsphere manufacturer. The clinical use experience should include at least three supervised hands-on *in-vitro* simulated cases for each type of Y-90 microsphere for which the individual is seeking AU status. *In-vitro* simulated cases should demonstrate issues that are encountered during Y-90 microsphere administration procedures. Following the license amendment that names the individual as an AU for Y-90 microsphere use, the first three patient cases completed by the individual should be hands-on and supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which the individual is authorized.

The applicant must submit documentation for the above training and experience. For individuals obtaining clinical use experience under pathway 1 above, this documentation includes the clinical use cases. For individuals obtaining clinical use experience under pathway 2 above, this documentation includes the *in-vitro* simulated cases and a commitment that each individual will complete at least the first three hands-on patient cases supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which authorization is sought. Additionally for pathway 2, the licensee's commitment will include submitting documentation from the manufacturer to the appropriate NRC Regional Office within 30 days of when these three patient cases have been satisfactorily completed.

In addition, the applicant shall commit to provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

If the NRC staff revises the training and experience criteria, physicians who were authorized for the medical use of a specific type of Y-90 microsphere under these criteria or previous criteria, do not have to meet the revised criteria for that type of microsphere.

Leak Tests

Leak tests are not required for Y-90 microspheres based on the criteria in 10 CFR 35.67(f).

Forster, Sara

From: Forster, Sara
Sent: Friday, August 31, 2012 7:44 AM
To: 'Berry.Stewart@franciscanalliance.org'
Subject: Franciscan St. Francis Health Amendment, License No. 13-02128-01, C/N 577926
Attachments: 02240.577926.13-02128-03 telecon signed.PDF

Dear Mr. Stewart:
Please see attached for additional information requested, regarding your two recent amendment requests. Please include a signed and dated cover letter with any response. Do not hesitate to contact me if you have any questions. As noted in our conversation, this message is the second of two; the first message relates to pending renewal application.

Sincerely,
Sara A. B. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclar Materials Safety
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Lisle, IL 60532-4352
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