

Sara A.B. Forster
MATERIALS LICENSING BRANCH



TELECON & FAX TRANSMITTAL

TO: file

COMPANY: N/A

NUCLEAR REGULATORY COMMISSION
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(630) 829-9892 FAX: (630) 515-1078

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CONVERSATION RECORD

		TIME	DATE
		11:45 am	November 29, 2011
NAME OF PERSON(S) CONTACTED	TELEPHONE NO.	ORGANIZATION	
Laura T. Smith, M.S., DABR Radiation Safety Officer (RSO)	(313) 609-2038 (pager)	Consultant RSO	
REPRESENTED PERSON or PERSONS		ORGANIZATION	
Laura T. Smith, M.S., DABR, RSO		St. John Macomb-Oakland Hospital	
SUBJECT			
License No.: 21-01190-05		Control No.: 576351	

SUMMARY

We have reviewed your requesting license amendment request 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/ML1128/ML11284A266.pdf>.

1. The letter submitted on November 6, 2011, lacks required commitments, as described on pages 3- 5 of the guidance identified above. Please submit the required commitments regarding the use of Y-90 microspheres at St. John Macomb-Oakland's use of Y-90 microspheres. In the November 29, 2011, conversation, the licensee contact indicated that the commitments would be submitted as required.
RESPONSE: As of February 2, 2012, commitments conforming to pages 3-5 of the microsphere guidance had not been received. The license will not be amended at this time. Additional information will be required to proceed with the request.
2. The letter submitted on November 6, 2011, lacks sufficient training and experience documentation to qualify Philip Adler, M.D., as an Authorized User for Y-90 microspheres. Training and experience requirements are outlined on pages 1-3 of the guidance. Please submit the following regarding Dr. Adler's training and experience:
 - (a) A copy of Dr. Adler'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. Adler's completion of classroom & lab training applicable to the use of Y-90 microspheres;
 - (c) Documentation showing Dr. Adler's work experience under the supervision of an Authorized User or a microsphere representative; AND
 - (d) Documentation showing that Dr. Adler has completed the hands-on SIR-spheres training, including both the in-vitro simulated cases completed with the manufacturer and the manufacturer's commitment to submit documentation of the final requirements to the NRC, as indicated in the microsphere guidance).

In the November 29, 2011, conversation, the licensee contact indicated that the additional information would be submitted as required, and that the manufacturer would be contacted regarding requirements outside the licensee's control..

RESPONSE: As of February 2, 2012, the licensee and/or manufacturer had submitted insufficient documentation regarding Dr. Adler's training and experience. The license will not be amended at this time. Additional information will be required to proceed with the request.

We have requested that you submit the referenced items

- Commitments regarding the St. John Macomb-Oakland's use of Y-90 microspheres; and
- Dr. Adler's Training and Experience documentation, including ABR subspecialty, Classroom & Lab training, and work experience

– via facsimile, to (630) 515-1078. Please reference the Control No. 576351, as listed at the top of this memo. We expect to hear from you on or before December 20, 2011.

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 **21** days of this record. **Include reference control number 576351, 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	<i>Sara A.B. Forster</i>	02/02/2012