



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
612 EAST LAMAR BLVD., SUITE 400
ARLINGTON, TEXAS 76011-4125

FACSIMILE



Name: Richard J. Massoth, Ph.D. License No. 40-16571-01
Organization: Avera McKennan Hospital Docket No. 030-11252
Control No. 574318
E-mail address: rmassoth@medx-ray.com ***[actually sent email on 04/16/11]***
Phone: 605-310-8136
From: Jacqueline D. Cook
Date: April 16, 2011
Subject: Application dated January 5, 2011 for License Amendment to add Y-90
Microspheres
Pages: 2

Dr. Massoth:

Per your application dated January 5, 2011, the items on the next page are deficiencies which require your response. **Please respond to this fax by Thursday, May 5, 2011.** If you are unable to respond by this due date, please don't hesitate to contact me so we can discuss an extension to the date. Our fax number is (817) 860-8263. You may respond by email in pdf format if you'd like. My email address is Jackie.Cook@nrc.gov. If you have any questions regarding this fax, please call me at (817) 860-8132. When responding to this fax, please include the license, docket and control numbers located at the top of this page.

Thanking you in advance for your cooperation, assistance, and prompt response in this matter.

/RA/
Jacqueline D. Cook
Senior Health Physicist

1. A. Please note that your amendment request was reviewed utilizing the Microsphere Brachytherapy Sources and Devices guidance revised January 2011 (please see attached) which supersedes previous versions of licensing guidance dated [September 2008](#), [August 2008](#), [December 2007](#), [September 2007](#), [January 2004](#), and [October 2002](#).

Please resubmit your amendment request using the attached guidance revised guidance (January 2011).

- B. Please resubmit your amendment request and change references to NRC Microsphere Brachytherapy Sources and Device guidance revision September 2008 to NRC Microsphere Brachytherapy Sources and Device guidance revision January 2011, as appropriate.
2. Please specify a maximum possession limit for each type of microspheres – SIR-Spheres[®] and TheraSphere. We can no longer specify the possession limits on licenses anymore as “As needed.”
3. Please note that both Dr. Michele M. Corsini and Dr. Matthew Casey are authorized for and have received training in only the SIR-Spheres system at this time. Please note that under the heading “LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE” in the Sealed Source and Device Certificate Number NR-0220-D-131-S, there is a note to the Reviewer that the clinical staff who administers the TheraSpheres must complete a training program that is specific to the TheraSphere administration procedure, as described above in the Sealed Source and Device Certificate Number NR-0220-D-131-S.

Please verify that Dr. Corsini and Dr. Casey will receive the appropriate training (undergo the TheraSphere training program as provided by the manufacturer or equivalent) in the TheraSphere system, as appropriate.