January 9, 2006

Curtis Lewis, MD, MBA
President, Society of Interventional Radiology
3975 Fair Ridge Drive, Suite 400 North
Fairfax, VA 22033

SUBJECT: SOCIETY OF INTERVENTIONAL RADIOLOGY LETTER, DATED OCTOBER 17, 2005

Dear Dr. Curtis:

I am responding to your October 17, 2005, letter in which you were seeking recognition by the U.S. Nuclear Regulatory Commission (NRC) of interventional radiologists as authorized users in the use of yttrium-90 (Y-90) microsphere cancer therapy. Your specific concerns with the requirements in 10 CFR 35.490 for microspheres are addressed below.

1. Under item 1 in your letter, you questioned whether microsphere use should be subject to the same training and experience (T&E) requirements as higher dose manual brachytherapy. In particular, you noted that "previously, microspheres fell under 10 CFR 35.1000, Emerging Technologies."

   Please note that use of this modality is still regulated under 10 CFR 35.1000. The T&E requirements for Y-90 microsphere therapy appear in the associated licensing guidance posted under 10 CFR 35.1000 uses on our website, http://www.nrc.gov/materials/miau/med-use-toolkit/microsphere.html. This guidance does not specifically indicate the acceptable medical specialty areas for authorized users using Y-90 microspheres, however, the guidance indicates that authorized users must meet the training and experience requirements of either 10 CFR 35.490, or until October 25, 2005, 10 CFR 35.940 as well as specific vendor training in the use of the microspheres and the microsphere delivery system.

2. You recommended either revising the regulations to recognize interventional radiologists as authorized users for this usage or extending Subpart J of 10 CFR 35.

   The NRC published a proposed rule to amend its requirements for T&E for medical use of byproduct material, 10 CFR Part 35 for a 75-day comment period on December 9, 2003 (68 FR 68549). The comment period ended on February 23, 2004. Significant public comments were received, considered and addressed. The final rule was published in the *Federal Register* on March 30, 2005 (70 FR 16335). It became effective on April 29, 2005. The rule amended the regulations to change requirements for recognition of certain specialty boards' certification processes. These boards' certifications may be used for demonstrating the adequacy of the training and experience of individuals to serve as authorized users, authorized medical physicists, authorized nuclear pharmacists, or radiation safety officers. The final rule also revised

the requirements for demonstrating the adequacy of T&E for the alternate pathway, other than the certification pathway, for achieving authorized status. Consequently, Subpart J of 10 CFR Part 35 expired on October 24, 2005, and it will not be extended.

3. You recommended that either microspheres be reclassified from 10 CFR 35.490 or an alternative training and educational pathway be created for physicians providing Y-90 therapies who are not radiation oncologists.

While the NRC staff recognizes that Interventional Radiologists are an integral part of microsphere therapy administration, the staff believes that an authorized user for Y-90 microsphere therapy must meet the T&E requirements set forth in 10 CFR 35.490. Note that any physician can use Y-90 microspheres under the supervision of an authorized user provided that the individual has received appropriate instruction and follows the instructions of the supervising authorized user and other applicable procedures, regulations, and license conditions with respect to the medical use of byproduct material; see 10 CFR 35.27, Supervision.

We believe that prior to the expiration of 10 CFR 35 Subpart J, an interventional radiologist, should have the specific training and experience described in 10 CFR 35.940, to be an authorized user for Y-90 microsphere therapy. If an interventional radiologist with appropriate T&E was named as an authorized user prior to the expiration of Subpart J on October 24, 2005, then the individual would continue to be an authorized user as provided by 10 CFR 35.57.

For further information or for questions, please contact me or Ms. Cindy Flannery, Team Leader of the Division of Industrial and Medical Nuclear Safety's Medical Team at (301) 415-0223, or via e-mail at cmf@nrc.gov.

Sincerely,

/RA/

Scott W. Moore, Chief
Rulemaking and Guidance Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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Scott W. Moore, Chief
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