



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4352

JAN 27 2005

Clete Yoder
Vice President
Goshen General Hospital
200 High Park Avenue
Goshen, IN 46527-0139

Dear Mr. Yoder:

We reviewed your letter dated November 26, 2004, requesting Seza A. Gulec, M.D. be approved for the use of Yttrium-90 (Y-90) microspheres, SIR-Spheres which are manual brachytherapy sources used for permanent brachytherapy implantation therapy under 10 CFR 35.1000. The information provided in your letter states that currently Dr. Gulec is authorized on your NRC license No. 13-18845-01 for materials permitted by 10 CFR 100, 200, and 300.

Current NRC guidance, which is found on the NRC internet website "<http://www.nrc.gov/materials/miau/med-use-toolkit/microsphere.html>" (copy enclosed), requires the use of Y-90 microspheres for manual brachytherapy be performed by a physician who meets the training and experience qualifications found in either 10 CFR 35.490 or 10 CFR 35.940. Since the information you provided concerning Dr. Gulec does not address the qualifications found in these sections, we cannot approve Dr. Gulec for Y-90 microsphere manual brachytherapy at this time.

You may in a future amendment provide information concerning Dr. Gulec which demonstrates that his training and experience satisfies the requirements of 10 CFR 35.490 or 940. If you determine that Dr. Gulec's training and experience does not satisfy these requirements, however, can provide sufficient justification why Dr. Gulec is otherwise qualified to perform manual brachytherapy using Y-90 microspheres, you may file for an exemption from these training requirements under 10 CFR 35.19. 10 CFR 35.19 states that the Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. This, however, does not preclude Dr. Gulec from performing these procedures while under the supervision of physician users who are authorized by your NRC license to perform manual brachytherapy procedures using Y-90 microspheres.

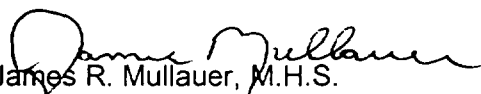
As we discussed with your consultant, David Close, on January 27, 2005, we have voided your request. This action is without prejudice to resubmission.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

If you have any question or require clarification on any of the information stated above, you may contact us at (630) 829-9887.

Sincerely,


James R. Mullauer, M.H.S.
Health Physicist
Materials Licensing Branch

License No. 13-18845-01
Docket No. 030-14254

Enclosure: Licensing Guidance -SIRSpheres Yttrium-90 Microspheres

cc: Eugene Long, M.D.
Radiation Safety Officer
Department of Nuclear Medicine