

January 31, 2003

To: Ruth McBurney,
Chairperson, Subcommittee on New Modalities
Advisory Committee on the Medical Use of Isotopes (ACMUI)

From: Thomas Essig/**RA**/
Designated Federal Official, ACMUI

Subject: Charter for the ACMUI Subcommittee on New Modalities to review, and make recommendations for, existing staff licensing guidance on Intervascular Brachytherapy, Yttrium-90 microspheres, and the GliaSite (TM) system

The Subcommittee on New Modalities of the Advisory Committee on the Medical Use of Isotopes (ACMUI) was formed for the purpose of providing NRC staff with recommendations on licensing guidance for new modalities that do not fit into Subparts D through H of 10 CFR Part 35. These new modalities are licensed under 10 CFR 35.1000, "Other Medical Uses of byproduct material or radiation from byproduct material." Licensing guidance for these modalities is intended to promote the timely completion of consistent licensing actions for all licensees or applicants who seek authorization under the § 35.1000 type of use.

The Subcommittee on New Modalities consists of Dr. Malmud, Dr. Nag, Ms. Schwarz, Dr. Vetter, Dr. Williamson, Dr. Brinker, Dr. Egli, Ms. Hobson, and yourself. We appreciate your willingness to serve as the chairperson of this subcommittee.

The existing staff licensing guidance on Intervascular Brachytherapy (IVB), Yttrium-90 microspheres, and the GliaSite (TM) system is available on the NRC's Medical Program web page at: <http://www.nrc.gov/materials/miau/miau-reg-initiatives/by-product.html>. As its initial task, the Subcommittee on New Modalities is requested to review this existing guidance, and to provide the NRC staff with any recommendations that the subcommittee may deem to be appropriate. I encourage the subcommittee to consider whether there are multiple acceptable options for achieving adequate assurance of safety, rather than focusing on a single licensing approach. The availability of multiple acceptable licensing approaches would provide desirable flexibility to licensees, and would assist NRC licensing staff in completing the prompt review of applications.

In developing its recommendations to the NRC staff, I suggest that the subcommittee obtain input on the radiation safety considerations for the new modalities from: the NRC staff, especially those who developed the existing guidance; the licensed community currently using the new modalities; and other interested stakeholders, such as the States and vendors, who can provide their unique perspectives on the current and future uses of the new modalities. To obtain public input, options such as publically noticed solicitations of written comments, telephone conferences, and regular or special meetings of the ACMUI or the subcommittee should be considered. Please work with Angela Williamson, arw@nrc.gov or (301) 415-5030, to make the necessary arrangements.

In order to support the timely updating of the existing licensing guidance, I would appreciate your recommendations at your earliest convenience, and certainly within a six to nine month time frame. The NRC staff will consider your recommendations in developing a revision to the existing licensing guidance. Our goal is to issue the revised guidance within one year, at the latest.

If you have any questions regarding the contents of this charter, please contact Mr. Frederick Brown at fdb@nrc.gov or (301) 415-8731.

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ADAMS ACCESSION NUMBER: ML030300010

ADAMS DOCUMENT TITLE:ACMUI Subcom Charter.wpd

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DATE	1/30/03		1/30/03		1/30/03	

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