Memo: Thomas Essig/RA/
Designated Federal Official, ACMUI

From: Leon S. Malmud, M.D.
Committee Member of ACMUI and Subcommittee on
New Modalities

Subject: Charter for the ACMUI Subcommittee on New Modalities to review, and make recommendations

Date: February 12, 2003

Background:

The group of medical practitioners with the greatest experience in the use of unsealed source therapies, i.e., unsealed byproduct material for which a written directive is required, is within the specialty of Nuclear Medicine. Isotopes such as I-131, P-32, etc. have been used for therapeutic and palliative treatment of hyperthyroidism, thyroid cancer, peritoneal metastases and bone metastases for over three decades.

Currently, individuals trained in the specialty of Nuclear Medicine perform diagnostic and therapeutic procedures using unsealed sources that are administered by inhalation, orally, intravenously, intraperitoneally, and by catheter into hollow organs or blood vessels.

Current Issue:

New therapies have been recently introduced (and will continue to be introduced in the future) which employ radioisotopes associated with monoclonal antibodies for the therapy of various diseases, as well as, radioisotopes encased in microspheres, including FDA-approved agents such as Zevalin (IDEC's Y-90 labeled monoclonal antibody for the treatment of non-Hodgkin's lymphoma).

In the development of one of the more recent products, MDS Nordion's TheraSphere Yttrium-90 microspheres, a team approach was used with the team consisting primarily of nuclear medicine specialists, as well as, interventional radiology and medical oncology specialists supported by medical physics and radiation safety staff. During the clinical trials, the primary team specialists

performing the administration were most frequently nuclear medicine physicians. The nuclear medicine physicians were considered to play a major role on the team because of their involvement as experienced physicians knowledgeable in dosimetry and in calibration.

Currently, the regulations under 10 CFR 35.1000 would require each nuclear medicine user to obtain individual permission from the NRC licensing staff in order to use Yttrium-90 microspheres. This would be a time consuming process, which would undoubtedly have the effect of discouraging or delaying the appropriate and timely clinical application of this valuable modality and place an inappropriate burden on the licensing agency staff.

Recommendation:

Therefore, it would be most useful if the existing approval under 10 CFR 35.1000 specifically included as providers those practitioners (including nuclear medicine specialists) who have during their period of training, received the requisite training and experience in both diagnostic and therapeutic nuclear medicine.

I am recommending a method that would not require that the manufacturer reapply for approval under 10 CFR 35.300 (I don't think the manufacturer has to do this), and which would avoid unnecessary time and expense. Specifically, the current regulations under 10 CFR 35.1000 be appended to include those practitioners who have the greatest experience and who received the requisite number of hours of diagnostic and therapeutic training, including nuclear medicine physicians, radiation oncologists, and nuclear radiologists.

In summary, I am recommending that during this process, while the T and E is again under consideration, that we take steps to remedy the problem.

Thank you.

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CC: All Subcommittee Members
Angela Williamson