DOCKET NUMBER
PETITION RULE PRM 35-9
(54FR 38229)

(163)

ST. LUKE'S
Episcopal Hospital

'89 NOV -6 P12:05

November 2, 1989

Secretary
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket #PRM-35-9
Washington, D.C. 20555

Dear Mr. Secretary:

I am writing in support of the Petition for Rulemaking filed by the American College of Nuclear Physicians/Society of Nuclear Medicine. I am a Nuclear Medicine physician at St. Luke's Episcopal Hospital in Houston, Texas, and I am concerned about 10 CFR 35 regulations governing the medical use of byproduct material. These regulations, if enforced, would greatly impair my ability to practice state-of-the-art Nuclear Medicine and in some cases prevent me from providing optimal care to patients.

For example, many radiopharmaceuticals (such as Tl-201) are not approved for pediatric applications despite widespread and longstanding use. Similarly, Tc-99 pertechnetate was for many years not approved for use in gastric mucosal imaging - an almost entirely pediatric application. Because many manufacturers are unable or unwilling to obtain FDA approval of specific applications of certain radiopharmaceuticals, the post-NDA utilization and efficacy testing have been left, defacto, to practitioners such as myself. IND regulations, though obviously with merit in some cases are needlessly stringent in many instances an unnecessarily hinder both my practice and the greater workings of the FDA. The landslide of applications for IND exemptions and subsequent modification requests which would result from full implementation of 10 CFR 35 would be a terminal blow to an already understaffed FDA regulatory system.

The NRC should recognize that the FDA allows uses of approved drugs "unapproved" purposes, and actively discourages the submission of physician-sponsored IND's that describe new indications for these drugs. The package insert, then, has not become a vehicle to prohibit physicians from safe but innovative medical practice. Modern medical advances proceed (for the public good) much faster than the FDA or NRC could ever hope to keep up with.

Currently, the regulatory provisions in Part 35 (35.100, 35.200, 35.300 and 33.17(a)(4) do not allow practices which are legitimate and legal under FDA regulations and Texas medical practice laws. These regulations therefore inappropriately interfere with the practice of medicine, which directly contradicts the NRC's Medical Policy statement against such interference.

Texas Medical Center
P.O. Box 20269
Houston, Texas 77225-0269

PS10

The current status places the average Nuclear Medicine physician in the position of either impairing patient care or violating (your) federal regulations. Neither alternative is necessary or acceptable.

Sincerely,

W H Moore MD

Warren H. Moore, M.D.
Chief, Nuclear Medicine Services
St. Luke's Episcopal Hospital
Texas Children's Hospital

WHM/dsh