MONTOUR COUNTY MEDICAL SOCIETY
DANVILLE, PENNSYLVANIA 17821

DOCKET NUMBER
PROPOSED RULE PR-35 (92) (43FR 29297)

September 22, 1978

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

ATTENTION: Docketing & Service Branch

Dear Sir:

On behalf of the Montour County (Pennsylvania) Medical Society, I wish to respond to the proposed rule change published in the Federal Register, Volume 43, No. 131 - Friday, July 7, 1978, Pages 29297 - 29298.

Radiation doses from diagnostic nuclear medicine procedures are typically quite low, so that with very few exceptions, the margin of safety is extremely wide and the administration of the wrong radiopharmaceutical will in no way constitute a hazard to that patient.

The ± 20 percent acceptable limits of error proposed for diagnostic radiopharmaceuticals are entirely too strict. A wide range of variability of dosages exists for many examinations between institutions so that a "misadministration" for one licensee may actually give less activity than the routine dose for another laboratory. Also, no attempt to separate diagnostic agents into those with short or long effective half-lives has been made and no consideration of the presence or absence of particulate radiation is given.

The sanctions proposed against licensees for "misadministrations" are unique and are not applied to any other form of pharmaceutical. This raises the prospect of broadening the scope of such regulations to include other agents which constitute unacceptable interference with the practice of medicine on the part of the government.

With regard to therapy with unsealed radionuclide source (i.e. iodine 131, phosphorus 32, and gold 198) the problem of "misadministrations" is more understandable, but we must be critical of the fact that no distinction is made between high and low dosages and long and short effective half-lives.

A strict requirement that patients and their families be notified of all "misadministrations" raises serious problems. The paperwork generated could be a real burden to all concerned and the potential for misunderstanding of the seriousness of the error could result in unfortunate and often unnecessary breaches between doctor and patient and could produce a drastic upswing in litigation. The

Acknowledged by card 10/4

scope of actions encompased by the term "misadministration" is very wide, so that errors of a very minor degree are the legal equivalent of much more serious mistakes. A decision to inform the patient or his family of the significant error should rest with the licensee and the referring physician and be based upon the seriousness of the error and the medical circumstances of the case.

Finally, the requirement that the NRC be notified of all "misadministrations" is especially bothersome, since these reports become part of the public record and are then available to anyone regardless of qualifications or motivation. The potential for malicious mischief is serious. Safeguards to protect the identity of the licensee and patients are imperative.

Sincerly yours,

Frederick G. Brown, M.D.
Secretary - Treasurer

FGB/sz
t:9/26/78