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October 13, 1989

Secretary of the Commission
Nuclear Regulatory Commission
Docketing and Service Branch
Docket #PRN-35-9
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Sir:

I am writing to support, with all my ability, the Petition for Rule Making of the American College of Nuclear Physicians/Society of Nuclear Medicine. I am a physician practicing Nuclear Medicine at the Jewish Hospital and University Hospital, Cincinnati, Ohio and am perturbed by the recently revised 10 CFR 35 regulations governing the medical use of by-product material. They are definitely an impediment to my practice of Nuclear Medicine! As new uses for radiopharmaceuticals become available these do not always appear on the manufacturers' label and yet the FDA has permitted us to use these to enhance patient diagnosis, as for example when sulfur colloid was first employed for gastric emptying studies. The NRC should recognize that the FDA does allow other clinical uses of approved drugs than those that appear on the label which was never meant to prohibit physicians from deviating from it for appropriate indications. Manufacturers may wait years to revise a package insert because it is costly and they know that clinical indications for new uses for their products have appeared in literature and are quite clear.

Currently the regulatory provisions in Part 35 do not allow practices which are legal under FDA regulations and those of the State of Ohio. Therefore, you are interfering with my practice of Medicine, which does not seem to fit with your own medical policy statement against such interference. I do not believe it appropriate for the NRC to regulate radiopharmaceutical use. I rely on the State of Ohio and the FDA for this.

I do support your regulating more tightly the therapeutic use of iodine-131 to avoid misadministrations in this area but doing this should in no way impinge upon the practice of Radiopharmacy.

Cordially,

Edward B. Silberstein

Edward B. Silberstein, M.D.
Professor of Medicine and Radiology

EBS/snm
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