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

Dear Mr. Secretary:

As a practicing Nuclear Medical physician since 1955, I wish to express my support for the petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. My practice of Nuclear Medicine is confined to the Ellis Hospital and St. Clare's Hospital in Schenectady, New York. My concern is over the revised 10CFR 35 regulations governing the medical use of byproduct material and their affect on practice of high quality Nuclear Medicine which, in turn, affects the care of the patients.

For example, in therapeutic services I must follow the instructions not only for kit preparation and expiration times but also for FDA approved indications, route of administration, activity levels, etc.

The NRC should recognize that the FDA does allow, and often encourages, other clinical uses of approved drugs and actively discourages the submission of physician-sponsored IND's that describe new indications for approved drugs. It is my understanding the package insert never intended to prohibit physicians from deviating from it for other indications so manufactures will rarely return to the FDA to revise a package insert to include new indications as it is not required by the FDA and there is simply no economic incentive to do so.

I also would like to point out that highly restrictive NRC regulations will only jeopardize public health and safety by restricting access to appropriate Nuclear Medical procedures. Also, patients will be exposed to higher radiation doses from alternative, legal but non-optimum studies.

Since the NRC's primary regulartory focus appears to be based on the unsubstantiated assumption that misadministrations, particularly those involving diagnostic radiopharmaceuticals pose a serious threat to the public health and safety, I strongly urge the NRC to pursue a comprehensive study by a reputable scientific panel, such as the

DS10

National Academy of Sciences to assess the radiobiological effects of misadministrations from Nuclear Medicine diagnostic and therapeutic studies. It is my opinion that the results of such a study will demonstrate the unnecessity of more stringent regulations, which if pursued will not be cost-effective.

In summary, I strongly urge the NRC to adopt the American College of Nuclear Physicians and the Society of Nuclear Medicine petition for Rulemaking as expeditiously as possible.

Sincerely,

Richard H. Lange, M.D.
Chief, Section of Nuclear Medicine
Ellis Hospital