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

Dear Mr. Secretary:

I am writing to express my support most emphatically for the Petition for Rulemaking filed by the Society of Nuclear Medicine and the American College of Nuclear Physicians. I am a practicing Nuclear Medicine Physicist at the University of Virginia Health Sciences Center. I am deeply concerned that the revised 10 CFR 35 (effective April, 1987) significantly and negatively impacts the practice of high quality nuclear medicine.

The FDA's process for regulating the use of pharmaceuticals, including radiopharmaceuticals, encourages the manufacturers to submit data in support of efficacy of a drug in the diagnosis or therapy of the most frequently-seen diseases and the most easily measured conditions. Only those indications for which data has been submitted to the FDA can be included in the package insert's list of indications. Thus, although a drug may be quite effective in a rare disease, such disease may not be mentioned in the package insert because too few documented cases existed in the manufacturer's records. The medical literature supplies the rest of the information that practitioners use in deciding what pharmaceutical might be best under certain circumstances. Nuclear Medicine physicians should have the same freedom in the use of radiopharmaceuticals that the rest of the practitioners have in the use of non-radioactive pharmaceuticals. The package insert's list of indications is only a starting point and does not delineate all the conditions for which a drug may be used. Such a list of all effective uses of a pharmaceutical would be impossible to construct and I do urge the NRC not to try to do this for radiopharmaceuticals. 10CFR35 as it is currently written requires that all the conditions for kit preparation be spelled out and that for therapeutic materials, every possible situation be described in the package insert. For the reasons given above, this is not the purpose of the package insert and is therefore impossible to base the practice of nuclear medicine on the package insert.

I do urge the NRC to consider the Petition for Rulemaking and adopt the modified version of 10CFR35 as expeditiously as possible to avoid a situation in which the rules cannot be enforced and are honored in the breach as is now the case.

Sincerely yours,

Barbara Y. Croft

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