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Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch
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Roanoke Memorial Hospitals
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Dear Mr. Secretary:

I am writing to express my strong support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a practicing nuclear pharmacist at Roanoke Memorial Hospital in Roanoke, Virginia. I am very concerned over the revised 10 CFR 35 Regulations governing the medical use of byproduct material as they significantly impact on my ability to practice nuclear pharmacy and are preventing me from providing optimal service to both the hospitals and patients I work with. For example, if we are forced to strictly follow the manufacturers instructions for kit preparation and expiration times, the cost of providing radiopharmaceuticals and radiopharmaceutical services will increase dramatically. This increase cost is primarily the result of having to prepare multiple vials of radiopharmaceutical kits and make additional deliveries to the hospitals utilizing our services. This would be forced upon us even though routine quality assurance testing with thin layer chromatography and years of practical experience have shown the activity limits and expiration times stated in the manufacturers package inserts are so conservative that they have no relationship to how the kits can be prepared to allow for maximal usage and still provide a product meeting the manufacturers specifications for quality.

Our nuclear pharmacy provides routine radiopharmaceutical services to three other hospitals. One of the major reasons for deciding to provide theses services was that it would allow each nuclear medicine department to lower the amount of money being spent on radiopharmaceuticals by eliminating duplication of preparation, obtaining reduced pricing associated with volume purchasing and decreasing waste of expensive radiopharmaceutical preparations.

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 State medicine and pharmacy laws. These regulations therefore inappropriately interfere with the practice of medicine, which directly contradicts the NRC's Medical Policy statement against such interference.

Since the NRC's primary regulatory focus appears to be based on the unsubstantiated assumption that

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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 National Academy of Sciences or the NCRP, to assess the radiobiological effects of misadministrations from Nuclear Medicine diagnostic and therapeutic studies. I firmly believe that the results of such a study will demonstrate that the NRC's efforts to impose more and more stringent regulations are unnecessary and not cost-effective in relation to the extremely low health risk of these studies.

In closing, I strongly urge the NRC to adopt the ACNP/SNM Petition for Rulemaking as expeditiously as possible.

Sincerely;

Robert W. Beightol

Robert W. Beightol, Pharm.D.
Director, Nuclear Pharmacy