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PETITION RULE PRM

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

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OFFICE OF THE SECRETARY  
DOCKETING & SERVICE  
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Sir:

Nuclear Medicine physicians, pharmacists and technologists must currently practice medicine under a different set of rules than other practitioners. NRC's existing Part 35 Medical Use regulations limit the use of approved radiopharmaceuticals, limit their use to a greater extent than applicable Food and Drug Administration regulations do.

The FDA has long supported the position that an approved drug could be used by a physician, using a legal prescription, in the manner and for the indication felt appropriate by the physician.

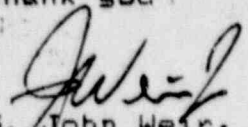
NRC's regulations do not recognize that position. Nuclear Medicine practitioners must use approved drugs only for approved indications and by approved routes of administration. Part 35 limits physicians to using only approved radiopharmaceuticals.

This position has increased patient exposure to radiation, has prevented physicians from using the best diagnostic tests available and has inhibited the development of nuclear medicine procedures which would further improve medical care.

One of the best examples of the problem has been that of radionuclide cystography. This highly efficacious test which greatly limits radiation exposure to the patient was long prohibited by these regulations. The alternative procedure was cystography by X-ray study. A procedure which was less efficacious and delivered a greater radiation exposure to the patient--often a young girl.

The American College of Nuclear Physicians and Society of Nuclear Medicine have filed a petition for Rulemaking which addresses these issues. I strongly urge adoption of the petition as expeditiously as possible.

Thank you.

  
G. John Weir, Jr. MD  
Nuclear Medicine  
Marshfield Clinic  
2000 N. Oak  
Marshfield, WI 54449

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