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February 7, 2006

Nils J.Diaz, Ph.D.
Chairman
Nuclear Regulatory Commission
One White Flint North Building
11555 Rockville Pike
Rockville, MD 20852

RE: Section 651(e) of the Energy Policy Act of 2005 / NRC Regulation of NARM

Dear Chairman Diaz:

The Society of Nuclear Medicine (SNM) appreciates the opportunity to discuss Section 651(e) of the Energy Policy Act of 2005 (EPAct), which grants the NRC regulatory authority over naturally occurring and accelerator produced nuclear material (NARM). We were pleased to participate with NRC staff and other organizations at the November 9, 2005 public roundtable meeting, and look forward to continued participation in the NARM rulemaking process future. As we stated at the public roundtable meeting, the SNM supports regulations that will protect the public from unnecessary exposure to radiation while simultaneously ensuring patient and medical-scientific access to the accelerator-produced materials that are used daily for life-saving nuclear medicine procedures and in biomedical research.

Accelerator products used in nuclear medicine procedures, such as Positron Emission Tomography (PET) and Single Photon Emission Computed Tomography (SPECT), are essential for the diagnosis and treatment of patients with cancer, cardiovascular disease, and Alzheimer's disease, for example. Additionally, accelerator products are the backbone of much biomedical research. Duplicative regulation will, in some cases, actually hinder access to accelerator products because potential users will deem the regulations too burdensome. In virtually all cases, the resources spent to address additional layers of regulatory burden will reduce patient access to nuclear medicine procedures and slow the pace of scientific innovation in this field. Most radioisotopes used in nuclear medicine pose little or no radiation risk for use in terrorist attacks because they are short-lived and are used in relatively small quantities. Accordingly, the public benefit gained from future NARM regulations should be carefully weighed against the potential costs and burdens to patient care and scientific progress in molecular imaging and therapy.

As stated above, we recognize and endorse the need to protect the public from unnecessary exposure to radiation, but we also urge the NRC to recognize the equally important need to ensure reasonable and legitimate access to accelerator products for medical and research uses. Given the real danger of unintended consequences to both patients and researchers from unnecessarily burdensome regulation, the SNM is concerned with the current fast-track approach to enacting these new regulations as charged by the EPAct. Congress has committed the NRC staff to the daunting task of completing the rulemaking process on NARM within a very short timeframe. We strongly recommended that the NRC seek to extend the deadline for promulgation of the NARM rules to ensure the development of a cautious and deliberate set of regulations with more input from experts within the medical-scientific community.

Additionally, to achieve a balance between radiation safety and quality patient care, the SNM suggests the following concepts be integrated into the future NRC NARM rules:

- **Regulate with Patient Access to Radiopharmaceuticals as a Primary Concern**
  The regulations should be written in such a way that accessibility to medical isotopes is protected, particularly those isotopes that are short-lived or pose low radiation risk. Many cyclotron products have half-lives of minutes or hours, and would be useless in a terrorist attack—but the delays resulting from overregulation could be extremely harmful to patients requiring molecular/nuclear medicine imaging and therapy procedures, as well as to biomedical research.

- **Use Successful Agreement State Models / Create Uniformity Between States**

There are several successful agreement-state programs (e.g., California) that could be used as models to create efficient NRC rules. The key to the success of these programs is that they effectively balance radiation safety with quality patient care and scientific innovation. The NRC should be extremely careful to avoid duplicative regulation and fees, and additional care should be taken to ease the transition and improve the infrastructure of non-agreement state programs. Additionally, the NRC should create consistent standards in all states to ensure the expedited development and transportation of medically used radioisotopes across state borders.

- **Regulate Based on EPAct Language**
  The EPAct grants the NRC regulatory authority over accelerator-produced material for a commercial, medical, or research activity. It does not grant regulatory authority over devices, processes, or waste—nor does it need to, as these are already comprehensively regulated in other ways. Unfortunately, during the November 9 public meeting, an interpretation of the EPAct was discussed by which rule-makers would create broad enough language to give the NRC regulatory authority over the accelerators/devices themselves, despite the fact that EPAct specifically states that it does not cover accelerators. The SNM strongly discourages this misinterpretation of the EPAct, as excessive and duplicative regulation will likely drive small cyclotron operators and industry startups out of business, thus limiting access to accelerator products and inhibiting further growth in nuclear diagnostic imaging and therapy.

- **Work Closely With the FDA**
  The FDA has expended substantial effort over the past decade (with extensive involvement by the nuclear medicine community) developing its recently published Proposed CGMP Rule and Draft Guidance for PET. Additionally, the FDA has worked extensively with the regulated community with respect to guidance on Exploratory INDs and the role of RDRC. The NRC should coordinate closely with the Food and Drug Administration and use the FDA's scientific and regulatory expertise to avoid duplicative regulations as it develops and implements the new rules.

- **Include a Mechanism to Resolve Problems Post-Implementation**
  There should be a mechanism in place—perhaps a working group of physicians and scientists (possibly the ACMUI)—to identify and, most importantly, immediately resolve any problems that materialize upon implementation of the new NARM regulations.

Section 651(e) of the EPAct has placed the NRC and medical-scientific community in a delicate situation where the fast-track federal regulation of all NARM—including short-lived medical radioisotopes—could have unintended, and extremely negative, consequences. The SNM again strongly recommends the NRC seek an extension to the rulemaking process that will allow the development of reasonable regulations that will protect the general public but at the same time, not negatively impact patient care and scientific advancement. Additionally, the SNM urges the NRC to work closely with experts from the nuclear medicine community who have successfully used these beneficial accelerator products to save the lives of patients for decades.

We look forward to working with you and NRC staff on this very important NARM rule. Please contact Hugh Cannon, SNM Director of Public Affairs, at 703-708-9000 x1322 should you have any questions or concerns. Thank you for your time and attention.

Sincerely,

Peter S. Conti, MD, PhD
President
Society of Nuclear Medicine