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Date: 11/18/05 3:41PM
Subject: NRC-NARM Comments (per the November 9 public meeting)

Hello Leslie,

Per the November 9 public meeting on the NRC regulation of NARM (Section 651(e) of the Energy Policy Act), attached are the Society of Nuclear Medicine's written comments for Scott Moore and his NARM rulemaking team.

These comments were compiled and approved by the SNM's NRC Task Force (an advisory group of physicians and research scientists from across the United States) on behalf of the Society.

Thank you,
Mike

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SNM Comments on NRC Regulation of NARM - 11-18-2005
Response to Request for Comments at the Nov. 9 Public Meeting

The Society of Nuclear Medicine (SNM) appreciates the opportunity to comment on Section 651(e) of the Energy Policy Act of 2005 (EPAc) before the NRC rulemaking staff proceeds with writing the NARM regulations. The SNM supports regulations that would guard the public from unnecessary exposure to radiation while simultaneously protecting medical/scientific accessibility to accelerator-produced materials for nuclear medicine procedures and 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, Alzheimer's, and other diseases. Duplicative regulation and the resulting additional resources spent dealing with another layer of regulatory burden would hamper scientific innovation and patient access to nuclear medicine procedures. Given that most of the isotopes used in nuclear medicine are short-lived and are used in relatively small quantities (thus posing little radiation risk from use in terrorist attacks), 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.

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 with the accessibility of medical isotopes in mind, 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 scientific 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 isotopes across state borders.
- **Regulate Based on EPAc Language**
The EPAc grants the NRC regulatory authority over accelerator-produced material for a commercial, medical, or research activity—not devices, processes, or waste. Unfortunately, during the November 9 public meeting, an interpretation of the EPAc was discussed by which rule-makers would create broad enough language to give the NRC regulatory authority over the accelerators/devices themselves. The SNM strongly discourages this misinterpretation of the EPAc, as excessive and duplicative regulation may drive small cyclotrons and industry startups out of business and/or discourage 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, 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 well as develop and implement 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.