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RULEMAKINGS AND
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PR 20,30,31,32,33,35,50,61,62,72,110,150,170, and 171 (71FR42952)

September 11, 2006

Dale E. Klein, Chairman
U.S. Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, Maryland 20852-2738

Dear Chairman Klein:

On behalf of the American Society of Nuclear Cardiology (ASNC), I would like to thank the Nuclear Regulatory Commission (NRC) for the opportunity to provide additional comment during the rulemaking process for establishing a regulatory framework for the expanded definition of byproduct material outlined under the Energy Policy Act of 2005. We greatly appreciate the commission's positive response to ASNC's comments made shortly after last November's stakeholder meeting regarding how the commission should approach regulation of Naturally Occurring and Accelerator-Produced Radioactive Material (NARM).

As you know, ASNC is a nearly 5,000 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology, develops standards and guidelines for training and practice, promotes accreditation and certification in this sub-specialty field, and is the principal advocacy voice for nuclear cardiology.

In evaluating the July 28 proposed rule, we are pleased that the NRC has not taken an overly restrictive regulatory approach to its oversight of NARM. Such an approach we believe could have ripple effects on continuing development and innovation of cardiac PET diagnostic imaging. In particular, ASNC appreciates the commission's decision to: accept current training and education requirements for authorized users as sufficient for the safe handling of cyclotron produced materials; promulgate risk-based regulations that distinguish between high and low-energy cyclotron produced material; and reasonable decommissioning requirements.

However, ASNC does remain concerned about continued access to PET radiopharmaceuticals. There are currently over 100 cyclotrons in the Untied States that are producing material for doing PET imaging. ASNC is deeply concerned that the current rule as proposed will place undo burdens on health care providers that use cyclotrons for the production of radiotracers. The language in the proposed rule leaves open the possibility of applying the FDA's "Good Manufacturing Practices" standard that is applied to commercial entities producing product for sale to the public. The application of the GMP standard (a commercial product development and sales standard) to non-commercial production of life saving drugs is inappropriate and potentially harmful to the practice of medicine.

ASNC believes NRC does not have the statutory mandate in the Act to require health care providers to follow GMP in their clinical practice. This is also an inappropriate regulation of care providers, because it would place the NRC in the position of enforcing the drug production quality standard (clearly the FDA's jurisdiction, for which the NRC has no expertise or authority to do). It also would have a very detrimental effect on the exploration of new treatment pathways that is typically done most efficaciously in the university environment.

Care givers have never been required to apply the commercial GMP standards in the practice of medicine. It is an inappropriate interpretation of the statute that will unnecessarily increase health care cost, limit access to life saving technologies and hamper the pace of research into new life saving technologies.

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ASNC strongly believes that the production of radio-pharmaceuticals using a cyclotron is no different than using a molybdenum or rubidium type generator, and that the regulation of the by-product material, as required by the Act, should not include processes involving drug production and patient care.

Again, thank you for this additional opportunity to provide guidance to the commission on this critical issue. While we understand the extraordinary tight time constraints that the commission is operating under for this rulemaking, we can't stress enough the importance of promulgating regulations that protect the public while not stifling expansion, innovation and access to quality diagnostic cardiac PET imaging.

Sincerely,

James A. Case, PhD
Director of Physics, Cardiovascular Imaging Technologies
Adjunct Professor
University of Missouri, Columbia, Department of Nuclear Engineering

From: <gallagher@asnc.org>
To: <SECY@nrc.gov>
Date: Mon, Sep 11, 2006 4:29 PM
Subject: ASNC comments regarding requirements for expanded definition of byproduct material

Attached are formal comments from the American Society of Nuclear Cardiology regarding the NPRM published in the July 28 Federal Register regarding NARM. Should you have any questions, please contact me at 301-215-7575 (ext 210) or via email at gallagher@asnc.org. Thank you.

Chris Gallagher
Director of Health Policy
American Society of Nuclear Cardiology

CC: <carter@asnc.org>, <gallagher@asnc.org>

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Subject: ASNC comments regarding requirements for expanded definition of byproduct material
Creation Date Mon, Sep 11, 2006 4:27 PM
From: <gallagher@asnc.org>

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