From: Gallagher <gallagher@asnc.org>
To: Leslie Kerr <LSK@nrc.gov>
Date: 11/18/05 4:35PM
Subject: Re: ASNC Comments re Nov 9 NARM Mtng

Here's the revised and final final version of ASNC's comments. thanks

> ok, no problem.
>
> >>> Gallagher <gallagher@asnc.org> 11/18/05 4:32 PM >>>
> Leslie, I'm going to send you a revised copy in about five minutes as > James Case just got back to me with his official title so if you could > please scrap the version I just sent you and use the one coming in five > minutes for the official record. thanks
>
> > Chris,
> >
> > Thank you for your comments.
> >
> > Leslie
> >
> > >>> Gallagher <gallagher@asnc.org> 11/18/05 4:25 PM >>>
> > Leslie,
> >
> > Attached are ASNC's comments regarding issues discussed during the > > November 9, 2005 Public Meeting at the NRC regarding NARM. We appreciate > > the opportunity to provide this feedback. Have a nice weekend and Turkey > > Day next week!
> >
> > Chris Gallagher
> > Director of Health Policy
> > American Society of Nuclear Cardiology
> > 301-493-2310
> > gallagher@asnc.org

CC: <jcase@cvit-online.com>

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Subject:	Re: ASNC Comments re Nov 9 NARM Mtng
Creation Date:	11/18/05 4:35PM
From:	Gallagher <gallagher@asnc.org>
Created By:	gallagher@asnc.org

Recipients
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LSK (Leslie Kerr)

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AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY

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November 18, 2005

Chairman Nils J. Diaz, Ph.D.
U.S. Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, Maryland 20852-2738

Dear Chairman Diaz:

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. I believe that last week's stakeholder meeting on this issue was a productive exchange 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.

Assessment of myocardial anatomy and physiology through positron emission tomography (PET) holds great promise for detecting coronary artery disease. As the NRC moves forward on regulating NARM, ASNC believes that the commission should be mindful of the ripple effects that an overly-restrictive regulation could have on continuing development and innovation of cardiac PET diagnostic imaging.

Following are some brief points that NRC should strongly consider in development of the proposed rule on this issue:

Amendment of 10 CFR, Part 35 Training and Education Requirements

ASNC is extremely concerned that NRC staff suggested reopening Part 35 to include accelerator-produced material under the Part 35 framework.[1] The nuclear cardiology community believes that given the long and arduous process (seven years) to finally come to closure on the training and education regulations regarding the medical use of byproduct material, the commission should not open up Part 35 to further manipulation. The end result could be additional changes to the T&E requirements and further delay in the implementation of the compatibility requirements for the Agreement States. NRC should allow the March 30 final regulations to mature and evaluate its impact before reopening the process again.

ASNC also believes that current training and education requirements for authorized users cover the safe handling of cyclotron produced materials. ASNC agrees with a number of other stakeholders who pointed out during the November 9 meeting that the radiation safety for NARM materials is identical to that of reactor produced byproduct material. Furthermore, experience consistently demonstrates that staff who work in areas that use PET tracers receive less absorbed radiation doses than their counterparts that work with Single Positron Emission Computed Tomography radiotracers, such as Tc-99m sestamibi.

Risk-Based Regulation

While the Energy Policy Act statutory language explicitly limits NRC regulation to accelerator/cyclotron activated material and prohibits the commission from regulating the accelerator/cyclotron itself, ASNC believes that the NRC should recognize the differences between small PET cyclotrons (F-18, N-13, O-15, C-11, Tc-94, I-124) and large cyclotrons (Tl-201, Sr-82, I-123) such as the different quantities of material that can be produced and the half-life of these materials. Taking into account these factors, it is clear that low-energy cyclotron produced material is not created in sufficient quantities to produce weaponizable material.

In assessing risk from PET tracers, it is important to use units for defining radiation-risk, based on absorbed radiation dosage and not exposure. Absorbed radiation dosage directly relates to the radiation risk.

Access to PET Radiopharmaceuticals

There are currently over 100 cyclotrons in the Untied States that are producing material for doing PET imaging. In addition, companies involved in producing perfusion agents for cardiac PET are already operating on extremely thin margins. These factors make for a very fragile foundation for continuing the great advancements that have occurred in this modality. Should NRC adopt an overly-restrictive approach to NARM, the end result may be the demise of cardiac PET in the United States. It is critical that whatever finally comes out of the commission represent a balanced approach between ensuring public safety while providing reasonable access to PET agents for clinicians practicing in the community.

Decommissioning

Regarding decommissioning, ASNC believes that self-shielded cyclotrons that produce less than 10mCi of activation should be exempted from posting a surety bond. This would be consistent with most SSRs currently in effect in states that do regulate cyclotron decommissioning. The NRC should also consider the low activation of concrete in most models of unshielded cyclotrons (<10 mCi Eu-152, 152, <2.0 mCi Co-60, <3.0 mCi Cs-134) and the fact that well designed cyclotrons shielding schemes would produce residual activation of ~ 10 mCi or less for all activated materials. As such, we feel that any surety bond for disposal for an unshielded cyclotron should be < $150,000.

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

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[i] Official Transcript of November 9, 2005 NRC Public Meeting; pages 93-94